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Dissertation Approval Sheet

Formal approval is hereby given to this submitted dissertation by Victoria M. Goode on *A Patient Safety Dilemma: Obesity in the Surgical Patient*

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Chapter One

Introduction

Patient Safety

Patient safety and the delivery of quality of care is a major investment for healthcare. There has been considerable public interest in the challenges of patient safety. Medical errors are a significant issue and much attention has been dedicated to its understanding. The Institute of Medicine (IOM), in their initial report, attributed 98,000 deaths annually in the United States due to medically related errors with associated costs between $17 and $29 billion per year (Kohn, Corrigan, & Donaldson, 2000). It is critical that hospitals, medical institutions, and healthcare providers develop test and evaluate measures to reduce such errors and improve patient safety outcomes.

Patient safety is of interest to both the professions of nursing and medicine. In fact, the IOM recognizes the importance of the Hippocratic oath 5 BC (physicians) and the Florence Nightingale pledge (nurses) in their initial report (Getter, 1893; Hippocrates of Kos, 5 BC; Kohn et al., 2000). These oaths, established years prior to the IOM report, are based on the premise of safe and equitable care and ask of its beholders to refrain from potential harm toward their patients. These oaths are in line with the aims of the IOM which state care should be safe, effective, patient-centered, timely, efficient, and equitable (Kohn et al., 2000).

Harvard Medical Practice Study and the IOM Commission

The IOM report was prompted by findings of the Harvard Medical Practice Study (Brennan et al., 2004). This report gained the attention of a United States Congressional subcommittee when the researchers briefed them on the state of human error management in the

United States medical industry. The study's primary goal was to develop accurate and reliable estimates of the incidence of adverse events in hospitalized patients in New York State. After analyzing the charts of over 30,000 inpatients, they estimated the occurrence of adverse events neared 3.7% (Brennan et al., 2004). They found the likelihood of occurrence of an adverse event increased with the patient's age, and the risk doubled for those greater than sixty-five years old (Brennan et al., 2004). Thus, identifying increased age as a vulnerable population in patient safety research. Prior to this report, very little data existed in the literature that quantified the rate and incidence of medical errors. The IOM's response exhorted healthcare providers to examine patient safety, address the prevalence of adverse events in the United States, and called for a 50% reduction in adverse events over a 5-year period (Kohn et al., 2000).

Identification of vulnerable populations and underlying barriers to the delivery of quality medical care could lead to a decrease in adverse patient outcomes and allows for a systematic analysis of the delivery of medical care to help guide informed decisions about outcomes. The potential for adverse sequelae of vulnerable populations, like the obese, contributes to the development and acquisition of evidence-based practice to promote safety.

Obesity

Obesity is a chronic disease associated with increased health risks that potentially impact the population during a hospitalization. As the individual's BMI increases, the associated health risks increase as well (Buchwald, 2005). The World Health Organization (WHO) classifies individuals with a Body Mass Index (BMI) of 25-29.99 kg/m^2 as overweight and those with a BMI greater than 30kg/m^2 as obese classes I-III (World Health Organization, 2000). National Health and Nutrition Education Survey (NHANES) data showed adjusted trends in obesity were 38.8% of the overall population and the combined category of overweight/obese (BMI greater than 25) to be as high as 68% of the population (Flegal, Carroll, Kit, & Ogden, 2012; Flegal, Carroll, Ogden, & Curtin, 2010). Patients who are overweight or obese have concomitant diseases such as diabetes mellitus, hypertension, asthma, arthritis, and elevated cholesterol (Buchwald, 2005; Flegal et al., 2010). Obesity is recognized as a global risk to mortality according to the WHO (World Health Organization, 2009).

With the rising rates of obesity, anesthesia providers will likely encounter obese patients frequently in their practice, necessitating the need for research in this vulnerable population. The associated comorbidities and health risks of the obese surgical patient, coupled with the risk associated with surgery, are additive for potential surgical and anesthesia complications. The examination of the impact of obesity on surgical outcomes addresses quality and mechanics of delivery of care to this population. An understanding of the potential adverse events will prevent untoward outcomes (Battles & Lilford, 2003; Buchwald, 2005).

Due to the nature of patient care, medical professionals are frequently required to make split second decisions and perform procedures that may affect patient safety. The obese surgical patient presents unique challenges to anesthetists. These patients are likely to present with difficulty in mask ventilation, increased risk for inability to secure adequate airway and tracheal intubation, and alterations in lung mechanics (Dixon et al., 2005). It is the aim of this research to examine patient safety in the obese surgical population. The purpose of this dissertation is to 1) quantify the prevalence of obesity in the surgical population, 2) to examine the degree to which undesirable outcomes occur in the obese surgical patient population, and 3) to determine the reliability of ICD-9 codes to identify obesity as a risk factor in adverse surgical outcomes. A systematic analysis in the delivery of care will help guide decisions to influence outcomes in the area of patient safety and quality. The results of this research will be presented in three manuscripts. Manuscript 1 presents a historical background on patient safety through the establishment of evidence-based practice as a model for nurse anesthesia. Manuscript 2 presents an original study of clinical and administrative data from one health system, which examines the prevalence of obesity in the surgical population and examines patient safety occurrences in the obese surgical population. Manuscript 3 presents a study, which questions the methodological use of administrative data to determine the reliability of ICD-9 codes to identify obesity as a risk factor in patient outcomes.

Evidence Based Practice

The first manuscript, *Alice Magaw: A model for Evidence-Based Practice* (EBP*)* (Goode, 2015) is to be published in the American Association of Nurse Anesthetist (AANA) Journal in February 2015 (See Appendix 1). This publication depicts Magaw and the practice of nurse anesthesia as an early pioneer in the model of patient safety and prophetic to the aims of the IOM. The Institute of Medicine (IOM), in its report, the Quality Chasm, identified six aims essential to improving the delivery of care. Magaw used her vast expertise in anesthetic administration to develop protocols and a body of knowledge that could be used as a template for practitioners near and far. This early use of EBP principles places nurse anesthesia at the forefront of the model and the movement essential to provide quality care. Practitioners sought her practice model out as she demonstrated her techniques to visiting providers as well as through her published ideal anesthetics in the literature. As a pioneer, she developed a body of knowledge, which served as a model for continuous improvement, publication of numerous findings and a basis for the practice of anesthesia. She set into motion the requirements of vigilance and education. This early use of EBP principles places Magaw at the forefront in the movement of patient safety. Alice Magaw exemplifies this EBP model.

Obesity In the Surgical Patient

Manuscript 2, *A Patient Safety Dilemma: Obesity In the Surgical Patient* (Goode et al., 2015) was prepared for submission to the AANA Journal (see Appendix 1). Through examination of clinical and administrative data created from a surgical population in one health system during a 2-year study period, this manuscript examines prevalence rates of obesity in the surgical populations as well as determines the relationship between obesity and post-surgical complications. Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators (PSIs) for perioperative pulmonary embolism and deep vein thrombosis, post-operative respiratory failure, and post-operative sepsis are used to examine the surgical population to compare outcomes in the obese patient population. Findings from this study can be used to reexamine practice and to develop evidence-based practice protocols that benefit this vulnerable population. The results of this study emphasize the importance of the aims established by the IOM regarding patient safety, specifically safe care.

Reliability of ICD Codes to Identify Obesity as a Risk Factor

In the third manuscript, *Are ICD Codes in Electronic Health Records Useful in Identifying Obesity as a Risk Factor When Evaluating Surgical Outcomes* (Goode et al, 2015) was prepared for submission to the American Journal of Medical Quality (see Appendix 2). This paper addresses an important methodological issue to inform the design of future research on this topic. Through the examination of clinical and administrative data, this manuscript assesses for the reliability of using International Classification of Diseases-9 (ICD-9) diagnoses codes alone to reliably identify obesity (278.00, 278.01, 278.02, 278.03, & 278.1) as a comorbidity and risk factor in care and management. It also asks whether ICD-9 codes accurately reflect the prevalence of obesity in the surgical population (Agency for Healthcare Research and Quality, 2014).

Improvements have been made in ICD-9 codes and ICD-10 codes to expand their clinical criteria and the number of available diagnoses in order to aid providers and coders in their ability to accurately and reliably identify diseases (Quan et al., 2005; Quan et al., 2008). Obesity, identified through the use of ICD-9 codes, is also considered one of 30 comorbidities recognized by AHRQ, which emphasizes the importance of this diagnosis (Agency for Healthcare Research and Quality, 2014). Despite this knowledge, the literature does not confirm improvement in the use of ICD-9 diagnoses for several comorbidities including obesity. Research is needed to understand the reliability of ICD-9 codes for obesity. The associated health risks, hospital costs, and potential adverse events associated with obesity make it imperative to continue to study the barriers to coding.

Overall it is the aim of this research to aid in the development of protocols and policy for healthcare systems regarding patient safety and quality. Chapter 2 of this dissertation will guide the reader through the approach used to conduct this research followed by three manuscripts, which report the research in chapters 3, 4, and 5. Chapter 6 reports the conclusions of the research. The implications of these findings will then be presented to guide further research for health systems, healthcare workers, and health policy for the obese population.

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Proposal Abstract

The IOM defined patient safety in terms of errors and adverse events. An error is defined as "the failure of a planned action to be competed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning). An adverse event is an injury caused by medical management rather than the underlying condition of the patient" (Kohn, Corrigan, & Donaldson, 2000, p.28). Identifying the underlying barriers to the delivery of quality medical care could lead to a decrease in medical errors and untoward patient outcomes. The identification of vulnerable populations is needed to address their potential for adverse outcome. Due to the alarming rates at which obesity presents in the United States, the obese patient is a critical vulnerable population to examine. The obese patient presents with unique associated disturbances that affect the body anatomically, physiologically and metabolically which predisposes the obese patient to an increased risk of morbidity from stroke, ischemic heart disease, diabetes, deep vein thrombosis, wound infection and death (Dindo et al., 2003; Dixon et al., 2005; Herron, 2004). This research aims to quantify the degree to which undesirable outcomes occur in the obese surgical patient population and highlight the need to further examine necessary systems as set forth by the aims of the IOM regarding patient safety and quality of care. Therefore it is essential for the healthcare provider to understand the differences the obese patient presents and the impact of these differences in order to prevent adverse events.

Chapter Two

Research Proposal

The IOM defined patient safety in terms of errors and adverse events. An error is defined as “the failure of a planned action to be competed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning). An adverse event is an injury caused by medical management rather than the underlying condition of the patient” (Kohn, Corrigan, & Donaldson, 2000, p.28). Hospitals and other medical institutions are thus being encouraged to find strategies and measures, to use technologies and systems, to develop protocols to reduce errors and adverse events, and to provide mechanisms of patient safety leading to quality outcomes. Identifying the underlying barriers to the delivery of quality medical care could lead to a decrease in medical errors and untoward patient outcomes. Studies to determine the incidence of adverse events and the development of interventions to curb the incidence are found throughout the literature but little progress has been made in the IOM’s call for a fifty percent reduction over a five year period (Kohn et al., 2000).

The obese patient is a critical patient to target in providing quality medical care (Dindo, Muller, Weber, & Clavien, 2003). The obese patient presents surgical departments with many challenges and the potential for adverse outcomes (Buchwald, 2005). The prevalence of obesity present in today’s surgical patient population is unknown. It is important to identify the prevalence of adverse outcomes and underlying factors that impact the delivery of care, which could lead to adverse patient outcomes in this special population. There are few current nationwide studies that address the complexity of the obese surgical patient including its prevalence in the surgical population. The obese patient presents with unique associated disturbances that affect the body anatomically, physiologically and metabolically which predisposes the obese patient to an increased risk of morbidity from stroke, ischemic heart disease, diabetes, deep vein thrombosis, wound infection and death (Dindo et al., 2003; Dixon et al., 2005; Herron, 2004). Therefore it is essential for the healthcare provider to understand the differences obese patient presents and the impact of these changes in order to prevent adverse events. Hospital operating room design should be with the obese patient in mind and emergency equipment should be readily available in order to be prepared for the possibility of complications the obese patient faces (Herron, 2004). The surgical and anesthesia team can be best prepared to avoid untoward events when possible complications are understood and systems and technology are in place to avoid inferior outcomes or death.

The major objective of this research is to examine the prevalence of obesity in the surgical population and to examine outcomes from surgical and anesthesia medical care for the obese surgical patient population through the use of the AHRQ PSIs. Through examination of these data, this research may help to quantify the degree to which undesirable outcomes occur in the obese surgical patient population and highlight the need to further examine necessary systems as set forth by the aims of the IOM regarding patient safety and quality of care. A systematic analysis in the delivery of medical care will help guide informed decisions about care to influence outcomes in the area of patient safety and quality of care. The specific aims of this study were to:

1. Determine the prevalence rate of obesity (per 1000 surgical cases) in patients undergoing surgical procedures.

2. Determine if BMI differs for patients with and without post-surgical complications.

3. Determine the relationship of obesity and other patient characteristics (age, gender, race, health resources) on post-surgical complications in the obese versus non-obese population, after controlling for comorbidities.

4. Determine the reliability of using ICD-9 codes to identify patients with obesity and compare with the patient's calculated BMI kg/m^2.

In order for errors to be reduced, patient safety and quality delivery of care needs to be of paramount importance. Knowledge of the potential sequelae that the obese surgical population faces is important. By analyzing the data from this population, healthcare workers can use systems and technology to help develop protocols and policies that will put into motion measures to diminish the occurrence of potential life threatening adverse events. These aims address the functionality of the healthcare system and patient safety. They specifically address the aims of the IOM that specifies healthcare should be safe, effective, based on scientific knowledge, patient centered, timely, efficient and equitable (Institute of Medicine Committee on Quality of Health Care in America, 2001).

A. Background and Significance

Obesity is a complex, multifactorial chronic disease. It is considered a leading cause in preventable death in the United States with approximately 300,000 deaths per year related to the complications associated with obesity and its impact on the body (Dindo et al., 2003). A 2003 estimated total annual health cost for obesity was over $117 billion (Bamgbade, Rutter, Nafiu, & Dorje, 2007) and 2008 estimates project it to skyrocket to $147 billion (Finkelstein et al., 2008). Its prevalence has increased since the 1980s for both men and women in all age groups. Obesity is considered a chronic disease and as such this classification presents the risk of serious health sequelae for which healthcare workers can prepare (Agency for Healthcare Research and

Quality, 2014; Buchwald, 2005; Frellick, 2013). Obesity is quantified through a measurement of Body Mass Index (BMI) and is stratified through a World Health Organization (WHO) classification system that includes underweight (BMI< 18), normal weight (BMI 18-24.99), overweight (BMI 25-29.99) and 3 Classes of obese. Class I obesity (BMI of 30-34.99) is considered obese, Class II obesity (BMI of 35-39.99) is considered morbidly obese, and Class III (BMI> 40) is considered super-obese. National Health and Nutrition Education Survey (NHANES), 2010 data show trends in obesity include 38.8% of the overall population (Flegal, Carroll, Kit, & Ogden, 2012; Flegal, Carroll, Ogden, & Curtin, 2010). NHANES data revealed the combined category of overweight and obese to be as high as 68% of the population (Flegal et al., 2012; Flegal et al., 2010). With this knowledge and data, it is evident that health service researchers need to investigate and report the outcomes for the obese population. Surgical and anesthesia healthcare providers will encounter obese patients frequently in their practice, necessitating the need for education about obesity and its impact on the patient to address quality indicators and delivery of care to the obese surgical and anesthesia population.

The obese surgical patient presents unique challenges to the healthcare provider specifically as it relates to anesthesia. They are likely to present with difficulty in mask ventilation, higher risk for hypoxia and desaturation during apnea periods, increased risk for inability to secure adequate airway and tracheal intubation (Dixon et al., 2005). The surgical obese patient requires expert support and knowledge of changes specific to the changes in the physiology and mechanics of the obese patient (Buchwald, 2005) to provide safe patient care and prevention adverse outcomes. The development of fundamental skill sets creates a framework for case management and leaves less to happenstance (Gwande, 2009). The risks associated with obesity are evident in the literature but little research has quantified the complication rates in the obese surgical patient versus the non-obese patient population.

In order for errors to be reduced, patient safety and quality delivery of care needs to be of paramount importance. Knowledge of the potential sequelae that the obese surgical population faces is important and this can be accomplished by creating care that is evidence-based (Berwick, 2002; Kohn et al., 2000). Obesity is a chronic disease in which the patient can experience a number of untoward events during the course of a procedure or hospitalization (Bamgbade, Rutter, Nafiu, & Dorje, 2007). The goal of this research affirms that healthcare should be safe and void of injury to patients (Institute of Medicine Committee on Quality of Health Care in America, 2001).

The Harvard Medical Practice Study (Brennan et al., 2004) highlighted the incidence of medical errors and adverse events in the United States. Their primary goal was to develop accurate and reliable estimates of the incidence of adverse events in hospitalized patients in New York State. The response to this report from the Institute of Medicine (IOM) determined nearly 98,000 annual deaths were attributed to medical related errors in the United States (Kohn et al., 2000) with associated health care costs between $8.5 and 14.5 billion and per year (Kohn et al., 2000; Rosenthal & Dudley, 2007). Patient safety and delivery of quality of care is a major concern for healthcare in the United States. The IOM reports a gap exists in healthcare delivery and healthcare systems are in need of fundamental change (Institute of Medicine Committee on Quality of Health in America, 2001).

Hospitals and providers are faced with soaring costs and limited reimbursements. Patients are faced with the fear of undue errors and devastating health consequences. The federal government is beginning a pay for service era that fails to reimburse for hospital-acquired complications and reform is quickly making its way through congress(Rosenthal & Dudley, 2007). Therefore this study impacts patients, hospitals and surgical settings, costs of healthcare, and the workforce of surgical providers. The increasing rates of obesity for our nation and obesity's impact on development of chronic disease (Frellick, 2013; Institute of Medicine Committee on Quality of Health Care in America, 2001; Thorpe, Florence, Howard, & Joski, 2004) place this population at increased risk. The increased health risk of the obese patient and the need for surgery has an additive impact on the potential for adverse outcomes.

It is evident there exists a need to address the aims of this study. Healthcare workers should expect to encounter the obese patient population and strive to provide care that is evidence based and abides by the recommendations of the AHRQ. It is necessary to use the measures of performance to gauge improvement and accountability, making patient safety and quality care delivery its overwhelming objective (Institute of Medicine Committee on Quality of Health in America, 2001).

In order to accomplish this research, Donabedian's conceptual model was used to examine this area of patient safety. This theoretical model for patient safety focuses on structure, process, and outcome (Donabedian, 1972; Donabedian, 1980). Structure refers to the properties of the organization where the patient receives care, processes are management or treatment(s) that are delivered as part of the care prescribed to the patient and require interactions with healthcare workers. It also incorporates properties of the organization in which the patient receives care such as surgical service location (inpatient or ambulatory) and also includes the critical attributes of leadership, research, tools/measurements, and protocols (Jensen, 2008; Kaafarani et al., 2011; Kohn et al., 2000). Processes are treatment(s) that are delivered as part of the care prescribed to the patient. Outcomes are the final results of the plan and may be desired or undesired consequences of events. Outcome measures of PSIs reflect the process of care that occurs in particular patient care through evidence based practice standards from a review of the literature, professional association or professional panel (Institute of Medicine Committee on Quality of Health Care in America, 2001). The established AHRQ PSIs will measure outcomes and Figure 1 describes the interaction of structure, process and outcome as they are used to guide this research. Through the use of measurement and analysis one can examine an organization's performance, which can then transfer to application for the workforce and institutional operation, yielding improved performance for the system and better outcomes for the patient (Baldrige National Quality Program, 2010).

This model incorporates patient safety management components to effectively assess how structure and process impact outcomes through the adaptation of structure and process in the obese surgical patient. Donabedian describes the importance of understanding quality, a necessary component of measuring the delivery of safe care. Quality is three pronged and includes technical care, the relationship between patient and provider, and the attributes of the healthcare setting. Each component is reliant on the other and it requires success in all three areas to deliver quality of care and quality has two major components: system design and performance monitoring. Both concepts are necessary to balance the provision of care to patients and the capability of their healthcare provider (Donabedian, 1989) and vigilance is an ever-present priority.

The importance of launching patient safety initiatives is to describe a process designed to incorporate a 3-tiered approach via identification of risks, implementation, and evaluation. Certain events have the potential to produce harm and as such are often associated with fragmentation in the organization's structure (Battles & Lilford, 2003). System design and performance monitoring are concepts necessary to balance the provision of care to patients and the capability of their healthcare provider (Donabedian, 1989). The focus of the research will examine performance monitoring through PSIs specifically that of the obese surgical patient.

The climate of the nursing unit is also an important element for patient safety. Unit climate and hospital climate are predictors of patient safety outcomes. If the two climates were maximized to incorporate orientation, professional development and teamwork a net positive impact could be seen. If the inverse, it could be related to poorer outcomes (Zohar, Livne, Tenne-Gazit, Admi, & Donchin, 2007). They highlight the importance of a strong nursing manager as a leader. This alone could provide the atmosphere necessary to counter a poor hospital climate and produce patient safety outcomes (Zohar et al., 2007). These findings support nurses, as strong proponents in the arena of patient safety. Research identifies general behavior and communication difficulties that present as barriers to patient safety and encourages the empowerment of nurses to initiate red-rules (during the surgical count), which would halt behaviors until compliance is restored and the "need for improved patient safety practice to include processes or structures whose application reduces the probability for the occurrence of an adverse event" (Rowlands & Steeves, 2010, p. 417). Finally, Alfredsdottir and Bjornsdottir report in their research that three factors are essential to patient safety: "preventative thinking, knowledgeable and experienced workers supported by good teamwork, and mutual trust based on many years of cooperation" (Alfredsdottir & Bjornsdottir, 2008, p. 33). Patient-centered care and knowledge of specific vulnerabilities of the population is of primary importance to prevent adverse outcomes. They emphasize the importance of the relationship with the operating room team, specifically the anesthesia team, in relaying the important information regarding the patient's record and ultimately patient safety (Alfredsdottir & Bjornsdottir, 2008). This could be applied to the need for the anesthesia team to address the particular concerns for special populations like those of the obese surgical patient.

While studies exist that quantify the prevalence of obesity in the general population this has not been quantified in the surgical population. A current study looked at the post-operative complications in the obese patient in surgery, but that study does not address the potential differences in post-operative complications for the degrees of obesity (Bamgbade et al., 2007). One can assume obese patient surgical complications are similar to the bariatric surgery patient (Buchwald, 2005), however; the rigor of examination and preparation the morbidly obese patient undergoes prior to bariatric surgery varies in both preparation and setting and as such this exceeds that of the obese in the general surgical population. This research will investigate this gap and propose a reexamination of protocols that would ameliorate potential harmful outcomes for the obese surgical patient.

B. Innovation

The IOM established new rules, which define Patient Safety as care, delivered which is evidence-based, transparent, and fully anticipates the patient's needs (Institute of Medicine Committee on Quality of Health Care in America, 2001). The Agency for Health Related Quality (AHRQ) establishes patient safety practice as an integration of processes and/or structures which diminish the probability of adverse outcomes from exposure to the health care system (Shojania, Duncan, McDonald, Wachter, & Markowitz, 2001). It is necessary to have this premise regarding patient safety because "without robust systems to prevent fumbles, the patient falls prey to the dangers inherent" (Gandhi, 2005, p. 354). Thus it is of paramount importance to explore the events that lead to delays in care, misdiagnosis, and medical error in order to identify potential areas of research for nursing and interdisciplinary approaches to help forge systems that address patient safety and effectiveness in care. Special populations (like the obese patient) are of utmost importance to health services research. Special populations are in need of research in order to support patient safety, quantify risks, advance education for healthcare-workers, establish healthcare policy, and promote leadership in the field.

Recognition and development of protocols for this special population provides a set framework of case management designed to leave less to happenstance (Gwande, 2009; Pronovost et al., 2006). The risks associated with surgery for the obese patient are evident but imprecisely quantified via BMI and the WHO obesity classification system. Without knowledge of risk of post-operative outcomes in the obese population, potential devastating events may occur for the patients, healthcare institutions, and healthcare workers. It behooves the researcher to examine which systems and processes should be developed to decrease the incidence of potential complications for this population and develop a best approach model for the surgical obese patient. It is not enough to recognize that a problem exists but efforts to improve patient safety and surgical complications should be examined.

C. Approach

Design/Methods

The proposed research design is a correlational study using secondary data analysis. Through the use of secondary data, the researcher hopes to gain new knowledge on the proposed research by addressing the following objectives: 1) Determine the prevalence rate of obesity in patients undergoing surgical procedures; 2) Determine the differences in BMI for patients with and without post-surgical complications: Postoperative Respiratory Failure (PSI-11); Perioperative Pulmonary Embolism Deep Vein Thrombosis (PSI-12), and Postoperative Sepsis (PSI-13); 3) Determine the influence of obesity and other patient characteristics on post-surgical complications to include: Postoperative Respiratory Failure (PSI-11), Perioperative Pulmonary Embolism Deep Vein Thrombosis (PSI-12), and Postoperative Sepsis (PSI-13) after controlling for comorbidities; and 4) Determine the sensitivity of using ICD-9 codes to identify patients with obesity and compare with the patient's BMI.

Obesity has reached epidemic levels in the United States making these important questions to examine. Obesity is hypothesized to increase complications in the surgical population. The researcher will look at patient factors (age, race, gender) health resources (insurance) comorbidities (as identified by AHRQ comorbid conditions), and BMI to determine if the occurrence of post-surgical complications: postoperative respiratory failure (PSI-11), postoperative pulmonary embolism or deep vein thrombosis (PSI-12), and postoperative sepsis (PSI-13) are significantly higher for the obese versus non-obese surgical population. Finally the researcher will evaluate the reliability of using ICD-9 codes to identify obesity. This will inform the design of future studies in patient safety.

Sample

The target population is patients between 18-85 years old admitted for a surgical procedure at a major academic medical center in the southeast for the years of 2011 and 2012.

Inclusion criteria

All patients within the designated age range who had a surgical procedure during the period indicated were included in the sample. Surgical procedures during both inpatient and outpatient surgeries were included. The qualification of cases was defined as surgeries in which an anesthetic was administered and the unit of analysis was the case. Only the first surgical case was recognized for study period.

Exclusion criteria

The following patient populations will be excluded from the study: those having cardiac surgery or bariatric surgery, any patient with the diagnosis of end stage renal disease (ESRD) who is receiving hemodialysis due to the severity of the coexisting disease and the increased risk of post-operative sequelae, and patients who are pregnant or admitted for childbirth. Each PSI population will result in a slightly different number (N) due to the additional specific inclusion/exclusion criteria for the varying PSI.

Setting

The research will be conducted in a major academic medical center in the southeast. This center ranks as a leader, ranked by U.S. News & World Report as one of the nation's top hospitals and is accredited by the Joint Commission on Accreditation of Healthcare Organizations. The Medical Center includes the hospital, trauma center and primary and specialty care locations in the southeast. According to most recent data, their 500+ bed capacity hospital has over 28,000 admissions with over 14,000 inpatient surgeries and over 53,000 outpatient surgeries for its most recent years data.

Database

The study institutions' Multicenter Perioperative Outcomes Group (MPOG) data elements and the hospital's Clinical Data Repository (CDR) will be utilized in the process of construction of the study dataset. The MPOG database includes standard patient observations via anesthesia records and included general case information, America Society of Anesthesiologists (ASA) classification, demographics, pre-operative physical exam, case providers, anesthesia technique, and anesthesia case times (Multicenter Perioperative Outcomes Group, 2011).

The Clinical Data Repository (CDR) is a data warehouse managed by the Clinical Informatics Division of the Dept. of Public Health Sciences at the university. This healthcare database contains information regarding patients' visits within health system over a 15-year time span and contains information on approximately 1million patients. It provides experienced and developing researchers a comprehensive source of clinical data that includes: patient demographics, diagnosis, medications, laboratory results and procedures, and death certificates, as well as a source of financial information that includes payers, costs and charges, and reimbursements. From the vast wealth of information stored within the dataset, it is possible for a researcher to propose a research question at the client level (with health outcomes). This database consists of a set of core clinical criteria, vital signs including BMI, non-clinical criteria, all diagnosis procedures (ICD-9), discharge status, patient demographics, total hospital charges, and payers both private and public (CDR, 2012).

In order to capture the required data elements in a single dataset, the information from MPOG will be linked to CDR information. MPOG will be used to identify all surgical procedures for the study period (2011-2012), cases will be matched by identification data and the CDR will be used to obtain procedure specific clinical and administrative data elements.

The researcher will examine the database thoroughly and assess each variable of interest for accuracy and for the level of missing values. The dataset is appropriately equipped to address the outcomes of this research question.

Data Collection Protocol

After approval from the applicant's dissertation committee, the proposed research will be submitted to the medical center's IRB. IRB exemption will be granted and dataset construction will begin for this study. The data will be housed on the University's secured data management system, which has the appropriate ability to store large databases. The database will be examined and recoded allowing for the appropriate variables to be developed. The applicant's dataset will have appropriate security measures in place to prevent tampering of the database and the research results. The applicant will be given access to the dataset through established School of Nursing procedures. All data will be de-identified with the option for future identification if necessary for chart review.

Power Analysis

Power analysis will be necessary and procedures for conducting the power analysis are still in development. The significance will be set at 0.05 and power at 0.8 as established in the literature. AHRQ published rates of patient safety indicators (PSI), observed rates per 1000 surgical cases (AHRQ, 2012), will be used to determine the expected occurrence of the outcome; this information will be considered in relation to the number of surgical procedures to determine an adequate sample size. The needed sample size will determine the number of years of data to use in the study. The power analysis will be conducted under the guidance of a statistician and the dissertation chair. Since there are approximately 55,000 surgeries performed throughout the health system and the rate of obesity is approximately 30% of the population, adequate power should be achieved for the planned study. It should be noted this original power analysis was modified and is reported in manuscript 2.

Concepts/Variables

To answer the proposed questions specified in the specific aims it will be necessary to examine the following concepts and variables: Demographic variables included patient factors gender (male or female), age, and race. The concept of health resources (insurer) followed. The concept of structure/treatment included the variable length of stay (the number of nights the patient remained in the hospital (HCUP, 2010), inpatient or outpatient status, and number of procedures and diagnosis as identified by ICD-9 coding. The next concept of health risk included variables reflecting health risks: comorbidities, obesity and BMI as calculated by weight (kg)/[height (m)2 and BMI classifications (underweight, normal weight, overweight, and obese class I-III) as designated by the WHO (World Health Organization, 1997; World Health Organization, 2009). Comorbidities were constructed using the AHRQ comorbidity algorithm developed by AHRQ for comorbid conditions (Agency for Healthcare Research and Quality, 2014), obesity classification by ICD-9 codes (278.00 obesity unspecified obesity, 278.01 morbid obesity, 278.02 overweight, 278.03 obesity hypoventilation syndrome, and 278.1 localized adiposity/fat pad) (Agency for Healthcare Research and Quality, 2014).

The final concept of PSIs includes the outcome variables as designated in the AHRQ patient safety indicators (version 4.2 2010) identified by using ICD-9 codes. These variables included postoperative respiratory failure (PSI-11), perioperative pulmonary embolism and deep vein thrombosis (PSI-12), and postoperative sepsis (PSI-13) (See Table 1).

Postoperative respiratory failure (PSI-11) is defined as cases of acute respiratory failure per 1,000 elective surgical discharges and by the number of surgical discharges among cases meeting the inclusion and exclusion rules for the denominator with ICD-9- CM codes for acute respiratory failure (518.81) in any secondary diagnosis field. PSI-11 excludes ICD-9 codes for re-intubation procedure as follows: 96.04, 96.70, 96.71, and 96.72. Perioperative pulmonary embolism and deep vein thrombosis (PSI-12) is defined as cases of PE/DVT per 1,000 elective surgery patients as the number of surgical discharges among cases meeting the inclusion and exclusion rules for the denominator with ICD-9- CM codes for deep vein thrombosis or pulmonary embolism in any secondary diagnosis field. Postoperative sepsis (PSI-13) is defined as cases of sepsis per 1,000 elective surgery patients, with length of stay more than 3 days (excludes principal diagnosis of infection) (AHRQ, version 4.5, 2012). An additional PSI, complication of anesthesia (EXP-1) will be eliminated as a study variable as it is considered an experimental PSI and will not meet the criteria for the AHRQ algorithm in the dataset.

For the development of the hierarchical logistic regression and as advised by the power analysis, two additional variables will be created. Race, which included White, Black, Hispanic, Asian, Native American and other, will be further reduced to a dichotomous minority variable (minority and non-minority). Insurer will be further reduced to dichotomous private insurance variable (private and public) (See Table 1).

Data Construction

Secondary data will be obtained from clinical and administrative data for each inpatient and outpatient surgical case. All patients within the designated age range, with an inpatient or outpatient surgical procedure will be included. For patients with multiple surgeries during the study time period, only the first surgery (index surgery) will be recognized for 2011-2012 study period will be included. The qualification of case is defined as a surgery in which an anesthetic was administered. The unit of analysis is the case.

If the case includes multiple procedures during one admission, the case will still be eligible. Procedure one (from the administrative data) will be selected as the principal procedure in the study. Following database construction, including data cleaning and construction of needed variables, a missing values analysis will be completed. Following that, decisions will be made regarding replacement of missing values and/or elimination of cases with incomplete data. Variables with more than 5% missing values will be evaluated to determine the need for using an imputation procedure or for case deletion.

Analysis Plan

The Statistical Analysis System (SAS) version 9.2 will be used to perform statistical tests. The general approach to the analysis plan for each specific aim is presented. First, descriptive statistics including means, standard deviations, and frequencies will be developed for all variables for the total population. Descriptive statistics for the study variables will be developed for the total sample, inpatients, outpatients, and each PSI (11,12, and 13) group.

Specific Aim 1

1. Determine the prevalence rate of obesity (per 1000 surgical cases) in patients undergoing surgical procedures

In specific aim 1, descriptive statistics will be calculated to determine the rates of obesity. This will be accomplished by calculating BMI by weight (kg)/[height (m)^2 and BMI classifications (underweight, normal weight, overweight, and obese class I-III) as designated by the WHO (World Health Organization, 1997; World Health Organization, 2009). A frequency distribution will be used determine the numerator of the prevalence rate.

Specific Aim 2

Determine the differences in BMI for patients with and without post-surgical complications to include post-operative rates of: postoperative respiratory failure (PSI-11), perioperative pulmonary embolism deep vein thrombosis (PSI-12), and postoperative sepsis (PSI-13).

Hypothesis 2.1 BMI will differ in patients with post-surgical complications compared to those patients without post-surgical complications.

Descriptive statistics including means, medians, and standard deviations; will be completed on the variables. The differences in means of BMI based on the post-surgical complications will be evaluated using a t-test. This test makes inferences about the probability of distribution and parameters of distributions of the population, allowing for the research to distinguish group differences. In order to use a t-test to evaluate hypothesis 2.1, the following assumptions must be met: independent groups, the dependent variable should be continuous, there should be no significant outliers, and should be normally distributed. After confirmation of assumptions, the independent t-test will be conducted (Meyers, 2005).

Specific Aim 3

Determine the influence of BMI on post-surgical complications to include: postoperative respiratory failure (PSI-11), perioperative pulmonary embolism deep vein thrombosis (PSI-12), and postoperative sepsis (PSI-13) in the obese versus non-obese population after controlling for patient factors, health resources, treatments, and comorbidities.

Hypothesis 3.1: After controlling for patient factors, health resources, treatments, and comorbidities, BMI will increase post-operative complications for the surgical population PSIs: postoperative respiratory failure (PSI-11), perioperative pulmonary embolism deep vein thrombosis (PSI-12), and postoperative sepsis (PSI-13).

Descriptive statistics will include frequencies, means and standard deviations for all variables. Hierarchical logistic regression (HLR) models will be developed for each PSI. In order to use hierarchical logistic regression to evaluate hypothesis 3.1, the follow assumptions and diagnostic must be met: adequate sample size must occur, the dependent variable must be dichotomous; normality of the independent variables will demonstrates skewness of less than 4.0; univariate normality met; missing values analysis all less than 5% (or as designated in the sample); mulitcollinearity (tolerance, variation inflation factor (VIF), condition index, variance proportions, Cooks', Leverages, Student Standardized) of the independent variables will be completed and all conditions will be met; and finally correlations will be used to examine relationships among variables by first examining BMI alone (Meyers, 2005). The patient level outcome variable is a 2 level variable (0=no complication and 1=complication present), hierarchical logistic regression models will be developed for each selected post-operative complication.

After confirmation of diagnostic and assumptions, separate models will be developed for each selected post-operative complication PSI, adding each block of variable(s), to the model including demographics, resources, health risks, and treatments for each outcome. Therefore, for each PSI model, the following models will be generated, reflecting each additional block of variables.

Model 1:

Perioperative Pulmonary Embolism Deep Vein Thrombosis Complication of Anesthesia (PSI-12) not present =0 present=1.

Block 1: Demographics: a model will be run for demographics, which include the patient's race, age and gender

Block 2: Resources: a model will be run for resources, which include the patient's insurer

Block 3: Health Risks: a model will be run for health risks, which include the patient's comorbidities

Block 4: Health Risks: a model will be run for health risks, which include the patient's BMI, the variable of interest.

Block 5 Treatments: a model will run be for treatments, which include the patient's length of stay.

An estimation of the above model will be constructed for each of the 3 PSIs (postoperative respiratory failure (PSI-11), perioperative pulmonary embolism deep vein thrombosis (PSI-12), and postoperative sepsis (PSI-13) individually and the final model will include all five blocks of variables.

Specific Aim 4

Determine the sensitivity of using of ICD-9 codes to identify patients with obesity and compare with the patient's calculated BMI.

Hypothesis 4.1: The ICD-9 codes for obesity, (278, 278.01, 278.02, 278.03, 278.1) may be absent from the diagnosis in the dataset and thus may not accurately reflect the presence of obesity in the surgical population.

Descriptive statistics will be used to calculate BMI, BMI classification, and percentage of patients who are classified accurately as obese via BMI classification when compared to ICD-9 codes for obesity (278, 278.01, 278.02, 278.03, 278.1). These ICD-9 codes may be absent from the diagnosis in the dataset and thus do not accurately reflect the presence of obesity in the surgical population, allowing for an underestimation of the prevalence and of complications. The importance of reliability testing helps to distinguish if the test or diagnosis reflects the actuality of the disease process. Its absence or presence may or may not negate the disease.

Protection of Human Subjects

The IRB (Title 45 CFR part 46, Subpart D) oversees the rights and welfare of human subjects involved in research by providing a governing body that ensures research protocols will not endanger the safety of the human subjects. Participants, after a comprehensive overview of the research protocol can choose to enter into research. The object to consider and maximize the benefits of research but to minimize harm to the participant, an expectation under the

Hippocratic oath, which guides the medical practitioners (Belmont Report, 1979). Three principles are involved in Human Subject Research: boundaries for practice and research, basic ethical principles, and applications. The first principle explains the boundaries between practice and research and interventions designed should be aimed at enhancing the well being of an individual patient or client. The principle of basic ethical applications of respect for persons, beneficence, and justice should be considered. It is important for the researcher to consider the applications of the Belmont Report as they develop informed consent guidelines, risk and benefits of the research, and participant selection.

The use of secondary data sets presents another consideration for human subject research. In some instances secondary datasets are exempt from requiring the approval of the IRB however there are conditions in which this exemption does not pertain. The federal regulations state, "if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, the data are considered exempt" (NHRPAC, 2002). It is this researcher's goal to maintain the data in the de-identified state. The proposed research will use a clinical healthcare dataset, which uses archival data with no planned involvement with human subjects. According to federal regulations, researchers requesting potentially identifiable data will also need to undergo the approval from IRB to obtain data access.

There is risk to loss of confidentiality if the dataset becomes identified. Investigators are encouraged to adopt the following principles in order to protect the confidentiality of subjects participating in research. There are specified protocols of the medical center that cover highly sensitive data which could identify a persons health conditions or history. Data should be void of HIPAA identifiers. The dataset will be stored on a secure site in accordance with the medical center's policy, which states highly sensitive data must be securely encrypted on the electronic device or media. The electronic device must at a minimum employ the basic security requirements described a login password must be enabled for the electronic device. The password must be appropriate complex and not shared. Data must be deleted from the individual-use device or media as soon as they are no longer required using secure methods. Written approval is necessary to include any other members to the research team and a file of approval is needed in a secure location for subsequent audit purposes. This dataset will be secured from tampering and stored in a HIPPA approved research server as per the medical center's protocol. All printed materials will be stored in a locked area. The researcher will request password protection and permission to obtain a locked account to store confidential analysis.

The dissemination of results could benefit the participants and the healthcare field at large. There are no direct benefits to the participants. This research will add to the field of health services research and patient safety. The results of this research will be shared via a peer-reviewed publication and will impact the healthcare field regarding patient safety and the delivery of quality care. The dataset contains health information about both men and women. It will include minorities as they are represented.

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Table 1. Variable Concepts and Definitions

Concepts/Variables	Definition	
I. PATIENT FACTORS and Health Resources		
	Coding	Description
AGE		Patient age in years at time of surgery
FEMALE	Male=0 Female =1	Gender is the listed SEX of the patient at surgery
RACE	White=1 Black=2 Hispanic=3 Asian=4 Native American =5 Other/unknown=6	Race is the listed race of the patient at surgery
Minority	Non-minority=0 Minority =1	Non-minority includes white and Minority includes Black, Hispanic, Asian, Native American and other.
Insurer	1=Medicare 2=Medicaid 3=Private 4= Self-pay 6=No charge/Other	Health Insurance payer Combined detailed categories into more general groups.
Private Insurance	0=public 1=private	Public includes Medicare and Medicaid and private includes private, self-pay and other.
II. HEALTH RISKS		
Co-Morbidities CHF VALVE PERIVASC HTN_C DM DMCX HYPOTHY RENALFAIL LIVER METS ALCOHOL DRUG PSYCH DEPRESS OBESE CHRNLUNG LYMPH TUMOR ARTH COAG WGTLOSS LYTES BLDLOSS ANEMDEF PULMCIRC ULCER AIDS PARA NEURO	NO=0 YES=1	AHRQ recognized comorbidities as described through ICD-9 codes Congestive Heart Failure Valvular Disease Peripheral Vascular Disease Hypertension Diabetes without complications Diabetes w complications Hypothyroidism Renal Failure Liver Disease Metastatic Cancer Alcohol Abuse Drug Abuse Psychoses Depression Obesity Chronic Pulmonary Disease Lymphoma Solid Tumor without Metastasis Rheumatoid Arthritis/Collagen Vascular Disease Coagulation Disorder Weight Loss Fluid and Electrolyte Disorders Blood Loss/Anemia Deficiency Anemia Pulmonary Circulation Disorders Chronic Peptic Ulcer disease HIV and AIDS Paralysis Other Neurological Disorders (AHRQ, 2012 Version 3.7)
NDX		Numbers of Diagnosis for their hospital encounter

COMORBS		Number comorbidities / case
BMI (calculated)		A reliable measure of obesity calculated from height and weight: Formula: weight (kg)/[height (m)]^2
BMI_Cat	BMI_Categories Underweight <18.50 = 1 Normal weight 18.50-24.99 = 2 Overweight 25-29.99 = 3 Obese Class I ≥ 30-34.99 = 4 Obese Class II ≥ 35.00 39.99 = 5 Obese Class III ≥ 40.00 = 6	Underweight <18.50 Normal weight 18.50-24.99 Overweight 25-29.99 Obese Class I ≥ 30-34.99 Obese Class II ≥ 35.00 39.99 Obese Class III ≥ 40.00 (WHO, 2008)
Obesity_ICD9	Not obese=0 Obese =1	Obesity as defined by ICD-9 codes for 2011 and 2012 The presence or absence of obesity codes as evidenced by ICD9 coding (SOURCE CDR) 278.00 obesity unspecified obesity NOS 278.01 Morbid obesity/severe obesity 278.02 overweight 278.03 obesity hypoventilation syndrome 278.1 localized adiposity/fat pad
III. TREATMENTS		
Surgical setting	IP=inpatient OP=outpatient	Setting of surgical case
NPX		Total numbers of Procedures performed for their hospital encounter
LOS		Number of nights the patient remained in the hospital. A patient admitted and discharged on the same day has a length of stay equal to 0.
IV. PATIENT LEVEL OUTCOMES (inpatient data only)		
RESPF PSI -11 POST-OPERATIVE RESP FAILURE	(PRESENT IN PSI-11) NO=0 YES=1	Number of surgical discharges among cases meeting the inclusion and exclusion rules for the denominator with ICD-9- CM codes for acute respiratory failure (518.81) in any secondary diagnosis field. Excludes codes for re-intubation procedure as follows: 96.04, 96.70, 96.71, 96.72 Eligible Cases present in the denominator for PSI-11 as designated in the AHRQ Algorithm (AHRQ, 2012) Version 4.5
PPS_RESPF	POSITIVE FOR PSI 11 NO=0 YES=1	Eligible Cases present in the Numerator for PSI-11 as designated in the AHRQ Algorithm Positive for postoperative respiratory failure (RESPF)
PEDVT PSI-12 PERI-OPERATIVE PE DVT	(PRESENT IN PSI-12) NO=0 YES=1	Number of surgical discharges among cases meeting the inclusion and exclusion rules for the denominator with ICD-9- CM codes for deep vein thrombosis or pulmonary embolism in any secondary diagnosis field Eligible Cases present in the denominator for PSI-12 as designated in the AHRQ Algorithm (AHRQ, 2012) Version 4.5
PPS_PEDVT	POSITIVE FOR PSI 12 NO=0 YES=1	Eligible Cases present in the Numerator for PSI-12 as designated in the AHRQ Algorithm. Positive for perioperative Pulmonary embolism and/or deep vein thrombosis (PEDVT)
SEPSI PSI-13 POST-OPERATIVE SEPSIS	(PRESENT IN PSI-13) NO=0 YES=1	Number of surgical discharges among cases meeting the inclusion and exclusion rules for the denominator with ICD-9- CM code for sepsis in any secondary diagnosis field

		Eligible Cases present in the denominator for PSI-13 as designated in the AHRQ Algorithm (AHRQ, 2012) Version 4.5
PPS_SEPSI	POSITIVE FOR PSI 13 NO=0 YES=1	Eligible Cases present in the Numerator for PSI-13 as designated in the AHRQ Algorithm Positive for post-operative sepsis (SEPSI)

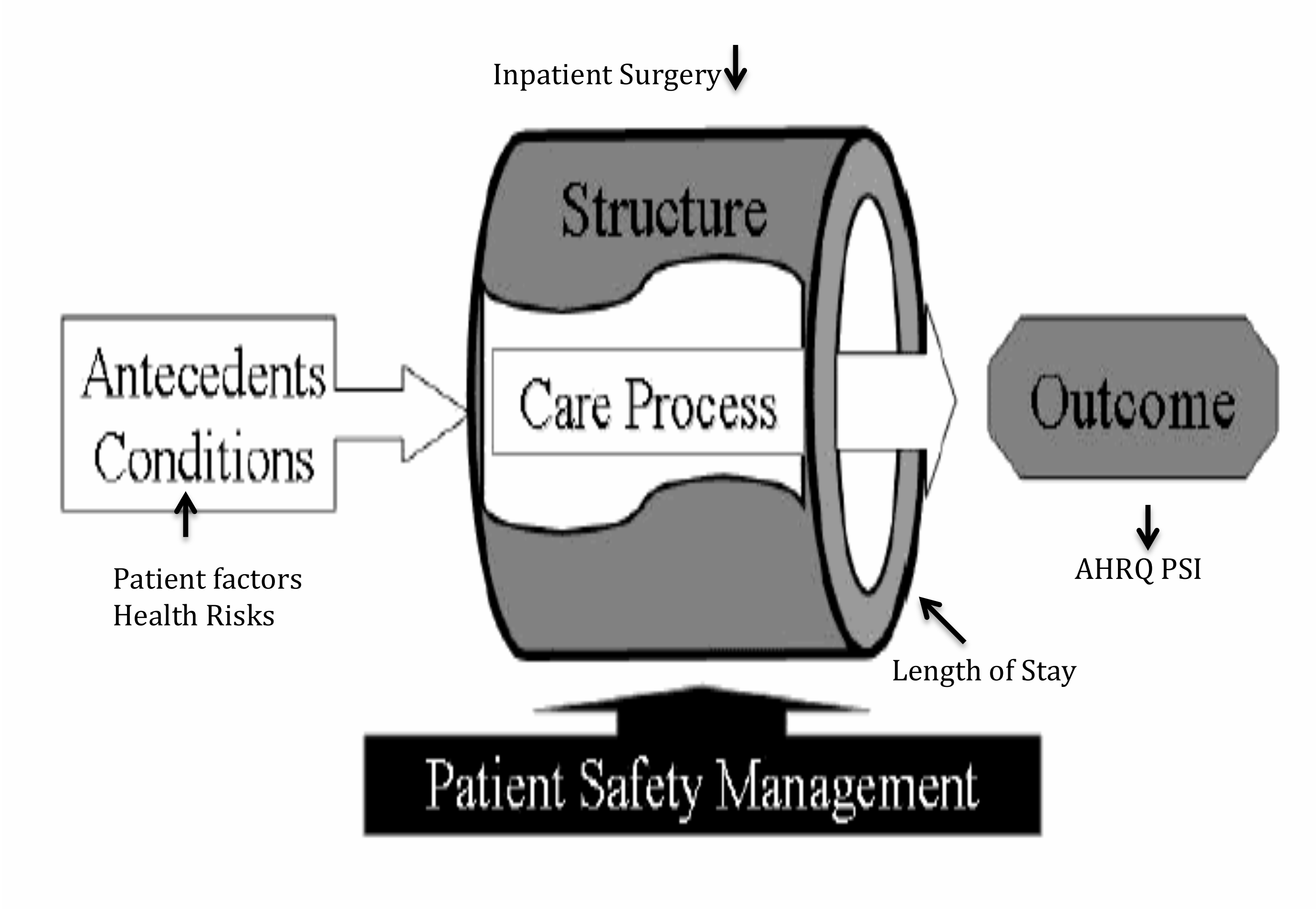

Figure 1. The Donabedian Model of Patient Safety: Medical Teamwork and Patient Safety: The Evidence-based Relation. July 2005. Agency for Healthcare Research and Quality (Adapted for the Obese Surgical Patient)

http://www.ahrq.gov/research/findings/final-reports/medteam/figure2.html

Chapter Three

Manuscript One

Abstract

Alice Magaw: A Model for Evidence-Based Practice

The model of Evidence-Based Practice of Magaw places the practice of nurse anesthesia as an early pioneer in the model of patient safety and prophetic to the aims of the IOM. The Institute of Medicine (IOM), in its report, the Quality Chasm, identified six aims essential to improving the delivery of care. These aims include safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity.[3,4] Magaw used her vast expertise in anesthetic administration to develop protocols and a body of knowledge that could be used as a template for practitioners near and far. This early use of EBP principles place nurse anesthesia at the forefront of the model and the movement essential to provide quality care. Practitioners sought her practice model out as she demonstrated her techniques to visiting providers as well as through her published ideal anesthetics in the literature.[7-9] "Pioneers are noted for building upon a body of knowledge, establishing a model for continuous improvement, and exemplifying notable methods of research with subsequent documentation of their findings."[19] Magaw exemplifies this EBP model.

"Every anesthetist should bear in mind that to administer an anesthetic properly is enough responsibility for one individual. No person can learn to be a surgeon while administering an anesthetic, therefore one should entertain no other care at this time." [1]

Alice Magaw, born in November 1860 is often referred to as "The Mother of Anesthesia."[2] Magaw entered the Women's Hospital of Chicago School of Nursing with her longtime friend, Edith Graham, in 1887. It was this training that is credited with establishing her with the necessary skills to make her mark on her future role as a nurse anesthetist. After the opening of St Mary's Hospital in Rochester, Minnesota, her classmate, Edith Graham, would initially serve to provide general surgical office duties as well as the administration of anesthesia for William and Charles Mayo. After the marriage of Edith to Charles Mayo, Magaw would be persuaded to move from Chicago, to replace her fellow classmate and friend as the primary anesthetist for physicians, Charles and William Mayo at St Mary's Hospital in Rochester.[1]

While Magaw was perfecting the art of nurse anesthesia for the Mayo brothers, the specialty of surgery and anesthesia itself was in a state of flux. The model of surgical training in the early 1900s included a surgical trainee administering the anesthetic while the surgeon performed the procedure. This model proved dangerous for the patient. Instead, the delivery of anesthesia recommended by the Mayo brothers highlighted a design, which emphasized the need for the anesthetist to be a constant, reliable member of the team whose only role was to provide anesthesia to the patient. This design would be embraced throughout the nation's new hospitals as practitioners flocked to the Midwest to observe the Mayo physicians' growing surgical practice and their anesthetists. Magaw understood the level of dedication necessary to make anesthetics successful. This historical review describes and analyzes the origin of nurse anesthesia in the United States, specifically identifying the impact of Magaw on the medical community of surgery and anesthesia from the 1893-1908. It addresses how Alice Magaw, as a nurse anesthetist, pioneered not only the practice of nurse anesthesia, but also pioneered an evidence based practice (EBP) that incorporated sound principles of anesthesia practice and patient safety and how she impacted the medical and surgical community worldwide then and now.

Evidence-Based Practice

The EBP of Magaw places the practice of nurse anesthesia as an early pioneer in the model of patient safety and prophetic to the aims of the Institute of Medicine (IOM). The IOM, in its report, the Quality Chasm, identified six aims essential to improving the delivery of care. These aims include safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. [3,4] In order to begin to embark on the changes needed in the current health delivery system the industry must recognize that adverse outcomes are the result of poor design of the industry and cannot alone be attributed to the healthcare worker. Changes are necessary throughout the continuum of the delivery system, which includes four levels: patients, microsystems, healthcare organizations, and healthcare environments.[3] The microsystem, according to Berwick [3] is the heart of where delivery of healthcare occurs. In order to improve microsystems, a redesign is needed. Change at this level relies on incorporating EBP and not the age-old practice of habit. Each patient brings unique characteristics that influence care received. The result is an individualized care package based on the evidence, which focuses on the physical and psychosocial needs of the patient and addresses the aims as established by the IOM.[3,4] EBP also relies upon improved collaboration among specialties as providers examine the science in order to incorporate an individualized plan of care directed at the characteristics of the patient, their comorbidities, and their physical exam. [5] EBP guides providers to seek out, in the literature, the information necessary to provide appropriate plan of care avoiding adverse outcomes. Magaw used her vast expertise in anesthetic administration to develop protocols and a body of knowledge that could be used as a template for practitioners near and far. This early use of EBP principles place nurse anesthesia at the forefront of the model and to the movement of patient safety. Practitioners sought her practice model out as she demonstrated her techniques to visiting providers as well as through her published ideal anesthetics in the literature. [6-8]

The Changing Hospital

In the late 1800s the specialty of surgery in the United States was increasing rapidly with the introduction of chloroform in the 1850s, the practice of ether anesthesia shortly thereafter, and the subsequent discovery of the germ theory. In 1870, Joseph Lister's Germ Theory would have a significant impact on the field of surgery, where mortality form surgical infections in Europe ranged from 26 to 66% following surgery. [9] The sterility for surgical procedures, the use of sutures, wound preparation and the need for the skills that nurses could provide wound care added to the advancing practice. [9] "Applying principles of asepsis and antisepsis in surgery, they (surgeons) could perform a great many more operations than formerly, especially in the internal cavities of the abdomen, chest and skull. The application of these principles increased the time and effort of the operating room for surgery. A nurse indeed could be of great assistance." [10] The overall death rates related to surgery and risks of surgical infection were diminishing. [9] Health care was being reformed through the increasing use of technology. There was an increase in the number of hospitals opening throughout the country between 1880 and 1920.[11] In a census of hospitals in 1873 there were 178 hospitals with a total patient capacity of approximately 50,000 this number increased to over 4000 by early 1920.[12] Hospitals became the setting for the delivery of care not only for the poor and destitute, but also for the upper and middle class.

Medical records evolved from the concept of a single page narrative to include standardized forms with objective data which contained essential information, detailed records of visits, and narrative notes to reflect all medical and nursing providers.[13] Surgeries were moved from being performed on the kitchen table to the operating room table where hospitals went to great lengths to offer the surgeons the necessities to enhance the delivery of surgery.[13] The creation of St Mary's Hospital (1889), in Rochester Minnesota, would allow the work of William Mayo, Sr. and his sons, William (junior) and Charles to move their surgical practice from their private residence to a hospital based practice that would encompass greater than 4000 surgeries annually with a mortality rate of less than two percent.[13] The sterile efficient environment of the hospital persuaded patients to utilize hospitals for treatment.[13] According to Howell, surgery was moved to a centralized location elevating surgical practice.[13] These factors, coupled together with the inception of trained nurse anesthesia providers and the opening of an increasing number of hospitals throughout the country greatly impacted the numbers of surgeries nationwide. With improvements in the delivery of anesthesia and the assignment of a primary provider in the delivery of anesthesia, surgeons could focus on the technical aspects of surgery. Advancements in technology would further improve the surgical advancement and include the use of dressings for wounds, improved lighting and electricity, investment in equipment such as that used for radiography, and laboratory standardization.[13]

"The most unique elaborate and scientific clinic in the history of medicine" [14]

Education was essential to the Mayo philosophy and practice."[11] The Mayo physicians gained notoriety and came to be known as expert surgical resources throughout the country. Many patients sought after their services. The Mayos kept detailed records of what they encountered and encouraged those involved in their team, (including Magaw), to take time to advance the knowledge of their specialty and to keep journals of what they observed including patient outcomes. This became a basis for scientific literature in the field of surgery and anesthesia. This practice mirrored the essentials from the St. Paul Medical Society as quoted by Harris; “The cultivation of science and art of medicine, the interchange of professional experience, the encouragement of professional zeal and the promotion of a friendly feeling among its members…While few of us who are engaged in active private practice can find time to engage in scientific research, we can very profitably interchange our medical experiences, and by keeping careful and accurate records of interesting cases make valuable contributions to medical literature. The object of the society should be first of all educational.” [2] The Mayo’s reputation brought patients to St Mary’s Hospital to benefit not only from the expertise of the famous surgeons but also of Magaw, a nurse anesthetist they relied heavily upon.

To explain the workings of the practice and its surgical success, historian Fye quotes William Mayo’s address to the medical college at Rush University in 1910: “The best interest of the patient is the only interest to be considered, and in order that the sick may have the benefit of advancing knowledge, union of forces is necessary. The first effort made to meet the situation was in the development of clinical specialties. Man was divided for treatment into parts, as a wagon is divided in the process of manufacture. Each part of a man was assigned to those who could devote special attention to their particular portion, giving the benefit of superior skill in treatment. Unlike a wagon, man could not be treated in parts but as a whole…[so] it became necessary to develop medicine as a cooperative science; the clinician, the specialist, and laboratory workers uniting for the good of the patient, each assisting in the elucidation of the problem at hand, and each dependent upon the other for support.” [14] This is translated into the contemporary design of interdisciplinary medicine.

The Mayos and their counterparts in practice were acutely aware of their impact on healthcare and education. They desired to share their expertise with those who would visit St Mary's Hospital to view their techniques and surgical theater first hand.[14] For those who could not visit, they provided a lens to their practice through the medical publications.[14,15] Due to their commitment to share the successes of their practice, they maintained a strong commitment to the medical literature. In fact much of the renown of their practice was attributed to their commitment to publications not only from the Mayo surgeons, but their chief anesthetist, Magaw as well. These publications were being utilized by professionals worldwide and would serve to give instruction about both their technique's failures and successes.[11,14] This model is another evidence of EBP.

The Open Drop Method

In 1885, Dr. James Moore, a surgeon, went to Germany to study chloroform. Dr. Moore returned to the states with a German anesthetizer to teach this method to the surgeons and the nurse anesthetist of St Mary's Hospital.[16] The German anesthetizer would describe this technique as quoted by Keeling: "A new technique for administering anesthesia… He recommended the gradual administration of chloroform and/or ether by using a wire frame covered with gauze, which was placed over the patient's mouth and nose. The anesthetizer would slowly place drops of the anesthetic agent on the cloth until the patient lost consciousness. This method, soon labeled the open-drop method prevented the anesthetist from giving large quantities of the agents too rapidly. "[16]

Alice Magaw: The Nurse Anesthesia specialty is pioneered

Pougiales[10] quoted Dr. Charles Mayo's 1905 paper in which he described his satisfaction and reliance on nurse anesthetists: "The question of anaesthesia is a most important one. We have regular anaesthetists whom we can depend so that I can devote my entire attention to the surgical work."[10] The training of Magaw would prove crucial to the development of the model for education for future nurse anesthetists and consisted of both apprenticeship as well as didactic.[16] Magaw [7] is quoted as saying "in giving an anesthetic remember that you are, as it were, carrying the patient along the edge of the precipice, and while there is no need of going over you must watch not to get to close to the edge"[7] . In fact Nelson and Wilstead, [17] quote Clapesattle, in his reference to Magaw: "Alice Magaw provided such leadership in that new field that her work drew more widespread attention than that of any other member of the Rochester group apart from the Mayo brothers themselves."[17] Magaw became adept at the administration of open drop ether. While she did not create the design method for its administration, Magaw perfected the technique and was frequently observed in its administration by visiting physicians. She described the technique in depth in her address: "The inhaler used is improved Esmarch mask, with two thickness of stockinette, and we always have both ether and chloroform ready to give whichever is indicated by the condition of the patient. In administering ether, we commence with the drop method as carefully and with as much air, as though it were chloroform, until the patient's face is flushed, when we have a large piece of surgeon's gauze of several thickness convenient and keep adding a few more layers of the gauze and giving ether a trifle faster until the patient is asleep, then remove the gauze and continue with the same covering as at the start and by the drop method. Should it produce difficult breathing, profuse secretions of mucus, or cough, or should the muscles be slow to relax, change to chloroform.[8] The Mayo physicians preferred their patients to receive ether unless there was an alternative indication.

Magaw noted: “As it requires very little ether to keep a patient surgically etherized, one can change to the smaller dropper during the operation. A much deeper narcosis is required to start an operation or to make an incision than later on, when the operation is in progress. It is useless to touch the cornea, as so many advocates, as it tells us nothing and is unscientific. Only the inexperienced take the pulse and touch the conjunctiva when giving ether.”[8] Many visiting physicians observed her administration of open drop ether and Magaw [6] would further discuss this technique at a Missouri Medical Society meeting. This detail description of Magaw’s techniques would benefit the anesthesia community and serve as a practice standard for the new evolving specialty. Magaw would proceed to document over 14,000 anesthetics without an anesthetic death;[8] her published work served as body of evidence for practicing anesthesia providers worldwide.

Promoting Safety

“Assure your patient that he is in safe hands and need not be afraid, at the same time be firm, especially with the hysterical. In fact, try to gain the confidence of the patient as much as possible before administering the anesthetic” [1]

Evidence Based Practice

Magaw demonstrated the ability to disseminate the ideal anesthetic techniques for other nurse anesthetists and physicians alike. As doctors from around the world were observing the Mayo physicians, it also gave Alice Magaw an audience by doctors and nurses near and far. As Magaw was administering anesthetics in the surgical theater, her ease was noted by visiting physicians and it became a template and practice model for surgeons. She was known to administer smooth anesthetics and experience in over 10,000 cases with ether.[2]

Magaw as Patient Safety Advocate

> ***"The dangers of general anaesthesia depend more on the lack of experience and incompetency of the anesthetist than on the drug itself"*** [8]

Magaw's publications on practice and the outcomes she shared helped to preserve and advance the practice of nurse anesthesia. As the primary anesthetist for the Mayo surgeons from 1893 until 1908, Magaw set a precedent for the practice through her involvement in the training of nurses and physicians through her dissemination of publications, research, and speaking engagements at the numerous meetings she attended during her tenure with the Mayo physicians. Magaw was forward thinking in setting the expectations necessary for successful administration of anesthetic. She recognized the need for pre-anesthetic review, documentation, record keeping, evaluating outcomes, nurse to patient communication, patient specific plans and early patient safety goals; all necessary components to EBP. She discussed these expectations in her address to the Olmstead County Medical Society where she concluded the importance of a thorough pre-operative visit, physical examination of the heart, lungs and kidneys, and advice to abstain from food the morning of surgery. [7] The Mayo surgeons would prefer the administration of ether for their cases but Magaw would emphasize, as evidenced in her speech to the Minnesota Valley Medical Center in 1901, *The Administration of Anesthetics*,[1] "the anesthetist should understand which circumstances make either choice better for the patient and the importance of standard of care and formulating a patient specific anesthetic plan and when she states; It is a duty we owe the patient to become an expert in its use…when a patient must have an operation he is usually able to have some kind of anesthetic and we feel sure that the mortality can be decreased by a careful selection of the anesthetic in each case." [18] Magaw would further identify patient concerns and safety considerations for improvement in care during her address to the Missouri Medical Society by acknowledging the risks to the patient regarding nerve and eye injury.[8] She would note the need to address safety. The nurse anesthetist should make adequate preparation for cases, complete pre-operative baseline observation, and maintain thorough periodic observational skills for the anesthetized patient.[7,18] In fact, Magaw set a precedent in regards to patient monitoring noting that observation of vital signs, which included respiration, pulse and color was essential.[10] To bolster her commitment to delivery of safe anesthetics, she notes in her speech the necessity to have ongoing assessment of the airway and to know how to handle emergencies should they arise:

> "Respiration is often interrupted with the obstruction caused by the tongue falling back and depressing the epiglottis…Should any of these symptoms arise during the administration of an anesthetic that has been given slowly and carefully all that is needed as a rule is to raise the lower jaw up and forward and instead of using tongue forceps, catch the tongue with a piece of gauze and draw it up and out…No anesthetist should form the habit of using the gag or tongue forceps; both are cruel and seldom needed. It is of far more importance that the anesthetist should become skillful in watching for the symptoms and preventing them, than to become proficient in the use of a certain gag, tongue forceps or use of artificial respiration." [1,6,8,18]

Keeling[16] described the importance of observation. "Observing the patient closely was key to successful anesthesia delivery, and the surgeons recognized that trained nurse anesthetists observed the patient more closely than did medical students and interns, "whose attention was more often directed to the operation."[16] Magaw had acute skills in observation and this helped her maintain excellent patient outcomes. In fact with over thirty-five hundred cases there was not a death related to the anesthetic.[7] She proceeded to give her audience advice on the necessary observation skills utilized by the anesthetist to prevent danger to the patient as well as encouraging the anesthetist to remain engaged in the anesthetic's delivery.[7]

Magaw was very concerned with patient outcomes and patient satisfaction. In her 1900 report on *Anesthesia with Nitrous Oxide and Ether,* she reports on findings of patient and nurses and uses these to further support her own patient specific designed anesthetic plan.[18] Koch[19] describes Magaw's vigilance during the administration of anesthesia. In preparation for the administration of the anesthetic, "Magaw notes in her initial contact with the patient, one must be quick to notice the temperament, and decide which mode of suggestion will be most effective in the particular case: the abrupt, crude, and very firm, or the reasonable, sensible, and natural…The subconscious or secondary self is particularly susceptible to suggestive influence; therefore, during the administration, the anaesthetist should make those suggestions that would be most pleasing to this particular subject. Patients should be prepared for each stage of anaesthesia with an explanation of just how the anaesthetic is expected to affect him; "talk him to sleep," with the addition of as little addition of ether as possible."[8]

Harris[2] refers to Magaw's scientific success by noting the fact that Magaw was frequently quoted in medical text. Magaw's anesthetic techniques were directed towards providing the patient an individualized plan. In her address to the Minnesota State Medical Association Magaw[6] shared observations on eleven thousand anesthetics. "During the administration of either ether or chloroform prepare the patient for explaining just how you expect the anesthetic to affect him, and go through each stage, giving him your undivided attention. In fact, talk him to sleep, with the addition of as little anesthetic as possible. It is surprising how much comfort and help this little attention is to the majority of cases, and how quickly they submit, doing away with that horrible anxiety and fear."[6] Magaw[8] kept thorough records of her cases and recorded these anesthetics. In her publication *A Review of over 14,000 Surgical Anesthetics*, Magaw indicates she successfully provided anesthesia without an anesthetic death.[8] Magaw describes in another article, *Observations on 1092 Cases,*[20] her administration of anesthetics; "We have administered an anesthetic 1092 times' ether alone 674 times; chloroform 245 times; ether and chloroform combined 173 times. I can report that out of this number, 1092 cases, we have not had an accident".[7] Magaw's records and outcomes would serve as a legacy defining that the delivery of anesthesia by nurses would serve the surgical community without increasing the risks to patients. In fact, Magaw's outcomes would eclipse those of practitioners today. The model of teaching the practicing nurse anesthetist was evolving from merely sitting on the stool next to the elder Mayo as he taught the steps to performing an anesthetic to the more concrete model involving a combination of theory and practical experience. Magaw's legacy and publications would serve as a strong support for the advance practice of nursing in the challenge that would unfold against the specialty of the practice of Nurse Anesthesia.

Magaw and Evidenced-based practice

"One death is one too many"[20]

Magaw's publications were used as defense in favor of the nurse's ability to successfully administer anesthesia in the landmark Chalmers versus Nelson (1936) lawsuit in California, which challenged the practice of nurse anesthetists. This case would go to appeal three times. Each appeal used the outcome driven data supplied by the publications of Magaw: *The Administration of Anesthetics,* (1902) and *A Review of over Fourteen Thousand Surgical*

Anaesthesias, (1906), to challenge the claims that nurses' outcomes were less desirable than physicians.[1,8,16] Nelson and Wilstead[17] describe the publications of Magaw as a "standard for safe, research-based anesthesia delivery. Her publications embodied practice principles that other anesthesia providers would reference in their desires to become more proficient in their own practice …Magaw's documentation was used as indispensable evidence to validate the decision by the court in a landmark case that challenged the nursing scope of practice with regard to the administration of anesthetics. The court assessed that the knowledge of administering anesthetics was not exclusively with the province of medicine; that when nurse administered anesthesia, she was practicing nursing."[17]

Alice Magaw, Model for the Future

Alice Magaw clearly earned the title of "Mother of Anesthesia." Magaw published six articles outlining the events, outcomes, and expectations that would serve as a model for practice with practitioners nationwide. She was also invited to speak before medical society meetings, something unheard of for nurses at that time. Magaw's successful anesthetic techniques included the open drop method, skills in observation, assessment of the depth of anesthesia, airway resuscitation, pre-operative assessment analysis, and patient specific anesthetic plans. Only a practitioner with experience would have the knowledge to engage in this level of skill. Magaw encouraged other anesthetizers to do the same. Magaw's model of anesthesia encouraged the nurse anesthetists to embrace and possess the skills of observation, practice within standards of care, and formulate a patient specific plan well before the profession understood the importance of incorporating this as a baseline to practice. These skills are now considered hallmarks of practice and standards as set the American Association of Nurse Anesthetists. Her accurate reporting of cases and outcomes helped to shape the development of safe anesthesia practice and her record keeping allowed the anesthetizer to follow steps of safe practice long before the nation would embrace these standards of care. Magaw's relationship with the Mayo physicians served as an impetus for her to excel in practice. Magaw's practice and training model conceived the birth of other training programs to begin to graduate nurse anesthetists with similar practice styles that would eventually become ancestry to the American Association of Nurse Anesthetists. Her publications of best practice models and outcomes helped to disseminate the evidence of effective practice to all anesthetizer and established her as an authority for the practice of anesthesia (medical and nursing) and the surgical community.[6] As patient advocates, we have a duty to protect patients from harm. "The best care results from the conscientious, explicit, and judicious use of current evidence and knowledge of patient values by well-trained experienced clinicians."[4] "Pioneers are noted for building upon a body of knowledge, establishing a model for continuous improvement, and exemplifying notable methods of research with subsequent documentation of their findings."[17] Magaw exemplifies this EBP model.

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Chapter Four

Manuscript Two

A Patient Safety Dilemma: Obesity in the Surgical Patient

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Abstract

Patient safety and the delivery of quality care is a major concern for healthcare in the United States.[1,2] Special populations, such as the obese patient, are in need of research in order to support patient safety, quantify risks, advance education for healthcare-workers, establish healthcare policy, and promote leadership in the field. Obesity is a complex, multifactorial chronic disease. It is considered the second leading cause of preventable death in the United States with approximately 300,000 deaths per year. [6] Obesity is recognized by the Agency for Healthcare Related Quality (AHRQ) as a comorbid condition with a corresponding International Classification of Diseases-9 (ICD-9) code. These concerns emphasize the need to focus further research on the obese patient. [7] Through the use of clinical and administrative data this study examines the incidence of adverse outcomes for the obese surgical population through the measurement of the Agency for Health Related Quality patient safety indicators. This allows for the engagement of performance measure as a guide to improve performance. In this study, the surgical population was overwhelmingly positive for obesity. The overall, inpatient, and outpatient surgical population, all had obesity rates greater than the general population. Body Mass Index (BMI) was also a significant positive predictor for two of three postoperative outcomes. This finding suggests that as BMI reaches the classification of obesity, the risk of adverse outcomes increases. It further suggests there exist a threshold BMI that requires anticipation of alterations to systems and processes to revise outcomes.

Introduction

Patient safety and the delivery of quality care is a major concern for healthcare in the United States.[1,2] Special populations, such as the obese patient, are in need of research in order to support patient safety, quantify risks, advance education for healthcare-workers, establish healthcare policy, and promote leadership in the field.

Obesity, which is associated with many health care risks, occurs in a large proportion of the U.S. population. It is determined according to Body Mass Index (BMI) and is stratified through a World Health Organization (WHO) classification system. Obesity is quantified as BMI of greater than 30 and contains Grades I-III (obese 30-34.99, morbidly obese 35-39.99, and super obese >40).[3] National Health and Nutrition Education Survey (NHANES), 2009-2010 data show adjusted trends in obesity were 38% of the population and the combined category of overweight and obese (BMI ≥ 25) to be as high as 68.8% of the population.[4] In addition to the related population health risks, obesity places a substantial financial burden on the healthcare system, which according to 2008 estimates costs $147 billion per year.[5] Obesity is a complex, multifactorial chronic disease. It is considered the second leading cause of preventable death in the United States with approximately 300,000 deaths per year.[6] Obesity is recognized by the Agency for Healthcare Related Quality (AHRQ) as a comorbid condition with a corresponding International Classification of Diseases-9 (ICD-9) code. These concerns emphasize the need to focus further research on the obese patient.[7]

This study determines the prevalence rate of obesity among patients undergoing surgical procedures, the differences in BMI for patients with and without post-surgical complications, and the relationship between obesity and post-surgical complications after controlling for other patient characteristics. The adverse outcomes examined included perioperative pulmonary embolism and deep vein thrombosis, post-operative respiratory failure, and post-operative sepsis using AHRQ patient safety indicators (PSI). Findings are likely to be significant for patients, hospitals and surgical settings, perioperative surgical teams, as well as for informing quality improvements and healthcare costs reductions.

The obese patient is a critical patient to target in providing quality medical care. [8] Using electronic clinical administrative data, this research quantifies the degree to which undesirable outcomes occur in the obese surgical patient population. It highlights the need to examine delivery of care including the use of technology and the need to develop and use protocols essential to diminish the occurrence of potentially life threatening adverse events. This research provides important information on the risks of post-operative outcomes in the obese population, potential devastating events that may impact patients, healthcare institutions, and healthcare workers. It also addresses the functionality of the healthcare system and patient safety and addresses the goal that "healthcare should be safe and void of injuries from care that was intended to help them, it should be effective and based on scientific knowledge, it should be patient centered, and should be timely, efficient and equitable." [2]

Conceptual Patient Safety Framework

The conceptual model of structure, process and outcome adapted by Coyle and Battles to incorporate patients' antecedent conditions as contributors to final outcomes, guides this study. [9-11] Each component is reliant on the other and requires success in all areas to deliver the highest quality of care. [12] In the adapted model, antecedent conditions include individual patient factors and health risks, including age, socioeconomic status, gender, and insurance coverage. Individual health risks comprise obesity, hypertension, chronic lung disease, metastasis, diabetes, perivascular disease, congestive heart failure, alcoholism, and hypothyroidism. Conditions commonly found in the patient with obesity include coronary artery disease (CAD), elevated cholesterol, non-insulin dependent diabetes (NIDDM), hypertension, cognitive dysfunction, cancer[13] and risk for stroke. According to the model, any or all of these can be expected and unfavorably influence adverse outcomes.

Structure, Process and Management

Patient safety practice as an integration of structure and processes is designed to diminish the probability of adverse outcomes that result from exposure to the health care systems. [14] According to the Donabedian model [9,12,15] structure refers to the properties of the organization where patient care is provided, for example urban teaching facility or rural hospital, and surgical setting, inpatient or ambulatory.[16] In this model structure is represented as inpatient surgery. Processes are typically defined as treatment(s) delivered as part of the prescribed plan and require interactions with the healthcare team. Processes also incorporate other elements such as technology, protocols, and systems changes.[1,17] However, in this study process is represented by length of inpatient stay. Adjustments to structure and process are needed to avoid adverse events related outcomes.[18]

Outcomes and Patient Safety Indicators

Outcomes are the final results of care delivered and may result in a desired or undesired event. AHRQ PSI's of postoperative respiratory failure (PSI-11), perioperative pulmonary embolism deep vein thrombosis (PSI-12), and postoperative sepsis (PSI-13) are used as adverse outcomes for surgical patients in this study. PSIs, as outcome measures, are dependent on structure and process of the healthcare organization.[19] PSI outcomes provide a standard for comparison of empirical data and allow examination of the system with the added goal of improved performance for the patient.[12,20]

Methods

The Institutional Review board at the study hospital approved this research. The research design was a correlational study using secondary electronic health data. The target study sample consisted of all patients 18 to 85 years old admitted for a surgical procedure at a major academic medical center in the southeast for the years 2011 and 2012. The following populations were excluded: patients with cardiac or bariatric surgery, those with end stage renal disease (ESRD) receiving hemodialysis, and obstetrical patients.

The study institutions' Multicenter Perioperative Outcomes Group (MPOG) database and the hospital's Clinical Data Repository (CDR) were utilized. The MPOG database includes standard patient data, for example, demographics, pre-operative physical exam, American Society of Anesthesiologists (ASA) classification, as well as surgical procedures, case providers, anesthesia technique, and anesthesia times.[21] The CDR contains patient demographics, core clinical criteria, diagnoses and procedures (by ICD-9 coding), and discharge status. [22] In order to capture the required data elements in a single dataset, the information from MPOG was linked to CDR information. MPOG was used to identify all surgical procedures for the study period (2011-2012), cases were matched by identification data and the CDR was used to obtain specific clinical and administrative data elements. The unit of analysis was a case, which was defined as a surgery in which an anesthetic was administered. The final sample included 30,549 total surgical cases (12,936 inpatient and 17,613 outpatient). A concurrent methodological study through the use of clinical data and ICD-9 coding to determine the usefulness of ICD-9 codes to identify obesity is being pursued in a parallel study.

Power analysis

A power analysis was run using N-query Advisor (7.0) program to determine effect size and alpha for each outcome and to inform the number of variables possible to include in the model for each adverse outcome.[23] AHRQ published rates of PSIs [24] were used to determine the expected occurrence of each adverse outcome; this information was considered in relation to the number of surgical procedures for each PSI. For each adverse outcome investigated, nQuery Advisor (7.0) was used to determine the effect size that could be detected with 80% power at the .05 level of significance by a *t*-test between two independent groups: those with and without the given PSI. The actual sample sizes in the project data were used for the calculations. For Postoperative Respiratory Failure (PSI-11), a medium-small effect size of .33 would be detectable. For Perioperative Pulmonary Embolism Deep Vein Thrombosis (PSI-12), a small effect size of .23 would be detectable. For Postoperative Sepsis (PSI-13), a medium-large effect size of .63 would be detectable. According to Harrell (2001), a fitted logistic regression model is likely to be reliable when the size of the less frequent of the two outcomes in the sample is at least 10 times the number of predictors in the model. This limited the number of predictors in the model for PSI-11 to 7-8, for PSI-12 to 15, and for PSI-13 to 2.

Variables Construction

The variables used to define the concepts of the study include patient factors and the demographic information age, gender, race. Health resources included insurer. For the development of the hierarchal logistic regression, race was reclassified into a two level variable, minority (non-minority or minority) and insurer was also reclassified into a two level variable private insurance (public or private). The concept of health risk included diagnostic labels (yes/no) and included number of diagnoses, comorbidities, calculated BMI, and obesity classification categories. Comorbidities were constructed using the AHRQ comorbidity algorithm (AHRQ, 2010), BMI as calculated by weight (kg)/height (m^2) and BMI classification categories were designated according to the World Health Organization (WHO) model.[25] Treatment variables included inpatient or outpatient status, numbers of procedure as determined by the use of ICD-9 coding, and length of stay. The final variables created included patient level adverse outcomes using the AHRQ PSI algorithm (version 4.2) (AHRQ, 2012). The PSI outcome variables include: postoperative respiratory failure (PSI-11), perioperative pulmonary embolism deep vein thrombosis (PSI-12), and postoperative sepsis (PSI-13). Each PSI population resulted in a different size population (N) due to the additional specific inclusion/exclusion criteria set by the AHRQ PSI algorithm. The patient level outcomes for postoperative respiratory failure (PSI-11), perioperative pulmonary embolism deep vein thrombosis (PSI-12), and postoperative sepsis (PSI-13) were constructed and the variable of positive or negative (0=negative for the PSI complication and 1= positive for PSI complication) for the adverse outcome was developed.

AHRQ PSI subpopulations

The inpatient group was further divided into 3 subpopulations in order to determine rates of adverse outcomes using the AHRQ QI Version 4.5 PSI algorithm. The eligible subpopulation for all PSI analyses included any elective surgical discharges for patients greater than 18 years old during the study period. The algorithm required the presence of data reflecting gender, age, quarter, year, and principal diagnosis (AHRQ, 2012). Each PSI had a unique set of ICD-9 exclusionary codes.

Analysis

Descriptive statistics including means, standard deviations, medians, and frequencies were calculated for all variables separately for the overall, inpatient, and outpatient populations and again for each PSI subpopulation eligible for adverse outcome evaluation. The prevalence rate of obesity (per 1000 surgical cases) was determined for all patients undergoing surgical procedures and for each PSI subpopulation. Differences in BMI for patients with and without each adverse outcome were analyzed using the t-test using a level of significance of $p < 0.05$. It was hypothesized that after controlling for patient characteristics, BMI would be a statistically significant predictor of post-operative complications. After assessing for mulitcollinearity (tolerance, variation inflation factor and condition index), a hierarchical logistic regression model was developed to test the hypothesis. A separate hierarchical logistic regression model was developed for each post-operative complication and study variables were entered into the model in blocks. Block 1 included patient factors and demographics (age minority, and gender) block 2 health resources (private or public), block 3 health risks (comorbidities), and block 4 the variable of interest, BMI. Block 5 included length of stay. Models were estimated after each block was entered, only as many variables were added as was recommended for effect size in order to avoid overfitting.[23]

Results

Prevalence and Demographic Data

Table 1 summarizes the descriptive statistics of the study population. The overall population included total (N=30,549), inpatient (N= 12,936) and outpatient (N=17,613) cases. The mean BMI for the overall population was 29.58 (overweight) and BMI classification proportions reflected 31.21% of the population was overweight and 40.03 % obese. The mean BMI for the inpatient population was 29.94 (overweight) and BMI classification proportions reflected 30.08% of the population was overweight and 42.11% obese. The mean BMI for the outpatient population was 29.31 and BMI classification proportions reflected 32.04% overweight and 38.49% obese. In all populations, combined proportions of the population with BMI ≥ 25 (overweight and obese) were greater than 70% reflecting a statistically significant difference (*p=< .001)* between the inpatient and outpatient population mean BMI.

Other health risks for the study population were reflected in the mean number of diagnoses for the total, inpatient, and outpatient populations 6.13, 9.93, and 3.31 respectively. The mean number of comorbid conditions for inpatients was just under 2 conditions per case, while the mean for outpatients approached 0. Length of stay (LOS) for the overall patient population was 2.44 days per case and 5.63 days per case for the inpatient group. The outpatient group had a mean LOS of 0.10 day per case, which reflects a small number of unexpected admissions. All populations were greater than 50% female. The mean age in years at the time of surgery for the total, inpatient, and outpatient population was 53.00, 56.56, and 50.39 years respectively.

AHRQ PSI Descriptive Statistics, T-Test, and Logistic Regression

PSI-12

The perioperative pulmonary embolism and deep vein thrombosis subpopulation excluded cases with principle or secondary ICD-9 codes that reflected pulmonary embolism or deep vein thrombosis, or vena cava interruption. Table 2 summarizes 149 PSI-12 cases that were positive for the adverse outcome and 11,714 cases were that negative. The mean BMI for the subset of patients who were negative for the adverse outcome was 30.04 and the BMI classification proportions were 30% overweight and 42.61% obese. The mean BMI for those experiencing the adverse outcome was 29.29 and the BMI classification proportions were 32.89% overweight and 38.92% obese. There was no statistically significant difference in mean BMI between those two groups (t=1.16, p =0.25).

Hierarchical Logistic regression was run with the occurrence (Yes/No) of perioperative pulmonary embolism and deep vein thrombosis (PSI-12) as the dependent variable (see table 3). In block 1, demographics, age was significant with a positive relationship. In block 2, with the addition of health resources, age did not retain its significant relationship. Health risks (comorbid conditions) were added in block 3, and the effects of alcohol abuse and metastatic cancer were significant (p <0.05), with estimated odds ratios of 2.97 and 2.18, respectively. Block 4 included the variable of interest, BMI. BMI was not a significant predictor of the occurrence of the adverse event when other patient characteristics were taken into account. Block 5 included the addition of LOS. The findings for block 5 were significant (P<0.05), for age and LOS, which both had a positive relationship.

PSI-11

The post-operative respiratory failure subpopulation excluded cases that represent procedures for tracheostomy, laryngeal, pharyngeal, craniofacial, esophageal resection, lung cancer, nose and mouth. This subpopulation also eliminated cases with the presence of disorders of the respiratory, neurological, and circulatory system. Table 4 summarizes 72 cases that were positive for the adverse outcome and 6427 cases that were negative. The mean BMI for the subset of patients who were negative for the adverse outcome was 30.69 and BMI classification categories reflected 30.43% overweight and 46.42% obese. The mean BMI for those experiencing the adverse outcome was 32.77 and the BMI classification categories reflected 23.61% overweight and 52.78% obese. There was no statistically significant difference in mean BMI between those two groups (t = -1.42, p =0.15). The mean age for the adverse outcome positive group was 61.44, they were 54% female, and had an average LOS of 19.05 days. The mean age for the adverse outcome negative group was 56.52, they were 57.6% female, and had an average LOS of 3.46 days. The mean number of comorbid conditions for the negative group was 1.40.

Hierarchal logistic regression was run with the occurrence (Yes/No) of post-operative respiratory failure (PSI-11) as the dependent variable (see table 5). In block 1, demographics, age had a significant positive effect on the probability of an adverse event (p=0.05), with an estimated odds ratio of 1.03. In block 2, with the addition of health resources, private insurance had a significant negative effect (p=0.05 and age was no longer significant. Block 3 included the addition of Health risks (comorbid conditions) and revealed a positive relationship for significance of the following conditions: chronic lung disease and hypothyroidism. Block 4 included the variable of interest, BMI. BMI was a significant positive predictor of the occurrence of post-operative respiratory failure when other patient characteristics were taken into account (p=0.05), with an odds ratio of 1.03. BMI remained a significant positive predictor of the occurrence of this adverse event (p=0.05) when length of stay, a strong correlation of an adverse event was added to the model in block 5. In addition to BMI and length of stay, age chronic lung disease, and hypothyroidism were also significant positive predictors of this adverse event, all at the α=0.05 level of significance. Odds ratios for these were 1.03, 1.22, 1.03, 3.15, and 3.09, respectively.

PSI 13

The postoperative sepsis (PSI-13) subpopulation excluded cases with principal of sepsis or secondary diagnosis on admission of sepsis, immune-compromised state or cancer. Table 6 summarizes 20 PSI-13 cases that were positive for the adverse outcome and 1817 cases that were negative. The mean BMI for the subset of patients who were negative for the adverse outcome was 30.51 and the mean BMI classification proportions were 30.57% overweight and 45.55% obese. The mean BMI for those experiencing the adverse outcome was 35.79 and the BMI classification proportions were 20% overweight and 60% obese. There was no statistically significant difference in mean BMI between those two groups (t = -1.73, *p* =0.10). The mean age for the adverse outcome positive group was 53.65, they were 55% female, and had an average LOS of 19.80 days. The mean number of comorbid conditions was 2.80. The mean age for the adverse outcome negative group was 57.91, they were 54% female, and had an average LOS of 6.39 days. The mean number of comorbid conditions for the negative group was 1.78. Hierarchal logistic regression was run with the occurrence (Yes/No) of post-operative sepsis (PSI-13) as the dependent variable and with two predictors in the model: BMI and length of stay (LOS). BMI was a significant positive predictor of the occurrence of this adverse event (*p*=0.05) when length of stay was taken into account. LOS was also a significant positive predictor (*p*=0.05). The odds ratios for BMI and LOS were 1.05 and 1.11, respectively.

Discussion

Prevalence of Obesity

In this study, the surgical population was overwhelmingly positive for obesity. The overall, inpatient, and outpatient surgical population, all had obesity rates greater than 38% (see table 2) and combined overweight/ obesity rates greater than 70%. There was statistically significant difference in the mean BMI between the inpatient group and the outpatient group (*p*=< .001). This distinction is important as we examine structure, process, adverse outcomes, and develop protocols for inpatient obese surgical patients. These findings alert providers to the existence of obesity rates in surgical suites, which are greater than in the general population, necessitating the need for research and education about obesity and its impact on patient safety. It calls for preparation and investments throughout healthcare systems in structure and process for the delivery of care to overweight and obese patients who undergo non-bariatric surgery in general operating rooms. In addition, when caring for overweight and obese patients, anesthesia providers require further understanding of patient positioning, blood volume and cardiac output changes, airway maintenance, and drug pharmacokinetics in the morbidly obese patient [26] in order to provide safe care and prevent adverse outcomes. The respiratory system of these patients is likely to create difficulties with mask ventilation, higher risk for hypoxia and desaturation during apnea periods, increased risk for inability to secure adequate airway and tracheal intubation.[27] Hospital operating rooms must be designed with the obese patient in mind. Emergency equipment should be readily available in order to be prepared for the possibility of complications the obese patient often faces.[28]

AHRQ PSI Outcomes

It is necessary to use measures of performance to gauge improvement. Bamgbade reported a complication rate among the obese surgical population at 32.7%. This study also found the subpopulation of patients with adverse outcomes was overwhelmingly overweight and obese. The inpatient population and the subpopulations positive for postoperative respiratory failure (PSI-11), and postoperative sepsis (PSI-13) overall had mean BMIs that reflected obesity. When examined alone, there was no difference in the mean BMI among the subpopulation negative and positive groups. The *t*-test showed no statistically significant difference in the mean BMI between those negative and positive for post-surgical adverse outcomes. However, clinically it is important to note that the mean BMI of patients positive for postoperative respiratory failure (PSI-11), and postoperative sepsis (PSI-13) was in the obesity range. The subpopulation for perioperative pulmonary embolism deep vein thrombosis (PSI-12) reflected that the group positive for the adverse outcome was overweight (BMI 25-29.99), not obese. The group negative for the adverse outcome was obese. The composition of the groups studied clearly reflects that anesthesia care and protocols developed for the normal weight patient need to be reexamined to reflect the make-up of the current inpatient population. Anesthesia delivery models should be developed with the obese patient and their potential for adverse outcomes in mind. The development of protocols for the perioperative period directed at how BMI impacts adverse outcomes is a concept that warrants continued examination.

The final aim examined the complication rates of AHRQ PSIs for the obese patient population. With the addition of antecedent conditions, BMI had a positive relationship and further increased the odds of adverse outcomes in two of the three PSIs: postoperative respiratory failure (PSI-11) and postoperative sepsis (PSI-13) and the findings of this study strongly suggest obesity has a major impact on postoperative respiratory failure (PSI-11) and postoperative sepsis (PSI-13) adverse outcomes. Post-operative respiratory failure is associated with increases in morbidity and mortality and increased length of stay.[29] Postoperative respiratory failure is one of the most costly postoperative complications with reported mean additional hospital costs/patient to be as high as $63,000.[30] The elective obese surgical patient requires thorough pre-operative respiratory status assessment to determine whether the patient is a better candidate for inpatient versus outpatient surgery. Optimization of pre-hospital status should be considered due to changes that affect the obese patient during induction, maintenance, emergence and the postoperative period.[31] Study results support a comprehensive approach to care for the inpatient obese elective surgical patient.

BMI was also a significant positive predictor for postoperative sepsis (PSI-13) Postoperative infections contribute to increased length of stay for patients with mean additional hospital costs/patient to be as high as $13,000.[30] This would imply obese surgical patients require interventions to reduce the incidence of this adverse outcome such as meticulous infection control standards, proper monitoring during the perioperative period, attention to dose and administration times of antibiotic, and blood sugar monitoring to avoid the incidence and cost associated with this outcome.[30] The use of pre-operative antibiotic is an important prophylaxis, but alone may not be able to thwart post-operative sepsis.

Finally, for perioperative pulmonary embolism deep vein thrombosis (PSI-12), BMI was not found to be a significant predictor. This finding was unique in that the mean BMI for the surgical subpopulation positive for the adverse outcome was overweight (BMI 25-29.99) rather than obese (BMI ≥30.00). Since in the other PSIs examined, the positive group was obese rather than overweight, BMI may still be considered a significant predictor of adverse outcome. This finding suggests that as BMI reaches the classification of obesity, the risk of adverse outcomes increases. It further suggests there exists a threshold BMI that requires anticipation of alterations to systems and processes to revise outcomes.

Limitations

This study had several limitations. The AHRQ PSI algorithm was designed for use at the hospital level and the study design required use at the patient level. The merging of administrative datasets, electronic medical records and the AHRQ algorithm required was cumbersome and resulted in several poorly constructed variables (indigent status, clinical classification, surgical service), which altered the impact of health resources and treatments in the logistic regression model used to examine PSI adverse outcomes. The incidence of adverse outcomes occurs infrequently and although we met the requirement for power in this study, it would have been more powerful had the number of outcomes been greater. Due to small numbers of adverse events, the number of predictors in the logistic regressions was restricted.

The use of the AHRQ PSI algorithm requires inpatient ICD-9 coding that is not present in outpatient discharge data thus the generalizability of results to this population is limited.

Future recommendations

The obese population is of interest nationwide and it is necessary to understand the impact of associated risks to adverse outcomes. Further research is needed to examine this population at the national level. The model of this study can be applied to clinical/administrative datasets across the nation to further validate the findings for the obese surgical population. Further research is also needed to identify whether a threshold exists for BMI and adverse outcomes, to identify surgical subspecialties where adverse outcomes may be more likely, and to reexamine the adverse outcome Perioperative Pulmonary Embolism Deep Vein Thrombosis (PSI-12) and the impact of BMI for this population. It is necessary to complete the next arm of this research to examine AHRQ PSI outcomes in the outpatient population. This process requires additional information and conversion of outpatient data to inpatient coding. As more surgical procedures are completed in the outpatient setting, the applicability of adverse outcomes in that setting is extremely important to the anesthesia community.

The clinical implications of this study support the existence of an overwhelming overweight/obese group. It is not enough to recognize that a problem exists but efforts to improve patient safety and surgical complications should be examined. The current practice of anesthesia should be directed at a patient care model that reflects the incidence of obesity as reflected in this study. Recognition and development of protocols for this special population provides a set framework of case management designed to leave less to happenstance.[32,33] As the obese population is now in epidemic numbers in both the general population as well as the surgical population; the impact of obesity needs further research. The analysis of data from this population can aid the development of systems, technologies, and protocols to diminish the occurrence of potential life threatening complications for the obese surgical population.

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Table 1. Descriptive Statistics of Demographics, Health Resources, and Health Risks for Total Population and First case between 2011 and 2012 in either inpatient and outpatient settings

Descriptive Statistics of Patient Factors, Health Resources			
	Total 30549 (100%)	Inpatient 12936 (42.35%)	Outpatient 17613 (57.65)
	Mean (SD)	Mean (SD)	Mean (SD)
Age in years	53.008 (16.78)	56.5609 (15.68)	50.399 (17.09)
	N (%)	N (%)	N (%)
Male	13963 (45.71)	6062 (46.86)	7901 (44.86)
Female	16586 (54.29)	6874 (53.14)	9712 (55.14)
White	25043 (81.98)	10874 (84.06)	14169 (80.45)
Black	3756 (12.30)	1580 (12.21)	2176 (12.35)
Hispanic	406 (1.33)	101 (0.78)	305 (1.73)
Asian	166 (0.54)	69 (0.53)	97 (0.55)
Native American	19 (0.06)	8 (0.06)	11 (0.06)
Other/unknown	1159 (3.79)	304 (2.35)	855 (4.85)
Medicare	9291 (31.40)	5126 (40.21)	4165 (24.74)
Medicaid	2272 (7.68)	1059 (8.31)	1213 (7.20)
Private	12932 (43.71)	4777 (37.47)	8155 (48.43)
Self-pay	4746 (16.04)	1543 (12.10)	3203 (19.02)
No charge/Other	345 (1.17)	244 (1.91)	101 (0.60)
Missing	963	187	776
Descriptive Statistics of Health Risks: Diagnosis, Procedures, and Comorbidities			
	Mean (SD)	Mean (SD)	Mean (SD)
Number of diagnosis	6.126 (6.61)	9.932 (8.407)	3.331 (2.354)
Number of procedures	3.123 (2.99)	3.856 (4.019)	2.585 (1.732)
AHRQ Comorbidity conditions	0.967 (1.47)	1.795 (1.743)	0.359 (0.806)
Length of Stay (LOS) days	2.445 (5.285)	5.639 (6.9355)	0.100 (0.352)
BMI Mean (SD)	29.575 (7.473)	29.935(7.890)*	29.311 (7.14)*
BMI Classifications	N (%)	N (%)	N (%)
Underweight	572 (1.87)	292 (2.26)	280 (1.59)
Normal weight	8216 (26.89)	3306 (25.56)	4910 (27.88)
Overweight	9534 (31.21)	3891 (30.08)	5643 (32.04)
Obese Class I	6262 (20.50)	2728 (21.09)	3534 (20.06)
Obese Class II	3235 (10.59)	1429 (11.05)	1806 (10.25)
Obese Class III	2730 (8.94)	1290 (9.97)	1440 (8.18)

* T-test significant for difference between inpatient and outpatient p=0.05

Table 2. Comparisons of Patient Characteristics Demographics/ Health Resources/Health Risks for the subgroup Perioperative Pulmonary Embolism and Deep Vein Thrombosis (PSI-12)

ELIGIBLE POPULATION N=11863	NEGATIVE FOR PS-12 N=11714	POSITIVE FOR PSI-12 N=149
	Mean(SD)	Mean(SD)
Age in years at surgery time	56.68 (15.55)	60.77(15.83)
BMI Mean (SD)	30.04 (7.90)	29.29(7.20)
Length of Stay (LOS) days	5.38 (6.28)	18.96 (16.61)
Comorbid conditions	1.63 (1.55)	3.10 (1.77)
	N (%)	N (%)
Male	5448(46.51)	74(49.66)
Female	6266(53.49)	75(50.34)
Non-minority	9998(84.28)	131(87.92)
Minority	1865(15.72)	18(12.08)
Public Insurance	5723(48.25)	88(59.86)
Private Insurance	6138(51.75)	59(40.14)
Missing		2
BMI_CAT		
Underweight	246 (2.10)	2 (1.34)
Normal weight	2963 (25.29)	40 (26.85)
Overweight	3514 (30.00)	49 (32.89)
Obese Class I	2482 (21.19)	27 (18.12)
Obese Class II	1314 (11.22)	21 (14.09)
Obese Class III	1195 (10.20)	10 (6.71)
Obesity_BMI		
Not obese	3209 (27.39)	42 (28.19)
Overweight	3514 (30.00)	49 (32.89)
Obese	4991 (42.61)	58 (38.93)
AHRQ COMORBID CONDITIONS		
Congestive Heart Fail	362 (3.09)	12 (8.05)
Peripheral Vasc Disease	609 (5.20)	13 (8.72)
Hypertension	5358 (45.74)	89 (59.73)
Diabetes w/o comp	1936 (16.53)	33 (22.15)
Metastatic Cancer	398 (3.40)	11 (7.38)
Alcohol Abuse	338 (2.89)	12 (8.05)
Chronic Pulm Disease	1737 (14.83)	31 (20.81)

Table 3. Logistic regression model with Odds Ratios showing the influence of BMI on Perioperative Pulmonary Embolism/Deep Vein Thrombosis (PSI 12)

Variable List	Model 1	Model 2	Model 3	Model 4	Model 5
Age	1.02*	1.01	1.01	1.01	1.02*
Female	0.89	0.88	0.99	1.00	1.17
Minority	0.81	0.77	0.69	0.69	0.66
Private		0.75	0.83	0.83	1.04
LOS					1.08*
CHF			1.82	1.83	1.01
ALCOHOL			2.97*	2.87*	1.82
METS			2.18*	2.14*	1.77
CHRNLUNG			1.25	1.23	1.22
PERIVASC			1.32	1.30	0.97
HTN_C			1.36	1.40	1.29
DM			1.20	1.25	1.05
BMI				0.99	1.00
CHI-SQUARE					
	11.70*	14.18*	40.55*	41.25*	224.51*

**p*=0.05

Table 4. Descriptive Statistics of Demographics/ Health Resources/Health Risks for Postoperative Respiratory failure (PSI-11)

ELIGIBLE POPULATION N=6499	NEGATIVE FOR PS-11 N=6427	POSITIVE FOR PSI-11 N=72
	Mean (SD)	Mean (SD)
Age in years at surgery time	56.52(14.55)	61.44(12.40)
BMI	30.69(7.73)	32.77(12.31)
Length of Stay (LOS) days	3.46(3.12)	19.05(16.58)
Comorbid conditions	1.40 (1.39)	3.21(2.08)
	N (%)	N (%)
Male Female	2723 (42.37) 3704 (57.63)	33(45.83) 39(54.17)
Non-minority Minority	5441(84.66) 986(15.34)	62(86.11) 10(13.89)
Public Insurance Private Insurance	3073(47.81) 3354(52.19)	48(66.27) 10(33.33)
BMI_CAT		
Underweight Normal weight Overweight Obese Class I Obese Class II Obese Class III	85 (1.32) 1403(21.83) 1956(30.43) 1470(22.87) 778(12.11) 735(11.44)	1(1.39) 16(22.22) 17(23.61) 17(23.61) 11(15.28) 10(13.89)
Obesity_BMI		
Not obese Overweight Obese	1488(23.15) 1956(30.43) 2983(46.41)	17(23.61) 17(23.61) 38(52.78)
AHRQ Comorbid Conditions		
Hypothyroidism Chronic Pulmonary Disease	530(8.25) 779(12.12)	17(23.61) 25(34.72)

Table 5. Logistic regression model with Odds Ratios showing the influence of BMI on Postoperative Respiratory Failure (PSI 11)

Variable List	Model 1	Model 2	Model 3	Model 4	Model 5
Age	1.03*	1.01	1.01	1.02	1.03*
Female	0.99	0.86	0.68	0.63	0.84
Minority	1.02	1.02	1.11	1.04	1.00
Private		0.55*	0.70	0.70	1.08
LOS					1.22*
HYPOTHY			3.10*	3.01*	3.09*
CHRNLUNG			3.45*	3.31*	3.15*
BMI				1.03*	1.03*
CHI-SQUARE					
	8.63*	13.01*	46.86*	52.00*	271.45*

* p=0.05

Table 6. Postoperative SEPSIS (PSI-13) Descriptive Statistics of Demographics/ Health Resources/Health Risks

ELIGIBLE POPULATION N=1917	NEGATIVE FOR PS-13 N=1897	POSITIVE FOR PSI-13 N=20
	Mean (SD)	Mean (SD)
Age in years at surgery time	57.91(15.34)	53.65 (15.69)
BMI	30.51 (7.85)	35.79 (13.64)
Number of Procedures	4.42 (3.15)	12.70 (9.45)
Length of Stay (LOS) days	6.39 (4.54)	19.80 (12.17)
Comorbid conditions	1.78 (1.59)	2.80 (2.14)
	N (%)	N (%)
Male Female	859(45.28) 1038(54.72)	9(45.00) 11(55.00)
Non-minority Minority	1637(86.29) 260(13.71)	16(80.00) 4(20.00)
Public Insurance Private Insurance	1013(53.40) 884(46.60)	9(45.00) 11(55.00)
BMI_CAT		
Underweight Normal weight Overweight Obese Class I Obese Class II Obese Class III	32 (1.69) 421 (22.19) 580 (30.57) 437 (23.04) 233 (12.28) 194 (10.23)	1(5.00) 3(15.00) 4(20.00) 4(20.00) 2(10.00) 6(30.00)
Obesity_BMI		
Not obese Overweight Obese	453(23.88) 580(30.37) 864(45.55)	4(45.00) 4 (45.00) 12(60.00)

Chapter Five

Manuscript Three

Are ICD Codes in Electronic Health Records Useful in Identifying Obesity as a Risk Factor When Evaluating Surgical Outcomes?

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Abstract

Clinical and administrative data were examined to determine if ICD-9 codes correctly identify patients with obesity. The data from this research addresses an important topic on patient safety and obesity for the purposes of examining the usefulness of ICD-9 coding alone to determine obesity. Clinical data was used to calculate the patient's BMI, which was then used to categorize the patients into BMI classification categories (World Health Organization, 1997). The findings of this research confirm that ICD-9 codes for the obese surgical populations were under-utilized. In fact, despite finding over 70% of patients were either overweight or obese, ICD-9 codes for obesity were assigned in less than 10% of the overall sample. Only 17% of inpatients and less than 4% of outpatients had ICD-9 codes assigned yet BMI classification showed 72% of inpatients and 71% of outpatients were classified as either overweight or obese using BMIs constructed from clinical data. It is important to assess the reliability of ICD-9 diagnoses and its impact on the public health crisis of obesity. For many in this study, the corresponding ICD-9 codes for obesity are missing. This research determined patients who were in the extreme category of obesity (BMI >40), were more likely to have a corresponding ICD-9 code for obesity when compared to patients in the BMI range of 25-40. However, ICD-9 coding for obesity was under-utilized for all with BMI > 25.

Introduction

Due to the nature of patient care, healthcare workers are frequently required to make split second decisions, perform procedures, and assimilate information that may impact delivery of care and ultimately patient safety. The rapid identification of vulnerable populations and the anticipation of an individual's risk are important determinants and should be considered in the development of outcome measures used for quality improvement and patient outcome studies. Obese patients constitute one of these critical populations.

Obesity is associated with the development of many health risks such as diabetes, hypertension, coronary heart disease, and hyperlipidemia. [1] Body Mass Index (BMI) is determined through the calculation of weight (kg)/[height (m)]^2 and is classified by the World Health Organization (WHO) as underweight (BMI<18.5), normal weight (BMI 18.5-24.99), overweight (BMI 25-29.99), obese class I (BMI 30-34.99), obese class II (BMI 35-39.99) and obese class III (BMI >40).[2,3] Based on 2009-2010 data from the National Health and Nutrition Education Survey (NHANES), the rate of the combined proportion of overweight and obese is reported to be as high as 68.8% of the U. S. population.[4] Furthermore, if obesity rates continue to increase, over 51% of adults will be obese by the year 2030.[5] In addition to the related health risks known to exist in the obese population, obesity places a substantial financial burden on the healthcare system. Per capita medical spending is 42% higher in the obese versus the non-obese representing approximately $1429 per/person and 2008 estimate approximately $147 billion per year for the obese population.[6] Special populations, like obese patients, are important to health services research and are in need of research in order to support patient safety, quantify risks, advance education for healthcare-workers, establish healthcare policy, and promote leadership in the field. While obesity is commonly recognized as contributing to complications of medical conditions, there has been scant attention given to obesity as a risk factor for the outcomes of individuals undergoing surgery.

<u>Obesity is a Disease</u>

In 2013, the American Medical Association (AMA) officially labeled obesity as a pathophysiologic disease that requires medical management, behavioral counseling, pharmacological therapy, and surgical intervention.[7] Buchwald in 2005 predicted obesity had the potential to be considered a chronic disease and presents serious health sequelae for which healthcare workers should prepare.[8] Surgical suites and anesthesia healthcare providers encounter obese patients frequently in their practice, necessitating the need for research to inform the quality indicators and delivery of care for the obese surgical population.

International Classification of Diseases-9 (ICD-9) diagnostic for overweight and obesity were recognized as early as 1997.[9] The Agency for Health Related Quality (AHRQ) comorbidity classification (which includes obesity) uses corresponding ICD-9 diagnostic codes to identify comorbid conditions from large health care electronic datasets.[9] The examination of the reliability of ICD-9 coding as a diagnosis criterion in the obese population is important to determine the usefulness of this measure in quantifying the clinical impact of this disease on health risks and the financial impact on healthcare systems. This study determines the sensitivity of using ICD-9 codes to identify patients with obesity compared to the clinical data of height and weight used to calculate the patient's BMI. The sensitivity of the diagnosis gives the rate at which the diagnosis identifies those who actually have the disease, while specificity gives the rate at which the absence of the diagnosis identifies those in whom the disease is actually present.[10] Classification systems, like ICD-9 codes along with administrative data assist health service researchers (HSR) investigate and report the outcomes for the obese populations. With this knowledge and data, the findings of this research will contribute to the field of HSR and the reliability of ICD-9 coding to identify vulnerable populations.

International Classification of Diseases (ICD)

Since its inception in 1900, ICD has grown from the use of identification of mortality rates in 179-disease classifications to over 21,000 clinical modification codes for diseases. These classifications provide criteria for administrative data and reimbursement.[11] In the 9th edition, (ICD-9) coding was reconfigured to include 12,000 codes with clinical modifications and the ICD-10 version further includes 21,000 codes that reflect diseases and their corresponding clinical details to aid providers in coding of patients and disease processes.[12] The use of ICD-9 coding as a reliable diagnostic marker (versus clinical data alone) informs providers (healthcare systems and healthcare workers) of the impact diseases have on healthcare outcomes. However, errors in commission and omission in ICD-9 coding occur during hospital visits due to insufficient information gathered on admission, deficits in communication with primary providers, and expertise of the transcriptionists or coders.[11] "Code accuracy, defined as the extent to which the ICD code reflects the underlying patients disease, directly impacts the quality of health care decisions."[11] AHRQ and the National Quality Forum (NQF) stipulate that new approaches to improve outcomes should be investigated and the use of information found in electronic medical data (EMD), like ICD-9 diagnoses and procedures allow a look across populations to address desired versus undesired healthcare outcomes.[13]

The increasing rates of obesity in the general population[4] and in surgical populations validate that healthcare workers will encounter obese patients frequently in their practice necessitating the use of a reliable indicator of obesity. The need to identify and communicate the presence of obesity as a disease through the accurate use of ICD classification is important to further examine the impact of the disease on the delivery of care in this population. The establishment of reliable measures contained in EMD is important to provide a uniform taxonomy and to consistently identify the presence of these risk factors in healthcare quality improvement and other patient outcome studies.

Methods

After approval by the study hospital's Institutional Review Board, a correlational study was conducted using electronic clinical administrative data to determine the reliability and sensitivity of using ICD-9 coding as a diagnostic test to measure obesity. Eligible patients (age 18-85) were selected from a surgical sample collected from a study of one health system during 2011-2012. Cases were excluded if they were admitted for cardiac or bariatric surgery, end stage renal disease receiving hemodialysis, and obstetrical procedures, or if their height and weight were judged to be missing or grossly inaccurate from the administrative data. A dataset was created combining the study institutions' Multicenter Perioperative Outcomes Group (MPOG) database and the hospital's Clinical Data Repository (CDR). The MPOG data contributed pertinent patient data including height and weight, which was used to compute BMI.[14] The CDR was the source of additional data elements including patient demographics and ICD-9 codes. The ICD-9 codes for obesity (278.00, 278.01, 278.02, 278.03, & 278.1) included a range of BMI scores that reflect overweight patients, those with obesity, morbid obesity, and obesity hypoventilation syndrome.[9] The final sample included 30,549 individuals who had a surgical procedure either as an inpatient or outpatient during the study period. If patients had more than one procedure during the study period, only their first surgical procedure was used.

The combined study database contained 12,936 inpatients and 17,613 outpatients. The variables of interest included BMI, BMI classification categories as designated by the WHO[3] and

BMI_ICD9 a dichotomous variable examining the presence (0=not present and 1=present) of associated ICD-9 code diagnoses for obesity in the patient's record.

Analysis

Descriptive statistics including means, standard deviations, and frequencies were calculated for the study variables. A chi square analysis for categorical data and a t-test for continuous variables were used to determine the reliability of using ICD-9 codes alone to identify patients with obesity. The level of significance was established to be p <0.05. Graphical analyses are presented to contrast patterns of inpatient and outpatient surgical populations' classification of obesity and their corresponding ICD-9 coding.

Results

The mean age for the overall, inpatient, and outpatient groups were 53, 57, and 50 years respectively. The sample was approximately 54% female. Table 1 summarizes the descriptive statistics of BMI classification and corresponding ICD-9 coding in the study sample. The mean BMI for the overall sample was 29.58 and the BMI classification proportions reflected 1.87% underweight, 26.89% normal weight, 31.21% overweight, Obese Class I 20.5%, Obese Class II 10.59%, and Obese Class III 8.94%. Over 70% of the patients had a BMI greater than 25 (combined overweight/obese). BMI classifications were compared to the presence of a corresponding ICD-9 diagnosis. In the BMI classification of underweight there were no corresponding ICD-9 diagnoses for obesity. Similarly, in patients with the BMI classification of normal weight the presence of a corresponding ICD-9 code was found in less than 0.5% of patients. In patients categorized overweight, based on BMI, the presence of a corresponding ICD-9 code was found in only 3% of the patients. In patients categorized Obese Class I, the presence of a corresponding ICD-9 code was found in 10% of patients. In patients categorized

Obese Class II, a corresponding ICD-9 code was found in 21% of patients. In patients categorized Obese Class III, a corresponding ICD-9 code was found in 45% of the patients.

The overall sample was divided into inpatient and outpatient groups. The mean BMI for inpatients was 29.94 and the BMI classification proportions were 2.26% underweight, 25.56% normal weight, 30.08% overweight and 42.11 % obese (Class 1 21.09%, Class II 11.05%, and Class III 9.97%). The mean BMI for outpatients was 29.31 and the BMI classification proportions were 1.59% underweight, 27.88% normal weight, 32.04% overweight and 38.49% obese (Class I 20.06%, Class II 10.25%, and Class III 8.18%).

BMI classifications were compared to the presence of a corresponding ICD-9 diagnosis. In the BMI classification of underweight there were no corresponding ICD 9 diagnoses for obesity in the inpatient or outpatient groups. In inpatients with the BMI classification category of normal weight the presence of a corresponding ICD-9 code was found in 1% of the inpatients and 0.1% of outpatients. In patients categorized overweight, the presence of a corresponding ICD-9 code was found in 7% of inpatients and 0.4% of outpatients. In patients categorized Obese Class I, a corresponding ICD-9 code was found in 19% of inpatients and 3% of outpatients. In patients categorized Obese Class II a corresponding ICD-9 code was found in 37% of inpatients and 9% of outpatients. In patients categorized Obese Class III a corresponding ICD-9 code was found in 67% of inpatients and 25% of outpatients.

The chi square analysis showed a statistically significant difference in the BMI category classification and the presence of corresponding ICD-9 coding with $p < 0.001$ for the overall sample, and inpatients and outpatients. Figure 1 presents the BMI classification categories and compared the presence of corresponding ICD-9 diagnosis and the absence of ICD-9 coding for the overall sample. Figure 2 examines BMI classification and compared the presence of corresponding ICD-9 diagnosis and the absence of ICD-9 coding for versus ICD-9 coding for inpatients versus outpatients.

Discussion

In the overall sample, the patients who are underweight and normal weight accurately lack associated ICD-9 coding for obesity (see Figure 1). However, the presence of corresponding ICD-9 coding increases as BMI increases. At the extreme BMI, class III obese, where virtually every patient should have triggered an ICD-9 obesity code, the presence of ICD-9 coding, though most consistent, was still missing in more than half the cases. The presence of ICD-9 diagnoses for patients with a BMI greater than 40 emphasizes that as patients are at the extreme of BMI, providers more often recognize the detriments of the comorbidity and code for it accordingly. ICD-9 diagnosis are significantly underrepresented in patients with BMI ranges from 25 to 40. This has potential implications for patients and providers that warrant further research. In a climate where greater than 68% of the population is overweight or obese,[4] and with associated health risks of obesity (hypertension, diabetes, and coronary artery disease)[8] this information confirms that obese patients are an at risk population. It is important to recognize obesity as a comorbidity throughout the ranges of excess BMI (25-40) as well as for those with a BMI greater than 40, in order to prepare for the physiologic impact and consequences of the disease, and the prevention and management of these consequences. The absence of ICD-9 coding implies insufficient data gathering from the provider or coder and lack of recognition of the disease consequences. [9,11] Obesity is recognized as a comorbidity that contributes to poor outcome, but whose diagnostic inclusion is underreported.[15] Preparation for predictable consequences that lead to poor outcomes is necessary for this population to avoid the risks of adverse outcomes.

In the inpatient and outpatient sample, (see Figure 2) for the patients who comprised the underweight and normal BMI classifications, ICD-9 coding is appropriately absent. However, ICD-9 diagnoses coding is under-utilized in the BMI classification ranges 25-40 in the comparison of inpatients and outpatients. The comorbidity of obesity is extremely important for the plan of care in the surgical patient for both settings. However, the lack of coding is more apparent in outpatients where ICD-9 coding reflects less than 1% of the overweight category, although more often present in the outpatient Obese Classes I-III, it remains largely unreported. The even more frequent absence of coding for obesity in outpatients is extremely concerning considering the importance of modifying plans of care, discharge status to home, and the potential risk of adverse outcomes.

It is important to assess the reliability of ICD-9 diagnoses and its impact on the public health crisis of obesity. For many in this study, the corresponding ICD-9 codes for obesity are missing. However, when present, ICD-9 and ICD-10 coding accurately identify patients as obese. The clinical and administrative data used in this research confirm that when ICD-9 codes were used for obesity, patients were correctly identified as obese. The administrative data (ICD-9 codes) supports the clinical data (BMI). However, ICD-9 codes are unreliable due to their under-reporting in patients. This was most acutely found in patients in the BMI range of 25-40. The absences of ICD-9 coding reveals that ICD-9 codes lack sensitivity. This translates to the inability to examine ICD-9 coding for obesity reliably as a risk factor for adverse outcomes.

A goal of patient safety initiatives is to "identify risk and hazards that cause or have the potential to cause health care associated injury or harm."[16] Clinical and administrative datasets are equipped to help researchers look at potential pitfalls that can impact patient safety.[16] Administrative data associated with EMD is useful to determine whether ICD-9 coding reliably identify comorbidities, like obesity. The move from ICD-9 to ICD-10 was intended to expand clinical criteria to aid providers and coders in more precisely incorporating additional diagnoses.[17] However despite this expansion of clinical criteria, administrative data are unreliable reflections of coding by providers and/or coders.[17] Other research has confirmed similar outcomes in the sensitivity of ICD-10 and ICD-9 to detect comorbidities, like obesity. Coding is deficient due to coder under-utilization as well as insufficient physicians' and nurses' notes.[17] In a review of charts, despite documentation to clinically support obesity in 8.3% of the patients, corresponding ICD-9 coding for obesity was detected in only 2.7% of charts reviewed and corresponding ICD-10 coding for obesity was found in only 1.9% of charts reviewed.[12,17]

In a similar study that examined pediatric obesity, researchers [18]also confirmed the low sensitivity of ICD-9 codes to identify obesity when compared to BMI. In a pediatric population with 21% obesity they found only 8% of the population had corresponding ICD-9 codes for obesity. This lack of coding impacts care and outcomes associated with the obese population. Among pediatric patients, researchers found a statistically significant difference for length of stay and hospital costs when comparing those with and without a secondary ICD-9 diagnosis of obesity.[19]

Alone, ICD-9 codes identified through electronic health data are not reliable to identify those patients who are overweight or obese. Further research is needed to understand the poor reliability of ICD-9 codes for obesity. An important implication of this study is to examine a national dataset (which includes BMI), to confirm these findings. It is also important investigate surgical outcomes in obese patients identified by ICD-9 codes in datasets where BMI is absent. With the current rate of obesity in the general and surgical population it is important for comorbidities, like obesity to be recognized. The obese population exceeds the normal weight population in surgical suites. A re-examination of once accepted protocols based on normal weight patients is needed in healthcare facilities and surgical suites in order to be prepared for the obese population. These changes begin preoperatively and include consultation from specialists, planning for difficulty with airway management, and unexpected admission. The associated health risks, hospital costs, and potential adverse events associated with obesity make it imperative to continue to study the barriers to coding in this population.

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Table 1. Descriptive Statistics of Obesity Classification and ICD-9 Code for the First Case in 2011 and 2012 in the Overall, Inpatient and Outpatient Surgical Settings

DESCRIPTIVE STATISTICS OF OBESITY CLASSIFICATION AND CORRESPONDING ICD-9 CODING						
	Overall Sample N	N (% of BMI class with ICD-9 code)	Inpatient N	N (% of BMI class with ICD-9 code)	Outpatient N	N (% of BMI class with ICD-9 code)
Underweight	572	0 0	292	0 0	280	0 0
Normal Weight	8216	40 (0.49)	3306	36 (1.09)	4910	4 (0.08)
Overweight	9534	293 (3.07)	3891	269 (6.91)	5643	24 (0.43)
Obese Class I	6262	624 (9.96)	2728	519 (19.02)	3534	105 (2.97)
Obese Class II	3235	694 (21.45)	1429	531 (37.16)	1806	163 (9.03)
Obese Class III	2730	1223 (44.80)	1290	865 (67.05)	1440	358 (24.86)

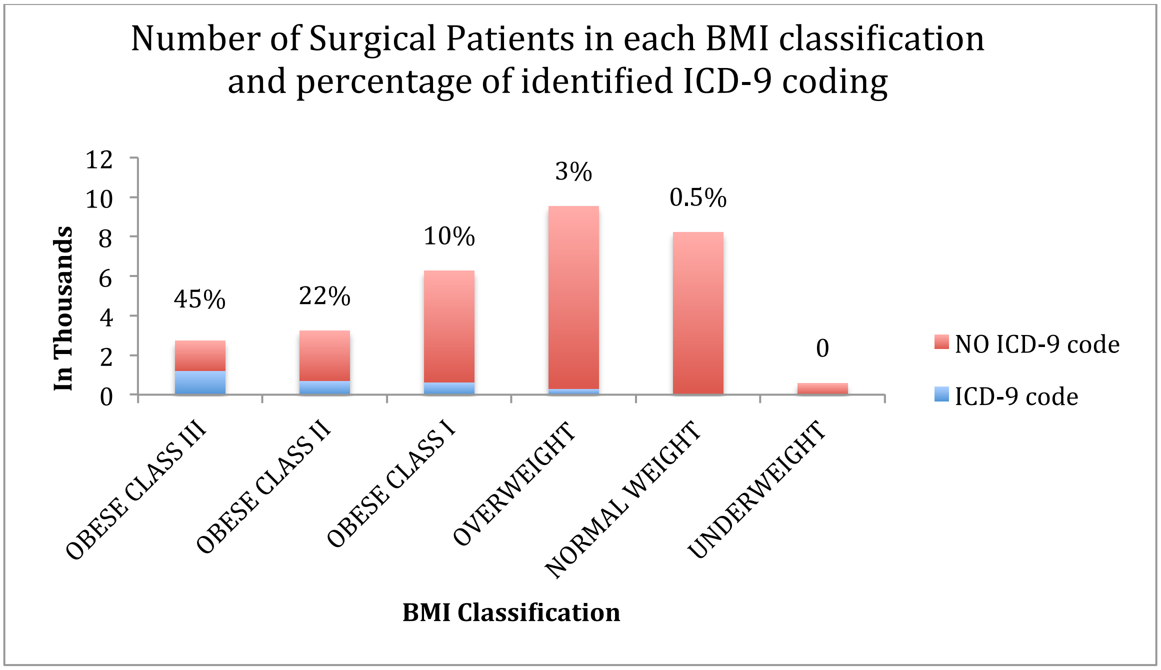
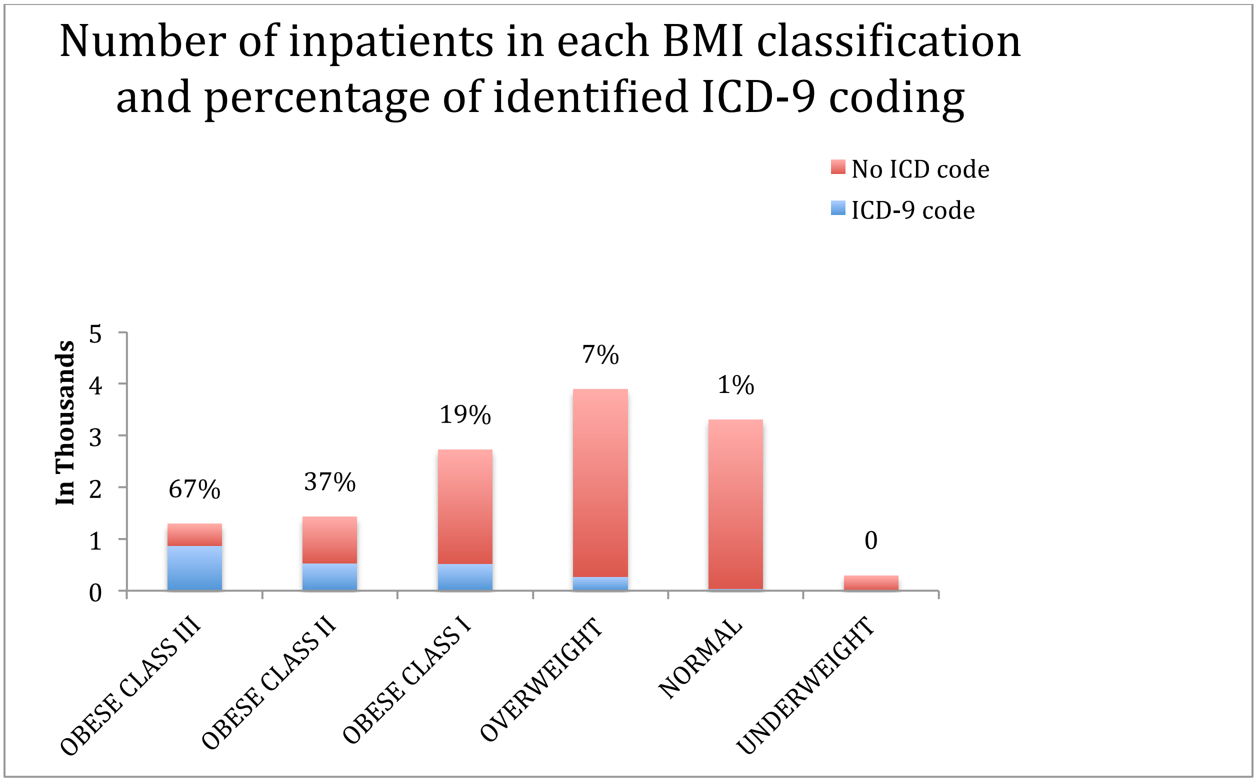


Figure 1. Identification of Obesity in Surgical Population using clinical data and BMI Classification comparing percentage identified with and without ICD-9 Diagnoses



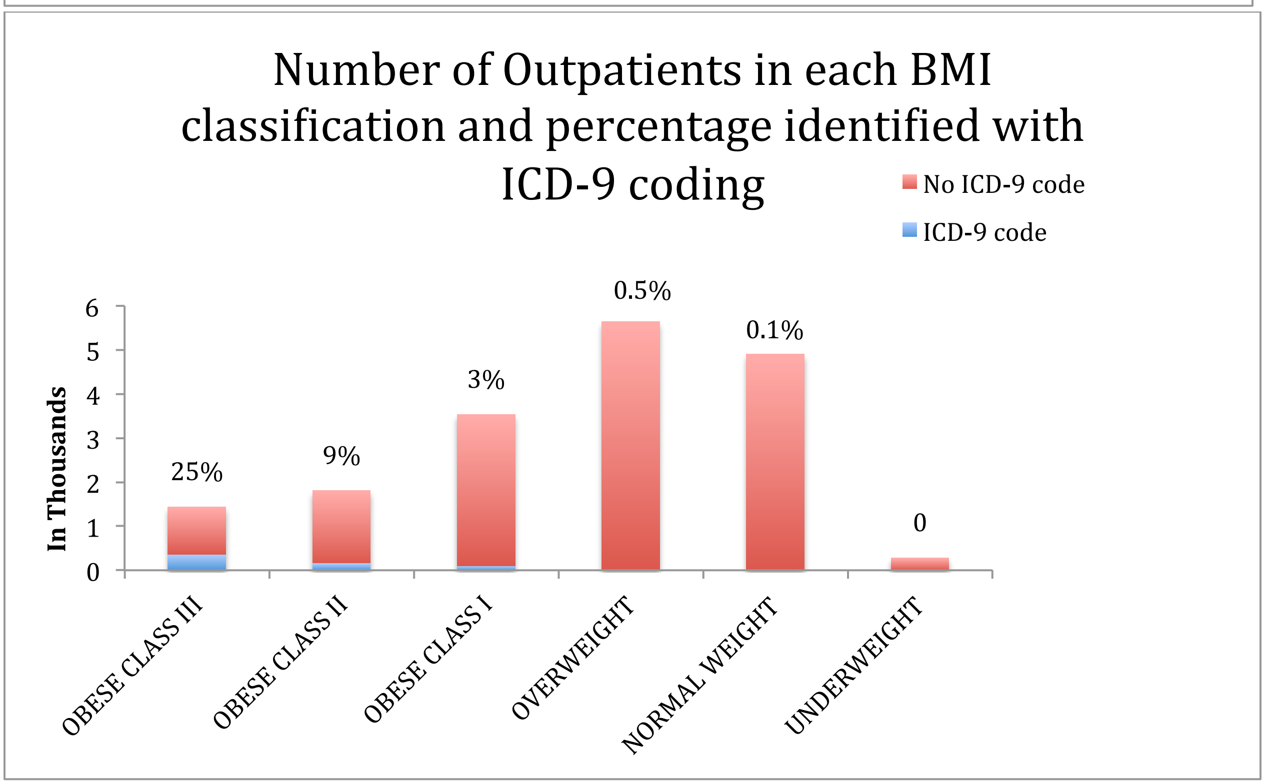


Figure 2. Identification of Obesity in Surgical Population using clinical data and BMI Classification comparing percentage with and without identified ICD-9 Diagnoses

Chapter Six

Conclusion

The purpose of this dissertation was to quantify the prevalence of obesity in the surgical population, to examine the degree to which undesirable outcomes occur in the obese surgical patient population, to understand factors associated with poor outcomes, and to determine the reliability of ICD-9 codes to identify the obese patient as a risk factor in adverse outcomes. The Donabedian Model of Patient Safety, which focused on structure, process, and outcome informed this study (AHRQ Agency for Healthcare Research and Quality, 2012; Coyle & Battles, 1999; Donabedian, 1972; Donabedian, 1980). The properties of the organization (structure), management and treatments (process) and the final results of the plan (outcomes), which may be desired or undesired, were examined through the research process and are described through three manuscripts. These manuscripts, reported in Chapters 3, 4, and 5, include *Alice Magaw: A model for Evidence-Based Practice, A Patient Safety Dilemma: Obesity In the Surgical Patient*, and *Are ICD Codes in Electronic Health Records Useful in Identifying Obesity as a Risk Factor When Evaluating Surgical Outcomes.* Together these manuscripts provide information that will influence decisions regarding patient safety outcomes.

In Manuscript 1, the historical background on patient safety, titled *Alice Magaw: A model for Evidence-Based Practice* (Goode, 2015) is presented. It describes the development of nurse anesthesia practice and the importance of Magaw's record of anesthetics for others to use as a guide for anesthetics in certain populations. This served as an early model of evidence-based practice over 100 years before ever established by the IOM. The importance of vigilance and education was emphasized, which are still recognized today as being important to patient safety outcomes and validates the importance of recognizing vulnerable populations when establishing protocols for patients. Magaw's contribution to patient safety helps practitioners recognize the potential for adverse events, and the necessity of the practice of anesthesia to seek to identify populations prone to adverse events and to examine alternative methods to prevent them.

In Manuscript 2, *A Patient Safety Dilemma: Obesity In the Surgical Patient,* the prevalence of obesity in the surgical population was found to be 70%, exceeding that of the general population, estimated to be 68% (Flegal, Carroll, Kit, & Ogden, 2012; Flegal, Carroll, Ogden, & Curtin, 2010). This study confirmed that a patient safety dilemma exists for healthcare systems and healthcare providers regarding caring for the obese patient population. In the examination of three AHRQ patient safety indicators (PSIs), for the inpatient population, obesity was found to increase the likelihood of adverse outcomes in two of three PSIs examined. The study revealed that the obese population (BMI > 30) is more likely to develop post-operative respiratory failure and post-operative sepsis. In the final outcome, perioperative pulmonary embolism and deep vein thrombosis, obesity did not prove to be a statistically significant predictor for the adverse outcome in the inpatient obese population. It is noted this subgroup had a mean BMI that reflected overweight (29.29) and not obese (BMI< 30).

In Manuscript 3, *Are ICD Codes in Electronic Health Records Useful in Identifying Obesity as a Risk Factor When Evaluating Surgical Outcomes,* clinical and administrative data were examined to determine if ICD-9 codes correctly identify patients with obesity. Clinical data was used to calculate the patient's BMI, which was then used to categorize the patients into BMI classification categories (World Health Organization, 1997). The findings of this research confirm that ICD-9 codes for the obese surgical populations were under-utilized. In fact, despite finding over 70% of patients were either overweight or obese, ICD-9 codes for obesity were assigned in less than 10% of the overall sample. Only 17% of inpatients and less than 4% of outpatients had ICD-9 codes assigned yet BMI classification showed 72% of inpatients and 71% of outpatients were classified as either overweight or obese using BMIs constructed from clinical data. This was an alarming finding for patient safety as it was determined in this research that obesity is a predictor of adverse events in the inpatient surgical obese population (Goode et al., 2015). This research also determined patients who were in the extreme category of obesity (BMI >40), were more likely to have a corresponding ICD-9 code for obesity when compared to patients in the BMI range of 25-40. However, ICD-9 coding for obesity was under-utilized for all with BMI > 25.

Limitations

This research was concluded in a single institution that was an academic medical center. It is not known if similar results would be found in similar institutions or in other types of hospitals. The quality of certain data elements (clinical classification of procedures, surgical service and indigent status) could not be constructed for use in the administrative dataset. The inability to identify the primary surgical service for each patient from the MPOG data, limited the use of the AHRQ clinical classification of procedures and thus the inability to use this as a variable in the study. The missing values for the variable of indigent status also made it an unsuitable variable to use in this study.

Future Research

This research has important value for health systems, healthcare workers, and health policy for the obese population. Further research is needed to establish healthcare protocols and policies for the vulnerable population of obesity. It is necessary to re-examine these findings in other inpatient populations at the national level. The outpatient population needs to be examined after appropriate conversion of the outpatient data to fit the AHRQ PSI algorithm. Further research is needed to determine differences, if present, between inpatients and outpatients. Further research is needed to determine whether a threshold BMI exists to trigger the occurrence of adverse events. This will allow for future research to make a comparison of data for inpatients versus outpatients to validate the need for changes in protocols and policies for the obese surgical patient. Future research is needed to address barriers to the recognition of obesity in ICD-9 coding to identify this population, specifically in light of the rates of obesity for our nation and worldwide. This study has an important impact across age ranges including pediatrics. Future research is also needed to address these finding in the pediatric population.

Conclusions

The obese surgical population is a vulnerable population in need of further research. The prevalence of obesity in the surgical setting exceeds the estimates of the general population. Thus, healthcare workers, specifically surgical staff, can expect to encounter this population frequently in practice. This research confirms the obese patient is at risk for adverse outcomes. The associated health risks, hospital costs, and potential for adverse events associated with obesity make it imperative to continue to examine the care delivered to this vulnerable population. It is also important for health service researchers to utilize, as available, the administrative data of the obese population to identify their risk. It is critical for healthcare workers to develop, test, and evaluate measures to reduce error and improve safety outcomes. This research begins to answer this call for the surgical obese patient.

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