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# Preoperative Predictors for 30-day Postoperative Emergency Department Visit After a Bariatric Surgery

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# PREOPERATIVE PREDICTORS FOR 30-DAY POSTOPERATIVE EMERGENCY DEPARTMENT VISIT AFTER A BARIATRIC SURGERY

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**ABSTRACT**

One of US hospitals' widely used critical performance or quality outcome measures is the 30-day emergency department (ED) visit after a surgical procedure. Such ED visits add millions of dollars each year as a cost burden to US healthcare. This study aimed to identify key predictors known before the patient's surgery, contributing to undesirable ED visits within 30 days of a bariatric surgical procedure. The study was conducted in three phases. The first phase of the study engaged a panel of experts to narrow down important preoperative factors for patients undergoing bariatric surgery in the form of a Delphi study. The second phase of the study included quantitative data analysis, which utilized the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program Participant Use Data File of the year 2019 to identify statistically significant preoperative factors that can contribute to the likelihood of patients returning to the emergency department within 30 days of bariatric surgery. There were N = 193,774 cases with complete information from 868 MBSAQIP-accredited bariatric surgery centers across the United States in the Data File among which 15,533 (8% of the total cases) visited an ED without needing admission as inpatients. The analysis also examined the feasibility of developing a predictive model with only statistically significant factors and checking if the model has an acceptable fit. The third phase of the study reengaged the same panel of experts from the first phase to validate the findings from the second phase and to document the subject matter experts' perception regarding the model developed and the overall findings.

Out of 33 preoperative variables, only 9 variables were selected in the first phase of the study

with the help of a panel of experts. Out of the 9 chosen variables, 8 variables, i.e., Pre-Op GERD requiring medication, Number of Hypertensive Medications, Pre-Op BMI closest to bariatric surgery, Highest Recorded Pre-Op BMI, Pre-Op vein thrombosis requiring therapy, Pre-Op diabetes mellitus, Pre-Op history of COPD, and Pre-Op Steroid/Immunosuppressant Use for Chronic Condition significantly contributed to the likelihood of patients coming back to ED within 30 days of bariatric surgery. The study's second phase also yielded a predictive model using only the statistically significant and weighted variables, and each predictor exhibited statistical significance. In the third phase, a panel of experts weighed in mostly with positive feedback deeming the study clinically and operationally valuable for the bariatric patient population. The practical implication of this study is that the MBSAQIP Centers can use the model to determine the probability of a patient's likelihood of returning to ED after a bariatric surgical procedure. Based on the set criteria, if the patient has a higher chance of returning to ED, the care team can take interventions during and in the first few days or weeks of the discharge to prevent potential postoperative ED visits within 30 days of bariatric surgery.

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I want to take this opportunity to thank my parents for the beautiful childhood they gave me, where I experienced and learned the value of education in the early stages of my life. I am a big proponent of continuous learning. I will continue to learn and contribute to the field of my study; however, this milestone means a lot to me in terms of learning opportunities and growth. What I have learned through this rigorous Ph.D. journey is priceless and will stay with me for the rest of my life. Thank you to my wonderful wife, Sapana, and my beautiful children, Rose, and Aditya, who were always there next to me. Thank you, my brothers, Suman and Krishna, for always inspiring and supporting me.

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# CHAPTER 1

## INTRODUCTION

The healthcare sector is an industry that touches the lives of most, if not all, human beings living in modern society. Healthcare is an essential component of human civilization, from the birth of a child to managing care toward the end of life. The healthcare industry is an integral part of today's society that helps build hope and social connectedness, and a well-trained, technologically driven healthcare workforce is essential for the community. Despite healthcare services being necessary to human existence and their tremendous contributions to modern society, it is an industry criticized for its high cost, difficulty navigating various processes and systems within the healthcare setting, and access to care issues. Currently, the healthcare sector stands at just over $9 trillion and is the second largest industry globally. It consumes approximately 10% of a country's gross domestic product (GDP). This industry is slow in its ability to replenish itself, transform, innovate, and become efficient in its systems and processes (Britnell, 2019a). In the USA, healthcare expenditure and various laws associated with healthcare reform have been a topic of constant debate, especially over the last few decades or so. The healthcare industry expects to see a rise in jobs, healthcare goods, and services in the next 10 to 20 years, and more patients wish to seek care in the coming years. According to the Healthcare occupations: Occupational outlook handbook (2021), healthcare occupations are expected to grow by 16% from 2020 to 2030, adding approximately 2.6 million new jobs in the

US job market. The healthcare system, with issues such as access, cost, workforce shortages, and deaths due to errors, makes it an excellent candidate to test novel ideas that will help the healthcare sector transform in many aspects. As Britnell (2019b) states, unfortunately, neither developed nor developing countries do an excellent job of ideally managing their healthcare workforce and workforce needs, and it is a global issue. In the context of operational and quality outcomes in the healthcare sector, undesired operational efficiencies and poor-quality metrics contribute to its reactive approach to solving operational and quality problems.

This research study addresses the quality concern for a specific case and patient population undergoing bariatric surgery. This study focuses on identifying preoperative factors that contribute to the undesired quality and operational outcomes, i.e., emergency department (ED) visits within 30 days of a bariatric surgery procedure that did not result in an inpatient admission. Understanding predictors of this undesirable outcome can help reduce cost and patient safety at Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accredited bariatric centers and bariatric centers without MBSAQIP accreditation. It can also help generalize the findings for a broader audience to help reduce similar opportunities in their health systems by being proactive and taking early interventions to help reduce the overall 30-day ED visits after bariatric surgery.

## Statement of the Problem

For decades, medical errors have continued to be a significant cause of death in the United States and worldwide. Medical errors cost approximately $20 billion a year in the US alone, and most medical errors typically include surgical, diagnostic, medication, devices, equipment, falls, healthcare technology, and system failures (Rodziewicz et al., 2021). Many of these errors repeat because of the lack of hospital systems' ability to establish sustainable systems that prevent the reoccurrence of similar events. Information systems, electronic health record (EHR) systems, and advancements in technologies have helped healthcare processes and procedures to be better in the present time than in the past; however, many small, independent, and community-based hospitals are unable to afford expensive systems and technologies (Anderson & Abrahamson, 2017). In terms of quality, medical error is a type of defect that should not be repeated. Due to the fear of reprisal, learning from medical errors is not widely shared, so they occur more than once (Health Quality and Medical Errors, 2002). The OECD stands for Organization for Economic Co-operation and Development, which brings together more than 100 member countries across the globe to help drive and anchor healthcare reform and build collective wisdom and shared values. The US currently spends approximately twice as much as the average OECD nation as a share of the economy (Our global reach, 2020). Additionally, compared to developed countries such as Canada, Australia, and the UK, the US has the highest number of hospitalizations from preventable causes and the highest rate of avoidable deaths (Tikkanen & Abrams, 2020a). Disjoined and lack of proper care coordination has been a massive opportunity for a long time in the US healthcare system. Recent studies suggest an enormous prospect to improve care immediately after a patient is discharged after a surgical procedure (Kocher et al., 2013a). An unplanned ED visit within 30 days of a postoperative period is considered vulnerable to patients. If an ED visit occurs, it could mean a high risk for patients and a higher cost burden to the healthcare system. Unfortunately, unplanned ED visits after a surgical procedure are common and costly in the US, with an estimated $12 to $17 billion lost opportunity annually for government-insured patients (Nasser et al., 2018a). In 2019, approximately 34.1% of the US population had insurance through some public plan, which means that the total cost to US healthcare due to unplanned ED visits after a surgical procedure could be a lot more if private insurance plans (approximately 68.0%) and uninsured (8% of the total population) were also counted (Keisler-Starkey & Bunch, 2020).

Although the US has the highest number of hospitalizations from avoidable causes and the highest number of preventable deaths, the US is leading its peer nations in preventable measures. The US has one of the highest rates of breast cancer screening among women between the age groups of 50 and 69 and the second-highest rate (after the United Kingdom) of flu vaccinations among the age group of 65 and older (Tikkanen & Abrams, 2020b). All problems cannot be solved simultaneously, but preventing an undesirable quality or operational outcome from happening or an ED visit from occurring can save a considerable cost burden on the US healthcare system and save the patients' lives. This research study builds upon the proactive approach in preventing an undesirable event for patients after surgery, i.e., preventing an ED visit within 30 days of a bariatric surgical procedure.

There is no current study emphasizing only the preoperative factors selected in this study that significantly contribute to the likelihood of patients returning to the ED within 30 days of bariatric surgery.

## Statement of the Purpose

This research study aimed to proactively understand and help manage healthcare outcomes, essential quality, and operational metrics for patients undergoing bariatric surgical procedures in the US. The study sought to understand preoperative factors contributing to the problem of interest, i.e., an ED visit within 30 days of a bariatric surgical procedure that did not result in an inpatient admission, narrowing down of vital few factors that significantly contribute to the problem statement, development of a predictive model that can predict the likelihood of a patient returning to the ED within 30 days of the procedure, and through direct engagement of subject matter experts, documentation of findings, and learning from the study. For patients going through the bariatric surgical procedure in the future, the same or similar model can help clinical and operational teams identify patients with a higher probability of going back to the ED after the surgical procedure. Based on the predicted outcome, the development of individualized interventions can proactively help patients avoid unnecessary ED visits.

This study contributes to what already existed in the literature regarding factors associated with the opportunity to prevent or minimize unnecessary 30-day postoperative ED visits for bariatric patients. A list of predictors significantly contributing to the 30-day postoperative ED visits for bariatric patients was gathered from the literature. Preoperative factors that have not been previously explored were the focus of this research. The novelty of this study is the development of a novel predictive model through a combined set of previously unexplored preoperative factors that significantly contribute to the likelihood of patients returning to the ED after a bariatric surgical procedure. This newly developed and validated model represents the relationship between independent and dependent variables to predict future events. This finding is expected to help researchers in this field to understand further how combining factors that can be known before bariatric surgery (i.e., preoperative factors) can help understand, manage, and minimize undesirable 30-day postoperative ED visits in the bariatric centers throughout the US

## Statement of the Need

The American Society for Metabolic and Bariatric Surgery (ASMBS) shows a continued rise in the number of bariatric surgical procedures performed between 2011 and 2018 across each type of procedure from 158,000 to 252,000, which is an increase of approximately 60% (Estimate of Bariatric Surgery Numbers 2011-2019, 2021a). It is one of the most underutilized treatments in the US because it is an elective surgery due to barriers to access, including insurance coverage, economic conditions, and other factors. In 2017, the number of patients who underwent a bariatric procedure in the US was 228,000, approximately 1 percent of the population eligible for bariatric surgery. According to the Centers for Disease Control and Prevention (CDC), nearly 30.8% of the adults in the US had obesity in 2015-2016, and no state had a prevalence of obesity under 20%, which is alarming (Hamilton, 2018). A recent study shows that close to half of the US population will have obesity by 2030, and this number is disturbing (Ward et al., 2019), which means that more patients will be eligible to have bariatric surgery performed in the US in the coming years.

This study is a need of time to help set the foundation in understanding the preoperative factors contributing to the problem statement that has potential to save lives and cost of care to both patients and healthcare providers in the short term and the long run, i.e., in the future when patients performing bariatrics surgical procedure in the US will be a lot more than in present time. Suppose a model with a unique set of preoperative factors can predict patients with higher chances of returning to ED within 30 days of bariatric surgery. In that case, attention can be given by the providers and care team to such patients to avoid their ED visits.

## Research Questions and Hypotheses

The research questions and hypotheses for this research study are listed below.

RQ1: What are important preoperative factors that may contribute to the likelihood that patients will have an ED visit within 30 days of bariatric surgery?

RQ2: What factors significantly contribute to the likelihood that patients will have an ED visit within 30 days of bariatric surgery?

RQ3: Can a model be developed using only the statistically significant and weighted predictors? Can it have an acceptable fit?

Research hypothesis was set up to support answers for RQ3:

Ho: Slope or regression value for each predictor equals zero, i.e.,$\beta_i = 0$ , $where\ i = 1\ to\ n.$

$H_a$: At least the slope or regression value for one predictor is not equal to zero, i.e.,$\beta_i \neq 0, for\ at\ least\ one\ i.$

RQ4: What are the subject matter experts' perceptions regarding the model developed and overall findings?

## Statement of Assumptions

This study assumes that bariatric surgical procedures will grow in the next several years, and an ED visit within 30 days of a bariatric surgical procedure continues to be an opportunity. Another underlying assumption is that the SMEs who work directly with this patient population, i.e., Bariatric Surgeon, Advanced Practice Provider, two Registered Nurses, and Metabolic & Bariatric Surgery Clinical Reviewer, have provided their candid feedback during the virtual focused group sessions or meetings. The data used for the quantitative analysis came directly from the MBSAQIP PUF database, which is the source of truth. These data are collected from 850+ centers throughout the US. The assumption here is that this information is accurate and without errors. Another assumption is that the features of the database used (rows, columns, definitions, labels, etc.) for the MBSAQIP database will not change drastically in the future, although some improvements are probable. In other words, the results of this study will be generalized for future patients undergoing bariatric surgery at one of the MBSAQIP centers if the database features do not change considerably. The assumptions for statistical tests and data inclusion and exclusion criteria are elaborated under the Methodology section.

## Statement of Limitations

This research study is limited to a specific patient population, i.e., patients going through a bariatric surgical procedure at MBSAQIP accredited centers in the USA. The results are applicable for future patients going through the same surgical procedure at one of the MBSAQIP accredited centers. The findings from this study can be used and applied with some modifications for the entire bariatric patient population if the data are readily available and the model is revised based on refreshed information. If a similar process is used, a similar prediction is possible for patients undergoing other surgical procedures.

Another limitation is that the experts for the Delphi study were selected from only one of the MBSAQIP accredited centers in the USA, including five subject matter experts: Bariatric Surgeon, Advanced Practice Provider, two Registered Nurses, and Metabolic & Bariatric Surgery Clinical Reviewer. Since this work utilized the data available in the MBSAQIP PUF database for the entire nation, selecting the panel experts from only one center may or may not limit the implications of this study. Arguably, a panel of experts with a larger sample size (>5) could yield a different consensus of the qualitative findings of this study.

## Statement of Terminologies

### Bariatric Surgery

Bariatric surgery is a surgical procedure that helps patients lose weight by making changes to the digestive system. There are different procedures to make the changes, such as making the stomach smaller, making changes to the small intestines, etc. Bariatric surgery may be an option for patients if they have severe obesity and have not been able to lose weight using other methods, such as lifestyle changes and medical treatments. (Definition and facts for bariatric surgery, 2016).

## Preoperative

According to Merriam-Webster (2021), preoperative surgery is defined as “having not yet undergone a surgical operation.”

## Postoperative

Cambridge Dictionary (2021) defines postoperative as “relating to the period of time that immediately follows a medical operation.”

## Emergency Department Visit

When a patient visits an emergency department to receive immediate medical care, it is termed an emergency department visit. Emergency department visits are also considered visits that result in admission versus visits that do not result in admission.

## Hospital Readmission

When a patient visits an emergency department following a discharge from the hospital and is admitted within 30 days of discharge, it is termed “Hospital readmission within 30 days of discharge”. Similarly, if a patient is admitted within 30 days of a surgical procedure, it is termed “Hospital readmission within 30 days of a surgical procedure”. Both metrics have a high significance in the healthcare sector. The Hospital Readmissions Reduction Program (2020) highlights the Hospital Readmission Reduction Program (HRRP) and its linkage of payment to the quality of hospital care. In simple terms, hospitals with a higher rate of readmissions are penalized for reimbursed payments, and hospitals with lower or no hospital readmissions are incentivized.

## Medical Error

Grober and Bohnen (2005) define a medical error as “an act of omission or commission in planning or execution that contributes or could contribute to an unintended result.” If an error happens intentionally or unintentionally that results in an undesired outcome to the patient during a patient’s treatment; it can be termed medical error.

**Electronic Health Record (EHR)**

Patient charts where the patient's medical history, diagnosis, and other relevant information are stored in a digital version are called electronic health records (EHRs) (What is an electronic health record (EHR)?, 2019).

**Obesity**

Defining adult overweight and obesity (2021) states if a person has a body mass index (BMI) of 30.0 or greater, he or she falls within the obesity range. High BMI means high body fatness.

**Advanced Practice Provider (APP)**

An Advanced Practice Provider is a medical professional who has gone through advanced training in medical care. Physician assistants (PA), nurse practitioners (NP), and clinical nurse specialists (CNSs) are some examples of Advanced Practice Providers (Advanced practice providers — who they are & what they do, 2019).

**Dependent and Independent Variables**

EMERG_VISIT_OUT: If the patient was seen in any ED within 30 days of bariatric surgery, which did not result in an inpatient admission, it was reported as 'Yes'; otherwise, it was reported as a 'No'. This variable is the study's dependent variable, which has a dichotomous outcome.

GERD: GERD is a short form of Gastroesophageal Reflex Disease, a condition where stomach acid frequently flows back into the tube that connects the patient's esophagus and mouth (Overview, 2020). This is the first independent variable in the study, a categorical variable with labels' Yes' or 'No'. If the patient takes medication for this disease within 30 days before surgery, this variable is reported as 'Yes'; otherwise, it is written as 'No'.

HTN_MEDS: This is the second independent variable in the study, representing the number of hypertensive medications the patient is taking before the surgery. It is also a categorical variable with four labels: 0, 1, 2, and more than 3.

BMI: The third independent variable in the study is BMI, a short form for Body Mass Index. This value is a continuous variable between 15 to 150 for the dataset used. BMI is calculated using a patient's weight in kilograms divided by the square of their height in meters (Body Mass Index (BMI), 2021). This value is calculated from preoperative weight and height closest to the surgery for the specific dataset used.

BMI_HIGH_BAR: The fourth independent variable BMI_HIGH_BAR is a continuous variable, mainly like the third variable, BMI, except this BMI uses the highest recorded preoperative weight.

HISTORY_DVT: The fifth independent variable in the study is a categorical variable that represents if the patient had a history of vein thrombosis before the surgery and has labeled 'Yes' or 'No'.

DIABETES: The sixth independent variable in the study reported that DIABETES reports a patient's history of diabetes mellitus requiring medication or therapy. It has three labels or categories, i.e., 'Non-Insulin', 'Insulin,' and 'No'.

FUNSTAT PRESURG: The seventh independent and categorical variable in the study represents the patient's preoperative functional health status and has four labels: Independent, Partially Dependent, Totally Dependent, and Unknown. Skube et al. (2018) define functional health status as a patient's ability to do daily activities to meet basic needs, accomplish usual roles, and maintain their well-being.

COPD: The eighth independent variable in the study is a categorical variable, COPD, which stands for Chronic Obstructive Pulmonary Disease. It has two labels, Yes and No. If the patient has a history of severe COPD, it is reported as a 'Yes'; otherwise, it is reported as a 'No'.

CHRONIC_STEROIDS: The ninth and last independent variable in the study is the CHRONIC_STEROIDS, a categorical variable with a 'Yes' or 'No' label. If the patient is using a steroid or immunosuppressant for some chronic condition, the value is 'Yes'; otherwise, it is reported as a 'No'.

# CHAPTER 2

## LITERATURE REVIEW

A thorough understanding and review of the current literature are integral to a thriving research study. In the field of medical education and research, researchers point out that a literature review can help researchers form the basis of high-quality research, help maximize significance, add to originality, and assist with understanding the actual gap in the existing literature related to the topic of study (Maggio et al., 2016). This chapter is divided into four main segments: History of Quality in US Healthcare, Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program, Trends in Obesity and Bariatrics Surgical Procedures, and Postoperative ED Visit for Bariatric Patients: A Systematic Review of Literature. The first part, History of Quality in US Healthcare, is a synopsis of how quality has evolved since medieval guilds to the present day. It attempts to understand the proper use of quality in the US healthcare sector, leading to the formation of accreditation entities in quality and programs with some form of oversight from the US government. The second part, the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program, provides the history of the American College of Surgeons and the efforts by this organization that has led to a streamlined and standardized accreditation program for bariatric patients, with quality being an essential part of various processes and the overall program. The third part, Trends in Obesity and Bariatrics Surgical Procedures, highlight the trends in obesity in the US and how it is expected to skyrocket in the upcoming years. This section also provides evidence of why this topic is essential for healthcare enthusiasts, researchers, and students in the healthcare quality and medical field. The last part of the chapter, Postoperative ED Visit for Bariatric Patients: A Systematic Review, provides a systematic and in-depth review of the literature published in this field and highlights critical gaps in the current literature based on the criteria used to conduct the systematic literature review.

## History of Quality in US Healthcare

History of quality – quality management history (2021) provides an overview of the history of quality that dates to medieval guilds of Europe in the late 13th century. Through the 19th century, manufacturing in the industrialized world practiced craftsmanship, mainly focused on customer needs and retention. The Industrial Revolution in Europe in the 19th century morphed the artisans into foundational quality techniques such as inspections and audits. The United States made a stride in the factory system with Frederick W. Taylor's system that helped establish a new management approach to increase productivity without increasing skilled artisans. This new management approach succeeded by assigning and dividing specific tasks and functions by expertise, i.e., specialized engineers were involved in factory planning, inspectors and supervisors were involved in inspecting and supervising the work and products produced, and managers managed and operationalized overall improvements. Taylor's management system helped US manufacturers increase productivity, but unfortunately, it negatively impacted quality. Management created inspection departments to address quality issues and catch defective parts before reaching the customers. This is where formal quality improvement practice came into life in the US manufacturing sector, which mostly involved inspecting and catching defective products before they reached customers. The next time quality made a stride in the US was during World War II, when military equipment and ammunition were required to be reliable. Inspecting products was still an essential quality function; however, as an increasing amount of military equipment and ammunition were needed, inspecting every product was impossible, giving birth to various sampling techniques. The creation of different military standards for suppliers who supplied military equipment and products to the US military resulted in improved quality. At approximately the same time, William Shewhart's statistical process control (SPC) techniques immensely helped monitor and control various processes involved during wartime. Soon after World War II, war-torn Japanese manufacturers invited W. Edwards Deming and Joseph M. Juran to help bring Japanese manufacturing to life. During World War II, Deming openly criticized the US management structure and the diminishing use of widely used statistical quality control techniques. On the other hand, after seeing Japanese manufacturers' enthusiasm for quality improvement, Juran predicted that the quality of goods produced by Japanese manufacturers would overtake the quality of goods produced in the US by the mid-1970s, which turned out to be true. Mclnnis (2014) outlines why US manufacturers did not like Deming and his teachings. Deming particularly criticized the widely accepted quality norm, i.e., inspecting products after they were manufactured. He also criticized upper-level management and their style of managing quality and company. US manufacturers such as Ford Motor Co., Xerox Corp., AT&T Inc., New York Times, etc., hired Deming in his 80s. Still, by then, US manufacturing was suffering a trade deficit, and many manufacturing firms were closed or closed because Japanese products had taken over the American economy.

Sheingold and Hahn (2014) point out that quality and quality improvement in healthcare dates to a few centuries. It is assumed that those events were unrelated rather than an organized effort. The author documents Florence Nightingale's quality improvement efforts in England in

1854, which includes her action in reducing overcrowded beds, provision of ventilation, measures to prevent infections to the patients, etc. The establishment of the Sanitary Commission in 1861 in the USA during the American Civil War can be considered one of the critical tipping points in healthcare quality improvement in the US. Few other critical developments in the field of healthcare around the world that contributed to improved and advanced healthcare in the US were the development of sterilization in Germany in 1879, the development of various technologies such as X-ray in Germany in 1895, and progress in the medical education system in the US in the early 1900s. Advancements in pharmaceuticals (development of vaccines such as anthrax in 1885, diphtheria in 1891, tetanus in 1924, polio in 1955, etc.) and healthcare financing also helped shape healthcare quality worldwide, especially in the western world. Hines et al. (2020) give credit to Abraham Flexner as one of the key contributors in the United States' effort to improve quality in healthcare. His report on poor and unorganized hospitals and medical school systems forced US healthcare to restructure medical education in the US, resulting in the closure or merging of more than half of the country's medical schools.

The US Congress established Medicare and Medicaid programs as Title XVIII and Title XIX of the Social Security Act in 1965. This creation resulted from an inadequate welfare medical program that qualified for public assistance. As part of the requirements for hospitals to allow to treat the patients covered by Medicare and Medicaid programs, a list of conditions of participation was prepared, which included staff credentials, 24-hour nursing services, and utilization review requirements. The formation of Utilization Review Committees effectively monitored the efficacy of the services provided by the hospitals. Still, it did not take long to realize the complexity and difficulty of managing the assessment, reviews, and monitoring process. In 1972, due to the ineffectiveness of Utilization Review Committees, pilot experimental review organizations were formed and were given the responsibility of reviewing healthcare delivery in inpatient (hospitals) and outpatient (clinics) settings and assessing the quality and appropriateness of care delivered to the patients. Unlike previous Utilization Review Committees, these pilot organizations successfully developed projects and models that connected the findings of the quality review process with appropriate improvement strategies. These findings became the foundation for Medicare's Professional Standards Review Organizations (PSROs), established soon after the success of this experiment. The goal of the PSROs was to ensure that hospitals and physicians met the requirements set by the government to provide high-quality care, which included but was not limited to avoidance of unnecessary overuse, inappropriate misuse, and nonindicated underuse of services. Unfortunately, by the 1980s, PSROs were also considered unsuccessful in improving quality and containing costs and were questioned regarding their prioritization of cost over quality. In 1983, the utilization and quality control of peer review organizations (PROs) replaced PSROs. In 1951, a nonprofit organization, now known as The Joint Commission, was established to provide voluntary accreditation of hospitals based on a rubric of defined minimum quality standards. Soon after, a prominent physician leader, Dr. Avedis Donabedian, suggested an effective and transformative model in healthcare quality that relied on the elements of structure, process, and outcomes to examine the quality of care delivered in 1966. The National Academics of Science established the Institute of Medicine (IOM) in 1970. Since its establishment, IOM has launched many concerted efforts focused on evaluating, informing, and improving healthcare quality. Similarly, the now known Agency for Healthcare Research and Quality (AHRQ) was created in 1989, which initially replaced the National Center for Health Services Research to address geographic variations in practice patterns. In 1990, the National Committee for Quality Assurance (NCQA) was established to improve healthcare quality, a nonprofit organization managing accreditation programs for individual physicians, health plans, and medical groups. It measures accreditation efficacy through the administration and submission of the Healthcare Effectiveness Data and Information Set (HEDIS) and the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey (Marjoua & Bozic, 2012).

As Evans and Lindsay (2012) state, quality can be confusing because many people view quality as a subjective term. Depending on the industry, situation, and criteria, quality may mean a different thing for different people. For example, a study surveyed managers from 86 firms in the eastern US to ask what quality meant to them. The response included several other things, such as perfection, consistency, eliminating waste, speed of delivery, compliance with policies and procedures, providing a usable product, doing it right the first time, delighting customers, customer satisfaction, etc. In healthcare, it is evident that the history of quality and quality improvement efforts has revolved chiefly around meeting regulatory requirements, quality improvement programs, and accreditation standards in the USA. These programs are at a city, state, and federal level for hospital and clinic operations, the service level (outpatient, inpatient, surgery, laboratory, etc.), and even the type of patient population. For example:

- The Joint Commission (TJC) 's accreditation areas include hospitals, home health care, long-term care, behavioral healthcare, clinical laboratories, ambulatory care, health networks, etc. (Viswanathan & Salmon, 2000).
- The Center for Improvement in Healthcare Quality (CIHQ) accreditation areas include acute care hospitals, free-standing emergency centers, congregate living health facilities, and urgent care centers (Welcome to CIHQ, n.d.).

- Accreditation Association for Ambulatory Health Care (AAHC) accreditation areas include ambulatory surgery centers.
- The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) focuses on measuring and improving the quality of surgical care using risk-adjusted clinical data (Participants, n.d.).
- MBSAQIP strives to advance safe and high-quality care for bariatric surgery patients (Bariatric surgery, n.d.).

**Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program**

The American College of Surgeons (ACS) was established in 1913 to improve surgical care and set standards, and the current Joint Commission was a product of the ACS Hospital Standards Committee in 1951. The ACS has accredited trauma programs since the establishment of the Trauma Verification Program in1987. It has also provided accreditation to cancer programs since 1930 through the Commission on Cancer. In 2005, due to increasing demand in the bariatric surgery community, ACS endorsed the first Bariatric Surgery Network (ACS BSCN) accreditation standards manual. In 1983, the American Society for Metabolic and Bariatric Surgery (ASMBS) was instituted to advance the art and science of metabolic and bariatric surgery by sustainably increasing the quality and safety of care for patients with obesity and related diseases. It leveraged education and support programs for surgeons and all health professionals in the care of the patients. In 2004, the ASMBS leadership released a specific set of accreditation standards for Bariatric Surgery Centers of Excellence (BSCOE), making it a second but similar accrediting body for bariatric surgery practice. The goal of both programs was established on the same three principles, i.e., the leadership of practitioners, i.e., surgeons, the certainty for a multidisciplinary team, and reporting of data and outcomes to a national registry.

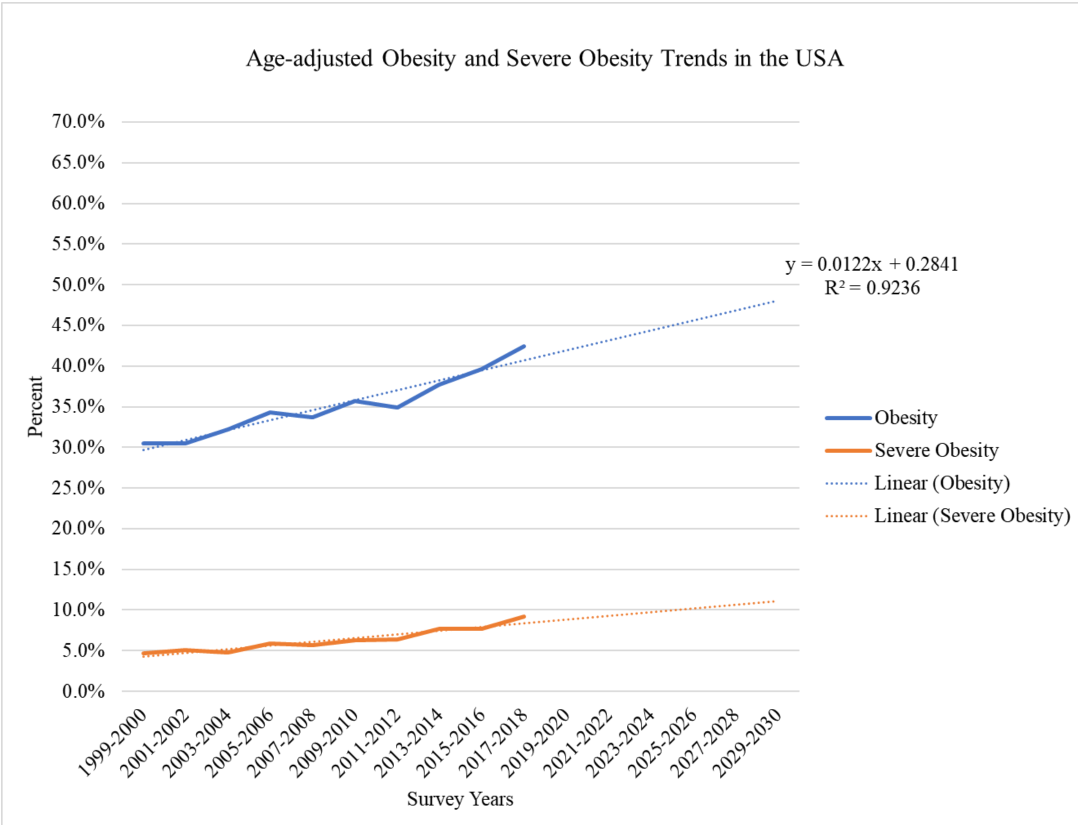
The framework for accreditation standards was established regarding procedure volume and many other factors (processes, metrics, etc.). For example, the introduction of laparoscopy led to a significant impact in increased laparoscopy procedures from 2.1% in 1998 to more than 90% in 2008 and including the gastric band metric in the data set (less 30-day mortality and morbidity), which can be credited to the adoption of accreditation standards, helped decrease the mortality rate from 0.5% (1 in 200 patients) to 0.06% (1/1750 patients). Recent studies have also shown positive results in implementing bariatric accreditation programs. Most patients choose to have their bariatric surgeries in accredited centers because most payers endorse and prefer that their patients go to accredited centers. Between 2006 and 2011, the data registries for both accrediting bodies were under development and had more than 100,000 patients per year being entered into one of the two registries. On April 1, 2012, ACS BSCN and ASMBS BSCOE were combined to become the MBSAQIP. ACS manages the new, streamlined, joint program, and centers now report their metrics through a single data registry (About, n.d.).

## Trends in Obesity and Bariatric Surgical Procedures

A recent study conducted by the National Center for Health Statistics (NCHS), a component of the Centers for Disease Control and Prevention (CDC), revealed an alarming statistic related to obesity in the United States. The findings showed that between 1999-2000 and 2-17-2018, obesity increased from 30.5% to 42.5%, and the prevalence of severe obesity increased from 4.7% to 9.2%. Obesity is not just a disease but is associated with other serious health risks, such as coronary heart disease and end-stage renal disease. If this trend continues in the same trajectory (Figure 1), obesity is expected to impact close to 50% of the US population by 2030, and severe obesity will impact close to 12% of the US population (Hales et al., 2020).

**Figure 1**

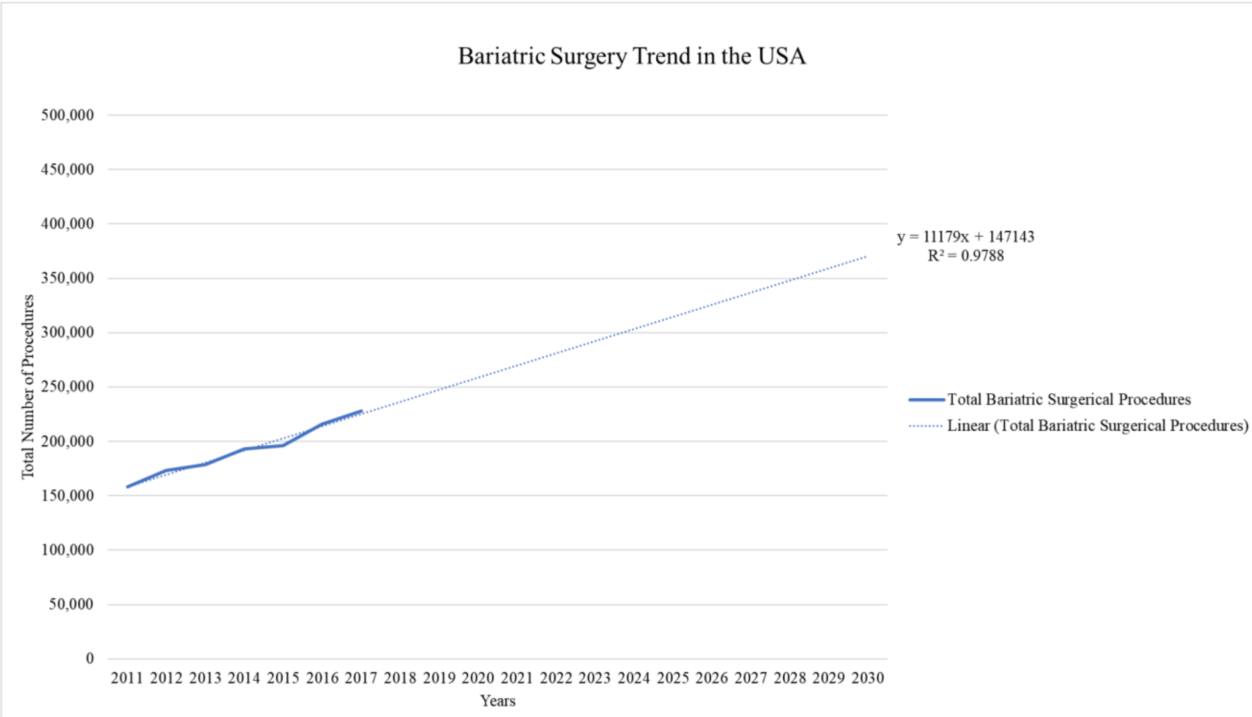
***Obesity and Severe Obesity Trends***




Similarly, as shown in the Estimate of Bariatric Surgery Numbers 2011-2019 (2021b), a trendline was plotted (Figure 2), which showed a strong positive trend in the total number of bariatric surgical procedures performed by MBSAQIP centers in the USA annually. It is also important to note that metabolic and bariatric surgery is considered an effective and durable treatment for obesity; however, it remains highly underused in treating the obesity epidemic in the United States. Based on past studies, approximately 1% of all patients who qualify as candidates for metabolic and bariatric surgery undergo the surgical procedure (English et al., 2020). A study conducted in 2014 reviewed 277,068 bariatric surgeries performed over three years and noted that 11.6% of the cases were performed at nonaccredited centers, which suggests that close to 90% of bariatric surgical procedures are performed at one of the MBSAQIP accredited centers in the US (Gebhart et al., 2014).

**Figure 2**

***Bariatric Surgery Trend in the United States***




## Preoperative and Postoperative factors for the 30-day postoperative ED Visit

Kocher et Al. (2013b) highlight the fact about the US government's sanctioning of hospitals for readmissions within 30 days of discharge in recent years as an appropriate step to guide the integration of the ED into location delivery system planning. The authors also highlight the importance of coordinated care between various subsystems within the hospital system to help appropriately manage care among ED providers, patient clinic providers, and surgeons, which can help reduce the need for readmission. Hospital readmissions are one of the key measures for the quality of patient care in the US. Various programs, such as the Centers for

Medicare & Medicaid Services Hospital Readmissions Reduction Program (HRRP) and the Partnership for Patients (PfP), reduce preventable hospital readmissions. A report published and summarized by the Agency for Healthcare Research and Quality (AHRQ) shows that government-insured patients had the highest 30-day all-cause readmission rates from 2010 through 2016, and patients covered through private insurance had the lowest 30-day all-cause readmission rates between the same period. The report also noted that the average cost of 30-day all-cause readmission per principal diagnosis was $14,400, with a high of $19,000 for congenital malfunctions and a low of $7,000 for pregnancy/childbirth-related diagnosis (Bailey et al., 2019). It is unfortunate for US healthcare that the rate of ED visits increased from 1996 through 2013. In 2017 alone, 144.8 million ED visits aggregated to a total cost of $76.3 billion. Furthermore, more than 50% of hospital inpatient admissions in 2017 included ED services before admission (Moore & Liang, 2020a). As stated in the previous chapter, unplanned 30-day postoperative ED visits also cost US healthcare billions of dollars annually for government-insured patients alone (Nasser et al., 2018b).

As of 2008, an estimated 50% of the adults in the US were meeting the definition of being overweight, making obesity reach higher epidemic proportions than ever before (Luber et al., 2008a). These statistics support the data showing increased obesity in the coming decades, which will increase the number of obesity-related surgeries. Research has proven multiple times that there are complications associated with obesity-related surgeries (Monkhouse et al., 2009). Luber et al. (2008b) state that the difficulty for emergency physicians in taking care of patients visiting the ED after bariatric surgery has increased over the past few years, and providers are concerned that this is only going to grow. Physicians working in the emergency department should be ready to integrate the complications associated with bariatric surgery into their clinical practice because they should expect to see more postoperative bariatric patients in the future. Researchers provide a futuristic and proactive approach of being ready by acquiring appropriate knowledge of the anatomical operative changes and understanding complications related to bariatric procedure practice at their institution (Ellison & Ellison, 2008). The number of bariatric surgery procedures is increasing worldwide, not just in the US. An international web-based survey was sent out to 197 emergency surgeons to collect data regarding emergency surgeons' experience in the management of patients admitted to the ED for acute abdominal pain (a common cause of ED visits for postoperative bariatric patients) after bariatric surgery. Researchers received an overwhelming response from the participants (59.4% response rate). The theme of the study for emergency surgeons was to be mindful of postoperative bariatric surgery complications and be aware and prepared for the next steps in the treatment process if things do not go as expected to obtain good patient outcomes (De Simone et al., 2020). Sometimes being proactive and educating patients proactively can help reduce avoidable ED visits. El Chaar et al. (2015) found that the use of IV acetaminophen for postoperative pain management showed decreased ED visits within 30 days of a bariatric procedure and realized notable indirect cost savings with good patient safety. Research has consistently shown, as previously mentioned, that the most common chief complaint of these ED visits has been abdominal pain. Stevens et al. (2018a) found a similar theme in the literature as predictors of ED visits for additional reasons such as patient socioeconomic status, functional status, and insurance type.

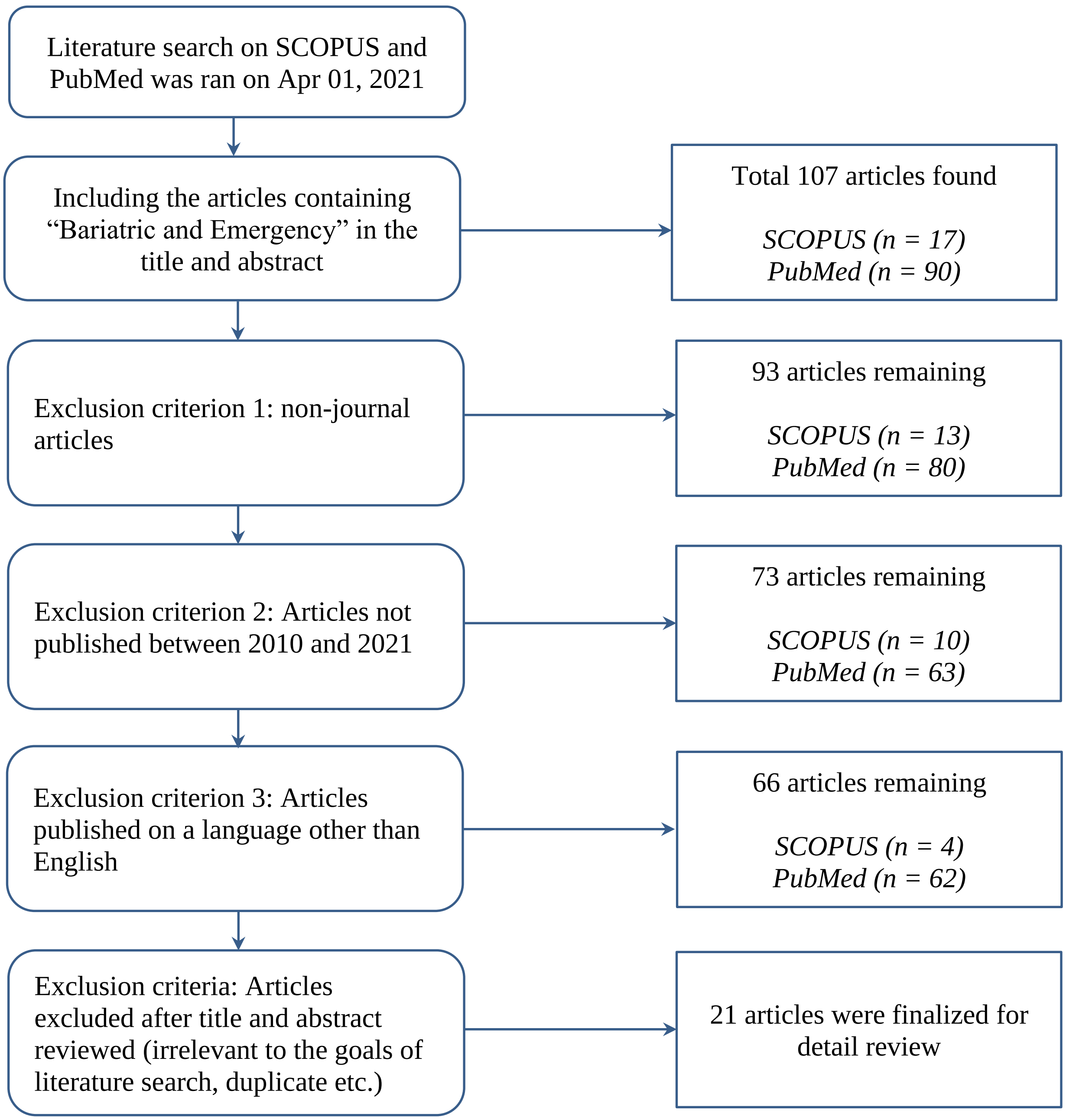
A systematic review of the literature was conducted to summarize the findings from the existing literature on preoperative and postoperative factors that significantly contributed to the likelihood of patients returning to the ED within 30 days after bariatric surgery. Researchers widely use a systematic literature review to help answer key research objectives in their research study. Multiple strategies can be utilized to narrow down articles of interest, including various methodologies, inclusion, and exclusion criteria (Al-Odeh et al., 2021; Guraja, Badar, Moayed & Kluse, 2022). For this research study, the three main goals of the systematic review were to:

- Synthesize the research being conducted in bariatric surgery practice related to the 30-day postoperative ED visit
- Shortlist preoperative factors (predictors) that have been identified as potential and significant predictors of 30-day postoperative ED visits from previous studies
- Outline gaps in the existing body of knowledge on this topic

This systematic review of the literature utilized two significant databases: SCOPUS and PubMed. The same criteria were used to shortlist the articles of interest in both databases. Figure 3 provides the steps and flowchart of this systematic literature review. The initial search was based on the keywords “bariatric” and “emergency” in the title or abstract of the literature, which yielded 107 articles. Next, the exclusion criterion was set not to include articles that were not journal articles narrowed down the articles to 93. Another exclusion criterion was established on the timeline, i.e., articles not published between 2010 and 2021 (year to date as of this writing, i.e., April 01, 2021) were excluded. Data available before 2010 was considered old because of rapid transformation and advancement in bariatric surgery and how data are recorded in the database. This criterion further narrowed the list of articles to a total of 73. Adding another criterion of excluding articles published in languages other than English resulted in 66 articles. These 66 articles were reviewed one by one to see the relevancy of the journal abstract and title to the research being conducted, which helped narrow down relevant articles to 21. The entire content of these 21 remaining articles was reviewed, and the information related to the article title, authors, journal, objective or focus of the publication, factors significantly contributing to postoperative ED visit at 30, 90, 120, 365, and 730+ days, as well as factors that can be available before the surgery, was documented.

**Figure 3**

***Flowchart showing inclusion and exclusion criteria for systematic literature review***



Findings from this systematic review of the literature are summarized in a tabularized form (Table 1) with the key information pertinent to this research study.

**Table 1**

***Summary of Selected Articles from the Literature Review***

| Article title | Authors | Journal | Objective or focus of the article | Factors significantly contributing to (30-day$^{x30}$, 90-day$^{x90}$, 120-day$^{x120}$ 1-year$^{x365}$, 2-year$^{x730+}$, or Unknown-days$^{xu}$) postoperative ED visit | Factors that are available or can be known prior to the surgery |
|---|---|---|---|---|---|
| Emergency Department Care of the PostMetabolic and Bariatric Surgery Patient | (Sacchetti, 2020) | Pediatr Emerg Care | Review of complications associated with bariatric surgery patients and appropriate management of care when patient show up in ED after the surgery | None | None |
| Emergency department management of patients with complications of bariatric surgery | (Ogunniyi, 2019) | Emerg Med Pract. | Overview of potential complications of bariatric procedures and recommendations regarding patient management and disposition in ED | None | None |
| Characterizing the preventable emergency department visit after bariatric surgery | (Khouri et al., 2020) | Surg Obes Relat Dis. | Characterization of patients who present to the ED but could have been treated in an alternative setting | Factors$^{x30}$<br>- Anxiolytic prescription at discharge<br>- Electrolyte abnormalities at discharge<br>- Leukocytosis at discharge<br>- Number of ED visits preoperatively | - Anxiolytic prescription at discharge<br>- Number of ED visits preoperatively |
| Hospitalizations and emergency department visits in heart failure patients after bariatric surgery | (Tsui et al., 2021) | Surg Obes Relat Dis. | To assess the impact of bariatric surgery on hospital-based healthcare utilization for patients with heart failure | None | Not applicable |
| Rates and reasons for emergency department presentations of patients wait- | (Kuzminov et al., 2019a) | Obes Res Clin Pract. | To describe and evaluate public ED presentation rates and reasons for presenting in a cohort | Factors$^{x30}$<br>- Digestive system and psychiatric diseases | - Digestive system and psychiatric diseases |

| Article title | Authors | Journal | Objective or focus of the article | Factors significantly contributing to (30-day$^{x30}$, 90-day$^{x90}$, 120-day$^{x120}$ 1-year$^{x365}$, 2-year$^{x730+}$, or Unknown-days$^{xu}$) postoperative ED visit | Factors that are available or can be known prior to the surgery |
|---|---|---|---|---|---|
| listed for public bariatric surgery in Tasmania, Australia | | | of patients wait-listed for public surgery in Tasmania, Australia | | |
| Predictors of postoperative emergency department visits after laparoscopic bariatric surgery | (Leonard-Murali et al., 2020) | Surg Obes Relat Dis. | To identify predictors of ED visits in patients without readmission after laparoscopic sleeve gastrectomy (LSG) and laparoscopic Roux-en-Y gastric bypass (LRYGB) | Factors$^{x30}$<br>- Outpatient treatment for dehydration<br>- Urinary tract infection<br>- Wound disruption<br>- Surgical site infection | None |
| Unplanned emergency department consultations and readmissions within 30 and 90 days of bariatric surgery | (Iskra et al., 2018) | Cirugía Española | To determine the incidence, causes, and risk factors related to emergency consultations and readmissions within 30 and 90 days in patients undergoing laparoscopic gastric bypass and laparoscopic sleeve gastrectomy | Factors$^{x90}$<br>- Noninfectious problems related to surgical wound<br>- Abdominal pain<br>- Postoperative complications<br>- Reintervention<br>- Associated surgery type<br>- Depression | - Depression |
| Patient perspectives on emergency department self-referral after bariatric surgery | (Stevens et al., 2018b) | Surg Obes Relat Dis. | To understand the circumstances surrounding patient self-referral to the ED after elective, primary bariatric surgery | Factors$^{x30}$<br>- Abdominal pain<br>- Nausea/vomiting | None |
| Emergency department visits and readmissions within 1 year of bariatric surgery: A statewide analysis using hospital discharge records | (Mora-Pinzon et al., 2017) | Surgery | Analysis of emergency department visits and readmissions to all facilities in Wisconsin within 1 year of bariatric surgery and identified their predictors | Factors$^{x365}$<br>- Gender<br>- Procedure type<br>- More than 4 comorbidities<br>- Insurance type<br>- Teaching versus nonteaching hospital<br>- Inpatient complications | - Gender<br>- More than 4 comorbidities<br>- Insurance type<br>- Teaching versus nonteaching hospital |
| Review article: Postoperative bariatric patients in the emergency department: Review of surgical | (Windish & Wong, 2019) | Emerg Med Australas. | Common bariatric procedures being performed and complications, clinical presentations, | None | None |

| Article title | Authors | Journal | Objective or focus of the article | Factors significantly contributing to (30-day$^{x30}$, 90-day$^{x90}$, 120-day$^{x120}$ 1-year$^{x365}$, 2-year$^{x730+}$, or Unknown-days$^{xu}$) postoperative ED visit | Factors that are available or can be known prior to the surgery |
|---|---|---|---|---|---|
| complications for the emergency physician | | | and management of the bariatric patients | | |
| Site-specific Approach to Reducing Emergency Department Visits Following Surgery | (Abdel Khalik et al., 2018) | Annals of Surgery | Efficacy exploration of current bariatric perioperative measures at reducing emergency department (ED) visits following bariatric surgery in the state of Michigan | Factors$^{x30}$<br>- Hospital's rate of sleeve gastrectomies<br>- Hospital's rate of readmissions<br>- Hospital's rate of venous thromboembolism complications | None |
| Effect of Bariatric Surgery on Emergency Department Visits and Hospitalizations for Atrial Fibrillation | (Shimada et al., 2017) | The American Journal of Cardiology | Association of bariatric surgery with an increased risk of Atrial fibrillation episodes requiring an ED visit or hospitalization for at least 2 years after surgery among obese patients with Atrial fibrillation | Factors$^{x365}$<br>- Obese patients with Atrial fibrillation | - Obese patients with Atrial fibrillation |
| Readmissions and Emergency Department Visits after Bariatric Surgery at Saudi Arabian Hospital: The Rates, Reasons, and Risk Factors | (Ahmed et al., 2017) | ObesityFacts | To evaluate the rates and reasons of hospital readmissions and ED visits related to surgical weight loss interventions at the King Abdulaziz Medical City - Riyadh | Factors$^{xu}$<br>- Age<br>- Type of bariatric surgical procedure<br>- Abdominal pain<br>- Nausea/vomiting<br>- Dyslipidemia | - Age<br>- Dyslipidemia |
| Factors associated with bariatric postoperative emergency department visits | (Macht et al., 2016a) | Surg Obes Relat Dis. | To describe the frequency of and risk factors associated with 90-day postoperative ED visits after bariatric surgery | Factors$^{x30}$<br>- Abdominal pain<br>- Dehydration<br>- Nausea/vomiting<br>- Age<br>- Sex<br>- Number of comorbidities<br>- Prior ED visits<br>- Initial length of stay | - Age<br>- Sex<br>- Number of comorbidities<br>- Prior ED visits |
| Bariatric Surgery and Emergency Department Visits and Hospitalizations | (Shimada et al., 2016) | Journal of the American College of Cardiology | Association between bariatric surgery and decreased rate of heart failure exacerbation | Factors$^{x370}$<br>- Rate of heart failure exacerbation | None |

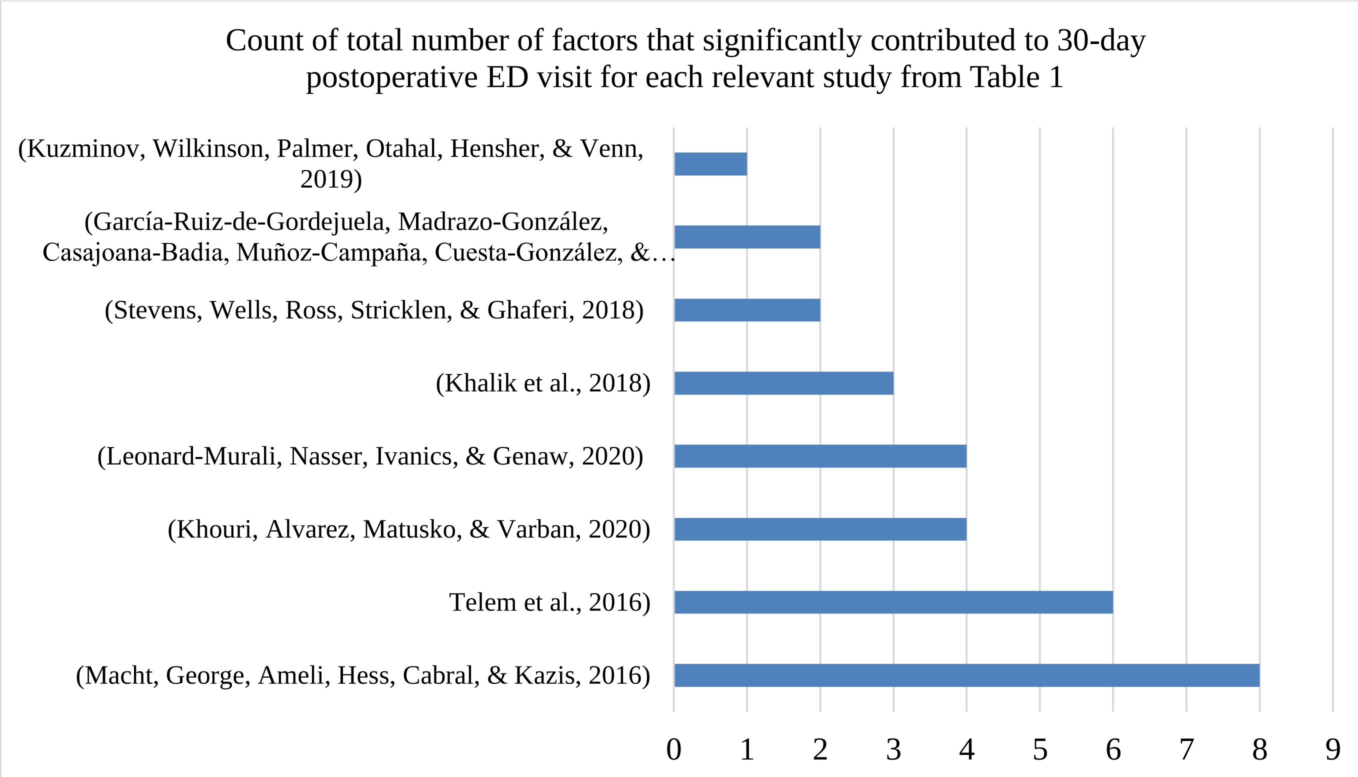
| Article title | Authors | Journal | Objective or focus of the article | Factors significantly contributing to (30-day$^{x30}$, 90-day$^{x90}$, 120-day$^{x120}$ 1-year$^{x365}$, 2-year$^{x730+}$, or Unknown-days$^{xu}$) postoperative ED visit | Factors that are available or can be known prior to the surgery |
|---|---|---|---|---|---|
| for Heart Failure Exacerbation: Population-Based, Self-Controlled Series | | | | | |
| Preventing Returns to the Emergency Department Following Bariatric Surgery | (Chen et al., 2017) | Obesity Surgery | To identify potential strategies aimed at preventing unnecessary returns to the ED following bariatric surgery. The study was conducted in University Hospital, USA | Factors$^{x90}$<br>- Nausea/vomiting<br>- Dehydration<br>- Postoperative pain<br>- Wound evaluations<br>- Compliance issues | None |
| Rates and Risk Factors for Unplanned Emergency Department Utilization and Hospital Readmission Following Bariatric Surgery | (Telem et al., 2016) | Annals of Surgery | To identify unplanned emergency resource utilization in the perioperative period following bariatric surgery | Factors$^{x30}$<br>- Race<br>- Pulmonary disease<br>- Insurance type<br>- Distance for index procedure<br>- Additional surgical procedure other than bariatric surgical procedure<br>- Patients presenting to index versus nonindex hospital | - Race<br>- Pulmonary disease<br>- Insurance type<br>- Distance for index procedure<br>- Patients presenting to index versus nonindex hospital |
| Evaluation of bariatric surgery patients at the emergency department of a tertiary referral hospital | (García-Ruiz-de-Gordejuela et al., 2015) | Rev Esp Enferm Dig. | To describe the profile of the bariatric surgery patients who were admitted to the Emergency Department (ED) | Factors$^{x30}$<br>- Abdominal pain<br>- Surgical wounds | None |
| Development of a bariatric patient readiness assessment tool for the emergency department | (Jones, 2012) | Adv Emerg Nurs J. | To develop an assessment tool to determine ED readiness to safely manage the morbidly obese patient | None | None |
| Emergency Department visits after bariatric surgery | (Gundogdu et al., 2021) | Minerva Surg. | To describe the frequency, and the risk factors associated with postoperative ED visits after BS | Factors$^{xu}$<br>- Abdominal pain | None |

| Article title | Authors | Journal | Objective or focus of the article | Factors significantly contributing to (30-day$^{x30}$, 90-day$^{x90}$, 120-day$^{x120}$ 1-year$^{x365}$, 2-year$^{x730+}$, or Unknown-days$^{xu}$) postoperative ED visit | Factors that are available or can be known prior to the surgery |
|---|---|---|---|---|---|
| Sleeve Gastrectomy: the first 3 Years: evaluation of emergency department visits, readmissions, and reoperations for 14,080 patients in New York State | (Altieri et al., 2018) | Surg Endosc. | To evaluate the indications for and incidence of both emergency department (ED) visits and hospital readmissions within the first postoperative year | Factors$^{x270+}$<br>- Abdominal pain<br>- Vomiting<br>- Dehydration<br>- Syncope | None |
| An approach to the assessment and management of the laparoscopic adjustable gastric band patient in the emergency department | (Freeman et al., 2011) | Emerg Med Australas. | Identification of the present scenario of various complications that can arise postoperatively, and describes an approach to the assessment and management of the laparoscopic adjustable gastric band (LAGB) patients in the ED. | Factors$^{xu}$<br>- Abdominal pain<br>- Vomiting/nausea<br>- Dysphagia | None |

From Table 1, the total number of preoperative factors that significantly contributed to the likelihood of patients returning to the ED within 30 days of bariatric surgery for each study ranged from one (Kuzminov et al., 2019b) to eight (Macht et al., 2016b), with 90% of studies having fewer than eight significant factors, as shown in Figure 4.

**Figure 4**

***Significant factors identified based on previously published article that were within the scope of the study***




Next, preoperative and postoperative factors that significantly contributed to the likelihood of 30-day postoperative ED visits were segmented out from the summarized table of literature search, and similar items were counted once. Figure 5 represents the breakdown of preoperative and postoperative factors that significantly contributed to postoperative ED visits within 30 days of bariatric surgery based on previously published articles, as shown in Table 1. The diagram's top half (preoperative factors) was within the scope of this research study, and the bottom half (postoperative factors) was summarized only as a reference.

**Figure 5**

***Preoperative and Postoperative Factors for 30-day Postoperative ED visits***

**Hospital Related Preoperative Factors**

- Patients presenting to index versus non-index hospital
- Distance for index procedure
- Hospital rate of readmissions
- Hospital rate of sleeve gastrectomies
- Hospital rate of venous thromboembolism complications

**Patient Related Preoperative Factors**

- Demographics: Age, Sex, Insurance Type
- Prior ED visits
- Number of ED visits preoperatively
- Digestive system and psychiatric diseases
- Number of comorbidities
- Pulmonary disease

**Provider/Procedure Related Postoperative Factors**

- Surgical wounds
- Anxiolytic prescription at discharge
- Surgical site infection
- Initial length of stay
- Additional surgical procedure other than bariatric surgical procedure

**Symptoms/Outcome Related Postoperative Factors**

- Dehydration
- Nausea/Vomiting
- Abdominal pain
- Wound disruption
- Electrolyte abnormalities at discharge
- Urinary tract infection
- Outpatient treatment for dehydration

To prevent an undesirable event from happening, one should know the factors contributing to the cause in advance to put appropriate preventive measures in place. In the case of a 30-day postoperative ED visit, which is an undesirable event for both patients and the care team, appropriate preventative or proactive action plans can be put in place, such as scheduling an early clinical intervention based on the likelihood of patients returning to the ED within 30 days of bariatric surgery. In other words, patients identified as high-risk patients who have a higher chance of returning to the ED within 30 days of bariatric surgery might be able to avoid an ED visit if appropriate preventive measures are put in place before the ED visit occurs. Limiting or reducing undesirable events can also be termed a 'defective' process outcome, especially if it is preventable and unnecessary. Controlling such defects from happening can be called 'quality control.' Borrowing concepts and theories related to product development from the manufacturing industry, quality control strategies can be distinctly classified into two main categories: reactive versus proactive. The strategy advocated in this study that institutionalizes processes and systems to control the quality or maintain the desired quality can be termed a proactive approach. DeFeo (2019) outlines Juran Trilogy as the underlying concept of quality management: quality planning, quality control, and quality improvement. As part of the quality control process, corrective action, i.e., a reactive approach, is critical in managing and controlling quality in the long run. Most importantly, it must be continuous and sustainable. This is where the third concept from Juran Trilogy, quality improvement, becomes an essential aspect of quality management. Short, Badar, Kluse, and Schafer (2021) make an important point that due to the ease of financial purpose, reactive or corrective action in quality improvement projects is more widely accepted and rewarded than the proactive approach, which can also have positive economic and safety outcomes for patients, family members, and care teams providing care to the patients.

## Summary

The systematic review of the literature in this specific patient population showed that some opportunities had not been previously explored. Based on the articles listed in Table 1, most researchers agree that many ED visits could have been prevented if a proactive approach had been used to manage patients at higher risk of returning to the ED within 30 days of a bariatric procedure. Potential gaps identified through the extensive literature review are listed below:

- Petrick et al. (2021) highlighted that between 2015 and 2018, 120 peer-reviewed articles were published that utilized the MBSAQIP database. Although MBSAQIP was formed in 2012 by combining two ACS programs, ACS BSCN and ASMBS BSCOE, the database collected for MBSAQIP for the first few years had some opportunities in quality of the dataset. Hence, reviewing the peer-reviewed articles was limited to 2015 and what was available at the publication, i.e., 2018. Through the literature search conducted for this study for 30-day postoperative visits with the selected criteria, there were only 107 articles. Most articles focused on a subset of preoperative and postoperative factors that significantly contributed to the undesirable outcome, i.e., 30-day postoperative ED visits for bariatric patients. Many research studies included preoperative, perioperative, intraoperative, and postoperative factors. There was no single article published with only preoperative factors as predictors of the 30-day postoperative ED visit.
- Based on search results from ProQuest (2021), which encompasses 90,000 authoritative sources and holds approximately 6 billion digital pages and articles, marking itself as the world's most extensive collection of dissertations and theses, there were only two dissertations and theses related to MBSAQIP published to date. The first dissertation was published in 2014 titled "The lived experience of couples after bariatric surgery: A qualitative description". The second dissertation was published in 2018 titled 'Examining factors that predict the maintenance of excess weight loss two or more years after bariatric surgery'.

The research proposed in this study will add to the existing body of knowledge in bariatric surgery, especially to patients undergoing bariatric surgical procedures at MBSAQIP centers throughout the USA. This study took a holistic approach with the help of a panel of experts in identifying and narrowing down preoperative factors significantly contributing to the likelihood of patients returning to the ED within 30 days of a bariatric surgical procedure, developing and testing a statistically valid model, and confirming findings with the help of subject matter experts.

# CHAPTER 3

## METHODOLOGY

This chapter includes the theoretical framework, research design, population, instruments used, reliability and validity, research questions and hypotheses, statistical analysis, and summary of this chapter. This research study takes a mixed-methods approach in which both qualitative and quantitative research methodologies are used. Creswell and Creswell (2018) suggest that a distinct mixed methods design should incorporate both qualitative and quantitative research methods, highlighting the procedure used in the study. Addressing the research questions involves qualitative and quantitative data, i.e., open-ended, and closed-ended data.

### Research Design

The research design of this study utilized mixed methods, i.e., both qualitative and quantitative methods. This study was carried out to primarily identify important preoperative predictors for 30-day postoperative visits to bariatric surgery and to determine what factors significantly contribute to the likelihood of patients returning to the ED within 30 days of the bariatric procedure. The subsequent goals of this research study were to develop a model based on the identified significant predictors for 30-day postoperative visits, validate the developed model statistically, and validate the findings from a panel of experts in the field of the study, i.e., bariatric surgery. In this research study, the dependent variable was dichotomous (positive and negative outcomes in the form of yes and no), and independent variables were both categorical and continuous. An outcome of 'yes' means the patient visited an ED that did not result in an inpatient admission and an outcome of 'no' means the patient did not have an ED visit or had an ED visit that resulted in an inpatient admission. Before identifying important preoperative factors, an extensive literature review was conducted to help understand the gaps in the existing literature. Limited availability of articles, no articles focused exclusively on the preoperative factors, and no dissertation published to date related to preoperative predictors of 30-day postoperative ED visit after bariatric surgery was the motivation of this work, which was taken as an opportunity to explore and study the proposed research topic. In the systematic literature review portion of the literature search, considerations were given to peer-reviewed and journal publications in the last ten years.

This research study was divided into 3 phases: Phase I, Phase II, and Phase III. Under Phase, I of the study, which included RQ1, consensus on independent variables (important preoperative predictors for 30-day postoperative visits to bariatric surgery) to be studied was obtained from a panel of experts. The Delphi study is a qualitative technique that can help researchers answer a research question through a consensus view across a panel of experts (Barrett & Heale, 2020; Short et al., 2020). To conduct the Delphi study, a panel of experts was recruited from one of the country's MBSAQIP accredited centers, including Bariatric Surgeon, Advanced Practice Provider, two Registered Nurses, and Metabolic & Bariatric Surgery Clinical Reviewer. The terminology, panel of experts, used throughout this research denotes these five experts who have expertise in the field of bariatric surgery based on their education, healthcare experience, and their experience working with bariatric patients directly. The first expert in the panel is a certified surgeon from the American Board of Surgery. She is also a fellow of the American Society for Metabolic and Bariatric Surgery and the American College of Surgeons.

Her expertise is on invasive bariatric surgery and advanced laparoscopy, including Roux-en-Y gastric bypass, Sleeve gastrectomy, ongoing and follow-up care for Bariatric patients. She has 20 years of extensive experience in healthcare, where nine years of her career was working with bariatrics patients. The second expert in the panel is an Advanced Practice Provider who is also a certified nurse specialist and bariatric nurse. She has more than 28 years of extensive experience in healthcare with nice and a half year of her career where she served and worked with bariatrics patients. The third expert is the MBSAQIP Quality Reviewer and a Licensed Practical Nurse. She understands MBSAQIP accreditation standards, requirements, and metrics very well because part of her role is to contribute to the program's sustainment and report all critical data and metrics to MBSAQIP on a required cadence. She has 12 years of experience in healthcare with 8 years of her career in bariatrics practice. The fourth expert is a registered nurse with a Bachelor of Science in nursing and has seven years of experience working as a registered nurse with bariatric patients. The fifth expert is also a registered nurse with 27 years of extensive experience in healthcare and currently works as a registered nurse with bariatric patients.

Phase II of the study included RQ2 and RQ3. From the selected factors from RQ1, RQ2 helped researchers narrow down preoperative factors that could significantly contribute to the likelihood of patients returning to the ED within 30 days of bariatric surgery through a quantitative technique called binary logistic regression. RQ3 also utilized various quantitative methods such as goodness-of-fit tests to check the model's significance, validity, and fit to the data.

Phase III of the study, which included RQ4, again utilized the Delphi study to gain consensus on the outcome of RQ2 and RQ3. A total of 7 questions were asked to the same panel of experts from Phase I of the study, and questions were open to being revised again based on the feedback and consensus received from the panel of experts if needed.

Institutional Review Board (IRB) submission process was planned before initiating the study to obtain clearance for research from Indiana State University for all phases of the research study. A consent form was developed to be provided to the participants taking part in the Delphi study before participating in either of the Delphi studies.

The Questionnaire for the Phase I Delphi instrument, Questionnaire for the Phase III Delphi instrument, Informed consent form used for both the Phase I and Phase III Delphi instruments, and Institutional Review Board (IRB) letter from Indiana State University are included in Appendix A, B, D, and C respectively.

## Population, Sample and Data Source

Participants for the panel of experts used in Phase I and Phase III of this study were the subject matter experts (Bariatric Surgeon, Advanced Practice Provider, two Registered Nurses, and Metabolic & Bariatric Surgery Clinical Reviewer) from one of the MBSAQIP centers in the USA. The MBSAQIP center selected is one of the community-based hospitals in Minnesota. The Delphi study for Phase I and III was conducted where subject matter experts were employed.

Data used in Phase II of the study consisted of all the patients who underwent bariatric surgery throughout the MBSAQIP Centers in the USA in 2019. This data set was released by MBSAQIP in October 2020 and can only be used after obtaining permission to use it from MBSAQIP. MBSAQIP and MBSAQIP accredited center's permission was obtained before analyzing the data (Appendix G). MBSAQIP centers must enter data into the MBSAQIP Registry at 30 days, six months, one year, and annually for each patient going through bariatric surgery at the center. The American College of Surgeons Metabolic and Bariatric Surgery

Accreditation and Quality Improvement Program and the centers participating in the ACS MBSAQIP are the data sources used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the researcher.

There is much debate among researchers and practitioners on the best method to calculate sample size for research studies that utilize binary logistic regression. In medical research, an events per variable (EPV) of 10 is widely used as the lower limit for developing prediction models that predict a binary outcome such as the one in this study. This method of identifying sample size for studies involving binary logistic regression has been generally accepted. However, some researchers have argued that EPV ≥ 10 rule-of-thumb is not based on convincing statistical rationale (Van Smeden et al., 2018). Researchers are cautioned when dealing with smaller sample sizes while using logistic regression. Bujang et al. (2018) suggest using a minimum sample size of 500 and reference the following formula to be used as a rule of thumb:

$$Sample\ size\ (n) = 100 + 50i \qquad \textit{Equation (1)}$$

where *i* = number of independent variables in the final model

With 9 IVs in this research study, $Sample\ size\ (n) = 100 + 50\ (9) = 550$

The MBSAQIP dataset used in this study for 2019 has 193,774 unique patients after elimination of missing or incomplete values, which makes this study statistically robust from a sample size perspective.

For the 2019 MBSAQIP data set used in this study, cases with the following criteria were not included (cases excluded):

- Patients who were admitted to the hospital that included a procedure to address cancer
- Patients who were admitted to the hospital that included a procedure to address traumatic injury

- A patient who is under ten years of age
- Multiple MBSAQIP assessed cases within 30 days are entered only once, and the subsequent procedures are added as reoperation or intervention.

For the 2019 MBSAQIP data set used in this study, centers with the following criteria were not included (hospitals excluded):

- Hospitals that have 30-day follow-up dates below 80% for the MBSAQIP Semiannual Report (SAR) timeframe. Centers with high outliers on the SAR are adjusted on the PUF file, and data from Centers not meeting SAR criteria are not included in the final database that is published (Optimal Resources for Metabolic and Bariatric Surgery: 2019 standards, 2019)
- Hospitals with a Data Integrity Audit disagreement rate of more than 5%
- Hospitals not meeting the annual Metabolic & Bariatric Surgery Clinical Reviewer Certification requirement
- Hospitals not compliant with MBSAQIP Standard 6, "Data Collection"

To safeguard the privacy of the patients at the participating centers, data limitations were enforced by MBSAQIP. Data limitations for the 2019 dataset are provided below based on the User Guide for the 2019 Participant Use Data File (2020a).

- Data only include patients over the age of 10
- Patients over the age of 80 are de-identified and can only be identified as patients over the age of 80.
- To be compliant with patient privacy requirements, absolute dates are not included. For example. The date of the surgery is reduced to the year of the surgery, and some dates are decoded into durations.

- Information linking patient information to a particular center and geographical information is not included.
- The data only include reported data from MBSAQIP centers in the USA.
- Some variables in this dataset have missing values that may or may not impact this research study. Missing values for each variable used in this research study will be addressed separately during the analysis segment of this study.

## Instruments Used

This research study is divided into 3 phases. Phase I of the study comprised the Delphi instrument with only two questions (Table 2). The intent of utilizing the Delphi method was to gain consensus from the subject matter experts on selecting independent variables to be studied for this research study. The Delphi method has been around for a few decades. It is proven to be a reliable measurement instrument in developing new theories, establishing consensus in many subject areas, and setting the foundation of future research (Vogel et al., 2018a).

The Delphi method in Phase I comprises one objective question and one open-ended question. In the first question, 33 preoperative factors or variables (Table 3) were presented to the panel of experts. In the first round, a panel of experts was asked to rank variables into the “low” category from the list of 33 variables in a focus group setting. In the second round, from the list of remaining variables, the panel of experts was asked to rank variables into the “medium” category. In the third and final round, through consensus from the panel of experts, whichever variables were left were ranked as the “high” category. On the second question, a panel of experts was asked if they suggested including any variables other than the 33 selected from the MBSAQIP database.

All the responses were collected, aggregated, and presented to the panel of experts. The nine highly ranked variables were aggregated and presented to the panel of experts with additional comments from the second question for a final revision. There were no suggested changes or amendments to the selected final nine variables, so these nine variables were chosen as independent variables for the proposed study. The researcher initially aimed to use 7 to 10 highly ranked factors from the panel of experts based on the literature review finding that showed that most published articles had less than ten independent variables that contributed to the likelihood of patients returning to the ED within 30 days of a bariatric procedure (Figure 4).

**Table 2**

***Questionnaire for Phase I Delphi Instrument***

| Question | Response |
| --- | --- |
| Q1. From the 33 variables (Table 3), rank the variables that are clinically significant (Low, Medium, High) for the bariatric patient population from your perspective that can contribute to the likelihood of patients coming back to ED within 30 days of bariatric surgery (3 rounds) | Shortlisted variables |
| Q2. Do you suggest including any other variables other than the 33 selected from the MBSAQIP database? | Commentary response |

**Table 3**

***List of 33 Preoperative Factors or Variables from MBSAQIP User Guide for the 2019 Participant Use Data File as Released on October 2020***

| Variable Name | Search Term in Variables and Definitions | Variable Options |
| --- | --- | --- |
| GERD | Variable Name: Gastroesophageal Reflux Disease (GERD) Requiring Medication (within 30 days prior to surgery) | Yes; No |
| MOBILITY_ DEVICE | Variable Name: Preoperative Is the Patient's Ambulation Limited Most or all of the Time | Yes; No |
| HIP | Variable Name: Preoperative Hypertension Requiring Medication | Yes; No |
| HTN_MEDS | Variable Name: Preoperative Number of Anti-Hypertensive Medications | 0 |
| | | 1 |

| Variable Name | Search Term in Variables and Definitions | Variable Options |
|---|---|---|
| | | 2 |
| | | 3+ |
| HYPERLIPIDEMIA | Variable Name: Preoperative Hyperlipidemia Requiring Medication | Yes; No |
| HGT | Variable Name: Preoperative Height | |
| WGT_HIGH_BAR | Variable Name: Highest Recorded Weight within 1 year at the Program | |
| WGT_HIGH_ UNIT_BAR | Highest Pre-op Weight Measurement Units | kg |
| | | lbs |
| WGT_CLOSEST | Variable Name: Weight Closest to Surgery | |
| WGTUNIT_ CLOSEST | Closest to Surgery Pre-op Weight Measurement Units | kg |
| | | lbs |
| BMI | Calculated from pre-op weight closest to surgery and height | |
| BMI_HIGH_BAR | Calculated from highest recorded pre-op weight and height | |
| HISTORY_DVT | Variable Name: Preoperative Vein Thrombosis Requiring Therapy | Yes; No |
| VENOUS_ STASIS | Variable Name: Preoperative Venous Stasis | Yes; No |
| DIALYSIS | Variable Name: Preoperative Currently Requiring or On Dialysis | Yes; No |
| RENAL_ INSUFFICIENCY | Variable Name: Preoperative Renal Insufficiency | Yes; No |
| THERAPEUTIC_ ANTICOAGULATION | Variable Name: Preoperative Therapeutic Anticoagulation | Yes; No |
| DIABETES | Variable Name: Preoperative Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin | Non-Insulin |
| | | Insulin |
| | | No |
| FUNSTAT PRESURG | Variable Name: Preoperative Functional Health Status | Independent |
| | | Partially Dependent |
| | | Totally Dependent |
| | | Unknown |
| COPD | Variable Name: History of Severe COPD | Yes; No |
| OXYGEN_ DEPENDENT | Variable Name: Preoperative Oxygen Dependent | Yes; No |
| SLEEP_APNEA | Variable Name: Preoperative Obstructive Sleep Apnea Requiring CPAP/BiPAP (or similar technology) | Yes; No |
| CHRONIC_ STEROIDS | Variable Name: Preoperative Steroid/Immunosuppressant Use for a Chronic Condition | Yes; No |

| Variable Name | Search Term in Variables and Definitions | Variable Options |
|---|---|---|
| IVC_FILTER | Variable Name: Preoperative Does the patient have an IVC filter | Yes; No |
| IVC_TIMING | IVC Filter Timing | IVC filter placed in anticipation of the metabolic or bariatric procedure |
| | | IVC filter was preexisting |
| | | Unknown |
| ALBUMIN | Variable Name: Preoperative Lab Value Information | |
| DPRALBUM | Days from pre-operative Albumin to initial bariatric surgery operation date | |
| HCT | Variable Name: Preoperative Lab Value Information | |
| DPRHCT | Days from pre-operative Hematocrit to initial bariatric surgery operation date | |
| CREATININE | Variable Name: Preoperative Lab Value Information | |
| DPRCREAT | Days from pre-operative Creatinine to initial bariatric surgery operation date | |
| HEMO | Variable Name: Preoperative Lab Value Information | |
| DPRHEMO | Days from pre-operative Hemoglobin A1c to initial bariatric surgery operation date | |

(User Guide for the 2019 Participant Use Data File, 2020b)

Phase II did not involve the use of an instrument. The data utilized to answer research questions RQ2 and RQ3 were derived directly from the User Guide for the 2019 MBSAQIP PUF database. This analysis used a column with a dependent variable (Was the patient seen in an emergency department (ED) that did not result in an inpatient admission?) which has a dichotomous outcome, i.e., Yes or No, and the necessary number of columns with independent variables confirmed through the third round of Phase I.

Phase III again utilized the same panel of experts in a virtual focus group setting similar to Phase I and used a Delphi instrument with four objective questions and three subjective questions. The developed questions were initially reviewed with the expert panel and finalized before Phase III of the study was conducted. The final version of the Delphi instrument for Phase III of this research study is provided in Table 4.

**Table 4**

***Questionnaire for Phase III Delphi Instrument***

| Question | Agree | Disagree |
|---|---|---|
| Q1. From a clinical perspective, understanding preoperative factors (with the level of significance and odds ratio) before surgery is beneficial for the bariatric patient population. | | |
| Q2. A proactive approach is preferred over the reactive approach when dealing with 30-day postoperative ED visits for bariatric patients. | | |
| Q3. Results from Phase II of the study have practical significance clinically and operationally. | | |
| Q4. Suppose Phase II findings are translated to your day-to-day operations and bariatrics practice. In that case, I see value in these findings for both patients and care teams providing care to the bariatric patient population. | | |
| Q5. If you suggest revising the list of independent variables in Phase II, recreating, and rerunning the model with a new set of IVs, please provide the name of variables you would like to include or exclude in the commentary response. | | |
| Q6. To further this area of research in the Bariatrics Surgery patient population and 30-day postoperative ED visits, what do you suggest future researchers should focus on? Please provide a commentary response. | | |
| Q7. Please provide a commentary response if you have any additional feedback or anything you would like the researcher to consider that is not on this questionnaire. | | |

Findings from Phase III of the study were primarily used to answer Research Question RQ4. Based on feedback and consolidated comments from the panel of experts, RQ1, RQ2, and RQ3 were planned to be revised, if needed.

## Reliability and Validity

McCain (2020) points to varying opinions on the reliability and validity of Delphi methods and instruments used. The reliability of larger panel sizes is better in representing the population's opinion; however, the disadvantage of larger panel sizes is that there can be an increased variation in the responses, making it difficult to reach a consensus. Vogel et al. (2018b) note that a minimum of 12 respondents is considered sufficient to achieve a good consensus and add that larger sample sizes can be disadvantageous related to the validity of findings. Lilja et al. (2011) argue that by design, a panel consists of selected experts that do not have a limit on the size of the group. The most crucial factor in determining the validity of the Delphi technique is to ensure that the group of participants selected are experts in their field of practice. Hence, in most cases, the size of the panel of experts remains small. There are ongoing debates regarding the reliability and validity of the Delphi method and the actual sample size required for a panel of experts. Researchers also suggest that to achieve a reliable result from a Delphi study, a panel of experts should comprise between 3 to 9 members as a minimum, and experts should be the true experts in the field of their practice (education and experience). Phase I and Phase III of this study utilized the Delphi study. Five experts were engaged, including Bariatric Surgeon, Advanced Practice Provider, two Registered Nurses, and Metabolic & Bariatric Surgery Clinical Reviewer. One of the limitations of this study regarding the methodology used was the use of the Delphi study with a small panel of experts, which was five, and it was because the MBSAQIP Center that the researcher chose to conduct the Delphi study had only five direct patient care team who were the subject matter experts. The use, application, and outcome of the Delphi study differ on a case-by-case basis, and it is also important to note that the panel of experts utilized in this study was to confirm and narrow down the independent variables (Phase I) and to validate the outcome and findings of this study (Phase III).

Phase II of this study utilized data from the MBSAQIP PUF database. MBSAQIP accredited centers must report data to MBSAQIP on a regular frequency. The data analyzed for Phase II of this study contained 193,774 cases. Each case represents a unique patient who underwent bariatric surgery in one of the 868 MBSAQIP accredited centers in 2019 (User Guide for the 2019 Participant Use Data File, 2020c). It is important to note that any data is as good as it is reported, and hence, it is assumed that all the data reported by MBSAQIP centers are accurate. Trained Metabolic & Bariatric Surgery Clinical Reviewers for each MBSAQIP center must report the data following specific standards. MBSAQIP also falls under ACS NSQIP, which regularly and randomly monitors timely and accurate data, accrual rates, and data sampling methodologies and performs interrater reliability audits. The regular training provided by ACS NSQIP, data collection, and auditing procedures has been consistently highly reliable. It is also important to note that reliability has improved over the years (Data Collection, Analysis, and Reporting, 2020). During the preparation and preprocessing phase of the data analysis, discrepancies in the data, missing values, and outliers were addressed. Before the data were statistically analyzed, statistical assumptions were validated to ensure that the data being used were statistically valid.

## Research Questions and Hypotheses

The research questions and hypotheses for this research study are listed below.

RQ1: What are important preoperative factors that may contribute to the likelihood that patients will have an ED visit within 30 days of bariatric surgery?

RQ2: What factors significantly contribute to the likelihood that patients will have an ED visit within 30 days of bariatric surgery?

RQ3: Can a model be developed using only the statistically significant and weighted predictors? Can it have an acceptable fit?

Research hypothesis was set up to support answers for RQ3:

Ho: Slope or regression value for each predictor equals zero, i.e.,$\beta_i = 0$ , $where\ i = 1\ to\ n$.

$H_a$: At least the slope or regression value for one predictor is not equal to zero, i.e.,$\beta_i \neq 0, for\ at\ least\ one\ i$.

RQ4: What are the subject matter experts' perceptions regarding the model developed and overall findings?

## Statistical Analysis

### Variables

The dependent variable of this research study was a 30-day postoperative ED visit in the form of Yes or No (dichotomous) and was predetermined. Consensus on what independent variables to use for this research study was obtained through the Delphi study in Phase I of the study. Three rounds of consensus gathering, and validation were carried out until vital few variables ranked as 'high' were finalized as independent variables or preoperative factors (potential predictors for dependent variables) of interest. Table 5 includes the finalized list of independent variables from Phase I of the study and the study's dependent variable.

**Table 5**

***Dependent and Independent Variables***

| Dependent Variable (DV) | Description of variable | Values or Labels |
|---|---|---|

| | | |
|---|---|---|
| EMERG_VISIT_OUT | Was the Patient Seen in any Emergency Department (ED) which did not result in an Inpatient Admission? | Yes, No |

| Independent Variable (IV) | Description of variable | Data Type |
|---|---|---|
| GERD | Gastroesophageal Reflux Disease (GERD) Requiring Medication (within 30 days prior to surgery) | Categorical (Yes, No) |
| HTN_MEDS | Preoperative Number of Anti-Hypertensive Medications | Categorical (0, 1, 2, 3+) |
| BMI | Calculated from pre-op weight closest to surgery and height | Continuous |
| BMI_HIGH_BAR | Calculated from highest recorded pre-op weight and height | Continuous |
| HISTORY_DVT | Preoperative Vein Thrombosis Requiring Therapy | Categorical (Yes, No) |
| DIABETES | Preoperative Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin | Categorical (Non-insulin, Insulin, No) |
| FUNSTAT PRESURG | Preoperative Functional Health Status | Categorical (Independent, Partially Dependent, Totally Dependent, Unknown) |
| COPD | History of Severe COPD | Categorical (Yes, No) |
| CHRONIC_STEROIDS | Preoperative Steroid/Immunosuppressant Use for a Chronic Condition | Categorical (Yes, No) |

(User Guide for the 2019 Participant Use Data File, 2020d)

**Data analysis procedure**

Phase I of the study is exploratory and qualitative to obtain consensus on the total number and type of independent variables and did not utilize any statistical technique to conclude the findings for RQ1. For Phase III of the study, a similar procedure was used for document validation and consensus from the panel of experts on the Phase II findings and learning, which also helped answer RQ4.

Phase II of this study utilized binomial logistic regression and pertinent statistical tests to answer research questions RQ2 and RQ3, respectively. Binary logistic regression is popular in medical research and is commonly used to analyze healthcare-related data. This technique is considered an extension of linear regression analysis. Therefore, it has many advantages over other similar approaches. For example, the expatiated logistic regression slope coefficient ($e^B$) can be interpreted as an odds ratio, which helps the researcher understand how much the odds of a particular outcome change for a 1-unit increase in the independent variable for continuous independent variables or a reference category for categorical variables (Abedin et al., 2016; Schober & Vetter, 2021a). Although Phase III of the study includes a practical significance check and validation from the subject matter experts on the study's overall findings, various statistical analyses were carried out to understand the effectiveness of the developed binary logistic regression model in this study. Binary logistic regression includes various predictive measures to conclude the model's efficacy, including the classification table, accuracy, area under the curve, and cutoff plot for sensitivity and specificity. The following data processing and statistical packages were utilized to process and conclude various sections of the data analysis:

- Microsoft Excel
- IBM SPSS Statistics 25
- Jamovi software version 1.6

Microsoft Excel is a commonly used data storing, processing, and analyzing software developed by Microsoft. Jamovi Software is a powerful open-source statistical platform that is intuitive and built on the top of the R statistical language. IBM is a popular statistical software used to answer business and research questions (Microsoft Excel, 2021; The Jamovi Project Version 1.6., 2021a; IBM SPSS Statistics 25, 2021a).

**Binary Logistic Regression**

Most researchers agree that logistic regression is a better predictor than linear regression and is much better at predicting future data points and it also provides biologically meaningful predictions and, in most cases, provides forecasts closer to the observations (Zhao et al., 2001; Stoltzfus, 2011; Schober & Vetter, 2021b). Binary logistic regression is a statistical technique used when the dependent variable is categorical and dichotomous, such as yes or no, success or failure, or on or off. This technique helps determine the impact of multiple independent variables (continuous or categorical) to predict the membership of one of the two dependent variable categories. This technique uses binominal probability theory, where only two prediction values are possible, i.e., Yes (1) or No (0), and can predict where the event or outcome belongs to the first or second category of interest. This is sometimes termed group membership determination (Hua et al., 2021). In this research study, the dependent or outcome variable was the 30-day postoperative visit in the form of "Yes" or "No". If patients returned to the ED within 30 days of a bariatric procedure that did not result in an inpatient admission, this was marked as "Yes". If the patient is admitted as part of the ED visit, it is deemed a non-avoidable ED visit. Hence, it is not counted as "Yes" on the MBSAQIP PUF. Independent variables for a binary logistic regression can be continuous or categorical, documented once confirmed through Phase I of the study.

Warner (2013a) makes essential points on the simple linear regression model's inadequacy when the outcome or dependent variable is dichotomous. The most challenging aspect of the simple linear regression model is that the probability value of an event occurring can only be between 0 and 1, but a simple linear regression equation such as the one provided in equation (2.1) would not always have its estimated values of $\hat{p}_i$ limited to 0 and 1.

$\hat{p}_i = B_0 + B_1X_1 + B_2X_2 + B_3X_3 + \dots\dots\dots\dots + B_nX_n$ *Equation (2.1)*

where

$\hat{p}_i$ = estimated probability that outcome *i* is a member of the target outcome group that corresponds to 1 (Yes) versus (No).

$B_0$ = intercept

$B_i$ = regression value for each independent variable or predictor *(i = 1,2, 3, …… n)*

$X_i$ = Value for each independent variable or predictor *(i = 1,2, 3, …… n)*

The estimated probability value of $\hat{p}_i$ could be less than or greater than 1, and such an outcome will not be practical and valid. A model needs to be set up so that the output probabilities are always between 0 and 1. Another issue arises when one or more independent variables are quantitative or continuous. The relationship between the predictor or independent variable and the dependent variable could be nonlinear and cannot be addressed by ordinary linear regression. To address such issues, equation (2.1) is transformed to make the outcome variable logit ($L_i$), instead of $\hat{p}_i$. Logit ($L_i$) is defined as the '*log of odds*', i.e.,

$L_i = Ln\ (Odds)$ where:

$$Odds = \frac{\hat{p}_i}{1-\hat{p}_i} = \frac{outcome\ of\ interest\ happen}{outcome\ of\ interest\ doesn't\ happen}$$ *Equation (2.2)*

The relationship between the logit ($L_i$) and odds becomes:

$$L_i = Ln\ (\frac{\hat{p}_i}{1-\hat{p}_i})$$ *Equation (2.3)*

To illustrate the significance of this translation, an example is provided by substituting values in equation (2.2). Suppose the primary outcome of interest (outcome or dependent variable) is to know if the patient has cancer or not. In a sample of N = 200 patients, 40 patients had cancer, and the rest did not.

The odds of having cancer for this entire group:

$$Odds_{Cancer} = \frac{40}{200} = 0.2$$

Conversely, the odds of not having cancer for this entire group are as follows:

$$Odds_{No\ cancer} = \frac{200}{40} = 5$$

Hence, in this example, the odds of having cancer in this study are 0.2, but the odds of not having cancer are 5. An odds ratio is considered better than the estimated probability value $\hat{p}_i$ because the probability value always needs to be between 0 and 1. Still, the odds ratio can be of any number. The only limitation of the odds ratio is that the lowest value can only be 0 (cannot be negative); the importance of the odds ratio is not always normally distributed and is not linearly related to values on predictor variables. These characteristics are not desired for a dependent or outcome variable. However, this issue can be addressed by transforming the odds ratio values by an exponential function (inverse of natural log), which can also be represented as exp(B) or $e^{B_i}$. Once the transformation is performed, interpreting $e^{B_i}$ is meaningful because it directly relates to the "change in odds" versus interpreting B, which represents the change in log odds.

Equation (2.3) can be further expanded to:

$$L_n\,(Odds) = B_0 + B_1X_1 + B_2X_2 + B_3X_3 + \dots\dots\dots\dots + B_nX_n \qquad \textit{Equation (2.4)}$$

Equation (2.4) shows that logit values can now be predicted as a linear function of scores on one or more independent variables or predictors. Predictors can be continuous or categorical. The same equation and coefficient associated with each predictor can provide important information regarding the nature and strength of the association of each predictor with the outcome or dependent variable (Warner, 2013b).

The following hypotheses can help researchers test the statistical significance of each independent variable with the dependent variable through equation (2.4).

Null Hypothesis ($H_{oa}$): The slope for each independent variable equals zero, i.e., $B_i = 0, where\ i = 1, 2, 3, \dots n$, where $n$ = number of predictors.

Alternative Hypothesis ($H_{1a}$): At least the slope of one independent variable is not equal to zero, i.e.,$B_i \neq 0$ for at least one i.

If the researcher fails to reject the null hypothesis, it can be concluded that there is no association between the independent variables and the dependent variable. However, if the slope of at least one or more independent variables is found to be greater than 0 or less than 0, further analysis needs to be performed to validate the significance of independent variables' likelihood of predicting outcome or dependent variable. If there are multiple independent variables with slopes greater than or less than 0, the Wald test needs to be carried out to determine statistical significance for each predictor. The $p$-value for each predictor is referenced to determine the statistical significance of the corresponding predictor. Predictors with $p$-values less than 0.05 are considered to have statistical significance. If multiple predictors have $p$-values greater than 0.05, it is suggested to rerun the model in the statistical software, eliminating one non-significant predictor at a time versus all together, which is also termed as model reduction. If predictors with no statistical significance are left in the model, the ability of the model to predict precisely may be compromised (Model Reduction, 2019). The final model is established when the model only consists of predictors with statistical significance and all other non-significant predictors are eliminated from the model.

Once the final binary logistic regression model is established, it is important to check and understand the model fit, statistical validity, and accuracy of the overall model. Among various goodness-of-fit tests, the Hosmer–Lemeshow goodness-of-fit test is used to determine whether the model adequately describes the data for a binary logistic regression model.

The hypotheses for the Hosmer–Lemeshow goodness-of-fit test can be denoted as follows:

Null Hypothesis ($H_{ob}$): The logistic regression model does not have a lack-of-fit.

Alternative Hypothesis ($H_{1b}$): The logistic regression model lacks a fit.

If a $p$-value greater than the significance level of 0.05 is obtained, we do not have evidence to reject null hypothesis, i.e., the Hosmer–Lemeshow statistic indicates that the model adequately fits the data (Warner, 2013c). However, if the model shows a lack of fit, researcher can use other logistics regression metrics to assess the accuracy of the model or the output. The accuracy of the model can also be analyzed using a classification table where true positive (TP), true negative (TN), false positive (FP), and false negative (RN) values are generated. This table can be used to evaluate the predictive accuracy of the logistic regression model. The information on the table can be used to calculate what percentage of outcomes are correctly predicted (Logistic Regression, 2021).

As an output from the statistical package used in this study (Figure 6), in addition to all other relevant statistical outputs and summary tables, a model coefficients table was executed that included important information for the variables of this study, such as predictor, estimate, standard error (SE), Z score, $p$-value, odds ratio and 95% confidence interval.

**Figure 6**

***Model Coefficients Table Headers***

| | | | | | | 95% Confidence Interval | |
|---|---|---|---|---|---|---|---|
| Predictor | Estimate | SE | Z | p | Odds ratio | Lower | Upper |

***Binary Logistic Regression Assumptions***

Warner (2013d) notes that binary logistic regression does not require vast and restrictive assumptions like the most general linear models (multiple linear regression, discriminant analysis, etc.) require. Below are the model assumptions that were validated before conducting the quantitative data analysis for binary logistic regression:

- Outcome variable is dichotomous and is usually coded 0 and 1 (Yes = 1, No = 0).
- Scores on the outcome variable are statistically independent of each other
- The model should include all relevant predictors, and irrelevant predictors should not be included in the model
- The categories in the outcome variable should be mutually exclusive (one outcome should be different from another)

## Summary

This study utilized a mixed-methods approach that included both qualitative and quantitative methods. Phase I and Phase III of the study utilized a qualitative method (Delphi study), where a panel of experts was consulted to gain consensus and finalize the independent variables. Phase II of the study used a quantitative method (binomial logistic regression) and subsequent statistical techniques, such as the Wald test and Hosmer–Lemeshow goodness-of-fit test. The minimum sample size recommended best practice for a binomial logistic regression was calculated to be 550 for 9 independent variables based on Eq. (1). The dataset used in this study utilized a sample size of 193,774 unique patients or cases, making this study a robust research study with ample sample size to represent the population. The IRB process was initiated and submitted once the committee members approved the dissertation proposal.

# CHAPTER 4

## RESULTS

This chapter includes findings of the research study from all three phases of the research study. In the first phase of the study, the Delphi technique and questionnaire were utilized with the help of a panel of experts in the field of bariatric surgery practice. The Delphi method used in the first phase of the research included three rounds of results based on consensus received from the panel of experts. The second phase of the study included further investigation of the shortlisted variables from Phase I of the study to identify which factors significantly contributed to the likelihood of patients returning to the ED within 30 days of a bariatric procedure. The second phase of the study also included the development of a robust predictive model utilizing the statistically significant and weighted predictors and validation that the model exhibits an acceptable fit. The third phase of the study included circling back with the same panel of experts from the first phase of the study to confirm the practical significance of the outcome achieved in the second phase of the research study through another round of Delphi questionnaires.

Before the first phase of the study, i.e., gathering the panel of experts and going through the round of questionnaire, the research proposal and Delphi questionnaires were submitted to Indiana State University Institutional Review Board (IRB). The Indiana State University Institutional Review Board determined that the proposed study did not meet the definition of human subject research under the purview of the IRB according to federal regulations (Appendix C).

## Phase I Delphi Study Findings

A virtual meeting was scheduled between the panel of experts from one of the MBSAQIP accredited medical centers and the researcher where phase I of the Delphi study was conducted. The panel of experts consisted of 5 members, which included Bariatric Surgeon, Advanced Practice Provider, MBSAQIP Clinical Reviewer, and two Registered Nurses.

The first question in Phase I of the Delphi study asked a panel of experts to rank the 33 preoperative variables from high to low clinical significance in terms of the individual impact of the variable on the outcome variable, i.e., ED visit within 30 days of bariatric surgery. From the list of 33 preoperative variables, a panel of experts suggested collectively ranking the clinically significant variables into three groups (red = low, yellow = medium, and green = high) from the context of how much impact these variables may have on the outcome variable, i.e., ED visit within 30 days of a bariatric procedure. This was also based on which variables are of interest to the clinicians in the 30-day postoperative ED visit.

In the first round of the Delphi study, eight variables were finalized and marked red and were marked as the ‘low’ category. In the second round of the Delphi study, a panel of experts landed on 16 variables with medium clinical significance to the outcome variable and marked yellow. In the third round of the Delphi study, i.e., whatever variables were not color-coded red or yellow by default became the variables of interest, i.e., independent variables for the proposed research, which were a total of 9 variables and were color coded green (Tables 6, 7, 8, and 9).

The second question in Phase I of the Delphi study asked a panel of experts if they had any suggestions to include other than the preselected 33 preoperative variables from the MBSAQIP PUF data registry. The response received from the panel of experts was none.

**Table 6**

***Outcome of the First Round of the Phase I Delphi Study***

| Variable Name | Search Term in Variables and Definitions | Variable Options | Ranking |
|---|---|---|---|
| GERD | Variable Name: Gastroesophageal Reflux Disease (GERD) Requiring Medication (within 30 days prior to surgery) | Yes; No | |
| MOBILITY_ DEVICE | Variable Name: Preoperative Is the Patient's Ambulation Limited Most or all of the Time | Yes; No | Low |
| HIP | Variable Name: Preoperative Hypertension Requiring Medication | Yes; No | Low |
| HTN_MEDS | Variable Name: Preoperative Number of Anti-Hypertensive Medications | 0, 1, 2, 3+ | |
| HYPERLIPIDEMIA | Variable Name: Preoperative Hyperlipidemia Requiring Medication | Yes; No | |
| HGT | Variable Name: Preoperative Height | | Low |
| WGT_HIGH_BAR | Variable Name: Highest Recorded Weight within 1 year at the Program | | |
| WGT_HIGH_ UNIT_BAR | Highest Pre-op Weight Measurement Units | kg | |
| WGT_CLOSEST | Variable Name: Weight Closest to Surgery | | |
| WGTUNIT_ CLOSEST | Closest to Surgery Pre-op Weight Measurement Units | kg | |
| BMI | Calculated from pre-op weight closest to surgery and height | | |
| BMI_HIGH_BAR | Calculated from highest recorded pre-op weight and height | | |
| HISTORY_DVT | Variable Name: Preoperative Vein Thrombosis Requiring Therapy | Yes; No | |
| VENOUS_ STASIS | Variable Name: Preoperative Venous Stasis | Yes; No | |
| DIALYSIS | Variable Name: Preoperative Currently Requiring or On Dialysis | Yes; No | |
| RENAL_ INSUFFICIENCY | Variable Name: Preoperative Renal Insufficiency | Yes; No | |
| THERAPEUTIC_ ANTICOAGULATION | Variable Name: Preoperative Therapeutic Anticoagulation | Yes; No | |
| DIABETES | Variable Name: Preoperative Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin | Non-Insulin<br>Insulin<br>No | |
| FUNSTAT PRESURG | Variable Name: Preoperative Functional Health Status | Independent<br>Partially Dependent<br>Totally Dependent<br>Unknown | |
| COPD | Variable Name: History of Severe COPD | Yes; No | |
| OXYGEN_ DEPENDENT | Variable Name: Preoperative Oxygen Dependent | Yes; No | |

| Variable Name | Search Term in Variables and Definitions | Variable Options | Ranking |
|---|---|---|---|
| SLEEP_APNEA | Variable Name: Preoperative Obstructive Sleep Apnea Requiring CPAP/BiPAP (or similar technology) | Yes; No | |
| CHRONIC_ STEROIDS | Variable Name: Preoperative Steroid/Immunosuppressant Use for a Chronic Condition | Yes; No | |
| IVC_FILTER | Variable Name: Preoperative Does the patient have an IVC filter | Yes; No | |
| IVC_TIMING | IVC Filter Timing | IVC filter placed in anticipation of the metabolic or bariatric procedure<br><br>IVC filter was preexisting<br>Unknown | |
| ALBUMIN | Variable Name: Preoperative Lab Value Information | | |
| DPRALBUM | Days from pre-operative Albumin to initial bariatric surgery operation date | | Low |
| HCT | Variable Name: Preoperative Lab Value Information | | Low |
| DPRHCT | Days from pre-operative Hematocrit to initial bariatric surgery operation date | | Low |
| CREATININE | Variable Name: Preoperative Lab Value Information | | |
| DPRCREAT | Days from pre-operative Creatinine to initial bariatric surgery operation date | | Low |
| HEMO | Variable Name: Preoperative Lab Value Information | | |
| DPRHEMO | Days from pre-operative Hemoglobin A1c to initial bariatric surgery operation date | | Low |

**Table 7**

***Outcome of the Second Round of the Phase I Delphi Study***

| Variable Name | Search Term in Variables and Definitions | Variable Options | Ranking |
|---|---|---|---|
| GERD | Variable Name: Gastroesophageal Reflux Disease (GERD) Requiring Medication (within 30 days prior to surgery) | Yes; No | |
| MOBILITY_ DEVICE | Variable Name: Preoperative Is the Patient's Ambulation Limited Most or all of the Time | Yes; No | Low |
| HIP | Variable Name: Preoperative Hypertension Requiring Medication | Yes; No | Low |
| HTN_MEDS | Variable Name: Preoperative Number of Anti-Hypertensive Medications | 0, 1, 2, 3+ | |
| HYPERLIPIDEMIA | Variable Name: Preoperative Hyperlipidemia Requiring Medication | Yes; No | Medium |
| HGT | Variable Name: Preoperative Height | | Low |
| WGT_HIGH_BAR | Variable Name: Highest Recorded Weight within 1 year at the Program | | Medium |
| WGT_HIGH_ UNIT_BAR | Highest Pre-op Weight Measurement Units | kg | Medium |
| WGT_CLOSEST | Variable Name: Weight Closest to Surgery | | Medium |

| Variable Name | Search Term in Variables and Definitions | Variable Options | Ranking |
|---|---|---|---|
| WGTUNIT_ CLOSEST | Closest to Surgery Pre-op Weight Measurement Units | kg | Medium |
| BMI | Calculated from pre-op weight closest to surgery and height | | |
| BMI_HIGH_BAR | Calculated from highest recorded pre-op weight and height | | |
| HISTORY_DVT | Variable Name: Preoperative Vein Thrombosis Requiring Therapy | Yes; No | |
| VENOUS_ STASIS | Variable Name: Preoperative Venous Stasis | Yes; No | Medium |
| DIALYSIS | Variable Name: Preoperative Currently Requiring or On Dialysis | Yes; No | Medium |
| RENAL_ INSUFFICIENCY | Variable Name: Preoperative Renal Insufficiency | Yes; No | Medium |
| THERAPEUTIC_ ANTICOAGULATION | Variable Name: Preoperative Therapeutic Anticoagulation | Yes; No | Medium |
| DIABETES | Variable Name: Preoperative Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin | Non-Insulin<br>Insulin<br>No | |
| FUNSTAT PRESURG | Variable Name: Preoperative Functional Health Status | Independent<br>Partially Dependent<br>Totally Dependent<br>Unknown | |
| COPD | Variable Name: History of Severe COPD | Yes; No | |
| OXYGEN_ DEPENDENT | Variable Name: Preoperative Oxygen Dependent | Yes; No | Medium |
| SLEEP_APNEA | Variable Name: Preoperative Obstructive Sleep Apnea Requiring CPAP/BiPAP (or similar technology) | Yes; No | Medium |
| CHRONIC_ STEROIDS | Variable Name: Preoperative Steroid/Immunosuppressant Use for a Chronic Condition | Yes; No | |
| IVC_FILTER | Variable Name: Preoperative Does the patient have an IVC filter | Yes; No | Medium |
| IVC_TIMING | IVC Filter Timing | IVC filter placed in anticipation of the metabolic or bariatric procedure<br><br>IVC filter was preexisting<br>Unknown | Medium |
| ALBUMIN | Variable Name: Preoperative Lab Value Information | | Medium |
| DPRALBUM | Days from pre-operative Albumin to initial bariatric surgery operation date | | Low |
| HCT | Variable Name: Preoperative Lab Value Information | | Low |
| DPRHCT | Days from pre-operative Hematocrit to initial bariatric surgery operation date | | Low |
| CREATININE | Variable Name: Preoperative Lab Value Information | | Medium |
| DPRCREAT | Days from pre-operative Creatinine to initial bariatric surgery operation date | | Low |
| HEMO | Variable Name: Preoperative Lab Value Information | | Medium |
| DPRHEMO | Days from pre-operative Hemoglobin A1c to initial bariatric surgery operation date | | Low |

**Table 8**

***Outcome of the Third Round of the Phase I Delphi Study***

| Variable Name | Search Term in Variables and Definitions | Variable Options | Ranking |
|---|---|---|---|
| GERD | Variable Name: Gastroesophageal Reflux Disease (GERD) Requiring Medication (within 30 days prior to surgery) | Yes; No | High |
| MOBILITY_ DEVICE | Variable Name: Preoperative Is the Patient's Ambulation Limited Most or all of the Time | Yes; No | Low |
| HIP | Variable Name: Preoperative Hypertension Requiring Medication | Yes; No | Low |
| HTN_MEDS | Variable Name: Preoperative Number of Anti-Hypertensive Medications | 0, 1, 2, 3+ | High |
| HYPERLIPIDEMIA | Variable Name: Preoperative Hyperlipidemia Requiring Medication | Yes; No | Medium |
| HGT | Variable Name: Preoperative Height | | Low |
| WGT_HIGH_BAR | Variable Name: Highest Recorded Weight within 1 year at the Program | | Medium |
| WGT_HIGH_ UNIT_BAR | Highest Pre-op Weight Measurement Units | kg | Medium |
| WGT_CLOSEST | Variable Name: Weight Closest to Surgery | | Medium |
| WGTUNIT_ CLOSEST | Closest to Surgery Pre-op Weight Measurement Units | kg | Medium |
| BMI | Calculated from pre-op weight closest to surgery and height | | High |
| BMI_HIGH_BAR | Calculated from highest recorded pre-op weight and height | | High |
| HISTORY_DVT | Variable Name: Preoperative Vein Thrombosis Requiring Therapy | Yes; No | High |
| VENOUS_ STASIS | Variable Name: Preoperative Venous Stasis | Yes; No | Medium |
| DIALYSIS | Variable Name: Preoperative Currently Requiring or On Dialysis | Yes; No | Medium |
| RENAL_ INSUFFICIENCY | Variable Name: Preoperative Renal Insufficiency | Yes; No | Medium |
| THERAPEUTIC_ ANTICOAGULATION | Variable Name: Preoperative Therapeutic Anticoagulation | Yes; No | Medium |
| DIABETES | Variable Name: Preoperative Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin | Non-Insulin<br>Insulin<br>No | High |
| FUNSTAT PRESURG | Variable Name: Preoperative Functional Health Status | Independent<br>Partially Dependent<br>Totally Dependent<br>Unknown | High |
| COPD | Variable Name: History of Severe COPD | Yes; No | High |
| OXYGEN_ DEPENDENT | Variable Name: Preoperative Oxygen Dependent | Yes; No | Medium |
| SLEEP_APNEA | Variable Name: Preoperative Obstructive Sleep Apnea Requiring CPAP/BiPAP (or similar technology) | Yes; No | Medium |
| CHRONIC_ STEROIDS | Variable Name: Preoperative Steroid/Immunosuppressant Use for a Chronic Condition | Yes; No | High |
| IVC_FILTER | Variable Name: Preoperative Does the patient have an IVC filter | Yes; No | Medium |

| Variable Name | Search Term in Variables and Definitions | Variable Options | Ranking |
|---|---|---|---|
| IVC_TIMING | IVC Filter Timing | IVC filter placed in anticipation of the metabolic or bariatric procedure<br><br>IVC filter was preexisting<br>Unknown | Medium |
| ALBUMIN | Variable Name: Preoperative Lab Value Information | | Medium |
| DPRALBUM | Days from pre-operative Albumin to initial bariatric surgery operation date | | Low |
| HCT | Variable Name: Preoperative Lab Value Information | | Low |
| DPRHCT | Days from pre-operative Hematocrit to initial bariatric surgery operation date | | Low |
| CREATININE | Variable Name: Preoperative Lab Value Information | | Medium |
| DPRCREAT | Days from pre-operative Creatinine to initial bariatric surgery operation date | | Low |
| HEMO | Variable Name: Preoperative Lab Value Information | | Medium |
| DPRHEMO | Days from pre-operative Hemoglobin A1c to initial bariatric surgery operation date | | Low |

**Table 9**

***Summary of all 3 rounds of Phase I Delphi Study Ranked from High to Low***

| Variable Name | Search Term in Variables and Definitions | Ranking |
|---|---|---|
| GERD | Variable Name: Gastroesophageal Reflux Disease (GERD) Requiring Medication (within 30 days prior to surgery) | High |
| HTN_MEDS | Variable Name: Preoperative Number of Anti-Hypertensive Medications | High |
| BMI | Calculated from pre-op weight closest to surgery and height | High |
| BMI_HIGH_BAR | Calculated from highest recorded pre-op weight and height | High |
| HISTORY_DVT | Variable Name: Preoperative Vein Thrombosis Requiring Therapy | High |
| DIABETES | Variable Name: Preoperative Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin | High |
| FUNSTAT PRESURG | Variable Name: Preoperative Functional Health Status | High |
| COPD | Variable Name: History of Severe COPD | High |
| CHRONIC_ STEROIDS | Variable Name: Preoperative Steroid/Immunosuppressant Use for a Chronic Condition | High |
| HYPERLIPIDEMIA | Variable Name: Preoperative Hyperlipidemia Requiring Medication | Medium |
| WGT_HIGH_BAR | Variable Name: Highest Recorded Weight within 1 year at the Program | Medium |
| WGT_HIGH_ UNIT_BAR | Highest Pre-op Weight Measurement Units | Medium |
| WGT_CLOSEST | Variable Name: Weight Closest to Surgery | Medium |
| WGTUNIT_ CLOSEST | Closest to Surgery Pre-op Weight Measurement Units | Medium |

| Variable Name | Search Term in Variables and Definitions | Ranking |
|---|---|---|
| VENOUS_ STASIS | Variable Name: Preoperative Venous Stasis | Medium |
| DIALYSIS | Variable Name: Preoperative Currently Requiring or On Dialysis | Medium |
| RENAL_ INSUFFICIENCY | Variable Name: Preoperative Renal Insufficiency | Medium |
| THERAPEUTIC_ ANTICOAGULATION | Variable Name: Preoperative Therapeutic Anticoagulation | Medium |
| OXYGEN_ DEPENDENT | Variable Name: Preoperative Oxygen Dependent | Medium |
| SLEEP_APNEA | Variable Name: Preoperative Obstructive Sleep Apnea Requiring CPAP/BiPAP (or similar technology) | Medium |
| IVC_FILTER | Variable Name: Preoperative Does the patient have an IVC filter | Medium |
| IVC_TIMING | IVC Filter Timing | Medium |
| ALBUMIN | Variable Name: Preoperative Lab Value Information | Medium |
| CREATININE | Variable Name: Preoperative Lab Value Information | Medium |
| HEMO | Variable Name: Preoperative Lab Value Information | Medium |
| MOBILITY_ DEVICE | Variable Name: Preoperative Is the Patient's Ambulation Limited Most or all of the Time | Low |
| HIP | Variable Name: Preoperative Hypertension Requiring Medication | Low |
| HGT | Variable Name: Preoperative Height | Low |
| DPRALBUM | Days from pre-operative Albumin to initial bariatric surgery operation date | Low |
| HCT | Variable Name: Preoperative Lab Value Information | Low |
| DPRHCT | Days from pre-operative Hematocrit to initial bariatric surgery operation date | Low |
| DPRCREAT | Days from pre-operative Creatinine to initial bariatric surgery operation date | Low |
| DPRHEMO | Days from pre-operative Hemoglobin A1c to initial bariatric surgery operation date | Low |

The first research question (RQ1) asked about the important preoperative factors that may contribute to the likelihood that patients will have an ED visit within 30 days of bariatric surgery. Based on the third round of the Phase I Delphi study, the first research question was answered. Below is the list of 9 essential preoperative factors that may contribute to patients' likelihood of an ED visit within 30 days of bariatric surgery. These factors were selected as the potential predictors or independent variables for this research study.

- GERD – Gastroesophageal Reflux Disease (GERD) Requiring Medication (within 30 days prior to surgery)
- HTN_MEDS – Preoperative Number of Antihypertensive Medications

- BMI – Calculated from preop weight closest to surgery and height
- BMI_HIGH_BAR – Calculated from highest recorded preop weight and height
- HISTORY_DVT – Preoperative Vein Thrombosis Requiring Therapy
- DIABETES – Preoperative Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin
- FUNSTAT PRESURG – Preoperative Functional Health Status
- COPD – History of Severe COPD
- CHRONIC_STEROIDS – Preoperative Steroid/Immunosuppressant Use for Chronic Conditions

## Phase II Quantitative Analysis Findings

This research study utilized the MBSAQIP 2019 Participant Use Data File (PUF) database, which includes 206,570 cases submitted by 868 MBSAQIP-accredited bariatric surgery centers across the United States in 2019. After addressing missing or incomplete values, the valid dataset analyzed in Phase II of the study included 193,774 unique patients or cases. Rows eliminated from the dataset with the missing values 6.09% of the total dataset were assumed to have been missed randomly. Additional exclusion criteria and data limitations provided by the MBSAQIP program are noted in the Methodology section.

### Population Demographics

For the selected variables in Phase I of this study, further analysis was conducted to determine the demographic information and descriptive statistics of the population represented by this study during the Phase II of the study. Figure 7 shows the distribution of patients' ages, ranging from 10 to 80 years old, with a sample size of 193,774 (M = 45.24, SD = 12.13). Figure 8 provides a breakdown of race and shows that most (69.82%) of the patients were White, followed by Black or African American (18.55%). Figure 9 shows a chart of patient sex, which shows that most of the patients undergoing bariatric surgery were female (80.61%) versus male (19.32%). Figure 10 provides a breakdown of the patient's Hispanic ethnicity and shows that most of the patients going through the surgery were non-Hispanic (77.34%), followed by Hispanic (13.54%). Table 10 provides a summary of overall population demographics in this study.

**Table 10**

***Demographic Characteristics Summary***

| Demographic Characteristic | Frequency | Percentage Contribution |
|---|---|---|
| Age | | |
| 10 – 20 | 1,544 | 0.80% |
| 20 – 30 | 19,785 | 10.21% |
| 30 – 40 | 47,875 | 24.71% |
| 40 – 50 | 56,625 | 29.22% |
| 50 – 60 | 43,541 | 22.47% |
| 60 – 70 | 20,953 | 10.81% |
| 70 – 80 | 3,451 | 1.78% |
| Race | | |
| White | 135,290 | 69.82% |
| Black or African American | 35,952 | 18.55% |
| Unknown/ Not Reported | 20,039 | 10.34% |
| Asian | 1,034 | 0.53% |
| American Indian or Alaska Native | 943 | 0.49% |
| Native Hawaiian or Other Pacific Islander | 516 | 0.27% |
| Gender | | |
| Female | 156,203 | 80.61% |
| Male | 37,428 | 19.32% |
| Unknown/ Not Reported | 143 | 0.07% |
| Hispanic Ethnicity | | |
| No | 149,864 | 77.34% |
| Yes | 26,235 | 13.54% |
| Unknown/ Not Reported | 17,675 | 9.12% |

**Figure 7**

*Histogram of Patient Age*

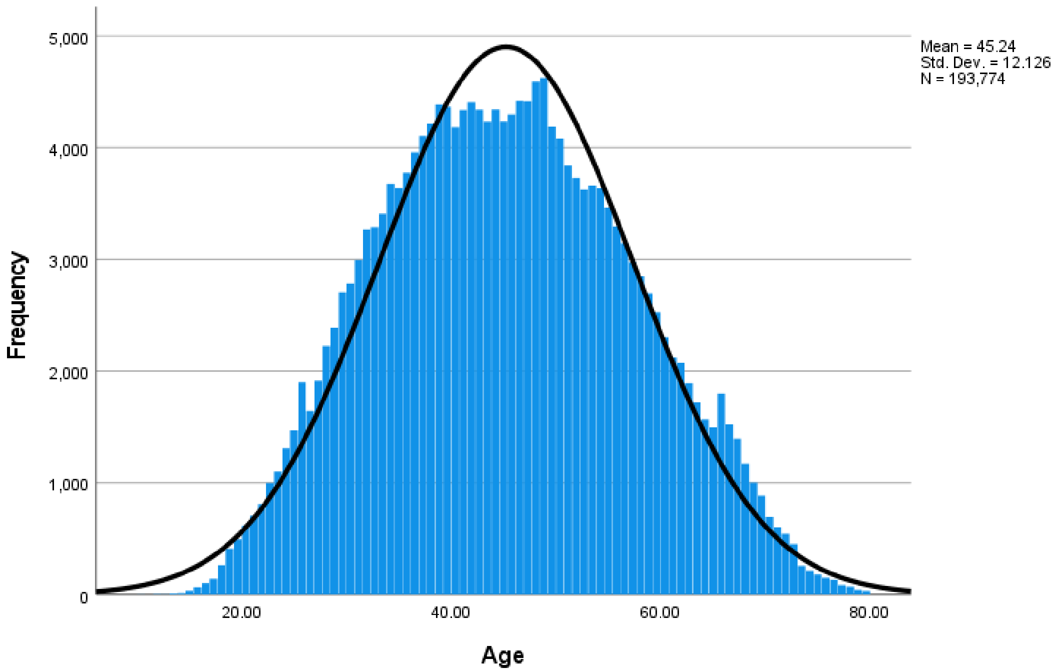



**Figure 8**

*Pie chart of the patient's race*

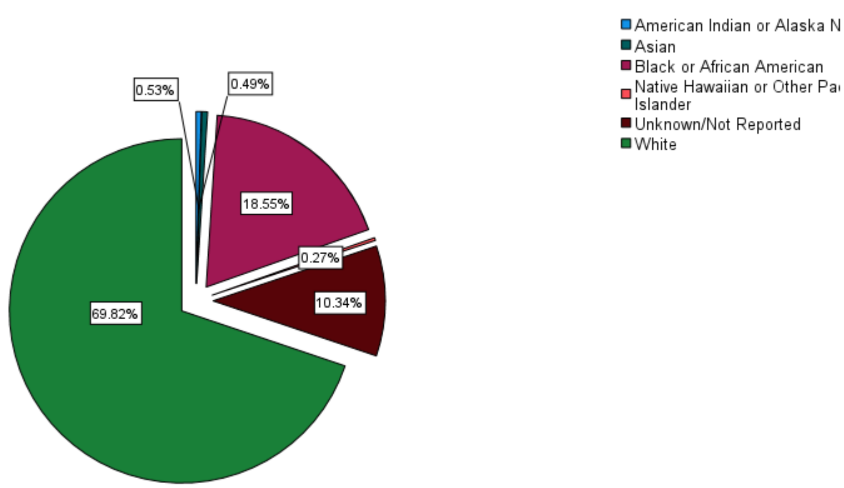



**Figure 9**

*Bar Chart of Patient's Gender*

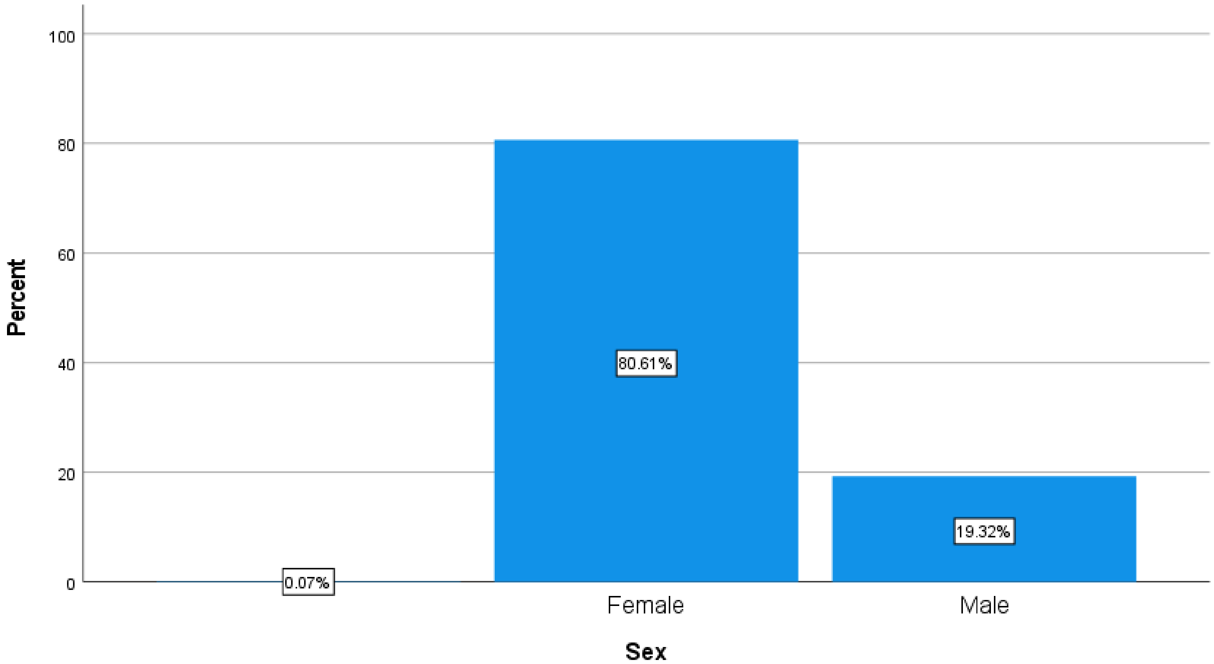
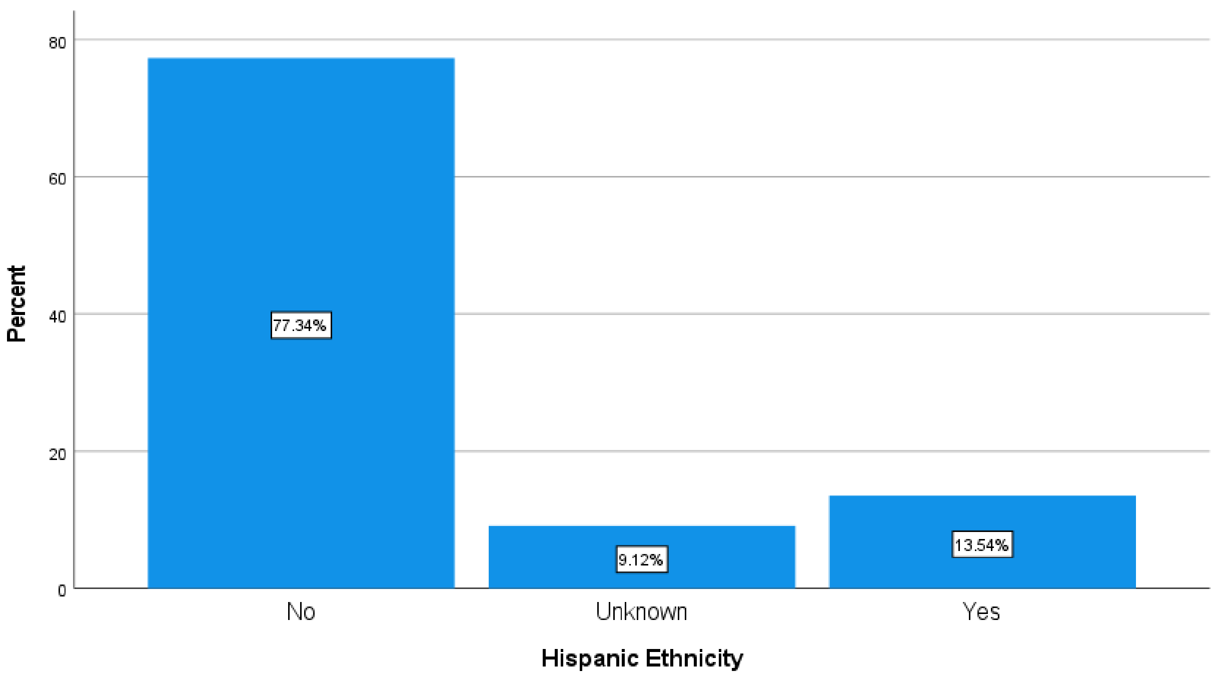



**Figure 10**

*Bar Chart of Patient Hispanic Ethnicity*



**Assumptions Testing for Binomial Logistics Regression**

Warner (2013e) states that, unlike analyses that are special cases of general linear models, such as discriminant analysis and multiple linear regression, binomial logistic regression does not require such restrictive assumptions. Before the analysis was conducted, the following assumptions for binomial logistic regression were confirmed to be plausible.

(a) The dependent or the outcome variable is dichotomous: This assumption is valid because the outcome variable is dichotomous, i.e., the outcome is either a ‘Yes’ or a ‘No’.

(b) There can be one or more independent variables that can be either categorical or continuous: There were seven categorical and two continuous variables for this study

(c) The model should be correctly specified, i.e., it should only include predictors or independent variables of relevant practical significance: This part was true because the independent variables were selected after consulting with the panel of experts.

(d) Data should not show multicollinearity: To validate this assumption, output from Jamovi Software (The Jamovi Project Version 1.6., 2021b) was utilized. A guideline to test the multicollinearity between all the independent variables in the equation suggests that the Variation Inflation Factor (VIF) value of 1 means the variables are not correlated. VIF value between 1 and 5 represents the moderately correlated variables. VIF value above five means variables are highly correlated (Daoud, 2017). Researchers also have a general rule of thumb that VIF < 5 is a generally acceptable level for multicollinearity (Information Resources Management Association, 2020). Since the output obtained from the Collinearity Statistics has all the values for VIF below 5 (Table 11), the assumption that the data does not show multicollinearity was correct. Only two variables out of 9 exhibited a VIF value of close to 3.5, and the other seven variables are close to the VIF value of 1.

**Table 11**

***Outcome of the Multicollinearity Test***

| | VIF | Tolerance |
|---|---|---|
| BMI | 3.49 | 0.287 |
| BMI_HIGH_BAR | 3.49 | 0.287 |
| GERD | 1.02 | 0.983 |
| HTN_MEDS | 1.02 | 0.977 |
| HISTORY_DVT | 1 | 0.995 |
| DIABETES | 1.03 | 0.972 |
| FUNSTATPRESURG | 1 | 0.998 |
| COPD | 1.01 | 0.99 |
| CHRONIC_STEROIDS | 1 | 0.996 |

(e) There should be a linear relationship between any continuous independent variables and the logit transformation of the dependent variable: This assumption was tested by utilizing the Box-Tidwell method in SPSS. To perform the Box-Tidwell test, the continuous independent variables Pre-Op BMI closest to bariatric surgery (BMI) and Highest Recorded Pre-Op BMI (BMI_HIGH_BAR) were transformed to create two new columns for their natural log transformation values. The newly created natural log value for each variable was multiplied with the original variable to create two new interaction terms (Pre-Op BMI closest to bariatric surgery by the natural log of Pre-Op BMI closest to bariatric surgery, and Highest Recorded Pre-Op BMI by the natural log of Highest Recorded Pre-Op BMI). Upon running a binominal logistic regression procedure with the interaction terms, Variables in the Equation for Box-Tidwell (Table 12) was obtained. Although the interaction terms for both variables were statistically significant ($p < 0.05$) suggesting the assumption of linearity in the logit was violated. However, based on O'Connell (2006) and Wuensch (2021a), it was concluded that the linearity in the logit was plausible for both continuous variables in this study given the larger sample size and meeting all of the other binominal logistics regression assumptions.

**Table 12**

***Variables in the Equation for Box-Tidwell Test***

| | | B | S.E. | Wald | df | Sig. |
|---|---|---|---|---|---|---|
| Step 1[a] | Pre-Op GERD requiring medication (1) | 0.290 | 0.018 | 271.122 | 1 | 0.000 |
| | Number of Hypertensive Medications | | | 75.810 | 3 | 0.000 |
| | Number of Hypertensive Medications (1) | -0.144 | 0.022 | 41.114 | 1 | 0.000 |
| | Number of Hypertensive Medications (2) | -0.168 | 0.025 | 43.737 | 1 | 0.000 |
| | Number of Hypertensive Medications (3) | -0.162 | 0.031 | 27.616 | 1 | 0.000 |
| | Pre-Op BMI closest to bariatric surgery | -0.327 | 0.067 | 23.535 | 1 | 0.000 |
| | Highest Recorded Pre-Op BMI | 0.239 | 0.065 | 13.318 | 1 | 0.000 |
| | Pre-Op Vein Thrombosis Requiring Therapy (1) | 0.351 | 0.053 | 44.200 | 1 | 0.000 |
| | Pre-Op Diabetes Mellitus | | | 16.937 | 2 | 0.000 |
| | Pre-Op Diabetes Mellitus (1) | -0.098 | 0.032 | 9.054 | 1 | 0.003 |
| | Pre-Op Diabetes Mellitus (2) | -0.150 | 0.037 | 16.875 | 1 | 0.000 |
| | Pre-Op Functional Health Status | | | 1.812 | 3 | 0.612 |
| | Pre-Op Functional Health Status (1) | 0.085 | 0.104 | 0.672 | 1 | 0.412 |
| | Pre-Op Functional Health Status (2) | 0.298 | 0.323 | 0.852 | 1 | 0.356 |
| | Pre-Op Functional Health Status (3) | 0.118 | 0.215 | 0.305 | 1 | 0.581 |
| | Pre-Op history of COPD (1) | 0.154 | 0.064 | 5.825 | 1 | 0.016 |
| | Pre-Op Steroid/Immunosuppressant Use for Chronic Condition (1) | 0.232 | 0.053 | 19.124 | 1 | 0.000 |
| | Pre-Op BMI closest to bariatric surgery by LN_BMI | 0.065 | 0.014 | 21.754 | 1 | 0.000 |
| | Highest Recorded Pre-Op BMI by LN_BMI_High | -0.045 | 0.013 | 11.406 | 1 | 0.00073 |
| | Constant | -1.887 | 0.283 | 44.558 | 1 | 0.000 |

| | B | S.E. | Wald | df | Sig. |
|---|---|---|---|---|---|

[a.] Variable(s) entered on step 1: Pre-Op GERD requiring medication, Number of Hypertensive Medications, Pre-Op BMI closest to bariatric surgery, Highest Recorded Pre-Op BMI, Pre-Op Vein Thrombosis Requiring Therapy, Pre-Op Diabetes Mellitus, Pre-Op Functional Health Status, Pre-Op history of COPD, Pre-Op Steroid/Immunosuppressant Use for Chronic Condition, Pre-Op BMI closest to bariatric surgery * LN_BMI, Highest Recorded Pre-Op BMI * LN_BMI_High

**Binomial Logistic Regression (The Enter Method)**

The Case Processing Summary (Table 13) provides information regarding the total number of cases included in the final analysis. There were a total of 193,774 unique cases or rows and zero missing cases.

**Table 13**

***Case Processing Summary***

| Unweighted Cases[a] | | N | Percent |
|---|---|---|---|
| Selected Cases | Included in Analysis | 193774 | 100.0 |
| | Missing Cases | 0 | 0.0 |
| | Total | 193774 | 100.0 |
| Unselected Cases | | 0 | 0.0 |
| Total | | 193774 | 100.0 |

[a.] If weight is in effect, see classification table for the total number of cases.

The dependent variable encoding (Table 14) provides information regarding how the outcome variable is encoded in the analysis. If the response to the outcome variable EMERG_VISIT_OUT (Was the Patient Seen in any Emergency Department (ED) which did not result in an Inpatient Admission?) is a ‘No’, the internal value is coded as ‘0’, and if the response of the outcome variable is ‘Yes’, the internal value is coded as ‘1’.

**Table 14**

***Dependent Variable Encoding***

| Original Value | Internal Value |
|---|---|
| No | 0 |
| Yes | 1 |

Similarly, all the seven categorical independent variables are coded automatically by the statistical software utilized (IBM SPSS Statistics 25, 2021b), and all the values coded are shown (Table 15).

**Table 15**

***Categorical Variables’ Coding***

| | | | Parameter coding | | |
|---|---|---|---|---|---|
| | | Frequency | (1) | (2) | (3) |
| Number of Hypertensive Medications | 0 | 105452 | 0.000 | 0.000 | 0.000 |
| | 1 | 40147 | 1.000 | 0.000 | 0.000 |
| | 2 | 29576 | 0.000 | 1.000 | 0.000 |
| | 3+ | 18599 | 0.000 | 0.000 | 1.000 |
| Pre-Op Functional Health Status | Independ | 192333 | 0.000 | 0.000 | 0.000 |
| | Partially | 1086 | 1.000 | 0.000 | 0.000 |
| | Totally | 91 | 0.000 | 1.000 | 0.000 |
| | Unknown | 264 | 0.000 | 0.000 | 1.000 |
| Pre-Op Diabetes Mellitus | Insulin | 14324 | 0.000 | 0.000 | |
| | No | 146848 | 1.000 | 0.000 | |
| | Non-Insulin | 32602 | 0.000 | 1.000 | |
| Pre-Op Vein Thrombosis Requiring Therapy | No | 190078 | 0.000 | | |
| | Yes | 3696 | 1.000 | | |
| Pre-Op Steroid/Immunosuppressant Use for Chronic Condition | No | 189746 | 0.000 | | |
| | Yes | 4028 | 1.000 | | |
| Pre-Op history of COPD | No | 190913 | 0.000 | | |

| | | Frequency | Parameter coding (1) | (2) | (3) |
|---|---|---|---|---|---|
| | Yes | 2861 | 1.000 | | |
| Pre-Op GERD requiring medication | No | 130472 | 0.000 | | |
| | Yes | 63302 | 1.000 | | |

The enter method in binomial logistic regression involves entering all the variables simultaneously in the same step. The omnibus tests of model coefficients are essential to understand how the new model, including all the explanatory variables (same as independent variables or predictors), compares to the baseline model, which does not include the explanatory variables. Table 16 shows that omnibus tests of model coefficients show that the chi-square value is highly significant ($\chi^2 = 477.937, df = 14, p < 0.001$), i.e., the null hypothesis is rejected, suggesting that the addition of the independent variables in the model improved the predictive power of the model and explains more of the variance in the outcome compared to the baseline model. Another way to interpret this is that the Model with the exploratory variables is highly statistically significant ($p < 0.001$).

**Table 16**

***Omnibus Tests of Model Coefficients***

| | | Chi-square | df | Sig. |
|---|---|---|---|---|
| Step 1 | Step | 477.937 | 14 | 0.000 |
| | Block | 477.937 | 14 | 0.000 |
| | Model | 477.937 | 14 | 0.000 |

Table 17 provides information on the -2 Log-likelihood value, Cox & Snell $R^2$ and Nagelkerke's $R^2$ values (also known as Pseudo $R^2$ values) for the full model. The Cox & Snell $R^2$ and Nagelkerke's $R^2$ values suggest that the model explains between 3% and 6% of the variation in the outcome variable. This value is low and shows poor fit; however, researchers suggest that

$R^2$ values for logistic regression are approximations and should not be overly emphasized (Using Statistical Regression Methods in Education Research, 2011).

**Table 17**

***Model Summary***

| Step | -2 Log likelihood | Cox & Snell R Square | Nagelkerke R Square |
|---|---|---|---|
| 1 | 107710.325[a] | 0.002 | 0.006 |

[a.] Estimation terminated at iteration number 5 because parameter estimates changed by less than .001.

As shown in Table 18, the Hosmer & Lemeshow test, sometimes referred to as the goodness of fit test, suggested that the model was not a good fit to the data ($\chi^2 = 20.958, df = 8, p < 0.05$). MacInnes (2016a) makes an essential point regarding the Hosmer & Lemeshow test that too much statistical power may occur if the sample size is larger than 1,000. Hosmer & Lemeshow highlight that failed Hosmer & Lemeshow test alone should not be used to conclude the findings regarding whether the model fits the data. Large cell frequencies with minor differences in each decile between observed and modeled outcomes should be considered to decide if the data has a good model fit despite a low $p$-value associated with the table chi-square.

**Table 18**

***Hosmer and Lemeshow Test***

| Step | Chi-square | df | Sig. |
|---|---|---|---|
| 1 | 20.958 | 8 | 0.007 |

Hosmer and Lemeshow Test suggested that there may not be an acceptable match between predicted and observed probabilities. To address this concern, as indicated by Hosmer and Lemeshow (MacInnes, 2016b), Contingency Table for Hosmer and Lemeshow Test was reviewed, which showed the observed and expected frequencies for the prediction model matched reasonably well (Table 19).

**Table 19**

***Contingency Table for Hosmer and Lemeshow Test***

| | | Was the patient seen in any emergency department (ED) which did not result in an inpatient admission? = No | | Was the patient seen in any emergency department (ED) which did not result in an inpatient admission? = Yes | | |
|---|---|---|---|---|---|---|
| | | Observed | Expected | Observed | Expected | Total |
| Step 1 | 1 | 18191 | 18174.081 | 1186 | 1202.919 | 19377 |
| | 2 | 18061 | 18084.072 | 1316 | 1292.928 | 19377 |
| | 3 | 18079 | 17995.432 | 1290 | 1373.568 | 19369 |
| | 4 | 17996 | 17951.104 | 1381 | 1425.896 | 19377 |
| | 5 | 17859 | 17910.065 | 1518 | 1466.935 | 19377 |
| | 6 | 17786 | 17857.937 | 1592 | 1520.063 | 19378 |
| | 7 | 17779 | 17781.137 | 1598 | 1595.863 | 19377 |
| | 8 | 17579 | 17669.005 | 1798 | 1707.995 | 19377 |
| | 9 | 17570 | 17529.329 | 1807 | 1847.671 | 19377 |
| | 10 | 17341 | 17288.838 | 2047 | 2099.162 | 19388 |

The core and most important output of the binary logistic regression lies in Table 20, called Variables in the Equation. This table provides the slope for each predictor (independent variable) and which of the predictors are statistically significant, contributing to the likelihood of patients returning to the ED within 30 days of bariatric surgery. It is important to note that each categorical variable termed a categorical covariate in SPSS, should be chosen to have a reference or baseline category as first or last. The default setting of contrast (Indicator) was selected during the set-up process. This means SPSS creates dummy variables for each category to compare against a specified reference category (Logistic Node Model Options, 2017).

As shown in Figure 11, the first label of all the categorical variables was selected as the baseline category. For example, GERD(Indicator(first)) means for this independent variable from the list of 7 categorical variables, the value of zero (which was coded from “No” value) will be selected as baseline or reference category based on Table 13, where SPSS coding of the different labels of categorical variables was taken as default. This indicates that if, say, the GERD variable has a positive coefficient (slope) with statistical significance ($p < 0.05$), this would mean that patients with GERD value of 1 (which is basically coded value of “Yes”) is associated with increased odds of coming back to ED within 30 days of a bariatric surgery. Also, if an independent variable has (1) next to it, it denotes that it is a reference category for that variable. Symbols (2) and (3) next to independent variables (such as in Table 20) represents the other labels of the categorical independent variable that are to be compared against the reference label of the same variable.

**Figure 11**

***Screen shot of categorical variables with reference categories in SPSS***

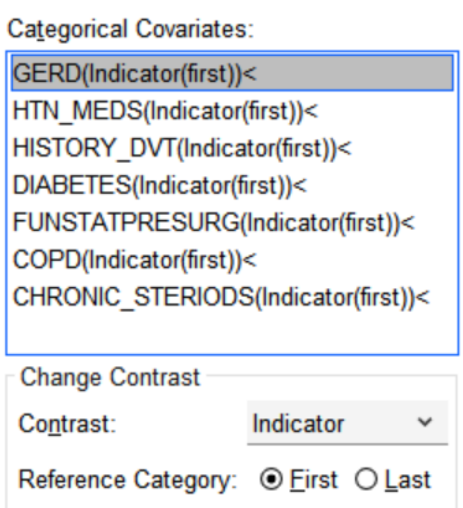



**Table 20**

***Variables in the Equation***

| | | B | S.E. | Wald | df | Sig. | Exp(B) |
|---|---|---|---|---|---|---|---|
| Step 1[a] | Pre-Op GERD requiring medication (1) | 0.293 | 0.018 | 278.918 | 1 | 0.000 | 1.341 |

| | B | S.E. | Wald | df | Sig. | Exp(B) |
|---|---|---|---|---|---|---|
| Number of Hypertensive Medications | | | 76.873 | 3 | 0.000 | |
| Number of Hypertensive Medications (1) | -0.144 | 0.022 | 41.205 | 1 | 0.000 | 0.866 |
| Number of Hypertensive Medications (2) | -0.170 | 0.025 | 44.585 | 1 | 0.000 | 0.844 |
| Number of Hypertensive Medications (3) | -0.164 | 0.031 | 28.258 | 1 | 0.000 | 0.849 |
| Pre-Op BMI closest to bariatric surgery | -0.012 | 0.003 | 12.153 | 1 | 0.000 | 0.988 |
| Highest Recorded Pre-Op BMI | 0.018 | 0.003 | 31.982 | 1 | 0.000 | 1.019 |
| Pre-Op Vein Thrombosis Requiring Therapy (1) | 0.354 | 0.053 | 44.997 | 1 | 0.000 | 1.425 |
| Pre-Op Diabetes Mellitus | | | 16.993 | 2 | 0.000 | |
| Pre-Op Diabetes Mellitus (1) | -0.096 | 0.032 | 8.787 | 1 | 0.003 | 0.908 |
| Pre-Op Diabetes Mellitus (2) | -0.151 | 0.037 | 16.891 | 1 | 0.000 | 0.860 |
| Pre-Op Functional Health Status | | | 2.046 | 3 | 0.563 | |
| Pre-Op Functional Health Status (1) | 0.097 | 0.104 | 0.877 | 1 | 0.349 | 1.102 |
| Pre-Op Functional Health Status (2) | 0.298 | 0.323 | 0.852 | 1 | 0.356 | 1.347 |
| Pre-Op Functional Health Status (3) | 0.124 | 0.215 | 0.332 | 1 | 0.564 | 1.132 |
| Pre-Op history of COPD (1) | 0.159 | 0.064 | 6.228 | 1 | 0.013 | 1.173 |
| Pre-Op Steroid/Immunosuppressant Use for Chronic Condition (1) | 0.233 | 0.053 | 19.206 | 1 | 0.000 | 1.262 |
| Constant | -2.710 | 0.056 | 2338.790 | 1 | 0.000 | 0.067 |

[a.] Variable(s) entered on step 1: Pre-Op GERD requiring medication, Number of Hypertensive Medications, Pre-Op BMI closest to bariatric surgery, Highest Recorded Pre-Op BMI, Pre-Op Vein Thrombosis Requiring Therapy, Pre-Op Diabetes Mellitus, Pre-Op Functional Health Status, Pre-Op history of COPD, Pre-Op Steroid/Immunosuppressant Use for Chronic Condition.

Substituting values from Table 20 into equations (2.3) and (2.4), equation (2.5) provides the fitted model based on the Enter Method of the Binary Logistic Regression.

$$Ln\left(\frac{\hat{p}_i}{1-\hat{p}_i}\right) = -2.710 + 0.293\,X_1 - 0.144\,X_{2a} - 0.170\,X_{2b} - 0.164\,X_{2c} - 0.012\,X_3 + 0.018\,X_4 + 0.354\,X_5 - 0.096\,X_{6a} - 0.151\,X_{6b} + 0.097\,X_{7a} + 0.298\,X_{7b} + 0.124\,X_{7c} + 0.159\,X_8 + 0.233\,X_9 \quad \textit{Equation (2.5)}$$

Where,

$X_1$ = Pre-Op GERD requiring medication (values of 0 or 1)

$X_{2a}$ = Number of Hypertensive Medications (values of 0 or 1)

$X_{2b}$ = Number of Hypertensive Medications (values of 0 or 2)

$X_{2c}$ = Number of Hypertensive Medications when values of 0 or 3)

$X_3$ = Pre-Op BMI closest to bariatric surgery (values between 15 and 150)

$X_4$ = Highest Recorded Pre-Op BMI (values between 15 and 150)

$X_5$ = Pre-Op vein thrombosis requiring therapy (values of 0 or 1)

$X_{6a}$ = Pre-Op Diabetes Mellitus (values of 0 or 1)

$X_{6b}$ = Pre-Op Diabetes Mellitus (values of 0 or 2)

$X_{7a}$ = Pre-Op Functional Health Status (values of 0 or 1)

$X_{7b}$ = Pre-Op Functional Health Status (values of 0 or 2)

$X_{7c}$ = Pre-Op Functional Health Status (values of 0 or 3)

$X_8$ = Pre-Op history of COPD (values of 0 or 4)

$X_9$ = Pre-Op Steroid/Immunosuppressant Use for Chronic Condition (values of 0 or 1)

The second research question asked to identify the factors that significantly contribute to the likelihood that patients will have an ED visit within 30 days of bariatric surgery. The proposed null hypothesis, slope or regression value for each predictor equals zero, i.e., $\beta_i =$

$0\ , where\ i = 1\ to\ 9$ was not true. This means rejecting the null hypothesis and going with an alternative hypothesis that was at least the slope or regression value for one predictor is not equal to zero, i.e., $\beta_i \neq 0$, for at least one independent variable.

Based on equation (2.5), Wald statistics and significance level $(p < 0.05)$ in Table 18, all independent variables except $X_7$ (Pre-Op Functional Health Status) were significant. The following variables were significant in predicting the odds of patients returning to the ED within 30 days of bariatric surgery:

$X_1$ = Pre-Op GERD requiring medication (values of 0 or 1)

$X_{2a}$ = Number of Hypertensive Medications (values of 0 or 1)

$X_{2b}$ = Number of Hypertensive Medications (values of 0 or 2)

$X_{2c}$ = Number of Hypertensive Medications when values of 0 or 3)

$X_3$ = Pre-Op BMI closest to bariatric surgery (values between 15 and 150)

$X_4$ = Highest Recorded Pre-Op BMI (values between 15 and 150)

$X_5$ = Pre-Op vein thrombosis requiring therapy (values of 0 or 1)

$X_{6a}$ = Pre-Op Diabetes Mellitus (values of 0 or 1)

$X_{6b}$ = Pre-Op Diabetes Mellitus (values of 0 or 2)

$X_8$ = Pre-Op history of COPD (values of 0 or 4)

$X_9$ = Pre-Op Steroid/Immunosuppressant Use for Chronic Condition (values of 0 or 1)

The third research question asked if a model can be developed using only the statistically significant and weighted predictors as well statistical validation of the model fit. Analysis was conducted again only by selecting the statistically significant factors that yielded a desired output (Table 21) with a model (equation 2.6) with all selected variables with Wald statistics giving a statistically significant effect $(p < 0.05)$. It is also important to note that only variable $X_{6a}$ had a p value of 0.003 ($p < 0.05$), and the rest of the variables had a p value of less than or equal to 0.001 ($p < 0.01$), denoting high statistical significance.

**Table 21**

***Variables in the Equation - Revised***

| | | B | S.E. | Wald | df | Sig. | Exp(B) |
|---|---|---|---|---|---|---|---|
| Step 1[a] | Pre-Op GERD requiring medication (1) | 0.294 | 0.018 | 279.862 | 1 | 0.000 | 1.341 |
| | Number of Hypertensive Medications | | | 76.618 | 3 | 0.000 | |
| | Number of Hypertensive Medications (1) | -0.144 | 0.022 | 41.110 | 1 | 0.000 | 0.866 |
| | Number of Hypertensive Medications (2) | -0.170 | 0.025 | 44.462 | 1 | 0.000 | 0.844 |
| | Number of Hypertensive Medications (3) | -0.164 | 0.031 | 28.058 | 1 | 0.000 | 0.849 |
| | Pre-Op BMI closest to bariatric surgery | -0.012 | 0.003 | 12.189 | 1 | 0.000 | 0.988 |
| | Highest Recorded Pre-Op BMI | 0.018 | 0.003 | 32.276 | 1 | 0.000 | 1.019 |
| | Pre-Op Vein Thrombosis Requiring Therapy (1) | 0.356 | 0.053 | 45.498 | 1 | 0.000 | 1.427 |
| | Pre-Op Diabetes Mellitus | | | 17.227 | 2 | 0.000 | |
| | Pre-Op Diabetes Mellitus (1) | -0.097 | 0.032 | 9.021 | 1 | 0.003 | 0.907 |
| | Pre-Op Diabetes Mellitus (2) | -0.152 | 0.037 | 17.141 | 1 | 0.000 | 0.859 |
| | Pre-Op history of COPD (1) | 0.163 | 0.064 | 6.531 | 1 | 0.011 | 1.177 |
| | Pre-Op Steroid/Immunosuppressant Use for Chronic Condition (1) | 0.234 | 0.053 | 19.505 | 1 | 0.000 | 1.264 |
| | Constant | -2.712 | 0.056 | 2341.940 | 1 | 0.000 | 0.066 |

a. Variable(s) entered on step 1: Pre-Op GERD requiring medication, Number of Hypertensive Medications, Pre-Op BMI closest to bariatric surgery, Highest Recorded Pre-Op BMI, Pre-Op Vein Thrombosis Requiring Therapy, Pre-Op Diabetes Mellitus, Pre-Op history of COPD, Pre-Op Steroid/Immunosuppressant Use for Chronic Condition.

The first part of the third research question was answered by equation (2.6), with all variables having a statistically significant impact on the odds of patients returning to the ED within 30 days of a bariatric procedure. It is important to note that impact of each independent variable on the dependent variable can be determined by running the binomial logistic regression model with only DV and one IV. However, researcher needs to make sure that such relationship between DV and IV has a practical significance. For example, in the context of 30-day postoperative ED visit, determining impact of each IV to the DV is mathematically possible but researcher decided that it would not add value to the overall analysis. In other words, the novelty and focus of this study is the collective impact of 9 IVs to the DV versus understanding one-on-one relationship between each IV and DV.

$$Ln\left(\frac{\hat{p}_i}{1-\hat{p}_i}\right) = -2.712 + 0.294\,X_1 - 0.144\,X_{2a} - 0.170\,X_{2b} - 0.164\,X_{2c} - 0.012\,X_3 + 0.018\,X_4 + 0.356\,X_5 - 0.097\,X_{6a} - 0.152\,X_{6b} + 0.163\,X_8 + 0.234\,X_9 \qquad \textit{Equation (2.6)}$$

Where,

$X_1$ = Pre-Op GERD requiring medication (values of 0 or 1)

$X_{2a}$ = Number of Hypertensive Medications (values of 0 or 1)

$X_{2b}$ = Number of Hypertensive Medications (values of 0 or 2)

$X_{2c}$ = Number of Hypertensive Medications when values of 0 or 3)

$X_3$ = Pre-Op BMI closest to bariatric surgery (values between 15 and 150)

$X_4$ = Highest Recorded Pre-Op BMI (values between 15 and 150)

$X_5$ = Pre-Op vein thrombosis requiring therapy (values of 0 or 1)

$X_{6a}$ = Pre-Op Diabetes Mellitus (values of 0 or 1)

$X_{6b}$ = Pre-Op Diabetes Mellitus (values of 0 or 2)

$X_8$ = Pre-Op history of COPD (values of 0 or 4)

$X_9$ = Pre-Op Steroid/Immunosuppressant Use for Chronic Condition (values of 0 or 1)

**Table 22**

***Hosmer and Lemeshow Test – Revised***

| Step | Chi-square | df | Sig. |
|---|---|---|---|
| 1 | 22.152 | 8 | 0.005 |

To answer the second part of the third research question, the Hosmer & Lemeshow test was utilized. Based on the output in Table 22, the findings suggest that the model was not a good fit to the data ($\chi^2 = 22.152, df = 8, p < 0.05$). In other words, the model was a poor fit to the data. Kramer and Zimmerman (2007) suggest that a significant Hosmer & Lemeshow test for studies with larger sample sizes does not mean that a predictive model is not useful. Researchers suggest that additional information and results should also be taken into consideration when making model decisions (Turner et al., 2015; Wuensch, 2021b). However, the omnibus tests of the model coefficients (Table 23) show that the chi-square value was highly significant ($\chi^2 = 475.982, df = 11, p < 0.001$) i.e., the null hypothesis is rejected, suggesting that the model with the exploratory variables was statistically significant.

**Table 23**

***Omnibus Tests of Model Coefficients – Revised***

| | | Chi-square | df | Sig. |
|---|---|---|---|---|
| Step 1 | Step | 475.982 | 11 | 0.000 |
| | Block | 475.982 | 11 | 0.000 |
| | Model | 475.982 | 11 | 0.000 |

To explore the model fit issue further and accuracy of the model as well as to explore practical application of the model, classification table was obtained (Table 24) for the dataset at the standard threshold or cut-off value for predicted probability of 0.5. With the standard threshold value of 0.5, overall model accuracy was 92% where model predicted "No" outcome 100% of the time, and model predicted "Yes" 0% of the time.

**Table 24**

***Classification Table with Standard Threshold Value for Predicted Probability of 0.5***

| Was the patient seen in any emergency department (ED) which did not result in an inpatient admission? | | | | |
|---|---|---|---|---|
| | | Predicted | | |
| | | No | Yes | Percentage Correct |
| Observed | No | 178241 | 0 | 100.0 |
| | Yes | 15533 | 0 | .0 |
| Overall Percentage | | | | 92.0 |

a. The cut off or threshold value is .500

## Phase III Delphi Study Findings

Like the Phase I Delphi Study, the Phase III Delphi study took place in a virtual setting. A structured virtual meeting was scheduled between the same panel of experts. The first part of the meeting included a review of the results from Phase I and Phase II of the study.

The findings of the Phase I Delphi study were to obtain consensus from the panel of experts on the final list of independent variables, which was the answer to the first research question. The panel of experts ranked 33 preoperative factors into low, medium, and high tiers. The panel of experts landed on nine independent variables for the study. The Phase II Quantitative Analysis findings were the answers to two research questions. The second research question was to identify significant factors from the list of 9 independent variables or factors that may contribute to the likelihood of patients returning to the ED within 30 days of a bariatric procedure. Eight variables among the list of nine independent variables were statistically significant. Next, the first part of the third research question was to answer if a model could be developed using only statistically significant and weighted predictors. The answer was ‘yes’, and the model was developed. The second part of the third research question was to check if the model had an acceptable fit that was false. In other words, the model did not show a good fit or showed a poor fit.

The fourth research question asked subject matter experts’ perceptions of the model developed and overall findings. The questionnaire handed to the panel of experts included four questions with ‘Agree’ and ‘Disagree’ options and three open-ended questions at the bottom of the questionnaire for commentary response. A panel of experts responded individually, and the following outcome was obtained.

The panel of experts unanimously agreed (100% agreement) on the first four questions and concluded the following:

- Understanding preoperative factors before surgery is beneficial for the bariatric patient population from a clinical perspective.
- The proactive approach is preferred over the reactive approach when dealing with 30-day postoperative ED visits for bariatric patients.
- The Phase II quantitative analysis section results make practical significance clinically and operationally.
- Suppose Phase II findings are translated to the bariatric department’s day-to-day operations and practice. In that case, there is value in these findings for both patients and care teams providing care to the bariatric patient population.

Below is the consolidated form of the commentary response received from the panel of experts.

- At this point, the panel of experts does not suggest revising the list of independent variables in Phase II of the study. However, this could be a potential research topic and exploration for future studies.
- Many variables have clinical and operational significance and are tracked in the clinic and hospital settings, but they are not reported to the MBSAQIP database. This study is limited in that it does not include the socioeconomic status of patients, such as insurance type and education level, and other pertinent factors that are tracked in the clinical and hospital settings but are not required to be reported MBSAQIP.
- For future research studies related to this topic, it is suggested that researchers work directly with MBSAQIP accredited centers to apply the findings to real-world practice.

CHAPTER 5

# CONCLUSION, DISCUSSION, AND RECOMMENDATIONS

This chapter includes the overall conclusion of the findings, a discussion of the research outcome, and recommendations for future work. This section provides a summary on the purpose of the study, summary of the research procedure with answers to the research questions and hypothesis proposed, reflection on the data source, population, and overall findings of the research study.

## Conclusion

Emergency department visits are costly. Preventing avoidable and unnecessary ED visits can help US Healthcare save billions of dollars annually. Unnecessary ED visits could mean poor care management, poor access to care, or poor patient choices due to a lack of knowledge or information. It is estimated that approximately one-fourth of ED visits in the United States could potentially be managed by doctors' offices, clinics, and urgent care centers (Preventable emergency department visits, 2018). This research study focused on a subset of the United States patient population, i.e., patients who underwent bariatric surgery in one of the MBSAQIP accredited centers in the United States. This study utilized the 2019 MBSAQIP Participant Use Data File (PUF), which includes 193,774 bariatric surgery cases submitted by 868 MBSAQIP accredited centers throughout the United States. Based on the MBSAQIP PUF database, 8% of the patients who underwent bariatric surgery were seen in an emergency department within 30 days of the procedure, which did not result in inpatient admission. In other words, 8% of the patients could have avoided an ED visit either by being seen in a clinic or urgent care setting or through appropriate coordination of care in various forms (medication, patient education, follow-up via phone or virtually, etc.). The MBSAQIP PUF Database is a Health Insurance Portability and Accountability Act (HIPAA)-compliant data file. MBSAQIP's purpose in making the dataset available to participating centers is to help researchers explore research questions to help advance the quality of care through data analysis and research. On April 1, 2012, the American College of Surgeons (ACS) and the American Society for Metabolic and Bariatric Surgery (ASMBS) merged their national bariatric accreditation programs into a single program called the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) (MBSAQIP, n.d.). MBSAQIP PUF database being comparatively new, extensive, and systematic literature review, yielded a handful of peer-reviewed articles. There were approximately 100 articles with 30-day ED visit-related keywords on their title and abstracts within the published articles. None of the articles focused on the impact of preoperative factors or variables only on the 30-day postop ED visit that did not result in an inpatient admission. It was also an important finding that there were no Ph.D. dissertations published utilizing the MBSAQIP PUF database as of the writing of this dissertation. The research study is expected to add to the existing body of knowledge in this field and benefit care team members, especially patients undergoing bariatric surgery.

The data analysis procedure was executed following the proposed breakdown of the entire study into 3 phases:

- Phase I Delphi Study
- Phase II Quantitative Analysis

- Phase III Delphi Study

The Phase I Delphi study involved a virtual meeting with the subject matter experts and was exploratory. Before the study, an application to Indiana State University Institutional Review Board (IRB) was submitted. The IRB Board provided a letter that determined that the research study did not meet the definition of human subject research under the purview of the ORB according to federal regulations. Once the IRB letter or approval was obtained, a virtual meeting with the panel of experts took place to explore the first research question.

The first research question (RQ1) in the Phase I Delphi Study identified the important preoperative factors that may contribute to the likelihood that patients will have an ED visit within 30 days of bariatric surgery. A panel of experts was provided and briefed on the Consent Form, Questionnaire for Phase I Delphi instrument and the list of 33 preoperative factors. RQ1 was answered through 3 rounds of ranking of the preoperative variables into low, medium, and high categories. The final list of variables that were ranked as high was selected as the final vital few factors, i.e., independent variables of the study, which were Gastroesophageal Reflux Disease (GERD) Requiring Medication (within 30 days prior to surgery), Preoperative Number of Antihypertensive Medications, Calculated from preop weight closest to surgery and height, Calculated from highest recorded preop weight and height, Preoperative Vein Thrombosis Requiring Therapy, Preoperative Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin, Preoperative Functional Health Status, History of Severe COPD, and Preoperative Steroid/Immunosuppressant Use for a Chronic Condition.

The second research question (RQ2) explored factors that significantly contributed to patients' likelihood of an ED visit within 30 days of bariatric surgery. This was obtained through quantitative data analysis and proposed null and alternative hypotheses. The findings suggested that at least one predictor's slope or regression value was not equal to zero, implying that each predictor positively or negatively impacted the likelihood of patients returning to the ED within 30 days of a bariatric procedure. After further investigation of predictors with statistically significant values in conjunction with the Wald test, it was identified that only preop GERD requiring medication, number of hypertensive medications at all levels, highest recorded preop BMI, preop vein thrombosis requiring therapy, preop albumin lab value, and preop hemoglobin A1c value were the factors that significantly contributed to the likelihood that patients would have an ED visit within 30 days of bariatric surgery.

The first part of the third research question (RQ3) investigated whether a model could be developed using only the statistically significant and weighted predictors identified in the second research question. The results obtained from the Phase II Qualitative Analysis showed that a model could be developed using only the statistically significant and weighted predictors, and all the predictors on the revised model were statistically significant $(p < 0.05)$. Equation (2.6) shows the equation yielded after rerunning the model with only statistically significant factors.

Now that the binomial logistic regression model (equation 2.6) was established, this model could be used to predict the odds that a patient will come back to ED or not within 30 days of a bariatric procedure. From (equation 2.6), the odds prediction equation can be also written as:

$$Odds_{30} = e^{-2.712+0.294X_1-0.144X_{2a}-0.170X_{2b}-0.164X_{2c}-0.012X_3+0.018X_4+0.356X_5-0.097X_{6a}-0.152X_{6b}+0.163X_8+0.234X_9}$$

*Equation (2.7)*

Suppose a patient has the following preoperative values prior to surgery:

$X_1$ = Pre-Op GERD requiring medication = (Yes) = 1

$X_{2a}$ = Number of Hypertensive Medications (taking 1) = 0

$X_{2b}$ = Number of Hypertensive Medications (taking 2) = 0

$X_{2c}$ = Number of Hypertensive Medications (taking 3+) = 1

$X_3$ = Pre-Op BMI closest to bariatric surgery = 45

$X_4$ = Highest Recorded Pre-Op BMI = 45

$X_5$ = Pre-Op vein thrombosis requiring therapy = (Yes) = 1

$X_{6a}$ = Pre-Op diabetes mellitus (No) = 0

$X_{6b}$ = Pre-Op Diabetes Mellitus = (Non-Insulin) = 1

$X_8$ = Pre-Op history of COPD = (No) = 0

$X_9$ = Pre-Op Steroid/Immunosuppressant Use for Chronic Condition= (Yes) = 1

After substituting real values with coded values in SPSS as shown above in equation (2.7):

$$Odds_{30} = e^{-2.712+0.294(1)-0.144(0)-0.170(0)-0.164(1)-0.012(45)+0.018(45)+0.356(1)-0.097(0)-0.152(1)+0.163(0)+0.234(1)}$$

$$Odds_{30} = e^{-1.874}$$

$$Odds_{30} = 0.15$$

Now, with this value of Odds, patient's probability of ED visit within 30 days of bariatric procedure ($P_{30}$) can be predicted.

Hence, ($P_{30}$) = $\frac{Odds_{30}}{1+ Odds_{30}} = \frac{0.15}{1+ 0.15}$ = 0.13

This means there is a 13% probability that this patient will visit ED within 30 days of the bariatric procedure. Wuensch (2021c) highlights the everyday use of binary logistic regression to classify subjects into one category versus another based on some threshold value of predicted probability. Most statistical software such as SPSS and Jamovi use the 0.50 value as the threshold value. If the predicted probability is 50% or greater, the outcome variable is deemed one, i.e., ‘Yes’. If this principle is applied and a 0.5 threshold value is used, a 13% probability of the patient coming back to ED within 30 days of the bariatric procedure would mean the patient will be classified as having no likelihood of returning to ED.

The second part of the third research question (RQ3) explored whether the developed model with only statistically significant predictors could have an acceptable fit. The Hosmer & Lemeshow test suggested that the revised model was not a good fit for the data ($\chi^2 = 17.727, df = 8, p < 0.05$). However, omnibus tests of model coefficients showed that the chi-square value was highly significant ($\chi^2 = 505.052, df = 8, p < 0.001$), suggesting that the revised model after the addition of exploratory variables is statistically significant compared to the null model without the exploratory variables or predictors.

The fourth research question (RQ4) in the Phase II Delphi Study explored the subject matter experts’ perception regarding the model developed and the overall findings of the research study. The same panel of experts was brought back in a single virtual meeting where the Consent Form and Questionnaire for the Phase III Delphi instrument were provided. The conclusion from the panel of experts is provided below in the bulleted form.

- Understanding preoperative factors before surgery is beneficial for the bariatric patient population from a clinical perspective.
- The proactive approach is preferred over the reactive approach when dealing with 30-day postoperative ED visits for bariatric patients.
- The results from the Phase II quantitative analysis section make practical significance clinically and operationally.

- Suppose Phase II findings are translated to the bariatric department's day-to-day operations and practice. In that case, there is value in these findings for both patients and care teams providing care to the bariatric patient population.
- At this point, the panel of experts does not suggest revising the list of independent variables in Phase II of the study. However, this could be a potential research topic and exploration for future studies.
- Many variables have clinical and operational significance and are tracked in the clinic and hospital settings, but they are not reported to the MBSAQIP database. This study is limited in that it does not include the socioeconomic status of patients, such as insurance type and education level, and other pertinent factors that are tracked in the clinic and hospital settings but are not required to be reported MBSAQIP.
- For future research studies related to this topic, it is suggested that researchers work directly with MBSAQIP accredited centers to apply the findings to actual-world practice.

To sum up, the predictive model that has been developed from this research study with the unique set of preoperative predictors can help predict patients who have high chances of coming back to ED within 30 days of bariatric surgery. The predictive model with a standard threshold value of the predictive probability of 0.5 would mean that patients with a predicted probability greater than 0.5 will be categorized as patients who have chances of returning to ED within 30 days of bariatric surgery. One of the benefits of a predictive model with preoperative predictors is that patients classified as high-risk patients can be identified before the surgery. The same patients can have a follow-up appointment or intervention scheduled, which can prevent probable ED visits in the future. Subject matter experts' feedback was crucial initially as the important preoperative factors were selected and, in the end, to validate the practical significance of the theoretical findings from the study, which was well-received based on the feedback from the panel of experts.

## Discussion

Obesity is a complex disease that is a cosmetic concern and a medical problem that increases the risk of many health problems, such as diabetes, high blood pressure, heart diseases, and various types of cancers. The cause of obesity is inherited, including physiological factors, environmental factors, imbalanced diet, and exercise (Obesity - Symptoms and causes, 2021). Reversing obesity to normal body weight is complex and involves appropriate diet, exercise, and lifestyle changes. Another way to reverse obesity to normal body weight is through surgery. Weight loss surgery is one of the most effective and sustainable treatment options for patients with severe obesity; however, it also requires a lifestyle change. Research shows that patients can lose anywhere from 35% to 65% of excess body weight through laparoscopic Roux-en-Y gastric bypass or laparoscopic adjustable gastric band (Madura & DiBaise, 2012). The first surgery designed primarily for weight loss was initially performed in the 1950s at the University of Minnesota. This technology and medical treatment are only approximately 70 years old (Story of Obesity Surgery, 2004). In 2012, the American College of Surgeons and the American Society for Metabolic and Bariatric Surgery merged to become a single national accreditation program for bariatric patients called MBSAQIP, which currently holds 850+ accredited bariatric centers throughout the US. The database collected by the same agency was utilized to conduct this research study.

The results from the study showed that there is a benefit to the researcher from subject matter experts' feedback on selecting the few vital independent variables. With the help of a panel of experts, the list of 33 preoperative predictors was narrowed down to 9 vital few factors. Using binomial logistic regression, factors significantly contributing to the likelihood of patients returning to the ED within 30 days of bariatric surgery were identified. The results also showed that a model could be developed utilizing the statistically significant and weighted predictors. The final model exhibited overall an acceptable fit; however, the data had a poor fit to the model, which is sometimes credited to a larger sample size. Finally, a panel of experts was engaged to document their perspectives on the findings and any final adjustments to the outcome of the research study.

Out of 9 independent variables, eight independent variables were statistically significant in contributing to the likelihood of patients returning to ED within 30 days of a bariatric surgery procedure. The binomial logistic regression model was established (equation 2.6). Among these eight statistically significant factors that contributed to the likelihood of patients returning to the ED within 30 days of bariatric surgery, Pre-Op GERD requiring medication, Pre-Op vein thrombosis requiring therapy, Pre-Op history of COPD, and Pre-Op Steroid/Immunosuppressant Use for Chronic Condition showed a positive relationship with the odds ratio. Variables Number of Hypertensive Medications, Pre-Op BMI closest to bariatric surgery, Highest Recorded Pre-Op BMI, and Pre-Op diabetes mellitus showed a statistically significant and negative relationship with the odds of patients returning to the ED within 30 days of bariatric surgery. When the odds ratio, i.e., Exp(B) or the exponential of the intercept, is greater than 1, it means that one unit change in the exploratory or independent variable results in a positive unit change in the log of the odds. As such, apart from the eight variables contributing to the likelihood of patients coming back to ED within 30 days of a bariatric procedure, odds of patients coming back to ED was highest in patients with Pre-Op Vein Thrombosis Requiring Therapy by a factor of 1.427, followed by patients with Pre-Op GERD requiring medication by a factor of 1.34. Patients with the Highest Recorded Pre-Op BMI, Pre-Op history of COPD, and Pre-Op Steroid/Immunosuppressant Use for Chronic Condition are likely to return to ED by a factor of 1.019, 1.177, and 1.264, respectively.

In logistic regression, the classification table is one of the crucial measures to summarize the predicted and actual results and ultimately evaluate the usefulness and fitness of the model. The actual or observed responses are displayed in rows, and predicted responses are displayed in the columns as shown in Table 22 (Logistic Regression and Classification, n.d.). In logistic regression, the classification of a case is dependent on the predicted probability. If the predicted probability is greater than the predicted probability of 0.5, the case is classified as 1, i.e., an outcome of a "Yes". However, if the event is rare in the sample or the dataset is imbalanced or skewed towards one outcome versus another, like in the case of this study, the chances of predicted probability being less than 0.5 is high. In that case, the cut-off or threshold value of predicted probability can be adjusted below 0.5. If this is done, the tradeoff would be that some true events could be classified as false and vice-versa. In other words, some of the nontrue events would be incorrectly classified as true events, and the overall model accuracy (the number of correctly classified events divided by the total number of events) will be below 0.5 (Classification table in logistic regression, 2020).

Table 24 also shows that the patients who did not have an ED visit within 30 days of a bariatric surgery procedure were predicted 100% of the time as a “No”; however, 15,533 patients who visited ED were also classified as a “No”. With the same threshold value of 0.5, Model Accuracy was obtained to be 92%. In other words, 178,241 patients were accurately classified as a “No”. Predicting all values as a single category can be attributed to an imbalanced dataset. An imbalanced dataset means when one classification category is heavily skewed, such as 10:100 (10% positive outcome, 90% negative outcome). Many techniques address dataset imbalance issues: collecting more datasets, resampling, generating synthetic samples, or adjusting or accurately interpreting the model's performance metric (Brownlee, 2020). In this research study, the ratio outcome "Yes" versus "No" was 8:100, which can be considered an imbalanced dataset based on the definition of an imbalanced dataset. To increase the ability of the model to predict "Yes" outcome, a threshold adjustment technique can be utilized. To illustrate the impact of change in the standard threshold value from 0.5 to 0.1, the model output was updated, and changes in classification table output were documented in the tabular and graphical form (Table 25, Figure 12, and Appendix E).

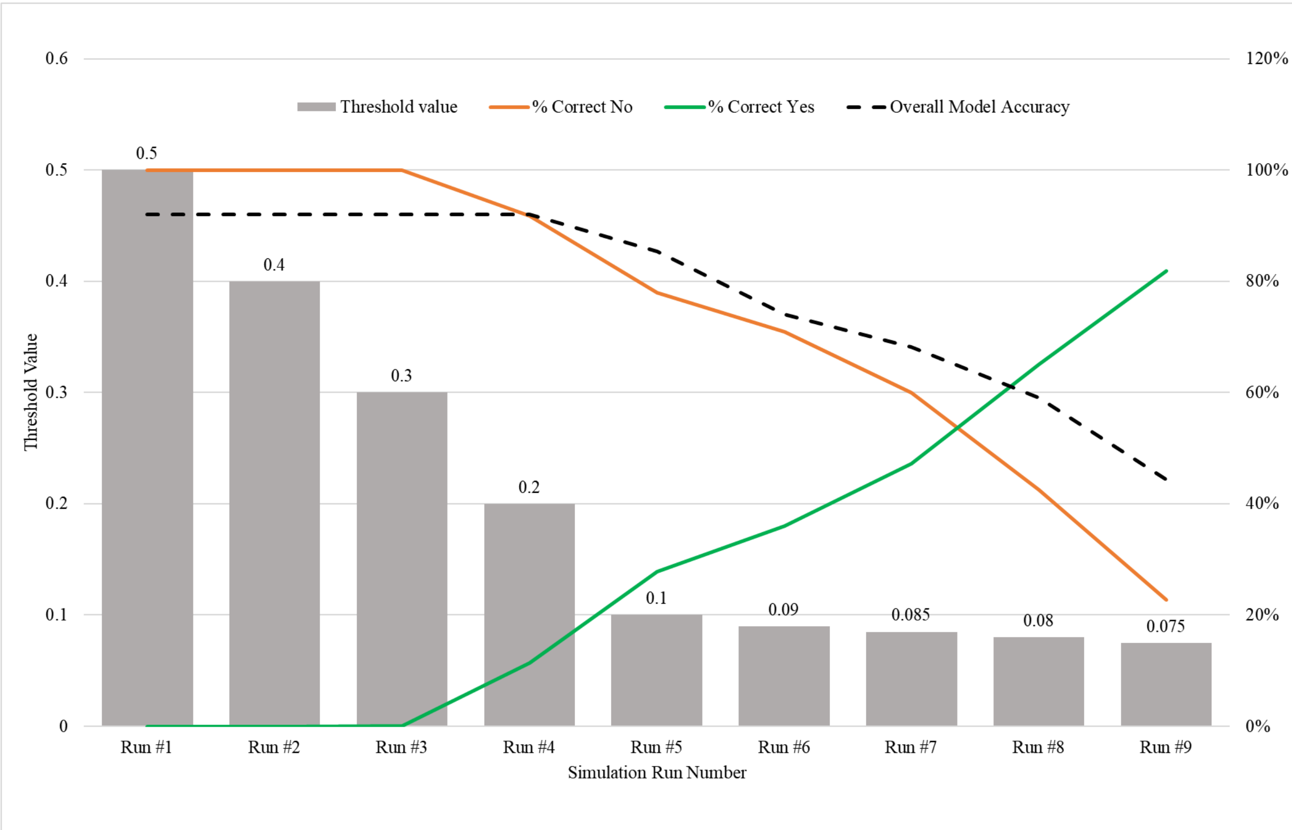
**Table 25**

***Classification Table Output under different Threshold Values***

| Simulation Run | Threshold value | Observed No & Predicted No | Observed Yes & Predicted Yes | Observed Yes but Predicted No | Observed No but Predicted Yes | % Correct No | % Correct Yes | Overall Model Accuracy |
|---|---|---|---|---|---|---|---|---|
| #1 | 0.5 | 178241 | 0 | 15533 | 0 | 100% | 0% | 92% |
| #2 | 0.4 | 178241 | 0 | 15533 | 0 | 100% | 0% | 92% |
| #3 | 0.3 | 178240 | 0 | 15533 | 1 | 100% | 0% | 92% |
| #4 | 0.2 | 178231 | 2 | 15531 | 10 | 92% | 11% | 92% |
| #5 | 0.1 | 163674 | 1763 | 13770 | 14567 | 78% | 28% | 85% |
| #6 | 0.09 | 139084 | 4321 | 11212 | 39157 | 71% | 36% | 74% |
| #7 | 0.085 | 126403 | 5594 | 9939 | 51838 | 60% | 47% | 68% |
| #8 | 0.08 | 107139 | 7329 | 8204 | 71102 | 43% | 65% | 59% |
| #9 | 0.075 | 75740 | 10089 | 5444 | 102501 | 23% | 82% | 44% |

**Figure 12**

***Graphical display of Classification Table Output under different Threshold Values***




From the perspective of the practical application of the model, depending on the quality or operational goal of an organization, the threshold value can be adjusted. However, as noted earlier and shown in Figure 12, there is some tradeoff associated with keeping the standard threshold value as 0.5 or reducing it down, which will increase the model's ability to predict the "Yes" output accurately, but that also means a decrease in model's ability to predict the "No" output accurately. For a big picture overview, graphs from estimated marginal means are provided in Appendix F comparing each IV with predicted probability for DV. These graphs help to understand increase or decrease in the predicted probability based on the value of continuous IV. For categorical IV, it shows which categorical variable contributes the most and least.

Researchers from previous studies have identified various preoperative, intraoperative, and postoperative factors contributing to the likelihood of patients returning to the ED within 30 days of bariatric surgery; however, this study establishes a model with a unique set of preoperative factors that are known before surgery. Based on the systematic literature review conducted for this research study, no study has considered these preoperative factors in establishing a model to predict the likelihood of patients returning to ED after a bariatric surgery procedure. The importance of the findings from this study is that in the future, healthcare institutions wanting to reduce the high ED utilization rate and visits for bariatric patients within 30 days of bariatric surgery can be modeled and based on the statistically significant preoperative factors, work in early interventions to focus on patients who have high odds of visiting the ED or have an increased risk of returning to the ED within 30 days of bariatric surgery. Organizations wanting to take a proactive approach in reducing their 30-day postoperative ED visit can enter the preoperative values for select variables. The model can provide predictive probability to show the likelihood of a patient's chance of coming back to ED within 30 days of bariatric surgery procedure. Suppose the predictive probability shows that patients are likely to return to ED within 30 days. In that case, interventions can be taken to carefully manage patients' care in an outpatient setting or at the patient's home versus going to ED. The same approach can be applied to bariatric patients and patients undergoing other types of surgeries and any hospitals that are seeing high ED utilization rates and visits within 30 days of a procedure or a discharge. Fewer ED visits translate to safer and less cost burden to patients and healthcare organizations. High Cost of Primary Care in Hospital EDs (2019) highlights that, on average, an ED visit costs a patient 12 times higher than a physician's office ($2,032 versus $167) and ten times higher than an urgent care visit ($2,032 versus $193). If a hospital can prevent even 100 avoidable ED visits per year and say these patients were seen in urgent care centers instead of ED, that would translate to approximate savings of $183,900, which is 91% less than what would have cost in ED visits.

## Recommendations

This research study provides an excellent synopsis of this history of quality in healthcare, metabolic and bariatric surgery accreditation and quality improvement programs, and trends in obesity and bariatric surgical procedures. By selecting a subset of the US patient population, i.e., patients undergoing bariatric surgery, this study provides an overview of preoperative, intraoperative, and postoperative factors for the 30-day postoperative ED visit. The study further drills down preoperative factors and identifies significant factors and a model contributing to the likelihood of patients returning to the ED within 30 days of a bariatric procedure. This extensive study can serve scholars and researchers in healthcare quality and performance improvement as well as clinical experts and operations in healthcare organizations. This study demonstrates how a simple subset of the patient population can add new knowledge and information to what already existed in this more recent and emerging field of study.

According to the Historical (2021), US healthcare spending reached $4.1 trillion in 2021, equivalent to $12,530 per person. In 2017 alone, 144.8 million ED visits incurred approximately $76.3 billion (Moore & Liang, 2020b). This makes avoidable ED visits a prime opportunity for healthcare organizations. Knowing that obesity is increasing (approximately 50% of the US population is expected to be obese by 2030), it is important to socialize the ways to prevent severe obesity. However, as seen through the analysis and literature, severe obesity is also increasing rapidly, increasing the rate of bariatric surgery in the United States every year. As the number of patients going through bariatric surgery increases, so is the total number of avoidable

ED visits within 30 days of bariatric surgery. Among researchers and experts in the field of healthcare and specific to obese patient populations and patients themselves, it is important to acknowledge why preventing avoidable ED visits is necessary.

The identified significant factors and the model developed in this research study provide essential information to clinicians and experts who work closely with severely obese patients and practice bariatric surgery in the United States and around the globe. For someone who sees potential patients who may go through bariatric surgery or those who already had bariatric surgery, information such as which preoperative factors are crucial to the likelihood of patients going back to the ED visit within 30 days of bariatric surgery is essential. Clinical teams such as Surgeons, Nursing Teams, Operations, or Quality personnel will find information such as which factors may positively impact patients’ future ED visits and which factors may negatively impact patients’ future ED visits. The findings from Phase II of the study suggested that preop GERD requiring medication, highest recorded preop BMI, preop vein thrombosis requiring therapy, preop albumin lab value, and preop hemoglobin A1c value have a statistically significant and positive impact on the likelihood of patients returning to the ED within 30 days of bariatric surgery. This information can help clinical teams appropriately manage care coordination, such as intervening and reaching out to patients before the ED visit occurs, which can benefit healthcare organizations, clinical groups, and, most importantly, the patients.

This research study has opened many potential opportunities for future research. The same dataset can be utilized to conduct extensive research that extends over a few years versus just one year. Unforeseen circumstances and nuances such as the COVID-19 global pandemic and changes in how the data are reported could be a potential challenge in extending similar research studies over a few years. There is also potential to utilize evolving machine learning and artificial intelligence programs and algorithms, which can have many benefits over the traditional research approach.

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# APPENDIX A: QUESTIONNAIRE FOR THE PHASE I DELPHI INSTRUMENT

| Question | Response |
|---|---|
| Q1. From the 33 variables (Table 3), rank the variables that are clinically significant (Low, Medium, High) for the bariatric patient population from your perspective that can contribute to the likelihood of patients coming back to ED within 30 days of bariatric surgery (3 rounds) | Shortlisted variables |
| Q2. Do you suggest including any other variables other than the 33 selected from the MBSAQIP database? | Commentary response |

**APPENDIX B: QUESTIONNAIRE FOR THE PHASE III DELPHI INSTRUMENT**

| Question | Agree | Disagree |
|---|---|---|
| Q1. From a clinical perspective, understanding preoperative factors (with the level of significance and odds ratio) before surgery is beneficial for the bariatric patient population. | | |
| Q2. A proactive approach is preferred over the reactive approach when dealing with 30-day postoperative ED visits for bariatric patients. | | |
| Q3. Results from Phase II of the study have practical significance clinically and operationally. | | |
| Q4. Suppose Phase II findings are translated to your day-to-day operations and bariatrics practice. In that case, I see value in these findings for both patients and care teams providing care to the bariatric patient population. | | |
| Q5. If you suggest revising the list of independent variables in Phase II, recreating, and rerunning the model with a new set of IVs, please provide the name of variables you would like to include or exclude in the commentary response. | | |
| Q6. To further this area of research in the Bariatrics Surgery patient population and 30-day postoperative ED visits, what do you suggest future researchers should focus on? Please provide a commentary response. | | |
| Q7. Please provide a commentary response if you have any additional feedback or anything you would like the researcher to consider that is not on this questionnaire. | | |

# APPENDIX C: INDIANA STATE UNIVERSITY IRB LETTER

Indiana State University
More. From day one.

Institutional Review Board
Terre Haute, Indiana 47809
812-237-3088
Fax 812-237-3092

| | |
|---|---|
| DATE: | January 5, 2022 |
| TO: | Pawan Bhandari |
| FROM: | Indiana State University Institutional Review Board |
| STUDY TITLE: | [1854368-1] PREOPERATIVE PREDICTORS FOR 30-DAY POSTOPERATIVE EMERGENCY DEPARTMENT VISIT AFTER A BARIATRIC SURGERY |
| IRB REFERENCE #: | |
| SUBMISSION TYPE: | New Project |
| ACTION: | DETERMINATION OF NOT RESEARCH |
| DECISION DATE: | January 5, 2022 |

Thank you for your submission of New Project materials for this research study. The Indiana State University Institutional Review Board has determined this project does not meet the definition of human subject research under the purview of the IRB according to federal regulations.

If you have any questions, please contact Anne Foster within IRBNet by clicking on the study title on the "My Projects" screen and the "Send Project Mail" button on the left side of the "New Project Message" screen.

## APPENDIX D: INFORMED CONSENT FORM

Introduction

Indiana State University supports the practice of protecting human subjects while participating in a research study. For my research, I am recruiting a panel of experts. The information below will help you decide whether you want to be part of the study. You have an option of not participating in this study by refusing to sign the form. You also have an option of withdrawing to participate at any time even if you agree to be part of the research study initially.

Purpose of the study

The purpose of this study was to identify a few vital preoperative factors that can contribute to the likelihood of patients returning to the emergency department within 30 days of a bariatric procedure based on consensus from a panel of experts through a Delphi study. Once a few vital preoperative factors are identified, analysis is conducted to identify factors that significantly contribute to the likelihood of patients returning to the ED within 30 days of a bariatric procedure. With the help of narrowing down significant factors, a model is proposed to predict the probability of a patient’s arrival to the emergency department within 30 days of a bariatric procedure. Once the model is developed, the same panel of experts is asked to evaluate and suggest the validity and practicality of the findings.

The database used in this study is from the American College of Surgeons’ Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) Participant Use Data File (PUF) 2019, which contains 219 Health Insurance Portability and Accountability Act

(HIPAA) compliant variables. This dataset includes all the patients who underwent bariatric procedures in one of the MBSAQIP accredited centers in the United States of America in 2019.

Procedure

If you agree to participate, in the first phase of the study, you will be asked to be part of a virtual meeting where a panel of experts (participants) will help identify a few vital preoperative factors through three rounds of ranking. At the beginning of the session (first round), the researcher will provide the list of preselected 33 preoperative variables included on the MBSAQIP's PUF file and ask participants to rank variables as the "low" category and mark them in red. In the second round of the first phase of the Delphi study, a panel of experts will be asked to rank variables as the "medium" category and mark them yellow. The variables left at the end will be ranked as the "high" category and marked green. These variables in green will become the selected variables and will be independent variables for the research study. Below is the instrument that will be used during the first phase of the study.

*Questionnaire for the Phase I Delphi instrument*

| Question | Response |
|---|---|
| Q1. From the 33 variables (Table 3), rank the variables that are clinically significant (Low, Medium, High) for the bariatric patient population from your perspective that can contribute to the likelihood of patients coming back to ED within 30 days of bariatric surgery (3 rounds) | Shortlisted variables |
| Q2. Do you suggest including any other variables other than the 33 selected from the MBSAQIP database? | Commentary response |

In the second phase, quantitative analysis will be conducted, which will not involve consent from the panel of experts. However, in the third phase of the study, in a virtual meeting setting such as the first phase of the study, a panel of experts will be presented with the findings from the second phase of the study, which is a prediction model with significant factors that contribute to the likelihood of patients returning to the emergency department within 30 days of a bariatric procedure. Below is the instrument that will be used during the third phase of the study.

*Questionnaire for the Phase III Delphi instrument*

| Question | Agree | Disagree |
|---|---|---|
| Q1. From a clinical perspective, understanding preoperative factors (with the level of significance and odds ratio) before surgery is beneficial for the bariatric patient population. | | |
| Q2. A proactive approach is preferred over the reactive approach when dealing with 30-day postoperative ED visits for bariatric patients. | | |
| Q3. Results from Phase II of the study have practical significance clinically and operationally. | | |
| Q4. Suppose Phase II findings are translated to your day-to-day operations and bariatrics practice. In that case, I see value in these findings for both patients and care teams providing care to the bariatric patient population. | | |
| Q5. If you suggest revising the list of independent variables in Phase II, recreating, and rerunning the model with a new set of IVs, please provide the name of variables you would like to include or exclude in the commentary response. | | |
| Q6. To further this area of research in the Bariatrics Surgery patient population and 30-day postoperative ED visits, what do you suggest future researchers should focus on? Please provide a commentary response. | | |
| Q7. Please provide a commentary response if you have any additional feedback or anything you would like the researcher to consider that is not on this questionnaire. | | |

The outcome and completed questionnaire from the first and third phases of the Delphi session will be saved by the researcher only to add content to the research study and will be kept confidential and not distributed publicly.

Risks

No risks or discomforts are anticipated to the participants.

Benefits

There will be no direct benefits or payment to the participants. However, input gathered from the first and third phases of the Delphi study is expected to help bariatric surgery practice leaders plan future interventions and improvements to reduce avoidable postoperative emergency department visits for bariatric surgery patients.

Participant confidentiality

Participant name will not be linked in any way with the information gathered about the participant or the feedback provided by the participant through both phases of the Delphi study. The researcher will not share any information regarding the participant's identity unless required by law or without your prior authorization in writing. By signing this consent form, you authorize for the use and disclosure of the information about you and the information provided by you for the purpose of this study at any time in the future.

Refusal to sign consent and authorization

You have the right to withdraw your consent to participate in this study at any time. You also have the right to cancel the authorization to use the information about you and the information provided by you for the purpose of this study any time in writing by sending your request to the researcher.

Questions about participation

Questions about the procedure should be sent to the researcher listed at the end of this consent form.

Participant certification

I have read this consent form in its entirety. I have had the opportunity to ask questions, and when I had a question, I was provided an answer regarding the study. I understand that if I have any follow-up questions regarding my rights as a participant, I may call, email, or write:

Office of Sponsored Programs
Indiana State University
Holmstedt Hall 272
Phone: (812) 237-3088; Fax: (812) 237-3092
research@indstate.edu

I hereby agree to take part in this research study as a research participant for the first and third phases of the Delphi study. By responding 'Yes', I affirm that I am at least 18 years old and that I have received a copy of this consent and authorization form.

- ☐ Yes
- ☐ No

Researcher Contact Information:

Pawan Bhandari, PhD Candidate

Indiana State University

650 Cherry Street, Terre Haute IN 47809

Phone: 347-622-9016

Email: pbhandari@sycamores.indstate.edu

*Note: This consent form was partially adapted from Dr. McCain's PhD dissertation titled "A Study of Quality Requirement Conveyance for Assignments in Technology and Engineering Master's Programs", Indiana State University, Terre Haute, IN 47809 (2020).*

# APPENDIX E: CLASSIFICATION TABLE OUTPUT AT DIFFERENT CUT-OFF OR THRESHOLD VALUES

Classification Table – EMERG_VISIT_OUT

| | Predicted | | |
|---|---|---|---|
| **Observed** | **No** | **Yes** | **% Correct** |
| No | 178241 | 0 | 100 |
| Yes | 15533 | 0 | 0.00 |

Note. The cut-off value is set to 0.4

Classification Table – EMERG_VISIT_OUT

| | Predicted | | |
|---|---|---|---|
| **Observed** | **No** | **Yes** | **% Correct** |
| No | 178240 | 1 | 100.0 |
| Yes | 15533 | 0 | 0.00 |

Note. The cut-off value is set to 0.3

Classification Table – EMERG_VISIT_OUT

| | Predicted | | |
|---|---|---|---|
| **Observed** | **No** | **Yes** | **% Correct** |
| No | 178231 | 10 | 100.0 |
| Yes | 15531 | 2 | 0.0129 |

Note. The cut-off value is set to 0.2

Classification Table – EMERG_VISIT_OUT

| | Predicted | | |
|---|---|---|---|
| **Observed** | **No** | **Yes** | **% Correct** |
| No | 163674 | 14567 | 91.8 |
| Yes | 13770 | 1763 | 11.4 |

Note. The cut-off value is set to 0.1

Classification Table – EMERG_VISIT_OUT

| | Predicted | | |
|---|---|---|---|
| **Observed** | **No** | **Yes** | **% Correct** |
| No | 139084 | 39157 | 78.0 |
| Yes | 11212 | 4321 | 27.8 |

Note. The cut-off value is set to 0.09

Classification Table – EMERG_VISIT_OUT

| | Predicted | | |
|---|---|---|---|
| **Observed** | **No** | **Yes** | **% Correct** |
| No | 126403 | 51838 | 70.9 |
| Yes | 9939 | 5594 | 36.0 |

Note. The cut-off value is set to 0.085

Classification Table – EMERG_VISIT_OUT

| | Predicted | | |
|---|---|---|---|
| **Observed** | **No** | **Yes** | **% Correct** |
| No | 117664 | 60577 | 66.0 |
| Yes | 9123 | 6410 | 41.3 |

Note. The cut-off value is set to 0.0825

Classification Table – EMERG_VISIT_OUT

| | Predicted | | |
|---|---|---|---|
| Observed | No | Yes | % Correct |
| No | 107139 | 71102 | 60.1 |
| Yes | 8204 | 7329 | 47.2 |

Note. The cut-off value is set to 0.08

Classification Table – EMERG_VISIT_OUT

| | Predicted | | |
|---|---|---|---|
| Observed | No | Yes | % Correct |
| No | 75740 | 102501 | 42.5 |
| Yes | 5444 | 10089 | 65.0 |

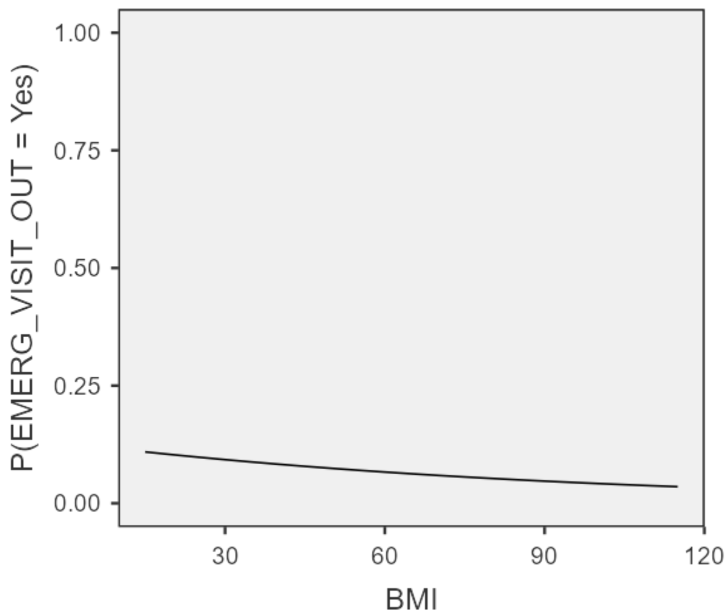
Note. The cut-off value is set to 0.075

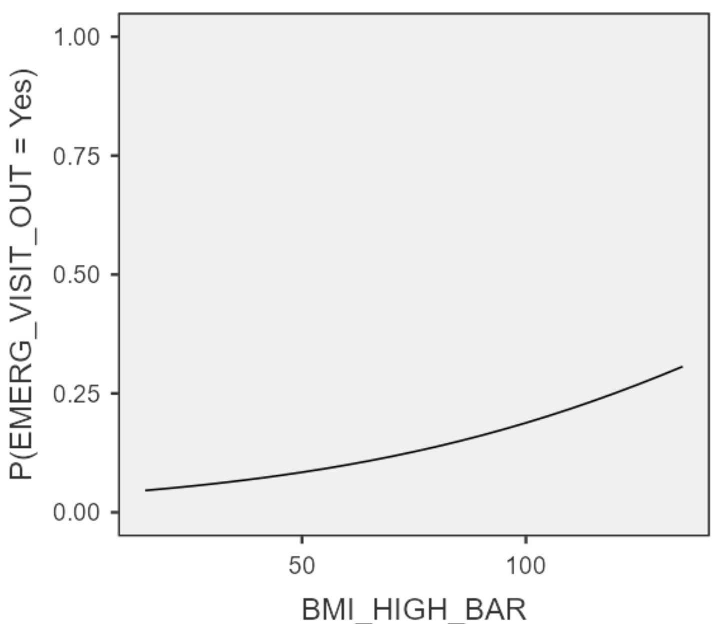
Classification Table – EMERG_VISIT_OUT

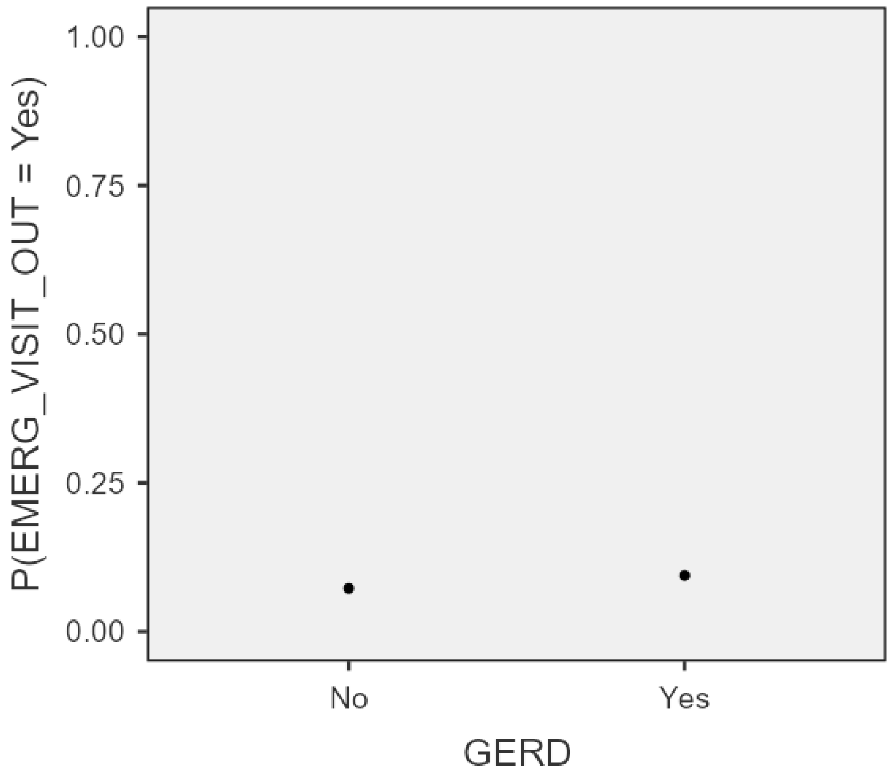
| | Predicted | | |
|---|---|---|---|
| Observed | No | Yes | % Correct |
| No | 40519 | 137722 | 22.7 |
| Yes | 2822 | 12711 | 81.8 |

Note. The cut-off value is set to 0.07

# APPENDIX F: ESTIMATED MARGINAL MEANS COMPARING EACH IV AND PREDICTED PROBABILITY FOR DV





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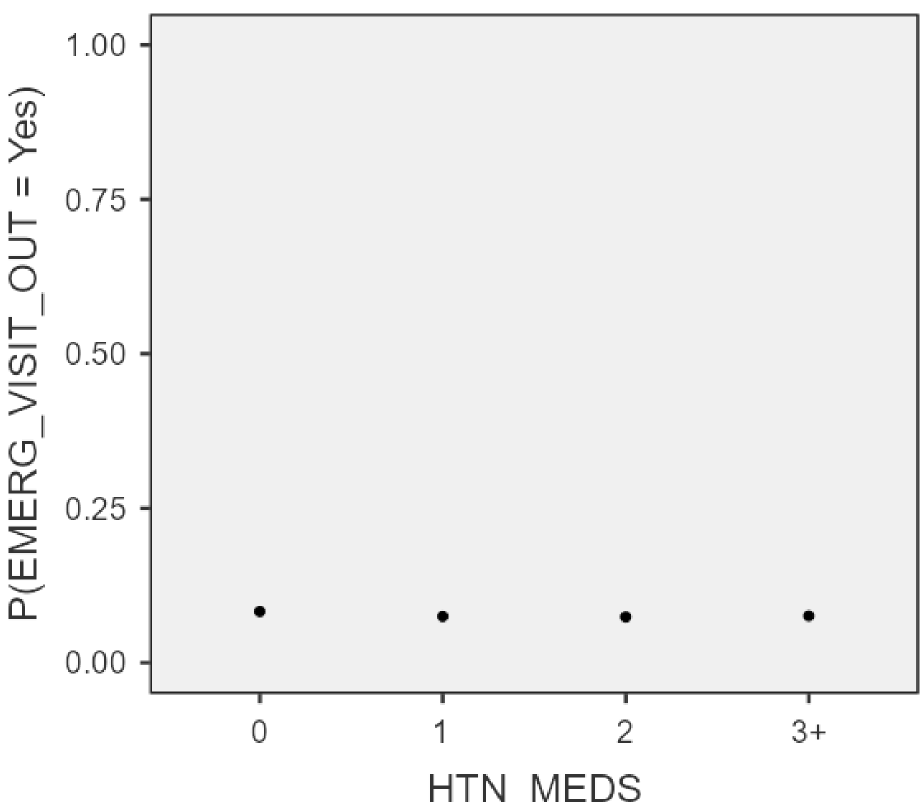

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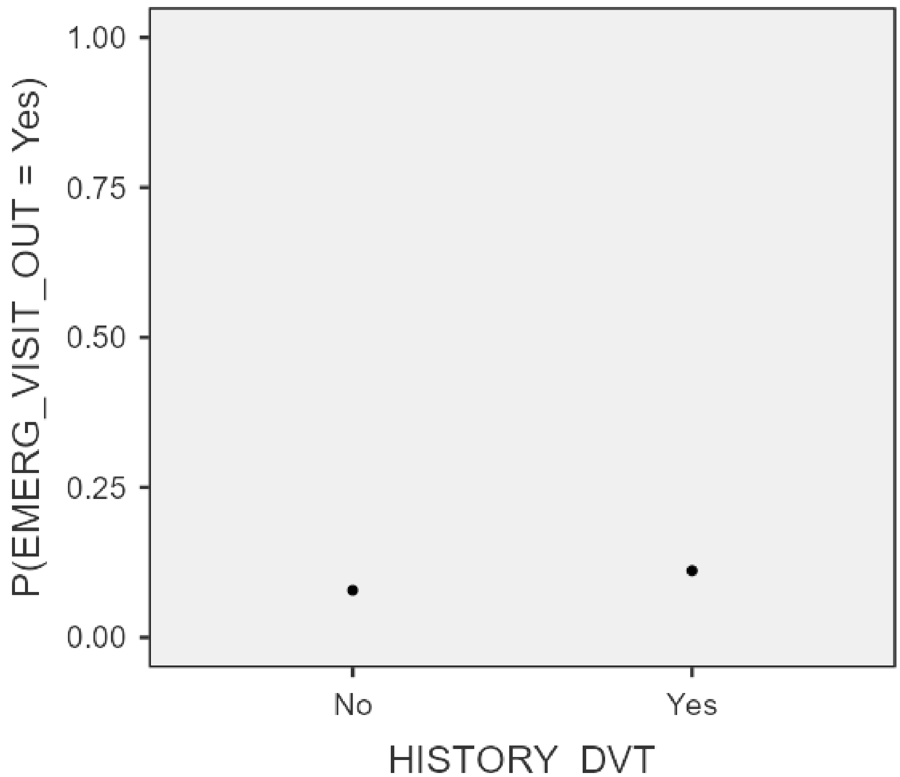
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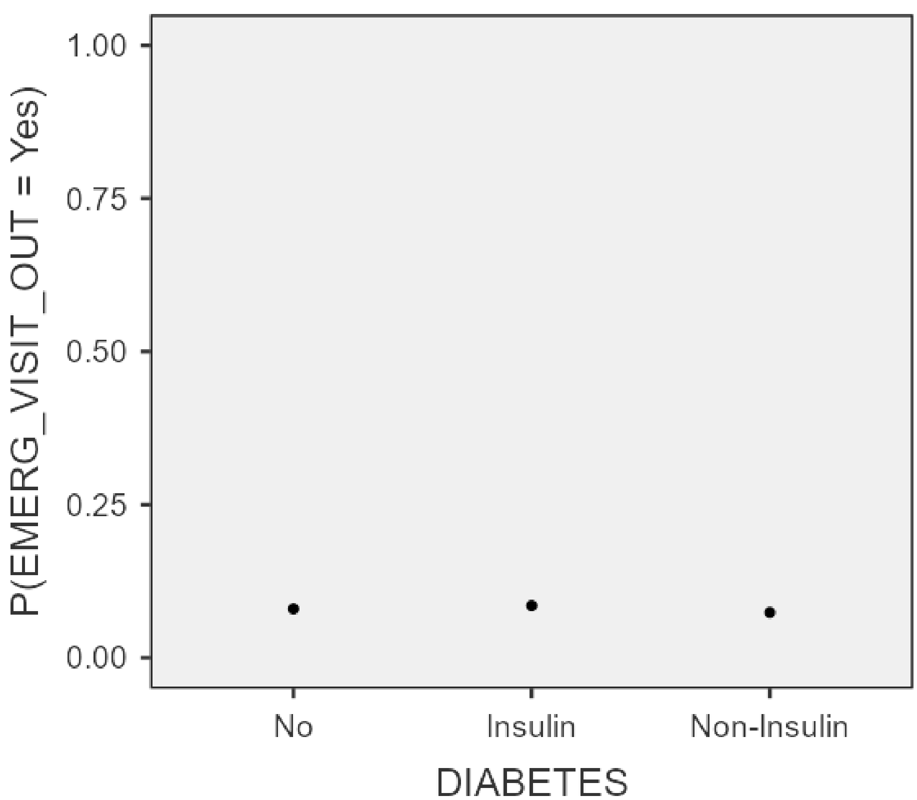
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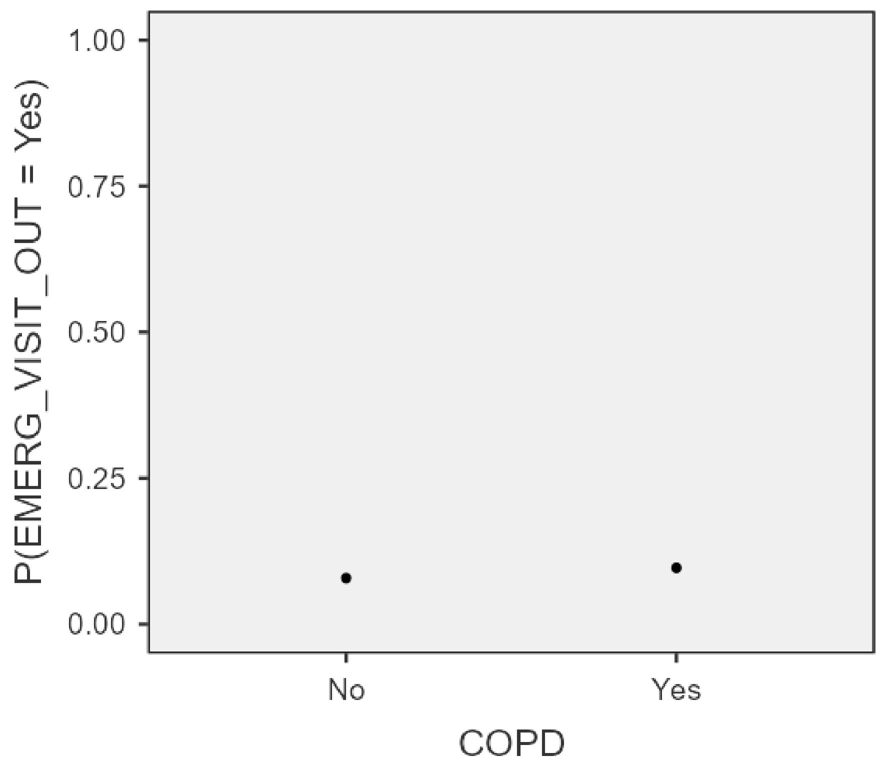
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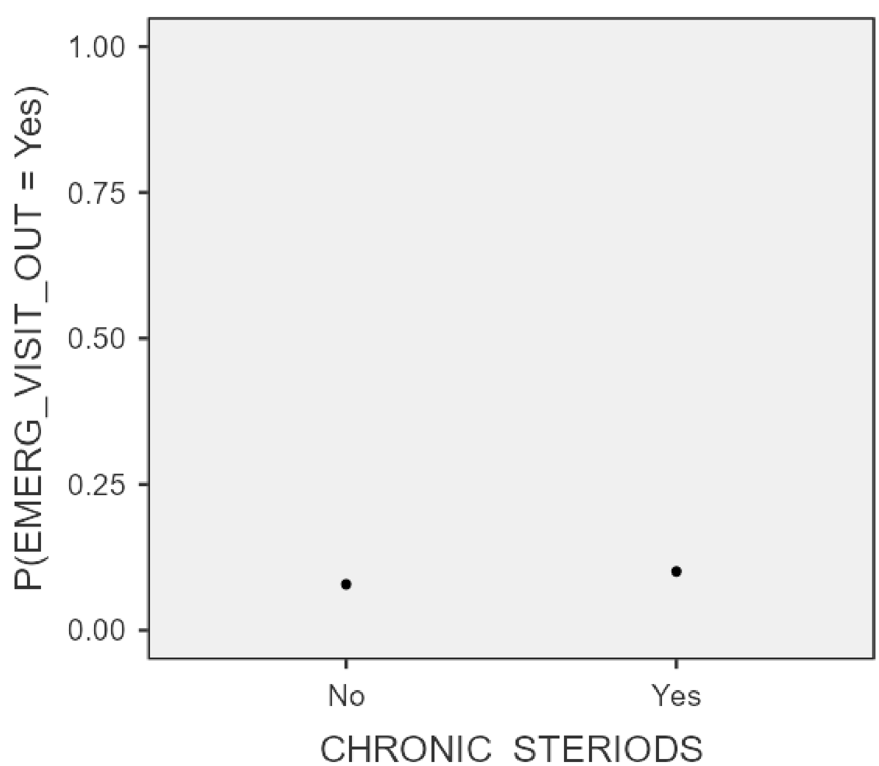
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# APPENDIX G: SIGNED DATA USE AGREEMENT BETWEEN MBSAQIP ACCREDITED BARIATRIC CENTER AND RESEARCHER

MBSAQIP®

METABOLIC AND BARIATRIC SURGERY
ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

**DATA USE AGREEMENT** for the
American College of Surgeons
Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program

This Data Use Agreement ("Agreement") implements the data protections of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the American College of Surgeons Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program ("ACS MBSAQIP") Hospital Participation Agreement ("HPA"). Any individual ("Data Recipient") seeking to obtain or use the data in the ACS MBSAQIP Participant Use Data File ("PUF") must be representing a ACS MBSAQIP Participating Center ("Center"), must agree to the terms in this Agreement, and must submit this Agreement to the ACS MBSAQIP before the PUF may be released.

Consistent with the ACS MBSAQIP Participation Agreement (PA) and in accordance with HIPAA, any Protected Health Information ("PHI"), as defined by 45 CFR 164.501, submitted to the ACS MBSAQIP by the Center for inclusion in the ACS MBSAQIP may be used, disclosed, or combined with other such data from additional ACS MBSAQIP participating centers to create a de-identified data set as defined by 45 CFR 164.514(b), containing aggregate, patient-level data, as it is with the PUF. The ACS MBSAQIP also retains the right to release the PUF at its discretion to ACS MBSAQIP participating centers for the purpose of engaging in research activities, quality improvement analysis, and aggregate statistical reporting.

**No Identification of Person(s):** Any effort to determine the identity of any individual, (including but not limited to patient, surgeon, and other health care provider or center), or to use the information for any purpose other than for research, quality improvement, and aggregate statistical reporting, would violate the PA, the conditions of this Agreement, and the HIPAA. Data Recipients of the PUF are prohibited under HIPAA and the PA, and this Agreement from releasing, disclosing, publishing or presenting any individually identifying information. The ACS MBSAQIP omits from the PUF all identifiers required to be excluded from de-identified data sets as defined by the HIPAA Privacy Rule. It may be possible, in limited situations, through deliberate technical analysis, and with outside information, to ascertain from the de-identified data set the identity of particular persons. Considerable harm could result if this were to occur. Therefore, any attempts to identify individuals are prohibited and information that could identify individuals directly or by inference must not be released or published. In addition, the users of the PUF must not attempt to contact any individuals for any purpose, including verifying information supplied in the PUF. Any questions about the PUF must be referred exclusively to the ACS MBSAQIP.

ACS MBSAQIP PUF Data Use Agreement (December 2016) Page 1 of 3

**No Identification of Hospital(s):** Section 924 (c) of the Public Health Service Act (42 U.S.C. 299c-3(c)) also restricts the use of information that permits the identification of establishments (hospitals) for purposes other than for which the information was originally supplied. Commercial or competitive purposes involving participating hospitals is not an allowable use of this data, and the hospitals must not be identified directly or indirectly in distributed materials. Any questions about the data should be forwarded to the ACS MBSAQIP. Users of the PUF should not attempt to contact any individual or hospital in the data set for any purpose including data verification.

**Access to the 2015 MBSAQIP PUF Variables and Definitions Manual:** The 2015 MBSAQIP PUF Variables and Definitions Manual contains proprietary ACS MBSAQIP programmatic information. Your use of the manual is restricted to clarifying definitions for your PUF-based research purposes. The contents of the manual shall not be shared, quoted, distributed, or disseminated in any published papers, reports, manuscripts, etc. Limited paraphrasing of the 2015 MBSAQIP PUF Variables and Definitions Manual to provide methodological clarity in research publications is permissible. Any use or redistribution of the 2015 MBSAQIP PUF Variables and Definitions Manual for commercial purposes is strictly prohibited.

**Permission to use and disclose the data:** Permission to use and disclose the PUF is granted from the ACS MBSAQIP to each Data Recipient. The Data Recipient must be an employee of the participating center. Intentional misrepresentation of employment at the center by the Data Recipient will void this Agreement, prohibit use of the PUF by the Data Recipient, and result in legal action taken by the ACS MBSAQIP. The ACS MBSAQIP also reserves the right to deny access to the PUF at its discretion.

**By signing this Agreement, the Data Recipient warrants that it:**

- Will not use or disclose the PUF other than as permitted by this Agreement for research activities, quality improvement analysis, and aggregate statistical reporting or as otherwise required by law;
- Will not use or further disclose the PUF in a manner that would violate the HIPAA regulations;
- Will use reasonable and appropriate safeguards to prevent use or disclosure of the PUF other than as provided for by this Agreement, including administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic PUF that it receives, maintains, or transmits on behalf of the center as required by 45 CFR 164.314;
- Will report to the ACS MBSAQIP any use or disclosure of the PUF not provided for by this Agreement and any security incident involving the PUF of which it becomes aware promptly and within ten (10) days of its discovery;
- Will not grant access to or share the PUF either in its entirety or as a subset to any party who is not an employee of the participating center at which the Data Recipient is employed;
- Will not sublease or permit other parties to use the PUF without advance written approval of the ACS MBSAQIP;
- Will ensure that any agents including contractors and subcontracts and researchers to whom the PUF is provided contractually agree in writing to the same restrictions and conditions that apply to the Data Recipient with respect to such information;
- Will make available to the ACS MBSAQIP its internal records related to the use and distribution of the PUF as requested;
- Will comply with any applicable Center IRB requirements;
- Will not use the PUF to identify or contact the individuals who are the subject of the information;
- Will not hold the ACS or the ACS MBSAQIP responsible for any claims arising from works based on the original data, text, tables, or figures;

- Will acknowledge in all reports that the source of the data is the participating centers that submitted data to the ACS MBSAQIP and will include the following disclosure on any presentation or published material:
  *The American College of Surgeons Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program and the centers participating in the ACS MBSAQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.*
- Will provide at a minimum an abstract and reference for any published materials resulting from the PUF to the ACS MBSAQIP.

**Additional Terms:**

- The Data Recipient agrees to indemnify the ACS and its employees and agents from liability, claims, or expenses arising from use of the PUF by Data Recipients negligence in Data use of the PUF by the Data Recipient;
- This Agreement will remain in effect as of the date of execution and terminate when all copies of the PUF are destroyed and the PUF is no longer in use;
- Any noncompliance by the Data Recipient with the terms of this Agreement or failure on the part of the Data Recipient to correct any breach or violation of this Agreement to the satisfaction of the ACS MBSAQIP will be grounds for immediate termination of the Agreement by the ACS MBSAQIP and the American College of Surgeons will report the Data Recipient's breach to the Secretary of the United States Department of Health and Human Services.

As the undersigned, my signature confirms my employment at the participating Hospital and my intention to comply with the above stated requirements. Violators of this Agreement may also be subject to penalties under statutes that may apply to these data.

| | |
|---|---|
| [signature] | 7/25/2021 |
| Data Recipient Signature | Date |
| PAWAN BHANDARI | Principal Health Systems Engineer |
| Print Full Name | Title |
| Mayo Clinic Health System - Mankato | Bariatric Surgery |
| ACS MBSAQIP Participating Hospital/Center | Department |
| 1025 Marsh Street, Mankato, MN, 56001 | |
| Address | |
| 507-594-4181 | Gilmore.Megan@mayo.edu |
| Phone / Fax | E-mail |

Any Inquiries about this Agreement can be made to the American College of Surgeons:

Rasa Krapikas, MS
MBSAQIP Data Registry Manager
American College of Surgeons
633 N. Saint Clair Street
Chicago, Illinois 60611
Phone: (312) 202-5646
Email: rkrapikas@facs.org