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Assessing the Adequacy of the Rate Based System of Enteral Nutrition Infusion in the ICU of a Community Hospital

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ASSESSING THE ADEQUACY OF THE RATE BASED SYSTEM OF ENTERAL
NUTRITION INFUSION IN THE ICU OF A COMMUNITY HOSPITAL

by

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A Thesis Presented in Partial Fulfillment
of the Requirements for the Degree
Master of Science

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Date

We hereby recommend that the dissertation prepared under our supervision by Callie Betman entitled Assessing the Adequacy of the Rate Based System of Enteral Nutrition Infusion in the ICU of a Community Hospital be accepted in partial fulfillment of the requirements for the Degree of Master of Science in Nutrition and Dietetics

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ABSTRACT

The rate based system for delivering enteral nutrition has been found to result in an average delivery of 60-65% of estimated energy and protein needs in ICU patients. Interruptions in tube feedings for surgery, intolerances, and turning/bathing cause underfeeding as the rate based system does not allow the rate to be adjusted for any lost volume. At Northwest Hospital, protocol is to calculate the hourly tube feeding rate over 20 hours, and run over 24 hours, in order to adjust for an expected 4 hours of interruptions per day; however, the effectiveness of this protocol has not been studied. The purpose of this study was to determine the adequacy of this protocol in delivering >80% of the prescribed energy and protein needs, as recommended by ASPEN, in order to determine if a volume based protocol, in which the hourly rate can be adjusted to make up for lost volume of tube feeding, may be more sufficient. This study was a prospective observational study involving 50 ICU patients on tube feeding for at least 24 hours. Kangaroo pumps were checked for all patients on tube feeding at 0700 each morning. Analysis was conducted using the SPSS software one sample t-test. Average tube feeding delivered (71.1 ± 28.3) was less than the accepted average of 80%, a statistically significant difference of 8.9 (95% CI, 0.84 to 16.92; $t(49) = -2.22$, $p = 0.031$). Surgeries and high gastric residual volume were found to be the most common reasons for tube feeding interruptions.

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CHAPTER 1

INTRODUCTION

Enteral nutrition in the critical care setting is essential to preserve lean body mass, reduce metabolic responses to stress, prevent oxidative cell injury, and promote immune responses (Heyland et al., 2003). The American Society for Parenteral and Enteral Nutrition (ASPEN) contends trophic feeds may maintain gut function, but greater than 50-65% of goal energy needs may be required in high risk patients to prevent further complications and mortality. Heyland et al. (2003) conducted a meta-analysis on intensive care unit (ICU) practices in Canada and found patients on average received 56% of calorie needs and 56.7% of protein needs. Enteral feedings are stopped or held for a variety of reasons such as high gastric residual volume, patient discomfort, medical procedures, position changes by nursing, and technical issues with feeding access. It has been reported that the average time of interruption of enteral feedings in critically ill patients is more than five hours per patient day (Stewart, 2014).

Many strategies have been proposed to resolve the obstacles in providing adequate nutrition in the ICU, such as use of prokinetic medications, limiting repositioning, correction of gastric residual volume (GRV) measurements and protocol, using post-pyloric feedings, and introducing nutrition support protocols (Stewart, 2014). A volume based feeding protocol has been one such program proposed to improve

nutrient delivery. In volume based feedings, it is the daily volume delivered, rather than an hourly rate, that is the focus. If the tube feeding needs to be held for any reason, the tube feeding will be restarted at a higher rate in order to ensure the goal volume is met (Heyland et al., 2010).

Statement of the Problem

Malnutrition is prevalent among hospitalized patients, with the occurrence reported to be 30-50% (Namme Luma et al., 2017). Malnutrition oppresses immune function, facilitates the loss of lean body mass, hinders wound healing, lengthens hospitalizations, increases health care costs, and increases mortality (Namme Luma et al., 2017). Therefore, it is imperative to prevent malnutrition to improve patient outcomes.

One obstacle in meeting the nutritional needs of patients receiving enteral nutrition is the interruption of tube feeding regimens for medical procedures, perceived gastrointestinal disturbances, and nursing needs to move the patient in order to prevent the development of pressure ulcers and to clean the patient and their linens (Elpern, Stutz, Peterson, Gurka, & Skipper, 2004). A protocol designed to effectively diminish nutritional losses while adhering to the overall prescribed plan of care for the patient is necessary. In doing so, the percent of energy loss must be determined.

The two primary tube feeding protocols being utilized in the acute care setting include a rate based and a volume based system. A rate based system involves providing tube feeding formula at a continuous goal rate that, if infused for the planned hours per day, will result in the patient's goal volume being obtained (Heyland et al., 2010). The goal of continuous feeding regimens is to deliver 100% of the patient's estimated nutritional needs within a 24 hour time frame. Therefore, it has been proposed that a

volume based protocol may be more effective in reaching goal energy and protein needs (Declercq, Deane, Wang, Chapman, & Heyland, 2016). The volume based protocol involves meeting a daily goal rate by adjusting the hourly rate of the tube feeding to make up for any interruption of the tube feeding throughout the day. This protocol has been found to yield a greater percentage of patient estimated energy and protein needs, although current research indicates it has not improved patient outcomes (Wang et al., 2017). However, this protocol has not been thoroughly investigated and some patients may not be able to tolerate the increased volume infused at higher hourly rates.

The amount of time tube feeding regimens are interrupted has been addressed by calculating the enteral nutrition over a shorter period of time to compensate for an anticipated amount of time the tube feeding will be interrupted. Protocol at Northwest Hospital in Randallstown, Maryland, is for all tube feedings to be calculated over 20 hours to assume and account for four hours of down time per patient day. This enteral feeding administration protocol has not been studied for adequacy at this healthcare institution. It is unclear where the estimated four hours of stoppage time originated; therefore, it is necessary to first evaluate the adequacy of the current protocol prior to suggesting the volume based protocol in this institution.

Purpose

Northwest Hospital currently uses a 20-hour rate based system protocol for continuous tube feedings (Northwest Hospital, 2017). The registered dietitian (RD) calculates the patient's energy and protein needs, selects the appropriate tube feeding formula, and determines the goal volume. The goal volume is divided by 20 hours to determine the goal hourly delivery rate. The goal delivery rate is then ordered by the RD.

This rate is infused for 24 hours per day if uninterrupted; however, it is anticipated there will be an average of four hours of interrupted feeding time due to medical procedures, repositioning of patients, perceived intolerances, and equipment malfunctions. Current research suggests the current rate based protocols for enteral nutrition in the critical care settings are inadequate for meeting patient nutritional needs (Declercq et al., 2016; Elpern et al., 2004; Uozumi et al., 2017). The purpose of this study is to estimate the percent of energy needs provided to patients receiving enteral nutrition using the current 20-hour rate based protocol in a 16-bed ICU in a community hospital. In doing so, the overall effectiveness of this protocol will be assessed. The volume based protocol involves the RD determining the goal total volume to be delivered over 24 hours with the rate being adjusted in response to any interruptions of the tube feeding regimen. The percent of tube feeding delivered will be compared to the volume of tube feeding prescribed by the registered dietitian (RD) over a 24-hour period. The RD will calculate each patient's specific energy needs and prescribe the appropriate tube feeding regimen based on the current tube feeding protocol at Northwest Hospital. The reason for stopping tube feedings and stoppage time will also be tracked. Categories will include tests/procedures, repositioning the patient, high GRV, and gastrointestinal disturbances. This information will determine if the majority of interrupted enteral feedings are avoidable and which reason contributes most to overall lost volume of tube feedings.

Hypotheses

Two hypotheses will be tested:

1. The current rate based protocol used to deliver enteral nutrition will meet less than 80% of the calculated goal volume per day.

2. Test/procedures will contribute the highest percent of stoppage time for tube feedings.

Justification

The adequacy of the proposed tube feeding protocol for Northwest Hospital must be investigated to assess its effectiveness in diminishing the nutrition loss during the interruptions of the tube feeding regimens. This study will provide valuable information needed to determine if this protocol is effective in meeting the nutritional needs of the hospital's patient population. This study will help clarify and identify reasons for interruptions of the enteral tube feeding regimens. In turn, the education needs of the healthcare practitioners will also be clear.

Most research on the adequacy of the rate based protocol have been focused on large institutions using a 24-hour calculation for tube feedings (Wang et al., 2017). Northwest Hospital uses a 4-hour buffer for interruption of enteral nutrition due to a variety of reasons. This study will determine if calculating tube feedings for over 20 hours in a small ICU is sufficient to deliver the calculated volume to meet nutritional needs or if a volume based protocol may need to be implemented to improve delivery of nutrients.

CHAPTER 2

REVIEW OF LITERATURE

The diagnosis of malnutrition includes any inadequacy in nutrients which may be induced by a catabolic disease state, an inadequate consumption of nutrients, or a combination of both. Malnutrition negatively affects practically every organ system in the body and increases the risk of poor outcomes (Barker, Gout, & Crowe, 2011). The risk of malnutrition while in the hospital setting and prior to admission is elevated, making nutritional status and delivery of optimal nutrition of the utmost importance (Namme Luma et al., 2017).

Prevalence of Malnutrition

Malnutrition is prevalent in the hospital setting and is reported to occur in 30-50% of hospitalized patients (Namme Luma et al., 2017). This high rate of malnutrition is not limited to the United States. Approximately 50% of hospitalized patients in South America have been found to be malnourished (Correia, 2016). This research is further supported by Kimiaei-Asadi and Tavakolitalab's study (2017) conducted using ICU patients in which 67% of the population was identified as malnourished. Moreover, the prevalence of malnutrition appears to increase with the severity of the patient's condition. In their study conducted in Iran, 84% of patients admitted to the trauma ICU were classified as malnourished. Thus, patients requiring surgery, especially those requiring

repair of the gastrointestinal tract often may have significant elevated nutritional needs to support wound healing and resistance to infection. Kimiaei-Asadi and Tavakolitalab (2017) found the incidence of malnutrition rose to 91% at time of discharge from the ICU. Similarly, Wang et al. (2017) found a rate of malnutrition in the ICU setting of 40-80%. Surgical ICU patients have an even higher occurrence of malnutrition due to the need to have no intake prior to surgeries and procedures or being unable to tolerate oral intake due to gastrointestinal surgeries (Peev et al., 2015).

The rate of malnutrition is higher in ICU patients due to clinical conditions making nutrient delivery more difficult, altered gastrointestinal function, and hypercatabolism (Kimiaei-Asadi & Tavakolitalab, 2017). Resting energy expenditure increases in response to stress and can increase by 5-20% in elective procedures postoperatively. Severe trauma and infections can raise resting energy expenditure by 50 to 60%. Additionally, for every one-degree Celsius increase in body temperature resting energy expenditure increases by 11%. This increase in metabolism provides energy and protein to the immune system in order to fight infection and repair tissues; however, increased catabolism causes protein wasting and rapidly causes malnutrition in this population (Sanches, De Goes, Bufarah, Balbi, & Ponce, 2016).

High occurrence of malnutrition in the hospital setting is not a new discovery. McWhirter and Pennington found 40% of patients to be undernourished and 67% of all patients in their 1994 study lost weight. Although the high prevalence of malnutrition has been identified, rates have not declined over the years (Barker et al., 2011; Martin-Palmero et al., 2017). Correia (2016) attributed this to clinicians inconsistently following optimal nutritional practices due to unawareness of best practices and insufficient time,

financial resources, and proper training. On the patient side, malnutrition is also exacerbated by preexisting malnutrition at admission, increased nutrient needs, and poor appetite/intake (Correia et al., 2016). Despite the well documented prevalence of malnutrition in the acute care setting, substantial progress has not been made in effectively addressing the problem of malnutrition especially among critical care patients. Currently, research indicates that 60% of patients discharged from the hospital have diminished nutritional status when compared to their condition upon admission (Martin-Palmero et al., 2017).

Nutrition Screening

Treatment and prevention of malnutrition first requires prompt identification of patients at risk and those who are already malnourished upon admission (Barker et al., 2011). The appropriate nutritional intervention must then be prescribed to treat it. Correia et al. (2016) found that one in three hospitalized patients in Brazil were fed nothing by mouth for greater than three days, with only 19% having nutritional status documented.

Malnutrition is diagnosed by institutions and researchers using different methods including low body mass index (BMI), weight loss, loss of muscle mass, loss of body fat, and inadequacy of intake (Barker et al., 2011). Namme Luma et al. (2017) defined malnutrition as low BMI and Mid-Upper Arm Circumference (MUAC) and found a prevalence rate of 11.5% and 8.4%, respectively, at Douala General Hospital. The best method for diagnosing malnutrition is not agreed upon and many different screening tools are used depending on the institution (Suarez-Llanos et al., 2017). Critical care patients are also more difficult to screen for malnutrition as obtaining a diet history may be

difficult or impossible depending on the patient's clinical status (Chakravarty, Hazarika, Goswami, & Ramasubban, 2013). Suarez-Llanos et al. (2017) recommended hospitals assess the patients' risk for malnutrition by choosing one screening tool according to the specific hospital's characteristics and patient population. These researchers indicated the Subjective Global Assessment is the standard screening tool used, although it has not been proven to be most effective or superior to other tools (Suarez-Llanos et al., 2017). Velasco et al. (2011) compared the use of four different nutritional screening tools in the same group of patients. They found the Nutrition Risk Screening (NRS-2002) identified 32.5% of patients at risk; the Malnutrition Universal Screening Tool (MUST) found 14% at medium risk and 27.5% at high risk; the Mini Nutrition Assessment (MNA) found 44% at nutritional risk and 14.5% with poor nutritional status; and the Subjective Global Assessment (SGA) found 28.5% as suspected malnourished and 6.8% as severely malnourished. Although nutritional screening has not been perfected, it has been found to be a cost effective and a timely process, regardless of the tool used, in identifying patients at nutrition risk (Suarez-Llanos et al., 2017).

Implications of Malnutrition

Malnutrition negatively affects both patient outcomes and the economic viability of the health care system (Barker et al., 2011). Malnutrition interferes with patient outcomes by interrupting the normal bodily functions and its ability to fight infections and promote repair (Barker et al., 2011). At the cellular level, malnutrition often weakens the immune system by limiting the body's ability to produce healthy cells for wound repair. Malnutrition increases the risk of pressure ulcers, inhibits wound healing, interferes with nutrient absorption, and hinders renal function (Barker et al., 2011).

Innate and acquired immunity are both diminished in malnourished patients, caused by an imbalance of T cells, low levels of CD69, inappropriate T helper cell response, impaired antibody response, and impaired phagocytosis (Takele et al., 2016). Depriving the gut of essential nutrients facilitates mucosal atrophy and increases the permeability of the intestines which enables infectious organisms to invade the cells and disrupt healthy cell reproduction (Sigalet, Mackenzie, & Hameed, 2004). These are some of the reasons there is an elevated risk for malnourished patients developing pressure ulcers and delayed wound healing. ICU patients with septic shock have a mortality rate of 30-50%. Malnutrition associated with sepsis has been found to have a large impact on cellular immunity which significantly increases the rate of mortality (Slotwinski et al., 2015).

Alhaug, Gay, Henriksen, and Lerdal (2017) found a significant association in patients at nutrition risk, identified using the Nutrition Risk Screening 2002, with the development of pressure ulcers in a mixed patient hospital setting. Infection causes an acute phase response which decreases nutrient absorption, further inducing malnutrition (Bresnahan & Tanumihardjo, 2014). Malnutrition also has been shown to decrease glomerular filtration and renal plasma flow (Kidney International, 1973). In the critical care setting, malnutrition was found to double the incidence of readmission to the ICU and increased the risk of mortality by eight times (Papapietro Vallejo et al., 2017). Malnutrition is also the third most common reason for 30-day readmission in surgical ICU patients (Peev et al., 2015).

Malnutrition affects patients physically by inducing muscle and fat loss, reducing respiratory and cardiac function, and causing weakening of internal organs (Barker et al.,

2011). Muscle and fat loss affects the patient's quality of life and ability to perform activities of daily living (Barker et al., 2011). Malnutrition also causes sarcopenia, or the loss of lean muscle tissue, and has been found to be present in 56% of geriatric hospital patients (Pierik et al., 2017). Sarcopenia has been found to have a significant correlation with prognosis in several types of malignancies (Nishikawa et al., 2017). In addition to poor nutritional status and immune system, poor prognosis is also related to shorter duration of therapy due to early dose limiting toxicities (Nishikawa et al., 2017). The onset of sarcopenia often impairs recovery and can in some populations, particularly the elderly, affect a patient's psychological health by facilitating apathy, depression, and dementia (Barker et al., 2011). Poor nutritional status also increases the rate of aging and functional dependence for activities of daily living. It has been found that malnutrition is correlated with depression and dementia in the elderly (Krzyminska-Siemaszko et al., 2016).

The aforementioned poor patient outcomes may result in extended hospital stays, increased medication usage, and overall higher medical costs (Barker et al., 2011). Alvarez-Hernandez et al. (2012) found that in Spanish hospitals malnutrition contributed an additional 5,829 Euro per patient which is equal to approximately 7,000 US dollars. In 2014, Stewart reported an estimated 20% higher treatment cost in patients with malnutrition as opposed to patients without malnutrition. Caring for an individual who has become debilitated due to malnutrition consumes a significantly higher amount of health care dollars. As the elderly population grows, healthcare practitioners must become vigilant in their efforts to establish effective standards of care and best practices

to prevent malnutrition as well as identifying and effectively treating in a timely manner. (Krzyminska-Siemaszko et al., 2016).

Obstacles in ICU Tube Fed Patients

Meeting nutritional needs in a tube fed patient in the ICU can be problematic as interrupted enteral feeding regimens due to patient repositioning, medical procedures, feeding intolerances, and equipment malfunctions decrease intake (Elpern et al., 2004). The consequences of undernutrition include poor outcomes for patients and increased health care costs (Barker et al., 2011). These risks are heightened in ICU patients because they often have elevated nutrient needs and are already at higher risk for complications such as infection (Heyland et al., 2003).

Many reasons for enteral tube feeding interruptions may be avoided if healthcare practitioners strategically plan and coordinate treatment interventions with the administration of enteral feedings (Peev et al., 2015). In a study using a 21- bed ICU researchers found an average of 64% of enteral feeding goal volume was met (Elpern et al, 2004). In this study the majority of interruptions (51%) were due to preparation for scheduled procedures and repositioning of the patient. Suspected intolerance to feedings due to nausea, vomiting, and high gastric residual volumes (GRVs) accounted for 21% of tube feeding interruptions. Similarly, Kozeniecki, McAndrew, and Patel (2016) found patients received an average of 51% of prescribed tube feeding volume in a tertiary Medical ICU (MICU). They reported inadequate energy delivered was caused mostly by slow advancement to goal rate. It was also found that patients on vasopressors received less of goal volume compared to patients not on vasopressors due to slow advancement of tube feeding rate. Anticipation of extubation and radiological procedures accounted for

13-29% loss of goal volume. Peev et al. (2015) found that in surgical ICU (SICU) patients intubation/extubation was the most common reason for holding tube feeds, followed by bedside procedures and imaging studies. In contrast to MICU patients, a larger number of interruptions was found to be unavoidable. The impact of tube feeding interruptions is calorie deficit, which impacts the nutrient needs of the body to promote recovery. Patients with the largest calorie deficits were found to have longer ICU and hospital length of stays.

Gastric Residual Volume (GRV)

GRVs historically have been thought to indicate intolerance to tube feedings; however, research has not supported this idea (Arabi et al., 2017). GRVs have been thought to measure the rate of gastric emptying; however, GRVs can also be affected by tube feeding rate, technique for measuring the GRV, gastric secretions, and duodeno-gastric reflux (Arabi et al., 2017). Reignier et al. (2017) found no difference in the development of ventilator associated pneumonia in patients with GRVs checked as opposed to GRVs not checked. Researchers also found that failure to check GRVs resulted in higher calorie delivery but did not affect the infection rate, hospital length of stay, or mortality rates. Reintam Blaser et al. (2017) recommended holding tube feedings only when GRV is above 500ml. They found GRV was not correlated with risk of aspiration pneumonia in ventilator dependent patients. The researchers recommended utilizing prokinetics or postpyloric feedings in patients with consistently high GRVs.

Diarrhea

The most common reason for enteral tube feeding regimens to be interrupted is the onset of diarrhea (Jakob, Butikofer, Berger, Coslovsky, & Takala, 2017). Critically

ill patients often require antibiotic therapy which frequently prompts the development of diarrhea. However, many healthcare practitioners typically hold tube feeding regimens when diarrhea occurs because they believe the diarrhea is caused by a tube feeding formula intolerance (Jakob et al., 2017). Jakob et al. (2017) found two-thirds of critically ill patients on tube feedings developed diarrhea, but diarrhea was not influenced by the enteral formula. Diarrhea, in this study, resulted in an energy deficit of greater than 500 calories per day. Reintam Blaser et al. (2017) recommended identifying the cause of diarrhea and treating with selective decontamination including antimicrobials and antibiotics and elemental or fiber enriched formulas.

Tube Feeding Protocols

The development of a “best practices approach” for the delivery of enteral nutrition will enhance patient outcomes and ensure meeting the standards of high quality care (Kim et al., 2017). However, the best protocol to meet nutritional needs has not been determined. To improve the delivery of enteral nutrition and enhance the nutritional status of ICU patients, current protocols must be evaluated and improvements must be implemented (Heyland, 2003). New protocols as well as nursing and physician education may be necessary in order to effectively and efficiently combat malnutrition among all patients, but especially among those receiving intensive critical care (Heyland, 2003).

Rate Based Protocol

Historically, enteral nutrition has been administered using an hourly rate to infuse an enteral formula over a 24-hour time frame in order to meet a goal volume per day (Heyland et al., 2010). Many healthcare institutions initiate the enteral formula at a low rate and increase the formula rate incrementally until the goal rate is achieved within 24

hours of starting the feeding regimen. However, there are no provisions made for capturing any nutritional loss during interruptions of the tube feeding regimen (Heyland et al., 2010). Practices such as this have resulted in suboptimal delivery of prescribed enteral nutrition (Elpern et al., 2004; Heyland et al., 2003; Kozeniecki et al., 2016). A Canadian survey using dietitians practicing in ICUs indicated that current protocols result in 56-62% delivery of prescribed energy needs (Heyland et al., 2003). Researchers reported tube feeding protocols, including head of bed elevation, small bowel feedings, and use of motility agents, are imperative to improving percent of prescribed tube feedings delivered.

Volume Based Protocol

A volume based protocol has been proposed as a proactive solution to reach goal energy and protein intake in tube fed patients (Heyland et al., 2010). In the volume based protocol semi-elemental formulas are utilized and tube feeds are started at goal rate. Daily goal volumes are used with compensation for interruptions in order to achieve optimum nutrient delivery. This protocol allows nursing to increase the tube feeding rate after holding the feeding in order to meet the total goal volume for the day. As a large percentage of interruptions have been found to be unavoidable or inevitable, this protocol is especially useful for making up for lost volume (Heyland et al., 2010). This protocol is used in hemodynamically stable patients, while a low volume trophic feed is proposed to maintain gut function in patients who are unable to tolerate high volumes. In addition, protein supplements are used to prevent protein deficiencies and are initiated in conjunction with the enteral feeding. Motility agents are also used as adjunctive therapy

and the GRV threshold is increased from 200mL to 250mL (Declercq et al., 2016; Heyland et al., 2010).

Heyland et al. (2010) introduced the above protocol. Their study found the protocol to be safe, feasible, and acceptable by nurses. Further data analysis indicated patients received 90% of estimated energy and protein goal as opposed to the previously reported 55-65% using current rate based protocols. Wang et al. (2017) reported the protocol increased energy delivery from 57.7% to 70.3% after implementation in their ICU in June 2015. However, Wang et al. (2017) also reported no improvement in morbidity or mortality rates with this increase in energy delivery. Further research is required to determine the benefits and challenges to this volume based protocol, and its impact on patient outcomes.

Permissive Underfeeding

Although malnutrition is known to be prevalent and detrimental in the critical care setting, some researchers have found that delivering goal calories and protein to these patients does not improve outcomes (Rice et al., 2012; Wang et al., 2017). Some have recommended that the goal should be 80% of patient energy needs delivered due to risk of overfeeding (Wang et al., 2017); however, some other professionals advocate for trophic or trickle feeds to improve outcomes (Wang et al., 2017; Wischmeyer, 2016). Weijs et al. (2014) found overfeeding, defined as 110% of estimated energy needs delivered, resulted in increased mortality and prolonged mechanical ventilation. However, protein intake of greater than 1.2g/kg by day four was found to decrease mortality rates and duration of mechanical ventilation. Results of the Weijs et al. (2014) study suggest protein may play a larger role in outcomes than energy intake.

Rice et al. (2012) researched the effect of trophic feedings, providing 15% of goal energy needs, versus goal feedings in mechanically ventilated patients on clinical outcomes. Clinical outcomes remained similar for the first six days of feedings. The trophic fed group also experienced fewer gastrointestinal disturbances than the group that was progressed to goal rates. Krishnan, Parce, Martinez, Diette, and Brower (2003) found patients receiving 33-65% of estimated energy needs had the highest survival rates, higher likelihood of being weaned off the ventilator, and a lower risk of sepsis. In contrast, Wischmeyer (2016) argued the best nutritional intervention is dependent on the specific patient's clinical condition. He suggested critically ill patients expected to be on mechanical ventilation for greater than eight days had increased mortality rates if fed less than 50% of estimated energy needs as opposed to patients who received greater than 80% of energy needs. Patients who were found not to benefit from reaching caloric goals were found to be overall younger patients, those who required less time on mechanical ventilation, and those with less organ dysfunction.

Summary

Malnutrition has been found to be both prevalent and detrimental to clinical outcomes in hospital patients (Alvarez-Hernandez et al., 2012; Barker et al., 2011; Kimiaei-Asadi & Tavakolitalab, 2017). Critically ill patients are at increased risk for malnutrition due to inadequate intake prior to admission, hypercatabolic illnesses, and poor intake (Kimiaei-Asadi & Tavakolitalab, 2017). Tube fed patients face obstacles in receiving 100% of their estimated energy needs due to regimen interruptions for procedures or perceived poor tolerance of formula (Elpern et al., 2004). The current rate based protocol used at many hospitals does not allow for those instances when tube

feeding regimens must be interrupted for various reasons (Heyland et al., 2010). The volume based protocol allows for changes in rate of formula in order to achieve optimal energy delivery (Heyland et al., 2010). However, further research is needed to determine if reaching goal estimated energy requirements improves clinical outcomes. Some researchers have found that trophic feedings or protein delivery may be more essential to decreasing mortality and complications (Krishnan et al., 2003; Weijs et al., 2014).

CHAPTER 3

METHODS

The purpose of this study was to identify the percent of energy needs being met with the current 20-hour rate based protocol in a community hospital 16-bed ICU in order to determine if a volume based protocol would be more effective in meeting patient needs. The percent of tube feeding delivered was compared to the volume of tube feeding prescribed by the registered dietitian (RD) over a 24-hour period.

Research Design

This study was a prospective observational study. All patients who remained on enteral nutrition for at least 24 hours in the Northwest Hospital ICU from January 2018 to May of 2018 were included in this study. The RD calculated each patient's specific energy needs and prescribed the appropriate tube feeding regimen based on the current tube feeding protocol at Northwest Hospital. Daily goal volumes were calculated by the RD typically using the Penn State 1998 or 2003 equation for ventilated patients and Mifflin St. Jeor for non-ventilated patients (Sanches et al., 2016). Total volume delivered to each patient over a 24-hour period was determined by checking the Kangaroo pumps which were used for all patients.

Subjects

Subjects were all continuously tube fed patients in the intensive care unit (ICU) at Northwest Hospital in Randallstown, Maryland. All patients who remained in the ICU on tube feedings for at least 24 hours were included in this study. Exclusion criteria included any patients on bolus feedings and patients taken off tube feeding within the first 24 hours. Northwest Hospital does not care for pediatric patients; however, any patient under the age of 18 was also excluded from this study. The study continued for a period of four months until data were collected on 50 patients. Patients were only monitored while in the ICU. Patients were no longer followed once moved to the acute care floor.

Instruments

Kangaroo enteral feeding pumps made by Metronic were used to deliver tube feedings to all patients. Data collection was recorded on the data collection instrument provided in Appendix A-1. Data recorded included researcher assigned non-identifiable code, date, admit diagnosis, length of stay in the ICU, days on enteral nutrition, tube feeding formula, goal tube feeding rate per hour, total volume goal, actual volume delivered, reasons for tube feeding holds, and amount of time held. This information was collected each day the patient remained on tube feedings and in the ICU. Appendix A-2 was used to record demographic information including age, gender, racial affiliation, comorbid conditions, and percent weight change while in the ICU from the medical record.

Data Collection Process

Before collecting data, this study was approved by the institutional review boards at Louisiana Tech University and Lifebridge Health (Appendix B). It was requested that patients be enrolled in this study without written informed consent as the study was an observation study with no foreseeable risk to patients. All identifying patient information was removed from the data collected and the patient was identified by a random subject number assigned by the researcher. Only the primary researcher, who is an employee of the hospital, had access to information that connected patients to the non-identifiable researcher assigned subject code. Data collection was carried out in a 16-bed medical ICU at Northwest Hospital in Randallstown, Maryland. All patients in the ICU who had been on continuous enteral nutrition for greater than 24 hours were included in this study. Kangaroo pumps were checked at 0700 each morning to determine total volume of feeding for the previous 24-hour period. To keep data collection consistent, total volumes were collected starting on the first day the patient had been on tube feedings for 24 hours at 0700. If a patient was started on tube feedings after 0700, the total volume was not collected until the next full 24 hours at 0700. Volume of tube feeding delivered was also documented in the "Ins and Outs" by nursing staff; however, checking kangaroo pumps gives higher accuracy of actual volume given and therefore was used exclusively for this study. Total tube feeding delivered for a total of 50 patients was monitored for a 4-month period for as long as each patient remained on enteral nutrition in the ICU. There is no standard documentation required by nursing at this institution for stoppage of enteral nutrition; therefore, review of the electronic medical record as well as

conversations with nursing staff were used to determine reasons for enteral feeding of downtimes.

Data Analysis

Data are presented as percentage of volume of tube feeding formula delivered compared to actual volume ordered by the RD. The percentage for all patients was averaged to determine the overall percent of prescribed tube feeding volume being delivered. Reasons for stoppage time was added and divided by the total number of stoppage time to determine what reason for stopping tube feeding contributed the most to lost volume in order to test hypothesis 2. Analysis was conducted using the SPSS software; one sample t-test was used to analyze the data.

CHAPTER 4

RESULTS

Demographic Data

The study included 50 patients with an average hospital length of stay (LOS) of 12.96 ± 8.02 days. Of the 50 patients, 21 were male (42%) and 29 were female (58%). The majority of patients were between ages 61 and 80 years (56%). Thirty-one patients (62%) identified as Black/African American, and 18 (36%) identified as White/Caucasian. Many patients had multiple comorbid conditions including cardiovascular disease (68%), diabetes (40%), Chronic Obstructive Pulmonary Disease (32%), renal disease (16%), cerebrovascular accidents (14%), and cancer (8%). Nine of the 50 were surgical patients, with four of those patients having less invasive procedures of percutaneous gastrostomy (PEG) placement, tracheostomy placement, and sacral debridement. Demographic characteristics of participants are summarized in Table 1.

Table 1

Baseline Demographics of Participants

Variable	# of Patients N=50	% of Patients %
Age, years		
18-40	2	4%
41-60	10	20%
61-80	28	56%
81-90	9	18%
>90	1	2%
Gender		
Male	21	42%
Female	29	58%
Ethnicity		
Caucasian	18	36%
African American	31	62%
American Indian/Alaskan Native	1	2%
Comorbid conditions*		
Cardiovascular Disease	34	68%
Diabetes	20	40%
COPD	16	32%
Renal Disease	8	16%
CVA	7	14%
Cancer	4	8%

* Some subjects had more than one comorbid condition

Tube Feedings

Tube feedings were delivered to the 50 patients for a total of 167 patient days while in the Intensive Care Unit (ICU). For the purpose of this study, a patient day is defined as a 24 hour period of tube feeding delivery. Patients spent an average of $3.32 \pm$

3.49 days on tube feedings while in the ICU. Formulas were prescribed by the Registered Dietitian (RD) and included Glucerna 1.2™ (N=13), Glucerna 1.5™ (N=6), Nepro Carb Steady™ (N=5), Jevity 1.2™ (N=9), Twocal™ (N=2), Osmolite 1.0™ (N=2), and Vital 1.2™ (N=17). Four patients had their tube feeding formula changed during the study which is why total N=54. Goal rates were calculated to meet 100% of each patient's energy and protein needs using the Penn state equation or the Mifflin equation as deemed appropriate by the RD.

Tube Feeding Delivered

On average, the 50 patients received $71.1 \pm 28.3\%$ of the volume of tube feeding prescribed. This translates into 68% of patients receiving 42.8-99.4% of the estimated calories and protein needs. Of the 50 patients, less than half (23 patients) received an average of 80% or more of tube feeding volume prescribed while in the ICU. The nine surgical patients received an average of $78.4 \pm 30.1\%$ of tube feeding ordered. A one sample ttest was performed in order to determine if the average tube feeding percent delivered in this study was significantly different than the accepted goal rate of 80% recommended by ASPEN (McClave et al., 2016). Average tube feeding delivered (71.1 ± 28.3) was less than the accepted average of 80%, a statistically significant difference of 8.9 (95% CI, 0.84 to 16.92; $t(49) = -2.22$, $p = 0.031$).

Reasons for Stoppage Time

The reasons for stoppage time were divided into the following categories turning/bathing/meds or other normal routine nursing care; high residuals; volume not advanced per protocol or started late after ordered by RD; change in formula;

surgeries/imaging; extubation; possible pump errors/change in pump; on trickle feeds and advanced to goal; vomiting, speech and language evaluation; clogged tube; oral gastric tube (OGT)/nasal gastric tube (NGT) pulled/confirmation of placement; possible aspiration; and unknown. The turning/bathing/meds or other normal routine nursing care category included interruptions with no discernable reasoning or recorded stoppage time as it is assumed all patients have tube feedings paused for these reasons. Therefore this category is essentially a minimal stoppage/no stoppage category. Of the 167 patient days, 89 days (52%) had minimal/no stoppage, or only stopped for routine nursing care, and 80 days (48%) included stoppage for one of the above stated categories. Aside from stoppage for routine nursing care the most common reasons for stopping a patient's tube feeding were high residuals (18) and surgeries/imaging (22). Average percent tube feeding volume delivered was calculated based on each stoppage reason listed above. Figure 1 shows these averages for the 167 patient days collected. A change in tube feeding formula resulted in the lowest average percent tube feeding volume delivered (12.6%). This category included only one patient day. Possible pump errors/change in pumps resulted in an average of 26.2% of tube feeding delivered. This reason for stopping a patient's tube feeding was recorded three times. Vomiting resulted in tube feeding stoppage six times and an average 36.8% of goal tube feeding was delivered. High residuals resulted in patients receiving an average of 44.3% of goal volume. An average of 55% of tube feeding volume was delivered in patients who underwent surgeries/procedures.

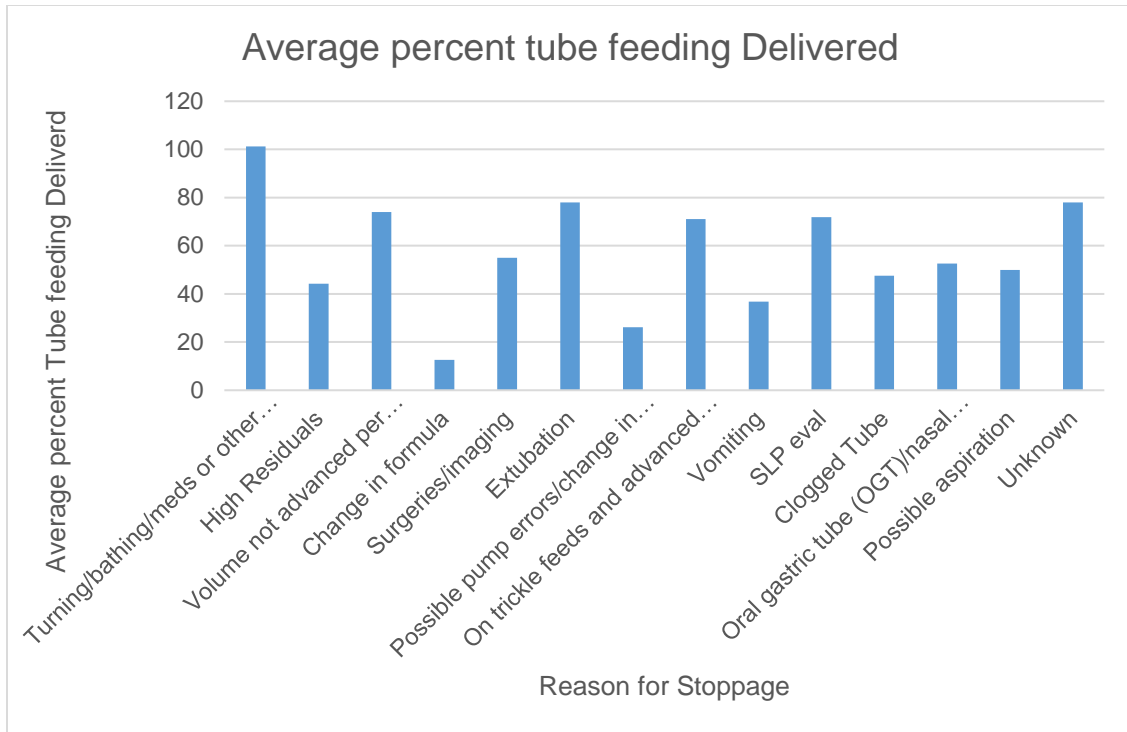


Figure 1. Average percent tube feeding delivered.

CHAPTER 5

DISCUSSION AND CONCLUSIONS

Adequate nutrition delivery is imperative in critically ill patients in order to reduce morbidity and mortality (Arabi et al., 2017). Obstacles to achieving adequate energy and protein delivery in critically ill patients include poor appetite, increased metabolic demand, gastrointestinal intolerance, and inability to swallow (Barker et al., 2011). Although initiating tube feeding in these patients may appear to ensure adequate nutrition, research suggests that most critically ill patients on tube feeding do not meet nutritional needs (Heyland et al., 2010). Some identified reasons for inadequate tube feeding delivery include stoppage time for procedures/surgeries, tube feeding intolerances such as vomiting or high residuals, and poor compliance with tube feeding protocols (Heyland et al., 2010).

Interruptions in tube feedings result in underfed patients because the protocol in most hospitals is to deliver enteral nutrition at a constant hourly rate with no way to make up for any stoppage time; in other words, total volume to meet nutritional needs is divided by 24 hours in a day. A potential solution to this obstacle is a volume based feeding protocol in which the patient is prescribed a total volume of tube feeding to receive throughout the day rather than a set volume at an hourly rate (Heyland et al., 2010). In this protocol the hourly rate can be adjusted if the patient has any interruptions

thereby ensuring the goal volume and thus goal energy and protein intake are met. This protocol, however, places greater burden on the nursing staff to adjust rates as needed. Some hospitals have attempted to improve tube feeding delivery by either calculating goal rate over fewer than 24 hours to account for stoppage time or increasing goal volume by a percentage to make up for stoppage time (Walker, Utech, Velez, & Schwartz, 2014; Kesey, Puckett, & Dissaniake, 2017; Lichtenberg, Guay-Berry, Pipitone, Bondy, and Rotello, 2010). Whether these adjustments work as well as a volume-based protocol is yet to be determined.

Current policy at Northwest Hospital in Randallstown, Maryland is to calculate goal tube feeding rate over 20 hours in order to account for an expected four hours per day of downtime per patient. The purpose of this study was to determine if the current protocol is sufficient to meet nutritional needs, or if a volume based feeding protocol should be considered in order to improve tube feeding delivery.

Although exact percentages continue to be debated, ASPEN guidelines for critical care medicine indicate that tube fed patients who receive >80% of estimated energy and protein needs have better clinical outcomes than those who receive less (McClave et al., 2016). At Northwest Hospital in Randallstown, MD, ICU patients in this study received an average of $71.1 \pm 28.3\%$ of prescribed tube feedings from January of 2018 to May of 2018. These results are comparable to similar studies investigating tube feeding delivery in the ICU setting, which reported an average of 60-65% of energy and protein needs delivered (Elpern et al., 2004; Heyland et al., 2010; Wang et al., 2017). Together these studies indicate current tube feeding protocols are not sufficient to meet ASPEN guidelines of >80% of goal nutrition needs.

Overall, although average percent tube feeding delivered was below 80%, on the majority of patients days (n=103, 62%), patients received greater than 80% of goal tube feeding volume. On patient days where feeds were limited to a brief hold for routine nursing care (n= 89, 53%) average tube feeding delivered was $101.3\pm 11.1\%$ of prescribed volume. In contrast, on days when tube feeding interruptions occurred due to identifiable reasons, an average of $53.7\pm 20.6\%$ of prescribed volume was delivered. On 19% (n=32) of patient days, less than half of the tube feeding goal volume was delivered. This polarization of results caused overall average tube feeding percent delivered to be lower than 80% while the majority of patient days did receive higher than 80% of goal volume.

As expected, tube feedings were interrupted in about half of all patient days (78 of 167) due to identifiable reasons. In 56 of the 89 patient days with no recorded reason for interruption, greater than 100% of goal volume was delivered. Delivery of nutrients in excess of goal is possible given the 20-hour delivery policy at Northwest Hospital. This is because some patients may actually receive the recommended volume/hour for greater than 20 hours. Lichtenberg et al. (2010) also found some incidence of overfeeding in a study similar to this one. In a 24 bed ICU in a similarly sized 220 bed hospital a 20 hour tube feeding policy was tested to determine improvement in tube feeding delivery. The research team found that a 20 hour feeding protocol improved average delivery of tube feeding from 79% in the control group to 97% in the experimental group. Patients were overfed (defined as $>110\%$ of nutrition needs administered) in 97 out of 268 (34%) patient days. However it should be noted that the study lasted for only six weeks and also relied solely on nursing documentation in the electronic medical record rather than examining pumps for actual tube feeding volume delivery. A large margin of human

error would be expected in this method of obtaining tube feeding delivery volumes as it requires nurses to record tube feeding intake every hour for 24 hours and does not account for short periods of tube feeding interruptions.

In contrast to using a 20 hour delivery system to compensate for tube feeding interruptions, another protocol is to add a safety factor or margin of error to estimated needs. In a recent study in a burn unit where the protocol is to use the Ireton-Jones equation and increase the rate by 10% to compensate for any stoppage of tube feedings, researchers reported an average of 79% of goal tube feedings delivered (Kesey et al., 2017). While these results are about 10 percentage points higher than those seen in the current study, nutrient delivery was still less than optimal. The intent of each of these protocols is to deliver 100% of the estimated nutrient needs via tube feeding given the fact that tube feedings are often interrupted. A potential problem with this is that patients who do not experience tube feeding interruptions could inadvertently be overfed. The major downfall of these protocols is that they assume all patients experience tube feeding interruptions and that in this way patients on tube feedings can be generalized. The advantage of the volume based protocol is that tube feeding can be adjusted based on each patient case and on the day-to-day obstacles that each patient faces. The volume based protocol accounts for the fact that all patients, and their hospitalizations are individualized and therefore may be best in delivering goal nutrient needs.

For example, in one hospital that was calculating tube feeding rates over 23 hours, researchers found that patients were being significantly overfed, receiving 105-121% of goal volume (Walker et al., 2014). Although this study included patients from long term care/rehabilitation and general medicine floors, average tube feeding volumes in ICU

patients were also high at 107%. It should also be noted that the method in determining tube feeding volume delivered to patients differed from this study. The patient's tube feeding ready-to-hang bottle was weighed every 24 hours to determine the volume delivered. The researchers suggested this method reduces any pump error; however, it can be argued that human error may skew their results as well. The results from Walker et al. (2014) as well as the data from the current study in which 56 patients received over 100% of estimated energy needs, shows the potential drawback of calculating for expected down time. Patients who do not have this downtime or interruptions can end up being overfed. Overfeeding can lead to lipogenesis, increased carbon dioxide output, and an increase in respiratory quotient (RQ). Although a rise in respiratory quotient is multifactorial and not solely dependent on nutritional intake, a rise in the RQ leads to respiratory compromise and for ventilated patients may increase days on mechanical ventilation (McClave et al., 2003).

In the current study, surgeries/imaging was the most common reason for tube feedings being held, which resulted in 55% of prescribed energy and protein delivery in these patients. Peev et al. (2015) found similar results of (re) intubation/extubation, major bedside interventions, and imaging studies being the most common reasons for tube feeding interruptions. Similarly, Uozimi et al. (2017) reported "airway manipulation" including intubation, tracheostomy tube placement, and extubation to be the leading discernable reason for tube feeding interruption. Surprisingly, the nine surgical patients in this study received an average of $78.4 \pm 30.1\%$ of goal volume. This may be due to the small sample and/or the fact that four of the nine patients had less invasive procedures such as tracheostomy and/or PEG placements as well. Surgeries and

procedures may seem to be an unavoidable obstacle; however, some studies are now debunking the long followed practice of 8-hour NPO prior to surgeries (McElroy, Codner, & Brasel, 2012; Diks et al., 2005). It has been proposed that preoperative feeding, specifically carbohydrate supplementation, can improve outcomes and reduce postoperative complications (Diks et al., 2005). Changing the protocol for keeping patients NPO prior to and after surgeries will increase nutrient delivery during this time.

Morgan, Dickerson, Alexander, Brown, and Minard (2004) evaluated factors causing tube feeding interruptions in surgical/trauma patients. These patients were found to receive an average of 67% of prescribed volume. Surgical interventions and diagnostic procedures were the leading cause of tube feeding interruptions. Gastrointestinal intolerance was not one of the major factors in holding tube feedings, as they reported no incidence of diarrhea; further, they reported few interruptions caused by high gastric residuals. The researchers noted that prokinetics were used aggressively; sorbitol containing medications were avoided; patients were well nourished prior to the current hospitalization; and some patients had jejunostomy feeding tubes placed all of which may have reduced the incidence of high gastric residuals. Interestingly, however, the Morgan et al. (2004) threshold for holding tube feedings (>150ml) was significantly lower than the protocol at Northwest Hospital (>500ml), yet fewer incidences of interruptions due to high GRV were noted. The use of prokinetics, avoiding sorbitol containing medications, and using jejunostomy tubes may have contributed to this difference in occurrence of high GRVs. The researchers reported $79 \pm 14\%$ of goal volume delivered to patients with jejunal (n=11) access in contrast to $64 \pm 19\%$ in patients with gastric access (n=45). The presence of jejunal tubes was not recorded in the present study; however, the majority of

patients at Northwest Hospital are fed via the gastric route which may have led to higher GRVs. Using jejunal access may be an alternative that can be considered at this facility to improve nutrition delivery in patients with gastric tolerance issues.

High gastric residual volumes (GRV) was the second most common reason for tube feeding interruptions in the current study, resulting in 44% of estimated energy needs delivered to patients. However, of the 18 tube feeding interruptions for high GRVs, only three were appropriate per hospital protocol. Hospital policy is to hold tube feedings for GRV of greater than 500ml if the patient is at their goal rate and to halt advancement if GRV is greater than 250ml when a patient is not at goal rate. After a patient is found to have a high GRV, tube feedings are often held until the next morning or after an imaging study, and the feeding restarted at a trophic rate and progressed back to goal.

Tube feeding protocol when starting patients on trophic feeds and advancing to goal rate has also been identified as a leading cause of suboptimal energy delivery (Kozeniecki et al., 2016). As this study required patients to be on tube feedings for 24 hours prior to inclusion in the study, this obstacle was not investigated in the study. Northwest Hospital follows a similar protocol for advancing patients to goal feedings and therefore it could certainly be expected that patients would receive less of goal energy and protein intake on their first day of tube feedings.

One of the biggest strengths of this study was the consistency in data collection. Data were collected at the same time daily every day for a period of four months. All patients had the same kangaroo pumps checked for total volume delivered. Another strength is that reasons for tube feeding interruption were well documented as the

investigator was able to speak to night nurses during shift change at 0700. Inclusion data in this study were broad, allowing the majority of patients in the ICU during the study period to be included. This eliminated bias and captured a comprehensive view of tube feeding adequacy of patients in the ICU of this hospital.

Limitations of this study include a small sample size (N= 50), potential pump errors, and inability to account for delay in beginning tube feedings. As this study was conducted at a small community hospital with a 16 bed ICU it took twice as long to collect data on 50 patients than was projected. A larger sample would be beneficial in drawing conclusions and generalizing the data to a larger population. Pump errors were documented in three patients; however, it is possible that there were undetected pump errors that could have skewed data as well. Data were collected on patients who had been started on tube feeding by 0700 the previous day; however, this was monitored by the time the tube feeding order was entered in the computer by the RD not when tube feedings were started by nursing. As discussed previously nursing documentation of tube feeding delivery via the electronic medical record can be erroneous and therefore was not relied on in this study; start time was determined by the time the order was submitted in the charting system. As the majority of patients in this institution are started on tube feeding by the RD, who only work day shifts, few if any patients would have been ordered tube feedings prior to 0700 and not started until later in the day. This possibility cannot be ruled out, however.

Areas for future research include implementing a volume based feeding protocol and comparing the adequacy of tube feeding delivery with the results of this study. The 20 hour tube feeding protocol should also be investigated for adequacy throughout the

hospital as this protocol is practiced at Northwest Hospital on all floors and it would be hypothesized that more patients on acute care floors would be overfed as they are typically more stable and not scheduled for as many procedures as the patients in the current study. However, as patients on the acute care floors are also not ventilator dependent, or assumedly in respiratory distress, excess calorie delivery would not be as grave a concern.

APPENDIX A

A-1 DATA COLLECTION INSTRUMENT

A-2 DEMOGRAPHIC DATA COLLECTION

A-1 Data Collection Instrument

Subject code	Date	Admit Dx	LOS	Days on EN	Formula	Goal TF Rate	Goal Volume	Volume delivered	Percent of Goal	Amount of Time Held	Reason TF Held

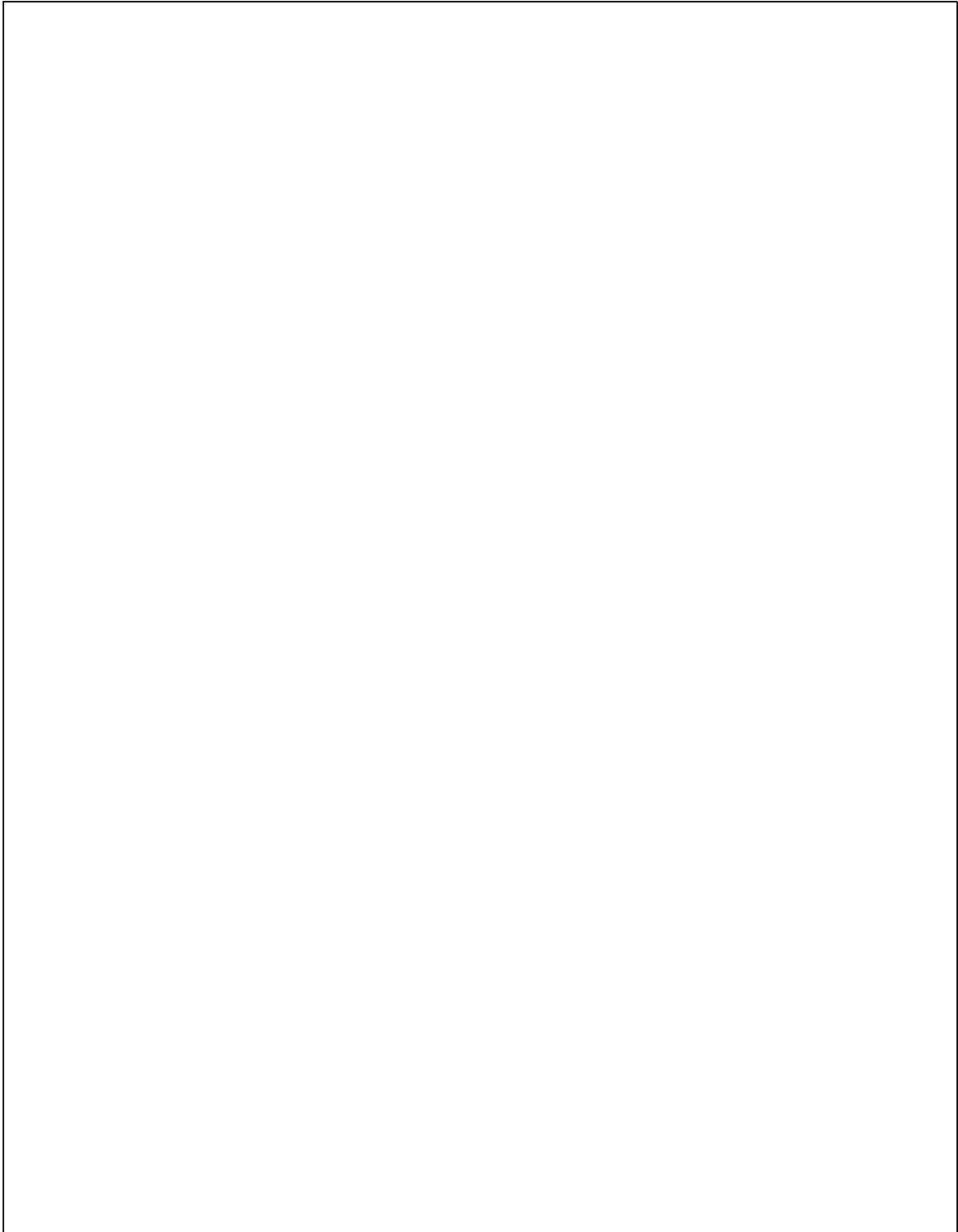
A-2 Demographic Information

Subject #	Gender	Age	Race	Percent weight change	Comorbid conditions

APPENDIX B

HUMAN SUBJECTS APPROVAL FORMS

APPENDIX B: Human Subjects Approval Forms





LOUISIANA TECH
UNIVERSITY.

MEMORANDUM

OFFICE OF SPONSORED PROJECTS

TO: Ms. Callie Betman and Dr. Janet Pope *RJK*
FROM: Dr. Richard Kordal, Director of Intellectual Property & Commercialization
(OIPC)
rkordal@latech.edu
SUBJECT: HUMAN USE COMMITTEE REVIEW
DATE: January 19, 2018

In order to facilitate your project, an EXPEDITED REVIEW has been done for your proposed study entitled:

**"Assessing the Adequacy of the Rate Based System of Enteral Nutrition
Infusion in the ICU of a Community Hospital"**

HUC 18-080

The proposed study's revised procedures were found to provide reasonable and adequate safeguards against possible risks involving human subjects. The information to be collected may be personal in nature or implication. Therefore, diligent care needs to be taken to protect the privacy of the participants and to assure that the data are kept confidential. Informed consent is a critical part of the research process. The subjects must be informed that their participation is voluntary. It is important that consent materials be presented in a language understandable to every participant. If you have participants in your study whose first language is not English, be sure that informed consent materials are adequately explained or translated. Since your reviewed project appears to do no damage to the participants, the Human Use Committee grants approval of the involvement of human subjects as outlined.

Projects should be renewed annually. *This approval was finalized on January 19, 2018 and this project will need to receive a continuation review by the IRB if the project continues beyond January 19, 2019.* ANY CHANGES to your protocol procedures, including minor changes, should be reported immediately to the IRB for approval before implementation. Projects involving NIH funds require annual education training to be documented. For more information regarding this, contact the Office of Sponsored Projects.

You are requested to maintain written records of your procedures, data collected, and subjects involved. These records will need to be available upon request during the conduct of the study and retained by the university for three years after the conclusion of the study. If changes occur in recruiting of subjects, informed consent process or in your research protocol, or if unanticipated problems should arise it is the Researchers responsibility to notify the Office of Sponsored Projects or IRB in writing. The project should be discontinued until modifications can be reviewed and approved.

Please be aware that you are responsible for reporting any adverse events or unanticipated problems.

A MEMBER OF THE UNIVERSITY OF LOUISIANA SYSTEM

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