NUTRITION SUPPORT PROTOCOLS AND EARLY FEEDING IN THE INTENSIVE CARE UNIT

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A Thesis

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ABSTRACT

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Background: While many studies have documented the importance of providing nutrition support in the critical care setting within 48 hours of Intensive Care Unit (ICU) admission in order to minimize undesirable clinical outcomes and malnutrition, few studies have reviewed how to achieve those recommendations. The present study will provide evidence on whether or not the implementation of a voluntary Nutrition Support Protocol across a healthcare system will shorten time to nutrition initiation and increase the number of patients who received nutrition within 48 hours.

Methods: The Nutrition Support Protocol was developed in support of evidence-based recommendations under the leadership of a critical care Registered Dietitian (RD). Data was collected via medical chart review over a near three year time period. Changes in the time of nutrition initiation were compared between the pre-and post-protocol implementation periods. In the post-protocol implementation period, different methods of administering nutrition (enteral, parenteral or oral) were compared along with the time to the initiation of nutrition, total percent of patients who received nutrition within 48 hours, and whether or not the nutrition was managed by the physician or utilizing the Nutrition Support Protocol (RD leadership). Differences between groups (pre-protocol versus post-protocol implementation periods and physician managed versus Nutrition Support Protocol managed) were tested using analysis of variance (ANOVA) and Wald’s Chi Square.
**Results:** The time to nutrition initiation significantly decreased from the pre-protocol to the post-protocol period, 36.3 ± 31.5 hours versus 28.9 ± 25.3, p<0.0001. The percent of patients fed within 48 hours of ICU admission also increased, 73.3% in the pre-protocol period versus 83.0% in the post-protocol period. After protocol implementation, patients whose nutrition was managed by the Nutrition Support Protocol were fed 12.7 hours sooner than patients managed by the physician alone (20.9 ± 18.8 versus 33.6 ± 27.3, respectively, p<0.0001). Nearly 97% of patients receiving enteral nutrition who were managed by the Nutrition Support Protocol were fed within 48 hours.

**Conclusions:** The use of a nutrition management protocol for the initiation of nutrition support to critically ill patients significantly improved the number of patients receiving nutrition support within 48 hours and should be considered as part of standard practice in the ICU setting.
This thesis is dedicated to my loving husband Bill.
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CHAPTER I. INTRODUCTION

The incidence of malnutrition in hospitalized patients is common and is associated with increased morbidity and mortality. It is estimated that greater than 40% of all patients are seriously malnourished at the time of admission (1) and are at risk (up to 65%) of becoming malnourished during their hospitalization (2). In particular, critically ill patients admitted to the intensive care unit (ICU) are more prone to suffer from the adverse effects of malnutrition such as declined ventilatory status, reduced resistance to infection and increased length of stay (3,4,5). Additionally, the delay of nutrition therapy can further obscure the nutritional well-being of the patient and ultimately increase the risk of adverse outcomes. Research suggests that initiating early nutrition support within the first 48 hours of ICU admission is advantageous for improving wound healing, reducing septic morbidity and decreasing the catabolic response to injury or illness (3,4,5,6).

The route of nutrition support has shown to influence clinical outcomes in medical and surgical ICU patients who have a variety of disease conditions and injuries. For those patients who cannot safely consume an oral diet and who have a functional gastrointestinal tract, enteral nutrition (EN) therapies are recommended over parenteral nutrition (PN) or prolonged starvation (2,7,8). EN is considered more physiologic because feeding the gut promotes mucosal flora and integrity, supports liver function, enhances collagen synthesis for wound healing and reduces associated nutrition therapy costs (9,10,11). In comparison, ICU patients receiving PN have demonstrated higher incidences of villous atrophy, bacterial translocation, wound infections and metabolic disturbances (3,4,12).
Although many position papers and researched guidelines continue to promote EN as the preferred route of nutrition, the use of EN in critically ill populations has been widely debated (3,4,12,13). Some of the questions related to the use of EN include determining the optimal time to initiate nutrition therapies, location of tube placement (gastric versus small bowel), and markers to indicate tolerance of enteral nutrition. Additionally, patients in the ICU receiving EN are often underfed or unable to achieve adequate amounts of calories, protein and essential nutrients (14,15).

While the administration of EN support does not go without associated risks, clinical guidelines and evidence-based research continues to advocate the use of enteral support in the ICU population. Because early initiation of nutrition support is vital to minimize the effects of fasting, hypermetabolism and hypercatabolism, EN should be considered within the first 48 hours of injury or illness once the patient is resuscitated and stabilized (2,6,7,9,14). There is evidence that the use of hospital-wide protocols for the infusion enteral feedings can improve success of EN by managing enteral feeding within appropriate guidelines and monitoring for potential complications (8,14). Therefore, many physicians and clinicians opt for infusion protocols to guide decision making in critically ill patients to improve adequacy and timeliness of nutrition support. However, there are not many studies examining the initiation of protocols for early EN. The development and use of a medical nutrition therapy protocol that critical care clinicians can apply to support evidence-based guidelines can ultimately enhance the overall care of the patient by further preventing risks of malnutrition and aid in the treatment of the underlying injury or illness when patients are unable to take nutrition by mouth.

The purpose of the present study was to determine whether the initiation of a nutrition support protocol in the ICUs across a healthcare system (four facilities) influenced the number of
adult critical care patients who were not appropriately fed within 48 hours of ICU admission. The Nutrition Support Protocol was established on evidence-based clinical practice guidelines for early enteral feeding. While many studies have documented the importance of providing early enteral nutrition support in the critical care setting in order to minimize undesirable clinical outcomes and malnutrition (3,4,5,6,9,10,11), few studies have reviewed how to achieve those recommendations. The present study will determine compliance with and the effectiveness of the implementation of a nutrition management protocol to help achieve evidence based recommendations and shorten time to nutrition initiation in a critically ill population.
CHAPTER II. REVIEW OF THE LITERATURE

Prevalence of Malnutrition in the Hospital Setting

Malnutrition is prevalent in critically ill patients. It is estimated that greater than 40% of all adult patients are seriously malnourished at the time of admission into the Intensive Care Unit (ICU) (1). As a result, these patients are more prone to suffer from the adverse consequences of malnutrition, including impaired immune function, decreased wound healing, and impaired ventilatory status. Weakened ventilator status could further exacerbate respiratory muscles, possibly leading to prolonged ventilator dependence and increased threat of morbidity and mortality (3,4). In the ICU setting, the body’s natural metabolic response to stress encourages a hypercatabolic state which can lead to lean muscle mass wasting and decline in visceral organ function and immune response (4). Giner et al showed that patients who entered the ICU after surgical intervention had an increased risk of being malnourished while in the unit; possibly due to a greater number of days without being fed or with decreased oral intake due to diagnostic testing, ventilator dependence, or lack of nutritional awareness (1).

Unfortunately, the definition of malnutrition or phrase “declined nutrition status” has been highly debated and inconsistently defined. In most cases and textbooks, malnutrition is often based upon long-term measures such as weight loss, a combination of laboratory parameters, and percentage of usual body weight; typically resulting in losses of lean body mass and subsequent losses of structure or function. Unintentional weight loss is often the first clinical marker of a much larger problem. Once weight loss is identified, often decreases in serum albumin, prealbumin and transferrin, reduced resistance to infection, impaired wound healing or risk of
pressure ulcers closely follow (2). Early identification, careful documentation and timely nutritional intervention can often halt or reverse these damaging effects.

In the acute care setting, short-term malnutrition resulting from the stress of injury, surgery and infection, as well as poor nutritional intake is of concern. Traditional markers of long-term malnutrition are less useful in the short-term, stress-induced malnutrition observed in the ICU (16). It is imperative to ensure that weight loss and its relationship to malnutrition is properly documented and given the appropriate diagnostic code. This documentation flags those patients needing intervention to provide accurate care and ultimately justify necessary payment and reimbursement from Medicare, Medicaid, and/or private insurance companies. Because malnutrition is seen as a comorbid condition to the primary reason that brought about the hospitalization, diagnostic codes have been assigned to increase reimbursements to offset the costs of needed nutritional therapy. International Classification of Disease (ICD) categorizes morbidity and mortality information based on the official version of the World Health Organization’s 9th Revision (ICD-9-CM). The ICD-9-CM is recommended for use in all clinical settings but is required for reporting diagnoses and diseases to all United States Public Health Service and Health Care Financing Administration Programs. The ICD-9-CM is used for Diagnosis-Related Grouping (DRG) coding of co-morbidities and conditions, particularly when dealing with involuntary weight loss which could lead to malnutrition. See Appendix A for common ICD-9-CM codes considered for high nutritional risk in the acute care setting (2,17).

Documentation and coding specialists utilize the following calculation to define malnutrition and unintentional weight loss according to the Omnibus Budget Reconciliation Act (OBRA) of 1987: usual weight – actual weight x 100 divided by usual weight to equal percentage of usual
body weight loss (2,17). Furthermore, the following table classifies weight loss as significant to severe.

Table 1. Evaluation of Body Weight Data and Classification of Malnutrition Status\(^{(2,17)}\)

<table>
<thead>
<tr>
<th></th>
<th>% IBW(^{a}) = (current wt(^{b}) ÷ IBW) x 100</th>
<th>% of UBW(^{c}) = (current wt ÷ usual wt) x 100</th>
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<tr>
<td>80-90% = Mild Malnutrition</td>
<td>85-95% = Mild Malnutrition</td>
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<tr>
<td>70-79% = Moderate Malnutrition</td>
<td>75-84% = Moderate Malnutrition</td>
<td></td>
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<tr>
<td>≤69% = Severe Malnutrition</td>
<td>≤74% = Severe Malnutrition</td>
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Severity of Usual Body Weight Loss

<table>
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<tr>
<th>Time</th>
<th>Significant Loss (%)</th>
<th>Severe Loss (%)</th>
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<tr>
<td>1 wk</td>
<td>1-2</td>
<td>&gt;2</td>
</tr>
<tr>
<td>1 mo</td>
<td>5</td>
<td>&gt;5</td>
</tr>
<tr>
<td>3 mos</td>
<td>7.5</td>
<td>&gt;7.5</td>
</tr>
<tr>
<td>6 mos</td>
<td>10</td>
<td>&gt;10</td>
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\(^{a}\)IBW=Ideal Body Weight  
\(^{b}\)Wt=Weight  
\(^{c}\)UBW=Usual Body Weight

When the loss of usual total body weight reaches 10% or more, the patient is at an increased risk of infection, compromised immunity, impaired respiratory function and poor wound healing (2). Acute and critical illness can further deteriorate the patient’s nutritional status. Hospitalized patients are at risk (up to 65%) of developing malnutrition (2), thus further increasing morbidity and mortality.

Changes in nutritional status during the course of hospitalization are of concern. McWhirter (1994) reported nutritional deterioration as measured by anthropometric data upon hospital admission and discharge. Nutritional markers considered were body mass index (<20; calculated
as weight in kilograms divided by the square of height in meters), triceps skin fold thickness, mid-arm muscle circumference and weight loss. Results indicated that two-thirds of all adult patients experienced a decline in their overall nutritional status during their hospital stay, whether admitted to the ICU or not (18). While utilizing anthropometric data (skin fold thickness and arm muscle circumference) may be beneficial to determine long-term nutritional status, it may be difficult to accurately and appropriately assess in non-ambulatory patients or those with fluid overload and renal dysfunction in the acute care setting (19).

Roberts et al classified malnutrition in their study as a combination of recent unintentional weight loss of 4.5 kg (10 lbs) in past 2 months, low body mass index (<19), recent poor oral intakes and presence of altered gastrointestinal signs and symptoms, including vomiting, diarrhea, and dysphagia. They observed a trend of association between the underlying disease process (assessed by Acute Physiology and Chronic Health Evaluation Score or APACHE II Score) and malnutrition at ICU admission, as defined above. In return, these greater values of disease scores and malnutrition status were directly associated with a decreased ICU survival (14).

Prolonged Starvation During Hospitalization

Understanding that the incidence of malnutrition prior to ICU care is prevalent, with the added stress of the inflammatory response to injury and infection, the question remains how long critically ill patients can continue without appropriate nutrition intervention. Prolonged undernourishment or starvation can disrupt the immunological effect of the gut, decreasing the inflammatory response by alternatively affecting the mucosal barrier and structure (4). In other words, this major immunological organ needs enteral stimulation to maintain its integrity.
Atrophy of the gut occurs in a matter of days without enteral feeding. This could ultimately expose the patient to greater infectious morbidity and, eventually, lead to death.

Although early nutrition intervention can change nutritional and, ultimately, medical outcomes, there is minimal research comparing the effects of nutrition support (enteral or parenteral) to prolonged starvation or “nil by mouth” (NPO) in the critically ill population. This is a difficult research topic given that the critically ill population is very diverse in terms of type of diagnosis, severity of stress, and complications. Furthermore, intentionally withholding feeding is not an ethical research practice. The American Gastroenterological Association states those patients who are not severely malnourished can likely tolerate at least one week of starvation without adverse effects (20). However, this depends greatly on current nutrition status, nature of nutrient inadequacies and catabolic rate of underlying disease (20). Prolonged starvation has been defined as the inability to take food by mouth for more than 14 days, despite use of intravenous fluids or dextrose (4).

Knowing the risks and prevalence of malnutrition, it does not make clinical sense to allow malnutrition to develop with prolonged starvation. However, because of the limited number of randomized controlled trials comparing patients who are NPO versus those receiving enteral or parenteral nutrition, some physicians conclude that nutrition support is not beneficial. However, much of the current literature review continues to indicate that prolonged starvation should be avoided in all circumstances when managing the nutritional care of all patients (2,4,13).

Parenteral Nutrition Support

Early nutrition support should be considered as an adjunctive therapy to prevent further malnutrition when patients are unable to take nutrition by mouth. The method of feeding when
oral intake is not possible or adequate can be via tube placed into the gastrointestinal track (enteral tube feeding), or bypassing the gastrointestinal track and infusing concentrated solutions of nutrients into central blood vessels (parenteral nutrition). There have been a number of randomized trials in human populations comparing the effects of enteral nutrition (EN) to parenteral nutrition (PN) in critically ill patients.

Parenteral nutrition is the infusion of intravenous nutrients to patients whose gastrointestinal tract is not functioning or cannot be adequately accessed. PN is reserved for those patients whose nutritional needs cannot be met with oral diets or enteral nutrition. PN was developed in the 1960’s, initially referred to as intravenous hyperalimentation and often infused into a central vein, called total parenteral nutrition (TPN). PN administered into a peripheral vein is called peripheral parenteral nutrition (PPN). An assortment of PN solutions can be compounded to contain specialized mixtures of amino acids, dextrose, lipid emulsions, electrolytes, vitamins and minerals administered intravenously to provide a source of total and complete nutrition. It is indicated for those patients who are hemodynamically stable, able to tolerate the fluid volume necessary to provide macro and micronutrient intake and who have central or peripheral vascular access.

Parenteral nutrition has received considerable recognition and advancement in the medical field over the past 50 or more years when studies showed that the infusion of glucose and amino acid on postsurgical patients helped to minimize protein loss and muscle wasting (13). Since this new knowledge and medical advancement, the surgical community frequently practiced PN in their patients, often times merely to “boost” nutritional status. Simply because of ease, PN was administered frequently and without patients falling under specific criterion or practice guidelines. This misuse of PN came to a halt soon thereafter when research revealed minimal
nutritional benefit in well-nourished patients compared to the potentially high risks and adverse outcomes involved with patients receiving hyperalimentation (13). Adverse complications of PN found included higher incidence of infections, post-operative wound complications, gastrointestinal bleeding, pressure ulcers, greater immune compromise, fluid/electrolyte imbalances and lack of research to support initiating early parenteral nutrition (8).

**Parenteral Nutrition and Bacterial Translocation**

Multiple animal studies have shown that disuse of the gastrointestinal tract can lead to some degree of villous atrophy and bacterial translocation. Xu (1998) demonstrated that TPN administration promoted bacterial translocation to the mesenteric lymph nodes and reduced immune cell levels in rats. Suppressed numbers of T and B cells which, in return, decrease immune response has also been reported in response in TPN (21). Similar studies with animal models have been repeated multiple times suggesting that in patients with functional gastrointestinal tracts, enteral routes of nutrition that continue to stimulate the gastrointestinal track should be chosen over parenteral nutrition support. However, controlled human trials to document the extent of intestinal atrophy with combinations of bowel rest and PN are needed (22).

**Risks of Infection with Parenteral Nutrition**

Over 200,000 nosocomial bloodstream infections occur yearly in the United States and approximately 35% are associated with central venous access devices, such as those used to deliver PN (23). The mortality rate from catheter sepsis may be as high as 15% (2,23). Additionally, metabolic complications induced by the administration of PN can lead to a
breeding ground for bacteria and infection to cultivate. PN management requires thorough assessment and close monitoring of laboratory values and clinical signs prior to initiation and during PN administration. Despite the fact that many of these infections could be attributed to hand-washing compliance, type of catheter material, catheter placement, and infection control programs, the push for therapies outside of venous access usage is also in progress (23).

In a randomized prospective study comparing the effects of early EN versus early PN in trauma patients during the first 15 days of hospitalization, Kudsk et al found PN usage was associated with an 11-fold increase in the risk of infection (15% infections in EN group versus 66.7% in the PN group). The EN group experienced less septic morbidity, defined as pneumonia, intra-abdominal abscess, empyema or line sepsis, and fewer numbers of infections in those who were infected. Only three of 15 enterally fed patients developed more than one infection, whereas 14 of 15 parenterally fed patients developed more than one infection. Additionally, those with blunt injuries had a higher infection rate if fed parenterally (60% versus 18.8% in the EN group). EN patients with penetrating wounds developed significantly fewer septic complications than did PN patients where the risk of infection increased 3.6 times in the PN group. As discussed above, this study supports the finding that line sepsis from central venous catheters for the infusion of PN poses a significant problem (24).

**Parenteral Nutrition in the Malnourished Surgical Patient**

In a meta-analysis of 26 randomized controlled trials, Heyland et al compared TPN to standard nutrition (oral diets plus intravenous dextrose) in 2,211 patients in critical and surgical care units. Although TPN had no effect on reducing the rate of complications, defined as pneumonia, intra-abdominal abscess, sepsis, line sepsis, myocardial infarction, pulmonary
emboli, heart failure, stroke, renal failure, liver failure and/or anastomotic leak, TPN significantly reduced morbidity in malnourished patients compared to those deemed adequately nourished upon admission. In those considered malnourished, defined as having a weight loss greater than 10% prior to study entrance, the rate of major complications was significantly lower among those receiving PN (12).

The Veterans Affairs Cooperative Study Group reviewed the incidence of serious complications after major abdominal or thoracic surgical procedures in patients receiving PN. Patients were randomly assigned to receive PN for 7 to 15 days perioperatively and three days postoperatively or no PN prior to surgical intervention. Patients were followed 90 days postoperatively. There were more infectious complications in the PN group (14.1% versus 6.4% without PN). On the contrary, those patients classified as severely malnourished according to Subjective Global Assessment or objective nutritional assessment had fewer complications; concluding that the use of perioperative PN should be limited to patients who are severely malnourished prior to surgical intervention (25).

Subsequent reviews of severely malnourished patients with gastric or colorectal cancer undergoing surgical intervention have shown significant reductions in infectious complications when receiving PN perioperatively. Ninety surgical patients classified as severely malnourished by a weight loss of greater than 10% of usual body weight were randomly assigned into two groups: those to receive perioperative PN ten days prior to surgery and continuing nine days after; or those who receive only 940 non-protein calories and 85 grams of amino acids postoperatively. Results indicated that 37% of perioperative PN patients had complications versus 57% in those receiving minimal postoperative support. Length of stay did not achieve significant difference in either group. Researchers concluded that ten days of preoperative PN
that is to continue postoperatively in severely malnourished patients with gastrointestinal cancer could reduce the complication rate by approximately one third and prevent risks of mortality (26).

In 2001, Koretz et al published a meta-analysis of 61 randomized control trials on postoperative surgical patients receiving PN. Results indicated that PN did not provide any nutritional benefit, but did not cause any harm (27). While indications for postoperative nutrition support are not always apparent at the time of surgery, patients should be closely monitored in the days afterward. Research indicates postoperative PN should be reserved for those patients who are unable to tolerate an oral diet or EN for 7 to 10 days after surgery (28). On the other hand, postoperative PN should be considered sooner if it is indicated that a patient will not be fed enterally within 7 to 10 days or is deemed severely malnourished prior to surgical intervention (7,28).

**Parenteral Nutrition and Risks of Refeeding and Overfeeding**

One of the most dangerous complications of PN involves overly aggressive refeeding. Refeeding of moderate to severely malnourished patients may result in “refeeding syndrome” which presents a constellation of fluid, micronutrient, electrolyte and vitamin imbalances that typically occur within the first few days of PN initiation. It is potentially life threatening and can affect nearly every organ system, specifically causing cardiac arrhythmias, heart failure, acute respiratory failure, coma, paralysis, nephropathy and liver dysfunction. The underlying mechanism of refeeding syndrome is the metabolic shift from stored body fat to exogenous carbohydrate as the primary fuel source. As serum insulin levels rise with carbohydrate feeding, a rapid shift of electrolytes from the extracellular to the intracellular spaces can result in life-
threatening hypophosphatemia, hypomagnesemia and hypokalemia. Risk factors for refeeding syndrome include alcoholism, anorexia nervosa, marasmus, rapid PN advancement, excessive dextrose infusion, and most importantly, recent malnutrition status defined by weight loss (2).

Many recent reviews have indicated that the use of PN in earlier years was detrimental secondary to the risks of overfeeding rather than the PN itself (13,29). Many adopted the philosophy that if some nutrition is good, then more must be better, resulting in excessive peripheral infusion of macronutrients which is easy to accomplish in comparison to enteral or oral nutrition. One study found that the total energy intake equated to approximately 46 calories per kilogram body weight (kcal/kg) when infused peripherally. This was deemed excessive in comparison to similar patient populations who orally consumed food *ad libitum* with only approximately 20 kcal/kg consumed daily (29). Overfeeding the critically ill patient can be harmful in regards to metabolic disturbances such as hyperglycemia, hypertriglyceridemia (a rise of > 50 mg/dL), hyponatremia due to excessive infusion of a hypotonic fluid, and axotemia to hepatic steatosis (13). Therefore, concentrations of macronutrients in PN solutions need to be carefully assessed in order to avoid overfeeding and increase risks of refeeding syndrome when advanced too rapidly.

More importantly, hyperglycemia is common under stressed states and is associated with adverse outcomes in the critically ill population. Patients with elevated blood glucose levels have a higher mortality rate than those with normal blood glucose levels, especially in patients with stroke and myocardial infarction (30). Cheung et al (2005) found that a relatively modest level of hyperglycemia (>140 mg/dL) is associated with adverse outcomes despite a history of diabetes mellitus prior to hospitalization. Predominant adverse outcomes noted included cardiac complications, infections, systemic sepsis, acute renal failure and death. Those patients with
serum glucose levels in the highest quartile (>163 mg/dL) had 10.9 times greater risk of mortality than those in the lowest quartile of glucose range. Furthermore, a longer duration of TPN usage resulted in longer hospitalizations and increased risk of adverse outcomes. Because even one incidence of hyperglycemia might be detrimental to clinical outcomes, careful insulin administration and close attention to dextrose in TPN must be in effect, as not to overestimate dextrose infusion rates in the critically ill patient (30).

In summary, because of its associated high risks, overfeeding of PN can be prevented by attentive and thorough calculations, careful progression of macronutrients and close monitoring of daily laboratory data to avoid unfavorable complications. It can be used to deliver adequate nutrition safely to critically ill patients, especially in the presence of malnutrition (12,22,25,26). PN is still considered better than prolonged NPO status (4). Additionally, PN is not recommended for those critically ill patients with an intact gastrointestinal tract which could equate to approximately 90% of the ICU population where enteral feeding is deemed preferred over parenteral nutrition (13).

*ASPEN Guidelines for Parenteral Nutrition*

The American Society for Parenteral and Enteral Nutrition (ASPEN) has published widely accepted clinical practice guidelines regarding pre- and postoperative patients and use of PN support. The following three guidelines have been endorsed by ASPEN regarding parenteral nutrition: “preoperative nutrition support should be give for 7 to 14 days to patients with moderate to severe protein calorie malnutrition who are undergoing major gastrointestinal surgery; TPN should not be given during the immediate postoperative period to patients who
have undergone major gastrointestinal surgery; nutrition support should be given to patients who will be unable to eat 7 to 10 days postoperatively.” (2,7)

Enteral Nutrition Support

Over the years, several advantages have been attributed to EN as the preferred method of feeding compared to PN. The gastrointestinal tract is the largest immune organ in the body, containing approximately 65% of immune tissue and up to 80% of the immunoglobulin-producing tissue in the body (31). Normal intestinal villi, a rich blood supply, and intracellular tight junctions bind together to maintain integrity of the gastrointestinal tract while in the fed state. The gut acts as an antigen-processing organ, stimulating the release of pluripotential stem cells which release into systemic circulation as B and T cell lymphocytes. Some of these cells return to the gastrointestinal tract as gut-associated lymphoid tissue (GALT). Some of the pluripotential stem cells mature and migrate out as mucosal-associated lymphoid tissue (MALT) to help protect lung, genitourinary, breast, and lacrimal glands. Utilizing the gut permits the generation of GALT and MALT, thus the incidence of nosocomial infections may be reduced (31) and preserve upper respiratory tract immune function (4,8).

Not using the gut, even briefly, may compromise intestinal integrity; villi could become weakened, blood supply could decline and intracellular tight junctions could fail. This deterioration could lead to diminished GALT and MALT, consequently permitting the translocation of bacteria; playing a large role in the reduction of the body’s inflammatory and immune function response. When enterally fed, patients show a significant improvement in septic morbidity, multiple organ failure and length of stay, both in the ICU and overall hospitalization (31).
Additionally, utilizing and stimulating the enteral route is considered more physiologic by promoting gastrointestinal function and integrity (8,13) and preventing bacterial translocation in the gut (4,8,13). Heyland (1998) further reviewed animal studies to demonstrate that EN, when compared to PN, results in higher levels of secretory IgA in biliary tract secretions, greater GI mucosal weight and thickness, decreased secretion of catabolic hormones following burn injury, and reduced mortality following a septic or hypotensive insult (4).

**Cost Effectiveness of Enteral Nutrition**

Furthermore, EN is found to be more cost-effective than parenteral support (4,5,8,13). In a study comparing EN with PN, EN administration rates were slower over the first 72 hours of ICU admit compared to PN in patients with mild acute pancreatitis. However, by day four, the percentage of caloric goal was not significantly different, 71.3% of caloric goal in EN patients versus 85.2% in PN patients. The striking variance between the two groups was the mean costs of nutrition therapy. The cost per PN patient was over four times greater than enterally fed patients, $3,294 versus $761 respectively (32). Similar results were reported by Hamaoui et al in their study of postoperative patients. After three days of a specialized enteral formula, they found a cost difference of $44.36 for EN versus $102.10 for PN fed patients per day. Because this study was based on a specialized enteral formula, it was concluded that the cost of EN could further be substantially reduced if a standardized house formula were utilized (33).

**Risks Associated with Enteral Nutrition**

Enteral feeding has resulted in growing popularity and is deemed the current preferred route of artificial nutrition in critically ill adults. However, enteral nutrition initiation is not considered
the “end all” solution and can be associated with undesirable outcomes. Research indicates that many critically ill patients present with upper digestive intolerance, such as delayed gastric emptying and decreased intestinal motility related to consequences of their critical illness or injury, especially in the presence of mechanical ventilation. This impairment and dysmotility of the gastrointestinal tract is prevalent and often times enteral feeding is poorly tolerated resulting in adverse complications such as increased gastric residual volumes, abdominal distention, gastrointestinal regurgitation, aspiration, diarrhea, constipation, and mesenteric ischemia (3,34,35). Furthermore, mechanical complications such as misplacement and dislodgement of tubes or malfunction from intestinal or luminal blockages, could occur. In turn, these obstacles could lead to inadequate and poor timeliness of nutrition administration needed in the critically ill population.

**Gastric Residual Volumes**

Because many patients in the critical care setting are dependent on mechanical ventilation, much of the gastrointestinal dysfunction results from the side effects of ventilatory dependence and use of sedatives, opiates, and catecholamines (13,35). Specifically, catecholamines tend to impair digestive motility by decreasing digestive blood flow and cause tissue hypoxia. This deprivation of adequate oxygen supply in the hypoxic state can severely limit gastric function and delay gastric emptying, leading to high gastric residual volumes. High gastric residual volumes in patients admitted in the ICU is frequent, occurring early (within 2-2.5 days), and more prevalent in patients on sedatives or catecholamines (35). High gastric residual volume has been reported in 32% of the ICU admits and positively correlated with an increased length of stay, higher incidence of nosocomial pneumonia and increased ICU mortality (35).
Similar results were reported by Roberts et al stating high gastric residual volume occurred in 38% of ICU patients (14). Unfortunately, the study site did not have a protocol quantifying high residual volume. Physicians specified a volume pending the patients’ status, which tended to be considered low in comparison to current literature stating tube feeding with gastric residual volumes greater than 200-250 milliliters (mL) after two consecutive checks should be held (36). This lack of protocol led to unnecessary holding of enteral feeds and ultimately the adequacy of nutrition was either never achieved or not attained in a timely manner (14).

Clinicians have debated which complication is more prominent in critically ill patients: decreased gastric motility or intolerance to gastric nutrition. Regardless, practice recommendations continue to be: rather than discontinuing gastric tube feedings or decreasing the delivery rate when gastric residual volumes are high, it is advised to administer prokinetic agents or motility agents, such as metoclopramide or erythromycin. The initiation of prokinetic therapies in the presence of elevated gastric residual volumes, despite whether the case is related to intolerance of enteral nutrition or decreased gastric motility, helps to deliver enteral feedings in order to preserve the patients’ nutritional goals (14,37).

Aspiration Risks and Placement of Enteric Tubes

Aspiration of pharyngeal secretions and enteral formula related to the high incidence of gastric residual volume can provide a pathophysiological route of bacterial development and growth in the lungs and is the leading cause of pneumonia (31). In the critical care setting, the body’s natural defense system may become compromised and be unable to protect against aspiration, the most serious complication of enteral feeding. Sedatives can decrease mental status, delaying swallow coordination and decreasing pharyngeal muscle contraction and upper
esophageal sphincter tone. All this combined may permit secretions and enteral formulas to be regurgitated into the larynx, allowing the opportunity for aspiration to occur. Additionally, endotracheal tubes result in chronic stimulation of the trachea, which decreases the cough/gag reflex that individuals depend on to help prevent aspiration into the lung. McClave reported that a reduced level of consciousness nearly doubles the incidence of aspiration compared to patients with normal mental status levels. Aspiration pneumonia is to blame for 5-15% of the community-associated pneumonia cases reported. In the critical care setting, the cause of ventilator-associated pneumonia is difficult to determine. Many have debated whether the cause is related to the colonization of our natural oropharyngeal secretions versus gastric contents including enteral formulas. Regardless, ventilator-associated pneumonia incidence in medical ICUs is 15-25%, 26-40% in surgical ICUs and greater than 55% in patients who present with head trauma that require mechanical ventilation (31).

Nasogastric tubes are commonly used in the intensive or critical care setting to deliver enteral nutrition. The presence of a nasogastric tube passing through the upper and lower esophageal sphincters can decrease the proficiency of these sphincters by allowing contents of the stomach to regurgitate into the oropharynx, thus increasing the risks of aspiration (31). This is especially true when large bore nasoenteric tubes are utilized in the critical care setting (3). Many clinicians recommend the placement of post-pyloric feeding tubes to reduce incidence of regurgitation and aspiration as the enteral formula will be introduced further away from the oropharyngeal cavity and site of aspiration into the lung. Additionally, the return of the small bowel function and motility occurs before gastric or colonic activity in post-operative patients and could result in greater tolerance of enteral feedings and help to ultimately achieve nutrition goals quicker when fed directly into the small bowel (4,38). Binnekade et al reported that the percentage of days with
successful feeding was greater in those patients receiving duodenal versus gastric feedings by a 19% difference (9).

On the other hand, many clinicians oppose placement of nasoenteric tubes beyond the pyloric sphincter, arguing they do not necessarily reduce risk of aspiration or associated pulmonary infections unless access can be obtained in the distal bowel, specifically beyond the ligament of Trietz (39). However, no trial was able to associate nasojejunal feedings with decreased aspiration and nosocomial pneumonia compared with nasogastric tube placement (38). Moreover, post-pyloric placement may be difficult and not feasible in all critical care cases. Placement of post pyloric tubes requires additional time to not only verify tube placement but also additional time needed for fluoroscopic, endoscopic, or ultra sound guided placement, time which some unstable patients may not have (4). In a study by Montecalvo et al gastric feeds were initiated, on average, 3.9 days after admission and 5.5 days for those fed into the jejunum (40).

A greater benefit of early enteral nutrition improved tolerance of enteral nutrition when surgical jejunostomies were utilized. However, this procedure often times requires even more time and delay to place unless the patient presents to the ICU with a previous jejunostomy placement (4). However, jejunal feeding is associated with a small but detrimental risk of mesenteric ischemia. In metabolically stressed patients, the absorption of intraluminal nutrients increases energy demands and could potentially put the intestine at risk for ischemia in the presence of hypoperfusion. In many cases the gut can survive periods of hypoperfusion by redistributing flow of oxygen within the intestinal wall (41). Because this risk of mesenteric ischemia is small, the benefits of jejunal feedings continue to outweigh the risks when post-pyloric feedings are deemed necessary.
Post pyloric feedings in conjunction with nasogastric decompression in the presence of delayed gastric emptying of high gastric residual volumes may be necessary in some critically ill populations (8). There is insufficient data in critically ill patients adequately comparing the benefits of gastric versus small bowel feeding. Evidence suggests that post-pyloric or jejunal feeds should be reserved for those individuals who do not tolerate gastric feeds after failed use of prokinetic agents, changes in formula, continuous infusion of sedatives or paralytic agents, or those deemed high risk of aspiration especially if the patient is to remain in supine position (head of bed <30 degrees) for therapy or hemodynamic instability (3).

Misplacement or dislodgement of the feeding tube (back into the esophagus) could further increase the risk of aspiration, not to mention, delay or prolong re-initiation of enteral nutrition support. The reported incidence of accidental placement of gastric tubes in airways varies between 1 and 15% (42). However, despite potential complications regarding dislodgement or misplacement of gastric tubes, current literature consistently recommends gastric feeding consideration first, then post-pyloric to deliver enteral nutrition in a time-efficient manner and decrease above consequences. When post-pyloric placement is deemed appropriate, the clinician needs to evaluate the additional time, energy and costs that may be associated with endoscopic and fluoroscopic procedures and compare to the overall benefit versus potential complications. More important than the location of tube is the nursing care and attention to detail needed to minimize complication with enteral access and continuation of enteral feeding. Additionally, the risks of dislodgement and associated aspiration could increase once a patient is transported out of the ICU where the patient to staff ratio is greater (13).
Diarrhea Associated with Enteral Nutrition

Although gastric residual volumes and risk of aspiration continue to complicate adequately feeding the patient, other gastrointestinal disturbances in the critical care setting can delay or prolong the initiation of enteral feeding. Roberts et al also examined diarrheal complications in the critical care setting and its impact on patient outcomes. Diarrhea was defined as three loose stools within a 24-hour time period and was the second most common gastrointestinal complication, presenting in 28% of ICU patients. Tube feeding rate was often slowed or halted altogether in patients presenting with diarrhea despite other possible contributing factors unrelated to enteral formula or feeding: medication, enteric pathogens, hypoalbuminemia, underlying disease state, inflammatory syndromes, and sepsis (14). On the other hand, those individuals fed gastrically could be more prone to frequent loose stools because large volumes of formula infused may lead to the secretion of water, sodium and chloride from the colon, thus diminishing its ability to appropriately absorb nutrients (43). In order to avoid delay in achieving nutrition goals, it is recommended to change the formula to a partially hydrolyzed product that uses guar as the fiber source or add banana flakes to the enteral formula to decrease possible diarrheal complications. If not appropriately addressed, diarrhea can further complicate the patients’ medical progress by exposing them to loss of electrolytes, skin care problems and increased infections (14,43).

ASPEN Guidelines for Enteral Nutrition

When the gastrointestinal tract is functional, enteral feeding is considered the preferred route for nutritional support. Tube feedings can provide adjunctive support or total and complete nutrition therapy. The American Society for Parenteral and Enteral Nutrition highlight
indications and contraindications of enteral nutrition in critical and acute care patients. The following are indications to advocate enteral access for providing appropriate nutritional care:

- Inability to consume or absorb adequate nutrients, both macronutrients and micronutrients by mouth.
- Oral intake does not meet two thirds to three fourths of patients’ estimated daily needs based on age, nutritional status, severity of illness, catabolic state and expected duration of poor nutrient intake or absorption.
- Functional or partially functional gut who are unable to consume foods by mouth. (7)

Potential contraindications to enteral nutrition include:

- Terminal Illness: before initiating EN, the benefits of EN should be measured against the potential risks
- Short bowel syndrome depending on the length of the remaining bowel.
- Complete mechanical obstruction of GI tract below duodenum
- GI Bleeding pending etiology, severity and location of acute bleed. Once thoroughly assessed, a small bowel feeding tube may be more appropriate than PN.
- Protracted vomiting and diarrhea: this needs careful consideration. Severe vomiting can be difficult to keep nasogastric tubes in place, but could be beneficial for gastric decompression with small bowel feedings or use of prokinetic agents. Source of diarrhea needs to be considered prior to start of PN (osmotic or secretory) such as Clostridium difficile or oral medications (sorbitol containing medications, antibiotics, laxatives, prokinetic agents, etc)
- High output fistulas
• GI ischemia: this needs careful consideration. EN has been shown to improve blood flow in the gut and to maintain the barrier effect of the intestine.

• Paralytic ileus

• GI inflammation or enteritis such as Crohn’s disease

• Pancreatitis: only when enteral access below the Ligament of Trietz cannot be obtained (2,7)

**Early Enteral Nutrition in the Critically Ill Population**

Evidence based recommendations indicate that enteral nutrition can be initiated in adult patients within 24-72 hours after injury or acute illness once the patient is resuscitated and stabilized in the intensive care setting (3,8). The majority of studies reviewed have defined early enteral feeding as a 48-hour window of opportunity to allow the intensivist, a physician who specializes in the care of critically ill patients, to consider the patient’s hemodynamic stability, fluid resuscitation volumes, and gastrointestinal disturbances, such as bowel distention, gastric residual volume and diarrhea. Early initiation of nutrition, preferably via the enteral route, is vital to minimize the effects of hypermetabolism and hypercatabolism. Additionally, early EN has been shown to improve clinical outcomes in a variety of critically ill populations by reducing septic morbidity, decreasing ICU and hospital length of stay, improving wound healing and preserving gastrointestinal mass, structure and function.

A meta-analysis of 15 randomized controlled trials comparing early versus delayed EN in 753 patients, found a lower risk of infections and decreased hospital length of stay in those fed early, defined as less than or equal to 36 hours of admission to hospital or of surgery. Patients in the early EN group had a 19% versus 41% lower risk of infection compared to those fed later in
their ICU admission. Additionally, those patients receiving early EN had a mean reduction in hospital length of stay by 2.2 days, especially for those patients with trauma, head injuries and burns. However, the analysis failed to show significant difference in mortality between the two groups (8% in the early EN versus 11.5% in delayed EN) (6).

More recently, similar results were reported in Artinian’s meta-analysis of 4,049 patients, 2,537 in the early EN group versus 1,512 patients in delayed EN group. For those in the early EN group, nutrition was initiated within 48 hours of the onset of mechanical ventilation. Early EN initiation was associated with lower ICU and hospital mortality (18.1% versus 21.4% and 28.7% versus 33.5%, respectively). However, the early EN group was associated with increased risks of ventilator-associated pneumonia (11.2% versus 9.5%), although this did not achieve statistical significance. Furthermore, the risk of ventilator-associated pneumonia did not translate into a greater risk of death, concluding the favorable effects of early EN can offset the potential risks (44).

In a study comparing the administration of early versus late EN among mechanically ventilated ICU patients, Ibrahim et al found that those patients in the early EN group achieved a higher intake of overall calories and protein during the first five days of ventilation. These results achieved statistical significance between early EN and delayed EN groups (2,370 ± 2,000 kcal versus 629 ± 575 kcal and 93.6 ± 77.2 grams of protein versus 26.7 ± 26.6 grams of protein, respectively). However, despite all efforts to meet targeted nutritional goals by initiating feeds earlier, only 27.9% of total caloric requirements and 26.9% of estimated protein needs were achieved within the first week of ICU admit (11).

In a study of 28 patients undergoing gastrointestinal resections, patients were either fed enterally immediately after surgery within 2-3 hours (n=14), or fed by mouth (n=14). The EN
group received a greater number of calories (1,622 kcal versus 377 kcal per day in the orally fed group) and protein (60.6 grams versus 0.8 grams per day). Gut mucosal permeability and integrity of bowel mucosa were assessed by differential sugar absorption tests. Mannitol is absorbed on the transcellular level and lactulose on the paracellular level. Increased intestinal permeability allows greater amounts of lactulose to be absorbed and is reflective in urinalysis. Those patients fed enterally were shown to have improved gut mucosal integrity postoperatively by lactulose: mannitol ratios (0.1 in the EN group versus 0.5 in the orally fed group). The authors concluded that achievement of nutritional goals early in the ICU leads to the prevention of increased gut mucosal permeability of bacteria and toxins (10).

In summary, for ICU patients, the use of EN and early initiation of feedings compared with PN or delayed EN is associated with lower complication rates, such as decreased infections, septic morbidity and gut mucosal atrophy. Additionally, clinical outcomes are improved among those patients receiving early introduction of EN, including reduced ICU and hospital length of stay, greater achievement of caloric intakes to reduce gut permeability and further offset the risks of malnutrition during hospitalization. Although there are unclear contraindications of EN such as ventilator-associated pneumonia, it appears the favorable effects of enteral feeds largely outweigh the potential risks.

Adequacy of Enteral Nutrition Support

Although early enteral nutrition support initiation has been indicated as beneficial to improve patient outcomes, the adequacy of achieving energy needs with nutrition support can be just as important. Goals for critically ill patients are commonly set at 25-35 kcal/kg pending the severity of illness or injury and body mass of the patient. A recent meta-analysis noted that initiating
feeding within 48 hours of ICU admission and achieving at least 60-70% of (14-18 kcal/kg) of the patient’s overall caloric needs during the first week of ICU admit is associated with shortened length of stay, ventilator time and reduced number of infectious complications (5). This review found only two of seven studies that showed patients fed greater than 70% of energy goals had less chance of being discharged from ICU alive or spontaneously breathing upon discharge from the ICU. These findings were noted in patients with Acute Physiology Scores greater than 50 (5).

Actual attainment of the full enteral nutrition goal during the first week of ICU admission is highly unusual. In a study of adequacy and timeliness of nutrition support, Roberts et al showed that advancements of feedings were slow with only 28% of their patients receiving adequate amounts of nutrients by day number three of ICU admit. Of that 28%, ICU length of stay was shorter for those who received sufficient energy intakes, defined as 20-35 kcal/kg. However, no correlation was made between energy intake and ventilator days (14). Providing insufficient nutrition support can be related to a variety of factors including: the requirement to halt enteral feedings prior to procedures, diagnostic testing, surgeries, tube displacement and gastrointestinal intolerance. Of all enteral nutrition cessations, McClave et al found that 66% could be avoided. Therefore, concluding that enteral feedings could be prolonged up to four hours prior to surgical interventions or endoscopic procedures without interference with these diagnostic procedures (15). Additionally, implementing educational in-services and nutrition support protocols could be beneficial in reporting these findings, especially in regards to only holding enteral feedings for gastric residual volumes greater than 200-250 mL after two consecutive checks in order to ensure adequacy of nutrition (15).
Importance of Nutrition Support Protocols

A protocol can be simply defined as “a rule that guides how an activity should be performed” (45). Evidence-based protocols, or a set of clinical care guidelines, are designed to assist physicians and other members of the interdisciplinary team in the decision making process to improve clinical outcomes. The implementation of clinical, evidenced-based protocols is intended to standardize care, enhance quality of care, reduce risks of poor outcomes and minimize the increasing costs of hospitalization and clinical interventions.

Early enteral nutrition support can influence morbidity and mortality in critically ill patients (3), decrease septic complications and lessen the stress response (46). Clinical practice guidelines have been developed to guide practitioners to make evidence-based decisions regarding nutrition support therapy to ultimately improve overall quality of direct patient care and outcomes. However, evidence-based guidelines may rely on physicians and clinicians to seek information in order to make informed decisions. General guidelines are necessary but not necessarily sufficient for active implementation of those recommendations (47). Protocols and performance improvement methods may need to include multiple tools to permit the action and implementation of evidence-based recommendations (47).

The development and use of enteral feeding protocols that reflect evidence-based practices are highly valuable to ensure patient improvement and minimize undesirable outcomes in the critical care setting. One proposed explanation of delayed initiation of nutrition support in many studies was the lack of a standardized protocol for initiating feedings and handling feeding complications. A study by Chapman et al found that when a standardized enteral nutrition order form was utilized, patients achieved their caloric goals 3.1 days sooner than those in the pre-implementation group (48). Spain et al found that by implementing an enteral infusion protocol,
it improved physician ordering and resulted in enteral feeding goals that related much closer to patient estimated needs (82% of goal versus 66% for pre-protocol implementation) and advancement of enteral nutrition within 72 hours of feeding initiation (57% post-protocol versus 14% post-protocol). Additionally, this led to a trend toward fewer interruptions in feeding (16% versus 11% lost time), especially for holding feeding for gastric residual volumes less than 200 mL without physical signs of gastrointestinal dysfunction (46).

In a prospective study, Barr et al (2004) gathered information pre and post-implementation of a nutrition support protocol and found that mechanical ventilation in the post-protocol group was reduced by an average of 9.5 days compared to the pre-protocol group. Patients receiving early EN had a 56% reduction in their risk of death, independent of their severity of illness, nutritional class, age, gender, or admitting diagnosis, compared to patients receiving parenteral nutrition or no nutritional support. When using a non-mandatory protocol, continued staff education and frequent feedback with revision of policies is imperative to success of evidence-based ICU protocols. The outcomes of implementing a nutrition support protocol in the Barr et al study concluded that voluntary use of nutrition protocols were more likely to be followed if: “1) clinicians have ongoing input as to how to improve the protocol after it is implemented (i.e. “stakeholder ownership”), 2) protocol performance and clinician adherence to the protocol are frequently measured and assessed and, 3) if clinician-specific feedback about their compliance with the protocol and related patient outcomes is given to them in a timely and constructive fashion.” (8)

The role of the Registered Dietitian (RD) in Roberts’ study showed a shorter ICU length of stay when nutrition status was assessed by the RD within the first three days of admission (14). This was suggested to be in part related to the timeliness and overall adequacy of nutrition
administered. Additionally, the presence of the dietitian in the ICU permitted opportunities to converge about nutritional status, needs, and tolerance of feedings with other vital members of the interdisciplinary team (14).

In conclusion, nutritional attention is fundamental in the overall care of the patient. Furthermore, the presence of a RD encourages an interdisciplinary approach to care by developing relationships between critical care physicians and nurses facilitating the exchange of communication in order to promote nutrition support, ensure adequate energy intakes, and reduce barriers to providing timely nutrition intervention and improve patient outcomes in the critically ill population. The purpose of the present study was to determine whether the implementation of a Nutrition Support Protocol, where nutrition initiation and management was driven by the dietitian, influenced the number of critical care patients fed early. The Nutrition Support Protocol was derived upon evidence-based research guidelines that support feeding the gastrointestinal system, either enterally or orally, within 48-hours of admission or resuscitation.

Statement of the Problem

The increased risk of malnutrition, nutrition-related complications, and unwanted outcomes in the ICU call for action to improve adequacy, timeliness, and appropriateness of nutrition support using evidence-based protocols. The translation and implementation of evidence-based recommendations into consistent practice can be challenging. The purpose of the present study is to determine whether the initiation of a Nutrition Support Protocol in the ICU of four facilities in a healthcare system will increase the number of adult critical care patients who receive initiation of nutrition support within 48 hours of admission. The Nutrition Support Protocol will be implemented based on evidence-based clinical practice guidelines.
Significance of the Problem

While many studies have documented the importance of providing early nutrition support in the critical care setting in order to minimize undesirable clinical outcomes, few studies have reviewed how to achieve those recommendations. This study will provide evidence on whether or not the implementation of a Nutrition Support Protocol can help achieve evidence-based recommendations and shorten time to nutrition initiation in the critically ill population. The dissemination and implementation of this Nutrition Support Protocol and decision-making tool should lead to improved nutrition support practice in the ICUs. In turn, this is expected to lead to improved clinical outcomes for critically ill patients and enhanced care across a healthcare system. The consistent provision of early and appropriate nutrition support holds the potential to significantly reduce ICU patient complications, morbidity, mortality and lengths of hospital stay.

Study Objectives

The present study will examine the effectiveness of the Nutrition Support Protocol versus physician management on early initiation of nutrition support in patients admitted to eight ICUs across four different hospitals from January 2006 to September 2007. Changes in the rates of early nutrition initiation (within 48 hours) will be compared between the pre-protocol and post-protocol implementation periods. Different methods of administering nutrition (enteral, parenteral or oral) will be compared along with the time to the initiation of nutrition, and whether or not the Nutrition Support Protocol was utilized.
Research Questions

1. Will the implementation of a voluntary Nutrition Support Protocol across eight ICUs in four hospitals result in increased numbers of patients receiving early initiation of nutrition support within 48 hours of ICU admission?

2. Do patients on the Nutrition Support Protocol receive nutrition earlier than patients not on Nutrition Support Protocol (physician management of nutrition therapy)?

3. Are there differences in the time to initiation of nutrition support pending route of nutrition (enteral, parenteral or oral) between those patients whose nutrition was managed via the Nutrition Support Protocol or physician managed?

4. Will the percentage of patients receiving PN inappropriately be decreased after the implementation of the Nutrition Support Protocol?
CHAPTER III. METHODOLOGY

Design

The effectiveness of implementing a Nutrition Support Protocol in eight intensive care units (ICUs) (medical, surgical and/or trauma) across four separate hospitals totaling 85 adult care beds was assessed by time to feeding, route of feeding, and feeding adequacy via medical records for one year before and 18 months after the implementation of a Nutrition Support Protocol. The pre-protocol period time frame consisted of all records from January 1, 2005 to December 31, 2005 prior to the implementation of the Nutrition Support Protocol. Data gathered from January 1, 2006 to September 2007 were divided based on whether they received nutrition management via the attending intensivist or Nutrition Support Protocol headed by the Registered Dietitian (RD). This study was approved by the Human Subjects Review Board (HSRB) at Bowling Green State University in Bowling Green, Ohio (Approval ID: H08T177GX4) and permission to gain access to Nutrition Support Records for the use and dissemination of this study was granted by the Clinical Nutrition Manager of the healthcare system. Patient confidentiality and privacy was maintained throughout the study.

Subjects

Medical records from all adult patients admitted to any of the eight ICUs within the hospital system from January 2005 to September 2007 were considered for the study. Selection criteria included both men and women, 16 years of age or older, and admission into one of the eight ICUs for a minimum of 48 hours. There were no distinguishing characteristics that separate intensive care patients as urgent, life-threatening, surgical or otherwise. Exclusion criteria
included patients admitted to the ICU for less than 48 hours and patients who died within 48 hours of ICU admit. Patient records were tracked for up to seven days of their ICU stay. RDs screened and assessed all eligible patients for nutrition needs using a standardized data collection record developed for this study, the Nutrition Support Record (Appendix B). At all hospitals, attending intensive care physicians, surgical teams, and the ICU interdisciplinary team maintained medical management and responsibility for all patients.

Measurements

Medical record review for baseline data included demographic data (sex and age only), admitting medical diagnosis, and the mode of medical nutrition therapy (oral, enteral or parenteral). The primary outcome measures were the percent of patients managed by the voluntary Nutrition Support Protocol versus standard physician managed care, the number of hours from admission to the initiation of nutrition therapy, the mode of nutrition (oral, enteral or parenteral), and the percent of patients under each protocol who received initiation of nutrition support within 48 hours of admission to the ICU.

Additional data collected included the date and time when the medical nutrition therapy goal was met, enteral access route (gastric vs. small bowel), volume of enteral feedings, composition of enteral feeds (formula used), mechanical ventilator status, duration of ventilator support, positive/negative ventilator associated pneumonia (VAP) and bloodstream infection (BSI), Propofol (Diprivan) volume, and blood glucose range (low-high). When data were sufficient, these variables were compared between the pre-and post-protocol periods and between patients managed under the Nutrition Support Protocol versus standard physician care.
Procedures

Instrument Development

Beginning in early 2005, a committee of eight RDs with expertise and experience in critical care nutrition conducted evidence-based research reviews of early enteral feeding in critical care adults which revealed a need to initiate a protocol based on such information across the hospital system. The primary concern was that many patients in the ICU setting were not fed (orally or enterally) within the recommended 48-hour guidelines set forth by the American Society of Parenteral and Enteral Nutrition (ASPEN) (7) and The American College of Chest Physicians (8). Also, clinical staff expressed need for an instrument to direct nursing and physician staff on how to implement nutrition therapy guidelines. Thus, the Nutrition Support Record was developed and in 2005, this committee began to collect preliminary data as a pilot test to determine the need for early EN management and, eventually, implementation of a voluntary Nutrition Support Protocol.

The Nutrition Support Protocol focuses on the timing and management of patient nutrition support in critical care units. Enteral feedings are to start within 48 hours of ICU admission at a rate of 20 milliliters per hour of the house tube feeding formula (Jevity 1.2, Abbott Nutrition, Columbus, OH) and increased according to the discretion of the RD. Patients, who are not candidates for enteral nutrition, are to be reassessed by the physician and dietitian within 24 hours to determine need for PN. There are no specific guidelines by the Nutrition Support Protocol to initiate early PN. However, if enteral access is unobtainable or contraindicated according to ASPEN guidelines (7), PN was deemed appropriate and encouraged to start within 72 hours of ICU admission, especially in the presence of malnutrition. The following table
(Table 2) reviews the indications and potential contraindications for EN addressed in the Nutrition Support Protocol Decision Tree (Appendix C).

**Table 2. American Society of Parenteral and Enteral Nutrition Guidelines for Enteral Nutrition**

<table>
<thead>
<tr>
<th>Contraindications for Enteral Nutrition</th>
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<tbody>
<tr>
<td>Mechanical Bowel Obstruction</td>
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<td>Hemodynamic Instability</td>
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<td>Small Bowel Ileus</td>
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<tr>
<td>Gastrointestinal Surgery</td>
</tr>
<tr>
<td>Bowel Ischemia</td>
</tr>
<tr>
<td>Pressor Use</td>
</tr>
<tr>
<td>Bowel Anastomosis</td>
</tr>
<tr>
<td>Gastric Surgery</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Contraindications to Gastric Enteral Nutrition (Gastric vs. Small Bowel Placement)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild/Acute Pancreatitis</td>
</tr>
<tr>
<td>GERD</td>
</tr>
<tr>
<td>Head Injury/Trauma</td>
</tr>
<tr>
<td>Gastric Residuals &gt;250 mL on</td>
</tr>
<tr>
<td>Prokinetic Agents</td>
</tr>
<tr>
<td>Gastroparesis/Poorly Controlled Diabetes</td>
</tr>
<tr>
<td>Bipap</td>
</tr>
<tr>
<td>Gastric Ileus</td>
</tr>
<tr>
<td>Aspiration Risk: history of aspiration or unable to control oral secretions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Enteral Nutrition Contraindications if Anticipate NPO &gt; 5-7 Days (EN vs. PN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Gastrointestinal Bleed</td>
</tr>
<tr>
<td>Necrotizing/Pseudocyst Pancreatitis</td>
</tr>
<tr>
<td>High Output Fistula (&gt;500 mL)</td>
</tr>
<tr>
<td>Severe Malnutrition on Admit</td>
</tr>
<tr>
<td>Ileus/Small Bowel Obstruction</td>
</tr>
<tr>
<td>Short Gut Syndrome</td>
</tr>
<tr>
<td>Failed Enteral Access Attempts</td>
</tr>
</tbody>
</table>

The Nutrition Support Record was tested prior to implementation by several different dietitians within the hospital system. An inter-rater reliability study was conducted in 2005 by the Clinical Nutrition Manager of all four hospitals. Ten different patient charts were evaluated by six dietitians using the Nutrition Support Record. There was 94% agreement among the six RDs with no disagreement in the primary data (time of nutrition initiation, formula, rate, time of ICU admit, etc). The 6% discrepancy was only among recording of the EN volumes and diprivan rates on the Nutrition Support Record.
Voluntary Use of the Nutrition Support Protocol

The Nutrition Support Protocol was made available in eight ICUs across four different hospitals within a healthcare system in January 2006. The Nutrition Support Protocol also employs the ICU RD to actively manage, in conjunction with the attending physicians, the route of feeding (oral, enteral, or parenteral) and time to initiate feeding for each patient on an individual presentation to the ICU.

In 2005 during the development of the Nutrition Support Protocol, the ICU Admission Order Set was also revised. This ICU Admission Order Set gave admitting physicians the opportunity to voluntary check whether they wanted their patient to be on the Nutrition Support Protocol, driven by the ICU RD, or managed strictly by the attending physician. The new ICU Admission Order Set was to be launched at all four hospitals no later than January 1, 2006. Each hospital implemented the ICU Admission Order Set and voluntary Nutrition Support Protocol at different times depending approval from individual medical executive committees at each hospital. Although time frames were variable, no hospital implemented the order set or Nutrition Support Protocol before September 2005 or after December 31, 2005. From January 1, 2006 to present time, each hospital still maintains the aforementioned ICU Admission Order Set and Nutrition Support Protocol.

Starting in August 2006, the hospital RDs held multiple in-service training sessions for physicians, nurses and clinical staff to promote early enteral feeding to improve clinical outcomes. Critical care RDs, the Clinical Nutrition Manager, and physician champions for each hospital, along with other ICU support staff, developed a Nutrition Support Protocol. Training sessions are held at the beginning of each month for new ICU staff members explaining the
importance of early EN, role of the RD in the ICU and presence of the Nutrition Support Protocol.

The newly revised ICU Admission Order Set permits the physician to voluntarily check whether the Nutrition Support Protocol should be employed on each patient admitted to the ICU. Once checked, the RD, in conjunction with the physician, will utilize the Nutrition Support Protocol Decision Tree (Appendix C) to determine the best appropriate mode of nutrition therapy. If the physician did not choose to utilize the Nutrition Support Protocol, they were encouraged to feed patients enterally, either gastric or post-pyloric, and within 48 hours of ICU admission, pending contraindications of enteral nutrition. Contraindications to enteral nutrition were primarily based on the American Society of Parenteral and Enteral Nutrition and the American College of Chest Physicians guidelines (7,8).

Use of the Nutrition Support Protocol and nutritional management was entirely voluntary, however, RDs attending daily rounds with the ICU interdisciplinary team were expected to encourage the use of the Nutrition Support Protocol and it’s guidelines for nutrition therapy initiation, route of therapy, volume and composition of feeds. Only one hospital within the four hospital system made the Nutrition Support Protocol mandatory for each patient after January 1, 2006.

Quarterly and/or monthly results were reviewed by a panel of dietitians and physicians at each hospital who determined the percentage of patients fed within 48 hours with and without use of the Nutrition Support Protocol. Results were distributed to all RDs within the hospital system, and those physicians and staff in the intensive care settings. RDs were encouraged to utilize the information collected on a monthly basis as means of promoting the use of the Nutrition Support Protocol or feeding within 48 hours.
Statistical Analysis

Statistical analysis was performed using the Statistical Analysis System (SAS 9.1 for Windows, Cary, NC). Difference in continuous variables (i.e. age, number of hours until nutrition initiation) among groups (pre-protocol and post-protocol periods, Nutrition Support Protocol and physician management, and between method of nutrition delivery) were compared using analysis of variance (ANOVA) with Fischer’s Least Significant Means post hoc correction for multiple comparisons. Categorical variables (i.e. gender, protocol, method of nutrition support) were expressed as frequencies and differences among groups were compared using Wald’s Chi Square. A P value of <0.05 was considered statistically significant.
CHAPTER IV. RESULTS

Patient Demographics

A total of 2,242 patients were eligible for the study. Of those patients, 37 patients were considered appropriately not fed within the 48 hour time frame for palliative care purposes, hemodynamic instability, high gastric output prior to feeding initiation, multiple non-abdominal surgical interventions within the first two days of ICU admit, or unable to gain gastric access after multiple failed attempts. There were no significant differences between age or gender among the pre-protocol and post-protocol implementation groups and the most common feeding route (49.1%) was via enteral nutrition (Table 3).

Table 3. Baseline Characteristics Among Pre-Protocol and Post-Protocol Intensive Care Patients

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Pre-Protocol Implementation 2005 (n = 814)</th>
<th>Post-Protocol Implementation 2006 and 2007 (n = 1428)</th>
<th>p&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean ± SD</td>
<td>64.1 ± 16.6</td>
<td>64.6 ± 16.3</td>
<td>63.8 ± 16.7</td>
<td>0.2740</td>
</tr>
<tr>
<td>(Range: 16-101)</td>
<td></td>
<td>(Range: 16-101)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender, % (n)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>50.6 (1127)</td>
<td>52 (420)</td>
<td>50 (707)</td>
<td>0.3654</td>
</tr>
<tr>
<td>Method of Nutrition, % (n)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enteral Nutrition</td>
<td>49.1 (1101)</td>
<td>45.1 (367)</td>
<td>51.4 (734)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Parenteral Nutrition</td>
<td>8.7 (194)</td>
<td>9.5 (77)</td>
<td>8.2 (117)</td>
<td></td>
</tr>
<tr>
<td>Oral Nutrition</td>
<td>40.6 (910)</td>
<td>45.0 (366)</td>
<td>38.1 (544)</td>
<td></td>
</tr>
<tr>
<td>Appropriately Not Fed</td>
<td>1.65 (37)</td>
<td>0.49 (4)</td>
<td>2.3 (33)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Differences across periods determined by ANOVA and Fischer’s Least Squares Method or Wald’s Chi Square.
Differences Among Pre-Protocol and Post-Protocol Implementation Periods

Over the three years of data collection most, 79.5% (n = 1752), of patients were fed within the first 48 hours of ICU admission with a mean ± standard deviation (SD) of 20.26 ± 13.48 (range 1-48) hours to the initiation of nutrition; 20.5% (n = 453) of patients were fed more than 48 hours after admission into the ICU with a mean of 75.31 ± 26.01 (Range 49-240) hours to the initiation of nutrition.

There were improvements in the time to nutrition initiation and percentage of patients fed within 48 hours of ICU admission after the implementation of the Nutrition Support Protocol (Table 4). The percentage of patients fed more than 48 hours of ICU admission significantly decreased from 26.7% pre-protocol to 17% post-protocol implementation. In addition, the mean time to initiation of nutrition support also decreased from 36.3 ± 31.5 hours before the Nutrition Support Protocol was implemented to 28.9 ± 25.3 hours afterwards (p<0.0001), which represents an improvement of 7.4 hours. Additionally, more patients were fed within 48 hours via the enteral route in the post-protocol implementation time period than during the pre-protocol period; 86.2% (633 of 734) versus 74.4% (273 of 367) respectively. Thus, despite the method of nutrition management chosen in the post-protocol period (physician managed or Nutrition Support Protocol), the time to nutrition support initiation and the percentage of patients receiving nutrition support within 48 hours significantly improved compared to the pre-protocol period.
### Table 4. Early Nutrition Support by Method of Feeding Among Pre-Protocol and Post-Protocol Implementation Time Frames

<table>
<thead>
<tr>
<th>Time to Nutrition Initiation&lt;sup&gt;b&lt;/sup&gt;&lt;br&gt;hrs, mean ± SD</th>
<th>Total</th>
<th>Pre-Protocol Implementation 2005</th>
<th>Post-Protocol Implementation 2006 and 2007</th>
<th>p&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>31.7 ± 27.9</td>
<td>36.3 ± 31.5</td>
<td>28.9 ± 25.3</td>
<td>0.0001</td>
</tr>
<tr>
<td>Enterally Fed</td>
<td>30.3 ± 23.7</td>
<td>35.3 ± 25.8</td>
<td>27.7 ± 22.1</td>
<td>0.0001</td>
</tr>
<tr>
<td>Orally Fed</td>
<td>31.8 ± 31.2</td>
<td>36.3 ± 35.4</td>
<td>28.8 ± 27.6</td>
<td>0.0004</td>
</tr>
<tr>
<td>Parenterally Fed</td>
<td>39.1 ± 33.3</td>
<td>41.3 ± 35.7</td>
<td>37.4 ± 31.6</td>
<td>0.4322</td>
</tr>
</tbody>
</table>

Fed within 48 hrs<sup>b</sup>, % (n)

<table>
<thead>
<tr>
<th>Total</th>
<th>Pre-Protocol Implementation 2005</th>
<th>Post-Protocol Implementation 2006 and 2007</th>
<th>p&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Patients</td>
<td>79.5 (1752)</td>
<td>73.3 (594)</td>
<td>83.0 (1158)</td>
</tr>
<tr>
<td>Enterally Fed</td>
<td>82.3 (906)</td>
<td>74.4 (273)</td>
<td>86.2 (633)</td>
</tr>
<tr>
<td>Orally Fed</td>
<td>77.7 (707)</td>
<td>74.0 (271)</td>
<td>80.2 (436)</td>
</tr>
<tr>
<td>Parenterally Fed</td>
<td>71.7 (139)</td>
<td>64.9 (50)</td>
<td>76.1 (89)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Differences across periods determined by ANOVA and Fischer’s Least Squares Method or Wald’s Chi Square.

<sup>b</sup>Patients who were appropriately not fed (n = 37) were excluded.


A total of 1,428 patients were enrolled in the post-protocol implementation group, 33 (2.31%) of those patients were considered appropriately not fed for palliative care or hemodynamic instability purposes, and were not included in the analysis. During the post-protocol implementation group, physicians could voluntarily place patients on the Nutrition Support Protocol or choose to manage nutrition independently (physician managed). After the implementation of the Nutrition Support Protocol, 63.7% (n = 910) of patients’ nutrition was managed by the physician alone. Only 36.3% (n = 518) of patients were on the Nutrition Support Protocol where the nutrition was managed by the ICU RD in collaboration with the attending intensivist, critical care nursing staff and other members of the interdisciplinary team. The percentage of patients fed after 48 hours of admission into the ICU was higher in the physician
managed group, 22.0%, compared to 8.4% in the Nutrition Support Protocol group, equating to a 13.6% difference of initiation rate among the two groups (Table 5). The mean time to feeding was reduced by 12.7 hours in the Nutrition Support Protocol group; 33.6 ± 27.3 hours in the physician managed group versus 20.9 ± 18.8 hours in the Nutrition Support Protocol (p< 0.0001).

The majority of patients (51.4%) in both the physician managed group and Nutrition Support Protocol group were fed via the enteral route. However, there were significant differences in the percentage of patients fed parenterally and orally (9.5% and 36.3% versus 6.0% and 41.3%) for physician managed versus Nutrition Support Protocol, respectively, p=0.0163. In addition, a great percentage of patients were appropriately not fed in the physician managed group (Table 5).

The time to initiation of nutrition support across protocols was examined by method of nutrition support in the post-protocol implementation period (Table 5). For enterally and orally fed patients, those managed by the Nutrition Support Protocol received nutrition support significantly (p<0.0001) sooner; 10.9 hours sooner for enterally fed and 17.5 hours sooner for orally fed, compared to patients fed a similar method managed by the physician alone in the post-protocol period. For parenterally fed patients, ASPEN guidelines (7) do not include a recommendation of feeding within 48 hours, and in the present study there was not a significant difference in the hours to initiation of parenteral nutrition between physician managed and patients on the Nutrition Support Protocol.
Table 5. Comparison of Physician Management and Nutrition Support Protocol (Lead by the Registered Dietitian) in the Post-Protocol Implementation Time Frames

<table>
<thead>
<tr>
<th></th>
<th>Post-Protocol Total (n = 1428)</th>
<th>Physician Management (n = 910)</th>
<th>Nutrition Support Protocol (n = 518)</th>
<th>p&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nutrition Management Method</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Patients, %</td>
<td>63.7</td>
<td>36.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Nutrition Support Method, % (n)</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.0163</td>
</tr>
<tr>
<td>Enteral Nutrition</td>
<td>51.4 (734)</td>
<td>51.4 (468)</td>
<td>51.4 (266)</td>
<td></td>
</tr>
<tr>
<td>Parenteral Nutrition</td>
<td>8.2 (117)</td>
<td>9.5 (86)</td>
<td>6.0 (31)</td>
<td></td>
</tr>
<tr>
<td>Oral Nutrition</td>
<td>38.1 (544)</td>
<td>36.3 (330)</td>
<td>41.3 (214)</td>
<td></td>
</tr>
<tr>
<td>Appropriately Not Fed</td>
<td>2.3 (33)</td>
<td>2.9 (26)</td>
<td>1.4 (7)</td>
<td></td>
</tr>
<tr>
<td><strong>Time to Nutrition Initiation&lt;sup&gt;b&lt;/sup&gt;</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All patients, hrs, mean ± SD</td>
<td>28.9 ± 25.3</td>
<td>33.6 ± 27.3</td>
<td>20.9 ± 18.8</td>
<td>0.0001</td>
</tr>
<tr>
<td>Enteral Nutrition</td>
<td>27.7 ± 22.1</td>
<td>31.7 ± 24.6</td>
<td>20.8 ± 14.3</td>
<td>0.0001</td>
</tr>
<tr>
<td>Oral Nutrition</td>
<td>28.8 ± 27.6</td>
<td>35.7 ± 29.5</td>
<td>18.2 ± 20.1</td>
<td>0.0004</td>
</tr>
<tr>
<td>Parenteral Nutrition</td>
<td>37.4 ± 31.6</td>
<td>35.5 ± 32.2</td>
<td>42.2 ± 29.9</td>
<td>0.4322</td>
</tr>
<tr>
<td>Fed within 48 hrs, % (n)</td>
<td>83.0 (1158)</td>
<td>78.0 (690)</td>
<td>91.6 (468)</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

<sup>a</sup>Differences across periods determined by ANOVA and Fischer’s Least Squares Method or Wald’s Chi Square.

<sup>b</sup>Patients who were appropriately not fed (n = 33) were excluded.

Including all methods of nutrition support (enteral, oral, and parenteral) significantly more patients (91.6%) on the Nutrition Support Protocol were fed within 48 hours of ICU admission compared to physician managed patients (78.0%) in the post-protocol period (Table 5). A more specific comparison of early nutrition support by method of nutrition is provided in Figure 1.

Significantly more enterally fed patients received nutrition support within 48 hours if they were managed by the Nutrition Support Protocol rather than by the physician (96.6% versus 80.3%, p<0.0001). A similar pattern and significance was evident in orally fed patients in the post-protocol period.
The implementation of the Nutrition Support Protocol appeared to affect physicians even if they did not adopt the protocol in the post-protocol period. Comparing only physician managed patients, there were significantly more enterally fed patients who received nutrition support within 48 hours in the post-protocol period compared to pre-protocol period (80.3% versus 74.0%, p<0.04, Table 5).

Figure 1. The percentage of patients fed early (within 48 hours) by method of nutrition support in the pre-protocol group (physician managed, hatched boxes) versus post-protocol implementation period (physician managed, hatched boxes and Nutrition Support Protocol, solid boxes). \(^a\)Significant difference between pre-protocol and post-protocol period, \(p=0.04\), Wald’s Chi Square. \(^b\)Significant differences between physician managed and Nutrition Support Protocol managed patients in the post-protocol period, \(p<0.0001\), Wald’s Chi Square.

Appropriateness of Parenteral Nutrition Support

A total of 194 patients were fed via the parenteral route during their ICU admission. In the pre-protocol implementation time period, 9.5% (n = 77) of patients were parenterally fed while
8.2% (n = 117) were given parenteral nutrition in the post-protocol implementation period. Appropriateness of parenteral nutrition was determined according to the ASPEN guidelines (7). The implementation and use of the Nutrition Support Protocol did not adversely affect rates of appropriate parenteral nutrition, 86.1% (n = 74) were appropriately given PN in the physician managed group versus 87.1% (n = 27) in the Nutrition Support Protocol group.
CHAPTER V. DISCUSSION

Evidence based medical literature indicates that there are improved outcomes when critically ill patients are fed within 48 hours after admission and/or resuscitation in the Intensive Care Unit (ICU) (2-7,9,14). While many studies have indicated the importance of early initiation of nutrition support in the critical care setting, techniques on how to achieve early nutrition support in the ICU have not been systematically studied. In the present study, the implementation of a voluntary Nutrition Support Protocol significantly decreased the time to the initiation of nutrition support across all patients by over seven hours. Including Registered Dietitians (RD) in the management of nutrition support resulted in a more timely initiation of feeding (nearly 13 hours sooner) than when attending intensivists managed nutrition support without active RD assistance. The large sample drawn from eight different ICUs across a healthcare system provides a good reflection of the nutritional management with and without the presence of a Nutrition Support Protocol.

During the pre-protocol period, many of the patients were eligible for early nutrition support, specifically enteral nutrition, but failed to receive it 26.7% of the time. Despite the presence of an established, well-trained and highly visible nutrition support team at each of the four hospitals, the number of patients not being fed within the recommended 48 hour time frame continued to be high. On the basis of the pre-protocol period observation, the development of the Nutrition Support Protocol for use in the ICU was created with the anticipation to reduce the number of patients not fed within the 48 hour time frame to less than 10% of all cases. During the first 21 months of the new protocol described in the present study, the number of patients who failed to receive nutrition support within 48 hours fell from 26.7% to 17%. More
importantly, patients on the Nutrition Support Protocol received nutrition within 48 hours of ICU admission 91.6% of the time.

One of the more interesting results to come out of the data collection was the comparison of the pre-protocol group with the post-protocol, physician management group. Patients’ nutrition support in these two groups was initiated and managed by the physician alone. In comparison to the pre-protocol group, the post-protocol physician managed group had only a 4.7% increase of patients fed early compared to an 18.3% increase of those on the Nutrition Support Protocol. Overall, this equated to only a 2.7 hour improvement to the time of nutrition initiation; 36.3 hours in the pre-protocol group versus 33.6 hours in the post-protocol physician managed group. It was anticipated that the percent increase among the two physician managed groups would be much greater given the presence of the Nutrition Support Protocol and promotion of early nutrition initiation. Conversely, there was a 15.4 hour improvement from the pre-protocol group to the post-protocol Nutrition Support Protocol group. The vast increase of patients fed within 48 hours between the pre-protocol group and the post-protocol, Nutrition Support Protocol managed groups are largely attributed to the role and guidance of the RD in the critical care setting.

The percentage of patients orally fed within 48 hours of ICU admission is lower than those fed enterally in the post-protocol group, 80.2% orally fed early versus 86.2% enterally fed early. This is likely due to physicians often waiting to place enteric tubes, especially when extubation from the ventilator was anticipated at or around the 48 hour position. While much of the literature advocates for the initiation of nutrition support within 48 hours, several studies did utilize a 72 hour time frame for nutrition onset. For future investigation, it would be advantageous to discern whether the majority of those patients not fed within 48 hours were fed utilizing the 72 hour benchmark.
There are a variety of reasons why the time to nutrition initiation was increased after the post-protocol period, much of which can be attributed to the role and increased involvement of the RD in the critical care setting. During the first year of data collection, much of the research and review of the literature regarding the importance of early nutrition initiation was headed by the clinical nutrition team. Observing that only 73.3% of all ICU admissions received nutrition within the 48 hour time frame deemed the creation of the Nutrition Support Protocol. The protocol development heightened awareness of the benefits of early nutrition support in the critical care setting and need for further observation of outcomes to promote best practices. Once the Nutrition Support Protocol was fully developed and all staff were trained on its intent and purpose, the mere presence, promotion, and awareness of Nutrition Support Protocol alone could have played a large role in the increase in the number of patients receiving early nutrition support, despite whether the attending physician wished to employ the Nutrition Support Protocol or not.

In a recent survey asking 182 intensivists in the ICU to rate how important the role nutrition is in the critically ill population, attending physicians provided a mean score of 4.60 out of 5.00, indicating nutrition is felt to be very important in the ICU. However, physicians rated their own understanding of nutrition, comfort level of providing nutrition support and confidence in nutrition knowledge at a mean level of 3.33 out of 5.00. Confidence in nutrition support teams, comprising of the attending intensivist, gastroenterologist, surgeon and clinical dietitians, and their recommendations were slightly higher at a mean score of 3.70. All physicians surveyed favored EN over PN as the preferred route of nutrition support but wished to wait an average of 2.43 days before initiating any type of nutrition support despite multiple resources indicating nutrition support within 48 hours of ICU admission is advantageous. The purpose of the survey
was to understand current physician practices and identify discordance in knowledge to facilitate physician education regarding evidence-based nutrition practice guidelines (49).

Knowing that the confidence level increases with team collaboration, the primary strength of the Nutrition Support Protocol implemented in this study is the initiation and management of nutrition support by the RD in partnership with the attending physician, critical care nurse, and other members of the interdisciplinary team. More importantly, these members of the critical care team were included in the development of the Nutrition Support Protocol. In a study regarding the outcomes of nutrition support after the implementation of a nutrition management protocol, Barr et al found that clinicians were more likely to follow protocol guidelines if clinicians felt “ownership” in the implementation and development stages of the protocol (8). The incorporation and feedback of nearly every intensivist in the ICU during the developmental phase of the Nutrition Support Protocol was key in hopes to gain a more widespread acceptance of the protocol. Despite the initial low rate (36.3%) of physicians choosing the Nutrition Support Protocol, there was an overall positive effect of the implementation of the protocol over the healthcare system. The onset of nutrition initiation was decreased by a mean of 7.4 hours from the pre-protocol time frame to the post-protocol time frame (36.3 hours to 28.9 hours) and even further reduced by 15.4 hours for those patients on the Nutrition Support Protocol in comparison to the pre-protocol group.

The use of standardized order forms may require additional patience to fully mature in regards of development, training of key practitioners, and gaining overall acceptability as standard practice for critical care patients. In a study measuring the effectiveness of delivering enteral nutrition with an infusion protocol, Spain et al found that physicians’ reluctance to use the protocol limited its value and efficacy. They noted that it took two to three years for the
protocol to be accepted and fully integrated into practice patterns (46). Continued educational resources demonstrating strategy successes should be provided to all physicians and vital team members to advance acceptance and promote adherence to new protocols (8).

Evidenced based guidelines use objective data to define “best practice” patterns, and then protocols are developed to direct care toward the achievement of those guidelines. Because there is an increased emphasis on patient safety, improved clinical outcomes and reduction of overall healthcare costs, evidence-based protocols are becoming more common in hospital settings (45). Although many clinicians have been exposed to protocols, some physicians can be reluctant to accept protocol usage, fearing loss of autonomy. However, freedom of choice in whether to follow protocols is becoming more difficult. More organizations are recognizing patient safety as key to reduce poor clinical outcomes and risks. Thus, they are providing additional education and technology to implement a framework to guide decision making in the form of protocols. These protocols are often followed for compliance and clinical disciplines are held accountable to follow protocols accordingly. More importantly, the Centers for Medicare and Medicaid Services are forecasted to provide organizations with financial incentives if following clinical care guidelines and protocols based on “best practices” (45). Weingarten’s review of how to change physician behaviors found that incentive programs could significantly change physician ordering and compliance of voluntary protocol usage and overall adherence to protocol guidelines (50). This, in conjunction with the Medicare and Medicaid incentives, could greatly enhance nutrition management protocol usage in healthcare systems.

Lack of protocol adherence could be in part of inadequate and timely feedback to physicians and nursing staff (8). Change is typically short-lived and care will typically revert back to that of which the physician feels most comfortable or to which was previously established prior to the
implementation of specific protocol guidelines. Prolonged retrospective feedback of greater than six months has been shown to be less impacting in making changes (50). In our study, feedback was provided by the Clinical Nutrition Manager and the ICU RD in written documentation through quarterly allotments. Additionally, verbal progress of the results was presented to intensivists and the critical care interdisciplinary team during monthly meetings. Unfortunately, not all clinicians are mandated to attend these meetings.

An additional strength of the present study was the use of a pre-experimental study design. During the first year of data collection, patient case reviews and observations made in relationship to the forthcoming literature review indicated need for early enteral nutrition support in the critically ill population. The utilization of a pre-protocol group from our own ICUs across the healthcare system was utilized to identify areas for improvement and ultimately develop the Nutrition Support Protocol. The two sets of groups (pre-protocol versus post-protocol periods and physician management versus Nutrition Support Protocol managed groups) were of similar characteristics and allowed adequate comparisons to be concluded.

One major limitation to the present study was the lack of specific data collected by the dietitians on the Nutrition Support Record. Much of the data for the secondary variables were not adequately filled to its completion (i.e. medical diagnosis, caloric and protein requirements, and daily enteral feeding and Propofol volumes). This data could have been utilized to determine relationships between time of nutrition initiation and severity of medical diagnosis, overall achievement of caloric and protein intakes at any given point of the ICU stay compared to the actual estimated needs of the patient, and how Propofol volumes effected the achievement of caloric values. At this current point in time, the healthcare system in this study is undergoing a large change of documentation practices from paper to electronic medical charting. Much of the
data entered into the nursing daily flow sheets and nutrition assessment forms can soon be quickly transferred to an electronic version of the Nutrition Support Record. This streamline of practice will allow easier completion of the Nutrition Support Record and alleviate “busy” work of copying one clinicians’ documentation to separate report and ultimately reduce potential human error in transferring data. More importantly, additional data will be available in order to be considered and utilized for future research studies to indicate the overall influence of the Nutrition Support Protocol and outcomes in the ICU.

In the future, it would be valuable to determine if the Nutrition Support Protocol and the earlier onset of nutrition initiation reduces gastric complications. The implementation of an enteral tube feeding protocol in the Arabi et al study showed a significant trend toward improved feeding delivery, especially in those receiving gastric feeds (51). There were smaller amounts of gastric residual volumes and episodes of vomiting reported with those on the protocol; indicating improved feeding tolerance with those patients on the protocol (51). More specifically, would the Nutrition Support Protocol lead to more attention to detail regarding gastric residual volumes, diarrhea, prokinetic agents, dislodgement of feeding tubes, scheduling of invasive and operative procedures and overall improvement of feeding practices? Additionally, how does the Nutrition Support Protocol effect cost in relationship to complications? Pending future data collection and results, the current Nutrition Support Protocol could be altered to address such complications in order to reduce occurrence and improve overall patient outcomes.

One question remains given the results of this study: how early is too early when it comes to the onset of nutrition initiation? In our study we found that those patients on the Nutrition Support Protocol were fed 12.7 hours earlier than those patients whose nutrition was managed by the physician. However, the mean time to initiation was still within the recommended guidelines
of 48 hours. It would be advantageous to determine if differences exist among complication rates and time of nutrition onset, specifically when comparing those whose nutrition was managed by the RD versus the attending physician.

Another limiting factor of our study is several months of Nutrition Support Records were missing from three of the four hospitals. The available data, despite some gaps in time, were utilized as this study was a system-wide approach to the implementation of the same protocol. This was felt to be highly appropriate because all patients were exposed to the same Nutrition Support Protocol, at the same time frame, within the same healthcare system. The study was conducted as an “intent to treat” design. The data presented was representative of a system-wide healthcare analysis. The coordination and management of nutrition practices across all facilities could alleviate any discrepancies among clinicians and physicians who practice among all hospitals within the system.

While this study focused on the early initiation of nutrition support in the ICU, the introduction of parenteral nutrition support within 48 hours of ICU admission is not a routine practice or endorsed by the American Society of Parenteral and Enteral Nutrition (ASPEN) (7). The potential onset of complications (higher infection rates, electrolyte imbalances, and risks of overfeeding) with parenteral nutrition was a focus during our study by the physicians, clinical pharmacists, and dietitians. While there was a decrease in the percentage of patients given parenteral nutrition from the pre-protocol group to the post-protocol groups (9.5% versus 8.2%), this could be attributed to one of two effects. First, the use of the Nutrition Support Protocol in the ICU could be gaining more attention on evidence-based guidelines supporting the need to feed patients enterally or orally in the presence of an intact, functional and accessible gastrointestinal tract. Therefore, increased research and review of the literature regarding early
enteral feedings and the mere presence and promotion of the Nutrition Support Protocol could affect rates of the enteral and oral nutrition routes. Secondly, the clinical nutrition team was collecting separate data on the use and appropriateness of parenteral nutrition simultaneous to the data collection for the present study. Although not statistically significant, the appropriateness of parenteral nutrition use in the critical care setting as deemed by the ASPEN guidelines (7), did slightly improve among those on the Nutrition Support Protocol versus those managed by the physician, 87.1% versus 86.1% respectively.

As stated earlier, protocol development and adherence to protocol implementation may take several years to allow clinicians to witness the overall benefits of nutrition management and enhancement of quality patient care. Several areas for improvement for this protocol may include provisions to not hold feedings for gastric residual volumes greater than 200-250 mL after two consecutive checks and guidelines for when to hold tube feedings for testing, procedures and surgical interventions (15,31,36). Making changes to the Nutrition Support Protocol Decision Tree to include such provisions may permit the attainment of nutrition goals and lead to reduction of undesirable outcomes related to malnutrition risks.

The healthcare system in this study is continuing the use of the aforementioned Nutrition Support Protocol. Ongoing monitoring and data collection is essential to establish the success of the protocol in meeting patients’ nutritional goals and provide documentation for improvements in patient safety and quality care (fewer infectious complications, correction of elevated gastric residual volumes, reduction in malnutrition during hospitalization), and potential cost savings (decreased length of stay and ventilator dependence). As the development of the protocol progresses, ongoing education and continued input from physicians, nurses, pharmacists and
RDs are in progress to further improve the Nutrition Support Protocol and progress toward mandatory use of the protocol given the favorable results as depicted in this study.
CHAPTER VI. CONCLUSIONS

In conclusion, the use of a nutrition management protocol for the initiation of nutrition support to critically ill patients improved time to nutrition initiation and should be considered as part of standard practice in the ICU setting. The presence of a voluntary Nutrition Support Protocol could lead to an overall improvement of onset of nutrition initiation. However, those patients whose nutrition was managed by an interdisciplinary team approach under the leadership of a registered dietitian showed an improved time to the initiation. Because multiple disciplines are needed to ensure appropriate monitoring and administration of nutrition support, the partnership and communication among physicians, clinical dietitians, nurses, pharmacists and other critical care disciplines was invaluable to the overall care of the patient. And thus it can be concluded that the implementation of the Nutrition Support Protocol resulted in more interdisciplinary team collaboration among the critical care staff and resulted in an overall improved time to the initiation of nutrition support.

The development of evidence-based protocols is only one step toward changing practices. Continued education to critical care nurses, physicians and staff is essential to promote current research, guidelines and enhance the overall nutritional well-being of the patient. Our results provide multiple opportunities for implementation of quality improvement by the critical care interdisciplinary team to improve the provision of nutrition support administration to the critically ill population across a healthcare system.

The use of a voluntary nutrition support protocol has been advocated to reach a compromise between meeting patients’ nutritional goals and reducing potential complications associated with lack of prompt initiation of nutrition support. The Nutrition Support Protocol was designed on
the basis of researched and published guidelines considered to be best practice. Given the increased focus on safety and quality care for all patients among healthcare organizations and recent plans for potential financial incentives from the Centers of Medicare and Medicaid Services for those organizations who have evidence-based protocols established, protocol development may be hard to avoid (45). After the conclusion of this study, if nutrition management protocols are not being utilized, the need for evaluation of nutrition practices including timeliness, route of nutrition support and groups of critical care staff aimed at analyzing research of best practices in order to initiate the implementation of evidence based protocols and standards of care is warranted.
REFERENCES


APPENDIX A. ICD-9-CM CODES FOR HIGH NUTRITION RISK

The following ICD-9-CM codes are considered high nutritional risk for patients in the acute care setting:

a) 99.15 – Parenteral infusion of concentrated nutritional substances

b) 96.6 – Enteral infusion of concentrated nutritional substances

c) 260.0 – Kwashiorkor: weight loss caused by stress combined with dietary deficiency, particularly low intake of protein

d) 261.0 – Marasmus: weight loss and wasting occurring in the course of chronic disease or emotional disturbance and primarily due to dietary deficiencies of protein and calories

e) 262.0 – Other severe protein-calorie malnutrition: nutritional edema without dyspigmentation of skin and hair

f) 263.0 – Malnutrition of moderate degree

g) 263.1 – Malnutrition of mild degree

h) 263.8 – Other protein-calorie malnutrition

i) 263.9 – Unspecified protein-calorie malnutrition (2,17)
APPENDIX B. NUTRITION SUPPORT RECORD

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APPENDIX C. NUTRITION SUPPORT PROTOCOL DECISION TREE