Distribution Agreement

In presenting this thesis as a partial fulfillment of the requirements for an advanced degree from Emory University, I hereby grant to Emory University and its agents the non-exclusive license to archive, make accessible, and display my thesis in whole or in part in all forms of media, now or hereafter known, including display on the World Wide Web. I understand that I may select some access restrictions as part of the online submission of this thesis. I retain all ownership rights to the copyright of the thesis. I also retain the right to use in future works (such as articles or books) all or part of this thesis.

_____ _____

Ozodimma Nwankwo Date

Understanding the Impact of Preoperative Nutrition Counseling given by Registered Dietitians on Complication Rates among Bariatric Surgery Patients

By

Ozodimma Nwankwo

Degree to be awarded: M.P.H.

Executive MPH

Rebecca Filipowicz, M.P.H., M.S., MCHES Committee Chairperson	Date
Kay Sandow, Ph.D, RD, CHES, Committee Member	Date
Laurie Gaydos, Ph.D. Associate Chair for Academic Affairs Executive MPH Program	Date

Understanding the Impact of Preoperative Nutrition Counseling given by Registered Dietitians on Complication Rates among Bariatric Surgery Patients

By

Ozodimma Nwankwo

M.P.H., Emory University, 2018

B.S., California State University Long Beach, 2007

Thesis Committee Chair: Rebecca Filipowicz, M.P.H., M.S., MCHES

An abstract of

A thesis submitted to the Faculty of the

Rollins School of Public Health of Emory University

in partial fulfillment of the requirements for the degree of

Master of Public Health in Prevention Science

2018

Abstract

Understanding the Impact of Preoperative Nutrition Counseling given by Registered Dietitians on Complication Rates among Bariatric Surgery Patients

By Ozodimma Nwankwo

Introduction

Bariatric surgery is an obesity intervention which produces sustained weight loss and improvement in many obesity-related medical comorbidities. Understanding the results of preoperative nutrition counseling (PNC) in the bariatric population is essential given that they assume a substantial burden of the growing obesity epidemic and there is evidence supporting the need for weight loss surgery to address the obesity epidemic. This study aimed to explore the relationship between PNC given by registered dietitians (RD) and the incidence of complications within nine months after bariatric surgery.

Methods

A retrospective study examined patients (N = 60) who underwent bariatric surgery at Johns Hopkins Center for Bariatric Surgery located in Baltimore, Maryland in 2017. The instrument used for data collection was an excel spreadsheet. Data were extracted from the clinical nutrition department's database and EPIC, the Johns Hopkins Medicine's electronic medical record (EMR) system, then analyzed using SPSS. Pearson's Correlation and logistic regression were used to analyze data.

Results

The mean age of the patient sample was 44 years old. There was no significant correlation found between bariatric patients who received PNC by an RD verses a counselor with unknown credentials and those that experienced complications post-bariatric surgery (Pearson's Correlation $\rho = 0.193$; $P = .139$). The results showed that surgery type is a protective factor from experiencing complications, (Point Estimate/Exp (B) = 0.848) suggesting that it lowers the risk of complications. After adjusting for surgery type and approach, the association between patients who received PNC by an RD and experiencing complications persisted ($\beta = 1.039$; 95% confidence interval, 0.807–9.904; $P = 0.104$).

Conclusion

Ultimately, the hypothesis was accepted, and there was no statistical difference in the odds of experiencing complications within nine months of surgery for the cohort of bariatric patients who received PNC from an RD compared to those who received PNC from a counselor with unknown credentials. Further investigation of the impact of the RD role in the multidisciplinary team and subsequently, the effects of PNC facilitated by any other healthcare professional should be done as an extension of this study.

Understanding the Impact of Preoperative Nutrition Counseling given by Registered Dietitians on Complication Rates among Bariatric Surgery Patients

By

Ozodimma Nwankwo

M.P.H., Emory University, 2018

B.S., California State University Long Beach, 2007

Thesis Committee Chair: Rebecca Filipowicz, M.P.H., M.S., MCHES

A thesis submitted to the Faculty of the

Rollins School of Public Health of Emory University

in partial fulfillment of the requirements for the degree of

Master of Public Health in Prevention Science

2018

Acknowledgments

I would like to thank my committee chair Rebecca Filipowicz for providing feedback and checking in with me often to keep me on track. Thank you to my committee field advisor Dr. Kay Sandow for believing in me when I didn't think I could do it. Thank you to my classmates and everyone else I met during this program, especially Lady Marth Wright for opening up her home to me whenever I visited Atlanta, Olawunmi Obisesan for being my practicum site supervisor, Johnnie Proby for being a voice of clarity and Loree Mincey for being a shoulder to laugh on.

Thank you to my mother and father for supporting and encouraging me. You are both my role models. Thank you to my little sister Ezinne Ihenachor for advising me every step of the way. Even with the demands of medical school, you still found time to comfort and reassure me. Thank you to my newborn twins, Victor and Theodora for motivating me to finish this thesis and to be your best role model. Most importantly, thank you to my wonderful husband, the love of my life, for holding down the fort and taking a back seat while I pursued my dreams. There were many times when I stumbled and you were there to catch me. I love you deeply babe. Lastly, I would like to thank God for blessing me with all these beautiful gifts; I am incredibly grateful.

I dedicate this thesis to my late mother-in-law Theodora Nwankwo. You don't know how much you inspired me to persevere during this academic experience. Thank you for all your support and guidance.

Table of Contents

CHAPTER 1 – INTRODUCTION **1**
Introduction and Rationale 1
Problem Statement 1
Theoretical Framework 3
Key Determinants of Health *5*
Purpose Statement 5
Research Question and Hypothesis 6
Significance Statement 7
Definition of Terms 7

CHAPTER 2 – REVIEW OF THE LITERATURE **10**
Introduction 10
Current State of Knowledge 11
Bariatric Surgery *11*
Roux-en-Y Gastric Bypass *11*
Biliopancreatic Diversion with Duodenal Switch *12*
Laparoscopic Adjustable Gastric Band *14*
Sleeve Gastrectomy *15*
Preoperative Assessment *16*
Gaps in Research 17
Addressing the Gaps 18
Summary of Current Problem and Study Relevance 18

CHAPTER 3 – METHODOLOGY **20**
Introduction 20
Population and sample 20
Population *20*
Setting *21*
Sample Selection Rationale *22*
Research design 23
Procedures 26
Instruments 27
Assumptions *29*
Data analysis methodology 29

CHAPTER 4 – RESULTS **34**
Introduction 34
Key findings 34
Correlations *34*
Logistic Regression *35*
Other findings 39
Summary 39

CHAPTER 5 – CONCLUSIONS, IMPLICATIONS, AND RECOMMENDATIONS **41**
Introduction 41
Summary of Study 41
Discussion of Key Results 42
Limitations 43

IMPLICATIONS 45
RECOMMENDATIONS 47
CONCLUSION 47
REFERENCES 49
APPENDIX A 52

List of Boxes

Box 1.. 4
Box 2.. 21
Box 3.. 24

List of Figures

Figure 1…… 12
Figure 2…… 13
Figure 3…… 15
Figure 4…… 16

List of Tables

Table 1……..…… 25
Table 2…….. 28
Table 3…….. 35
Table 4…….. 36
Table 5…….. 36
Table 6…….. 37
Table 7…….. 37
Table 8…….. 38

Chapter 1 – Introduction

INTRODUCTION AND RATIONALE

This chapter discusses the thesis problem by providing a context for the research study, the theoretical framework by explaining the Social Cognitive Theory (SCT) and how it will be used to guide the study, and the purpose statement which includes the hypotheses and the research question to be addressed. There is also a statement of the significance of the thesis and how the research applies to public health practice.

PROBLEM STATEMENT

Obesity is characterized by an accumulation of excess adipose tissue in the body. Excess adiposity or obesity causes increased levels of circulating fatty acids and inflammation. It can lead to insulin resistance, which causes type 2 diabetes, a disease characterized by high blood glucose levels (Smith, 2007). The health risks of obesity are well documented. It increases the risk of cardiovascular diseases (CVDs), (Hubert, Feinleib, McNamara, & Castelli, 1983) certain types of cancer, depression, reduced health-related quality of life, premature death, and has adverse effects on overall health (Smith, 2007). Body mass index (BMI), estimated as weight in kilogram (kg) divided by height in meters squared (World Health Organization, 2017a), is one of the most commonly used screening tools to diagnose obesity. A BMI of 25 to <30 kg/m^2 is defined as overweight and BMI ≥ 30 kg/m^2 is considered obese (Centers for Disease Control and Prevention, 2016). The World Health Organization reported that in 2014 over 600 million people worldwide were obese. That represents about 13% of adults which has doubled since 1980 (World Health Organization, 2017b).

Obesity is also a serious and increasing problem among children and adolescents (Flegal, Kruszon-Moran, Carroll, Fryar, & Ogden, 2016). It levies a massive economic burden worldwide which is primarily reflected in rising healthcare cost. In 2014 the worldwide financial impact of obesity was estimated to be $2.0 trillion of the global gross domestic product (GDP) (Tremmel, Gerdtham, Nilsson, & Saha, 2017). It is also associated with multiple medical comorbidities, including type 2 diabetes mellitus, (Ma & Madura, 2015) which, in 2012, had an estimated cost of $245 billion, a 41% increase from a previous estimate of $174 billion in 2007 (American Diabetes Association, 2013). These costs include increased absenteeism ($5 billion) and lower productivity at work ($20.8 billion), more depressed productivity for those unemployed ($2.7 billion), incapacity to work due to disability ($21.6 billion), and lost productive capacity as a result of mortality ($18.5 billion) (American Diabetes Association, 2013). A study showed that type 2 diabetes was linked to the occurrence of postoperative complications in bariatric patients (Wrzesinski et al., 2015).

Systematic reviews of quantitative evidence have shown that bariatric surgery is the most effective treatment for severe and complex obesity, defined as a BMI ≥40, or between 35 and 40 (Kissler & Settmacher). When compared to traditional therapies for weight loss, bariatric surgery facilitates a loss of up to 110 – 132 pounds (Kissler & Settmacher) leading to more significant weight loss and improvement in some obesity-related comorbidities (such as diabetes) in the short-term (up to 2 years post-surgery). Although bariatric surgery has a significant effect on the patients' health, decreased food intake can lead to nutritional and vitamin deficiencies (de'Angelis, Carra, & Vincenzi, 2012). For this reason, registered dietitians (RDs) play a significant role pre- and post-surgery and are a vital part of the multidisciplinary bariatric team. They are involved in preoperative care that prepares patients for substantial lifestyle changes by

performing dietary assessments, evaluation for nutritional deficiencies, and providing counseling to help patients meet post-surgery weight loss goals (Kulick, Hark, & Deen, 2010). While previous quantitative research mainly focuses on clinical outcomes of bariatric surgery, more research is needed on the contributions made by the RD as part of the multidisciplinary health professional team before weight loss surgery and how they promote positive postoperative outcomes.

THEORETICAL FRAMEWORK

The Social Cognitive Theory (SCT) "is a model of triadic reciprocal causation in which personal factors in the form of cognitive, effective and biological events, behavioral patterns, and environmental events all operate as interacting determinants that influence one another bidirectionally." (Bandura, 2001). In other words, because personal factors, behavior and the environment are reciprocal, they are continuously influencing each other. This is the idea of reciprocal determinism; the foundation of the SCT. The connection between a person and their behavior is influenced by their thoughts and actions. The relationship between the environment and their behavior involves the person's behavior determining their environment, which in turn, affects their environment. The link includes beliefs and cognitive competencies developed and modified by social influences.

Personal factors in the theory involve the cognitive or mental representations of the environment. They are goals, sense of efficacy/outcome expectations, attribution and the process of self-control. Behavioral patterns involve goal progress, motivation, attention, and retention. It concludes that if a person behaves in a manner, they must identify the behavior and have the skills to perform it. Environmental events refer to the social and physical environments. Socially

they involve family members, friends, and colleagues in the form of role models, instruction, reinforcement, and feedback. Example of the physical environment is room size, temperature or the availability of certain foods. (Glanz, 2002). Critical constructs of the SCT are summarized in Box 1.

Box 1: Key constructs of the Social Cognitive Theory (SCT):
Source: (Glanz, 2002)

- *Reciprocal determinism*
  The active interaction of the person, the behavior, and the environment in which the behavior is performed.
- *Self-efficacy*
  The person's belief in executing a certain behavior.
- *Self-control*
  Personal regulation of goal-directed behavior or performance.
- *Outcome Expectations*
  Anticipatory outcomes of a behavior.
- *Behavioral capability*
  Knowledge and skill to perform a given behavior.
- *Environment*
  Factors physically external to the person.
- *Observational learning*
  Behavioral acquisition that occurs by watching the actions and outcomes of others' behavior.
- *Reinforcements*
  Responses to a person's behavior that increase or decrease the likelihood of reoccurrence.

The SCT was chosen to inform this study because it relates to the variables that influence health-related behaviors and physical health. In this study, the behavior is the adherence to post-treatment recommendations to prevent complications. Compliance is a major factor for the change necessary to have successful bariatric surgery. High self-efficacy is associated with compliance after surgery (Boeka, Prentice-Dunn, & Lokken, 2010). This reflects the idea that

people are driven to act in ways that help them succeed and will, therefore, comply with recommendations if they believe in their ability to achieve their goals.

Key Determinants of Health

Social determinants of health are "conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks" (Centers for Disease Control and Prevention, 2018). The primary social determinants of health that relate to the SCT are personal factors, behavioral pattern, and environmental events. Personal factors are addressed during preoperative nutrition counseling (PNC) when RDs work with patients to create specific, measurable, attainable, realistic and timely (SMART) goals for lifestyle change. This is the opportunity for patients to engage in self-reflection, improve self-efficacy to overcome barriers to exercise or reducing caloric intake and celebrate successes such as meeting preoperative weight loss goals. Behavioral patterns are addressed by providing knowledge-based and skill-based training to participants and providing tools, resources, or environmental changes that make new behaviors easier to accomplish. This is also reflected in the preoperative counseling sessions. Environmental events are addressed by encouraging lifestyle changes before bariatric surgery. This may mean a rearrangement of the physical environment to accommodate dietary changes and support increased physical activity.

PURPOSE STATEMENT

The overarching purpose of this retrospective study will be to use the SCT to inform the association between PNC with complications after surgery for a sample size of 60 patients who underwent bariatric surgery at The Johns Hopkins Center for Bariatric Surgery in Baltimore,

Maryland. The key independent variable is “preoperative nutrition counseling” and will be defined as “specific healthcare professional who facilitated the preoperative nutrition counseling: registered dietitian, primary care physician, health coach, nurse practitioner, physician assistant, or other." The key dependent variable is “complications” which will be defined as “complication/adverse outcome documented in patient electronic medical record (EMR) within nine months post bariatric surgery that was not documented prior to surgery: hospitalization, dehydration/intravenous fluids, infection, malabsorption, vitamin/mineral deficiency, malabsorption, other and none”. The intervening variables are “surgery type” and “surgery approach” which will be statistically controlled in the study.

RESEARCH QUESTION AND HYPOTHESIS

The research question being answered is:

1. Does preoperative nutrition counseling given by registered dietitians, as opposed to non-dietitians, result in more favorable outcomes as defined by no complications within nine months post-surgery in a cohort of patients who underwent bariatric surgery at Johns Hopkins Center for Bariatric Surgery in 2017?

Hypothesis

H_0: When type and approach of surgery are controlled, there is no statistical difference in the odds of experiencing complications within nine months of surgery for bariatric patients who received preoperative nutrition counseling by an RD compared to those who received preoperative nutrition counseling by non-RDs.

H_1: When type and approach of surgery are controlled, there is a statistical difference in the odds of experiencing complications within nine months of surgery for bariatric patients who received

preoperative nutrition counseling by an RD compared to those who received preoperative nutrition counseling by non-RDs.

SIGNIFICANCE STATEMENT

This study is important because it assesses new predictors of successful bariatric surgery. If it yields results that support PNC by an RD as a predictor of the elimination of post-bariatric surgery complications, it will serve to inform pre-surgery education programming better. This could affect public health practice by prompting health insurance providers to mandate that nutrition counseling be facilitated solely by RDs. Furthermore, this study supports the absolute need for further research to investigate the impact of pre-surgical behavior change on short-term and long-term outcomes. A more substantial integration of the SCT in preliminary measures leading up to surgery may assist in the prevention of complications. It could also foster the development of generalizable methods to determine proper candidates for bariatric surgery, leading to optimal health and lower healthcare costs.

DEFINITION OF TERMS

Obesity - overweight and obesity are defined as abnormal or excessive fat accumulation that may impair health (World Health Organization, 2018).

Bariatric Surgery - a surgical procedure that causes weight loss by restricting the amount of food the stomach can hold, causing malabsorption of nutrients, or by a combination of both gastric restriction and malabsorption (American Society for Metabolic and Bariatric Surgery, 2018)

Adipose Tissue - connective tissue in which fat is stored and which has the cells distended by droplets of fat (Merriam-Webster, 2018a).

Body Mass Index (BMI) - "BMI is a simple index of weight-for-height that is commonly used to classify overweight and obesity in adults. It is defined as a person's weight in kilograms divided by the square of his height in meters (kg/m^2)." BMI categorizes weight as follows: Below 18.5 = Underweight; 18.5-24.9 = Normal; 25.0-29.9 = Overweight; 30.0-39.9 = Obese; 40 and above = Morbidly Obese (World Health Organization, 2018).

Registered Dietitian (RD) or Registered Dietitian Nutritionist (RDN) - “are the food and nutrition experts who can translate the science of nutrition into practical solutions for healthy living” (Academy of Nutrition and Dietetics, 2018).

Social Cognitive Theory (SCT) - a model of triadic reciprocal causation in which personal factors in the form of cognitive, effective and biological events, behavioral patterns, and environmental events all operate as interacting determinants that influence one another bidirectionally (Bandura, 2001).

Complications - complication/adverse outcome documented in the patient electronic medical record (EMR) within nine months post bariatric surgery that was not documented prior to surgery: hospitalization, dehydration/intravenous fluids, infection, malabsorption, vitamin/mineral deficiency, malabsorption, other and none.

Bile – “a yellow or greenish viscid alkaline fluid secreted by the liver and passed into the duodenum where it aids especially in the emulsification and absorption of fats” (Merriam-Webster, 2018b)

Pancreatic enzymes - “help break down fats, proteins, and carbohydrates. A normally functioning pancreas secretes about 8 cups of pancreatic juice into the duodenum, daily. This fluid contains pancreatic enzymes to help with digestion and bicarbonate to neutralize stomach acid as it enters the small intestine” (The Pancreatic Cancer Action Network, 2018).

EPIC - the Johns Hopkins Medicine’s single, integrated electronic medical record system for the entire enterprise (Johns Hopkins Medicine, 2018a).

Favorable outcomes - outcomes resulting in no complications within nine months of bariatric surgery.

Chapter 2 – Review of the Literature

INTRODUCTION

Nutrient intake of bariatric surgery patients is improved with dietary counseling (Shah et al., 2013). RDs can identify and help manage impulse eating, inactive lifestyle, inappropriate food intake and all other associated behaviors that contribute to regaining weight (Kulick et al., 2010). They can also help detect and prevent complications such as micronutrient deficiencies, severe malnutrition, and dumping syndrome.

The common micronutrient deficiencies that occur after surgery are potassium, B1, B3, B6, B12, folate, iron, copper, zinc, selenium, and vitamins A, D, E, K, and C (Fujioka, 2005). The failure to adhere to postoperative recommendations, uncontrolled dietary supplementation or restrictive eating can lead to severe complications, so it is crucial that patients are cared for by a multidisciplinary team of specialists during their bariatric therapy. Regular nutrition consultations with an RD should be at six weeks, three months, and then every three months for the first year (Karmali et al., 2010). Failure to do so puts patients at a much higher risk of developing medical complications (Hwang et al., 2009).

This chapter discusses current knowledge of bariatric surgery, expand on what is missing or could be improved, how this thesis will address gaps in research, and a summary of the ongoing problem and relevance. The literature reviewed was chosen to assess the current knowledge of the effects of preoperative counseling with dietitians compared to non-dietitians and if there is a difference in complication rates post-bariatric surgery.

CURRENT STATE OF KNOWLEDGE

Bariatric Surgery

Bariatric surgery promotes weight loss by preventing the stomach from holding large amounts of food, thus increasing the risk of nutrient malabsorption and hormonal alterations. The most commonly performed bariatric surgery procedures are Roux-en-Y gastric bypass (RYGB), biliopancreatic diversion with duodenal switch (BPD/DS), the laparoscopic adjustable gastric band (LAGB), and sleeve gastrectomy (SG) (American Society for Metabolic and Bariatric Surgery, 2017). Bariatric surgery is categorized by surgical technique (i.e., restrictive procedure or a combination of restrictive and malabsorptive procedures) (Hydock, 2005). The combination restrictive–malabsorptive procedures most commonly performed include the RYGB and BPD/DS.

Roux-en-Y Gastric Bypass

The Roux-en-Y gastric bypass (RYGB) is referred to as the “gold standard” of bariatric surgery. This procedure involves dividing the top of the stomach from the rest of the stomach to create a small stomach pouch. Then the opening portion of the small intestine is separated, “and the bottom end of the divided small intestine is brought up and connected to the newly created small stomach pouch. The procedure is completed by connecting the top portion of the" isolated small intestine to the small intestine further down so that the stomach acids and digestive enzymes from the bypassed stomach and first” (Peace Health, 2017) part of the small intestine will eventually blend with the food (Figure 1). This procedure enables significantly smaller meals and decreased caloric intake, but substantially reduces the surface area for absorption. The rerouting of the food flow also creates changes in the hormones that boost satiety, suppress hunger, and reverse the mechanisms that induce type 2 diabetes (National Institute of Diabetes

and Digestive and Kidney Diseases, 2017). Although this procedure is highly effective for weight loss, malabsorption can occur due to the bypassing of the lower stomach and most of the small intestine, (Hydock, 2005) which can lead to nutritional and vitamin deficiencies.

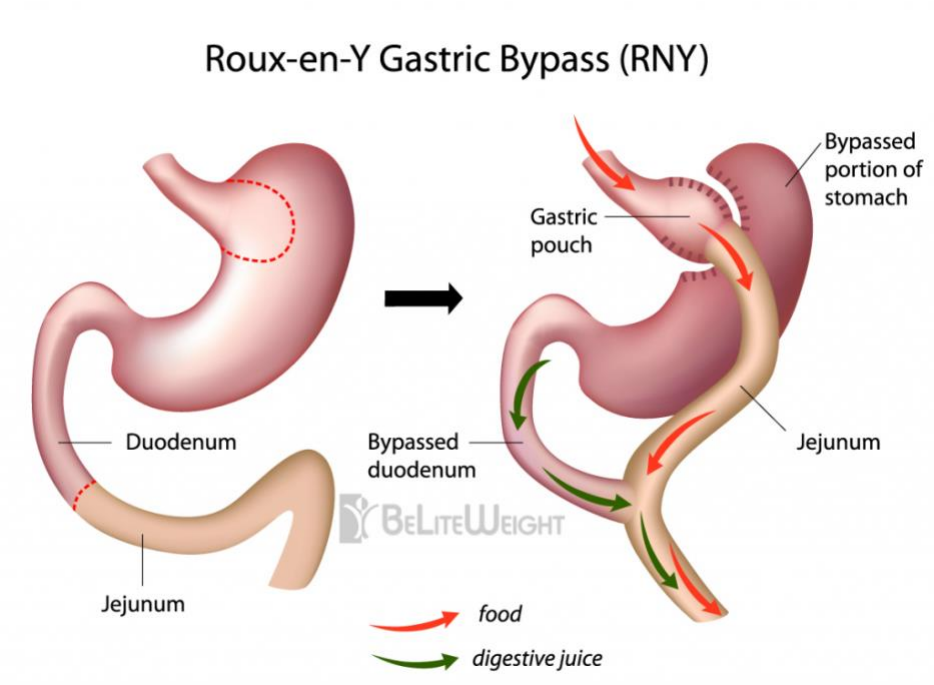

Figure 1: This image is a depiction of the Roux-en-Y gastric bypass surgery. Source (Belite Weight, 2017)

Biliopancreatic Diversion with Duodenal Switch

The biliopancreatic diversion with duodenal switch (BPD/DS) is a procedure that creates a smaller, tubular stomach pouch by removing a portion of the stomach. Then, a large part of the small intestine is bypassed. The first portion of the small intestine, which is the duodenum, is divided at the point a bit beyond the outlet of the stomach. Then, a segment of the last portion small intestine is brought up and connected to the outlet of the newly created stomach (Figure 2).

So when a patient eats, the food goes through a newly formed smaller stomach pouch and empties quickly into the last portion of the small intestine (Hydock, 2005).

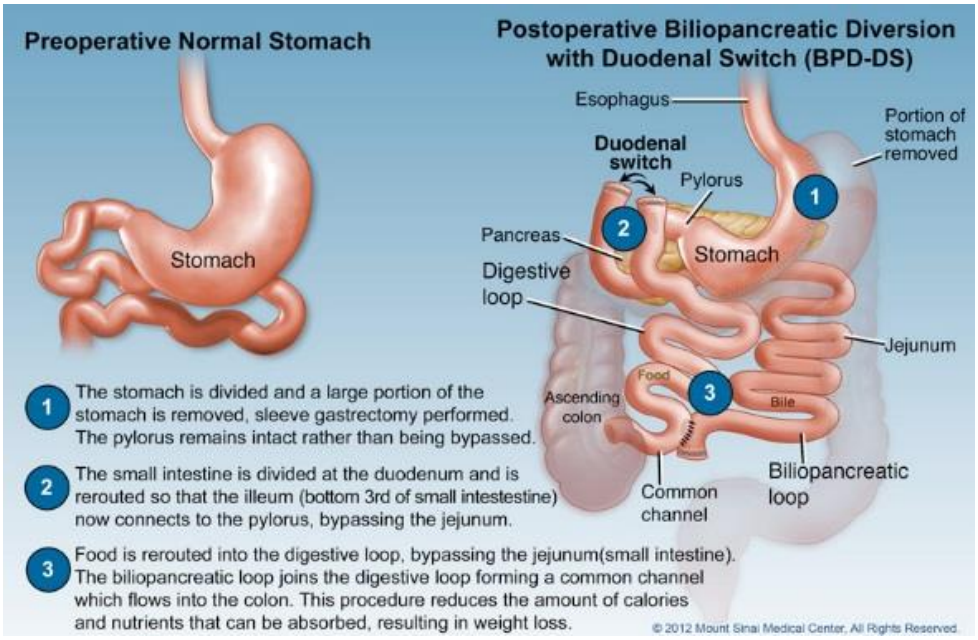

Figure 2: This image is a depiction of the normal preoperative stomach and the postoperative Biliopancreatic Diversion with Duodenal Switch. Source (Riverside Surgical Weight Loss, 2017)

The bypassed small intestine carries the bile and pancreatic enzymes that are necessary for the breakdown and absorption of protein and fat. It is reconnected to the last portion of the small intestine so that they can eventually mix with the food flowing in. For that reason, very little of the consumed fat and protein are absorbed, and there is a notable reduction in the absorption of calories, fat-soluble vitamins, and nutrients. This procedure also affects gut hormones which impact satiety and blood sugar control, which is why it is thought to be the most effective surgery for the treatment of diabetes. Although BPD/DS helps to reduce the number of calories consumed, like the RYGB, over time patients are eventually able to consume near "normal" amounts of food. This procedure is highly effective, but the extreme reduction in

functional intestine length puts patients at risk for nutritional deficiencies that can be challenging to replace (Hydock, 2005).

Laparoscopic Adjustable Gastric Band

The laparoscopic adjustable gastric band (LAGB) involves a silicone ring that is fixed around the upper part of the stomach, creating a small stomach pouch above the band, an opening through the band, and the remainder of the stomach below the band. Food passes through the small hole created at the bottom of the pouch and then through the rest of the gastrointestinal (GI) tract (Figure 3). The idea is to promote the feeling of fullness or reduce hunger, through eating small quantities of food. The smaller pouch restricts the quantity of food that patients can consume, and the small opening slows emptying to create a prolonged sensation of satiety (Hydock, 2005). The diameter of the opening can slowly be adjusted over time. This procedure is considered restrictive because it restricts the number of calories that can be consumed per meal and by limiting the emptying of the food through the band opening. Food is digested and normally absorbed, so there is no malabsorption which eliminates the need for vitamin and mineral supplementation post-operation. LAGB is also the least invasive surgical technique and does not require gastric incisions or removal and rerouting of the intestines (Pilone, Vitiello, Monda, Giglio, & Forestieri, 2016).

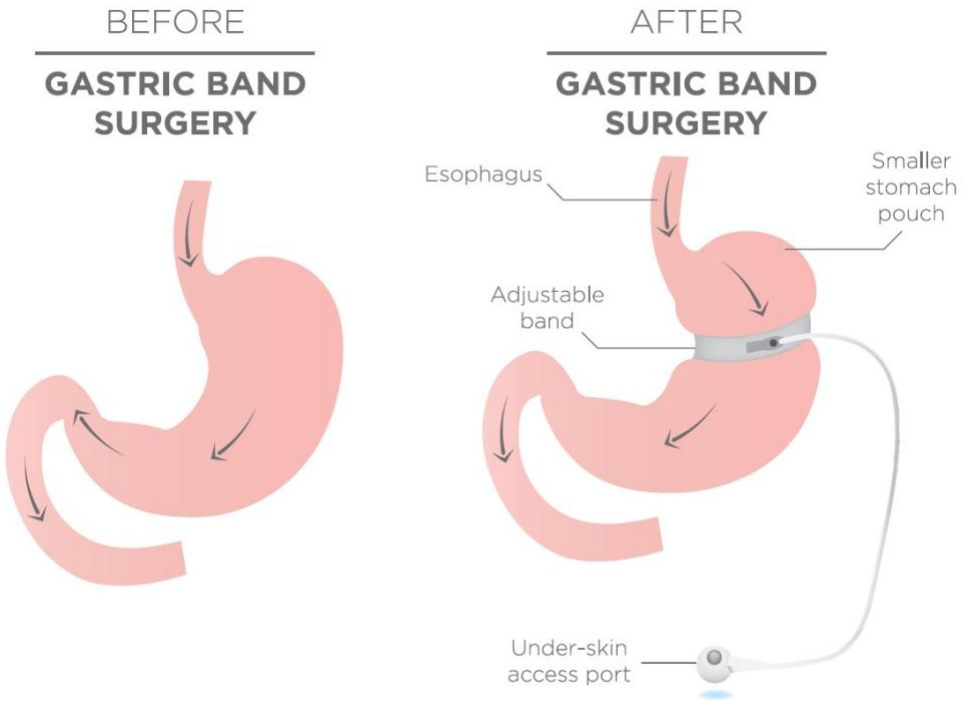

Figure 3: This image is a depiction of the normal preoperative stomach and the postoperative laparoscopic adjustable gastric banding. Source (Riverside Surgical Weight Loss, 2017)

Sleeve Gastrectomy

Sleeve gastrectomy (SG) is a procedure where about 80 percent of the stomach is removed resulting in a banana-shaped pouch (Figure 4). The new stomach pouch holds a significantly smaller volume than the normal stomach which forces the patient to limit their food intake substantially. The evidence in the literature shows that the SG is as effective as the RYGB in regards to weight loss and reduction or elimination of type 2 diabetes, but it has significant impacts on gut hormones that effect several mechanisms such as hunger and satiety. The procedure does not affect the intestines, so dietary supplementation is not required, but it does impact the absorption of iron and B-group vitamins. Postoperative iron and B12 supplementation

are recommended based on the deficiency risk associated with this procedure (Kwon et al., 2014).

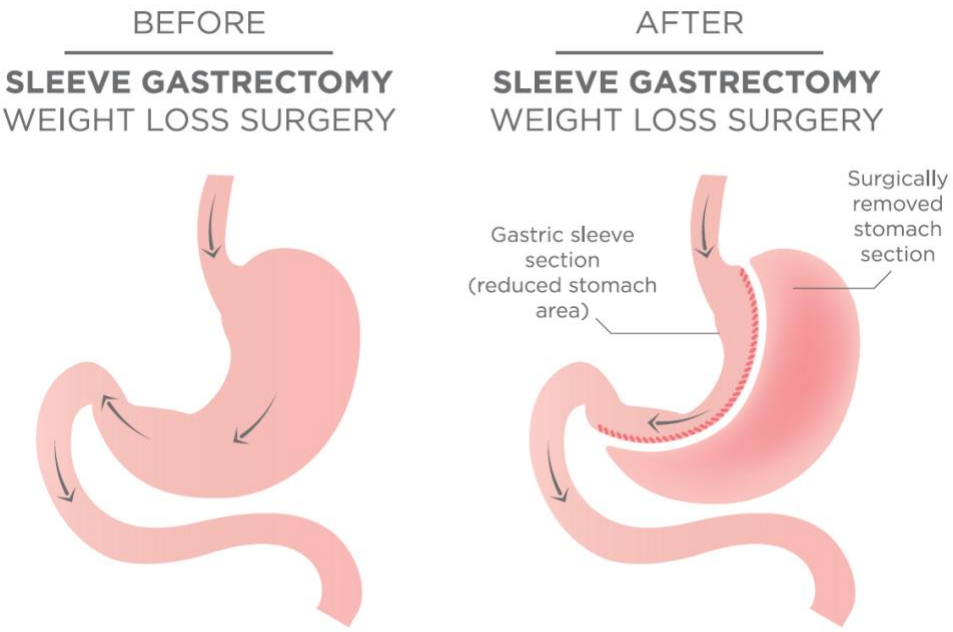

Figure 4: This image is a depiction of the normal preoperative stomach and the postoperative sleeve gastrectomy. Source (Riverside Surgical Weight Loss, 2017)

Preoperative Assessment

A preoperative dietary assessment is an essential stage in the process of determining a patient's eligibility for bariatric surgery. The ideal candidate would have a body mass index (BMI) of 35–40 or a BMI higher than or equal 40 and has been diagnosed with associated comorbidities such as type 2 diabetes and heart disease (Endevelt, Ben-Assuli, Klain, & Zelber-Sagi, 2013). The reviewed literature suggests that diabetic patients should receive priority for bariatric surgery because it reduces the total treatment expenditures (Lopes et al., 2015). During the assessment, patients are also screened for diseases and behaviors that could increase

perioperative risk and impede postoperative recovery. Exclusion criteria include mental illness, psychiatric disorders, and clinical depression. Other diseases that may exclude a potential patient from bariatric surgery are a diagnosis of inflammatory bowel disease and celiac disease (CD). These conditions increase the risk of deep vein thrombosis (DVT) post-surgery and pulmonary embolism (PE) which can lead to death (World Health Organization, 2000). CD also causes malabsorption, which can result in malnutrition, iron deficiency anemia, folic acid and vitamin B deficiency, and vitamin K-dependent clotting factor deficiency (Valletta et al., 2010).

GAPS IN RESEARCH

The literature reviewed examines bariatric patient outcomes and provides useful knowledge to inform the evidence base and clinical practice. However, the current published research lacks investigation of the specific activities that impact bariatric surgery outcomes particularly preoperative counseling given exclusively by dietitians as opposed to those given by non-dietitians. Which begs the question: what source of counseling makes the most significant impact on preventing complications? This thesis can be used to generate new insights on how preoperative counseling facilitated solely by a dietitian effects outcomes of bariatric surgery, which could be used to influence clinical practice and future research. It can also be used in the public health arena to improve preventative care services. Effective prevention measures prior to surgery may lead to better outcomes and huge cost savings in US health care. Additionally, the findings of this research may be beneficial for healthcare professionals and policymakers to inform the future development of bariatric services and legislation that are more in line with patient needs.

ADDRESSING THE GAPS

This thesis will address gaps in the literature by attempting to determine which source of preoperative counseling has the most influence on preventing medical complications associated with bariatric surgery. An analysis will be performed on secondary quantitative data retrieved from the Johns Hopkins Center for Bariatric Surgery database in 2017. The variables of focus will be the type of health professional that provided the preoperative nutrition counseling, the surgery type, the surgery approach, and if any complications occurred after surgery, i.e., hospitalization, infection, bowel obstruction, dumping syndrome, hernias, hypoglycemia, malnutrition, ulcers, and vomiting (Monkhouse, Morgan, & Norton, 2009).

SUMMARY OF CURRENT PROBLEM AND STUDY RELEVANCE

Due to the multiple medical comorbidities and the massive economic burden associated with obesity, more research is needed on how to sustain the intended outcomes of bariatric surgery since it is the most effective treatment for obesity. Therefore, there must be a more in-depth investigation into primary preventative measures, precisely the source of counseling and method of preparation leading up to bariatric surgery.

This thesis aims to explore the relationship between the number of nutrition visits a patient made with RDs and with non-RDs prior to bariatric surgery and complication rates in a cohort of patients who underwent bariatric surgery at the Johns Hopkins Center for Bariatric Surgery in 2017. Identifying the source of pre-operative counseling that makes the most impact is essential given that about half of all patients regain the weight lost within two years after gastric bypass surgery (Odom et al., 2010) and experience medical complications even with preoperative counseling by any healthcare provider. Thus, increasing health care costs and

adding to the economic burden. Data suggest that weight regain can be anticipated, in part, during the preoperative evaluation and potentially reduced with self-monitoring strategies (Odom et al., 2010). Therefore, if pre-operative counseling with an RD, as opposed to a non-dietitian, substantially reduces the risk of weight regain and complication rates in this population post-bariatric surgery, then this source of counseling may prove to be most cost-effective.

Chapter 3 – Methodology

INTRODUCTION

This chapter provides a detailed description of the population involved in the project, the setting of the study, and the rationale for the selection of this population follows. It identifies the type of research design used and how that design was applied to the specific project, describes the procedures of the thesis, the instruments used and the process of collecting the data, the assumptions regarding the statistical analysis that will be tested, and rationale for each statistical technique chosen. It also describes the source of the data, relevant variables, and the data analysis methods.

The project was accomplished by defining the sample population of individuals who underwent bariatric surgery in 2017 at The Johns Hopkins Center for Bariatric Surgery in Baltimore, Maryland. A research design was chosen based on the variables of interests and the appropriate method to address the research question and test the hypothesis. The instrument used for data collection was an excel spreadsheet with defined variables. Data were extracted from the clinical nutrition department's database and EPIC, the Johns Hopkins Medicine's single, integrated electronic medical record (EMR) system, then analyzed using IBM SPSS Statistics 25.0 software.

POPULATION AND SAMPLE

Population

Subjects included a random sample of 60 patients who underwent bariatric surgery at The Johns Hopkins Center for Bariatric Surgery between in 2017. The study sample had significantly more females (90%) than males (10%). Of the Non-Hispanic or Latino part of the population,

which accounted for 95% of the entire population, 51.67% were White or Caucasian, 40% were Black or African American, 1.67% were Asian, and 1.67% reported their race as “Other." Of the Hispanic or Latino part of the population, which accounted for 3.33% of the entire population, 1.67% were White or Caucasian, and 1.67% were Black or African American. 1.67% of the population refused to disclose their ethnicity but reported their race as Black or African American. 1.67% of patients were ≤ 20 years of age, 13.33% were 21 – 30 years of age, 33.33% were 31 – 40 years of age, 21.67% were 41 – 50 years of age, 16.67% were 51 – 60 years of age, and 13.33% were ≥ 61 years of age. The primary population characteristics are summarized in Box 2.

Box 2: Major Characteristics of the Study Population (N = 60), Effect of Preoperative Nutrition Counseling on Bariatric Surgery Outcomes among patients of the Johns Hopkins Bariatric Surgery Center in 2017.

Age, y
Mean, 44

Gender
Male, 6 (10%)
Female, 54 (90%)

Ethnicity
Non-Hispanic or Latino, 57 (95%)
Hispanic or Latino, 2 (3.33%)

Race
White or Caucasian, 31 (51.67%)
Black or African American, 24 (40%)

Setting

The Johns Hopkins Health System (JHHS) is headquartered in Baltimore, Maryland, and is known as one of the prime healthcare systems in the United States. It operates six academic and community hospitals, four suburban health care and surgery centers, and 39 primary and

specialty care outpatient sites. “The health system offers patient care at The Johns Hopkins Hospital, (including Brady Urological Institute, Johns Hopkins Children’s Center, Kimmel Comprehensive Cancer Center and Wilmer Eye Institute), Johns Hopkins Bayview Medical Center, Howard County General Hospital, Sibley Memorial Hospital, Suburban Hospital, across Maryland communities through Johns Hopkins Community Physicians and our Health Care and Surgery Centers in White Marsh, Odenton, Lutherville and Bethesda, and pediatric care at Johns Hopkins All Children's Hospital in St. Petersburg, Florida” (Johns Hopkins Medicine, 2017). The Johns Hopkins Center for Bariatric Surgery operates at the Johns Hopkins Bayview Medical Center location also in Baltimore, Maryland. The center is recognized by the American Society for Metabolic and Bariatric Surgery (ASMBS) accreditation and quality improvement program as a comprehensive center with adolescent qualifications (Johns Hopkins Medicine, 2017).

Sample Selection Rationale

Bariatric surgery is an obesity intervention which produces sustained weight loss and improvement in many obesity-related medical comorbidities. While there is abundant research showing a significant reduction in medical costs and sustained reductions in hemoglobin A1c (HbA1c), there is little information about how preoperative counseling influences post-bariatric surgery outcomes. Furthermore, understanding the results of preoperative counseling in the bariatric population is essential given that they assume a substantial burden of the growing obesity epidemic and there is evidence supporting the need for weight loss surgery to address the obesity epidemic in the United States (Bour, 2015). If preoperative counseling with a specific healthcare professional substantially reduces complication rates in this population post-bariatric surgery, then counseling with that health care professional may prove to be most cost-effective.

RESEARCH DESIGN

The study aim was to examine whether the type of health care professional providing the preoperative counseling was associated with the risk of complications post-bariatric surgery and whether the PNC given by RDs resulted in more favorable post-surgery outcomes than with non-dietitians in a cohort of patients who underwent bariatric surgery at Johns Hopkins Center for Bariatric Surgery in 2017.

The research used a mix of a correlational and a quasi-experimental retrospective study design. The correlational design portion of the study explored the relationship between four quantitative variables from the sample group of patients using statistical analyses and was mostly observational regarding data collection. The independent variable, or predictor, was the type of health care professional providing the PNC, the type of surgery performed, and the surgical approach. The dependent variable, or outcome, was the occurrence complications that resulted from the surgery. The quasi-experimental design portion established a cause-effect relationship between PNC given by RDs, compared to non-dietitians and complication outcomes. There were

no assigned groups or manipulation of the independent variable or predictor. The key variables are identified in Box 3 along with their operational definitions of variables in Table 1.

Box 3: Study Key Variables
Effect of Preoperative Nutrition Counseling on Bariatric Surgery outcomes among patients of the Johns Hopkins Bariatric Surgery Center in 2017.

RD_YN
- Question: Was preoperative nutrition counseling facilitated by a registered dietitian (RD)?
- Answer Choices: Yes, No, or Unknown
- Categorical, nominal
- Independent variable

SURG_TYPE
- Question: What was the type of bariatric procedure?
- Answer Choices: RNY (Roux-en-Y Gastric Bypass) or Sleeve Gastrectomy
- Categorical, nominal
- Independent variable

APPROACH
- Question: What was the method in which the bariatric procedure was carried out?
- Answer Choices: Lap (Laparoscopic) or Open
- Categorical, nominal
- Independent variable

COMP_YN
- Question: Was at least one complication experienced?
- Answer Choices: Yes or No
- Categorical, nominal
- Dependent variable

Table 1: Operational Definitions of Variables

Variable	Operational Definitions
ID	Identification number.
DOB	Patient date of birth; month, day and year.
AGE	Patient years of age.
GENDER	Male, female, or other.
ETHNICITY	Hispanic or Latino or Non-Hispanic or Latino.
RACE	American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Pacific Islander, White of Caucasian, or Other.
HT	Self-reported patient height in meters recorded in EPIC the Johns Hopkins Health System electronic medical record.
INITIAL_WT	Patient weight measured at first pre-operation bariatric nutrition counseling visit in kilograms recorded in EPIC the Johns Hopkins Health System electronic medical record.
LAST_WT	Most recent patient weight recorded in EPIC the Johns Hopkins Health System electronic medical record measured in kilograms.
INITIAL_BMI	Patient body mass index (BMI) measured at first pre-operation bariatric nutrition counseling. Calculated as initial weight (in kg) divided by height (m^2).
LAST_BMI	Most recent patient body mass index (BMI) recorded in EPIC the electronic medical record. Calculated as last weight (in kg) divided by height (m^2).
NUTR_ASSESS	Patient has at least one formal preoperative bariatric initial nutrition assessment and education or refresher nutrition assessment and education documented in the electronic medical record (EMR) by an RD within the Johns Hopkins Health System.
COUNS	Specific healthcare professional who facilitated the preoperative nutrition counseling: registered dietitian, primary care physician, health coach, nurse practitioner, physician assistant, or other.
RD_YN	Preoperative nutrition counseling facilitated by a registered dietitian (RD); yes, no, or unknown.
COUNS_DUR	Total number of months preoperative nutrition counseling visits lasted excluding preoperative bariatric initial nutrition assessment and education or refresher nutrition assessment and education.
COUNS_NUM	Total number of preoperative nutrition counseling visits excluding preoperative bariatric initial nutrition assessment and education or refresher nutrition assessment and education.
JHHS	Preoperative nutrition counseling facilitated at any facility within the Johns Hopkins Health System, excluding preoperative bariatric initial nutrition assessment and education or refresher nutrition assessment and education.
SURG_DATE	Month, day and year of surgery.

SURG_TYPE	Type of bariatric procedure: Roux-en-Y Gastric Bypass or Sleeve Gastrectomy.
APPROACH	Method in which the bariatric procedure was carried out: laparoscopic or open.
COMP_YN	Experienced at least one complication; yes or no.
COMP 1	First complication/adverse outcome documented in patient electronic medical record (EMR) within nine months post bariatric surgery that was not documented prior to surgery: hospitalization, dehydration/intravenous fluids, infection, malabsorption, vitamin/mineral deficiency, malabsorption, other and none.
COMP 2	Second complication/adverse outcome documented in patient electronic medical record (EMR) within nine months post bariatric surgery that was not documented prior to surgery: hospitalization, dehydration/intravenous fluids, infection, malabsorption, vitamin/mineral deficiency, malabsorption, other and none.
COMP 3	Third complication/adverse outcome documented in patient electronic medical record (EMR) within nine months post bariatric surgery that was not documented prior to surgery: hospitalization, dehydration/intravenous fluids, infection, malabsorption, vitamin/mineral deficiency, malabsorption, other and none.

PROCEDURES

An electronic literature search was performed using PubMed and the Cochrane Library databases from 2010-2017 with the headings: bariatric surgery, obesity surgery, gastric band, gastric bypass, sleeve gastrectomy, weight-loss surgery, Roux-en-Y, gastric bypass AND complications; postoperative complications AND gastric bypass; preoperative bariatric counseling AND complications; registered dietitian AND bariatric complications. Google was also used to search for grey literature. Studies were limited to the English language.

An inquiry regarding the determination of review was submitted via email to The Emory University Institutional Review Board (IRB). The board responded to the email with an attached determination letter, listed in Appendix A, stating that the study does not meet the definition of research with “human subjects" as outlined in Emory policies and procedures and federal rules, therefore, no IRB review was required. Additionally, an application was submitted to the Johns Hopkins Institutional Review Board (IRB) indicating that this was a non-human subjects study and exempt from IRB review.

Before analysis, patient records and information were de-identified to ensure anonymity. A review of retrospective data was conducted at the Johns Hopkins Center for Bariatric Surgery in Baltimore, Maryland using the clinical nutrition department's database and EPIC, the Johns Hopkins Medicine's single, integrated electronic medical record system for the entire enterprise. EPIC incorporates scheduling and registration, clinical documentation, computerized provider order entry (CPOE), ePrescribing and Charge Capture. Information in both the database and EMR was collected from patients at enrollment and throughout care (Johns Hopkins Medicine, 2018a). Race/ethnicity was collected using a self-report form when patients have an inpatient and/or outpatient visit. In general, height was measured or self-reported by the patients and weights were measured by health care professionals using a standing scale during clinic visits. BMI was computed as weight in kilograms (kg) divided by height in meters squared (m^2). Date of birth, gender, ethnicity, race, height, initial and last weight, initial and last body mass index (BMI), if initial bariatric nutrition assessment and education was done with an RD, counselor (type of healthcare professional who facilitated the PNC), if counseling was facilitated by an RD or non-RD, duration of PNC, number of PNC visits, if PNC was facilitated within the Johns Hopkins Health System (JHHS), date of surgery, type of surgery, surgical approach, and post-surgery complications for 60 patients were extracted from the database and EPIC.

INSTRUMENTS

A data extraction spreadsheet was created in Microsoft Excel, listed in Appendix B, and used to annotate relevant information from the department's database and EPIC to create a new dataset for analysis. Drop-down lists for most data categories were created for ease of use and to reduce the potential for human error during data extraction as shown in Table 2. Data were

retrieved only from the department's database and the EMR, and no attempt was made to obtain missing data from the authors.

Table 2: Data Category Containing a Drop-Down List

GENDER	ETHNICITY	RACE	NUTR_ASSESS	COUNS	RD_YN	JHHS	COMP_YN	COMP_1	COMP_2	COMP_3
Male	Hispanic or Latino	American Indian or Alaska Native	Yes	RD	Yes	Yes	Yes	Hospitalization	Hospitalization	Hospitalization
Female	Non-Hispanic or Latino	Asian	No	PCP	No	No	No	Dehydration/IVF	Dehydration/IVF	Dehydration/IVF
Other	Unknown	Black or African American	Unknown	Health Coach	Unknown	Unknown	Unknown	Infection	Infection	Infection
Unknown	Refused	Native Hawaiian or Pacific Islander		NP				Malnutrition	Malnutrition	Malnutrition
Refused		White or Caucasian		PA				Vitamin/Mineral Deficiency	Vitamin/Mineral Deficiency	Vitamin/Mineral Deficiency
		Other		Other				Malabsorption	Malabsorption	Malabsorption
		Unknown		Unknown				Other	Other	Other
		Refused						None	None	None

Research Question

1. Does preoperative nutrition counseling given by registered dietitians, as opposed to non-dietitians, result in more favorable outcomes as defined by no complications within nine months post-surgery in a cohort of patients who underwent bariatric surgery at Johns Hopkins Center for Bariatric Surgery in 2017?

Hypothesis

H_0: When type and approach of surgery are controlled, there is no statistical difference in the odds of experiencing complications within nine months of surgery for bariatric patients who received preoperative nutrition counseling by a registered dietitian compared to those who received preoperative nutrition counseling by non-registered dietitians.

H_1: When type and approach of surgery are controlled, there is a statistical difference in the odds of experiencing complications within nine months of surgery for bariatric patients who received preoperative nutrition counseling by an RD compared to those who received preoperative nutrition counseling by non-RDs.

The overall goal was to determine the association between counseling administered by an RD and complication outcomes and the effects of PNC given by an RD compared to a non-RD on complication outcomes. The statistical analysis chosen to address the research question and hypothesis was logistic regression analysis. This test explored the relationship between the key variables using statistical analyses and sought to establish between them a cause-effect relationship. IBM SPSS Statistics 25.0 statistical software was used to analyze the data extracted from the clinical nutrition department's database and EPIC. A *P* value of <.05 was regarded significant for this test.

Assumptions

1. The dependent variable should be measured on a dichotomous scale.
2. There should be one or more independent variables, which can be either continuous or categorical.
3. There should be the independence of observations, and the dependent variable should have mutually exclusive and exhaustive categories.
4. There should be a linear correlation between any continuous independent variables and the logit transformation of the dependent variable.

DATA ANALYSIS METHODOLOGY

The data analysis method used was logistic regression to determine the association between patients who received PNC by an RD and complications post-bariatric surgery compared to those who received PNC by non-RDs when the type of surgery and surgery approach were controlled. Type of surgery and surgery approach was controlled because the literature shows that these variables are more likely to influence the incidence of complications or illness post-surgery (Janik, Rogula, Bielecka, Kwiatkowski, & Paśnik, 2016). The purpose of

using logistic regression to analyze this data was because there were two or more categorical variables being investigated; the independent variable, PNC facilitated by either an RD or non-RD and the dependent, variable of experiencing complications or not experiencing complications.

Using the dataset from the Excel extraction spreadsheet, it was first determined whether each patient experienced complications within nine months after bariatric surgery, and then coded as “1” if they experienced complications and “0” if they did not. It was also determined whether they received PNC by an RD (1) or did not receive PNC by an RD (0), if their surgery type was RNY (1) or sleeve gastrectomy (0), and if their surgery approach was lap (1) or open (0). If the counselor type was unknown, it was coded as PNC by a non-RD for statistical purposes. Next, a correlation matrix was done to make sure none of the independent variables were highly correlated. Lastly, logistic regression was performed in which post-surgery complications was the dependent variable, and PNC by an RD, type of surgery, and surgery approach are the independent variables.

A regression analysis was performed by first opening the IBM SPSS Statistics 25.0 software. “File” was selected in the toolbar at the top of the program, and the Excel spreadsheet that was created to extract data was opened and converted to a file that was readable in SPSS. Then, a new variable was created from the existing variable "RD_YN." The new variable was called “RD_COUNS” and was coded as “1” when “RD_YN” equaled “Yes” and coded “0” when “RD_YN” equaled “No." This was done by selecting "Transform," then “Compute Variable” in the menu at the top of the main screen. “RD_COUNS” was typed into the “Target Variable” box, then “1” was typed into the box after the “=” sign. The “If” box was clicked, then the circle to the right of the statement “Include if case satisfies condition” was clicked, and “RD_YN =

‘Yes’” was typed in the box below that statement. Then “Continue” and “Ok” was selected to finalize the recoding. “Transform” then “Compute Variable” was clicked again. The “1” was changed to a “0” in the box after the “=” sign. The “If” box was selected, and “RD_YN = ‘No’” was typed in the box below. The “Continue” and “Ok” command was selected. A prompt appeared on the screen asking if there was a desire to change the existing variable. At that point, “Ok” was selected again to finalize the recoding.

Next, another new variable was created from SURG_TYPE. The new variable was called "SURG." First, the "Reset” button was selected to remove the variables previously defined. Then “Transform” and then “Compute Variable” was clicked in the menu at the top of the main screen. “SURG” was typed into the “Target Variable” box, then “1” was typed into the box after the “=” sign. The “If” box was selected, then the circle to the right of the statement “Include if case satisfies condition” was selected, and “SURG_TYPE = ‘RNY” was typed in the box below that statement. Then “Continue” and “Ok” commands were clicked to finalize the recoding. “Transform” then “Compute Variable” was clicked again. The “1” was changed to a “0” in the box after the “=” sign. The “If” box was selected, and “SURG_TYPE = ‘Sleeve Gastrectomy” was typed in the box below. “Continue” and then “Ok” was clicked. A prompt appeared on the screen asking if there was a desire to change the existing variable. The “Ok” command was selected again to finalize the recoding.

Another new variable was created, this time from APPROACH. The new variable was called "APPRO." First, the "Reset” button was selected to remove the variables previously defined. Then “Transform” and then “Compute Variable” was selected in the menu at the top of the main screen. “APPRO” was typed into the “Target Variable” box, then “1” was typed into the box after the “=” sign. The “If” box was clicked, then the circle to the right of the statement

“Include if case satisfies condition” was selected, and “APPROACH = ‘Lap” was typed in the box below that statement. Then “Continue” and “Ok” was clicked to finalize the recoding. “Transform” then “Compute Variable” was clicked again. The “1” was changed to a “0” in the box after the “=” sign. The “If” box was selected, and “APPROACH = ‘Open” was typed in the box below. “Continue” and then “Ok” was selected. A prompt appeared on the screen asking if there was a desire to change the existing variable. At that point, “Ok” was selected again to finalize the recoding.

The last new variable was created from COMP_YN by first, selecting the “Reset” button to remove the variables previously defined. Then “Transform” and then “Compute Variable” was selected in the menu at the top of the main screen. “COMPLI” was typed into the “Target Variable” box, then “1” was typed into the box after the “=” sign. The “If” box was clicked, then the circle to the right of the statement “Include if case satisfies condition” was selected, and “COMP_YN = ‘Yes” was typed in the box below that statement. Then “Continue” and "Ok" was selected to finalize the recoding. “Transform” then “Compute Variable” was selected again. The “1” was changed to a “0” in the box after the “=” sign. The “If” box was selected, and “COMP_YN = ‘No” was typed in the box below. “Continue” and then “Ok” was clicked. A prompt appeared on the screen asking if there was a desire to change the existing variable. At that point, “Ok” was selected again to finalize the recoding.

A correlation matrix was generated to make sure none of the independent variables were highly correlated (i.e., > .70). This was initiated by selecting the “Analyze” command in the menu at the top of the main screen, then “Correlate," then “Bivariate." The variables RD_COUNS, SURG, APPRO, COMPLI, were then moved into the “Variables” box. Then the

“Ok” command was selected. The correlation matrix was reviewed to determine if any of the independent variables were highly correlated (e.g., absolute value of 0.70 or above).

To run the logistic regression, the “Analyze” command was selected from the menu at the top of the main screen, then “Regression," then "Binary Logistic." A box with the variables listed on the left, a box for the dependent variable on the right, and a box for covariates below appeared on the screen. “COMPLI” was moved into the box for the dependent variable. RD_COUNS, SURG, and APPRO were moved into the box for the covariates. Then the option “Enter” was selected under “Method." "Options" was clicked, then "Hosmer-Lemeshow goodness of fit" and "CI for exp(B)" were selected and then "Continue." Next, the "Categorical" command was selected, and the variables RD_COUNS, SURG, and APPRO were moved over to the "Categorical Covariates" box using the arrow icon. After all three variables were moved to the box, each was selected one at a time, and after each click, the option for “First” was selected under the reference category and then “Change” was clicked. Finally, the "Continue" and then “Ok” commands were selected to run the analysis.

Chapter 4 – Results

INTRODUCTION

This chapter presents the major results of the study and its significance. There is a discussion about the correlational matrix showing that there was no correlation between any of the variables and the percentage disruption of patients who experienced complications and those who did not. The chi-square statistic yielded a non-significant result, and the overall model was not significant with a p-value >0.05. An unexpected finding was that surgery type showed to be a protective factor from experiencing complications post-bariatric surgery.

KEY FINDINGS

Correlations

A correlational matrix among variables is presented showing the correlation between each of the variables as shown in Table 3. The three vertical numbers for each variable combination are examined. Looking at RD_COUNS, the first top number is the Pearson correlation or the r value. The middle number is the p-value, Sig. (2-tailed) and is the significance of the correlation. The bottom number, N, is the frequency.

Collinearity is the intercorrelation of independent variables. It is usually problematic when correlations are between 0.6 and 0.8. If two explanatory variables are highly correlated with each other, they can skew the results of multivariable analysis because they are explaining practically the same variability in the outcome. It also makes it difficult to measure the distinctive role of each variable in the regression. In other words, we cannot distinguish the independent variables individual influences on the dependents variable. So, it is beneficial to examine associations between explanatory variables and exclude one of a pair of highly

correlated variables before conducting logistic regression analysis. None of the variables have a correlation greater than 0.7, so there is no collinearity. Thus, there was no correlation between any of the variables, and it was ok to proceed to logistic regression analysis.

Table 3: Correlations Matrix Among the Variables

		RD_COUNS	SURG	APPRO	COMPLI
RD_COUNS	Pearson Correlation	1	-.129	-.123	.193
	Sig. (2-tailed)		.327	.349	.139
	N	60	60	60	60
SURG	Pearson Correlation	-.129	1	.166	-.025
	Sig. (2-tailed)	.327		.204	.851
	N	60	60	60	60
APPRO	Pearson Correlation	-.123	.166	1	.166
	Sig. (2-tailed)	.349	.204		.204
	N	60	60	60	60
COMPLI	Pearson Correlation	.193	-.025	.166	1
	Sig. (2-tailed)	.139	.851	.204	
	N	60	60	60	60

Logistic Regression

Next, the output of the logistic regression analysis is examined. The classification table shows the response profile for those who experienced at least one complication complications post-surgery as shown in Table 4. Experience of at least one complication is determined by “1” and no experience of at least one complication is determined by "0". The table shows that precisely 23.3% experienced complications and 76.7% did not experience complications.

Table 4: Classification Table[a,b]

Observed			Predicted COMPLI .00	Predicted COMPLI 1.00	Percentage Correct
Step 0	COMPLI	.00	46	0	100.0
		1.00	14	0	.0
	Overall Percentage				76.7

Next is the Hosmer-Lemeshow Goodness of Fit Test and the contingency table for Hosmer and Lemeshow Test as shown in Table 5 and Table 5.1. The Hosmer-Lemshow statistic evaluates the goodness-of-fit by creating ten ordered groups of subjects and then compares the number in each group (observed) to the number predicted by the logistic regression model (predicted). Thus, the test statistic is a chi-square statistic with a desirable outcome of nonsignificance, indicating that the model prediction does not significantly differ from the observed. The goodness of fit test is used most commonly in tests where the sample is greater than 400. In this case, if the goodness of fit test is significant, we can stop, as our model will not be significant. This chi-square statistic yields a non-significant result, which is the most important part of this test.

Table 5: Hosmer and Lemeshow Test

Step	Chi-square	df	Sig.
1	.379	3	.945

Table 5.1: Contingency Table for Hosmer and Lemeshow Test

		COMPLI = .00		COMPLI = 1.00		
		Observed	Expected	Observed	Expected	Total
Step 1	1	5	5.000	0	.000	5
	2	8	8.400	2	1.600	10
	3	20	19.600	4	4.400	24
	4	3	2.600	1	1.400	4
	5	10	10.400	7	6.600	17

Next is to determine if the overall model is significant by reviewing the model summary as shown in Table 6. In other words, when the type of surgery and surgery approach are controlled, is there a significant difference in the odds of experiencing complications within nine months of surgery for bariatric patients who received PNC by an RD compared to those who did not. This is determined by observing the Likelihood Ratio, which is the chi-square and the significance under the omnibus test of model coefficients as shown in Table 7. The likelihood ratio is usually observed as it has more power (lower Type II errors) than other tests. The results show that the p-value is 0.130. It is evident that the overall model is not significant since the p-value is greater than 0.05.

Table 6: Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	59.551[a]	.090	.135

Table 7: Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	5.642	3	.130
	Block	5.642	3	.130
	Model	5.642	3	.130

The variables in the equation, as shown in Table 8, are as follows: RD_COUNS(1) = preoperative nutrition counseling by an RD, SURG(1) = type of surgical procedure, and APPRO(1) = type of surgical approach. The results indicate that specific controlled variables were significant in the model, even though it was concluded that the overall model is not significant. The last essential part of the results is the Odds Ratio Estimates. SPSS uses the

Exp(B) as the point estimate for the odds ratio. This estimate shows information regarding what controlled variables were protective factors from experiencing complications post-bariatric surgery and which were risk factors for experiencing complications post-bariatric surgery. Protective factors are those that have a Point Estimate/Exp (B) of < 1.0 and risk factors are those that have a Point Estimate/Exp (B) of >= 1.0. The table results show that there is one protective factor and two risk factors. SURG(1) has a Point Estimate/Exp (B) of 0.848 which is less than 1.0, which suggests that surgery type is a protective factor from experiencing complications post-bariatric surgery. RD_COUNS(1) has a Point Estimate/Exp (B) of 2.827, and APPRO(1) has a Point Estimate/Exp (B) of 730262084.343. They are both greater than 1.0, thus suggesting they are not protective factors from experiencing complications post-bariatric surgery.

Table 8: Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B) Lower	Upper
Step 1[a]	RD_COUNS(1)	1.039	.640	2.639	1	.104	2.827	.807	9.904
	SURG(1)	-.164	.762	.046	1	.829	.848	.190	3.780
	APPRO(1)	20.409	17617.514	.000	1	.999	730262084.343	.000	.
	Constant	-21.903	17617.514	.000	1	.999	.000		

Research Question

1. Does preoperative nutrition counseling given by registered dietitians, as opposed to non-dietitians, result in more favorable outcomes as defined by no complications within nine months post-surgery in a cohort of patients who underwent bariatric surgery at Johns Hopkins Center for Bariatric Surgery in 2017?

Hypothesis

H_0: When type and approach of surgery are controlled, there is no statistical difference in the odds of experiencing complications within nine months of surgery for bariatric patients who received preoperative nutrition counseling by a registered dietitian compared to those who received preoperative nutrition counseling by non-RDs or unknown practitioners.

H_1: When type and approach of surgery are controlled, there is a statistical difference in the odds of experiencing complications within nine months of surgery for bariatric patients who received preoperative nutrition counseling by an RD compared to those who received preoperative nutrition counseling by non-RDs or unknown practitioners.

OTHER FINDINGS

The results showed that surgery type is a protective factor from experiencing complications post-bariatric surgery, suggesting that it lowers the risk of complications.

SUMMARY

Characteristics of the sample are shown in the Box 1. The mean age of the patient sample was 44 years old. No significant correlation was found between bariatric patients who received PNC by an RD and those that experienced complications post-bariatric surgery (Pearson's Correlation $\rho = 0.193$; $P = .139$) as shown in Table 3. The chi-square and the significance under the omnibus test of model coefficients as shown in Table 7 indicates that the overall model is not significant ($p = 0.130$). Surgery type appears to be a protective factor from experiencing complications post-bariatric surgery, (Point Estimate/Exp (B) = 0.848) suggesting that it lowers the risk of complications post-surgery. Counseling done by an RD and surgery approach does not

prove to be protective factors from experiencing complications post-bariatric surgery. After adjusting for surgery type and approach, the association between patients who received PNC by an RD and experiencing complications persisted (β = 1.039; 95% confidence interval, 0.807–9.904; *P* = 0.104) as shown in Table 8.

Disclaimer: It should be noted that of the 60 patients reviewed, 22 were seen by an RD, one was seen by a primary care physician (PCP), and 37 were seen by an unknown practitioner for PNC. Given that the majority of counseling was done by an unknown practitioner, it is not possible to make conclusions on RD effectivity. It is possible that the unknown practitioners were RDs at a location outside of the Johns Hopkins Health System.

Chapter 5 – Conclusions, Implications, and Recommendations

INTRODUCTION

This chapter discusses the overall study and the explanation of the key results with supporting literature. It addresses the limitations that are beyond the control of the researcher and how they impact the thesis findings. Implications for public health practice are also highlighted. The chapter offers suggestions for a study that would further clarify the conclusions of the study and recommendations to inform for public health practice.

SUMMARY OF STUDY

The problem examined in this study is the economic burden of obesity in the United States. Since bariatric surgery is proven to be an effective obesity intervention, it was essential to investigate preoperative characteristics that impact surgery outcomes. Research has shown that nutrition education with an RD can ensure sustained weight loss, but there are not many studies illustrating its effects on preventing or lowering the risk of weight loss surgery-associated complications. The research method used to explore the relationship between PNC given by RDs and the incidence of complications after bariatric surgery was a mix of a correlational and a quasi-experimental retrospective study design. Key variables were identified along with their operational definitions and data was extracted from the clinical nutrition department database and the hospital's electronic medical record (EMR). A correlation matrix and logistic regression were used to analyze the data. The matrix showed that there was no significant correlation between bariatric patients who received PNC by an RD and those that experienced complications post-bariatric surgery, so there was confidence in the ability to measure the distinctive role of each variable in the regression. In the end, PNC given by RDs did not appear to result in more

favorable outcomes, and an unintended finding was that surgery type lowers the risk of complications post-surgery. Disclaimer: It should be noted that of the 60 patients reviewed, 22 were seen by an RD, one was seen by a primary care physician (PCP), and 37 were seen by an unknown practitioner for PNC. Given that the majority of counseling were done by an unknown practitioner, it is not possible to make conclusions on RD effectivity. It is possible that the unknown practitioners were RDs at a location outside of the Johns Hopkins Health System.

DISCUSSION OF KEY RESULTS

After adjusting for surgery type and approach, the results showed there was no statistical difference in the odds of experiencing complications within nine months of surgery for the cohort of bariatric patients who received PNC by an RD compared to those who received PNC by non-RDs or unknown practitioner. Patients in the sample were mostly female. A study found that women had the highest incidence complication post-bariatric surgery (Wrzesinski et al., 2015). Males only accounted for 10% of the sample. Anastomotic insufficiency/leakage and mortality rates were significantly higher in male than in female patients (Stroh, Weiner, Wolff, Knoll, & Manger, 2014). Noninvasive interventions cannot change gender predisposition. Therefore, increased risk of adverse outcomes among the genders is inevitable even with PNC. Another study showed that age and gender were confounders for the quality of life outcome and morbidity (Janik et al., 2016). Gender should be considered in further studies on bariatric surgery outcomes. This relates to the SCT because it is a personal factor in the form of a biological event as the determinant that influences behavior.

The results showed that surgery type is a protective factor from experiencing complications post-bariatric surgery, suggesting that it lowers the risk of complications. The

RYGB and sleeve gastrectomy procedures are equal regarding excess weight loss (Janik et al., 2016) but have a different influence on morbidity. As mentioned in chapter 1, type 2 diabetes was linked to the occurrence of postoperative complications in bariatric patients (Wrzesinski et al., 2015). The RYGB procedure may perhaps be more effective in improving glycemic control (Janik et al., 2016) which would further reduce the risk of complications. In the literature, there is little about the difference between the RYGB and sleeve gastrectomy procedures as they relate to complication rates, hence, there is a need for new studies comparing outcome after these procedures.

LIMITATIONS

1. Unavailable data

    Presence of any complications that occurred post-surgery could not be confirmed that it was an existing concern or a problem related to any health issues before bariatric surgery. This limitation was circumvented by thoroughly reviewing patient notes from each visit in the medical record to determine if there was documentation of complications before the bariatric procedure. If the complication was a new occurrence, was documented after the bariatric procedure, and is a common complication after bariatric surgery, then it was assumed to be an adverse outcome of the bariatric procedure. A complication was labeled as an "adverse outcome documented in patient electronic medical record (EMR) within nine months post bariatric surgery that was not documented prior to surgery: hospitalization, dehydration/intravenous fluids, infection, malabsorption, vitamin/mineral deficiency, malabsorption, other and none." The complications identified

in this definition were observed in the review of the literature as the most common complications associated with bariatric surgery.

2. Lack of reliable data

The diagnosis "malnutrition" and "malabsorption" documented in EPIC at post-operation clinic visits were the results of anticipated and planned rapid weight loss due to the removal and resection of a substantial amount of the digestive system (Johns Hopkins Medicine, 2018b). The validity of this documentation is questionable but cannot be confirmed whether are not they were true, unplanned complications. Given that it was a retrospective study, there is no way to validate questionable information. Even if there were tests confirming these diagnoses, malnutrition and malabsorption is expected due to the nature of the procedure and therefore, under the care of medical supervision, is a normal outcome of bariatric surgery. Thus, it was decided that "malnutrition" and "malabsorption" would be disregarded as a genuine complication for this study.

3. Lack of available data/access

It is expected that if preoperative nutrition counseling was conducted outside the Johns Hopkins System, it would be found in the form of scanned documentation received from other facilities. Many of the records did not have this documentation so the counselor type could not be confirmed. It was concluded that for the records that did not have information on who facilitated the preoperative counseling (N=37), counselor type would be recorded as “unknown” and treated as counseling done by a “non-RD” professional. Some of these unknown practitioners could have been RDs, explaining the lack of significant difference between groups.

4. Lack of generalizability

There is a lack of generalized data of the sample to the overall population because the sample had a disproportionate number of males with only a 10% representation of the patients. Use of a convenience sample also contributed to the lack of generalization because the study only looked at Johns Hopkins patients. These findings may not interpret results for patients of other weight loss programs; however, the results may still be widely applicable as they can help with patient-specific treatment in all parts of the world.

5. Confounders and Proxy measures

This analysis cannot address unobserved confounding factors that may persist after matching because this was a retrospective study design and not a randomized trial. Confounders are variables that have been shown to be associated with the outcome as well as exposure. They are likely to confound the association between the exposure and outcome and should be forced into all multivariable models (Pourhoseingholi, Baghestani, & Vahedi, 2012). A proxy is an obscure measure of the desired outcome which is itself strongly correlated to that outcome (Johns Hopkins University, 2017). To exclude or control confounding variables in this study, patient records were selected at random and logistic regression was the chosen method of statistical analysis to control for potentially confounding effects.

IMPLICATIONS

This study brings awareness to the value of healthcare professionals to assist patients in prevention and management of bariatric surgery complications prior to bariatric surgery. In addition to physical complications, patients are faced with the possibility of other difficult

aspects of life post-surgery, so they must have constant support to maximize the benefit of their treatments. For example, they may experience challenges coping with a return of uncontrollable hunger feelings, weight re-gain and changes to personal identity and body image. These behavioral outcomes can induce the physical complications discussed in this study. Therefore, it is especially imperative for bariatric services to offer access to long-term dietary and psychological support not only before but after surgery.

Direction relating to the preoperative care of bariatric surgery patients mainly puts consideration on the monitoring and treatment of physical symptoms, comorbidities, and nutritional deficiencies, with little guidance on prevention of these issues following surgery. There is a need for more examination to advance and assess primary prevention interventions to support patients with long-term treatment maintenance and to avoid adverse health problems. The findings of this research are beneficial for healthcare professionals and policymakers working in bariatric surgery services to inform the future development of these services to be more in line with patient needs. Improved preventative care services prior to surgery may lead to better outcomes. This could mean huge cost savings in health care while effectively managing obesity-related health problems.

This study also sheds light on the effects of statistical analysis on health care access for prospective bariatric surgery patients. The results of this investigation proved that there was no statistical difference between PNC by an RD and a non-RD or unknown practitioner with experiencing complications. This could be used to inform policy or practice decisions but additional research and complete data are needed to determine efficacy. When the results of statistical analysis are used for policy determination, the consequences for patient care can be substantial.

RECOMMENDATIONS

The findings warrant further research. Perhaps the focus should be on the duration or amount of PNC visits rather than whether it was facilitated by an RD. This begs the question: is the duration or number of PNC visits associated with complications after bariatric surgery? If there is an association, then further research needs to be conducted to determine how much of an impact the exact duration and number of PNC facilitated by each health professional individually that resulted in the least amount of complications. The key independent variables would be the specified healthcare professional, the number of months of counseling and the total counseling sessions prior to the bariatric procedure. The dependent variable would once again be complications. Logistic regression could be used to establish a cause-effect relationship between these variables.

CONCLUSION

Ultimately, the hypothesis was accepted, and there was no statistical difference in the odds of experiencing complications within nine months of surgery for the cohort of bariatric patients who received PNC by an RD compared to those who received PNC by non-RDs or unknown provider type. Thus, PNC given by RDs did not appear to result in more favorable outcomes. Further investigation of the impact of the RD role in the multidisciplinary team and subsequently, the effects of PNC facilitated by any other healthcare professional should be done as an extension of this study. Other findings observed was that the type of procedure chosen could lower the risk of complications within nine months after bariatric surgery. This

underscores the importance of pre-surgery evaluation and assessment to make informed decisions regarding which type of procedure will yield the most desirable results.

References

Academy of Nutrition and Dietetics. (2018). RDN and NDTR Overview. Retrieved from https://www.eatrightpro.org/about-us/what-is-an-rdn-and-dtr/rdn-and-ndtr-overview

American Diabetes Association. (2013). Economic costs of diabetes in the U.S. in 2012. Diabetes Care 2013;36:1033–1046. *Diabetes Care, 36*(6), 1797.

American Society for Metabolic and Bariatric Surgery. (2017). Bariatric Surgery Procedures. Retrieved from https://asmbs.org/patients/bariatric-surgery-procedures

American Society for Metabolic and Bariatric Surgery. (2018). Bariatric Surgery Procedures. Retrieved from https://asmbs.org/patients/bariatric-surgery-procedures

Bandura, A. (2001). Social cognitive theory: an agentic perspective. *Annu Rev Psychol, 52*, 1-26. doi:10.1146/annurev.psych.52.1.1

Belite Weight. (2017). Roux-en-Y Gastric Bypass. Retrieved from https://www.beliteweight.com/weight-loss-surgery-procedures/gastric-bypass-roux-en-y/

Boeka, A. G., Prentice-Dunn, S., & Lokken, K. L. (2010). Psychosocial predictors of intentions to comply with bariatric surgery guidelines. *Psychol Health Med, 15*(2), 188-197. doi:10.1080/13548501003615282

Bour, E. S. (2015). Evidence supporting the need for bariatric surgery to address the obesity epidemic in the United States. *Curr Sports Med Rep, 14*(2), 100-103. doi:10.1249/jsr.0000000000000135

Centers for Disease Control and Prevention. (2016). Overweight & Obesity. Retrieved from https://www.cdc.gov/obesity/adult/defining.html.

Centers for Disease Control and Prevention. (2018). Social Determinants of Health: Know What Affects Health. Retrieved from https://www.cdc.gov/socialdeterminants/faqs/index.htm

de'Angelis, N., Carra, M. C., & Vincenzi, F. (2012). Gluten-free diet in obese patients with celiac disease: an enemy of the bariatric surgeon? *Obes Surg, 22*(6), 995-996. doi:10.1007/s11695-012-0626-z

Endevelt, R., Ben-Assuli, O., Klain, E., & Zelber-Sagi, S. (2013). The role of dietician follow-up in the success of bariatric surgery. *Surg Obes Relat Dis, 9*(6), 963-968. doi:10.1016/j.soard.2013.01.006

Flegal, K. M., Kruszon-Moran, D., Carroll, M. D., Fryar, C. D., & Ogden, C. L. (2016). Trends in Obesity Among Adults in the United States, 2005 to 2014. *JAMA, 315*(21), 2284-2291. doi:10.1001/jama.2016.6458

Fujioka, K. (2005). Follow-up of nutritional and metabolic problems after bariatric surgery. *Diabetes Care, 28*(2), 481-484.

Glanz, K., Rimer, B.K. & Lewis, F.M. . (2002). Health Behavior and Health Education. Theory, Research and Practice. 4. Retrieved from http://www.sanjeshp.ir/phd/phd_91/Pages/Refrences/health education and promotion/[Karen_Glanz,_Barbara_K._Rimer,_K._Viswanath]_Heal(BookFi.or.pdf

Hubert, H. B., Feinleib, M., McNamara, P. M., & Castelli, W. P. (1983). Obesity as an independent risk factor for cardiovascular disease: a 26-year follow-up of participants in the Framingham Heart Study. *Circulation, 67*(5), 968-977.

Hwang, K. O., Childs, J. H., Goodrick, G. K., Aboughali, W. A., Thomas, E. J., Johnson, C. W., . . . Bernstam, E. V. (2009). Explanations for Unsuccessful Weight Loss Among Bariatric Surgery Candidates. *Obesity Surgery, 19*(10), 1377-1383. doi:10.1007/s11695-008-9573-0

Hydock, C. M. (2005). A brief overview of bariatric surgical procedures currently being used to treat the obese patient. *Crit Care Nurs Q, 28*(3), 217-226.

Janik, M. R., Rogula, T., Bielecka, I., Kwiatkowski, A., & Paśnik, K. (2016). Quality of Life and Bariatric Surgery: Cross-Sectional Study and Analysis of Factors Influencing Outcome. *Obesity Surgery, 26*(12), 2849-2855. doi:10.1007/s11695-016-2220-2

Johns Hopkins Medicine. (2017). About Johns Hopkins Medicine. Retrieved from https://www.hopkinsmedicine.org/about/index.html

Johns Hopkins Medicine. (2018a). Epic at Johns Hopkins. Retrieved from https://www.hopkinsmedicine.org/epic/index.html

Johns Hopkins Medicine. (2018b). Gastric Bypass (Malabsorptive) Surgery Procedure. Retrieved from https://www.hopkinsmedicine.org/healthlibrary/test_procedures/gastroenterology/gastric_bypass_malabsorptive_surgery_procedure_92,p07988

Johns Hopkins University. (2017). Proxy Measure. Retrieved from https://govex.jhu.edu/wiki/proxy-measure/

Karmali, S., Stoklossa, C. J., Sharma, A., Stadnyk, J., Christiansen, S., Cottreau, D., & Birch, D. W. (2010). Bariatric surgery: A primer. *Canadian Family Physician, 56*(9), 873-879.

Kissler, H. J., & Settmacher, U. Bariatric Surgery to Treat Obesity. *Seminars in Nephrology, 33*(1), 75-89. doi:10.1016/j.semnephrol.2012.12.004

Kulick, D., Hark, L., & Deen, D. (2010). The bariatric surgery patient: a growing role for registered dietitians. *J Am Diet Assoc, 110*(4), 593-599. doi:10.1016/j.jada.2009.12.021

Kwon, Y., Kim, H. J., Lo Menzo, E., Park, S., Szomstein, S., & Rosenthal, R. J. (2014). Anemia, iron and vitamin B12 deficiencies after sleeve gastrectomy compared to Roux-en-Y gastric bypass: a meta-analysis. *Surg Obes Relat Dis, 10*(4), 589-597. doi:10.1016/j.soard.2013.12.005

Lopes, E. C., Heineck, I., Athaydes, G., Meinhardt, N. G., Souto, K. E., & Stein, A. T. (2015). Is Bariatric Surgery Effective in Reducing Comorbidities and Drug Costs? A Systematic Review and Meta-Analysis. *Obes Surg, 25*(9), 1741-1749. doi:10.1007/s11695-015-1777-5

Ma, I. T., & Madura, J. A. (2015). Gastrointestinal Complications After Bariatric Surgery. *Gastroenterology & Hepatology, 11*(8), 526-535.

Merriam-Webster. (2018a). Adipose Tissue. Retrieved from https://www.merriam-webster.com/dictionary/adipose tissue

Merriam-Webster. (2018b). Bile. Retrieved from https://www.merriam-webster.com/dictionary/bile

Monkhouse, S. J. W., Morgan, J. D. T., & Norton, S. A. (2009). Complications of Bariatric Surgery: Presentation and Emergency Management – a Review. *Annals of The Royal College of Surgeons of England, 91*(4), 280-286. doi:10.1308/003588409X392072

National Institute of Diabetes and Digestive and Kidney Diseases. (2017). Types of Bariatric Surgery. Retrieved from https://www.niddk.nih.gov/health-information/weight-management/bariatric-surgery/types

Odom, J., Zalesin, K. C., Washington, T. L., Miller, W. W., Hakmeh, B., Zaremba, D. L., . . . McCullough, P. A. (2010). Behavioral predictors of weight regain after bariatric surgery. *Obes Surg, 20*(3), 349-356. doi:10.1007/s11695-009-9895-6

Peace Health. (2017). Roux-en-Y Gastric Bypass. Retrieved from https://www.peacehealth.org/southwest/services/weight-management/weight-loss-surgery/Pages/roux-en-y-bypass

Pilone, V., Vitiello, A., Monda, A., Giglio, F., & Forestieri, P. (2016). Laparoscopic Adjustable Gastric Banding (LAGB) Plus Anterior Fundoplication Versus LAGB Alone: A Prospective Comparative Study. *Surg Laparosc Endosc Percutan Tech, 26*(3), 216-220. doi:10.1097/sle.0000000000000275

Pourhoseingholi, M. A., Baghestani, A. R., & Vahedi, M. (2012). How to control confounding effects by statistical analysis. *Gastroenterology and Hepatology From Bed to Bench, 5*(2), 79-83.

Riverside Surgical Weight Loss. (2017). Biliopancreatic Diversion With Duodenal Switch (Traditional). Retrieved from http://www.riversidesurgicalweightloss.com/biliopancreatic-diversion-duodenal-switch

Shah, M., Adams-Huet, B., Rao, S., Snell, P., Quittner, C., & Garg, A. (2013). The Effect of Dietary Counseling on Nutrient Intakes in Gastric Banding Surgery Patients. *Journal of investigative medicine : the official publication of the American Federation for Clinical Research, 61*(8), 1165-1172. doi:10.231/JIM.0000000000000002

Smith, S. C., Jr. (2007). Multiple risk factors for cardiovascular disease and diabetes mellitus. *Am J Med, 120*(3 Suppl 1), S3-s11. doi:10.1016/j.amjmed.2007.01.002

Stroh, C., Weiner, R., Wolff, S., Knoll, C., & Manger, T. (2014). Influences of gender on complication rate and outcome after Roux-en-Y gastric bypass: data analysis of more than 10,000 operations from the German Bariatric Surgery Registry. *Obes Surg, 24*(10), 1625-1633. doi:10.1007/s11695-014-1252-8

The Pancreatic Cancer Action Network. (2018). Pancreatic Enzymes. Retrieved from https://www.pancan.org/facing-pancreatic-cancer/living-with-pancreatic-cancer/diet-and-nutrition/pancreatic-enzymes/

Tremmel, M., Gerdtham, U.-G., Nilsson, P. M., & Saha, S. (2017). Economic Burden of Obesity: A Systematic Literature Review. *International Journal of Environmental Research and Public Health, 14*(4), 435. doi:10.3390/ijerph14040435

Valletta, E., Fornaro, M., Cipolli, M., Conte, S., Bissolo, F., & Danchielli, C. (2010). Celiac disease and obesity: need for nutritional follow-up after diagnosis. *Eur J Clin Nutr, 64*(11), 1371-1372. doi:10.1038/ejcn.2010.161

World Health Organization. (2000). Obesity: preventing and managing the global epidemic. Report of a WHO consultation. *World Health Organ Tech Rep Ser, 894*, i-xii, 1-253.

World Health Organization. (2017a). Health Topics. Obesity. Retrieved from http://www.who.int/topics/obesity/en/

World Health Organization. (2017b). Obesity and overweight. Fact sheet. Retrieved from http://www.who.int/mediacentre/factsheets/fs311/en/.

World Health Organization. (2018). Obesity and overweight. Retrieved from http://www.who.int/mediacentre/factsheets/fs311/en/

Wrzesinski, A., CorrÊA, J. M., Fernandes, T. M. B., Monteiro, L. F., Trevisol, F. S., & do Nascimento, R. R. (2015). COMPLICATIONS REQUIRING HOSPITAL MANAGEMENT AFTER BARIATRIC SURGERY. *Arquivos Brasileiros de Cirurgia Digestiva : ABCD, 28*(Suppl 1), 03-06. doi:10.1590/S0102-6720201500S100003

Appendix A

EMORY UNIVERSITY

Institutional Review Board

March 12, 2018

RE: Determination: No IRB Review Required
Title: *Impact of Pre-Op Counseling on Bariatric Adults*
PI: Ozodimma Yvonne Nwankwo

Dear Ozodimma Yvonne Nwankwo,

Thank you for requesting a determination from our office about the above-referenced project. Based on our review of the materials you provided, we have determined that it does not require IRB review because it does not meet the definition of research with" human subjects" as set forth in Emory policies and procedures and federal rules, if applicable. Specifically, this study there is no plan to seek identifiers, privacy will be protected, and the study team intend to generalize the finding.

Please note that this determination does not mean that you cannot publish the results. This determination could be affected by substantive changes in the study design, subject populations, or identifiability of data. If the project changes in any substantive way, please contact our office for clarification.

Thank you for consulting the IRB.

Sincerely,

Clarissa Dupree

Clarissa Dupree, BS
IRB Analyst Assistant

Emory University
1599 Clifton Road, 5th Floor - Atlanta, Georgia 30322
Tel: 404.712.0720 - Fax: 404.727.1358 - Email: irb@emory.edu - Web: http://www.irb.emory.edu