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THE RELATIONSHIP BETWEEN OUTCOMES ASSOCIATED WITH PATIENT BLOOD MANAGEMENT PROGRAMS AND TRANSFUSION SAFETY OFFICERS

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THE RELATIONSHIP BETWEEN OUTCOMES ASSOCIATED WITH PATIENT BLOOD MANAGEMENT PROGRAMS AND TRANSFUSION SAFETY OFFICERS

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

by

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ABSTRACT

THE RELATIONSHIP BETWEEN OUTCOMES ASSOCIATED WITH PATIENT BLOOD MANAGEMENT PROGRAMS AND TRANSFUSION SAFETY OFFICERS

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BACKGROUND: Patient Blood Management (PBM) has become the standard of care for transfusion services in hospitals. Transfusion Safety Officers (TSOs) have been identified by some as being a crucial part of a successful PBM program; however, no studies have been done to show their effectives, or if there is even a relationship between having a TSO and outcomes associated with PBM programs. The purpose of this study was to describe and test the relationship between having a TSO and six outcomes associated with PBM programs including blood product wastage (red blood cells, plasma, and platelets), hospital lengths of stay, rates of 30-day readmissions, and rates of hospital-acquired infections. Further, this study described and tested the relationship between a TSO being a nurse and the same six outcomes.

METHOD: An anonymous pre-validated online survey was used to collect data from blood transfusion professionals using purposive and snowball sampling. Participants were recruited via email and flyers posted on blood transfusion professional networks. Forty-three participants gave complete responses to all six outcome variables.

RESULTS: There were very few reporting hospitals that had a PBM program without a TSO (n = 8); therefore, these hospitals were merged with those hospitals that did not have a PBM

program (n = 21) for statistical analyses. Pearson correlations showed moderate to strong, negative, statistically significant correlational relationships between having a TSO and all six of the outcomes, indicating that having a TSO was associated with less blood product wastage, lower hospital lengths of stay, lower rates of 30-day readmissions, and lower rates of hospital-acquired infections. Each of the outcomes had statistically significant differences in the means between the groups that had a TSO and those that did not. Additionally, logistic regression analyses were able to predict whether the hospital had a TSO or not from each outcome at a statistically significant level. There was a small, statistically nonsignificant correlational relationship between the TSO being a nurse and each of the six outcomes; there was no statistically significant difference in outcomes between the TSO being a nurse group and the TSO group that was not a nurse. However, these groups had smaller sample sizes and may not have been adequately powered to detect differences.

CONCLUSIONS: The TSO role is still a relatively new position in hospitals. No studies have been performed to show their effectiveness with PBM programs. This study was the first to show that there is a strong relationship between having a TSO and six outcomes associated with PBM programs. However, due to the small number of responding hospitals that had a PBM program and no TSO (n = 8) and the subsequent merging of this group with the responding hospitals that did not have a PBM program (n = 21), it was not possible to separate the effects of having a TSO from the effects of the hospital having a PBM program. Additionally, the results of this study did not give any evidence that there is a difference in PBM outcomes when the TSO is a nurse as opposed to when the TSO is not a nurse. This study provided the first step in exploring the relationship between having a TSO and outcomes that are associated with PBM programs.

Keywords: Transfusion Safety Officer, Patient Blood Management, Outcomes

CHAPTER 1: INTRODUCTION AND PURPOSE

The purpose of this study was to gain insight into the relationship of a relatively new role, that of Transfusion Safety Officer (TSO), with Patient Blood Management (PBM) programs in blood transfusion facilities. While one small survey had been done to identify who is performing the duties of this new role, no other systematic studies have investigated the impact that a TSO has on a PBM program (Jacobs, et al., 2021). Hence, this survey was a first step in measuring the impact of a TSO on the PBM-associated outcomes of their facility. The impact of this study is at the organizational and systems level of healthcare rather than at the clinician-patient level, and it could inform the policy decisions of managers and administrators. The information gained from this study provides the basis for further research on this new role and will add to the existing literature on transfusion safety, which often involves life and death situations.

Overview

This chapter provides an overview of the significance of Patient Blood Management (PBM) and the impact that it has on the quality of outcomes in healthcare settings. The Transfusion Safety Officer (TSO) role has been identified by some as an important part of a successful PBM program (Ghiglione & Puca, 2014). By 2017, there was a call for setting up multi-disciplinary teams for managing blood use in patients and a call to designate TSOs to guide PBM programs (WHO, 2017). This chapter includes background information, the significance of this study, the aim of the study, and the associated research questions and hypotheses; in addition, this chapter has as an introduction to the theoretical framework used to guide this study and a brief description of the methodology used in this survey.

Background Information

Blood Transfusion is one of the most performed medical procedures in the United States. In 2011, over 13.5 million red blood cell (RBC) transfusions were performed at an estimated cost of $10 Billion, with blood transfusion being the single most billed procedure in hospitals (Ghiglione & Puca, 2014). In recent years, there has been a decline in red cell transfusions due to newer Association for the Advancement of Blood & Biotherapies (AABB) guidelines for more restrictive blood transfusion thresholds (Ellingston, et. al, 2017). The newer guidelines were in response to a need for a more evidence-based approach in blood transfusion decision making (Ghiglione & Puca, 2014).

In the past the decision to transfuse was highly variable with no standardization in the decision-making process (Bennet-Gurerro, Zhao, O'Brien, Ferguson, Gammie, & Song, 2010; Qian, et. al., 2013). Clinicians often used a higher (or what has been termed a more liberal) transfusion trigger of 10.0 g/dL hemoglobin as a threshold for transfusing a patient (Nester, Jain, & Poisson, 2014). A meta-analysis of 19 random controlled trials (RCTs) indicated that a lower (or what has been termed more conservative or restrictive) transfusion trigger of 7.0 – 8.0 g/dL for hemoglobin threshold gave similar patient outcomes as those patients who had more liberal transfusion triggers of 10.0 g/dL or higher: The patient outcomes reported in this meta-analysis included mortality, morbidity, and time of recovery (Carson, Carless, & Hebert, 2013). In this study, there were no significant differences in complications such as stroke, pulmonary edema, or infection between patients transfused with higher or lower transfusion triggers. Conversely, several studies showed a link between blood transfusion and worse patient outcomes (Ghiglione & Puca, 2014).

In part due to the above research, the AABB transfusion committee assembled a group of experts to establish new guidelines to aide clinicians in making transfusion decisions. This committee recommended that a transfusion trigger of 7 g/dL was appropriate for a hemodynamically stable adult patient, while a transfusion trigger of 8 g/dL was recommended for patients undergoing orthopedic and cardiac surgeries, and for patients with a previously diagnosed cardiovascular disease (Carson, et al., 2016).

There are several noninfectious risks to patients who have been transfused with blood products (Ghiglione & Puca, 2014). Approximately, 15% of inpatients receive a transfusion of blood products with approximately 1% of those transfused products resulting in a serious adverse reaction (Panch, Montemayor-Garcia, & Klein, 2019). These noninfectious risks include transfusion-related acute lung injury (TRALI), ABO- and non-ABO-associated hemolytic transfusion reactions (HTR), transfusion-associated graft-*versus*-host disease (TA-GVHD), transfusion-associated circulatory overload (TACO), and transfusion-related immune modulation (TRIM). TRALI, TACO, and HTR are the three most reported causes of transfusion-related mortality (Mazzei, Popovsky, & Kopko, 2014). Appearing within 6 hours of transfusion, TRALI is characterized by fever, chills, dyspnea, cyanosis, and new-onset bilateral pulmonary edema. TRALI is an immunological response to transfused blood products containing plasma. It occurs approximately once in every 5,000 transfusions and can be fatal if not detected and treated soon after the presentation of symptoms (Peak, Davis, & Walton, 2019). Blood products containing plasma, such as fresh frozen plasma, platelets, red blood cells, and cryoprecipitate, have been linked to TRALI with volumes as small as 15 mL of plasma leading to TRALI (Mazzei, Popovsky, & Kopko, 2014). Often confused with TRALI, TACO is pulmonary edema caused by volume overload with infants and patients over the age of 70 being at the greatest risk (Mazzei,

Popovsky, & Kopko, 2014). Food and Drug Administration (FDA) reports have indicated that approximately 30% of transfusion-related fatalities are associated with TACO (Semple, Rebetz, & Kapur, 2019). Delayed HTRs are involved in 4.3% of transfusion reactions and in 16% of all serious reactions (Panch, Montemayor-Garcia, & Klein, 2019).

Patient Blood Management

Many hospitals began using Patient Blood Management (PBM) programs following the World Health Organization (WHO) recommendations for more evidence-based transfusion decision making, more research on patient transfusion outcomes, as well as more standardization in transfusion practices (WHO, 2017). PBM is an evidence-based, multidisciplinary, patient-centered approach to the transfusion of blood products with a focus on improving patient outcomes (Ghiglione & Puca, 2014). Usually, it has a restrictive, versus liberal, approach to transfusing blood products to a nonbleeding patient. PBM has been associated with fewer adverse clinical outcomes (Kleinerüschkamp, Meybohm, Straub, Zacharowski, & Choorapoikay, 2019). Restrictive and liberal red blood cell transfusion strategies gave similar outcomes (Chen, Wang, Liu, Shao, Yu, & Zheng, 2018).

A recent review found that the systematic application of a PBM program in the perioperative period has been consistently found to improve patients' clinical outcomes following surgery, and more recently, PBM programs have been extended to include non-surgical indications (Franchini, et al., 2019). PBM is currently considered the standard of care for a nonbleeding patient (Zacharowski & Spahn, 2016). With the adoption of PBM programs, a new role was created to coordinate these programs. Although there are varying designations for this new role, most often they are called Transfusion Safety Officers.

Transfusion Safety Officers

In the WHO (2017) priorities for action in PBM, there was a call for setting up multi-disciplinary teams for managing blood use in patients and a call to designate Transfusion Safety Officers (TSOs) to guide PBM programs. In addition to traditional transfusion safety duties, TSOs also commonly perform the functions of PBM, such as blood utilization reviews, documentation reviews, and minimization of perioperative blood loss (Dunbar & Szczepiorkowski, 2015). While most TSOs are involved in the administrative and educational aspects of a PBM program, some TSOs are involved in reviewing transfusion reactions (Jacobs, et al., 2021). TSOs have been found by some to be a crucial part of a multi-disciplinary team in reducing blood transfusions (Ghiglione & Puca, 2014). However, no studies have been done to show their effectiveness in improving PBM associated outcomes. While some hospitals have a requirement that the TSO is a nurse, other hospitals do not have this requirement, which gives a wide variation in the backgrounds and skills of those who are performing the duties of a TSO. There are no published studies that have indicated the necessity for a TSO to be a nurse.

Theoretical Framework

Systems level approaches to understanding quality and reducing costs in health care were being sought by the 1990s, having been introduced for the most part by managed health care organizations (Shi & Singh, 2015). One of the major models used to assess health care quality is the framework developed by Donabedian (Polit & Beck, 2012).

Donabedian Framework

The Donabedian model was first introduced in 1966 by Avedis Donabedian who at the time was a physician at the University of Michigan. As a health services researcher, Donabedian developed a framework, or conceptual model, for examining and evaluating health care settings and services. This framework is centered around three constructs, or domains: structure, process, and outcome (Donabedian, 1966). Although there have been updates and additions to the framework, the basic domains have remained constant.

Structure Domain

The structure domain consists of resource inputs into the system, such as the facility itself (including licensing and accreditation), equipment, staffing levels, distribution of hospital beds and physicians, as well as the qualifications (education, licensure, and certification) of the staff (Shi & Singh, 2015). This domain looks at the broad organizational and administrative features of the facility (Poilit & Beck, 2012). This domain also addresses aspects of the system such as cost of care, access to the care provided, and the physical environment of the facility (Smith, Schussler-Fiorenza, & Rockwood, 2006). The training of health care providers is included in this domain (Kane, 2006).

Process Domain

The process domain has to do with the technical aspects of care (correct diagnosis and treatment procedures, correct and accurate administration of prescriptions, cost, and communication between health care workers and with patients), as well as the dignity, compassion, respect, and concern for patients and coworkers (Shi & Singh, 2015). Communication and interpersonal interactions between healthcare providers is included in this domain, as well as continuity of care (Smith, Schussler-Fiorenza, & Rockwood, 2006). This

domain assesses whether the correct action was taken and how skillfully that action was performed (Kane, 2016).

Outcome Domain

Whereas the structure domain has to do with inputs into the system, the outcome domain has to do with the outputs of the system. The outcome domain has to do with the end results of the health care system (Polit & Beck, 2012). This domain includes hospital-acquired infections, readmission, morbidity, and mortality (Shi & Singh, 2015). While the process domain looks at what was done in the system, the outcome domain looks at the results of the actions taken in the process domain (Kane, 2006).

The Donabedian theoretical framework will be utilized as a foundation for this preliminary study of the impact of TSOs on PBM outcomes. Using this basic framework, the TSO structure factors can be associated with the perception of PBM-associated outcome factors. Data can be collected from the factors representing each domain.

Problem Statement

With Transfusion Safety Officers being identified by some as an important part of a successful PBM program (Ghiglione & Puca, 2014), it is important to understand the role played by a TSO in a transfusion facility and how that role impacts PBM outcomes. To date, there has only been one small study on what role a TSO plays in a transfusion facility, which is usually a large, academic based hospital, and no studies have been done to show their effectiveness. There is variation in the backgrounds of TSOs: Usually it is a nurse or medical laboratory scientist performing TSO duties; however, other professionals also perform TSO duties, such as quality assurance personnel, or it is made part of the duties of a blood bank or nurse supervisor. Some facilities have a requirement for the TSO to be a nurse, while other facilities do not. There has

been no published research on the necessity of this requirement. This variance in who performs the duties of a TSO also means that there is a range of educational and training backgrounds across TSOs.

Purpose Statement

The purpose of this study was to use the Donabedian Framework to describe the relationship between the role of TSO with PBM associated outcomes of a facility, using self-reporting of outcome results from transfusion service directors or their designee. Because no studies have been done to show the effectiveness of TSOs, this descriptive study was the first step in evaluating the impact that a TSO has on the outcomes of a PBM program. This purpose was accomplished through the following aims.

Study Aims

The target construct of this study was transfusion safety and blood management outcomes often assessed by PBM programs. Self-reporting from transfusion department directors (or their designee) was relied upon to assess the PBM outcomes by asking the participants to give information on the quality indices associated with the PBM outcomes at their facility. These outcomes include decreasing blood wastage (red blood cells, plasma, and platelets), decreasing the rates of hospital acquired infections, decreasing patient lengths of stay in the hospital, and decreasing the rates of 30-day readmissions. Some PBM associated outcomes, such as hospital-acquired infections are reported quality indicators to Centers for Medicare and Medicaid Services (CMS). Other outcomes, such as wastage, are not reported to outside agencies. All outcomes are tracked by the blood bank department or by quality assurance. The structure (qualities of the TSO) and outcome (PBM outcomes) domains of the Donabedian Quality Framework provided the theoretical framework of the study. The proposition for this study was

that TSOs will improve PBM-associated outcomes of a facility. This study was guided by the following aims.

Aim 1: Describe and test (depending on the sample size obtained) the relationship between having a TSO and the PBM associated outcomes of a facility. This analysis provided information on the impact that a TSO has on PBM associated outcomes. These results were the first on the effectiveness of having a TSO and they can be used as a basis for further study on TSOs while helping to guide policy decisions for transfusion managers and directors.

Aim 2: Describe and test (depending on the sample size obtained) the relationship between the having a TSO that is a nurse and the PBM associated outcomes of a facility. This analysis provided information on the impact of having a TSO who is a nurse. These results were the first on the effectiveness of having a TSO who is a nurse and they can be used as a basis for further study on TSOs while helping to guide policy decisions on transfusion managers and directors.

Research Questions and Hypotheses

This study was guided by the following research questions:

RQ1: Is there a relationship between a facility having a TSO and the PBM-associated outcomes of that facility?

H1: It was hypothesized that there is a relationship between having a TSO and the PBM-associated outcomes of a facility.

RQ2: Is there a relationship between a facility having a TSO that is a nurse and the PBM-associated outcomes of that facility?

H2: It was hypothesized that there is a relationship between the PBM-associated outcomes and having a TSO who is a nurse.

Significance of the Study

Transfusion safety is often a matter of life and death to patients being administered blood products. PBM has been shown to reduce patient morbidity and mortality in blood transfusion settings (Franchini, et al., 2019; Zacharowski & Spahn, 2016). TSOs have been identified by some as a crucial element to the success of PBM programs (Ghiglione & Puca, 2014). To date, no known studies have been done on the impact of TSOs on PBM associated outcomes. The lack of research on TSOs is a gap in the current knowledge of PBM programs. Research in this area can provide a better understanding of the role TSOs play in a successful PBM program.

This study took the first step in gaining insight into the impact a TSO has on the outcomes of a PBM program by asking transfusion directors to report PBM-associated outcomes of their facility. Knowledge of these factors can aid in increasing the positive impact that the role of a TSO has on a PBM program, which is significant in that more qualified TSOs (such as those who are registered nurses) can lead to a more effective PBM program. In turn, more successful PBM programs will lead to increased transfusion safety.

Study Design

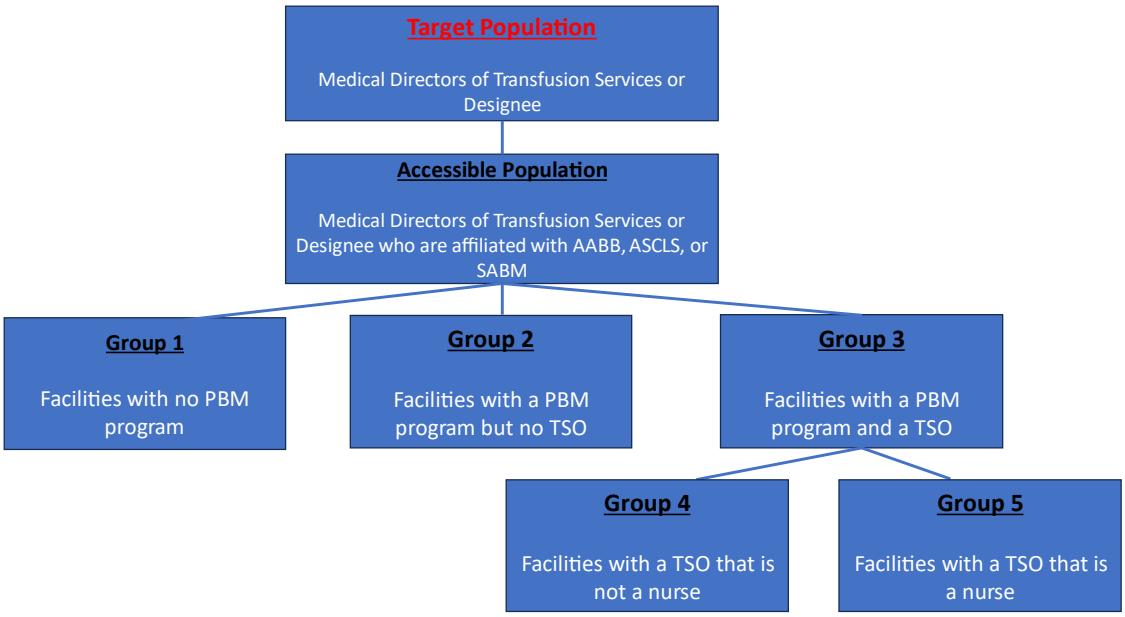
This study was a descriptive, nonexperimental, quantitative survey utilizing purposive sampling and snowball sampling with a respondent driven sampling component. The target population is the population to which the results of a study are generalized (Polit & Beck, 2012). In this study, the target population was transfusion department directors (or their designee). The accessible population was blood transfusion directors who could be contacted through professional directories in organizations such as AABB, American Society for Clinical Laboratory Science (ASCLS), or the Society for the Advancement of Patient Blood Management (SABM). In addition, other professional organizations were utilized to identify transfusion

directors such as LinkedIn or Specialist in Blood Banking (SBB) programs. SBB programs are designed to assist blood transfusion professionals in attaining certification from the American Society for Clinical Pathology (ASCP): SBB(ASCP). The students of these SBB programs were contacted and asked to forward the survey to their transfusion director. Any transfusion professional who was not a transfusion director (or a designee), or who was not in the United States was excluded from this study. Because there was no directory of TSOs, there was no sampling frame; therefore, an attempt was made to find facilities that utilize PBM, and further those that also have a TSO, through RDS techniques. RDS is a form of snowball sampling, which in turn is a form or purposive sampling (Polit & Beck, 2012). RDS has been used by the Centers for Disease Control (CDC) to find and identify "hidden populations," such as the homeless or injection drug users. Johnston and colleagues (2016) provide a systematic review of the uses of RDS in the behavioral and biological sciences.

Figure 1 shows comparison groups formed from the status of facilities having a PBM program and a TSO. Group 1 was hospitals that do not have a formal PBM program. Group 2 was hospitals that have a PBM program, but do not have a TSO. Group 3 was hospitals that have a TSO. Group 4 was hospitals that have a TSO that is not a nurse. Group 5 was hospitals that have a TSO that is a nurse.

Figure 1

Diagram of Target and Accessible Population



Note: This figure shows the groups formed by the status of facilities having a Patient Blood Management (PBM) program and a Transfusion Safety Officer (TSO). AABB = Association for the Advancement of Blood & Biotherapies. ASCLS = American Society for Clinical Laboratory Science. SABM = Society for the Advancement of Patient Blood Management.

According to Polit & Beck (2012) for a power of .80, the sample size needed for the medium effect of d = .50 is 64 subjects in each group. However, smaller sample sizes can still detect medium to large differences between groups: the sample size needed with the larger effect size of d = .70 is 33 per group. With d = .80, the sample size can be as low as 25 per group: a total sample size of 50 could be used to compare two groups of 25 each. The above calculations show that small sample sizes can detect large effect size differences between groups.

Because there was no known sampling frame of TSOs, sampling began with professional organizations such as AABB, the American Society for Clinical Laboratory Science (ASCLS), and the Society for the Advancement of Patient Blood Management (SABM) to attempt to contact transfusion directors. Other professional organizations, such as LinkedIn and Specialist in Blood Banking (SBB) programs were used to identify more participants. An attempt was made to widen the sample subjects as much as possible, especially by geographical region. Jacobs and colleagues (2021) began with the SABM directory, which contained contact information for 86 hospitals with a PBM program, then through internet searches found 18 more hospitals with a PBM program for a total of 104 hospitals with 52 of the hospitals responding.

A survey was designed and administered through REDCap at VCU, which collected the data. It was necessary to validate this survey and to show it was reliable. Because this was a descriptive study, the data analysis consisted of descriptive statistics. As the study by Jacobs and colleagues (2021) has shown sample sizes could be small; therefore, multivariate inferential statistics were sample size dependent. Since non-response is a major concern in surveys, announcements and updates were posted on forums in the professional organizations to increase the response rate.

Prior to the start of this study, approval was obtained from the Institutional Review Board (IRB) of Virginia Commonwealth University (VCU). Because the survey asked “about what” rather than “about whom,” the VCU IRB considered this study to be exempt from IRB review. Participants were informed in a cover letter that clicking the link for the web-based survey gives consent from the participant to be surveyed.

Summary

Patient blood management improves patient outcomes by decreasing morbidity and mortality, decreasing hospital-acquired infections, and decreasing hospital length of stay. Transfusion safety officers have been identified as an important component of a successful PBM program. There is very little existing literature about the impact of TSOs on patient outcomes. There is a great amount of variability in educational backgrounds and certifications/licenses of those who perform the duties of a TSO. This study expands the knowledge base on TSOs and their impact on PBM outcomes.

Organization of Remaining Chapters

Chapter two provides a review of the literature concerning the history of patient blood management with its impact on patient outcomes and literature gaps. Chapter three describes the study design and methodology. Chapter 4 gives the study results and Chapter 5 provides a discussion of the results.

CHAPTER 2: LITERATURE REVIEW

Overview

This chapter reviews research literature on the topic of Patient Blood Management (PBM) which is necessary for a discussion of the impact that a Transfusion Safety Officer (TSO) has on a PBM program. This chapter begins with general information regarding the need for PBM in the improvement of patient outcomes, including hospital acquired infections as an outcome, the role of anemia management in a PBM program and its effect on patient outcomes, and the role of a TSO in a PBM program. Next, this chapter provides an overview of the Donabedian theoretical framework. The domains, or constructs, of this framework are structure, process, and outcome. Finally, a summary will be provided regarding gaps in the literature related to the role of TSOs in hospital settings. Chapter three focuses on the methodology of this study to address these gaps in the research literature.

The Need for Patient Blood Management

Blood Transfusion Indicators

In the past, with no standardized guidelines, there was much variation in ordering blood products for transfusion, which was shown in cardiac (Bennet-Gurerro, Zhao, O'Brien, Ferguson, Gammie, & Song, 2010) and non-cardiac surgeries (Qian, et. al., 2013). A higher transfusion trigger of 10.0 g/dL hemoglobin was used as a threshold for transfusing a patient (Nester, Jain, & Poisson, 2014). However, a lower hemoglobin trigger of 7.0 – 8.0 g/dL was shown to have similar patient outcomes as a higher threshold (Carson, Carless, & Hebert, 2013). By 2015, an Association for the Advancement of Blood & Biotherapies (AABB) committee recommended that a transfusion trigger of 7 g/dL was appropriate for a nonbleeding adult patient (Carson, et al., 2016).

Impact of Blood Transfusion

Patient Outcomes from Blood Transfusion

Blood transfusion has been shown to lead to poorer patient outcomes (Ghiglione & Puca, 2014). As early as 1986 in a prospective study of colorectal patients, blood transfusion and admission hematocrit were significantly related to postoperative infectious complications. (Tartter, Quintero, & Barron. 1986). A review of observational studies in 1994 suggested an increased risk of postoperative infections in patients who have been transfused (Vamvakas, 1994). A 2008 systematic review observational studies indicated that red blood cell transfusion was associated with higher odds of mortality and higher odds of developing an infection (Marik & Corwin, 2008). A 2011 review of observational studies also associated red blood cell transfusions with increased postoperative infections, in addition to increased morbidity and mortality, and increased length of hospital stay (Isbister, Shander, Spahn, Erhard, Farmer, & Hofman, 2011). In a dose dependent manner, red blood cell transfusion has been linked to longer length of hospital stays and to morbidity and mortality (Ghiglione & Puca, 2014).

Hospital Acquired Infections

More recent research has linked hospital acquired infections (HAIs) to specific blood components such as red blood cells or platelets. Several studies have indicated that patients transfused with red blood cells have a two to four times higher risk of developing a nosocomial infection (Ghiglione & Puca, 2014). One study estimated a 29% increase of postoperative infections for each RBC unit transfused (Horvath, et al., 2013): In this study platelet transfusion was not associated with increased risk of infection. However, in another study, platelet transfusions were associated with nosocomial infections in critically ill patients (Engele, et al.,

2016). In addition, another study found platelet transfusions were associated with infections in intensive care units (Aubron, et al., 2017).

Patient Blood Management

PBM Background

With the above results indicating the importance of transfusion safety in patient care, by 2010 the World Health Organization (WHO) was recommending the use of PBM programs (WHO, 2017). The term patient blood management was first used in 2005 by Professor James Isbister, an Australian hematologist (Isbister, 2005). PBM uses an evidence-based approach to improve patient outcomes (Ghiglione & Puca, 2014). AABB (2018) has issued PBM standards that include optimizing erythropoiesis, minimizing blood loss, and managing anemia. The second edition of the PBM standards included two new standards. Standard 5.3 was added to ensure that patient blood management programs create transfusion indications that are program defined. Standard 6.2.3.2, was added to ensure that patient records are linked to those contained in the laboratory information system.

The AABB standards align with the objectives of PBM. In their review of the literature Franchini and colleagues (2019) identified three objectives of PBM: (1) improving red cell mass by means other than transfusion, in other words reducing the need for transfusion; (2) minimizing blood loss during medical procedures; and (3) managing anemia which includes a restrictive transfusion threshold. Because reducing blood loss is beyond the scope of a transfusion service, the focus of this study will include reducing the need for transfusion and the management of anemia.

Reducing Blood Transfusion

In a 2008 systematic review of the literature, 42 of the 45 studies indicated that the risks of RBC transfusion outweighed the benefits: the pooled results from the observational studies found that RBC transfusion was independently associated with higher odds of mortality and higher odds of developing an infection (Marik & Corwin, 2008). This systematic review of observational studies found 1.7 times higher odds of mortality in transfused patients (95% CI = 1.4–2.2). However, in a meta-analysis of 20 randomized trials with 8598 patients, the pooled risk of all serious infections was 10.6% (95%CI,5.6%-15.9%) in the restrictive group and 12.7% (95% CI,7.0%18.7%) in the liberal group (Rohde, et al., 2014). The risk ratio (RR) in the meta-analysis of RCTs was 0.92 (95% CI = 0.82-1.04) for the association between transfusion strategies and infection. A more recent meta-analysis of 22 studies indicated that the pooled relative risk of any complication in the restrictive transfusion group was 0.43 for non-cardiac and 0.34 for cardiac surgical patients, thus indicating that PBM may be associated with fewer adverse clinical outcomes compared to control management (Kleinerüschkamp, Meybohm, Straub, Zacharowski, & Choorapoikay, 2019).

The restrictive strategy remains controversial for patients undergoing cardiac surgery. Cardiac surgeries consume some of the greatest amounts of blood products with approximately half of the patients undergoing this surgery requiring blood products with 2% to 8% requiring a reoperation (Mehta, et al., 2009). A meta-analysis of randomized controlled trials demonstrated that the restrictive red blood cell (RBC) transfusion strategy gave similar outcomes to the liberal strategy with respect to 30-day mortality, pulmonary morbidity, postoperative infection, cerebrovascular accidents, acute kidney injury, or acute myocardial infarction (Chen, Wang, Liu, Shao, Yu, & Zheng, 2018).

Anemia Management

Anemia management, including the detection and etiology of anemia, is a core principle of a successful PBM program and is often the first step in a PBM program (Sullivan & Roback, 2019). Although anemia is common in peri-operative cardiac patients, its effect on patient outcomes has been controversial. To address this issue, a recent meta-analysis was conducted by Padmanabhan, et. al, (2019). The results indicated that anemia was associated with increased mortality (OR = 2.74), acute kidney injury (OR = 3.13), stroke (OR = 1.46), and infection (OR = 2.65).

Investigators for the Virginia Cardiac Services Quality Initiative have questioned whether it is the transfusion of blood products or the underlying need for transfusion (e.g., anemia) which is linked to poor patient outcomes in cardiac surgery (LaPar, et al., 2018). In this large, multicenter study, Lapar and colleagues (2018) used hierarchical logistic regression to assess the likelihoods of postoperative mortality and morbidity from baseline preoperative hematocrit level and red blood cell transfusion, after adjusting for baseline patient risk. In this study, red blood cells demonstrated strong associations with postoperative mortality (OR = 4.3), renal failure (OR = 6.3), and stroke (OR = 2.4). After adjustment, anemia did not increase the odds ratios associated with these patient outcomes; however, anemia did remain a strong independent predictor of those outcomes. The authors modeled pre-operative hematocrit; however, they did not take into consideration peri-operative hematocrit levels. In an accompanying editorial commentary, it was noted that no information was given regarding conditions or indications for the underlying need for transfusion, which is the case with most other studies on outcomes related to transfusion (Paone, 2018).

In a retrospective study of 1552 patients undergoing isolated coronary artery bypass grafting (CABG) from January 2013 to May 2016, there was no association between hemoglobin level below the institution mean for CABG patients with an increased 30-day readmission rate (Cho, et al., 2019). In this study, the most common reasons for readmission were volume overload, infections, and arrhythmias. Anemia management is an important component of PBM programs.

Effectiveness of PBM

Whether due to anemia or to transfusion itself, patient outcomes are improved by avoiding transfusion. PBM programs have been found to improve patient outcomes following surgery (Franchini, et al., 2019). PBM has been successfully implemented with hematopoietic stem cell transplantation (HSCT) patients, who often have a high use of blood products (Warner, et al., 2019). PBM programs have been used in intensive care units and in obstetrics (Franchini, et al., 2019). PBM is currently considered a safety and quality standard for patient care (Zacharowski & Spahn, 2016). AABB and The Joint Commission now offer a new, voluntary Patient Blood Management Certification (AABB, 2019).

With the demonstrated effectiveness of PBM, attention has turned to how best to manage a PBM program. The role of Transfusion Safety Officer (TSO) was created to manage these programs. TSOs have been identified by some as an integral part of a successful PBM program (Ghiglione & Puca, 2014).

Transfusion Safety Officers

TSO Role

The World Health Organization has designated Transfusion Safety Officers (TSOs) to guide PBM programs in setting up multi-disciplinary teams for managing blood use in patients (WHO, 2017). TSOs have been found by some to be a crucial in reducing blood transfusions through educational efforts (Ghiglione & Puca, 2014). In addition to offering alternatives to transfusion, blood utilization and document reviews are other common duties of TSOs (Dunbar & Szczepiorkowski, 2015). A survey found that many TSOs participate in transfusion committees, manage many PBM quality initiatives, and investigate transfusion safety events (Jacobs, et al., 2021). These duties are important components of PBM programs.

NBCUS 2011

Every two years, the CDC along with the Office of the Assistant Secretary of Health (OASH) conduct the National Blood Collection and Utilization Survey (NBCUS), which is a questionnaire sent to blood collection and transfusion facilities. The NBCUS 2011 survey covered the years of 2011 and 2012, and the results were reported the following year in 2013. A new section on PBM was added to the NBCUS survey in 2011. In 2013, at the end of that survey, it was found that 30% of the responding facilities had a PBM program: 98% of these facilities were hospitals (AABB, 2013). In the reported hospital PBM programs, 34% were coordinated by a medical director only and another 51% were coordinated by a combination of medical and other staff. These other staff members included nurses, blood bank staff, anesthesiologists, cardiologists, hematologists/oncologists, risk management staff, healthcare improvement staff, transfusion committees, blood utilization committees, and what was termed "patient safety officers" (AABB, 2013).

In the NBCUS survey released in 2013 (covering 2011 and 2012), 15% of hospitals (n = 201, out of 953 hospitals) reported having a TSO (AABB, 2013). Of the hospitals with a TSO, 61% reported having full-time TSOs: 81% of the TSOs were hospital employees, and 14% were blood center employees (AABB, 2013). In the 2015 NBCUS survey results released in 2017, the percentage of hospitals that reported having a TSO dropped to 16.2% (n = 305, out of 1,885) with almost 95% of the TSOs being employees of the hospital rather than a blood center (Sapiano, et al., 2017).

In the 2015 NBCUS survey results released in 2017, 74.7% listed the medical director as a PBM program coordinator, 29.8% listed a nurse coordinator, 35.5 listed a non-nursing coordinator, and 34.3% listed other personnel (Sapiano, et al., 2017). Multiple responses were allowed in the survey. Many facilities in the survey reported using College of American Pathologists (32.3%), AABB (72.5%), American Society of Anesthesiologists (2.3%), or American Red Cross (11.7%) for transfusion guidelines. A Computerized Physician Order Entry (CPOE) was reported as being required at 85.1% of facilities and 56.1% of the CPOEs included transfusion guidelines or an algorithm to assist with proper transfusion ordering.

The survey results covering the period between 2019 to 2020 were released in 2021. According to Mowla and colleagues (2021), the number of TSOs declined from 19.3% to 17.9%, with 93.2% (315/338) reporting TSO employment by the hospital and 4.1% (14/338) reporting employment by a blood center, and 2.7% (9/338) did not identify the employer. No further information was given about the TSOs identified by the respondents in this survey. These results indicate that only 17.9% of hospitals used a TSO in the 2019 to 2020 survey period, and further, the rate was less than the previous survey period.

TSO Backgrounds

Although not reported in the NBCUS survey, the job postings for some facilities have a requirement that a TSO must be a nurse, while other facilities will accept a registered nurse or a medical laboratory scientist with a background in blood banking. Although a level of education is not always specified in these job postings, the requirement for a registered nurse implies a bachelor's level of education; however, it is possible to be a registered nurse with an associate's level of education. In addition, some job postings have a requirement for a master's degree in nursing or a master's degree in medical laboratory science. These job postings indicate a range of educational and licensure requirements for those who perform the duties of a TSO. It is unknown if this variation in background and credentials affect the job performance of those performing the duties of a TSO; for example, do nurses perform the duties of a TSO better than those who are not nurses?

2021 TSO Survey

To date there has only been one systematic study performed regarding TSOs. In 2021, Jacobs and colleagues (2021) at Vanderbilt University administered a survey to 104 hospitals. With a 51% response rate (n = 52), the survey asked about the presence of a TSO, as well as the role responsibilities of the TSOs and their characteristics, backgrounds, and education. Most respondents (77%, n = 44) had a PBM program and 33 of those respondents (63%) with a PBM program had at least one TSO. These results show that not all facilities have a formal PBM program, and of those who do have a PBM program, not all have a TSO.

Most of the 52 TSOs in the Jacobs and colleagues (2021) study were nurses (61%) with 41% of the TSOs having a PBM certification. Five of the 52 TSOs had the Specialist in Blood Banking, SBB (ASCP), certification. Five of the 52 TSOs had a Medical Laboratory Scientist

background, three of the 52 had perfusionist training, one had informatics training, and six had a background in business administration.

Jacobs and colleagues (2021) noted there was no centralized database of institutions utilizing PBM programs and no registry of TSOs. Therefore, no sampling frame exists from which to randomly sample these institutions. The researchers also stated that no other study in the United States had addressed TSOs before theirs. After searching the internet for institutions with a valid email address, they sent their 20 question surveys anonymously via REDCap. The researchers note that they developed their questions with input from TSOs and PBM directors and performed a pilot of their survey among colleagues at other institutions to improve face and content validity, including test-retest reliability, in an iterative process that took 6 to 8 months. However, no further details were given on the validation of their instrument, such as the sample size they used for their pilot study or results of reliability indices.

Because contact information for faculty and staff in many facilities are not available, Jacobs and colleagues (2021) began their search for participants with the Society for the Advancement of Patient Blood Management (SABM). SABM is a voluntary educational resource for PBM and they had a contact list of 86 hospitals with PBM oriented practitioners. The only exclusion criteria noted by the researchers was stand-alone blood donor centers that were not affiliated with a hospital. They then tried to include as many additional institutions as possible to increase the representativeness of their sample. They identified 18 more hospitals that have a TSO by internet searches for a total sample of 104 hospitals. To prevent more than one person from an institution from responding, personalized links for the 104 hospitals were sent via REDCap, which then automatically uploaded and deidentified survey responses.

Brief Summary and Identification of Literature Gap

PBM has been shown to be safe and effective with diverse patient demographics. TSOs have been identified by some as being important components of PBM programs. However, only one systematic study, by Jacobs and colleagues (2021), has been attempted to describe the TSO population. This survey had (n = 52) respondents for what appeared to be a fully developed survey: there was no mention of this survey being a pilot survey. The authors of this survey mentioned that they did a small pilot study before launching their survey.

A search of PubMed for the term "Transfusion Safety Officer" gave (n = 8) results, as did a search of the CINAHL database. None of these results included any information on the impact of a TSO on the outcomes of a PBM program. It was not until 2021 that any systematic attempt was made to understand the role of TSO in a survey by Jacobs and Colleagues (2021). No systematic studies have been attempted to describe the relationship between PBM programs and TSOs or the impact that TSOs have on a PBM program if they have any impact at all. To better understand the role TSOs play in a PBM program, a theoretical framework was utilized to build a foundation for this knowledge.

Donabedian Theoretical Framework

Defining Quality

According to Shi and Singh (2015), quality is often difficult to define and measure, and this is one of the reasons that the pursuit of quality has stagnated behind considerations of cost and access in the health care system. Quality is defined differently by patients, providers, and payers, and this is one of the reasons why there has been no one definition of "quality" (Shi & Singh, 2015). McGlynn (1997, pg. 8) has used the Institute of Medicine (IOM) definition of quality as being "the degree to which health services for individuals and populations increase the

likelihood of desired health outcomes and are consistent with current professional knowledge." With cost containment becoming more of an issue in health care, there has been an increased focus on how decreasing costs affects quality. There are two major models of quality currently in use; one was proposed by the Institute of Medicine and the other by Avedis Donabedian (Cromwell, Trisolini, Pope, Mitchell, & Greenwald, 2011). This study utilized the Donabedian Framework to guide its methodology and instrument development.

Donabedian Domains

Avedis Donabedian has been recognized as a pioneer in quality assessment in health care and has had a major impact on the development of the field (Harolds, 2015). According to Harrington (2005), the Donabedian model is utilized for most quality studies in healthcare. The model proposed by Donabedian (1980) discusses three constructs, or domains, for defining the quality of health care: the characteristics of an organization (Structure) are linked to what is done to the patient (Process), which, in turn, is linked to what happens to the patient (Outcome). Traditionally, the model was thought of as a linear process: Structure → Process → Outcome. Figure 1 shows this original, linear version of the Donabedian model. However, to simplify the model, some researchers have focused on Structure → Outcome directly without considering the Process domain, while others have focused on the Process and Outcome domains (Harolds, 2015).

Figure 2

Donabedian Model for Relating Structure, Process, and Outcome: The Linear Version

Structure Domain

The structure domain includes equipment, supplies, and staff training, as well as the availability of technology (Donabedian. 1980). This domain can be thought of as the resource inputs into the health care production process, such as the availability of staff (nurses, physicians, and other health care professionals), necessary equipment, facilities management, information technology, medical technology, and other resources (Cromwell, Trisolini, Pope, Mitchell, & Greenwald, 2011). This domain also includes the financial aspects of the system such as insurance and the appropriate training of the available staff (Harolds. 2015); it also includes patient-provider interactions, leadership, and the culture of safety in an organization are parts of this domain (Donabedian, 2005). The structure domain includes the availability of personnel as well as their qualifications (Donabedian, 1988). Structure is considered by many to be the foundation of the quality of health care (Shi & Singh, 2015).

Some researchers have theorized that structure has a primary impact on process and only a secondary impact on patient outcomes (Shi & Singh, 2015). Although traditionally it is not thought of as being as important as process and outcome by some researchers, other researchers

have found that structure can have a very significant relationship with both process and outcome domains directly (Harolds, 2015). This type of relationship can be visualized as a triangle with structure being one of the three sides. A study of the quality systems of 386 hospital departments in Sweden, which utilized confirmatory factor analysis and structural equation modeling, found much higher correlations of structure with process and structure with outcomes, than the correlation between process and outcome (Kunkel, Rosenqvist, & Westerling, 2007). This study shows that although researchers can focus on the relationship between process and outcome, the importance of structure cannot be minimized. A good structure is required for good processes (Shi & Singh, 2015).

Process Domain

The process domain has to do with the actual delivery of health care, which includes the use and appropriateness of diagnostic tests, as well as actions to evaluate and treat patients, especially the interactions between patients and health care professionals (Donabedian, 1980). The process domain can be divided into technical and interpersonal processes (Harold, 2015). The technical aspects of care include correct diagnosis and treatment procedures, correct and accurate administration of prescriptions, cost, communication between health care workers and with patients, as well as including the interpersonal aspects of dignity, compassion, respect, and concern for patients and coworkers (Shi & Singh, 2015).

Many researchers have come to view the process domain in the context of how closely a process conforms to accepted standards of care and evidence-based medicine (Harolds, 2015). A process measure needs to be closely correlated with a corresponding patient outcome measure for it to have relevance; as an example, correct colorectal cancer screening (process) will be associated with an outcome measure, such as the reduction in mortality attributable to colon

cancer (Cromwell, Trisolini, Pope, Mitchell, & Greenwald, 2011). In the previous example, the availability of colorectal screening would be a variable for the structure domain, the correct results of the testing would be a variable in the process domain, and reduction in mortality attributable to colon cancer would be a measurable variable for the outcome construct when deriving hypotheses for the Donabedian model.

The process domain was thought to be very important in quality measures in the original writings by Donabedian (Harolds, 2015). The process of evidence-based care is assessed in this domain including accurate patient identification and the proper administration of medical products (Donabedian, 2005). The process domain has a direct impact on the outcome domain (Shi & Singh, 2015).

Outcome Domain

The outcome domain has been defined in many ways, as have the structure and process domains (Donabedian, 2005). The outcome domain has to do with the final-results of the health care system, such as patient satisfaction, health status, recovery, nosocomial infections, iatrogenic illnesses, rehospitalization, and mortality (Shi & Singh, 2015). Outcomes can also be defined as the final-results of actions taken in the process domain (Kane, 2006). Clinical measurements of patient care, such as patient morbidity, mortality, and satisfaction are included in this domain (Donabedian, 1980). Although outcomes often represent the ultimate goals being investigated, they are often difficult to measure, especially in a short time span (Cromwell, et al., 2011).

From an outcome perspective, high quality health care may be related to the reduction of the frequency of relapse from a certain disease, such as cancer. With respect to diabetes care, possible outcomes for diabetic interventions could be glycemic control, morbidity, or mortality.

Age, co-morbidities, diet, exercise, and risky behaviors could be outcomes, or could be considered as co-factors that can affect morbidity, mortality, and other outcome variables for diabetic management (Cromwell, et al., 2011). Process and Outcomes are often the focus of many measurements of quality (Harolds, 2015). Medicare's Physician Quality Reporting Initiative and the Hospital Quality Initiative have focused on Process and Outcomes exclusively (Cromwell, et al., 2011).

The quality of the outcome domain is determined by the quality of the structure and process domains and can be improved by clinical practice guidelines, risk management, evidence-based care, and other process improvements (Shi & Singh, 2015). Having better educated and more highly licensed and certified workers can improve the structure domain and therefore improve the measured outcome factors in the outcome domain.

Intermediate Outcomes

In theorizing about the outcome domain, some outcomes take so long to manifest (upwards of years at times) that is more advantageous to focus on biological indicators that are correlated with health; these are known as intermediate outcomes and can be thought of as short-term outcomes (Mainz, 2003). For example, most cancer treatments focus on 5-year survival rates. Rather than waiting for 5 years to evaluate the progress of treatment, many researchers have focused on 6 months to yearly evaluations of cancer treatment, which can often still be too long to wait for quality health care. Donabedian believed that it was not beneficial to wait for infrequent outcomes such as death to occur before having some kind of outcome measurement to evaluate (Harolds, 2015).

Although they are not true final outcomes in the sense of measuring morbidity or mortality, intermediate outcomes are clinical values so they can be viewed as outcomes, rather

than as process variables (Cromwell, et al., 2015). In the case of diabetes management, which is a long-term, chronic condition, a researcher can focus on an indicator of blood sugar management, or glycemic control, such as levels of hemoglobin A1c (Selby, 2013). Blood pressure and a lipid profile are two commonly used intermediate outcomes for diabetes care (Mainz, 2003). The risk for developing severe diabetic complications, such as retinopathy, nephropathy, and neuropathy, can be indicated by the level of glycemic control which is in turn correlated with the Hemoglobin A1c clinical values (Cromwell, et al., 2011).

A beneficial feature of intermediate outcomes is that they can be measured more often and in a greater frequency than final outcomes (Mainz, 2003). Hemoglobin A1c can be measured every 3 months and blood glucose can be measured several times a day, whereas amputations due to diabetic complications are much rarer occurrences. Amputations could be tracked as performance measures, but this would require much larger sample sizes and would better serve as an annual performance measure for a larger group of healthcare providers (Cromwell, et al., 2013).

Balancing Measures

The Donabedian domains can be so interdependent that changes designed to improve one part of the system can cause problems in another part of the system. In measuring or tracking quality indicators for the purpose of quality or process improvement, the concept of balancing measures has been introduced. When measuring parts of the system for improvement, it is important to use a balanced set of measures to ensure the overall improvement of the system. According to the National Health System (NHS, 2021 pg.1) online library in England, “monitoring emergency re-admission rates following initiatives to reduce length of stay would be an example of a balancing measure.” In this example, reducing the length of stay could increase

or decrease the re-admission rates. This same example was also given by the Institute for Healthcare Improvement (IHI, 2021). IHI suggests that the system be looked upon from multiple perspectives and they give another example of balancing measures: monitoring reintubation rates when reducing the time that a patient spends on a ventilator (IHI, 2021).

An Example: Donabedian Applied to Diabetes Care

The Donabedian model has been utilized by a group of diabetes researchers to assess the level of quality in diabetes health care. The Translating Research into Action for Diabetes (TRIAD) study was launched in 1998 by the CDC and the National Institute of Diabetes and Digestive Diseases and Kidney diseases; it used variables framed within the three constructs, or domains, proposed by Donabedian (Selby, 2010).

TRIAD was a multicenter, observational prospective study with more than 180,000 enrolled diabetic patients (Selby, 2010). This study assessed the quality of diabetic care and patient outcomes by looking at how quality was related to system level structures. They extended the model to include patient level characteristics that may influence patient outcomes. For the structure domain, this study looked at the health systems structure, disease management strategies, cost containment strategies, and data systems. The process domain included periodic testing for hemoglobin A, lipids, and microalbuminuria, as well as periodic foot and retinal examinations, among other measures. The outcome domain included health status and utilization, mortality, glycemic control, blood pressure control, cholesterol control, cardiovascular disease, nephropathy, among other measures.

Some Critiques of the Donabedian Framework

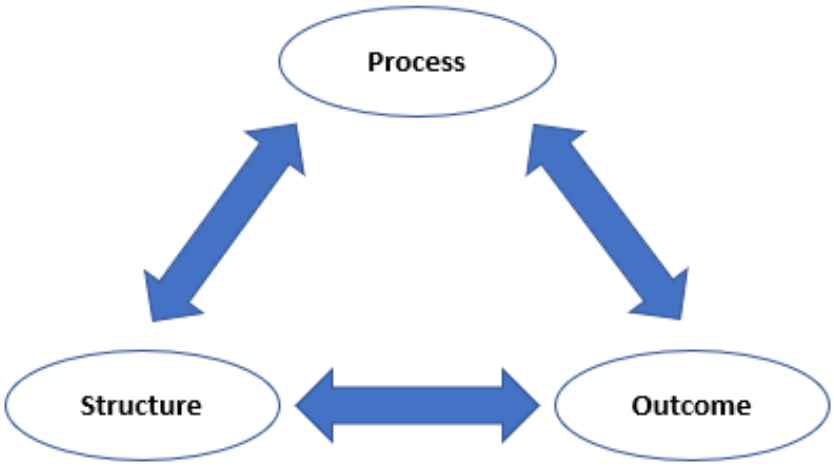
A major limitation in utilizing the Donabedian model is in finding valid variables to measure for each of the three major constructs in the model. Many studies utilizing the model

have not demonstrated the validity of the variables that they are measuring and have not shown that each process variable being measured is actually-correlated to its corresponding outcome variable, assuming that the relevant variables were included in the first place (Coyle & Battles, 1999). In addition, to capture certain outcomes, especially rare outcomes, a very high sample size is often needed to find significant results (Cromwell, et al., 2011).

A strict adherence to the original linear form of the model was critiqued early on, and the model has been altered by some to look more like a triangle with each of the three domains at the three vertices of a triangle. Although the original Donabedian Model was often criticized for its strict linear form and it did not focus on antecedent patient characteristics of the patient (such as culture, socioeconomic status, or attitude), his later writings did discuss more of these areas (Harolds, 2015). Figure 3 shows a more circular model between the three Donabedian domains with each domain having a bidirectional effect on the other two domains.

Figure 3

Revised Donabedian Framework Model with Domain Interactions



When these two deficiencies are addressed, the Donabedian model becomes much more comprehensive for quality research (Harolds, 2015). The Donabedian Model has been extended to include many of these antecedent patient characteristics, which has created a more comprehensive model for clinical use (Selby, 2010). Even with these limitations, the Donabedian model is still widely used and is useful for the measurement of quality in health care (Harolds, 2015).

Summary of the Theoretical Framework

In conclusion, this study used the Donabedian Framework as its theoretical foundation. Using this basic framework, the TSO structure domain associated factors (status of having a PBM program or a TSO) can be assessed with the PBM factors of the process and outcome domains (quality indices of the facility). Data was collected from the structure and outcome domains in relation to TSOs and their associated PBM programs.

Conclusion

In this literature review, Patient Blood Management (PBM) was shown to improve patient outcomes. Avoiding transfusion, or a more restrictive transfusion strategy, has been shown to give outcomes equivalent to a liberal strategy, and often improves patient outcomes. In addition, PBM programs have lowered healthcare costs. Although there has been an increase in the use of standardized transfusion guidelines, there is still much observed variance in transfusion strategies across facilities (Franchini, et al., 2019).

Although there have been conflicting results about the impact of infections on patient outcomes and more research needs to be done on which blood component increases the likelihood of developing an infection, hospital acquired infections should be included as an outcome measurement in studies on the efficacy of PBM programs.

The management of anemia is one of the principles of PBM. Anemia has been shown to influence patient outcomes that is independent of the transfusion of blood products. Anemia management is an important part of a PBM program.

TSOs have been identified as a crucial part of a multi-disciplinary team in reducing blood transfusions. TSOs also commonly perform the functions of PBM, such as blood utilization reviews, documentation reviews, and minimization of perioperative blood loss. Many different types of employees have been found to be performing the role of TSO, including medical directors, nurses, blood bank staff, anesthesiologists, cardiologists, hematologists/oncologists, and risk management staff, among others.

There were gaps in the state of knowledge regarding the relationship between TSOs and PBM outcomes. There was almost no published literature on the role of TSOs. A search of PubMed for the term "Transfusion Safety Officer" gave 8 results, as did a search of the CINAHL database. None of the results obtained from the database addressed the impact that a TSO has on PBM outcomes (i.e., decreased errors, better patient safety indices, less blood wastage, lower rates of hospital acquired infections) To date, only one systematic study has attempted to describe TSOs and their role in a PBM program, and that study had a small sample size.

As this literature review discussed, a literature base dedicated to TSOs has barely begun. More research is needed, especially with larger sample sizes, to elucidate the relationship between TSOs and PBM outcomes. Large sample sizes will be difficult to obtain: Jacobs and colleagues (2021) were only able to find 104 hospitals with a TSO starting with the SABM voluntary directory that contained only 86 hospitals with a TSO with only 52 responding. In addition, response rates to surveys are often very low. The first step is to describe the relationship between TSOs and PBM outcomes. This literature review proposed that variables

from the Donabedian structure and outcome domains were used to describe the relationship between TSOs and PBM outcomes. Hence, this research project addressed this gap in the research literature by laying the foundation for future research into the relationship between TSOs and PBM outcomes. This study was an internet-based survey that collected data relating to the Donabedian structure and outcome domains. Chapter 3 addresses the methodology of survey.

Search Terms

PubMed: “Transfusion Safety Officer” gave 8 results

“Patient blood management” gave 540 results (Systematic reviews: 42)

“Blood Transfusion/standards” gave 2168 results

CINAHL: Transfusion Safety Officer gave 8 results

“Patient Blood Management” gave 198 results

Patient Blood Management AND Transfusion Safety gave 285 results

CHAPTER 3: METHODOLOGY

Overview

Chapter 1 presented the problem statement, the significance of the problem, and the aim that guides this research. Chapter 2 included a literature review of the outcomes associated with Patient Blood Management (PBM) programs, as well as introducing the Donabedian theoretical framework which will be used as a foundation for the current study. This chapter describes the design of the overall study, the sampling plan, and design of the survey. This chapter will address the methodology associated with survey development. The topics in this chapter include research design topics such as internal and external validity, reliability, sample size calculation, assessment of power, selection of subjects, as well as collection and analysis of data from this survey.

Introduction

This descriptive, nonexperimental study utilized a cross-sectional design for a survey to describe the relationship between a Transfusion Safety Officer (TSO) and the PBM-associated outcomes of a facility. Transfusion directors or their designee were surveyed through REDCap from Virginia Commonwealth University. These participants were asked about PBM-associated outcomes of their facility in a first step towards measuring the impact of a TSO. Part one of the survey asked about the organizational structure of the facility being reported on, such as how many beds the facility has, the state it is in, and whether the facility has a PBM program or TSO. Part two of the survey pertained to the PBM associated outcomes of the facility being reported upon. Any respondents who are outside the United States were excluded from this study. A review of the study aim, research questions, and hypotheses are presented next.

Purpose Statement

The purpose of this study was to use the Donabedian theoretical framework to describe the relationship between the role of TSO with the PBM associated outcomes of a facility, using self-reporting of outcome results from transfusion service directors or their designee. Because no studies have been done to show the effectiveness of TSOs, this descriptive study was the first step in evaluating the impact that a TSO has on a PBM program. This purpose was accomplished through the following aim.

Study Aim

As outlined in Chapter 1, the overall aim of this study was to preliminarily assess the impact of TSOs on PBM quality outcomes of the health care system. Self-reporting from transfusion department directors (or a designee) was relied upon to assess the PBM outcomes by asking the participants to give information on the quality indices associated with the PBM outcomes at their facility. These outcomes included decreasing blood wastage, decreasing the rate of hospital acquired infections, decreasing patient length of stay in the hospital, and decreasing the rate of 30-day readmissions. Some PBM outcomes, such as hospital-acquired infections are reported quality indicators to Centers for Medicare and Medicaid Services (CMS). Other outcomes, such as wastage, are not reported to outside agencies. All outcomes are tracked by the blood bank department or by quality assurance. The structure (qualities of the TSO), process (improved procedures) and outcome (PBM outcomes) domains of the Donabedian Quality Framework provided the theoretical framework of the study. This study was guided by the following aims.

Aim 1: Describe and test (depending on the sample size obtained) the relationship between the having a TSO and the PBM associated outcomes of a facility. This analysis provided

information on the impact that a TSO has on PBM associated outcomes. These results were the first on the effectiveness of having a TSO and they can be used as a basis for further study on TSOs while helping to guide policy decisions for transfusion managers and directors.

Aim 2: Describe and test (depending on the sample size obtained) the relationship between the having a TSO that is a nurse and the PBM associated outcomes of a facility. This analysis provided information on the impact of having a TSO who is a nurse. These results were the first on the effectiveness of having a TSO who is a nurse and they can be used as a basis for further study on TSOs while helping to guide policy decisions on transfusion managers and directors.

Research Questions and Hypotheses Addressed by the Study

This study was guided by the following research questions:

RQ1: Is there a relationship between a facility having a TSO and the PBM-associated outcomes of that facility?

H1: It was hypothesized that there is a relationship between having a TSO and the PBM-associated outcomes of a facility.

RQ2: Is there a relationship between a facility having a TSO that is a nurse and the PBM-associated outcomes of that facility?

H2: It was hypothesized that there is a relationship between the PBM-associated outcomes and having a TSO who is a nurse.

The results of this descriptive, cross-sectional, nonexperimental survey design can be used to inform future researchers in transfusion safety, which often is a matter of life or death to a patient in a hospital setting. The data from this survey can be utilized for future research in this

new area. In addition, this research can be used to gain a better understanding of whether it is necessary to have a requirement for a TSO to be a nurse.

Research Design

Introduction

As discussed in Chapter 2, there have been no previous studies on the impact of TSOs. Further, TSOs have barely been mentioned at all in the existing literature: almost nothing is known about TSOs. In health sciences, surveys are often utilized for descriptive studies. This study was the first known descriptive study on the impact of this population of health care workers. Many descriptive studies utilize a cross-sectional design, which is useful when measuring a study's variables at the same time, identifying the associations between those variables, as well as generating hypotheses for future research (Setia, 2016). Because no previous studies have been conducted on the impact of TSOs on PBM programs, this study utilized a cross-sectional, descriptive, nonexperimental research design to survey transfusion professionals to begin to understand the impact of TSOs and their role in health care settings.

This study utilized purposive sampling and snowball sampling with a respondent-driven sampling (RDS) component to identify as many transfusion service directors as possible. The increased sample size could give the survey more power to detect differences between groups of subjects.

Study Variables

The structure (qualities of the TSO), process (interactions between TSOs and other transfusion professionals), and outcome (transfusion quality indices) domains of the Donabedian Quality Framework provided the theoretical framework of the study (Shi & Singh, 2015). This theoretical framework was used to identify and operationally define variables for the structure

and outcome constructs, which were used to guide the development of survey questions. Although some of the questions asked about variables that underly the process domain, because the questions asked the participant about the end-result of these variables over monthly or yearly periods, these questions were included in the outcome domain. Table 1 provides an overview of the variables used in this study.

Table 1

Variable Names and Operational Definitions

Variable Type	Variable Name	Operational Definition
IV	PBM	Patient Blood Management program status
	TSO	Transfusion Safety Officer status
	Nurse	Nurse or non-nurse status of TSO
DV	Waste RBC	Lowering waste of RBCs rating
	Waste Plasma	Lowering waste of plasma rating
	Waste Platelets	Lowering waste of platelets rating
	HAI	Rate of hospital-acquired infections
	Length of Stay	Average length of stay for hospital patients rating
	30 Day Readmission	Rate of discharged patients needing to be readmitted within 30 days of hospital discharge

Note: IV = Independent Variable, DV = Dependent Variable, PBM = Patient Blood Management, TSO = Transfusion Safety Officers

Independent Variables

Table 1 lists each independent variable (IV) and each dependent variable (DV) in addition to operationally defining each of the variables that were used in this descriptive study. There were three predictor variables relating to the structure of the facility being surveyed that were expected to influence the outcome variables. One predictor variable was PBM, which is

whether the facility has a formal PBM program. The second predictor was TSO, which is whether those facilities with a PBM program have a position for a TSO. The third predictor variable was Nurse, which has to do with whether the TSO is a nurse. These three predictor variable questions were answered in a Yes/No answer format.

Dependent Variables

The dependent variables in this study relied on self-report of transfusion service directors (or their designee) based on 6 outcome variables: (1) the waste RBC variable had to do with red blood cell products that are not suitable to be used by a patient due to misuse of those products by healthcare professionals outside of the transfusion facility; (2) the waste plasma variable had to do with plasma products that are not suitable to be used by a patient due to misuse of those products by healthcare professionals outside of the transfusion facility; (3) the waste platelet variable had to do with platelet products that are not suitable to be used by a patient due to misuse of those products by healthcare professionals outside of the transfusion facility; (4) the length of stay variable had to do with how well the hospital is performing in lowering the length of stay for their patients; (5) the 30 day readmission variable had to do with how well the hospital is performing in reducing their rate of readmission within 30 days of discharge; (6) the hospital-acquired infection variable had to do with how well the hospital is reducing their rate of hospital-acquired infections.

Population and Sample Description

Data Sources

Transfusion directors (or their designee) were identified through professional organizations such as AABB, ASCLS, and SABM. Additionally, transfusion service directors for this study were identified through LinkedIn and Specialist in Blood Banking (SBB) programs.

There are 12 SBB programs in the United States with students from across the country. The students in these programs were asked to forward the survey to their transfusion directors.

Table 2 lists the names and locations of the 12 SBB programs and their approximate yearly student capacity (AABB, 2013). These programs are located across the country and the students in these programs can be from anywhere in the country. This type of geographical dispersion help to enhance the external validity of the results. It should be noted that some programs, such as the Rush University program offer a second year of classes to receive a master's degree, which could potentially double the number of possible participants for that program. In addition, the previous year's graduates often maintain contact with the SBB program as they are preparing to take the SBB exam: the survey could reach these new graduates as well as the alumni of the SBB program.

Table 2

Specialist in Blood Banking (SBB) Program Names, Locations, and Yearly Student Capacity

Program Name	Program Location	Student Capacity Annually
LifeSouth Blood Centers	Gainesville, FL	5
OneBlood, Inc.	St. Petersburg, FL	8
Rush University	Chicago, IL	25
LifeShare Blood Center	Baton Rouge, LA	6
University Medical Center	New Orleans	12
Armed Services Blood Bank Fellowship	Bethesda, MD	8
Johns Hopkins Hospital	Baltimore, MD	3
National Institutes of Health	Bethesda, MD	3
Minnesota American Red Cross	St. Paul, MN	15
BioBridge Global	San Antonio, TX	4
University of Texas Medical Branch	Galveston, TX	25
Versiti Wisconsin, Inc.	Milwaukee, WI	4

Kinney and colleagues (2016) surveyed SBB programs and program graduates to determine if there was a need for education in molecular biology to be included in SBB programs. They emailed their survey to 15 SBB program coordinators, 59 AABB Immunohematology Reference Laboratories (IRLs), and to 82 graduates of SBB programs. All the coordinators of the SBB programs responded to their survey. Thirty, or 51%, of the IRLs responded. Of the SBB graduates, all 82 responded to the survey, representing 13 of the 15 programs. The AABB directory only lists 12 programs, while Kinney and colleagues (2016) listed 15 program coordinators that they contacted. It should be noted that all 82 graduates of the SBB programs who were contacted responded to this survey. As shown in the study by Kinney and colleagues (2016) graduates of the SBB programs are highly likely to respond to a survey administered through an SBB program.

Population and Sample

The target population was transfusion department directors (or their designee). The accessible population was blood transfusion directors who could be contacted through professional directories in organizations such as AABB, American Society for Clinical Laboratory Science (ASCLS), or the Society for the Advancement of Patient Blood Management (SABM). In addition, other professional organizations were utilized to identify transfusion directors such as LinkedIn or Specialist in Blood Banking (SBB) programs. SBB programs are designed to assist blood transfusion professionals in attaining certification from the American Society for Clinical Pathology (ASCP): SBB(ASCP). The students in these SBB programs were be asked to forward the survey to their transfusion director. Any transfusion professional who is not a transfusion director (or a designee), or who is not in the United States was excluded from this study.

In the 2015 National Blood Center Utilization Study (NBCUS) survey results released in 2017, 16.2% (n = 305, out of 1,885) of respondents reported having a TSO, of which 74.7% listed the medical director as a PBM program coordinator, 29.8% listed a nurse coordinator, 35.5% listed a non-nursing coordinator, and 34.3% listed other personnel (Sapiano, et al., 2017). Although not addressed in the NBCUS survey, it was expected that only larger hospital systems, and especially academic medical centers, will have a TSO. Therefore, those facilities with a TSO will consist mainly of larger, academic medical centers. An effort was made to reach as large of a geographical area as possible to represent as many regions of the United States as possible: Northeast, South, Midwest, and West Coast regions.

Inclusion and Exclusion Criteria

Inclusion criteria

The main inclusion criteria were transfusion directors (or someone that they designate to respond to the survey) who had extensive knowledge of their hospitals PBM-associated outcomes.

Exclusion criteria

The main exclusion criteria were facility employees with no knowledge of the transfusion practices at their facility. This included nurses who do not transfuse blood products, clinical laboratory scientists who do not work extensively in a transfusion medicine laboratory, or directors who have no knowledge of the characteristics of the transfusion department, such as directors of chemistry or hematology, who do not direct transfusion medicine.

Sampling

Purposive Sampling

Because there was no known sampling frame and participants did not have an equal chance of being recruited for the study, purposive sampling was used to recruit members of the target population (Polit & Beck, 2012; Etikan et al., 2016). Purposive sampling is commonly used in social science and health-related research because subjects are recruited based on whether they meet the inclusion criteria of the study (Acharya, et al., 2013). When the sampling frame is not known, this type of sampling is used in studies to obtain basic data to be used as the basis for future research (Rowley, 2014).

Respondent-Driven Sampling (RDS)

RDS is a form or snowball sampling, which, in turn, is a form or purposive sampling (Polit & Beck, 2012). RDS has been used by the Centers for Disease Control (CDC) to find and identify "hidden populations," such as the homeless or injection drug users (Johnston, et al., 2016). Johnston and colleagues (2016) provide a systematic review of the uses of RDS in the behavioral and biological sciences.

Because there is no known sampling frame, purposive sampling began with professional associations such as AABB, ASCLS, and SABM. Additional professional organizations included LinkedIn and the students of SBB programs. An attempt was made to widen the sample subjects as much as possible, especially by geographical region. When possible, snowball sampling with an RDS component was used to help identify more participants.

Sample Size and Maximizing Power

Power Analysis

To ensure that the sample size was large enough to detect an association between a predictor and an outcome, a power analysis was performed. With $\alpha < 0.05$, there is a 5% chance of committing a Type I error: rejecting the null hypothesis when it is true, or a false-positive result. Beta (β) is the probability of making a Type II error: failing to reject the null hypothesis when it is false (Browner, Newman, & Hulley, 2013). With a typical $\beta = 0.20$, the resulting power is $1- \beta = 0.80$. In general, large effects are easy to find and require a smaller sample size, while small effects are difficult to detect and require large sample sizes.

According to Polit & Beck (2012), medium effects range from d = .50 to d = .80. With a power of .80, the sample size needed to detect the medium effect size of d = .50 is 64 subjects in each group. With d = .60, 44 subjects are needed in each group, while a d = .70 requires 33 subjects in each group, and a d = .80 effect size would require 25 subjects per group. Browner, Newman, & Hulley (2013) give a shortcut method for calculating sample size when using a two-sided t-test with power set at .80 and $\alpha = 0.05$: sample size is equal to 16/d^2. For d = .50, n = 16/(.50)^2 = 64, which is the same size as given by Polit and Beck (2012) for this effect size.

As shown above, sample sizes as low as 33 in each group could still detect medium effects (d = .70) and a sample size of 25 per group for a total (n = 50) could detect a medium to large effect size (d = .80). For these smaller samples, a t-test was used to compare two groups. The groups being compared were the TSO variable (facilities with a TSO compared to facilities without a TSO) and the Nurse variable (TSOs who are a nurse compared with those who are not a TSO). The t-test is robust to departures from normality and can be used with smaller sample

sizes, unless the sample size is very small (less than 30 total subjects or 15 per group) or there are extreme outliers present in the sample (Browner, Newman, & Hulley, 2013).

According to Polit and Beck (2012), small effect sizes would require very large sample sizes: d = .15 would require 701 subjects per group and d = .10 would require 1576 subjects in each group. These small effect size differences are unlikely to be found and would require very large sample sizes. In addition, facility administrators are unlikely to be interested in small to medium differences between groups. Although an attempt was made to get as many respondents as possible to respond to the survey, the goal was to get approximately 25 in each group to be able to detect medium to large effect sizes, with a total sample size of approximately (n = 50), which is almost the total sample size (n = 52) from the Jacobs and colleagues (2021) full survey of TSOs. The next section discusses ways to maximize power with a small sample size.

Strategies to maximize power and minimize sample size

Browner and colleagues (2013) give several strategies that can maximize power and minimize the required sample size in a study. These strategies include using continuous outcome variables, using unequal group sizes, and using a more common outcome. Outcome variables will be measured as continuous variables (Nunnally & Bernstein, 1994). The outcome variables being measured are commonly measured variables that are tracked by the hospital, transfusion service, or quality assurance: many of these variables are measured monthly. An attempt will be made to have equal group sizes to make comparisons; however, if there are more TSOs who are nurses than those who are not nurses, these unequal group sizes could still be compared without losing power.

Sample Size for Pilot Studies

There has been much debate regarding the minimum sample size required for a pilot study. Hill (1998) recommended a sample size of at least 10 to 30 per group while noting that this size may be too small to detect statistical significance. Julius (2005) has suggested a sample size of 12 per group for clinical trial pilot studies. Hertzog (2008) concluded that 10 to 40 participants would be needed for each group, noting that more than 40 in each group is not likely given the constraints of time and cost. In addition, Hertzog (2008) states that for a coefficient alpha set at 0.8, a sample size of 50 (25 per group) would give a confidence interval of 13 points (ranging from .73 to .86). Johanson and Brooks (2010) concluded that a sample size of 30 to 36 participants had only a minimal gain in precision over a sample of 24 to 30 participants, and suggest a minimum sample of 30 participants for a pilot study.

The best compromise of the results of these pilot sample size studies with the power analysis calculations for a full study given above seems to be a total sample size of approximately (n = 50) with approximately (n = 25) in each comparison group. This minimum total sample size (n = 50) would be stable enough to assess reliability (Hertzog, 2008) and would be able to detect medium to large differences between the groups.

Data Collection and Management

A survey was self-administered through Research Electronic Data Capture (REDCap) at VCU, which collected the self-reported data. REDCap utilizes software developed by a consortium at Vanderbilt University and is designed for data storage and management (Harris, Harris, Taylor, Robert, Payne, Gonzales & Conde, 2009). This software is provided for research use from VCU technology services.

Sample Recruitment

Recruitment of potential participants began with postings via VCU email on professional sites such as AABB, ASCLS, and SABM via VCU email. Additionally, professional sites such as LinkedIn and Specialist in Blood Banking (SBB) programs were utilized for sampling. This posting provided an open link to take the survey, along with a cover letter from the department informing participants that clicking the survey link gives consent to participate in the study.

Email Messaging

An email posting was placed on professional sites. The postings specified that the research is part of PhD dissertation work at Virginia Commonwealth University and contained the following information: cover letter, a brief introduction to the study, request for assistance from the participant, participation consent, a link to the survey, approximate time needed to answer the questions, statement of confidentiality including that no identifying information will be published on participants, attachment with a copy of the survey, statement of appreciation for participation, and researcher's contact information. A PDF of the survey is in appendix 1 and the cover letter/flyer is in appendix 2.

After clicking the URL link, the participant was taken to an introductory screen, which contained a brief introduction to the purpose of the study, stated the approximate time needed for completion, directions for completing the survey, statement of confidentiality and voluntary participation, and contact information for any questions. Participants were informed that proceeding in the survey will give their consent to participate in the study. A closing screen thanked the participants for their participation.

Survey Development Overview

Since it was necessary to develop a new survey instrument, it was necessary to validate this instrument and to assess its internal and external validity. The greatest threat to both internal and external validity is nonresponse from the selected participants (Polit & Beck, 2012). Efforts to increase the response rate will be addressed.

Internal Validity

Although it does not ensure internal validity, it is necessary to show that a survey instrument is reliable. Cronbach's alpha is a measure that can statistically test the internal consistency of a scale by showing the correlations between individual items (Bland & Altman, 1997). Generally, alpha values between 0.50 and 0.80 are found to be acceptable. Values above 0.80 show excellent internal consistency, while values below 0.50 are unacceptable and can indicate that different characteristics are being measured between the items (Cummings, Kohn, & Hulley, 2013).

According to Polit and Beck (2012), selection bias is one of the greatest and most frequently encountered threats to internal validity in studies using nonexperimental designs. This type of bias happens when there are differences between subjects who agree to participate and those who do not agree to participate. To a certain extent, this threat to internal validity can be checked by looking at the publicly available demographics of those hospitals that choose to participate and those who choose not to participate.

External Validity

External validity refers to how well the results from the sample obtained translate to the population of interest. According to Hulley, Newman, and Cummings (2013), there are threats to external validity when the intended variables and sample does not represent the target

population. They further assert that the actual sample obtained is often different from the intended sample. In addition, those who agree to participate may be different from those who do not agree to participate in the survey.

As mentioned earlier, nonresponse bias can affect internal and external validity. One of the best ways to prevent this bias and its threats to validity is to increase the response rate of those who are invited to participate. Email reminders and update postings on LinkedIn and to the SBB programs were used to increase the number of participants. In addition, a letter from the research advisor accompanied the survey to attest to the importance of the results to enhance participation. Participation rates have been found to increase when a statement of university sponsorship is included with a survey (Edwards, et al., 2009)

Ensuring that all geographical regions of the country are represented in the sampling can enhance the generalizability to facilities nationwide. In addition, it is important to stress to potential participants that their anonymity and confidentiality will be protected for the participants to be as candid as possible. Since most of the participants who have a TSO at their facility will be from larger hospitals and academic medical schools, they will all be similar in the size demographic. Increasing the sample size and including as many hospitals as possible within a geographic region will also help to protect the anonymity of the participants in the study.

Specific Survey Development

Survey Development

For this study, data were collected from a survey that had been developed to measure variables associated with Patient Blood Management (PBM) outcomes. Survey questions assessed the Donabedian domains of structure and outcome. The survey questions were created to address constructs associated with blood transfusion safety and blood management.

Administration

Survey questions were uploaded into REDCap, which is an internet-based survey tool. Internet-based surveys are the fastest growing survey mode in the United States, and has the advantages of faster response, lower cost, and decreased errors (Dillman, Smyth, & Christian, 2014). This mode of surveying is also increasing in health care research (McPeake, et al., 2014). However, selection bias can be a major concern for internet-based surveying since the demographics of subjects using the internet can be different from those who prefer other modes of survey participation. Polit and Beck (2012) suggest using oversampling of each group of participants and recruiting participants from multiple sources to control for selection bias.

Dillman and colleagues (2014) suggested some guidelines to increase the response rates of the population being sampled. To decrease the burden of responding to the survey, they suggest minimizing the length of the survey, embedding the link directly into the invitation email, giving an estimated time it will take to complete the survey, and including a copy of the survey with the invitation email. They also suggest including response rate in reminder emails with up to 3 reminder emails sent.

Further guidelines suggested by Dillman and colleagues (2014) to improve the visual enhancement of surveys include using darker and lighter print and bolding to differentiate the areas on the screen to visually guide the participant to the most important part of the screen and to differentiate between the questions and the answer choices. Another suggestion is to standardize the spacing of the items. They suggest the visual enhancement of elements that are important to the respondent while deemphasizing the things that are not important, which can be done by changing the font size and differential coloring of backgrounds. A fourth suggestion

concerns increasing legibility in the choice of font and line length: specifically, a 10-to-12-point font size, such as 12-point Arial, and a line or item length of 3 to 5 inches.

Instrument Design

According to Dillman et al. (2014), surveys are usually designed in three phases: pretesting, pilot testing, and final testing with a larger sample. In the pretest phase (or expert review), feedback was obtained on draft questions from content, questionnaire, and analysis experts. These experts had the technical knowledge to identify problems with the questions themselves as well as the overall design of the questionnaire. Recommendations for selecting these experts include using more than one expert to evaluate the questions, choosing a wide variety of experts, and including experts from outside of colleagues in the same department or the study population.

The pretesting phase utilized experts in the fields of survey development and transfusion services. One expert, Trish Rinald MS, MLS(ASCP)SBB is Director of the Medical Laboratory Technician program at Piedmont Virginia Community College and has over 30 years of experience in transfusion services including experience as a transfusion supervisor. A second expert, Kenzie Hurst MLS(ASCP) is a transfusion professional at a Kansas City transfusion hospital with over 15 years of transfusion service experience. A third expert, Yvette Hammond BB(ASCP) is manager of transfusion services at Holy Cross hospital and has more than 20 years of transfusion services experience. A fourth expert, Mary Moore, PhD is Director of Field Research for Survey & Evaluation Research Laboratory at Virginia Commonwealth University. A fifth expert, Sylvia Brow MLS(ASCP)SBB has over 30 years of experience in numerous transfusion services across the country. The input of these experts was utilized in developing the

questions for the survey and were used to assess the face and content validities of the survey prior to the pilot testing phase of the survey.

The second phase of survey development is known as pilot testing. In this phase, the survey is administered to a small sample of the population being surveyed to refine and evaluate the survey and to identify any potential problems with the questions in the survey. According to Polit and Beck (2012), pretesting can serve many purposes and include identifying problem questions that may be objectionable or offensive, assessing the sensibility of question sequencing, and determining if the data have enough variability in the measures. They further explain, regarding the last purpose, that it would be impossible to detect differences in outcome variables among the participants if the "instrument yields data with limited variability" (Polit & Beck, 2012, pg. 296). The results of the pre-sampling study were used to refine survey procedures before beginning the larger study. Although time consuming, Dillman and colleagues (2014) suggest that survey procedures can be evaluated with a small pre-sampling study with at least 5 reviewers. The pilot survey was administered through REDCap.

Administering the finalized survey questions to a larger target population was the final phase of survey design. After receiving Virginia Commonwealth University (VCU) Institutional Review Board (IRB) approval. Data collected from the final sample was uploaded into the Statistical Package for Social Sciences (IBM SPSS v. 22) which provided composite reliability, internal consistency reliability, convergent validity, and discriminate validity. These validity, reliability, and statistical results from this study helped to validate which predictors and outcomes are significant for PBM studies.

Measurement

According to Frytak and Kane (2006), there is no universally accepted, single approach to the measurement of any construct. The difference between the ideal measurement and the obtained response is known as measurement error (Groves, et al., 2009). Reliability refers to the degree of consistency or repeatability of an instrument that is measuring an attribute, while validity refers to the degree to which an instrument measures what it intends to measure (Polit & Beck, 2012).

Reliability

The Statistical Package for Social Sciences (IBM SPSS v. 22) measures two types of reliability: internal consistency and construct reliability. Both types of reliability are measured in IBM SPSS by Cronbach's alpha, also known as coefficient alpha. When items are highly correlated on a measure, the alpha value is high; the alpha level is low when there is no correlation between the items (Frytak & Kane, 2008). An alpha level of 0.7 to 0.8 is generally considered adequate to compare groups; however, an alpha as low as 0.60 can be acceptable in the early stages of construct validation (Nunally & Bernstein, 1994).

One of the easiest ways to increase the reliability of a scale is to increase the number of items on the scale (Nunally & Bernstein, 1994). Longer scales yield more reliable results than shorter scales (Traub & Rowley, 1991). The redundancy of items increases the alpha coefficient (Gorsuch, 1997). However, an increased number of items can increase the burden of responding to the survey, so a balance must be found with the need to increase reliability.

The heterogeneity of the groups regarding what is being measured is critical to how reliable the measurement can be: it is important to have heterogeneous groups (Traub & Rowley, 1991). If all the participants are very similar in the responses they give, then it will be difficult to

detect any differences between the groups, which could be the case with this target population. It is difficult to detect reliable differences when respondents differ very little from one another, especially when the items ask about a limited range of performance tasks in which the participants are highly skilled (Traub & Rowley, 1991).

Validity

Although it is crucial to the measurement process, validity is difficult to establish firmly. Showing that a measure is reliable is necessary but not sufficient for measurement validity (Frytak & Kane, 2008). Validating a scale concerns the degree of confidence one has in the inferences being made on the population of interest from the scores obtained from the instrument being used (Frytak & Kane, 2008). The types of validity addressed here are face validity, content validity, and construct validity.

Face Validity

When the survey appears to measure what it is supposed to measure, it is said to have face validity (Polit & Beck, 2012). Since no previous studies had been done linking TSOs to PBM outcomes, this study used the Donabedian structure and outcome domains to establish a theoretical basis for the constructs being used. See Chapter 2. For this study, pretesting with the five experts and the small pre-sampling survey were used to help establish the face validity of this instrument.

Content Validity

Content validity has to do with the degree to which the items in the instrument has enough items in the questionnaire to cover all aspects of the concept being measured (Polit & Beck, 2012). For many measures in the health sciences, content validity often becomes a form of face validity (Frytak & Kane, 2008). Adequate content validity was assessed from the 5 experts

in the pretesting phase and the results of the pilot testing phase of survey development. The questions on the instrument were aligned with the constructs identified in the study. See Chapter 2.

Construct Validity

Construct Validity is the degree to which the instrument measures the unobservable constructs being studied (Polit & Beck, 2012). It is composed of two types: convergent validity and discriminant validity. Both types are calculated in the Statistical Package for Social Sciences (IBM SPSS v. 22) results. Convergent validity assesses the degree to which two different methods for measuring a construct give similar information, or converge to one another (Polit & Beck, 2012). The average variance extracted (AVE) numbers measure convergent validity: values of 0.5 or higher are preferred. Discriminant validity assesses the degree to which two measures measuring two constructs gives different results, or diverge from one another (Polit & Beck, 2012). Discriminant Validity is also measured in IBM SPSS by the AVE, and is established when the correlations among the constructs are less than the square root of the AVE for each construct.

Model Statistics

The main statistics were reliability and descriptive statistics. ANOVAs were performed using the results of the 6 questions from part 2 as dependent variables and the first 3 groups from Figure 1 as independent variables. Groups 1 and 2 were merged to form a composite group (No TSO), which would give 2 groups as independent variables with 6 dependent variables for 6 separate ANOVAs. ANOVAs were performed using groups 5 and 6 as independent variables with the 6 dependent variables. When the normality assumptions were not met, nonparametric

tests were performed. Logistic regression was utilized with the 6 outcome variables being used as independent variables to predict the TSO and Nurse structure variables in separate analyses.

Data Collection and Procedure

Internet Based Survey

This study utilized an Internet-based survey delivery mode. All communication with the participants will be via REDCap and email. In the initial email soliciting survey participants, a copy of the survey was attached to the email for the participants to view the entire survey ahead of time; thus, they could get an idea of the length of the survey and what is being asked of them.

Dillman and colleagues (2014) review a large volume of literature from which they make suggestions to enhance survey response rates, which can often be very low, especially for the internet only mode. These researchers use Social Exchange Theory from Sociology as a framework for their recommendations. This theory posits that human interactions, or exchanges, are based on a benefit versus cost determination: in other words, the benefit of participating outweighs the costs associated with participating. It is incumbent upon the researcher to help the participants to trust and believe that the benefits of helping the researcher will outweigh the costs of that participation. This is accomplished by increasing the benefits and lowering the costs.

Benefits of Participation

Benefits can come from a wide range of possible sources, ranging from a sense of satisfaction from helping another person and receiving praise for doing so to sending a token gift to the participant along with the initial request for participation, such as a couple of dollars. The authors note that participants can feel a particular sense of satisfaction if the person they are helping is a part of group (school, community, or country) to which someone belongs. Other techniques to enhance participation include specifying how the results will be useful, asking for

advice or help, and utilizing sponsorship by a legitimate organization. The design of this study will utilize these suggestions, but will not be sending tokens or gifts.

Cost of Participation

The cost of participation can be substantial for some potential participants. According to Dillman and colleagues (2014), the costs of participating in a survey include the burden of responding to long, detailed, and sometimes inappropriate questions or questions that they cannot understand or answer. Among the suggestions they make to reduce the costs of participation include reducing the burden of lengthy and complex questionnaires, making it easy to respond, and minimizing requests for sensitive information. All these suggestions were utilized. Including the survey as an attachment with the initial email request could help to enhance the number of people agreeing to participate by lowering the costs of participation.

Establishing Trust

Dillman and colleagues (2014) maintain that establishing trust is probably the single most important factor affecting response rates. It is important that personal information from the participants is kept secure and confidential. Among their suggestions for establishing trust is to provide ways for potential participants to assess the authenticity of a survey request and to ask questions about it, to emphasize sponsorship by a legitimate authority, build upon previously established relationships and friendships, and to assure that responses will be protected and kept confidential. An attempt was made to incorporate all these suggestions in soliciting participation from potential respondents.

For security purposes, all communication with participants, including initial and follow up emails, were via the researcher's university email account.

Ethical Considerations

Exemption from Institutional Review Board (IRB) approval was obtained from Virginia Commonwealth University prior to recruiting subjects and collecting data using the internet-based survey. This study was determined by the IRB to be exempt from review because the survey was completely anonymous and was asking "about what" questions, rather than "about whom" questions (see VCU IRB# HM20029175.)

Data Analysis

Coding and Storage

Survey results were downloaded from REDCap and into IBM SPSS for statistical analyses. Missing data were addressed using procedures outlined in Tabachnick & Fidell (2013). Data cleaning was performed to identify and remove any outliers. All data was stored in the researcher's Virginia Commonwealth University email account, which is password protected using two-factor authentication. Stored data did not contain any identifying information.

Statistical Analysis

Descriptive Statistics

Descriptive univariate statistics were used to summarize all variables measured, including means and standard deviations. Frequencies for each predictor group were tabulated to describe group differences in each outcome variable.

Bivariate Statistics

Due to an expected small sample size, bivariate statistics were limited. However, since this sample will be homogenous, it was possible to make some limited generalizations. Independent t-tests will be used to assess the relationship between domains in which any group has less than 30 subjects. The strength of the relationship between the independent and dependent variables will be described by the Pearson correlation coefficient.

Multivariate Statistics

Multivariate statistical analysis was sample size dependent. One of the requirements for MANOVA, is that there are more cases in each cell than there are dependent variables (Tabachnick & Fidell, 2013). Because there are 6 DVs, there will need to be more than 6 subjects in each cell. Other major assumptions are that the variables are normally distributed and there are no outliers. If assumptions for MANOVA are not met, then alternative analyses could be performed as outlined above in model statistics.

Summary

This chapter gives details on the methodology behind this survey, which used a cross-sectional design to describe the relationship between a TSO and the outcomes of a PBM program, and to preliminarily assess the impact that a TSO has on PBM outcomes. This study served as a first step for further studies on TSOs by establishing a foundation on which to build future studies in this area. Potential participants were recruited from transfusion professional networks to answer the research questions developed and the associated hypotheses generated from those questions, utilizing the Donabedian Theoretical Framework. The results of this study can serve to give feasibility results for future studies of these associated constructs.

The following chapter contains the statistical analyses obtained from this study. Chapter five provides a discussion of the results obtained in chapter four including limitations of the study and suggestions for future research.

CHAPTER 4: RESULTS

Data Collection Review

The purpose of this study was to describe the relationship between having a Transfusion Safety Officer (TSO) and outcomes that are associated with Patient Blood Management (PBM) programs, as well as to describe the relationship of the TSO being a nurse on the PBM outcomes. A link to a pre-validated online survey from Research Electronic Data Capture (REDCap) was used to collect data (REDCap, 2024). The study consisted of blood transfusion professionals, who were recruited from blood transfusion professional networks. Potential participants were notified via email and online postings.

Methodology Review

A flyer (cover letter) containing an online link to the survey was posted or sent out to potential participants in blood transfusion professional networks: These are shown in Appendix 1 and 2. In addition to the flyer being sent to potential participants via the researcher's Virginia Commonwealth University email, the flyer was posted onto online forums on Facebook, LinkedIn, the American Society for Clinical Laboratory Science (ASCLS), Association for the Advancement of Blood & Biotherapies (AABB), Society for the Advancement of Patient Blood Management (SABM), and Specialist in Blood Banking (SBB) programs. Potential participants were also asked to forward the flyer to their colleagues at another hospital who met the inclusion criteria and would be willing to participate. Follow-up messages were sent via the above methods. The data collection period lasted for two months. A total of 81 responses were received in REDCap, with 75 respondents completing the survey.

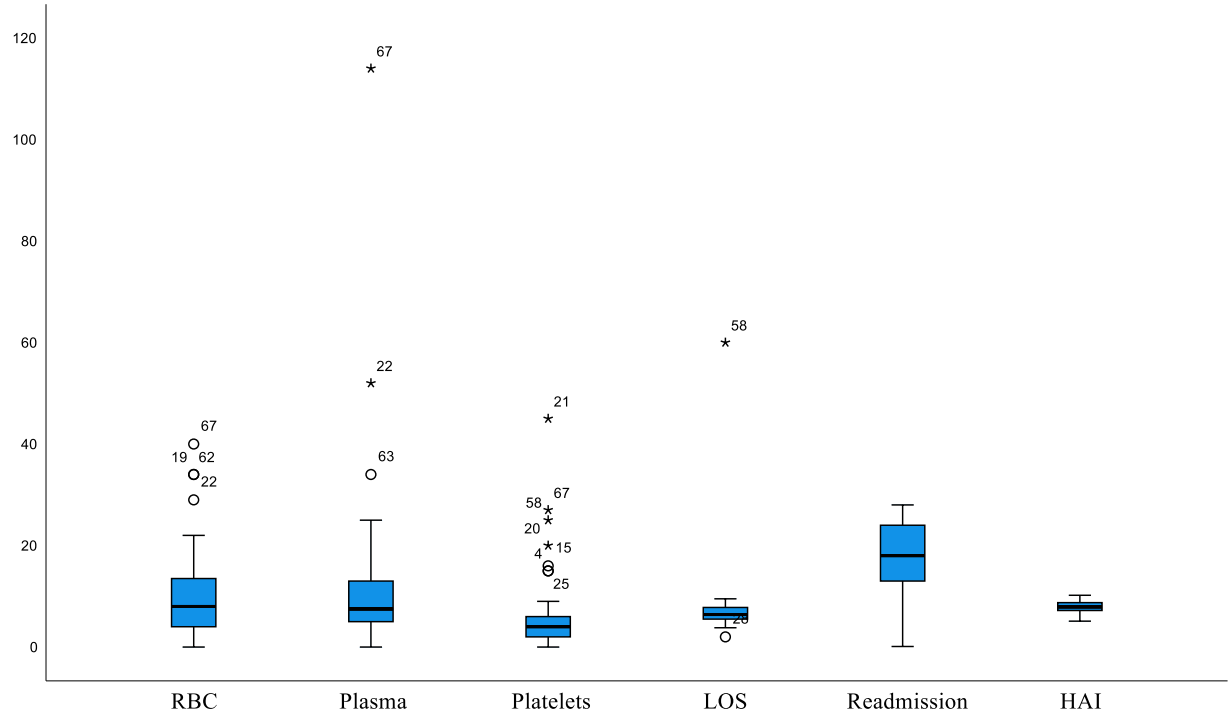
Data Preparation and Cleaning

Data were exported from REDCap and imported into the Statistical Package for Social Sciences (IBM SPSS v. 28). There were 81 responses to the survey. Five participants did not fully complete the survey and one respondent (case 44) completed the survey, but responded "Don't know" to all variables in the study: These 6 responses were deleted, which left 75 valid responses. Five respondents (cases 9, 12, 15, 23, and 64) answered "Don't know" when asked if their hospital had a PBM program; these five responses were deleted from the data set. One respondent (case 44), answered "Yes" to both PBM and TSO questions, but "Don't Know" to all 6 outcome variables; and one respondent answered "Don't Know" to having a TSO. These seven responses were deleted which left 68 responses.

Before statistical analysis, the data were checked for outliers. Figure 4 shows the boxplots of the six outcome variables to check for data points that were outliers (n = 68). As shown in Figure 4, SPSS case 67 (Excel case 22) and case 58 (Excel case 4) were obvious outliers and eliminated from any further statistical analyses. The other identified potential outliers were retained to preserve their values for the LOS, readmission, and HAI variables, as those outliers only affected the RBC, plasma, and platelets variables, which left 66 cases for further analysis. See Figure 5 for an overview of this process.

Figure 4

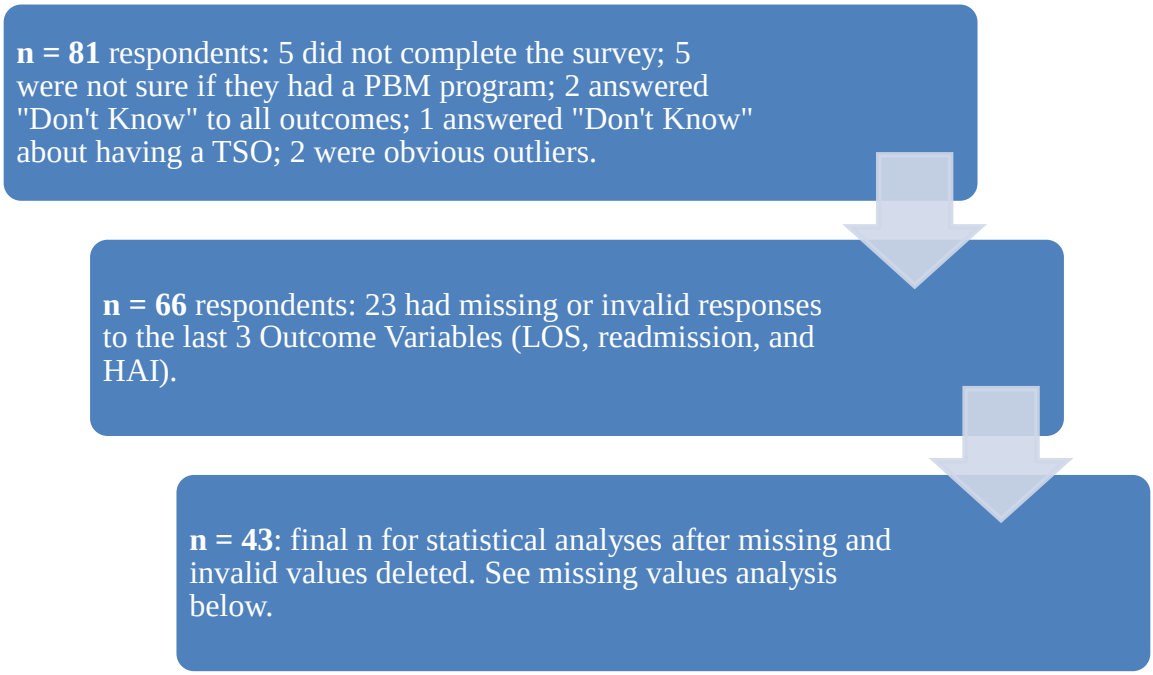
Boxplots Showing Outliers in the Six Outcome Variables (n = 68)



Note: Numbers associated with datapoints indicate the case number of the outlier. LOS = hospital length of stay HAI = hospital-acquired infection rate

Figure 5

Overview of Study's Sample



Merging of Groups 1 and 2

Table 3 shows the PBM frequencies of the hospitals: 68% had a PBM program (n = 45) and 32% did not have a PBM program (n = 21). Of the 45 hospitals that had a PBM program, 37 had a TSO and 8 did not have a TSO. Because there were so few of the PBM programs that did not have a TSO (n = 8), the 21 hospitals without a PBM program were added to the TSO "No" responses as they do not have a TSO at their hospital. Table 4 shows the frequencies resulting from the merging of groups 1 and 2: the PBM "No" responses with the TSO "No" responses. The final groups had 37 in the TSO "Yes" group and 29 in the "No" group.

Table 3

Patient Blood Management Variable Frequencies

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	21	31.8	31.8	31.8
	Yes	45	68.2	68.2	100.0
	Total	66	100.0	100.0	

Table 4

Frequencies of the TSO Variable After Adding PBM "No" Responses

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	8	12.1	12.1	12.1
	No PBM	21	31.8	31.8	43.9
	Yes	37	56.1	56.1	100.0

Table 5 gives the descriptive statistics for this data set and Table 6 shows the kurtosis and skewness results. As seen in Figure 5 (above) and Tables 5 and 6, this data set had many potential outliers and the plasma and platelets variables have high kurtosis and skewness statistical values. Before further analysis, a missing values analysis was performed.

Table 5

Descriptive Statistics for the Data Set (n = 66)

	n	Minimum	Maximum	M	SD
RBC	66	0	34	9.85	7.57
Plasma	66	0	52	10.24	8.71
Platelets	66	0	45	4.92	6.30
LOS	50	2	9.50	6.45	1.51
Readmission	48	0.11	28.00	17.93	7.36
HAI	43	5.10	10.20	7.90	1.19
Valid n	42				

Table 6

Skewness and Kurtosis Values for the Outcome Variables (n = 66)

	N	Skewness		Kurtosis	
	Statistic	Statistic	Std. Error	Statistic	Std. Error
RBC	66	1.26	.29	1.93	.58
Plasma	66	2.29	.29	7.52	.58
Platelets	66	4.45	.29	25.56	.58
LOS	50	-.28	.34	.31	.66
Readmission	48	-.89	.34	.59	.67
HAI	43	-.29	.36	-.10	.71
Valid N (listwise)	42				

Missing Values Analysis

A missing values analysis was performed on the six outcome variables using IBM SPSS. Table 7 shows the results of the univariate statistics for the missing values: RBC, plasma, and platelets had one missing value each, LOS had 17 missing values, readmission had 19 missing values, and HAI had 24 missing values, which was 36 percent of the respondents.

Table 7

Univariate Descriptive Statistics for the Outcome Variables (n = 66)

				Missing		No. of Extremes [a]	
	n	*M*	*SD*	Count	Percent	Low	High
RBC	66	9.85	7.57	1	1.5	0	3
Plasma	66	10.24	8.71	1	1.5	0	4
Platelets	66	4.92	6.30	1	1.5	0	5
LOS	50	6.45	1.51	17	25.4	1	0
Readmit	48	17.93	7.36	19	28.4	0	0
HAI	43	7.90	1.19	24	35.8	0	0

a. Number of cases outside the range (Q1 - 1.5*IQR, Q3 + 1.5*IQR).

Separate variance t tests were performed on the outcome variables that had greater than five percent of their cases missing. Table 8 shows the results of these t tests. The RBC, plasma, and platelets variables had less than five percent of their values missing, so were not included in the analysis. After adjusting the p values for multiple comparison tests, the separate variance t tests showed no systematic relationship between missing values on any of the outcome variables tested.

Table 8

Separate Variance t Tests

		RBC	Plasma	Platelets	LOS	Readmit	HAI
LOS	t	.8	-1.6	-.7	.	2.8	.
	df	18.1	21.0	15.9	.	2.2	.
	# Present	50	50	50	50	45	43
	# Missing	16	16	16	0	3	0
	M(Present)	10.42	9.18	4.44	6.45	18.77	7.90
	M(Missing)	8.06	13.56	6.44	.	5.40	.
Readmit	t	.7	-.9	-.5	2.3	.	.
	df	21.0	25.6	18.4	4.4	.	.
	# Present	48	48	48	45	48	42
	# Missing	18	18	18	5	0	1
	M(Present)	10.40	9.56	4.60	6.66	17.93	7.85
	M(Missing)	8.39	12.06	5.78	4.56	.	10.00
HAI	t	1.0	-2.0	-.6	2.6	5.8	.
	df	27.2	25.7	24.6	7.0	6.0	.
	# Present	43	43	43	43	42	43
	# Missing	23	23	23	7	6	0
	M(Present)	10.65	8.33	4.51	6.70	19.88	7.90
	M(Missing)	8.35	13.83	5.70	4.86	4.31	.

For each quantitative variable, pairs of groups are formed by indicator variables (present, missing).

a. Indicator variables with less than 5% missing are not displayed.

Data Analysis

The first research question asked if there was a relationship between having a TSO and six outcomes associated with PBM programs, namely red blood cell (RBC) waste, plasma waste, platelets waste, hospital length of stay (LOS), hospital 30-day readmission rates (readmission), and the hospital's rate of hospital-acquired infections (HAI); and the associated null hypothesis was that there was not a relationship between having a TSO and the PBM associated outcomes. The second research question asked if there was a relationship between the TSO being a nurse

and the PBM associated outcomes of the hospital; and the associated null hypothesis was that there was not a relationship between having a nurse as TSO and the PBM outcomes.

Analyses were performed for each null hypothesis separately to look at the relationship between the grouping variables (TSO and nurse) and each of the six outcomes for each question. With so many respondents not giving values for LOS, readmission, and HAI (usually all three together), those cases were deleted listwise.

Respondents seemed to struggle the most with the HAI question. In addition to those not answering that question, some answered the question but gave invalid answers such as a negative rate, gave a decimal response (i.e. 0.31 that when converted to a percent would have been a probable outlier), and one respondent gave multiple HAI rates broken down by departments, but not the overall hospital rate: all of these were coded as N/A and eventually deleted. Because the HAI variable had so few responses, the data set was sorted by those respondents who gave valid responses to the HAI question; this provided a data set (n = 43) that contained all 6 variables from those 43 respondents with no missing values and no invalid responses on the HAI variable. In doing so, this also deleted values on other variables, such as LOS and readmission. As seen in Table 5 above, while HAI had 43 “Yes” responses that gave valid data, LOS had 50 who gave data, and readmission had 48 who gave data, which means that an additional seven LOS and five readmission questions were not used in this data set. Including these additional five to seven responses would have caused missing value problems with the HAI variable; in addition, giving invalid responses on the HAI question would call into doubt those respondents’ values on the LOS and readmission variables.

Cleaned Data Set (n = 43)

Tables 9 and 10 show the descriptive statistics for the resulting cleaned data set (n = 43). Figure 6 shows the resulting boxplots of the six outcome variables together. Cleaning the data set seems to have eliminated many of the potential outliers that were in the initial data set, but still identifies some potential outliers. The platelets variable has a standard deviation almost as high as its mean value with high kurtosis and skewness statistics, all of which indicate possible violations of statistical test assumptions.

Table 9

Descriptive Statistics for the Cleaned Data Set

	n	Minimum	Maximum	*M*	*SD*
RBC	43	1.00	22.00	10.65	5.03
Plasma	43	2.00	24.00	8.33	4.92
Platelets	43	.00	16.00	4.51	3.25
LOS	43	4.50	9.50	6.68	1.29
Readmission	43	12.00	28.00	19.88	5.06
HAI	43	5.10	10.20	7.90	1.19
Valid N (listwise)	43				

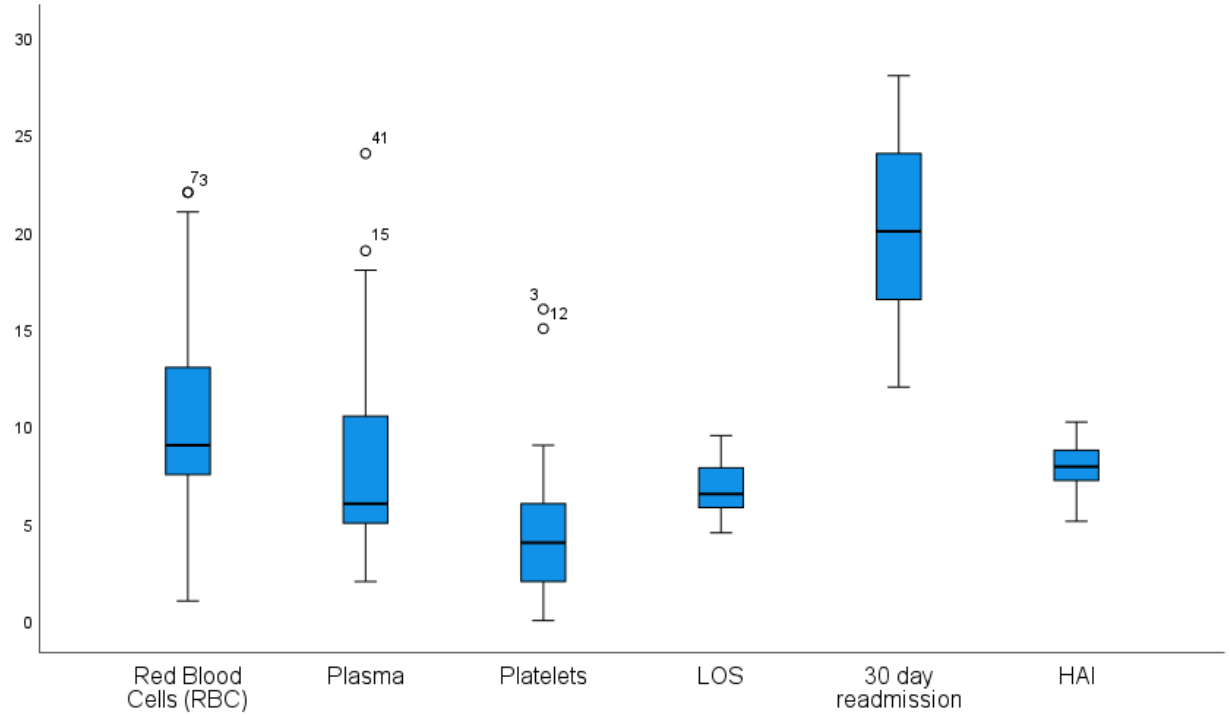
Table 10

Skewness and Kurtosis Statistics for the Cleaned Data Set

	n	Skewness		Kurtosis	
	Statistic	Statistic	Std. Error	Statistic	Std. Error
RBC	43	.70	.36	-.03	.71
Plasma	43	1.29	.36	1.46	.71
Platelets	43	1.87	.36	4.58	.71
LOS	43	.32	.36	-.71	.71
Readmission	43	-.05	.36	-1.05	.71
HAI	43	-.29	.36	-.10	.71
Valid N (listwise)	43				

Figure 6

Boxplots for the Six Outcomes (n = 43)



Missing Values Analysis on the Cleaned Data Set (n = 43)

A missing values analysis was performed on the six outcome variables using IBM SPSS. Table 11 shows two missing values, one each for the LOS and readmission variables. Because the missing values were each less than five percent of its variables sample size, each missing value was replaced with that variable's respective mean: M = 6.68 for LOS and 19.88 for readmission.

Table 11

Missing Values Analysis on the Six Outcomes (n = 43)

				Missing		No. of Extremes [a]	
	n	*M*	*SD*	Count	Percent	Low	High
RBC	43	10.65	5.03	0	.0	0	2
Plasma	43	8.33	4.92	0	.0	0	1
Platelets	43	4.51	3.25	0	.0	0	2
LOS	42	6.68	1.31	1	2.3	0	0
Readmit	42	19.88	5.12	1	2.3	0	0
HAI	43	7.90	1.19	0	.0	0	0

a. Number of cases outside the range (Q1 - 1.5*IQR, Q3 + 1.5*IQR).

Validity and Reliability

Table 12 shows the reliability results: Cronbach's alpha was equal to .81, which indicated good reliability for these six outcome variables. The face, content, and construct validities of the survey questions were evaluated previously in pretesting the survey questions before the survey went live. Additional content, construct, and face validity were performed by:

1. Carolyn Burns MD: President of SABM

2. Hind Jaber Daou PhD: Former TSO for VCU

3. Lorraine Blagg EdD: Program Director of Johns Hopkins SBB program

4. Kaycie Atchison: TSO at Vanderbilt University and coauthor of the (Jacobs, 2021) survey

Table 12

Reliability for all Six Outcome Variables

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.814	.872	6

Hypothesis Testing

Hypothesis 1

Hypothesis 1 focused on the effects that a TSO has on a hospital by comparing those hospitals that had a TSO with those that did not have a TSO. The purpose of this hypothesis was to describe and test the relationship between having a TSO and the six outcome variables associated with PBM programs.

Correlation Analyses for TSO groups

Correlation analyses were performed on this set of complete variable values to get a macro view of how these six outcomes interact with one another and with the TSO variable. Table 13 shows the Pearson correlations between each outcome variable and the TSO variable. The correlation between the dichotomous TSO variable and each of the continuous outcome variables is known as a Point-biserial correlation; it is a special case of the Pearson Correlation. Because of expected violations of parametric assumptions, such as normality, the nonparametric Spearman correlations of the same variables were performed, which is shown in Table 14. Except for the Pearson correlation between HAI and plasma, all other variables indicated a moderate to high statistically significant Pearson correlation with one another. Except for the correlations of the TSO with the six outcome variables, all the correlations were positive: The TSO variable was negatively and statistically significantly correlated with all six outcome variables. The nonparametric Spearman correlations were very similar to the Pearson correlations, except that HAI and plasma were also positively and statistically significantly correlated in the Spearman analysis. The beds variable was highly, positively correlated with the TSO variable indicating that larger hospitals were more likely to have a TSO than smaller hospitals. The beds variable had a small, negative correlation with the waste variables (RBC,

plasma, and platelets) that was not statistically significant, which indicated that larger hospitals had slightly lower levels of blood product waste than smaller hospitals, but not at a level that was statistically significant. The beds variable had moderate, negative correlations with the LOS, readmission, and HAI variables that were statistically significant.

Table 13

Pearson Correlations Between the Six Outcome Variables and the TSO and Beds Variables

		RBC	Plasma	Platelets	LOS	Readmission	HAI	Beds	TSO
RBC	Pearson Correlation	--							
	N	43							
Plasma	Pearson Correlation	.790**	--						
	Sig. (2-tailed)	<.001							
	N	43	43						
Platelets	Pearson Correlation	.602**	.569**	--					
	Sig. (2-tailed)	<.001	<.001						
	N	43	43	43					
LOS	Pearson Correlation	.698**	.505**	.510**	--				
	Sig. (2-tailed)	<.001	<.001	<.001					
	N	43	43	43	43				
Readmission	Pearson Correlation	.456**	.471**	.474**	.758**	--			
	Sig. (2-tailed)	.002	.001	.001	<.001				
	N	43	43	43	43	43			
HAI	Pearson Correlation	.358*	.226	.326*	.670**	.580**	--		
	Sig. (2-tailed)	.018	.145	.033	<.001	<.001			
	N	43	43	43	43	43	43		
Beds	Pearson Correlation	-.188	-.124	-.177	-.415**	-.355*	-.496**	--	
	Sig. (2-tailed)	.227	.429	.255	.006	.020	<.001		
	N	43	43	43	43	43	43	43	
TSO	Pearson Correlation	-.440**	-.435**	-.360*	-.739**	-.713**	-.764**	.597**	--
	Sig. (2-tailed)	.003	.004	.018	<.001	<.001	<.001	<.001	
	N	43	43	43	43	43	43	43	43

**: Correlation is significant at the 0.01 level (2-tailed).

*: Correlation is significant at the 0.05 level (2-tailed).

Table 14

Nonparametric Spearman's Correlation Between the Outcome Variables and the TSO Variable

			RBC	Plasma	Platelets	LOS	Readmission	HAI	Beds	TSO
Spearman's rho	RBC	Correlation Coefficient	--							
		Sig. (2-tailed)	.							
		N	43							
	Plasma	Correlation Coefficient	.837**	--						
		Sig. (2-tailed)	<.001	.						
		N	43	43						
	Platelets	Correlation Coefficient	.654**	.696**	--					
		Sig. (2-tailed)	<.001	<.001	.					
		N	43	43	43					
	LOS	Correlation Coefficient	.674**	.634**	.532**	--				
		Sig. (2-tailed)	<.001	<.001	<.001	.				
		N	43	43	43	43				
	Readmission	Correlation Coefficient	.444**	.611**	.499**	.749**	--			
		Sig. (2-tailed)	.003	<.001	<.001	<.001	.			
		N	43	43	43	43	43			
	HAI	Correlation Coefficient	.443**	.403**	.290	.697**	.595**	--		
		Sig. (2-tailed)	.003	.007	.059	<.001	<.001	.		
		N	43	43	43	43	43	43		
	Beds	Correlation Coefficient	-.180	-.205	-.048	-.418**	-.384*	-.567**	--	
		Sig. (2-tailed)	.249	.187	.758	.005	.011	<.001	.	
		N	43	43	43	43	43	43	43	
	TSO	Correlation Coefficient	-.437**	-.460**	-.304*	-.734**	-.714**	-.829**	.596**	--
		Sig. (2-tailed)	.003	.002	.047	<.001	<.001	<.001	<.001	.
		N	43	43	43	43	43	43	43	43

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

TSO Relationship with Outcome Variables

The first research question asked if there was a relationship between having a TSO and the outcomes associated with PBM programs, and it was hypothesized that there was a relationship between having a TSO and the PBM program outcomes. Statistical analyses were performed to evaluate the relationship between TSO groups (Yes/No) on each outcome variable. This hypothesized relationship was evaluated in a "forward" sense by testing for statistical difference between group means (or medians) utilizing standard statistical techniques such as the analysis of variance (ANOVA), robust ANOVA techniques, or the nonparametric Mann-Whitney U statistic when parametric assumptions are violated, by using the TSO grouping

variable as an independent variable and the outcome variables as dependent variables. Alternatively, this hypothesized relationship was also evaluated in a "reverse" or "backward" sense on some outcome variables by using the continuous outcome variables as predictor (independent) variables to predict the group membership of the TSO variable by using it as a dependent variable in binary logistic regression. Because there were unequal sample sizes, and therefore most likely unequal variances, between each level of the TSO groups, robust and nonparametric statistics were utilized as necessary. The Welch and Brown-Forsythe robust ANOVA tests consider unequal group sizes and calculate different degrees of freedom that are more conservative than standard F tests.

TSO Relationship with RBC Waste

Table 13 shows a moderate, negative correlation (r = -.440) between the TSO and RBC variables, which means that having a TSO was associated with a decrease in RBC waste. Table 15 shows the descriptive statistics and Figure 7 shows boxplots for the RBC variable by TSO groups. The TSO no group had a higher mean, median, and variance than the TSO yes group. Figure 8 shows a histogram of the RBC variable indicating some potential departures from normality. Table 16 includes the tests for normality which show that the distribution of the RBC yes group is significantly different from what would be expected in a normal distribution. Table 17 shows the results of the Levene's test of equal variance showing that the variances of the two RBC groups are significantly different indicating the need for robust ANOVA tests.

Table 15

RBC Variable by TSO Group Descriptive Statistics

	TSO			Statistic	Std. Error
RBC	No	Mean		13.35	1.43
		95% Confidence Interval for Mean	Lower Bound	10.32	
			Upper Bound	16.39	
		5% Trimmed Mean		13.56	
		Median		13.00	
		Variance		34.87	
		Std. Deviation		5.90	
		Minimum		1.00	
		Maximum		22.00	
		Range		21.00	
		Interquartile Range		10.00	
		Skewness		-.17	.55
		Kurtosis		-.42	1.06
	Yes	Mean		8.88	.68
		95% Confidence Interval for Mean	Lower Bound	7.49	
			Upper Bound	10.28	
		5% Trimmed Mean		8.68	
		Median		8.00	
		Variance		11.95	
		Std. Deviation		3.46	
		Minimum		4.00	
		Maximum		18.00	
		Range		14.00	
		Interquartile Range		5.25	
		Skewness		.99	.46
		Kurtosis		.82	.89

Figure 7

Boxplots of the RBC Variable by TSO Groups

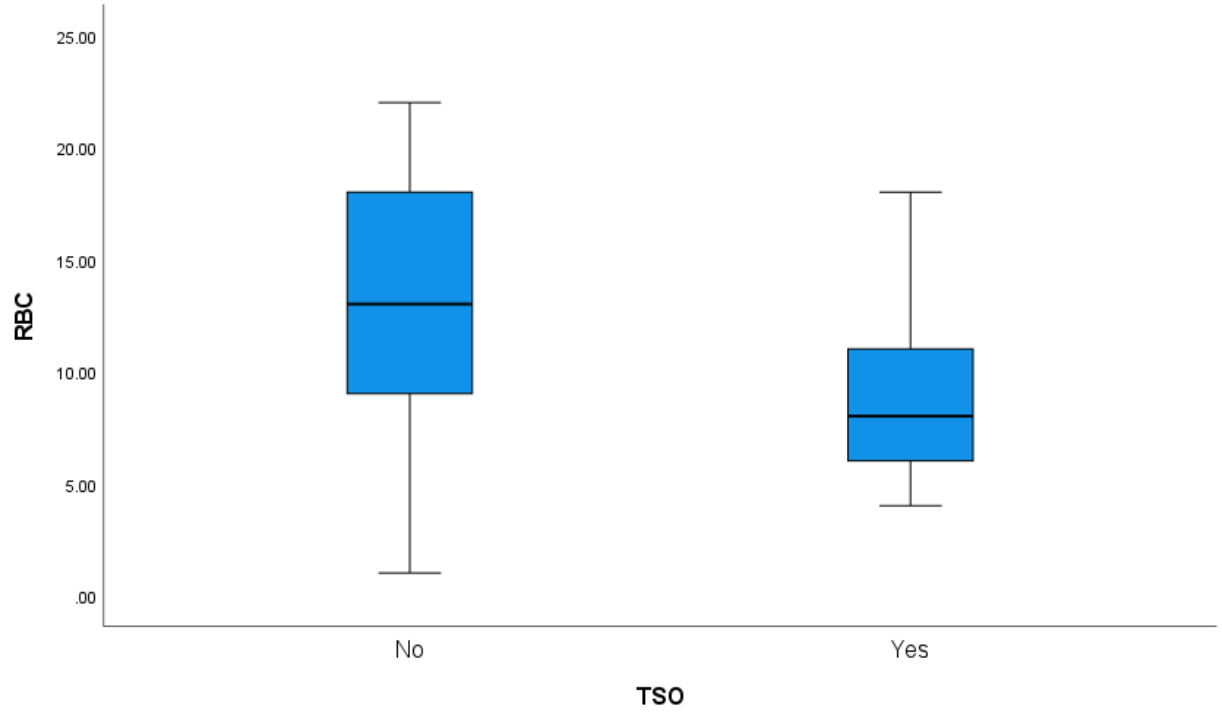


Figure 8

Histogram of RBC Values

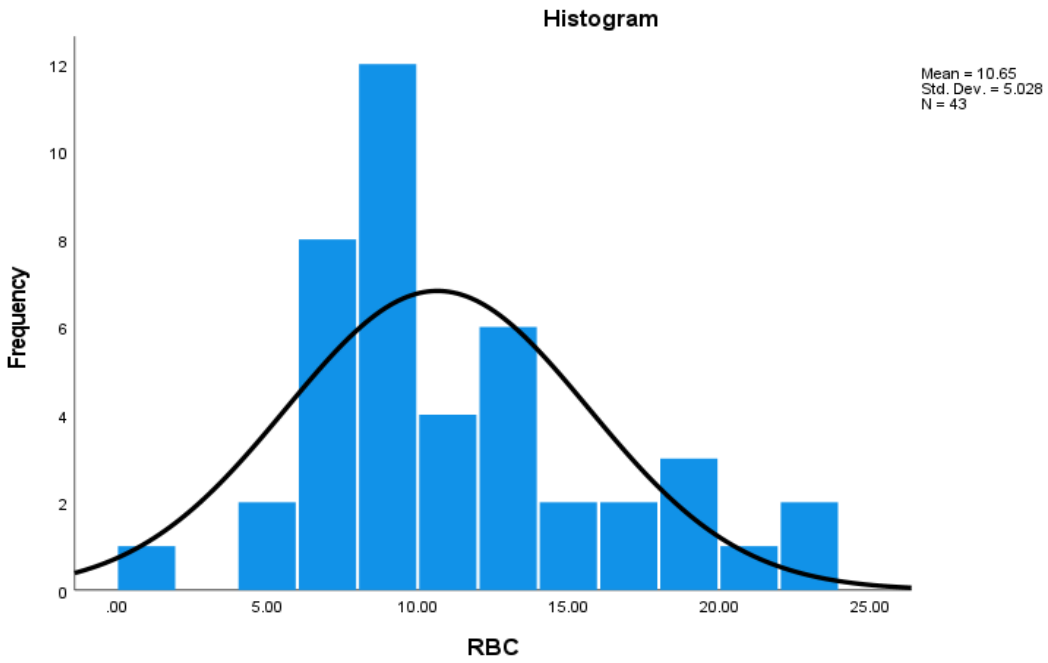


Table 16

Test of Normality for the RBC Groups

		Shapiro-Wilk		
	TSO	Statistic	df	Sig.
RBC	No	.96	17	.652
	Yes	.92	26	.035

Table 17

Tests of Homogeneity of Variances for RBC

		Levene Statistic	df1	df2	Sig.
RBC	Based on Mean	6.22	1.00	41.00	.017
	Based on Median	6.03	1.00	41.00	.018
	Based on adjusted Median	6.03	1.00	37.48	.019
	Based on trimmed mean	6.39	1	41	.015

An Analysis of Variance (ANOVA) was performed on the TSO groups of the RBC variable. Table 18 shows there was a statistically significant difference between the means of the two groups, F = 9.82, p = .003. Table 19 shows the effect size estimates with η^2 = .193 CI (.02 to .39) indicating a moderate effect size. Because the two groups had unequal sample sizes and unequal variances, robust ANOVA tests were performed. Table 20 shows the results of two robust ANOVA tests (Welch and Brown-Forsythe) and both showed statistically significant differences between the two groups. Because the TSO yes group failed the normality tests, a nonparametric Mann-Whitney U test was performed, which showed a statistically significant result with Z = -2.84, p = .005. See Table 21.

Table 18

ANOVA Results for the RBC Groups

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	205.23	1.00	205.23	9.82	.003
Within Groups	856.54	41.00	20.89		
Total	1061.77	42.00			

Table 19

Effect Size Estimates for the RBC by TSO Groups ANOVA

			95% Confidence Interval	
		Point Estimate	Lower	Upper
RBC	Eta-squared	.19	.02	.39
	Epsilon-squared	.17	.00	.37
	Omega-squared Fixed-effect	.17	.00	.36
	Omega-squared Random-effect	.17	.00	.36

Table 20

Robust Tests of Equality of Means for ANOVA

RBC

	Statistic [a]	df1	df2	Sig.
Welch	7.95	1.00	23.23	.010
Brown-Forsythe	7.95	1.00	23.23	.010

a. Asymptotically F distributed.

Table 21

Nonparametric Mann-Whitney U Test Results

	RBC
Mann-Whitney U	107.50
Wilcoxon W	458.50
Z	-2.84
Asymp. Sig. (2-tailed)	.005

In a backward (or reverse sense), a binary logistic regression was performed to see if the TSO group membership could be predicted from the RBC results. Table 22 shows the regression coefficients, Wald statistics, and odds ratios. According to the Wald criterion, the RBC variable was statistically significant in this model with $\chi 2 = 6.79$, $p = .009$. The odds ratio was .81 CI (.69 to .95) indicating that the odds of having high RBC waste was 19% less in those hospitals having a TSO as opposed to those that did not have a TSO. Table 23 contains the classification table showing that the addition of the RBC variable with the regression constant in the model was able to predict 72% of the TSO group memberships. Table 24 shows the pseudo-R- squared effect size estimates were between .18 and .25 meaning that 18% to 25% of the variance between the TSO groups could be explained by the RBC variable. The above results taken together indicate a statistically significant relationship between the TSO and RBC variables.

Table 22

Logistic Regression Model Results Predicting TSO Groups From RBC

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	RBC	-.21	.08	6.79	1	.009	.81	.69	.95
	Constant	2.69	.94	8.27	1	.004	14.76		

[a]. Variable(s) entered on step 1: RBC.

Table 23

Logistic Regression Prediction Table of TSO Groups from RBC

			Predicted		
			TSO		Percentage
	Observed		No	Yes	Correct
Step 1	TSO	No	9	8	52.9
		Yes	4	22	84.6
	Overall Percentage				72.1

Table 24

Effect Size Estimates for the RBC Logistic Regression Model

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	48.92[a]	.18	.25

[a]. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

TSO with Plasma

Table 13 shows a moderate, negative correlation (r = -.435) between the TSO and plasma variables, which means that having a TSO is associated with a decrease in plasma waste. Table 25 and Figure 8 show that the TSO yes group had a lower mean, median, and variance than the TSO no group. The Yes group had a potential outlier. Review of the data indicated that this was a large hospital and this amount of waste is possible, so this potential outlier was left in the analysis.

Table 25

Descriptive Statistics of Plasma Variable by TSO Groups

	TSO			Statistic	Std. Error
Plasma	No	Mean		10.94	1.22
		95% Confidence Interval for Mean	Lower Bound	8.36	
			Upper Bound	13.52	
		5% Trimmed Mean		10.99	
		Median		11.00	
		Variance		25.18	
		Std. Deviation		5.02	
		Minimum		2.00	
		Maximum		19.00	
		Range		17.00	
		Interquartile Range		9.00	
		Skewness		-.06	.55
		Kurtosis		-.94	1.06
	Yes	Mean		6.62	.81
		95% Confidence Interval for Mean	Lower Bound	4.96	
			Upper Bound	8.28	
		5% Trimmed Mean		6.03	
		Median		6.00	
		Variance		16.89	
		Std. Deviation		4.11	
		Minimum		3.00	
		Maximum		24.00	
		Range		21.00	
		Interquartile Range		3.25	
		Skewness		3.20	.46
		Kurtosis		13.10	.89

Figure 9

Boxplots of the Plasma Variable by TSO Groups

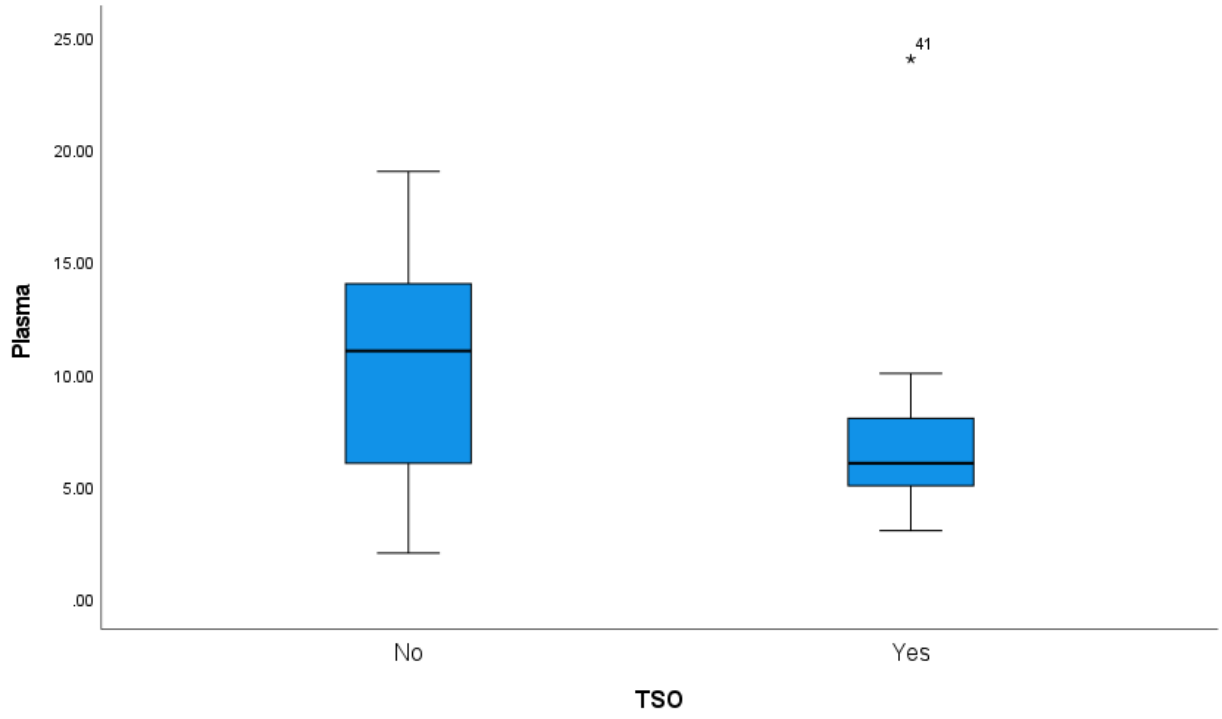


Figure 9 shows a histogram of the plasma values indicating a substantial departure from normality. Figures 10 and 11 show histograms of the TSO groups which shows that much of the departure from normality is due to the positive (right) skew of the TSO yes group with most values lower than the TSO no group, but with a potential outlier as a higher value. Table 26 shows the normality tests confirming that it is the TSO yes group distribution that is significantly different from what is expected from a normal distribution.

Figure 10

Histogram of Plasma Values

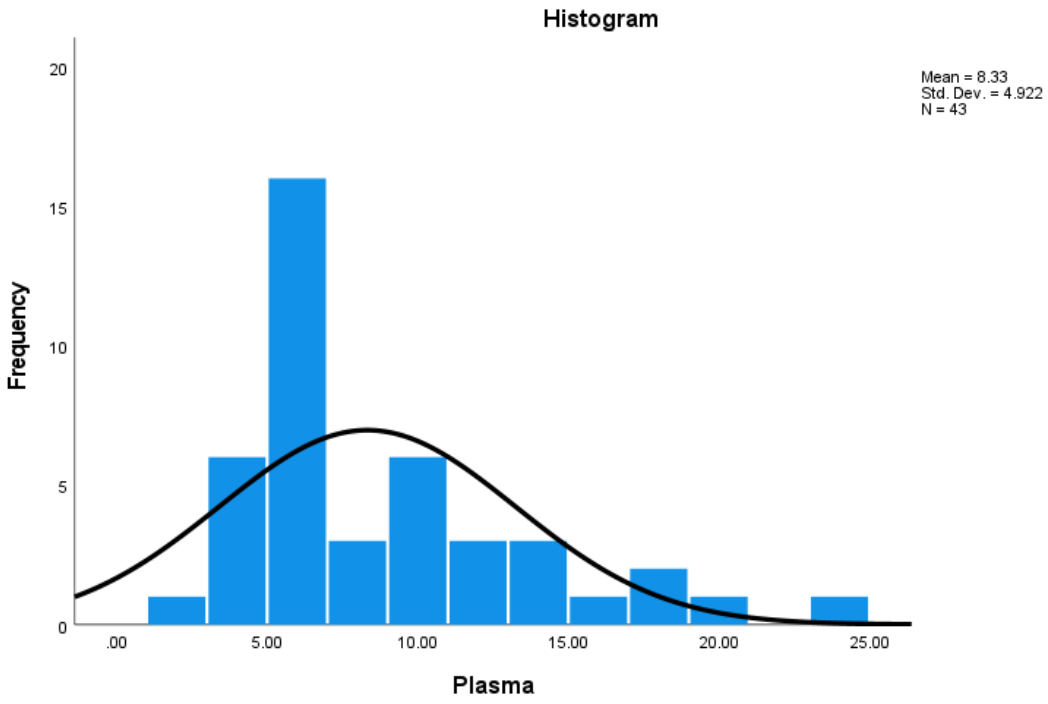


Figure 11

Histogram of TSO No Plasma Values

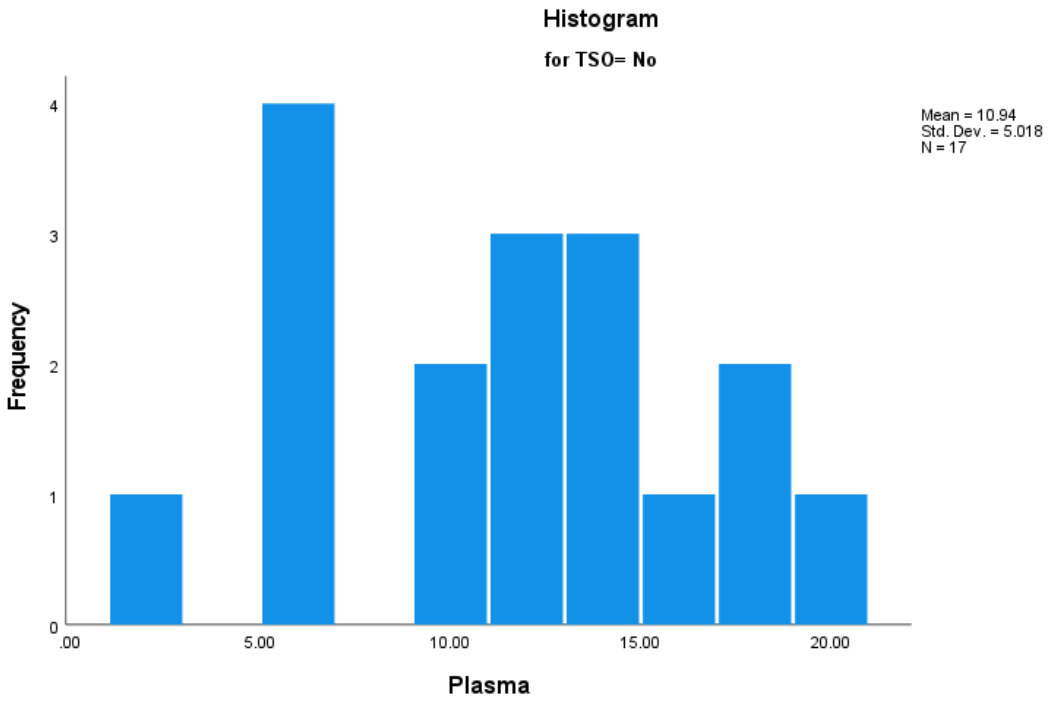


Figure 12

Histogram of TSO Yes Plasma Values

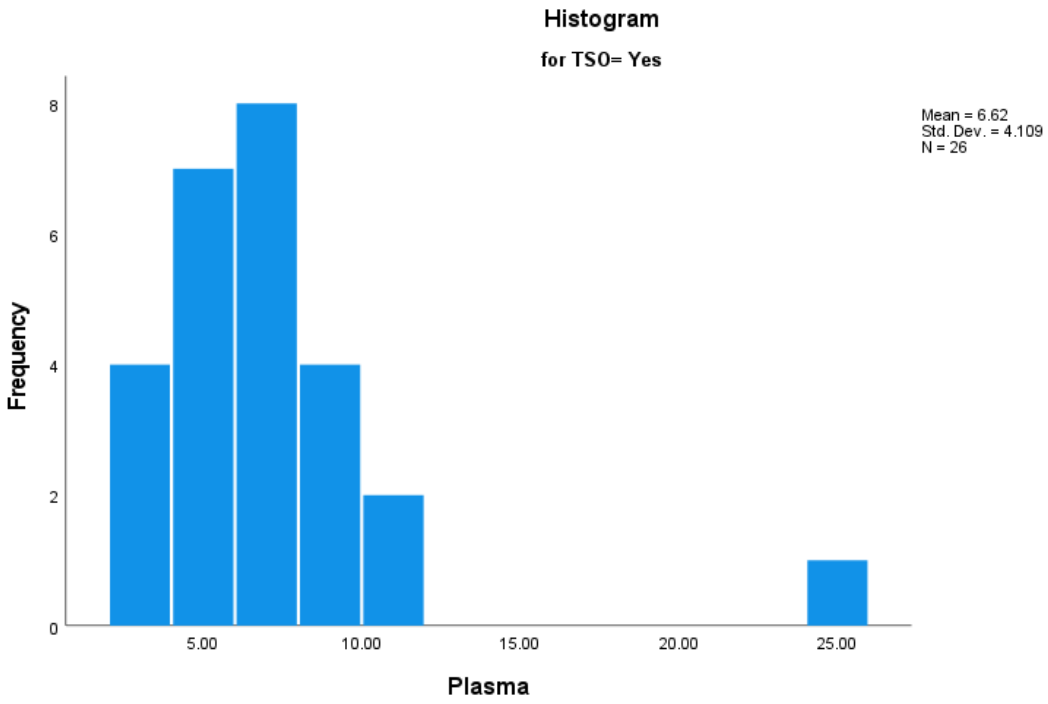


Table 26

Plasma Normality Tests by TSO Grouping

		Shapiro-Wilk		
	TSO	Statistic	df	Sig.
Plasma	No	.97	17	.734
	Yes	.67	26	<.001

Table 27 shows the mean ranks between the TSO groups for the plasma variable, which lessens the impact of an outlier by making it a higher rank. Table 28 gives the results of the Mann-Whitney U test showing a statistically significant difference between the two TSO groups, Z = -2.98, p = .003. The plasma variables departure from normality and it having a probable outlier makes this variable difficult to include in statistical modeling. Table 13 shows that the plasma variable is highly correlated (r = .790) with the RBC variable; therefore, most of the variance the plasma variable could explain would already be explained by the RBC variable. Although it has a relationship with the TSO variable as evidenced by the above negative correlation (r = -.435) with the TSO groups differing significantly from one another, the plasma variable was not used for any further statistical analysis for this hypothesis.

Table 27

Plasma Mean Ranks by TSO Grouping

	TSO	N	Mean Rank	Sum of Ranks
Plasma	No	17	29.00	493.00
	Yes	26	17.42	453.00
	Total	43		

Table 28

Nonparametric Mann-Whitney Test Results

	Plasma
Mann-Whitney U	102.00
Wilcoxon W	453.00
Z	-2.98
Asymp. Sig. (2-tailed)	.003

TSO Relationship with Platelets

Table 13 shows that there is moderate sized, negative correlation (r = - .360) between the TSO and platelets variables, indicating that having a TSO is associated with a decrease in the waste of platelets. Table 29 contains descriptive statistics and Figure 13 contains boxplots of the platelets variable divided into TSO groups with a potential outlier. The TSO yes group has a lower mean, median, and variance than the no group with the no group having a potential outlier.

Figure 13 contains a histogram of the platelets variable showing several departures from normality, including a skewed distribution and potential outliers. Table 30 contains the normality test results showing that the TSO no group distribution is significantly different from a normal distribution with the Shapiro-Wilks test.

Table 29

Descriptive Statistics of the Platelets Variable by TSO Group

	TSO			Statistic	Std. Error
Platelets	No	Mean		5.94	1.05
		95% Confidence Interval for Mean	Lower Bound	3.71	
			Upper Bound	8.17	
		5% Trimmed Mean		5.71	
		Median		5.00	
		Variance		18.81	
		Std. Deviation		4.34	
		Minimum		.00	
		Maximum		16.00	
		Range		16.00	
		Interquartile Range		5.50	
		Skewness		1.19	.55
		Kurtosis		1.28	1.06
	Yes	Mean		3.58	.36
		95% Confidence Interval for Mean	Lower Bound	2.84	
			Upper Bound	4.32	
		5% Trimmed Mean		3.49	
		Median		3.00	
		Variance		3.37	
		Std. Deviation		1.84	
		Minimum		1.00	
		Maximum		8.00	
		Range		7.00	
		Interquartile Range		3.00	
		Skewness		.73	.46
		Kurtosis		-.10	.89

Figure 13

Boxplots of Platelets Variable by TSO Groups

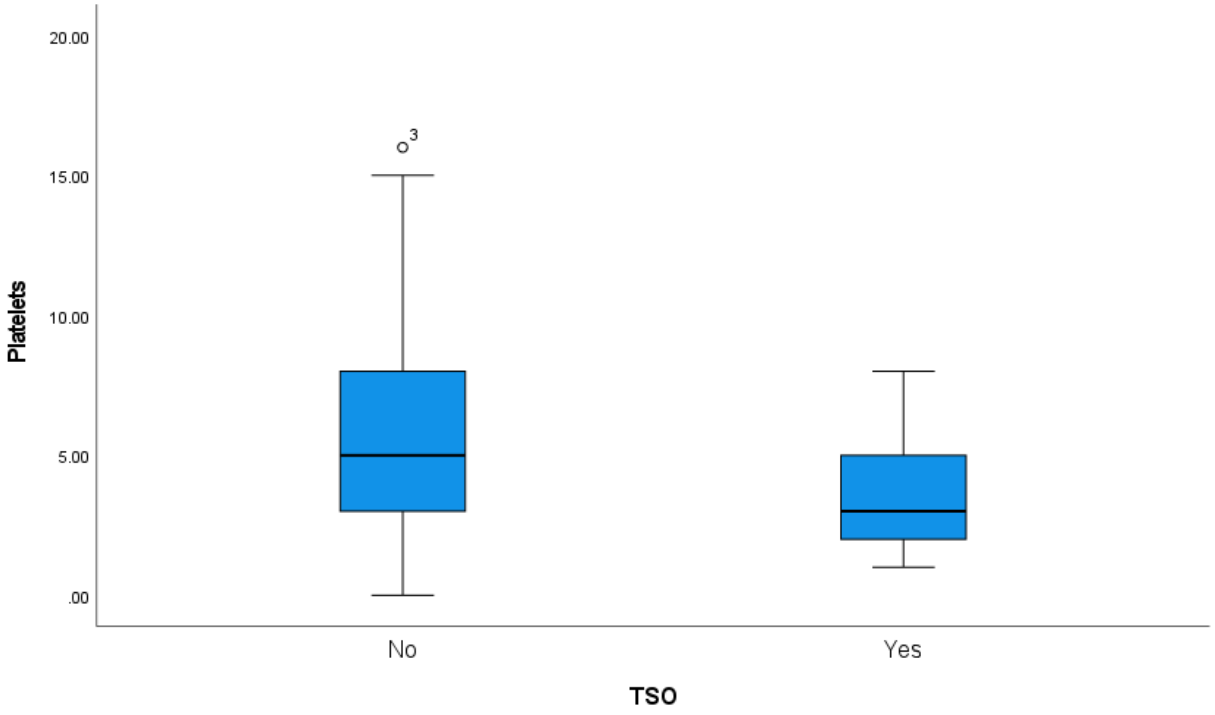


Figure 14

Histogram of the Platelets Variables

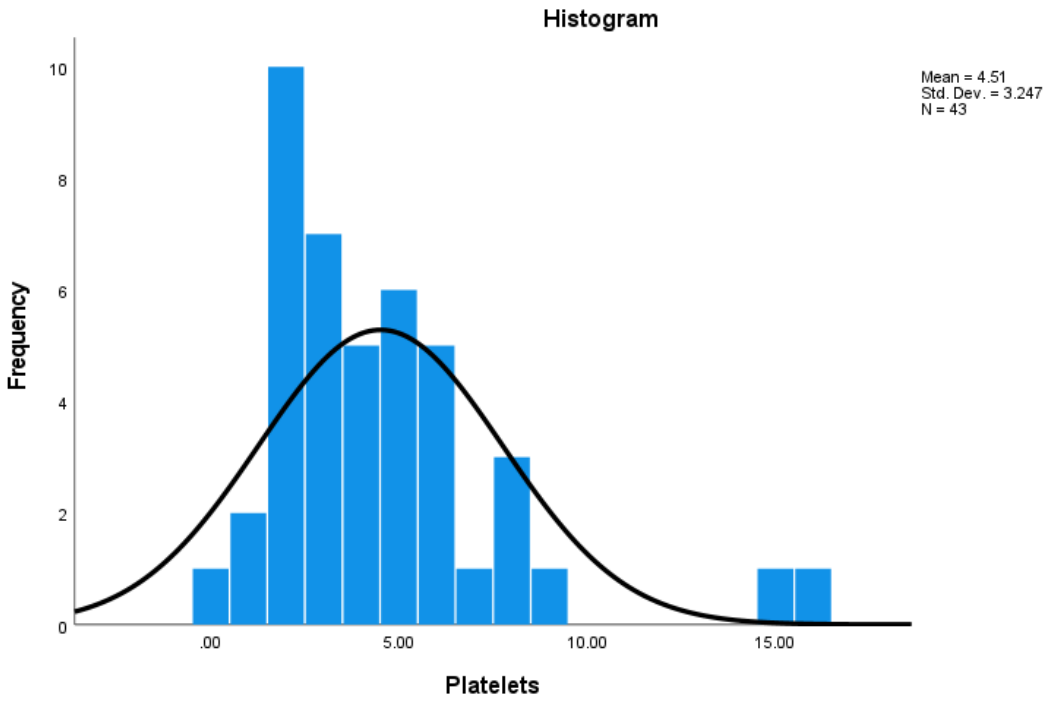


Table 30

Normality Test Results for Platelets Variable by TSO Groups

		Shapiro-Wilk		
	TSO	Statistic	df	Sig.
Platelets	No	.89	17	.042
	Yes	.92	26	.053

The results of the Mann-Whitney U test are shown in Table 31, which shows a statistically significant difference between the TSO groups, Z = -1.972, p = .049. The platelets variable's departure from normality and it having a probable outlier makes this variable difficult to include in statistical modeling. Table 13 shows that the platelets variable is moderately correlated (r = .602) with the RBC variable; therefore, most of the variance the platelets variable could explain would already be explained by the RBC variable. Although it has a relationship with the TSO variable as evidenced by the above negative correlation (r = -.360) with the TSO groups differing significantly from one another, the platelets variable was not used for any further statistical analysis for this hypothesis

Table 31

Mann-Whitney U Group Results for Platelets

	Platelets
Mann-Whitney U	142.50
Wilcoxon W	493.50
Z	-1.972
Asymp. Sig. (2-tailed)	.049

TSO and LOS

Table 13 shows that the TSO and LOS variables have a strong, negative Pearson correlation (r = -.739), which indicates that having a TSO is associated with a lower hospital length of stay. Table 32 and Figure 15 show that the TSO yes group had a lower mean, median, and variance than the TSO no group with a potential outlier in the no group.

Table 32

LOS Descriptive Statistics by TSO Groups

	TSO			Statistic	Std. Error
LOS	No	Mean		7.85	.28
		95% Confidence Interval for Mean	Lower Bound	7.26	
			Upper Bound	8.43	
		5% Trimmed Mean		7.93	
		Median		7.90	
		Variance		1.29	
		Std. Deviation		1.14	
		Minimum		4.60	
		Maximum		9.50	
		Range		4.90	
		Interquartile Range		1.35	
		Skewness		-1.46	.55
		Kurtosis		3.18	1.06
	Yes	Mean		5.92	.13
		95% Confidence Interval for Mean	Lower Bound	5.64	
			Upper Bound	6.19	
		5% Trimmed Mean		5.94	
		Median		6.20	
		Variance		.45	
		Std. Deviation		.67	
		Minimum		4.50	
		Maximum		6.90	
		Range		2.40	
		Interquartile Range		1.08	
		Skewness		-.59	.46
		Kurtosis		-.59	.89

Figure 15

Boxplots of LOS Variable by TSO Groups

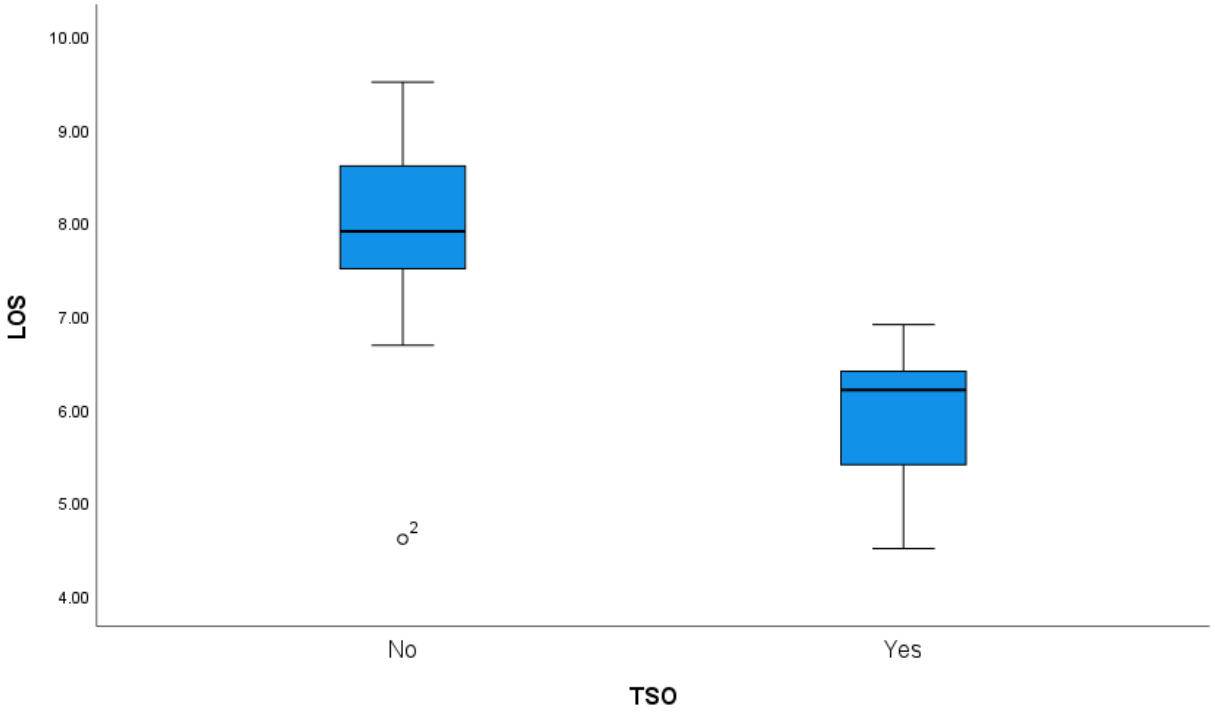


Figure 16 shows a histogram of the LOS variable with some slight departures from a normal distribution. Table 33 shows that the TSO no group to be statistically different from a normal distribution by the Shapiro-Wilks test.

Figure 16

Histogram of LOS Variable

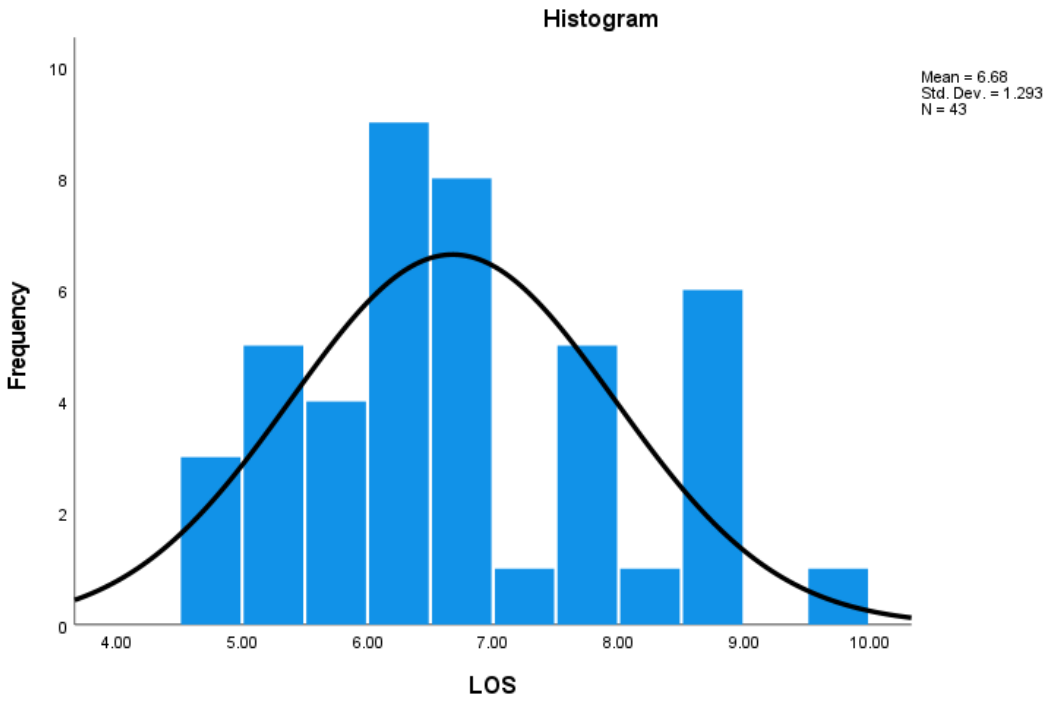


Table 33

Normality Test Results for LOS by TSO Groups

		Shapiro-Wilk		
	TSO	Statistic	df	Sig.
LOS	No	.88	17	.034
	Yes	.93	26	.077

An ANOVA was performed to test for differences between the means of the two TSO groups of the LOS variable. Table 34 shows the results of the Levene's test indicating that there were no statistically significant differences in the variances between to the two TSO groups. Table 35 shows the results for the ANOVA showing a statistically significant difference between the two TSO groups in the LOS variable, $F = 49.23$, $p < .001$.

Table 34

Levene's Tests for LOS

		Levene Statistic	df1	df2	Sig.
LOS	Based on Mean	1.80	1	41	.187
	Based on Median	1.73	1	41	.195
	Based on adjusted Median	1.73	1	33.41	.197
	Based on trimmed mean	1.57	1	41	.218

Table 35

ANOVA Results for LOS

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	38.31	1	38.31	49.23	<.001
Within Groups	31.90	41	.78		
Total					

Table 36 shows the robust ANOVA results, which both were statistically significant $p < .001$. Table 37 gives effect size estimates with $\eta^2 = .55$, CI (.32 - .68). These results confirm a statistically significant difference between the means of the TSO groups of the LOS variable with a moderate to high effect size difference.

Table 36

Robust ANOVA Results for LOS

	Statistic [a]	df1	df2	Sig.
Welch	39.96	1.00	23.33	<.001
Brown-Forsythe	39.96	1.00	23.33	<.001

a. Asymptotically F distributed.

Table 37

ANOVA Effect Size Estimates for LOS

			95% Confidence Interval	
		Point Estimate	Lower	Upper
LOS	Eta-squared	.55	.32	.68
	Epsilon-squared	.53	.30	.67
	Omega-squared Fixed-effect	.53	.30	.66
	Omega-squared Random-effect	.53	.30	.66

A binary logistic regression analysis was performed using the TSO groups as a dependent variable with LOS as a continuous predictor. Table 38 shows the regression coefficients, Wald statistics, odds ratios for the LOS predictor. The analysis gave a statistically significant result by the Wald criterion, $\chi 2$= 10.53, p = .001, odds ratio = .10 CI (.02 - .40), which indicates that there is a 90% less chance of a hospital having a longer length of stay with a TSO than without a TSO. Table 39 gives the pseudo-R-squared effect size estimates between .51 and .69, which indicates that between 51% and 69% of the variance in the TSO groups could be explained by the LOS variable. Table 40 gives the classification table from this analysis showing that the LOS results were able to accurately predict 93% of the TSO group memberships.

Table 38

Logistic Regression Results for LOS

		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B) Lower	Upper
Step 1[a]	LOS	-2.34	.72	10.53	1	.001	.10	.023	.396
	Constant	16.33	4.88	11.18	1	<.001	12306538.56		

a. Variable(s) entered on step 1: LOS .

Table 39

Logistic Regression Effect Size Estimates LOS

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	27.03[a]	.51	.69

a. Estimation terminated at iteration number 6 because parameter estimates changed by less than .001.

Table 40

TSO Group Membership Predictions Using LOS

			Predicted TSO		Percentage
	Observed		No	Yes	Correct
Step 1	TSO	No	14	3	82.4
		Yes	0	26	100.0
	Overall Percentage				93.0

These results indicated that the TSO and LOS variables have a strong association as shown by the Pearson correlation results (r = - .739). Statistical results indicated a statistically significant difference in LOS values between the means of the TSO groups. Likewise, the LOS values were a very strong predictor of TSO group membership. These results show a strong relationship between the TSO and LOS variables.

TSO and readmission

Table 13 shows that the TSO and readmission variables are highly negatively correlated (r = -.713) indicating that having a TSO is associated with a lower rate of 30-day readmissions. Table 41 and Figure 17 show that the TSO yes group has a lower mean, median, and variance than the TSO no group with the TSO no group showing some potential outliers. Figure 18 gives a histogram of readmission values showing some departures from normality. Table 42 contains the Shapiro-Wilks tests showing both groups as having distributions that are significantly different from what would be expected from normal distributions.

Table 43 shows the Levene's statistics for equality of variances among the TSO groups; none of the statistics were statistically significant indicating that the groups had equal variances. Table 44 shows the ANOVA results with a statistically significant difference between the means of the two TSO groups, $F = 42.32$, $p < .001$. Table 45 shows the robust statistical results with both showing statistical significance. Table 46 contains the effect size estimates, with $\eta^2 = .51$, CI (.28 to .65), which is a moderate to high effect size.

Table 41

Readmission Descriptive Statistics by TSO Groups

	TSO			Statistic	Std. Error
Readmission	No	Mean		24.29	.91
		95% Confidence Interval for Mean	Lower Bound	22.36	
			Upper Bound	26.21	
		5% Trimmed Mean		24.65	
		Median		25.00	
		Variance		14.04	
		Std. Deviation		3.75	
		Minimum		14.00	
		Maximum		28.00	
		Range		14.00	
		Interquartile Range		4.00	
		Skewness		-1.52	.55
		Kurtosis		2.39	1.06
	Yes	Mean		17.00	.68
		95% Confidence Interval for Mean	Lower Bound	15.59	
			Upper Bound	18.41	
		5% Trimmed Mean		17.01	
		Median		18.00	
		Variance		12.19	
		Std. Deviation		3.49	
		Minimum		12.00	
		Maximum		22.00	
		Range		10.00	
		Interquartile Range		7.28	
		Skewness		-.28	.46
		Kurtosis		-1.40	.89

Figure 17

Boxplots of Readmission Values by TSO Group

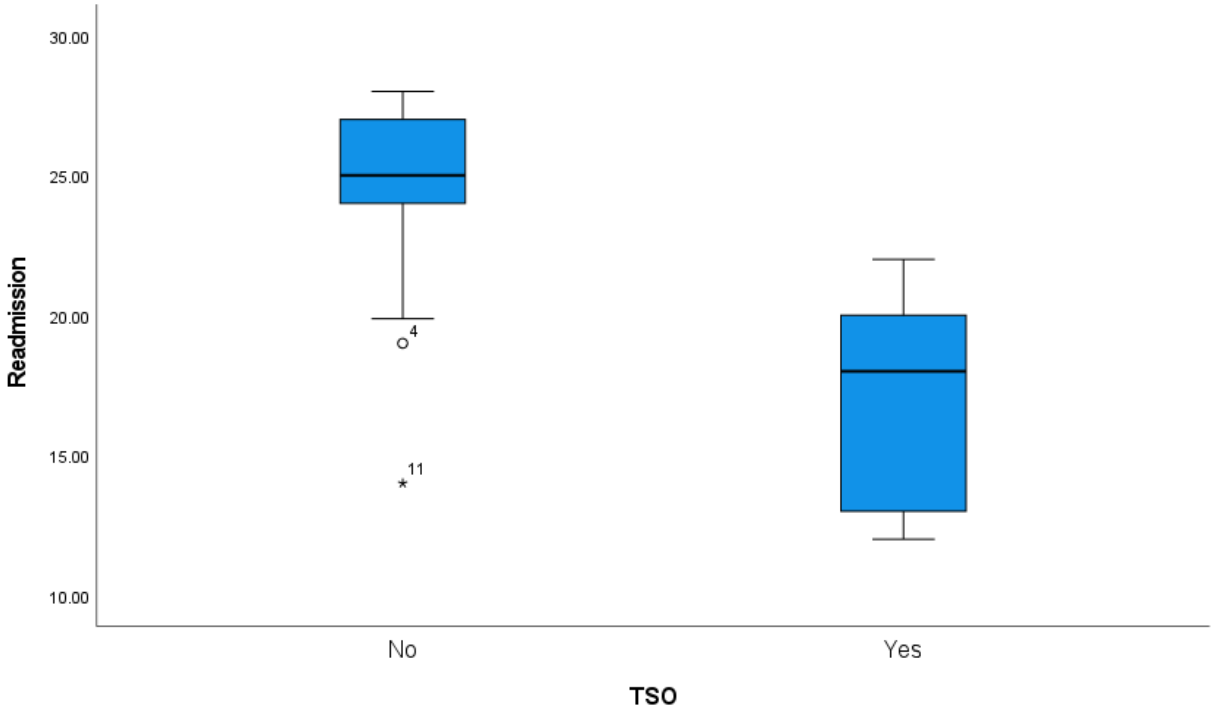


Figure 18

Histogram of Readmission Values

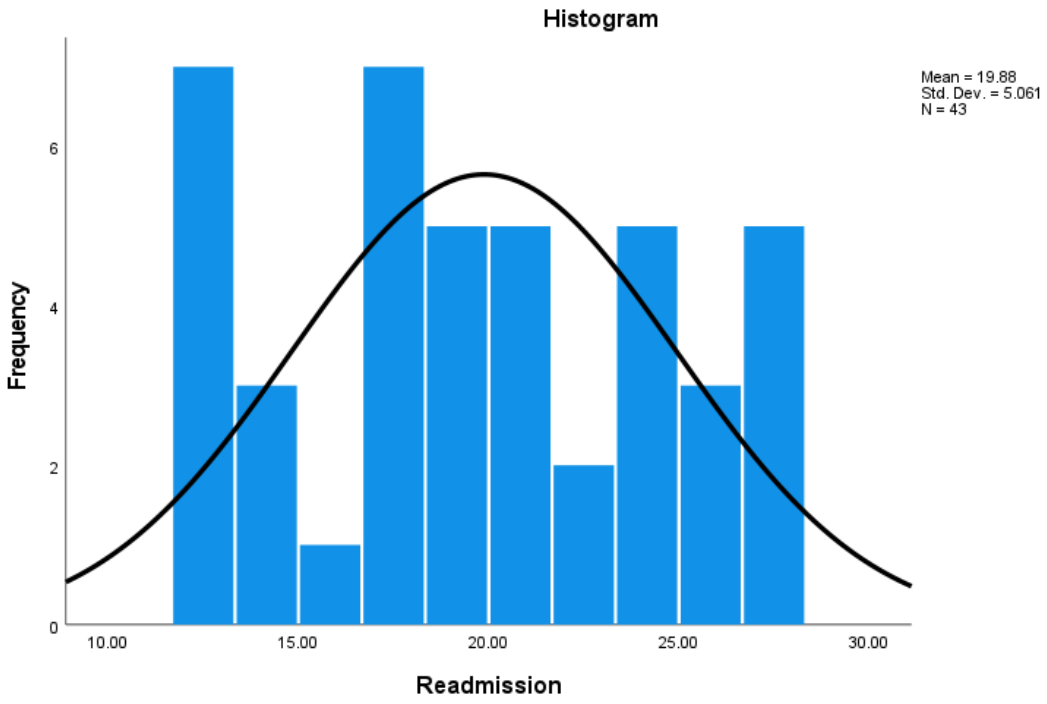


Table 42

Normality Tests for Readmission

		Shapiro-Wilk		
	TSO	Statistic	df	Sig.
Readmission	No	.85	17	.011
	Yes	.88	26	.007

Table 43

Levene's Test for Readmission

		Levene Statistic	df1	df2	Sig.
Readmission	Based on Mean	.20	1	41.00	.656
	Based on Median	.11	1	41.00	.737
	Based on Median and with adjusted df	.11	1	39.10	.737
	Based on trimmed mean	.28	1	41.00	.597

Table 44

ANOVA Results Between the TSO Groups of the Readmission Variable

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	546.41	1	546.41	42.32	<.001
Within Groups	529.38	41	12.91		
Total	1075.79	42			

Table 45

Robust ANOVA Statistics for Readmission

	Statistic [a]	df1	df2	Sig.
Welch	41.06	1	32.60	<.001
Brown-Forsythe	41.06	1	32.60	<.001

a. Asymptotically F distributed.

Table 46

Effect Size Estimates Readmission

			95% Confidence Interval	
		Point Estimate	Lower	Upper
Readmission	Eta-squared	.51	.28	.65
	Epsilon-squared	.50	.26	.64
	Omega-squared Fixed-effect	.49	.26	.63
	Omega-squared Random-effect	.49	.26	.63

Table 47 contains the results of the nonparametric Mann-Whitney U test showing statistically significant differences between the ranked means of the TSO groups, $Z = -4.62$, $p < .001$. These statistically significant results confirm the parametric significance despite the departures from normality and potential outliers.

A binary logistic regression analysis was performed using TSO groups as a dependent variable with readmission as a predictor variable. Table 48 shows the regression coefficients, Wald statistics, and odds ratios for the readmission predictor. The analysis gave a statistically significant result by the Wald criterion, $\chi 2 = 11.14$, $p < .001$, odds ratio = .57 CI (.41 - .79), which indicates that there is 43% less chance of having higher 30-day readmission rates in those hospitals with a TSO than those without a TSO. Table 49 gives the pseudo-R-squared effect size estimates between .49 and .66, which indicates that between 49% to 66% of the variance of the TSO groups could be explained by the readmission values. Table 50 gives the classification table from this analysis showing that the readmission results were able to accurately predict 90.7% of the TSO group memberships.

Table 47

Nonparametric Mann-Whitney Test for the Readmission

	Readmission
Mann-Whitney U	35.50
Wilcoxon W	386.50
Z	-4.62
Asymp. Sig. (2-tailed)	<.001

Table 48

Logistic Regression Results for Readmission

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	Readmission	-.56	.17	11.14	1	<.001	.57	.41	.79
	Constant	12.05	3.57	11.40	1	<.001	170903.08		

a. Variable(s) entered on step 1: Readmission.

Table 49

Logistic Regression Effect Size Estimates for Readmission

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	29.10[a]	.49	.66

a. Estimation terminated at iteration number 6 because parameter estimates changed by less than .001.

Table 50

TSO Group Predictions Using Readmission

			Predicted		
			TSO		Percentage
	Observed		No	Yes	Correct
Step 1	TSO	No	14	3	82.4
		Yes	1	25	96.2
	Overall Percentage				90.7

These results indicated that the TSO and readmission variables have a strong association as shown by the Pearson correlation results (r = - .713). Statistical results indicated a statistically significant difference in readmission mean values between the TSO groups. Likewise, the readmission values were a very strong predictor of TSO group membership. These results show a strong relationship between the TSO and readmission variables.

TSO and HAI

Table 13 shows a strong negative association between the TSO and HAI variables (r = -.764) indicating that having a TSO is associated with a lower rate of hospital-acquired infections. Table 51 and Figure 19 show that the mean and median are lower in the TSO yes group; however, it does have a slightly larger variance, most likely due to having a potential outlier. Figure 20 shows a histogram of the HAI results showing some slight departures from normality. Table 52 shows the normality test results indicating that the TSO yes group had a statistically significant result from a normal distribution on the Shapiro-Wilks test.

Table 53 shows the Levene's statistics for equality of variances among the TSO groups; none of the statistics were statistically significant indicating that the groups had equal variances. Table 54 shows the ANOVA results with a statistically significant difference between the means of the two TSO groups, $F = 57.48$, $p < .001$. Table 55 shows the robust statistical results with both showing statistical significance. Table 56 contains the effect size estimates, with $\eta^2 = .58$, CI (.28 to .65), which is a moderate effect size.

Table 51

HAI Descriptive Statistics by TSO Groups

	TSO			Statistic	Std. Error
HAI	No	Mean		9.01	.15
		95% Confidence Interval for Mean	Lower Bound	8.69	
			Upper Bound	9.34	
		5% Trimmed Mean		9.00	
		Median		9.00	
		Variance		.40	
		Std. Deviation		.63	
		Minimum		8.00	
		Maximum		10.20	
		Range		2.20	
		Interquartile Range		.80	
		Skewness		.13	.55
		Kurtosis		-.41	1.06
	Yes	Mean		7.18	.17
		95% Confidence Interval for Mean	Lower Bound	6.83	
			Upper Bound	7.52	
		5% Trimmed Mean		7.23	
		Median		7.45	
		Variance		.73	
		Std. Deviation		.86	
		Minimum		5.10	
		Maximum		8.20	
		Range		3.10	
		Interquartile Range		1.10	
		Skewness		-1.03	.46
		Kurtosis		.23	.89

Figure 19

Boxplots of HAI by TSO Groups

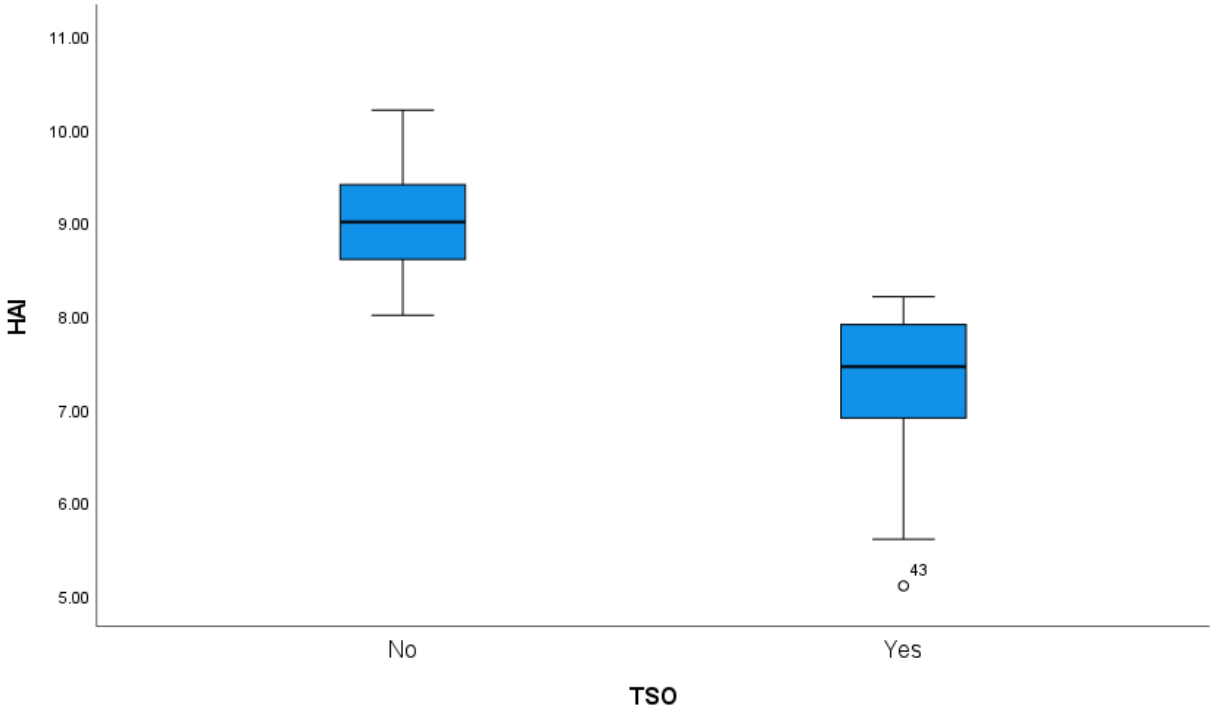


Figure 20

Histogram of HAI Values

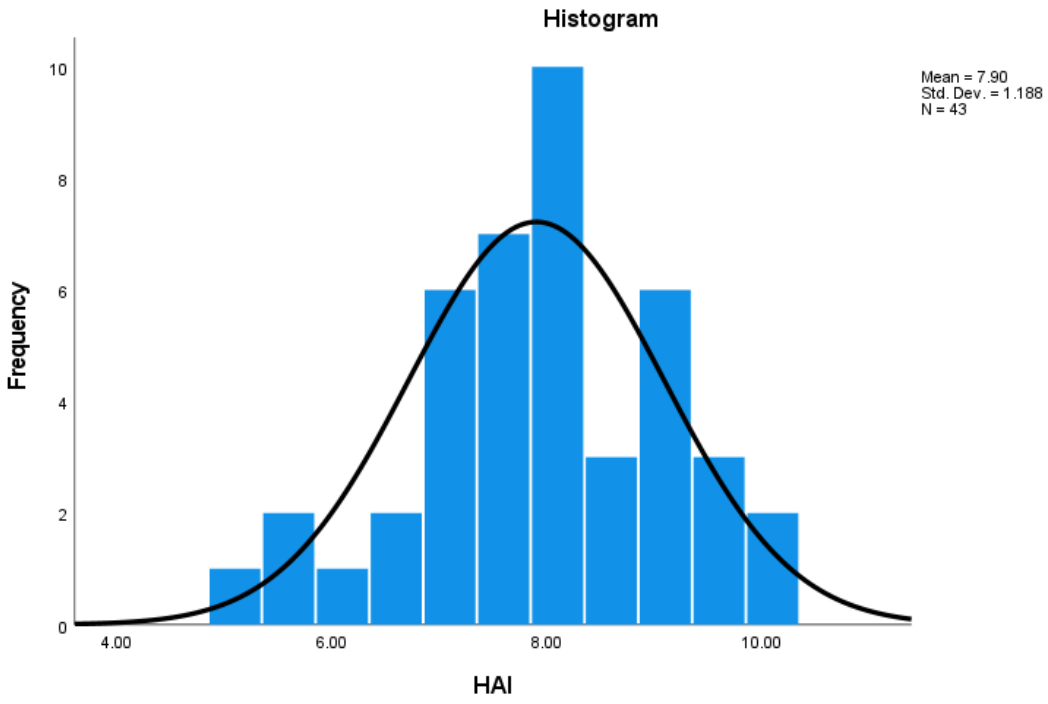


Table 52

Normality Test Results for HAI by TSO Groups

		Shapiro-Wilk		
	TSO	Statistic	df	Sig.
HAI	No	.97	17	.864
	Yes	.89	26	.010

Table 53

Levene's Tests Results for HAI

		Levene Statistic	df1	df2	Sig.
HAI	Based on Mean	1.43	1.00	41.00	.238
	Based on Median	.84	1.00	41.00	.365
	Based on Median	.84	1.00	35.18	.366
	Based on trimmed mean	1.23	1.00	41.00	.273

Table 54

ANOVA Results of HAI Values by TSO groups

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	34.61	1	34.61	57.48	<.001
Within Groups	24.68	41	.60		
Total	59.29	42			

Table 55

Robust ANOVA Results of HAI Values by TSO Groups

	Statistic [a]	df1	df2	Sig.
Welch	65.23	1	40.31	<.001
Brown-Forsythe	65.23	1	40.31	<.001

a. Asymptotically F distributed.

Table 56

ANOVA Effect Size Estimates for HAI

			95% Confidence Interval	
		Point Estimate	Lower	Upper
HAI	Eta-squared	.58	.37	.70
	Epsilon-squared	.57	.35	.70
	Omega-squared Fixed-effect	.57	.35	.69
	Omega-squared Random-effect	.57	.35	.69

A binary logistic regression analysis was performed on TSO groups as a dependent variable with HAI as a predictor. Table 57 shows the regression coefficients, Wald statistics, odds ratios for the readmission predictor. The analysis gave a statistically significant result by the Wald criterion, $\chi 2 = 5.17$, $p = .023$, odds ratio < .001 CI (.00 - .34), which indicates that there is almost 100 % less chance of having a high hospital-acquired infection rate in those hospitals with a TSO than those without a TSO. Table 58 gives the pseudo-R-squared effect size estimates between .65 and .89, which indicates that between 65% to 89% of the variance of the TSO groups could be explained by the HAI values. Table59 gives the classification table from this analysis showing that the readmission results were able to accurately predict 90.7% of the TSO group memberships.

Table 57

Logistic Regression Results for HAI

		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B) Lower	Upper
Step 1[a]	HAI	-7.79	3.43	5.17	1	.023	.000	.00	.34
	Constant	63.57	27.69	5.27	1	.022	4.058E+27		

a. Variable(s) entered on step 1: HAI.

Table 58

Logistic Regression Effect Size Estimates for HAI

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	11.98[a]	.65	.89

a. Estimation terminated at iteration number 9 because parameter estimates changed by less than .001.

Table 59

TSO Group Predictions Using HAI

			Predicted		
			TSO		Percentage
	Observed		No	Yes	Correct
Step 1	TSO	No	15	2	88.2
		Yes	2	24	92.3
	Overall Percentage				90.7

The results indicated that the TSO and HAI variables have a strong association as shown by the Pearson correlation results (r = - .764). Statistical results indicated a statistically significant difference in hospital-acquired infection rates between the means of the TSO groups. Likewise, the HAI values were a very strong predictor of TSO group membership. These results show a strong relationship between the TSO and HAI variables.

Summary of First Null Hypothesis

Hypothesis testing for the first null hypothesis was performed by using correlational analyses and statistical analyses in both “forward” and “reverse” directions. All six of the outcome variables showed moderate to strong and statistically significant negative correlations with the TSO variable, all six outcome variables had statistically significant differences between the TSO groups, and all six outcomes could be used to predict TSO group membership; therefore, the first null hypothesis was rejected. All the correlational and statistical results indicated that having a TSO was associated with less waste of blood products, shorter hospital lengths of stay, lower rates of 30-day readmissions, and lower rates of hospital acquired infections.

Second Null Hypothesis

There is no relationship between a TSO being a nurse and the PBM associated outcomes.

Nurse Variable and Outcomes

Of the 37 respondents who said their hospital had a TSO, two responded that they did not know if the TSO was a nurse, and a further 19 had missing values on all the last three variables as a group (LOS, readmission, and HAI) and were deleted as missing values, which left 26 respondents for further analyses. Table 58 shows the frequencies of the TSO being a nurse (Yes/No) with 69% responding that the TSO of their hospital was a nurse (n = 18) and 31% responding that their TSO was not a nurse (n = 8). Figure 21 shows boxplots of the six outcome variables indicating some potential outliers. Figure 22 shows boxplots of the same six outcome variables but paneled by the two nurse variable groups (Yes/No).

Table 60

Frequencies of TSOs Being Nurses

	Frequency	Percent
No	8	30.8
Yes	18	69.2
Total	26	100.0

Figure 21

Boxplots of the Six Outcome Variables

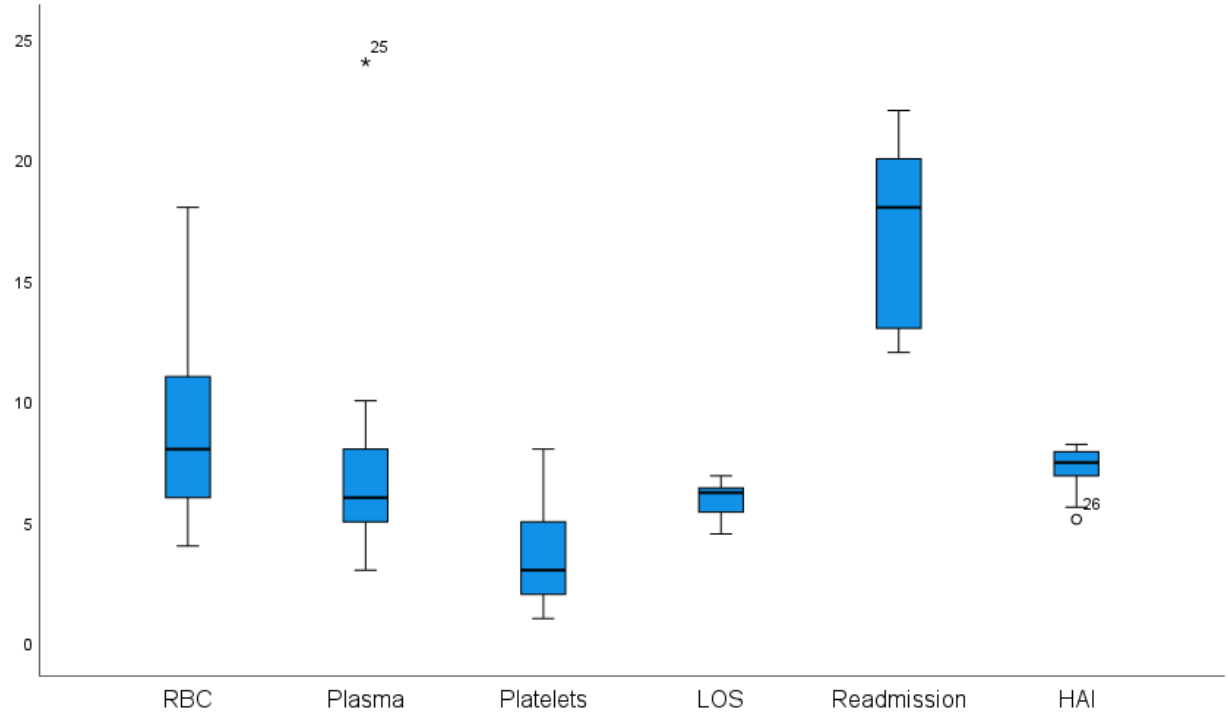
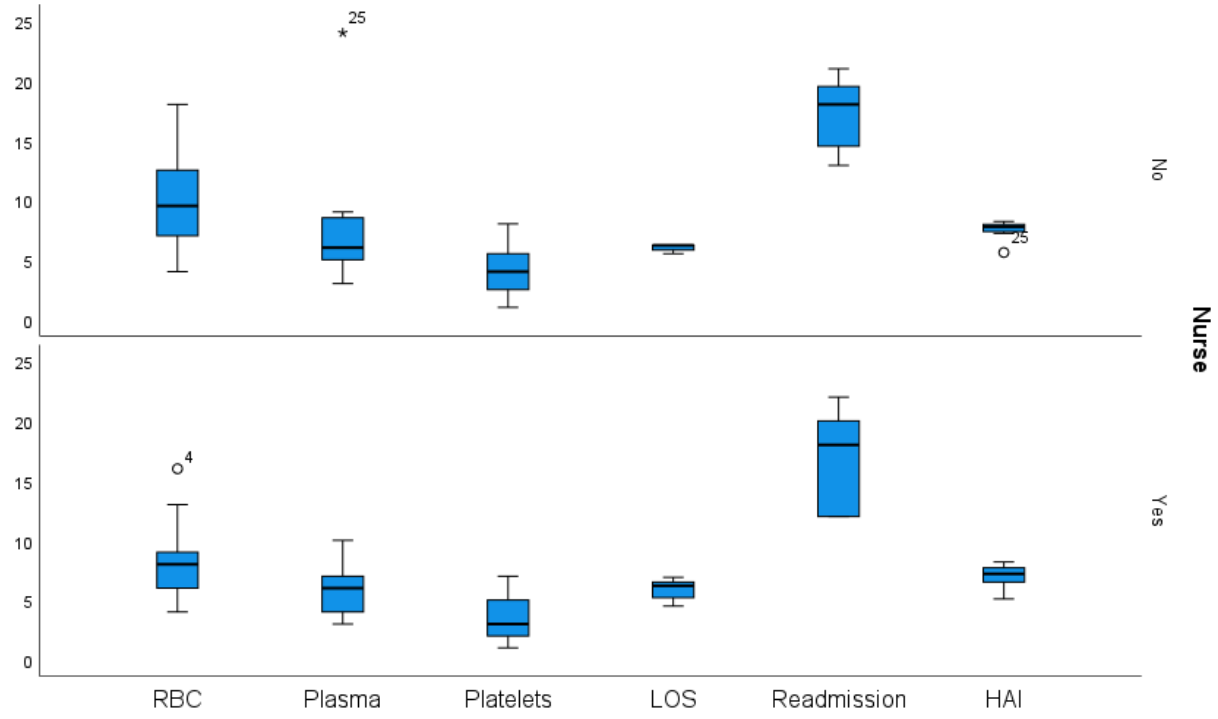


Figure 22

Boxplots of the Six Outcome Variables Paneled by Nurse Variable (Yes/No)



Nurse Correlation Analyses

Correlation analyses were performed between the six outcome variables and the Nurse variable, shown in Table 61. The correlation between the dichotomous Nurse variable and each of the continuous outcome variables is knows as a Point-biserial correlation; it is a special case of the Pearson Correlation. Because of expected violations of parametric assumptions, such as normality, the nonparametric Spearman correlations of the same variables were performed, which is shown in Table 62. The Nurse variable was negatively correlated with the six outcomes, but none were significant statistically. The nonparametric Spearman correlations were like the Pearson correlations: the nurse variable had small, negative correlations with each outcome (except the LOS variable), but none were statistically significant.

Table 61

Pearson Correlations Between the Six Outcome Variables and the Nurse Variable

		RBC	Plasma	Platelets	LOS	Readmission	HAI	Nurse
RBC	Pearson Correlation	--						
	N	26						
Plasma	Pearson Correlation	.791**	--					
	Sig. (2-tailed)	<.001						
	N	26	26					
Platelets	Pearson Correlation	.477*	.386	--				
	Sig. (2-tailed)	.014	.052					
	N	26	26	26				
LOS	Pearson Correlation	.367	.185	.431*	--			
	Sig. (2-tailed)	.065	.365	.028				
	N	26	26	26	26			
Readmission	Pearson Correlation	.017	.045	.335	.486*	--		
	Sig. (2-tailed)	.935	.826	.094	.012			
	N	26	26	26	26	26		
HAI	Pearson Correlation	.137	-.165	.202	.481*	.188	--	
	Sig. (2-tailed)	.504	.420	.322	.013	.357		
	N	26	26	26	26	26	26	
Nurse	Pearson Correlation	-.219	-.270	-.203	-.098	-.047	-.247	--
	Sig. (2-tailed)	.282	.181	.320	.632	.820	.224	
	N	26	26	26	26	26	26	26

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Table 62

Nonparametric Spearman Correlations Between the Six Outcome Variables and Nurse

			RBC	Plasma	Platelets	LOS	Readmission	HAI	Nurse
Spearman's rho	RBC	Correlation Coefficient	--						
		Sig. (2-tailed)	.						
		N	26						
	Plasma	Correlation Coefficient	.736**	--					
		Sig. (2-tailed)	<.001	.					
		N	26	26					
	Platelets	Correlation Coefficient	.430*	.364	--				
		Sig. (2-tailed)	.028	.067	.				
		N	26	26	26				
	LOS	Correlation Coefficient	.454*	.481*	.450*	--			
		Sig. (2-tailed)	.020	.013	.021	.			
		N	26	26	26	26			
	Readmission	Correlation Coefficient	.103	.468*	.314	.468*	--		
		Sig. (2-tailed)	.618	.016	.118	.016	.		
		N	26	26	26	26	26		
	HAI	Correlation Coefficient	.327	.222	.154	.424*	.097	--	
		Sig. (2-tailed)	.102	.276	.451	.031	.637	.	
		N	26	26	26	26	26	26	
	Nurse	Correlation Coefficient	-.208	-.130	-.181	.039	-.051	-.323	--
		Sig. (2-tailed)	.307	.527	.376	.849	.806	.107	.
		N	26	26	26	26	26	26	26

**: Correlation is significant at the 0.01 level (2-tailed).

*: Correlation is significant at the 0.05 level (2-tailed).

Nurse Relationship with Outcome Variables

The second research question asked if there was a relationship between having a TSO that was nurse and the outcomes associated with PBM programs, and the associated null hypothesis was that there was not a relationship between having a TSO that was a nurse and the PBM program outcomes. Statistical analyses were performed to evaluate the relationship between Nurse groups (Yes/No) with each outcome variable. This hypothesized relationship was evaluated in a "forward" sense by testing for statistical difference between group means (or medians) utilizing standard statistical techniques such as analysis of variance (ANOVA) or the nonparametric Mann-Whitney U statistic when parametric assumptions are violated, by using the Nurse grouping variable as an independent variable and the outcome variables as dependent

variables. Alternatively, this hypothesized relationship was also evaluated in a “backward” sense on some variables by using the continuous outcome variables as predictor (independent) variables to predict the group membership of the Nurse variable by using it as a dependent variable in binary logistic regression. Because there were unequal sample sizes, and therefore most likely unequal variances, between each level of the TSO groups, robust and nonparametric statistics were utilized as necessary.

Nurse Relationship with RBC Waste

Table 61 shows a small, negative correlation (r = -.219) between the nurse and RBC variables, which means that having a nurse was associated with a decrease in RBC waste, but not at a level that was statistically significant. Table 63 shows the descriptive statistics and Figure 23 shows boxplots for the RBC variable by nurse groups with a potential outlier in the yes group. The nurse no group had a higher mean, median, and variance than the yes group. Figure 24 shows a histogram of the RBC variable indicating some potential departures from normality. Table 64 includes the tests for normality which show that the distribution of the RBC yes group is significantly different from what would be expected in a normal distribution.

Table 63

RBC Descriptive Statistics by Nurse Group

	Nurse			Statistic	Std. Error
RBC	No	Mean		10.00	1.55
		95% Confidence Interval for Mean	Lower Bound	6.34	
			Upper Bound	13.66	
		5% Trimmed Mean		9.89	
		Median		9.50	
		Variance		19.14	
		Std. Deviation		4.38	
		Minimum		4.00	
		Maximum		18.00	
		Range		14.00	
		Interquartile Range		6.25	
		Skewness		.59	.75
		Kurtosis		.49	1.48
	Yes	Mean		8.39	.70
		95% Confidence Interval for Mean	Lower Bound	6.91	
			Upper Bound	9.87	
		5% Trimmed Mean		8.21	
		Median		8.00	
		Variance		8.84	
		Std. Deviation		2.97	
		Minimum		4.00	
		Maximum		16.00	
		Range		12.00	
		Interquartile Range		3.50	
		Skewness		1.13	.54
		Kurtosis		1.28	1.04

Figure 23

Boxplots for RBC Variable by Nurse Groups

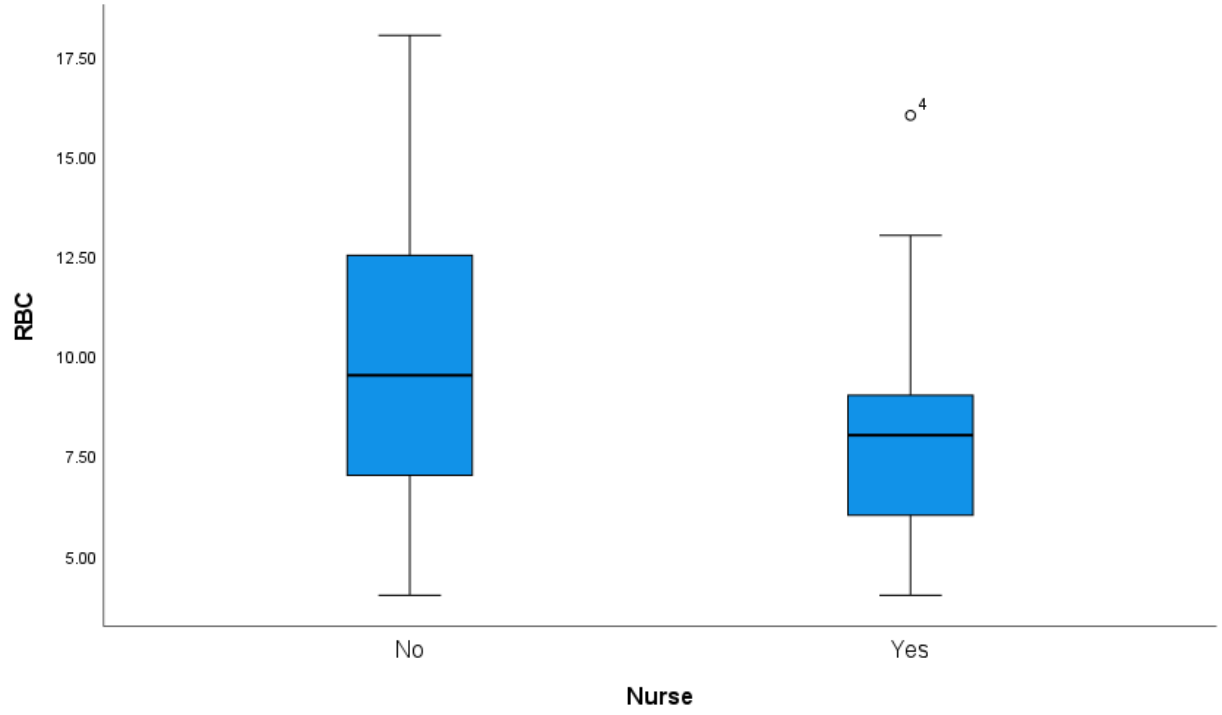


Figure 24

Histogram of RBC Values

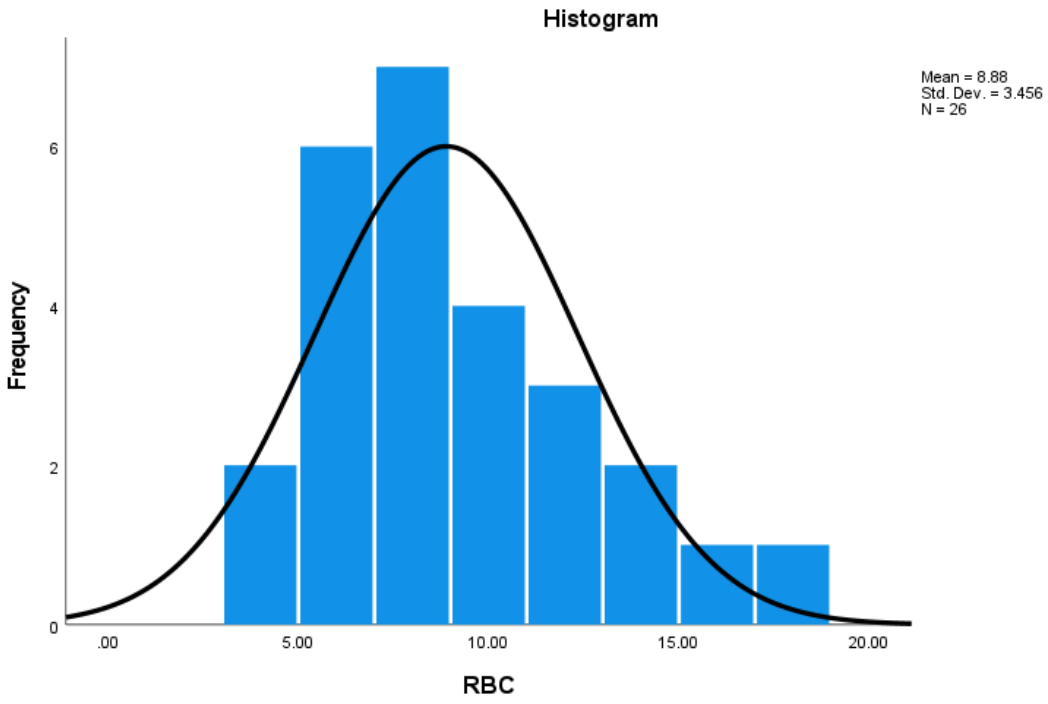


Table 64

Normality Statistics for the Nurse Groups of RBC

		Shapiro-Wilk		
	Nurse	Statistic	df	Sig.
RBC	No	.98	8	.947
	Yes	.90	18	.049

An ANOVA was performed between the two nurse groups on the RBC variable. Table 65 shows the results of the Levene's tests indicating that there was no significant difference in variances between the nurse groups. Table 66 shows the ANOVA result which was not significant with F = 1.21, p = .282. Although not shown, there were no statistical differences between the groups using robust ANOVA tests, independent t-test, Mann-Whitney, or with logistic regression. Sample sizes may not have had enough power to detect differences between the groups.

Table 65

Levene's Tests for RBC ANOVA

		Levene Statistic	df1	df2	Sig.
RBC	Based on Mean	1.32	1.00	24.00	.261
	Based on Median	1.48	1.00	24.00	.236
	Based on adjusted Median	1.48	1.00	22.69	.237
	Based on trimmed mean	1.41	1.00	24.00	.247

Table 66

ANOVA for RBC

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	14.38	1	14.38	1.21	.282
Within Groups	284.28	24	11.85		
Total	298.65	25			

Nurse with Plasma

Table 59 shows a small, negative correlation (r = -.219) between the nurse and plasma variables, which means that having a nurse was associated with a decrease in plasma waste, but not at a level that was statistically significant. Table 67 shows the descriptive statistics and

Figure 25 shows boxplots for the plasma variable by nurse groups with a potential outlier in the no group. The nurse no group had a higher mean and variance than the yes group, due to the outlier, but their medians were the same. Figure 26 shows a histogram of the plasma variable indicating some potential departures from normality. Table 68 includes the tests for normality which show that the distribution of the plasma no group is significantly different from what would be expected in a normal distribution. Table 69 shows the results of the Mann-Whitney test which found no statistically significant differences between the nurse groups on plasma waste, Z = -.65 p = .516

Table 67

Plasma Descriptive Statistics by Nurse Groups

	Nurse			Statistic	Std. Error
Plasma	No	Mean		8.25	2.34
		95% Confidence Interval for Mean	Lower Bound	2.71	
			Upper Bound	13.79	
		5% Trimmed Mean		7.67	
		Median		6.00	
		Variance		43.93	
		Std. Deviation		6.63	
		Minimum		3.00	
		Maximum		24.00	
		Range		21.00	
		Interquartile Range		3.75	
		Skewness		2.40	.75
		Kurtosis		6.22	1.48
	Yes	Mean		5.89	.52
		95% Confidence Interval for Mean	Lower Bound	4.78	
			Upper Bound	6.99	
		5% Trimmed Mean		5.82	
		Median		6.00	
		Variance		4.93	
		Std. Deviation		2.22	
		Minimum		3.00	
		Maximum		10.00	
		Range		7.00	
		Interquartile Range		3.25	
		Skewness		.56	.54
		Kurtosis		-.43	1.04

Figure 25

Boxplots of Plasma Values by Nurse Groups

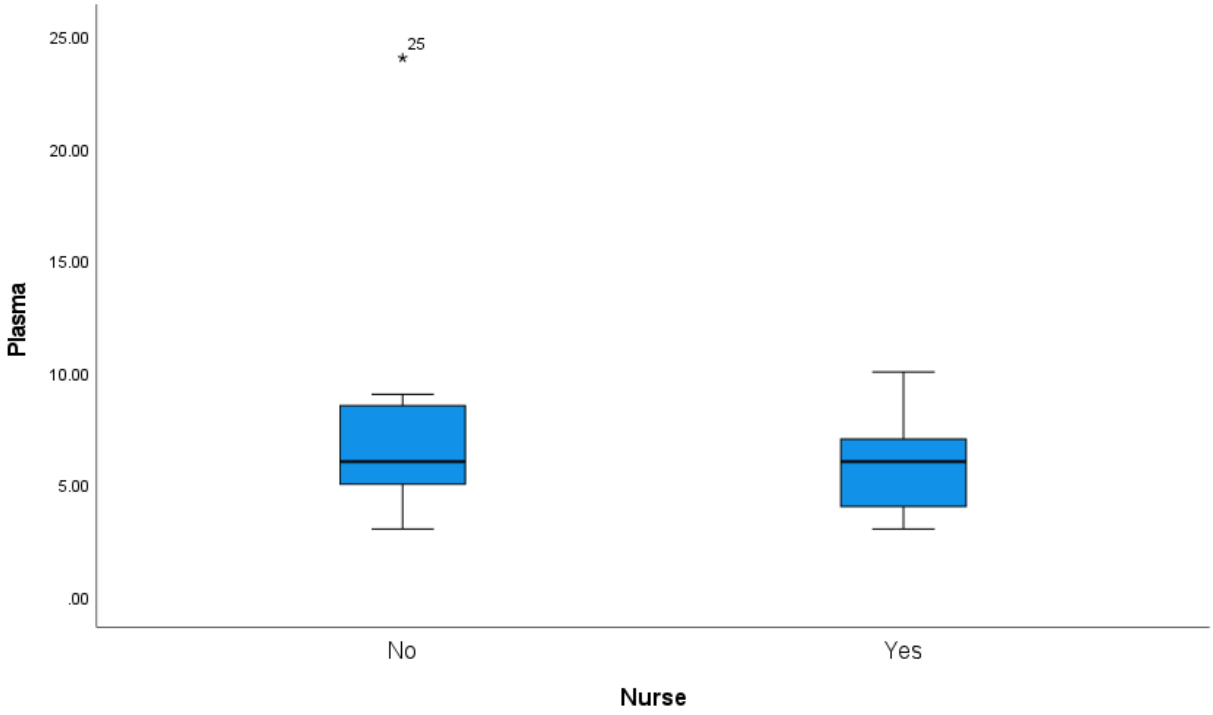


Table 68

Normality Tests for Plasma Variable

		Shapiro-Wilk		
	Nurse	Statistic	df	Sig.
Plasma	No	.68	8	.001
	Yes	.92	18	.117

Figure 26

Histogram of Plasma Values

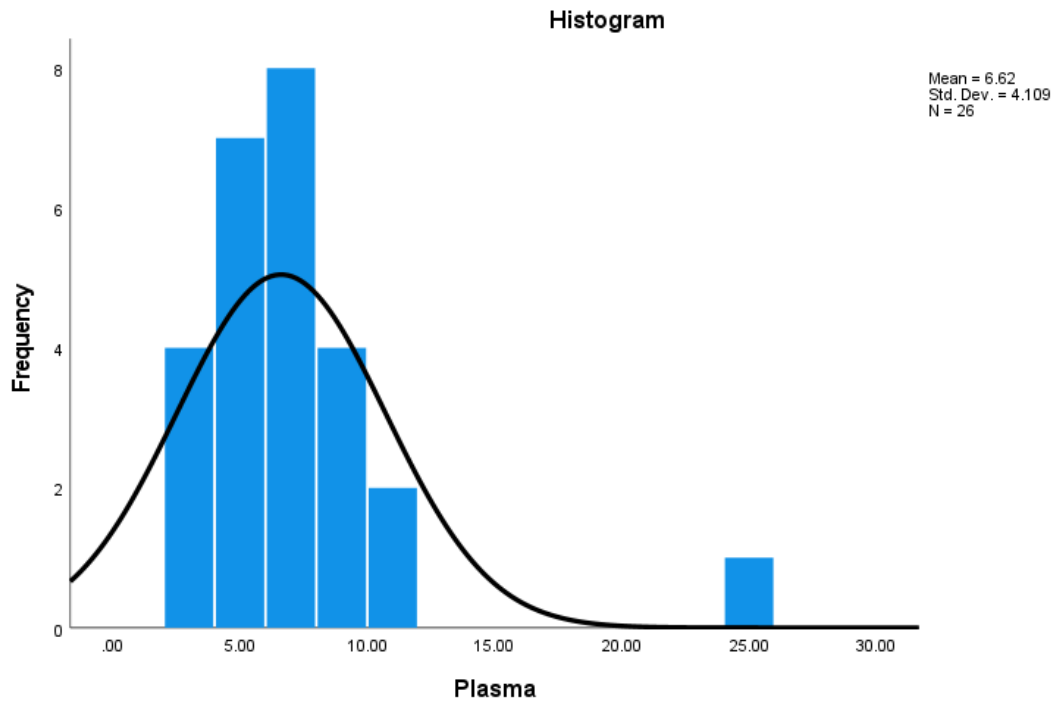


Table 69

Nonparametric Mann-Whitey Test for Plasma

	Plasma
Mann-Whitney U	60.50
Wilcoxon W	231.50
Z	-.65
Asymp. Sig. (2-tailed)	.516
Exact Sig. [2*(1-tailed Sig.)]	.531[b]

b. Not corrected for ties.

Nurse with Platelets

Table 59 shows a small, negative correlation (r = -.219) between the nurse and platelets variables, which means that having a nurse was associated with a decrease in platelet waste, but not at a level that was statistically significant. Table 70 shows the descriptive statistics and Figure 27 shows boxplots for the platelets variable by nurse groups. The nurse no group had a higher mean, median, and variance than the yes group. Figure 28 shows a histogram of the platelets variable indicating some potential departures from normality. Table 71 includes the tests for normality which show that the distribution of the platelets yes group is significantly different from what would be expected in a normal distribution. Table 72 gives the results of the Levene's test which was not significant indicating that the variances of the two groups were similar. Table 73 gives the ANOVA results, which were not significant, F = 1.03, p = .320. Although not shown, no statistical significance was found in tests using robust ANOVA statistics, Mann-Whitney, or logistic regression.

Table 70

Platelet Descriptive Statistics by Nurse Groups

	Nurse			Statistic	Std. Error
Platelets	No	Mean		4.13	.79
		95% Confidence Interval for Mean	Lower Bound	2.26	
			Upper Bound	5.99	
		5% Trimmed Mean		4.08	
		Median		4.00	
		Variance		4.98	
		Std. Deviation		2.23	
		Minimum		1.00	
		Maximum		8.00	
		Range		7.00	
		Interquartile Range		3.50	
		Skewness		.41	.75
		Kurtosis		.01	1.48
	Yes	Mean		3.33	.39
		95% Confidence Interval for Mean	Lower Bound	2.52	
			Upper Bound	4.15	
		5% Trimmed Mean		3.26	
		Median		3.00	
		Variance		2.71	
		Std. Deviation		1.64	
		Minimum		1.00	
		Maximum		7.00	
		Range		6.00	
		Interquartile Range		3.00	
		Skewness		.82	.54
		Kurtosis		-.14	1.04

Figure 27

Boxplots of Platelets Values by Nurse Groups

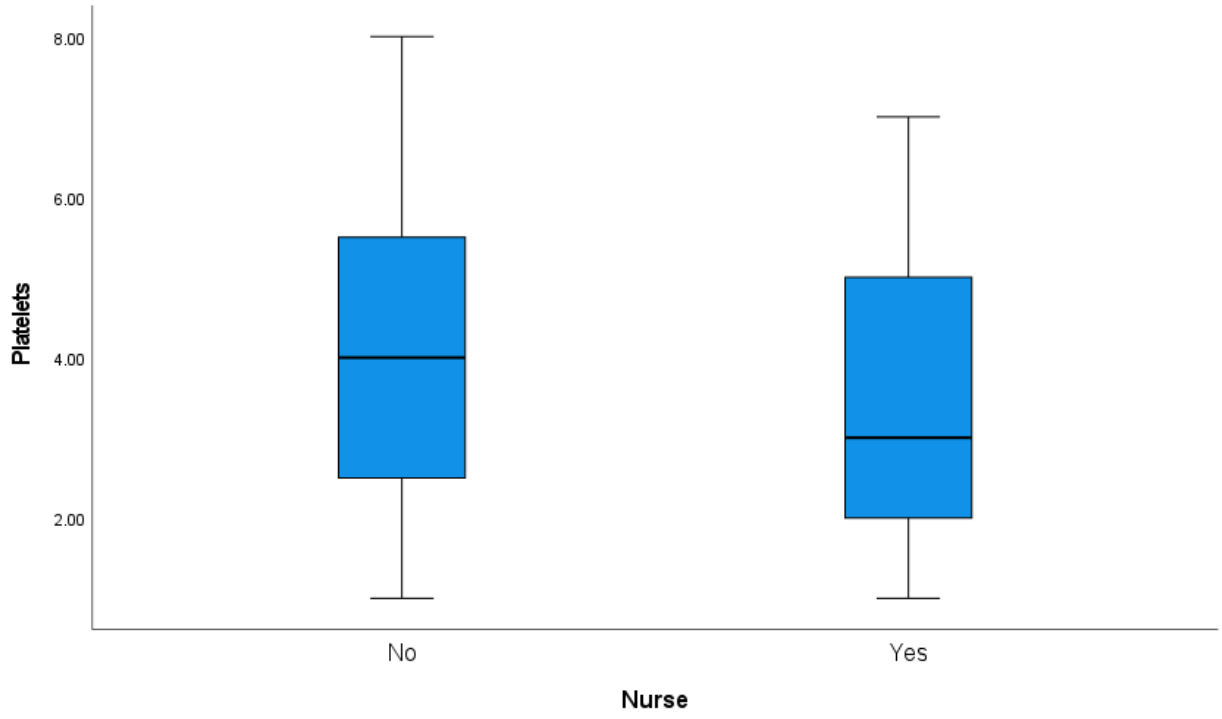


Table 71

Normality Tests for Platelets

		Shapiro-Wilk		
	Nurse	Statistic	df	Sig.
Platelets	No	.98	8	.970
	Yes	.89	18	.042

Figure 28

Histogram of Platelets Values

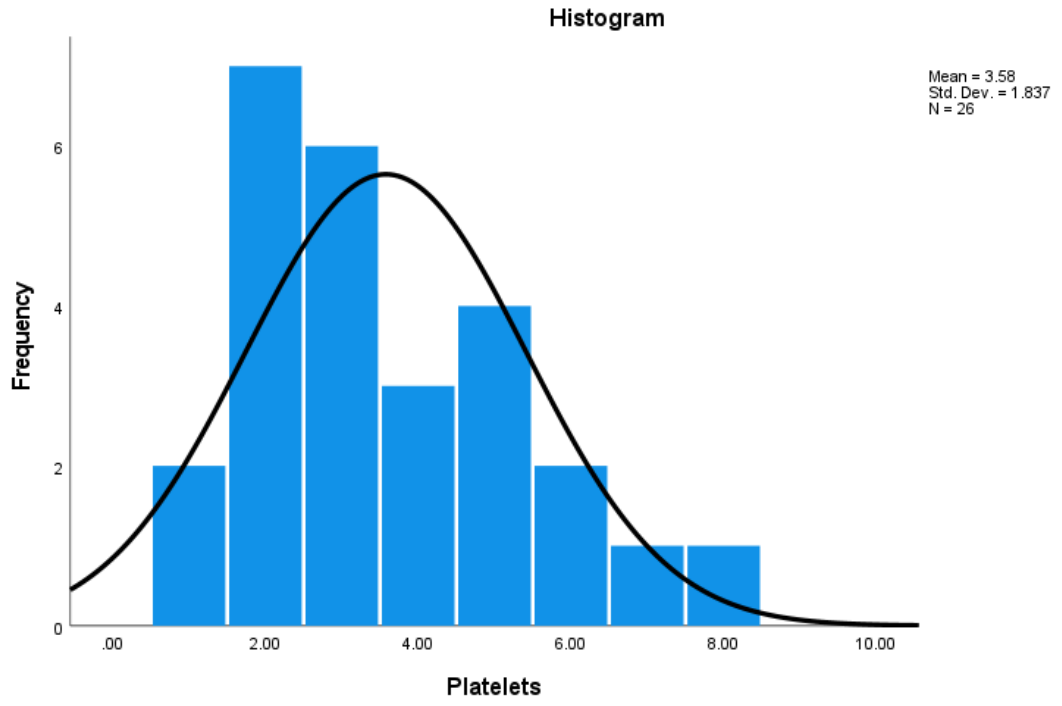


Table 72

Levene's Tests for Platelets

		Levene Statistic	df1	df2	Sig.
Platelets	Based on Mean	.51	1.00	24.00	.480
	Based on Median	.62	1.00	24.00	.440
	Based on adjusted Median	.62	1.00	22.79	.440
	Based on trimmed mean	.53	1.00	24.00	.473

Table 73

ANOVA for Platelets

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	3.47	1	3.47	1.03	.320
Within Groups	80.88	24	3.37		
Total	84.35	25			

Nurse with LOS

Table 59 shows a small, negative correlation (r = -.098) between the nurse and LOS variables, which means that having a nurse was associated with a decrease in hospital length of stay, but not at a level that was statistically significant. Table 74 shows the descriptive statistics and Figure 29 shows boxplots for the LOS variable by nurse groups. Both groups had similar means and medians, but the yes group had a slightly higher variance and much longer range. Figure 30 shows a histogram of the LOS values; Figure 31 shows a histogram of yes values; and Figure 32 shows a histogram of no values: All three histograms show large departures from normality. Table 75 includes the tests for normality which show that the distribution of the no group to be different from what would be expected in a normal distribution. Table 76 gives the Levene's test results in which all tests were statistically significant indicating that the two groups did not have equal variances. Table 77 gives the ANOVA results, which were not significant, F = .24, p = .632. Table 78 gives the Mann-Whitney test results which were not significant, Z = -.20, p = .844. Although not shown, no statistical significance was found in tests using robust ANOVA or logistic regression.

Table 74

LOS Descriptive Statistics by Nurse Group

	Nurse			Statistic	Std. Error
LOS	No	Mean		6.01	.10
		95% Confidence Interval for Mean	Lower Bound	5.78	
			Upper Bound	6.25	
		5% Trimmed Mean		6.03	
		Median		6.20	
		Variance		.08	
		Std. Deviation		.28	
		Minimum		5.50	
		Maximum		6.20	
		Range		.70	
		Interquartile Range		.45	
		Skewness		-1.16	.75
		Kurtosis		-.17	1.48
	Yes	Mean		5.87	.19
		95% Confidence Interval for Mean	Lower Bound	5.48	
			Upper Bound	6.26	
		5% Trimmed Mean		5.89	
		Median		6.20	
		Variance		.62	
		Std. Deviation		.79	
		Minimum		4.50	
		Maximum		6.90	
		Range		2.40	
		Interquartile Range		1.33	
		Skewness		-.37	.54
		Kurtosis		-1.34	1.04

Figure 29

Boxplots of LOS Values by Nurse Groups

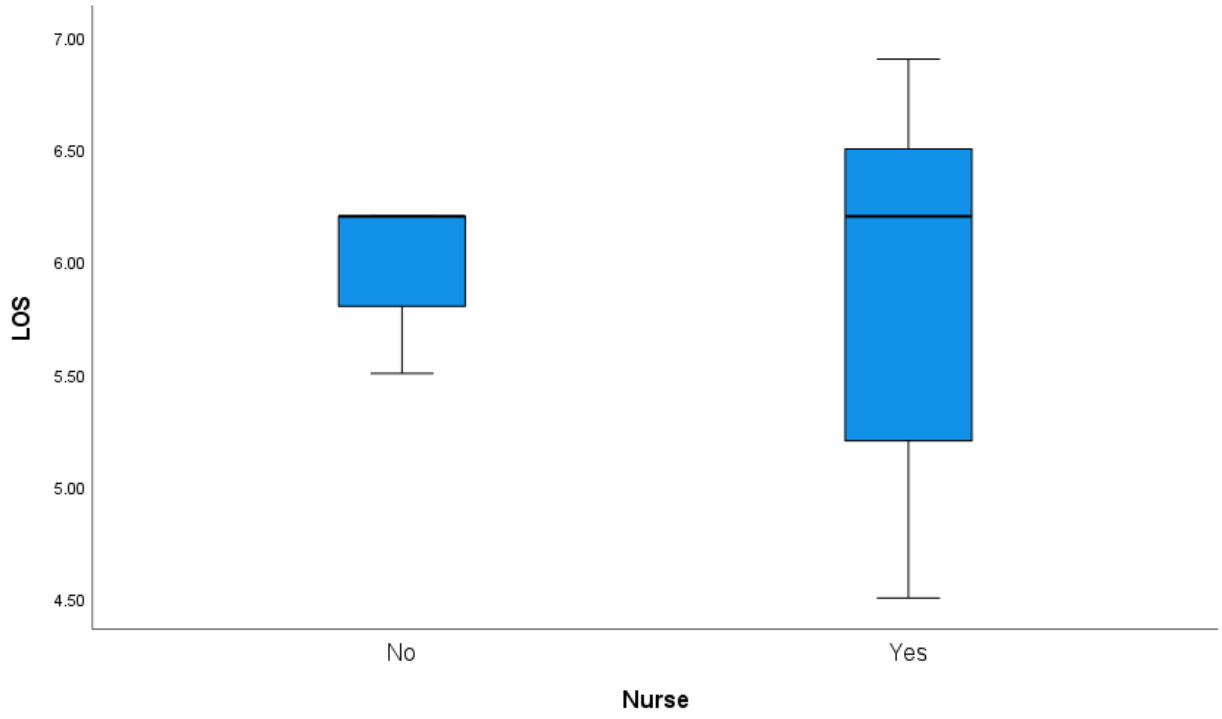


Figure 30

Histogram of LOS Values

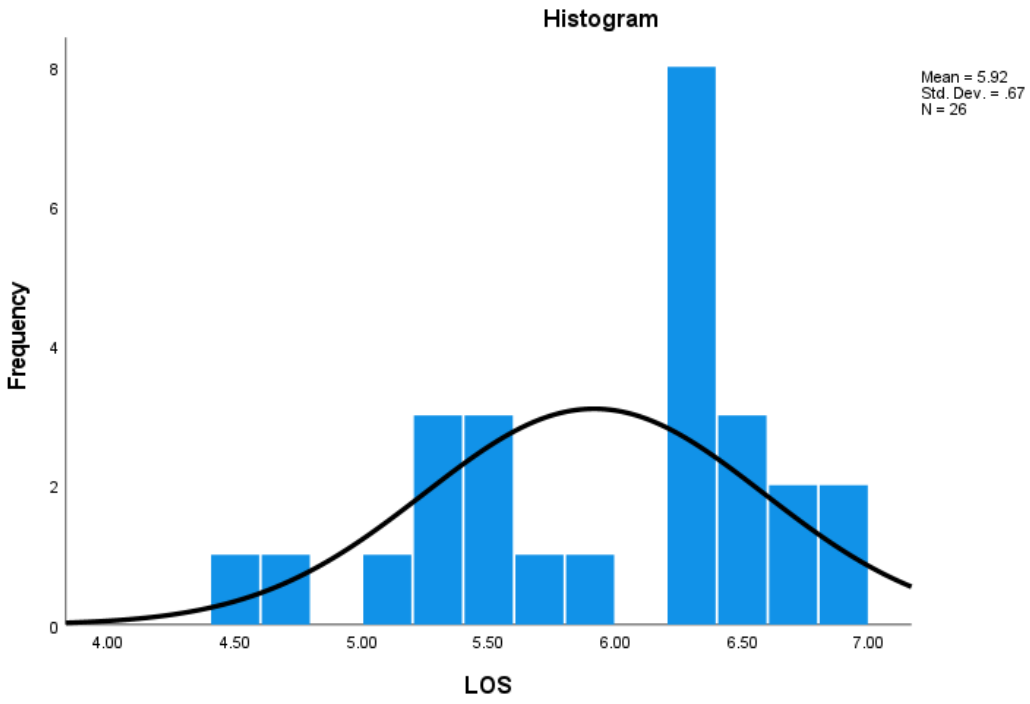


Figure 31

Histogram of Nurse Yes Values for LOS

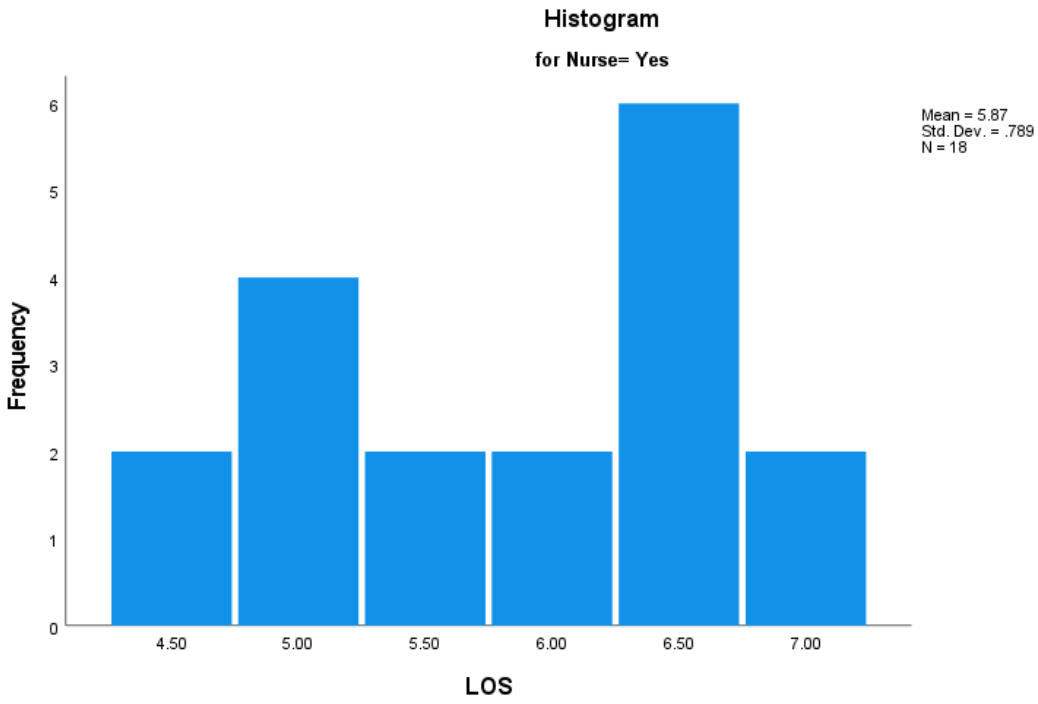


Figure 32

Histogram of Nurse Yes Values for LOS

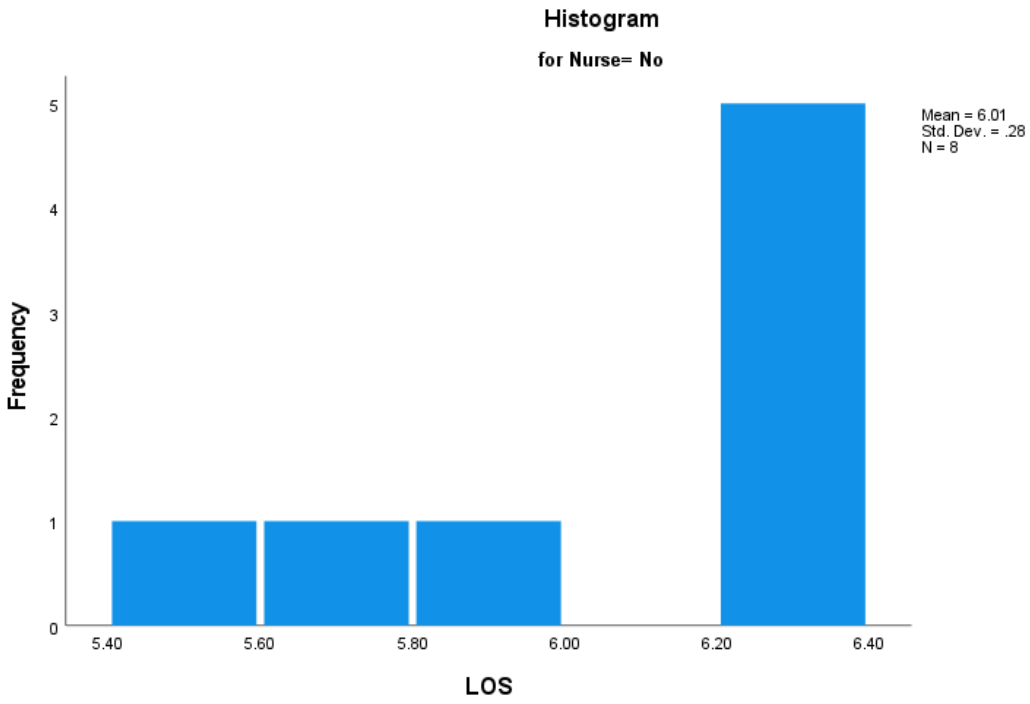


Table 75

Normality Tests for LOS

		Shapiro-Wilk		
	Nurse	Statistic	df	Sig.
LOS	No	.73	8	.005
	Yes	.90	18	.067

Table 76

Levene's Test Results for LOS

		Levene Statistic	df1	df2	Sig.
LOS	Based on Mean	18.16	1.00	24.00	<.001
	Based on Median	6.34	1.00	24.00	.019
	Based on Median and with adjusted df	6.34	1.00	20.74	.020
	Based on trimmed mean	17.49	1.00	24.00	<.001

Table 77

ANOVA for LOS

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.11	1	.11	.24	.632
Within Groups	11.12	24	.46		
Total	11.23	25			

Table 78

Mann-Whitney Results for LOS

	LOS
Mann-Whitney U	68.50
Wilcoxon W	104.50
Z	-.20
Asymp. Sig. (2-tailed)	.844
Exact Sig. [2*(1-tailed Sig.)]	.849[b]

b. Not corrected for ties.

Nurse with Readmission

Table 59 shows a small, negative correlation (r = -.047) between the nurse and readmission variables, which means that having a nurse was associated with a decrease in 30-day readmission rates, but not at a level that was statistically significant. Table 79 shows the

descriptive statistics and Figure 33 shows boxplots for the readmission variable by nurse groups. Both groups had similar means and the same median, but the yes group had a slightly higher variance and a slightly longer range. Figure 34 shows a histogram of the readmission values indicating some departures from normality. Table 80 includes the tests for normality which show that the distribution of the yes group is significantly different from normality on the Shapiro Wilks test. Table 81 gives the Levene's test results in which all tests were not statistically significant indicating that the two groups did have equal variances. Table 82 gives the ANOVA results, which were not significant, $F = .05$, $p = .820$. Although not shown, no statistical significance was found in tests using robust ANOVA, Mann-Whitney, or logistic regression.

Table 79

Readmission Descriptive Statistics by Nurse Groups

	Nurse			Statistic	Std. Error
Readmission	No	Mean		17.24	1.10
		95% Confidence Interval for Mean	Lower Bound	14.62	
			Upper Bound	19.85	
		5% Trimmed Mean		17.27	
		Median		18.00	
		Variance		9.77	
		Std. Deviation		3.12	
		Minimum		12.90	
		Maximum		21.00	
		Range		8.10	
		Interquartile Range		6.50	
		Skewness		-.32	.75
		Kurtosis		-1.02	1.48
	Yes	Mean		16.89	.88
		95% Confidence Interval for Mean	Lower Bound	15.04	
			Upper Bound	18.74	
		5% Trimmed Mean		16.88	
		Median		18.00	
		Variance		13.87	
		Std. Deviation		3.72	
		Minimum		12.00	
		Maximum		22.00	
		Range		10.00	
		Interquartile Range		8.25	
		Skewness		-.26	.54
		Kurtosis		-1.57	1.04

Figure 33

Boxplots of Readmission Values by Nurse Group

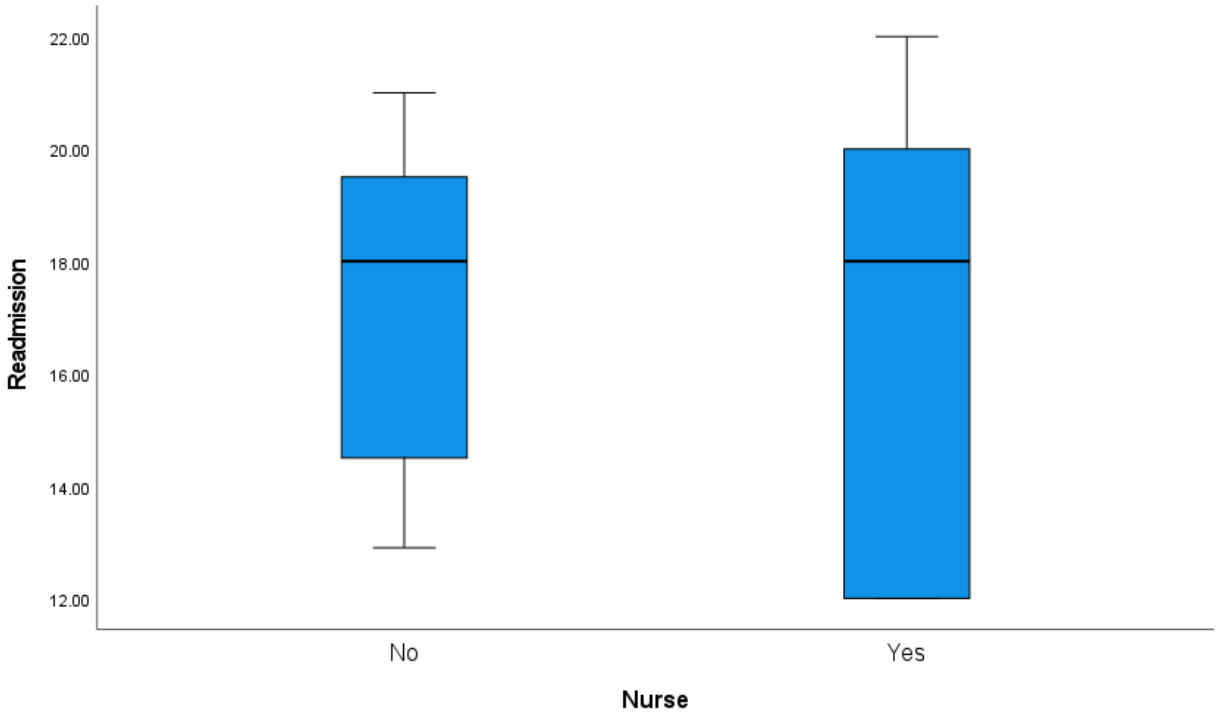


Figure 34

Histogram of Readmission Values

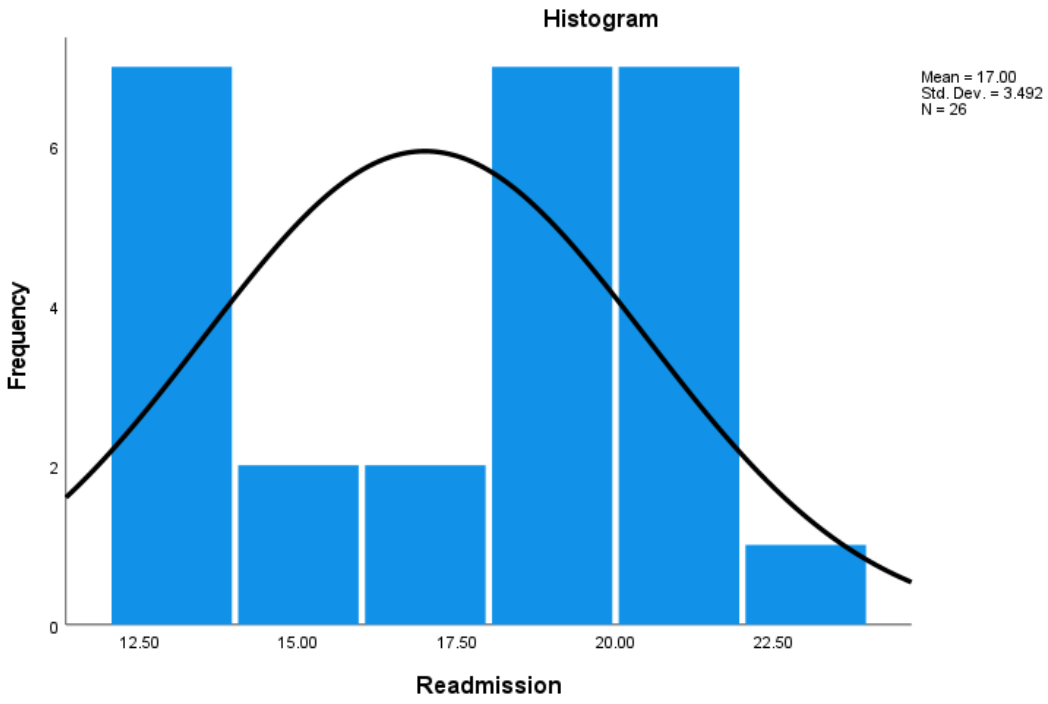


Table 80

Normality Tests for Readmission

		Shapiro-Wilk		
	Nurse	Statistic	df	Sig.
Readmission	No	.89	8	.214
	Yes	.87	18	.017

Table 81

Levene's Test for Readmission

		Levene Statistic	df1	df2	Sig.
Readmit	Based on Mean	1.26	1.00	24.00	.272
	Based on Median	.83	1.00	24.00	.372
	Based on Median and with adjusted df	.83	1.00	23.97	.372
	Based on trimmed mean	1.30	1.00	24.00	.266

Table 82

ANOVA Results for Readmission

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.67	1	.67	.05	.820
Within Groups	304.14	24	12.67		
Total	304.81	25			

Nurse with HAI

Table 59 shows a small, negative correlation (r = -.247) between the nurse and HAI variables, which means that having a nurse was associated with a decrease in hospital-acquired infection rates, but not at a level that was statistically significant. Table 83 shows the descriptive statistics and Figure 35 shows boxplots for the HAI variable by nurse groups indicating a potential outlier. The no group had slightly higher mean and median, but the yes group had a slightly higher variance. Figure 36 shows a histogram of the HAI values indicating some departures from normality. Table 84 includes the tests for normality which show that the distribution of the no group is significantly different from normality by the Shapiro Wilks test. Table 85 gives the Levene's test results; none of the tests were statistically significant indicating that the two groups did have equal variances. Table 86 gives the ANOVA results, which were

not significant, F = 1.56, p = .820. Although not shown, no statistical significance was found in tests using robust ANOVA, Mann-Whitney, or logistic regression.

Table 83

HAI Descriptive Statistics by Nurse Group

	Nurse			Statistic	Std. Error
HAI	No	Mean		7.49	.29
		95% Confidence Interval for Mean	Lower Bound	6.80	
			Upper Bound	8.18	
		5% Trimmed Mean		7.55	
		Median		7.75	
		Variance		.68	
		Std. Deviation		.83	
		Minimum		5.60	
		Maximum		8.20	
		Range		2.60	
		Interquartile Range		.70	
		Skewness		-2.07	.75
		Kurtosis		4.77	1.48
	Yes	Mean		7.04	.20
		95% Confidence Interval for Mean	Lower Bound	6.61	
			Upper Bound	7.46	
		5% Trimmed Mean		7.08	
		Median		7.20	
		Variance		.73	
		Std. Deviation		.85	
		Minimum		5.10	
		Maximum		8.20	
		Range		3.10	
		Interquartile Range		1.25	
		Skewness		-.88	.54
		Kurtosis		.15	1.04

Figure 35

Boxplots of HAI Values by Nurse Groups

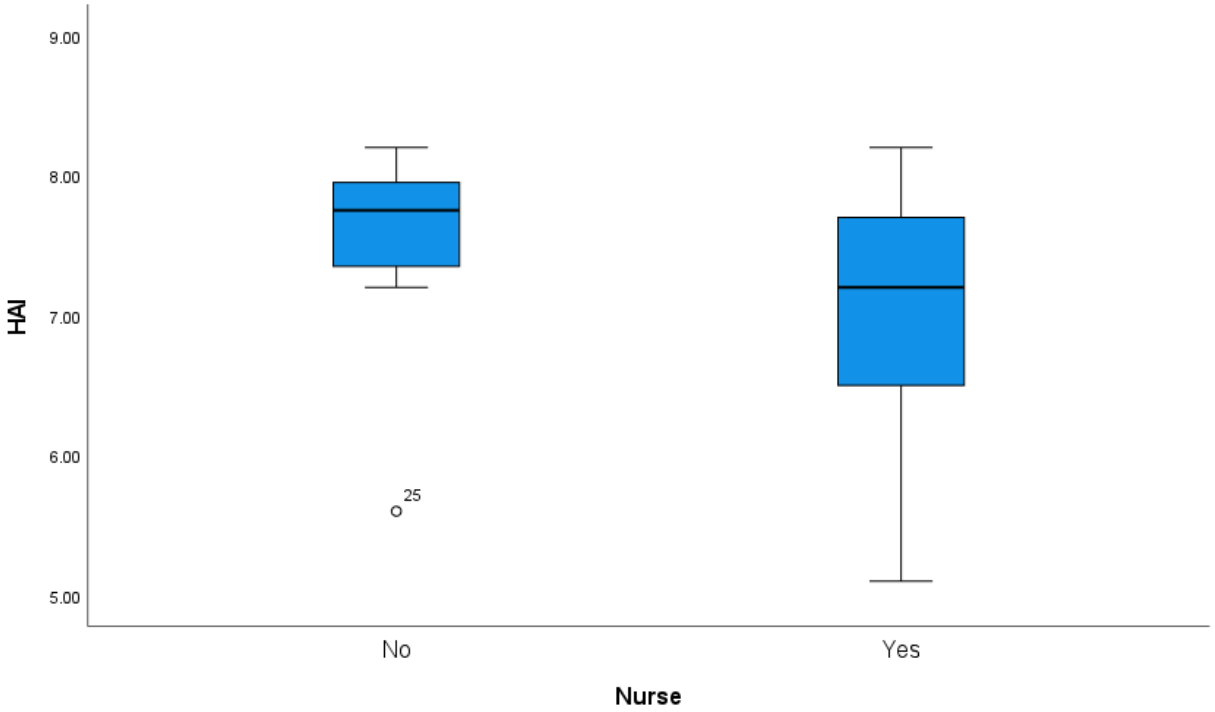


Figure 36

Histogram of HAI Values

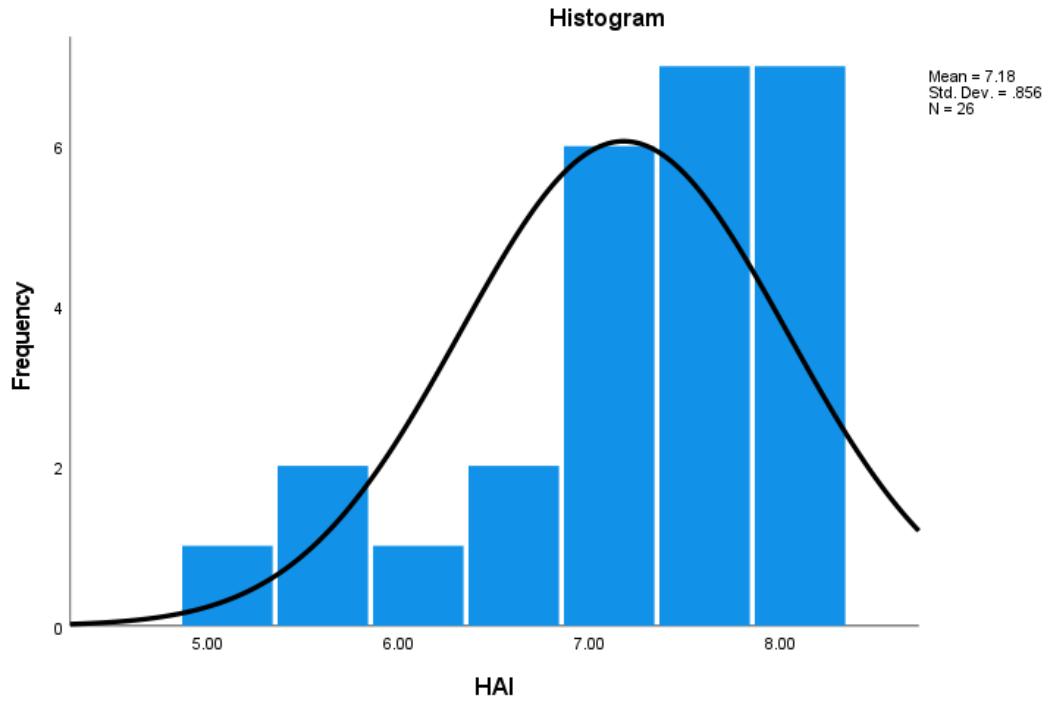


Table 84

Normality Tests for HAI

		Shapiro-Wilk		
	Nurse	Statistic	df	Sig.
HAI	No	.77	8	.013
	Yes	.93	18	.204

Table 85

Levene's Test for HAI

		Levene Statistic	df1	df2	Sig.
HAI	Based on Mean	.30	1.00	24.00	.588
	Based on Median	.30	1.00	24.00	.592
	Based on Median and with adjusted df	.30	1.00	23.15	.592
	Based on trimmed mean	.36	1.00	24.00	.555

Table 86

ANOVA for HAI

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1.11	1	1.12	1.56	.224
Within Groups	17.19	24	.72		
Total	18.31	25			

Summary of Second Null Hypothesis

Hypothesis testing for the second null hypothesis was performed by using correlational analyses and statistical analyses in both "forward" and "reverse" directions. All six of the outcome variables showed weak, negative correlations that were statistically non-significant with the nurse variable with no statistically significant differences between the nurse groups on each outcome; therefore, the second null hypothesis was accepted. Because the sample sizes were so small, it is possible that the sample did not have adequate power and larger sample sizes could detect stronger relationships between these variables. However, there results provide no evidence that a requirement for a TSO to be a nurse is necessary.

Chapter Summary

This chapter addressed the data analyses and statistical results of the two main grouping variables (TSO and nurse), and evaluated the null hypotheses presented in Chapter 3. The next chapter will be a discussion of these findings including study limitations and suggestions for future research.

CHAPTER 5: DISCUSSION

Introduction

This chapter will discuss the study results, limitations, conclusions, and implications for future research. The purpose of this study was to examine the relationship between having a Transfusion Safety Officer (TSO) and the outcomes associated with Patient Blood Management (PBM) programs, as well as the relationship of the TSO being a nurse to the PBM outcomes. The aims of this quantitative, nonexperimental, descriptive study were to describe and test these relationships by utilizing a cross-sectional survey design with a pre-validated instrument. There were two research questions associated with this study asking if there was a relationship between having a TSO and the PBM outcomes, and if there was a relationship between the TSO being a nurse and the PBM outcomes; the null hypotheses for each question were that there was no relationship between either group (TSO or nurse) and the outcomes of the PBM programs. The TSO null hypothesis was rejected, but the nurse null hypothesis was accepted. To date, no other studies have looked at these relationships.

Blood transfusion is often a matter of life and death; therefore, it is important that hospitals have adequate safety systems in place to protect their patients. PBM programs are often the standard of care in most hospitals. A TSO has been identified by some as being a crucial part of successful PBM programs; further, some hospitals have a requirement that the TSO is a nurse. To date, no studies have been performed to show the effects that a TSO has on PBM outcomes, or that there even is a relationship between these variables. The theoretical constructs used in the study were the Donabedian domains of structure and outcome: The TSO and nurse grouping variables were used for the structure domain, and the six PBM associated outcome variables were used for the outcome domain.

Sampling Overview

This study utilized purposive and snowball sampling to identify transfusion professionals from as many hospitals as possible. Subjects were recruited via email or by posting a flyer with a link to the survey to professional groups or organizations such as Facebook, LinkedIn, Association for the Advancement of Blood & Biotherapies (AABB), Society for the Advancement of Patient Blood Management (SABM), American Society for Clinical Laboratory Science (ASCLS), and Specialist in Blood Banking (SBB) student programs. The only other survey of TSOs by Jacobs and colleagues (2021) obtained responses from 54 hospitals.

There were 81 respondents to the survey. Five of the respondents did not complete the survey and five answered "not sure" to having a PBM program. Two respondents answered the PBM and TSO questions, but responded "Don't Know" to all the outcome questions. One respondent answered "Not Sure" to having a TSO. Two respondents had responses that contained obvious outliers. All these responses were deleted, which left n = 66 respondents for further analysis.

All the respondents were able to answer the first three outcome variables about blood product waste (RBC, plasma, and platelets), which are more closely linked to the blood transfusion service. However, many respondents struggled with the last three outcome variables that were more hospital-wide (LOS, readmission, and HAI). Therefore, the resulting data set had many responses that were missing the last three outcomes as a block. Many of these problematic responses came early in the sampling when the survey had only gone out to students in the SBB programs; most likely they were only knowledgeable about the first three outcome variables having to do with product waste that is closely aligned to blood transfusion departments in which they work. When the survey began making its way through the TSO networks, there were responses in greater number and quality.

The HAI question seemed to be particularly problematic for respondents. Because only 43 respondents gave valid responses to this variable, the data set was sorted by this variable, and the other incomplete responses were deleted. It is questionable as to whether these responses can be considered "missing data" because the respondents answered "No" or "Don't Know" to the question that asked about their knowledge of that outcome variable, or they gave an invalid answer. As shown in Chapter 4, the separate variance t tests in a missing values analysis showed no systematic relationship between missingness on these variables with the other variables. Therefore, most likely these missing values were due to poor sampling techniques, i.e. not finding the best respondents to provide this information. The clean data set showed many less outliers than the original data set.

Results and Hypotheses

TSO group. This study was the first to look at the relationship between having a TSO and outcomes associated with PBM programs. These outcomes are tracked by the hospital quality assurance and all are reported to agencies or organizations such as the Centers for Medicare & Medicaid Services.

Null Hypothesis 1

The purpose of hypothesis 1 was to describe and test the relationship between having a TSO and the outcome variables that are associated with PBM programs. The correlational and statistical analyses support a strong, negative correlational relationship between having a TSO and each of the outcome variables tested, meaning that having a TSO was associated with a decrease of blood product wastage (red blood cells, plasma, and platelets), lower hospital lengths of stay, lower rates of 30-day readmissions, and lower rates of hospital-acquired infections. The

null hypothesis of there being no relationship between having a TSO and the PBM outcomes was rejected.

The TSO groups showed statistically significant differences in their means or medians in each outcome variable with moderate effect sizes between the two groups. Further, each outcome variable could be used to predict the group membership of the TSO variable; or in other words, each outcome variable could predict whether the hospital had a TSO or not. Outside of occasional outliers, the groups with a TSO usually had much lower variances and ranges in each outcome indicating that the process was more uniform with less variability. All these results indicate a very strong statistical relationship between the TSO variable and the six outcome variables. The beds variable was highly positively correlated with the TSO variable indicating that larger hospitals were more likely to have a TSO than smaller hospitals. Interestingly, the beds variable showed small, negative correlations with the waste variables that were not statistically significant, but had moderate to strong, negative correlations with the LOS, readmission, and HAI variables.

These statistical results need to be interpreted with caution due to the study's small sample sizes, until the results are replicated in other studies with larger sample sizes, and due to the inability to sperate the effects of having a PBM program from having a TSO since the PBM no group (n = 21) was merged with the small group (n = 8) of hospitals that had a PBM program but no TSO. In addition, all these statistical results are correlational in nature and cannot determine causation or the direction of the relationship. There could be a third variable that controls these relationships: those hospitals that are diligent about reducing their blood product wastage, lengths of stays, 30-day readmissions, and hospital-acquired infections also employ a

TSO, which could mean that these variables are all measuring the same thing. Perhaps having a PBM program is the main factor that is causing all of the effects on the outcomes.

Franchini and colleagues (2019) in their literature review showed that PBM programs significantly reduced the number of blood transfusions and hospital outcomes such as LOS. These results of this study indicated that having a TSO can be viewed in the same light as the other hospital-wide outcomes (LOS, readmission, and HAI): As being part of the overall safety features of higher performing hospitals that have better quality indicators. Having a TSO can increase safety and help reduce the variance in the six PBM outcomes. A TSO can also help to reduce wastage of blood products and costs associated with blood transfusion.

The TSO fits into the larger profile of higher performing hospitals that have better performance and quality indicators. Most likely, all these variables vary together in one direction and may all be measuring the same underlying safety construct. If a larger sample size can be obtained, then exploratory and confirmatory factor analyses can give an indication of the underlying constructs in the data by performing a dimensionality test to indicate whether there is only one underlying construct that is being measured or more than one construct. These types of tests often require sample sizes well over one hundred, so were not possible with the results of this data set.

This study also highlighted the difficulties in getting the information needed for data analysis. When it was possible to get responses, many respondents were not aware of the set of three hospital-wide outcomes, whether their hospital had a PBM program, a TSO, or whether the TSO was a nurse. Some personnel were hesitant to give the information requested for fear of making the hospital look bad.

These results can be reflective of a lack of communication about quality goals, or lack of feedback to personnel. The employees of many hospitals file one or multiple quality reports and often are not notified of the results or if anything has been done about what they reported. In addition, the results are indicative of a lack of knowledge of hospital outcomes and goals, including PBM programs. These results could indicate a need for better communication between hospital administrators and personnel. Higher performing hospitals often have quality goals and metrics clearly available for their personnel to see, usually as part of screen savers or on the dashboards of computer terminals when personnel sign into the hospital computer system to perform their job duties. More awareness of these quality results and hospital goals could lead to better knowledge and performance in these outcomes.

Nurse group: This study was the first to look at the relationship between having a TSO who is a nurse and the six outcomes associated with PBM programs. Some hospitals have a requirement that the TSO is a nurse.

Null Hypothesis 2

The purpose of null hypothesis 2 was to describe and test the relationship between having a TSO who was nurse and the outcomes of PBM programs. The results for this null hypothesis are almost exactly the opposite of the results for the first null hypothesis: There was a weak negative correlation between the nurse variable and each of the outcomes, but it was not statistically significant. None of the statistical analyses were significant; therefore, the null hypothesis was not rejected.

The nurse sample had very small group sizes and it is possible that the sample did not have enough statistical power to reject the null hypothesis. Larger sample sizes will be needed to

determine the strength of this relationship. However, there is no evidence from this study to support the requirement that some hospitals have that a TSO is a nurse.

Most likely other blood transfusion professionals could fill this role equally as well as a nurse, which can be important when there are staffing shortages. In addition, the question remains about whether this role can be filled by only one person or should there be a team of professionals performing these duties. The Jacobs and colleagues (2021) survey indicated that some hospitals had multiple TSOs; it would be interesting to know the outcomes of those hospitals with multiple TSOs. Franchini and colleagues (2019) indicated that combinations of different strategies tend to increase PBM effectiveness. Perhaps those hospitals with more than one TSO have better outcomes than those that only have one TSO.

Study Limitations

This study had several limitations with the biggest limitation being a lack of sampling frame; therefore, there was no chance of random sampling and it was very difficult to find people to contact to invite to participate in a survey. The lack of random sampling can create unequal comparison groups that may not be representative of the larger population. A related limitation was that there was a very low response rate with many missing values, which makes the likelihood greater that there is sampling bias and the sample is not representative of the larger population. Due to the merging of groups 1 and 2, it was not possible to differentiate the effects of having a PBM program from the effects of having a TSO.

Another major limitation had to do with human error. There were several people who were hesitant to give information and were concerned about divulging possible bad outcomes of their hospital. In addition to the typical limitations of self-reporting, many of the early responders were students from the SBB programs who were not as knowledgeable as those who were TSOs or in quality departments, which contributed to missing and invalid responses. In addition, there

could have been entry errors and a lack of understanding of what the questions were asking. Some respondents gave invalid responses to some of the questions, such as a negative rate or decimals that if changed to percentages would have been outliers, which indicated a lack of knowledge of the information or lack of understanding of what the question on the survey was asking.

Although the survey questions were pretested with some blood transfusion professionals who were not TSOs and it appeared that the answers to the questions were readily available to be easily input into the survey link from these respondents, other respondents may not have been as aware of the availability of this information. The TSOs who validated the survey found the questions easy to understand and the information easy to find, but this might not be true for the average blood transfusion professional who may not have the awareness or knowledge of the results of these hospital outcomes, such as length of stay, rate of 30-day readmission, and rate of hospital-acquired infections. Conversely, TSOs and quality personnel handle this information as part of their job duties and are very aware of these results and what they mean.

Clinical Implications

The success of PBM programs have been revolutionizing the practice of transfusion medicine and have been providing the means to increase patient safety and the chances of having better hospital outcomes, such as reduced lengths of stay, reduced 30-day readmission rates, and reduced rates of hospital-acquired infections. The groups with a TSO showed better outcomes: There was less wastage, lower hospital lengths of stay, lower rates of readmission, and lower rates of HAI in the group that had a TSO. The TSO groups had statistically significant differences in each of the six outcome variables. Furthermore, the groups with a TSO had less variability in these outcomes indicating more uniform results in these groups. This study indicates that having a TSO is an important part in attaining better PBM associated outcomes.

Although the waste of blood products is not a good outcome in any sense, perhaps high rates of blood product waste could be another indicator of a poorly performing hospital, as the other three hospital-wide outcomes in this study are viewed. In this view, perhaps the high correlations between RBC wastage and the three hospital outcomes should not be as surprising as it was. It seems plausible that those hospitals with longer lengths of stay, higher rates of 30-day readmissions and higher rates of hospital-acquired infection would also have higher amounts of blood product wastage. All these variables could vary together in lock step, a poor value on one of these variables could be indicative of a poor value on the other variables.

This study provides preliminary information for the future studies of the relationship between having a TSO and the PBM outcomes to better elucidate these relationships and perhaps for the design of a study to show causation. This study and future studies could help to inform hospital managers and administrators in their decisions to have a TSO and whether the TSO needs to be a nurse.

Recommendations for Future Research

This study was the only known study to look at the relationship between having a TSO and the outcomes of PBM. This study would need to be replicated with a larger sample size for firmer inferences to be drawn. In addition, more hospitals that have a PBM program but not a TSO need to be identified to separate the effects of having a TSO from the effects of having a PBM program.

The variables in this study could be expanded to include additional outcomes associated with PBM such as the decrease in product usage. Some of these outcome variables in this study could be eliminated: Because RBC waste was highly correlated with the plasma and platelets variables, it is the only one of the three waste variables that needs to be measured as it already

explains almost all the waste variance. In addition, the plasma and platelets variables had many more outliers which makes statistical interpretation more difficult; most likely they would be eliminated from future studies.

In deciding which variables to measure and in planning for the statistical analyses of future studies, it should be noted that many of these outcomes presented challenges for statistical analysis, especially those relying on parametric techniques: many of the distributions were skewed or non-normal, with many potential outliers. Conversely, it was somewhat surprising how well the parametric tests performed in samples that failed the in the assumptions underlying the tests. Likewise, robust, and nonparametric techniques should be utilized where appropriate to handle the departures from parametric assumptions.

The inclusion criteria should be changed to target TSOs or quality assurance participants, rather than blood transfusion directors or blood transfusion professionals at large. The TSO participants gave better quantity and quality of information to the questions. TSOs were also more likely to respond to the survey through TSO professional networks.

Better sampling techniques are needed to improve the response rate. If a survey is used, then more effort is needed to make sure that they questions are clear and understandable. Perhaps including information about how to find the reported data from their hospitals via internet searches or more encouragement to contact quality personnel.

The survey branching logic should be carefully considered. There were several respondents who did not know if they had a PBM program, but some may have known that there was a TSO at their hospital.

This study would have been better performed as a secondary data analysis. However, no available database was found to search for reported information. Often these types of data are

reported in aggregate or by region. The National Blood Collection & Utilization Survey mentioned previously asks about TSOs but does not link the TSO with the PBM outcomes. Likewise, it is not known if access is allowed to the raw data from these surveys. Most of the organizations contacted for this survey would not even give out their mailing lists to directly contact their members.

A sampling frame would greatly benefit future researchers who are doing a survey. The question about how best to collect this information remains, as well as the availability of any reported hospital data: what is the best way to approach studying this relationship. A sampling frame would provide better ways to contact people to ask for the information and would make inferential statistics more viable.

As mentioned above, future surveys need to be designed to address the problem of poor response rates. The inclusion criteria need to be changed from targeting medical directors to targeting TSO and quality personnel networks, which gave more responses of better quality. Most likely several modes of sampling will need to be utilized to get a higher response rate. If resources permit, perhaps including an interviewer to help in understanding the questions.

Conclusion

The purpose of this study was to describe and test the relationship between having a TSO and the outcomes associated with PBM programs, as well as describing and testing the relationship between the TSO being a nurse and the same outcomes. Blood transfusion is often a matter of life and death and adequate safety systems need to be in place for enhanced patient safety.

This study provided preliminary evidence about the strength of the relationship between having a TSO and outcomes associated with PBM programs. The study helps to establish that

there is a relationship between having a TSO and outcomes associated with PBM. This study shows that the relationship could be measured and that the relationship appears to be strong. This study showed that the groups with a TSO had less blood product wastage, lower hospital lengths of stay, lower rates of 30-day readmissions, and lower rates of hospital-acquired infections. Furthermore, the groups with a TSO had less variability in the results of their outcomes indicating more uniform processes. This study will need to be replicated with larger sample sizes to enhance the generalizability of these results.

The results of this study could better inform hospital managers and administrators on the importance of having a TSO. In addition, this study could aid in the decision of whether the TSO needs to be a nurse or another blood transfusion professional.

This study highlighted the problems inherent in measuring these variables. With no known sampling frame, random sampling was not possible. When participants were found to provide information, there was often a lack of knowledge about the systems the hospital has in place, such as having a PBM program or a TSO, as well as a lack of knowledge about how well the hospital is performing in key outcomes, such as length of stay, rates of 30-day readmission, and rates of hospital-acquired infections.

Larger sample sizes are needed to better understand the relationship between having a nurse as a TSO and the PBM outcomes, although this study did establish that it is possible to measure this relationship. This study did not provide any evidence that a requirement is needed for a TSO to be a nurse. Most likely, multiple professionals could be effective in filling this role which is important when there are staffing shortages.

This study is the first study to describe and test these relationships and can inform future researchers and policy makers about the necessity of having a TSO and whether the TSO needs to be a nurse.

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APPENDIX 1

Blood Management and Transfusion Safety

WELCOME fellow blood transfusion professionals!

You have been invited to participate in a doctoral research study entitled "The Relationship Between Outcomes Associated with Patient Blood Management Programs and Transfusion Safety Officers." This survey will ask questions about outcomes associated with blood management and transfusion safety. Responses are welcome from hospitals of all sizes, regardless of whether they have an official Patient Blood Management program or a designated Transfusion Safety Officer. We hope that our results will give insight into how well transfusion facilities are performing by asking questions about quality metrics that are usually collected in blood banks or reported by the hospital. Your responses are very valuable: They will let us know how improvements can be made to make transfusion workflow more productive and improve patient safety.

Your responses will be based on quality outcomes at your facility. The information you provide will be strictly confidential and will only be used for research purposes. You have the right to refuse to answer any question or withdraw from the survey at any time.

This survey has two (2) sections. This survey is designed to be completed in 20 to 25 minutes, depending on how familiar you are with the quality outcomes at your facility. There are some facility demographic and quality outcome questions which may not be readily available to you, but which should be easy to find by conducting an internet search of your facility or asking your manager or quality coordinator.

Thank you for participating in this doctoral study. Your input is valued and appreciated!

If you have any technical difficulties, questions, or concerns, please feel free to contact: Gary Morral MS, MLS(ASCP)SBB at morralgw@vcu.edu or (540) 705-7731. As a transfusion professional, I welcome any feedback that you may have!

Thank you!

Section 1: The questions in this section will ask about the administrative systems and demographics of your hospital.	
Approximately how many beds does your hospital contain?	_____
What state is your hospital located in (state abbreviation)?	_____
Does your facility have a Patient Blood Management program?	◯ Yes ◯ No ◯ Not Sure
Does your hospital have a Transfusion Safety Officer?	◯ Yes ◯ No ◯ Not Sure

Section 2: This section of the survey will ask questions about how well your hospital is performing in certain outcomes that are usually reported or tracked by the blood bank, quality assurance, or the hospital.

As a reminder, the results of this survey will be strictly confidential and used only for research purposes. Feel free to give approximate answers. When you respond that you know or can find out the information being asked in each question by clicking "Yes", then a second question will appear asking for more specific information. Please attempt to answer all questions in the given text box.

Thank you!

Do you know or can you find out how many units of red blood cells your hospital wasted last month?	◯ Yes ◯ No ◯ Don't Know
Approximately, how many units of red blood cells did your hospital waste last month?	_____
Do you know or can you find out how many units of plasma your hospital wasted last month?	◯ Yes ◯ No ◯ Don't Know
Approximately, how many units of plasma did your hospital waste last month?	_____
Do you know or can you find out how many doses of platelets your hospital wasted last month?	◯ Yes ◯ No ◯ Don't Know
Approximately, how many doses of platelets did your hospital waste last month?	_____
Do you know or can you find out what your hospital's average length of stay was in 2023?	◯ Yes ◯ No ◯ Don't Know
Approximately, what was your hospital's average length of stay in 2023?	_____
Do you know or can you find out what your hospital's average 30-day patient readmission rate was in 2023?	◯ Yes ◯ No ◯ Don't Know

Approximately, what was your hospital's average length of stay in 2023?	_____
Do you know or can you find out what your hospital's average 30-day patient readmission rate was in 2023?	◯ Yes ◯ No ◯ Don't Know
Approximately, what was your hospital's average 30-day patient readmission rate in 2023?	_____
Do you know of can you find out what your hospital's average rate of hospital-acquired infections were in 2023?	◯ Yes ◯ No ◯ Don't Know
Approximately, what was your hospital's rate of hospital-acquired infections in 2023?	_____

APPENDIX 2

Fellow Blood Transfusion Professionals:

Your responses are requested for a survey on blood transfusion safety and blood management, as part of a doctoral dissertation entitled "**The Relationship Between Outcomes Associated with Patient Blood Management Programs and Transfusion Safety Officers"** under the direction of Melissa Jamerson, PhD in the department of Medical Laboratory Sciences. I am a doctoral student at Virginia Commonwealth University in the Health-Related Sciences program. I am MLS(ASCP) and SBB(ASCP) certified. I graduated from the SBB program at Rush University. I welcome your responses!

Responses are requested from hospitals of all sizes, regardless of the hospital having a formal Patient Blood Management program or a designated Transfusion Safety Officer. Responses are requested from Transfusion Directors or someone that a director consents to respond (such as a blood bank manager, supervisor, blood bank specialist, or lead technologist). If you are not a transfusion director, I ask that you forward this message to your transfusion director. The director can consent for you to answer the questions on the survey, if they choose.

This survey is designed to **take 10 to 25 minutes**, depending on how familiar you are with the outcomes of your hospital; the outcomes the survey will ask about are blood product waste at your hospital, and some reported quality indicators such as the hospitals length of stay, rate of hospital-acquired infections, and the hospitals rate of 30-day readmissions. If you are familiar with this information, you could respond very quickly! If you are not familiar with a particular outcome, then quality assurance or a quick internet search of your hospital could provide the information to you.

The information you provide will be used for research purposes only and will be **strictly confidential**. You are free to leave the survey at any time for any reason. Clicking on the link below gives **consent** to participate in this study.

Please feel free to contact me with any questions or concerns via text or phone: (540) 705-7731. Or at morralgw@vcu.edu. Or Melissa Jamerson, PhD: hrickomj@vcu.edu

Gary Morral MS, MLS(ASCP)SBB

Thank you for your time!

https://redcap.vcu.edu/surveys/?s=4ATLE8FNTACRLF39

APPENDIX 3

Gary Morral MS, MLS(ASCP)SBB
2023 Lone Oak Lane, Dayton, VA 22821
540-705-7731
morralgw@gmail.com

Professional Summary

- Masters of Science degree in Clinical Laboratory Management.
- 7+ years of experience in hospital blood banks and reference laboratories.
- 2+ years of non-hospital lab experience in Serology, Microbiology, and Chemistry.
- Nationally certified in Blood Banking (SBB) and Medical Laboratory Science (MLS).
- 20+ years of customer service experience with populations that include physicians, nurses, laboratory scientists, and other clinical support staff.
- 5 yrs of experience using Galileo Echo (Immucor) solid phase antibody detection.
- EPIC (Hospital Information System), SunQuest (Laboratory Information System)

Certifications (American Society for Clinical Pathology)

SBB (Specialist in Blood Banking): score = 430 (mean = 426, SD = 145, 43% failed) in 2010

MLS (Medical Laboratory Scientist): score = 647 (mean = 487, SD = 105, 21% failed) in 2011

BB (Technologist in Blood Banking): score = 620 (mean = 426, SD = 108, 40% failed) in 2009

MLT (Medical Lab Technician): score = 676 (mean = 479, SD = 121, 28% failed) in 2009

Experience

Virginia Commonwealth University (June 2015 to June 2024): Doctoral Student

Rush University (Jan 2016 to Jan 2017): Adjunct Instructor: Transfusion Services

American Red Cross: Nov 2012 to Nov 2013 Immunohematology Reference Technologist:

- Performed routine and complex antibody identifications for various hospital laboratories.
- Performed differential adsorptions, antibody elution, and EGA treatment of cells.
- Screened available inventory for antigen negative units
- Labeled blood products.
- Trained in Compliance and cGMP.
- Worked independently, usually alone, without supervision.
- Prepared Consultation Reports and Billing Documents for hospital testing
- Consulted and interacted extensively with hospital laboratory scientists, supervisors, and physicians.

University of Virginia Health System: Jan 2007 to Oct 2012 Clinical Lab Scientist:

- Blood Bank (partial reference lab for other hospitals).
- Worked night shift in a level I trauma center (and teaching hospital) in all areas of the blood bank, usually as senior tech, and often with no supervisor.
- Performed routine and complex testing using tube (LISS and PeG), gel, and solid phase (Galileo Echo) technology.
- Performed differential adsorptions, antibody elution and titration, and EGA treatment of cells for antibody identification.
- Screened blood products to find antigen negative units
- Labeled blood products using Hematrax
- Performed Fetal Bleed Screens and Kleihauer-Betke tests
- Pooled platelets and cryoprecipitate
- Split and labeled blood products for neonatal and pediatric patients
- Performed Platelet Serology using solid phase technology.
- Irradiated blood products
- Performed stat platelet counts and PT/PTT coagulation testing for the OR using Sysmex and Cascade POC analyzers.
- Performed QC (daily, quarterly, and yearly), QA blood audits, and Quality reporting.
- Calibrated timers and centrifuges
- Used SunQuest (LIS) and Epic (HIS)
- Trained new employees and served as lead technologist
- Maintained inventory and ordered blood products.

American Type Cell Culture/Kelly Services: Sept. 2005 to Jan. 2006 Laboratory Technician/Microbiologist:

- Temporary job in bio-production for an international biological repository.
- Cultured and harvested numerous microbiological organisms under BSL 2 and 3 conditions.
- Cultured Mycoplasmas and Mycobacteria
- Harvested DNA from various microbes.
- Trained in QC and QA testing, documentation, and GLP.

USDA (Kelly Services): May 2002 to Jan. 2003
Laboratory Technician/Serology/Microbiology:

- Temporary Employee, as part of the USDA's task force on avian influenza, at an extraordinarily high volume VA state lab during an outbreak of avian influenza.
- Performed tests on samples from various avian sera (blood, eggs, and tracheal swabs).
- Used the ELISA based Directigen Flu A test kit to test for viral flu antigens.
- Set up Agarose Gel Immuno-diffusion plates for antibodies to flu virus.
- Performed antigen-antibody plate testing for various species of mycoplasma.
- Set up slide tests for Corona virus.
- Performed Hemagglutination Inhibition tests for New Castle Disease Virus and as a follow up to positive mycoplasma tests.
- Set up BA, EMB, and antibiotic sensitivity plates on swabs from various tissues/organs from animal necropsies.

- Trained numerous federal employees in laboratory practices
- Awarded for outstanding service to the state of Virginia

Perdue Farms Inc.: Oct. 1990 to Nov. 1991: Laboratory Technician:

- USDA accredited Laboratory
- Performed chemical and microbiological analysis on production, quality control, shelf life, and research and development samples.
- Performed chemical tests for pH, fat, free fatty acids, rancidity (TBA test), protein, and nutritional label verification.

Responsive Management: December 2000 to February 2001: Data Analyst and Research

Associate:

- Analyzed data and edited reports.
  See http://sites.state.pa.us/PA_Exec/Fish_Boat/rmconsume.pdf for sample (or search google using "Gary Morral Pennsylvania Trout" as key words).

Education

Master of Science (2014): Rush University: Clinical Laboratory Management

- GPA = 3.7; Management practicum and thesis/project performed at University of Virginia Health System
- Management Practicum Mentor: Jennifer De Arment MSHA, Medical Laboratory Administrator, University of Virginia Health System
- Thesis/Project: "The Frequency of Falsely Elevated Glucose Meter Readings in Patients Taking Nepro® with Carb Steady® at the University of Virginia Health System."
- Project Advisors: Dr. Denise Harmening, PhD and Robert Harr MS, MLS(ASCP)
- Classes in Management, Finance, Method Evaluation and Process Validation, Quality Assurance and Regulatory issues, Information Systems
- Dossier of Management activities available.

Bachelor of Science (2011): Virginia Commonwealth University: Clinical Laboratory Sciences

- Second Bachelor of Science degree: GPA = 3.25
- All clinical rotations at the University of Virginia Health System

Graduate Certificate (2010): Rush University: Specialist in Blood Banking

- *Summa cum laude*: GPA = 3.9
- All Blood Bank practicums at the University of Virginia Health System

Associate of Applied Science (2009): J. Sargeant Reynolds Community College

- Medical Laboratory Technician Program
- *Magna cum laude:* GPA = 3.5

Bachelor of Science (1997): James Madison University: Psychology/Biology/Chemistry

- Advanced Undergraduate Classes: Recombinant DNA, Molecular Biology, Virology, Medical Microbiology, Biochemistry, Intermediate Organic Chemistry, Calculus I-II, Probability and Math Statistics I-III, Instrumental Analysis, Technical Writing, University Physics I & II
- Graduate Classes in Psychology and Statistics (**after graduation**): Analysis of Variance and Experimental Design, Multivariate Statistics, Advanced Physiological Psychology, Structural Equation Modeling, Linear Models
- Graduate Classes in Biology and Technical and Scientific Communication (**after graduation)**: Seminar in Technical and Scientific Communication, Molecular Biology (2004), Microbial Ecology (2004), Immunology (2008), Medical Microbiology (2008)

Statistical Software Packages and Languages Used:

- SPSS, SAS, Excel, S plus, R

Research Experience:

- Participated in research into biodegradable plastics using genetic engineering in a Recombinant DNA class at James Madison University (JMU).
- Isolation of DNA and Proteins from 2 species of plants using RT-PCR, Western Blotting with Antibody Detection, and Bradford Assay (contact Dr. Terrie Rife: rifetk@jmu.edu).
- DNA Microarray Analysis of Yeast stains (contact Dr. Terrie Rife).

Presentations and Lectures Given

- CLLS 414: Senior Seminar (VCU): “Hepatic Failure from Toxic Shock Syndrome”.
- Continuing Education Presentation (UVA): “Tissue Rejection during Solid Organ Transplantation”; given to Blood Bank colleagues for ASCP continuing education credit.
- Continuing Education Presentation (UVA): “Microcytic Anemias: A Case Presentation”; given to Blood Bank colleagues for ASCP continuing education credit.
- CLLS 411: Principles of Education and Management (VCU): “Solid Organ Transplantation: New Drugs to Prevent Graft Rejection”. Presentation given to Blood Bank Supervisors and Managers at UVA for the CLLS 411 class.
- Bio 548: Medical Microbiology (JMU, Dr. Kyle Seifert): “Sulfated Polysaccharides as a New Class of Anti-Microbial Compounds”. Presentation to undergraduates.

- Bio 548: Medical Microbiology (JMU, Dr. Kyle Seifert): “Pseudomonas”. Gave the lecture on the material from the chapter in the textbook. Made the reading quiz on the textbook chapter, selected a related research article, and lead class discussion on the article.
- Bio 548: Medical Microbiology (JMU, Dr. Kyle Seifert): “Herpes”. Gave the lecture on the material from the chapter in the textbook. Made the reading quiz on the textbook chapter, selected a related research article, and lead class discussion on the article.
- Bio 548: Medical Microbiology (JMU, Dr. Kyle Seifert): “Influenza”. Gave the lecture on the material from the chapter in the textbook. Made the reading quiz on the textbook chapter, selected a related research article, and lead class discussion on the article.
- Bio 542: Immunology (JMU, Dr. Chris Lantz): “Transplantation Immunology”. Gave the lecture from the textbook. The students were tested on the information from the lecture.
- Bio 580: Advanced Molecular Biology (JMU, Dr. Terrie Rife): “Molecular Biology of Influenza Virus”. Presentation to undergraduates.
- Bio 553: Microbial Ecology (JMU, Dr. Jim Herrick): “Influenza: Microbial Ecological Aspects”. Presentation to undergraduates.

References:

“An asset to night shift”: Jane Mangione MT(ASCP)SBB, Blood Bank Supervisor, University of Virginia Health System, letter of recommendation.

“A valuable asset to the Immunohematology Reference Lab”: LeeAnn McCall MT(ASCP)SBB, IRL Director, American Red Cross, letter of recommendation.

“Your knowledge of procedures and protocols is very reassuring. Having you as a resource is such a benefit. Thank you very much for your consistent caring”: Patricia Kirby RN, OR Charge Nurse (UVA), letter of recommendation.