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Barriers to Blood Availability Within the New Orleans Area

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This is to certify that the doctoral dissertation by

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has been found to be complete and satisfactory in all respects,
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2022

Title

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by

Tishawn M. Francis

MBA/HCM, University of Phoenix, 2005

BS, Dillard University, 2000

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health/Epidemiology

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Abstract

An adequate and reliable supply of blood and blood components is becoming an increasing public health concern. Over the past decade, researchers have indicated a continued decline in the collection of blood products. An insufficient blood supply may present a risk to both patients and reserves for emergencies and disasters. The purpose of this quantitative, cross-sectional study was to determine whether gender, age group, ethnicity, year, serological tests, and discard factors were associated with the availability of the donated blood supply throughout the New Orleans region. The donated blood supply chain model guided this study. Secondary data were retrieved from The Blood Center of New Orleans, Louisiana. A simple random sample technique was used to select the sample, consisting of 286,625 allogeneic blood donors. Bivariate logistic regression and multiple logistic regression were used to analyze data collected between 2008 and 2017. The bivariate logistic regression showed a statistically significant association (p = .000) between gender (OR = .760; 95% CI .753 – .767), age group (OR = 1.554; 95% CI 1.522 – 1.588), ethnicity (OR = .635; 95% CI .627 – .643), year (OR = .713; 95% CI .696 – .731), and available blood. Similarly, the multiple logistic regression also revealed a statistically significant association (p = .000) between gender (OR = .796; 95% CI .789 – .804), age group (OR = 1.426; 95% CI 1.395 – 1.458), ethnicity (OR = .672; 95% CI .664 – .681), year (OR = .726; 95% CI .708 – .744), and available blood. The knowledge presented in this study promotes positive social change by guiding blood center practitioners on ways to improve current work practices to increase the available donated blood supply and maintain a satisfactory blood inventory.

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Dedication

This dissertation is dedicated to my late stepfather, Cecil McFarland. Although he passed away in 2010, the knowledge and leadership skills he instilled in me from young allowed me to successfully complete this program. Also, a special dedication is rendered to my late friend, Kelli Daigle. When I first thought about pursuing my doctorate degree, Kelli not only was my biggest supporter/cheerleader, but she also influenced my area of research study. While both did not have an opportunity to endure this doctoral process with me, the inspiration I received from them pushed me persevere. You two will always remain in my heart.

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Chapter 1: Introduction to the Study

Introduction

Sufficient availability of safe blood and blood products is a key component of public health practice. Whether in support of natural disasters or medical emergencies, blood is a necessary commodity used to support the health and well-being of the community. According to Klein et al. (2017), more than 35,000 units of blood are collected daily in the United States to support patients and reserves for emergencies and disasters. In addition, nearly 21 million blood components are transfused annually. Nevertheless, researchers have indicated a continued decline in the collection and utilization of blood and blood products (Chung et al., 2016; Ellingson et al., 2017; Jones et al., 2020; & Whitaker et al., 2016).

Human blood is a scarce, perishable resource (Najafi et al., 2017). Currently there is no other product or alternative that can be used to generate or substitute blood and blood products. As such, the nation's blood supply holds a vital role in healthcare and public health systems. Yet, little is known as to why there is a national decrease in blood collections and use. Several researchers have presented factors that may have contributed to its decline. For instance, Khurram et al. (2016) determined that a prior history of infectious disease and low hemoglobin levels were common reasons for blood donor deferrals. Kurup et al. (2016) discovered that how blood units were handled after collection were major reasons for wastage. However, Klein et al. (2017) indicated that more information remains to be collected to better understand the vulnerabilities of the U.S. blood system. There is a gap, then, in understanding the potential declines in the

amount of usable blood once donated, and the variables that may contribute to the reduction of the donated blood supply. Additionally, no researchers have examined factors that have contributed to the availability of the donated blood supply throughout the New Orleans region. Therefore, my goal was to investigate distinct variables, such as gender, age groups, ethnicity, year, serological tests, and discard reasons associated with the availability of the donated blood supply. I also sought to illustrate trends in blood collection and availability, as well as the quantity of individuals presenting to donate blood. The social change implications of this study could be the promotion of changes to current blood center practices, increase awareness of wastage issues, and influence the development of public health interventions that would increase individual blood donation efforts, reduce the quantity of discarded blood, and maintain a satisfactory blood inventory to meet routine and emergent demands throughout New Orleans and its surrounding areas.

This chapter begins with a description of the research topic, why it was necessary to conduct the study, and an explanation of the potential for positive social change implications. I present a brief literature review in the background of the study, in which I illustrate the importance and need to conduct the research. The problem statement section includes a discussion of evidence related to barriers affecting blood availability, as provided by relevant studies conducted within the last 5 years. I describe my intentions for the study as well as the independent and dependent variables in the purpose section. I detail the research questions and hypotheses that I used to identify and examine the barriers to blood availability. I give a detailed description of the conceptual framework

and its relevance to this study. I also discuss the nature and design of the study as well as its key variables. I define and explain important definitions, assumptions, scope and delimitations, and limitations. I also identify potential contributions and social change implications in this chapter. The chapter concludes with a brief summary of the main points of Chapter 1, along with an overview of the information provided in the following chapters.

Background

Review of literature on barriers affecting availability of blood and blood components revealed a focus on the continuous decline of the national blood supply and minimizing wastage to maximize availability. Chung et al. (2016) investigated the number of blood and blood components collected and transfused in the United States based on data obtained from the 2013 National Blood Collection and Utilization Survey (NBCUS). Results of the study by Chung et al. (2016) showed a 4.4% decline in both blood collection and utilization compared to the 2011 NBCUS results.

Ellingson et al. (2017) described the findings from the 2015 NBCUS. Since the 2011 and 2013 NBCUS revealed declines in blood collection and utilization in the United States, the researchers sought to confirm whether this trend had continued. Their results showed a consistent decline in demand for blood and blood products in 2015, which could have resulted in fewer units collected and distributed. Similarly, Jones et al. (2020) described the results of the 2017 NBCUS. The authors additionally sought to evaluate the declining trend in blood collection and utilization in the United States. The researchers' findings revealed that 12,211,000 (95% CI, 11,680,000-12,742,000 units) whole blood

(WB) and apheresis RBC units were collected in the United States in 2017, which indicated a 3.0% decline in RBC collections since 2015. The researchers further indicated that in the United States, the rate of whole blood and RBC units collected per 1000 population decreased from 60.4 units in 2015 to 58.2 units in 2017.

Whitaker et al. (2016) summarized data from the 2013 AABB (formerly known as the American Association of Blood Banks) Blood Collection, Utilization, and Patient Blood Management Survey (AABB Blood Survey). The researchers indicated a significant decline in both blood collections and transfusions. However, the authors also revealed a decrease in the number of outdated and wasted components by hospitals that suggested improvements in product and inventory management.

Khurram et al. (2016) used a cross-sectional study to investigate the frequency and reasons for donor deferral prior to the blood donation process. They found that out of a total of 25,901 attempted donations, 280 candidates were permanently deferred, while 2,876 individuals were temporarily deferred. A history of hepatitis B infection and low hemoglobin levels were the most common factors for permanent and temporary deferrals, which may contribute to the continual decline in blood collections.

Regarding blood wastage, Collins et al. (2015) evaluated the impact of the waste reduction interventions on reducing RBCs, platelets (PLTs), and plasma wastage. Using a Chi-Square test, the authors discovered a decrease in the RBC (0.67% to 0.56%; $p = .001$) and PLT (3.71% to 2.81%; $p < .001$) wastage rates, but conversely an increase in the plasma wastage rate (1.14% to 1.40%; $p < .001$). Kurup et al. (2016) conducted a retrospective study to analyze the usage and wastage of blood and blood products at

Georgetown Public Hospital Cooperation (GPHC) in Guyana. Out of a total of 16,426 units of blood, 25% (n = 4,167 units) were wasted due to various reasons. The authors concluded that the major reason for wastage was due to how the blood units were handled after collection. Shahshahani and Taghvai (2017) examined the rate of blood component wastage before and after interventions were implemented at Yazd Blood Transfusion Center. The researchers found that after the implementation of multiple interventions, the wastage of blood components was significantly reduced (RBCs: from 9.7 to 2.9, $p <$ 0.001; PLT: from 18.5 to 10.6%, $p < 0.001$; and plasma: from 5.4 to 2.3%, $p < 0.001$).

Although the reduction of discarded blood could increase the efficiency of blood inventory within blood banks, and furthermore, improve productivity, little is known about the quantity and availability of donated blood products. Additionally, no researchers have examined factors that are associated with the availability of the donated blood supply throughout the New Orleans region. Several researchers have examined factors that may have contributed to its decline; however, Klein et al. (2017) indicated that more information remains to be collected to better understand the weaknesses within the donated blood supply chain. There is a gap, then, in understanding the potential declines in the amount of usable blood once donated, and variables that may contribute to the possible reduction of the donated blood supply.

Problem Statement

In 2015, the United States Department of Health and Human Services, NBCUS indicated a continued decline in blood collection and blood utilization in the United States (Ellingson et al., 2017). Because a sufficient supply of blood products is needed to

meet disaster preparedness and other public health challenges (Chung et al., 2016; Ellingson et al., 2017; & Whitaker et al., 2016), this decline poses a considerable public health concern. Although much is known about the decreasing trend in blood collection, few researchers have examined the factors influencing the quantity of available donated blood products. There is a continuous need for blood components; thus, regular replenishment of the blood supply is a necessity (Shahshahani & Taghvai, 2017; Yazer et al., 2016). However, rising cost and a growing need for safe blood products are constantly pressuring blood centers to improve their efficiency (Collins et al., 2015; Shahshahani & Taghvai, 2017). Although the overall demand for blood products within the United States has steadily decreased over the past decade, many regions are now experiencing a rise in demand of blood components due to population growth (Satyavarapu & Wagle, 2020). For instance, in the Pacific Northwest, the decline in blood donation, coupled with population growth, has caused blood stocks to dip to critical levels more frequently than seen 10 years ago. Bloodworks Northwest reported critical blood inventory levels of at least one blood type for more than 80% of 2019 (Satyavarapu & Wagle, 2020). Reducing the quantity of discarded blood can minimize this cost and increase productivity (Collins et al., 2015; Kurup et al., 2016; Shahshahani & Taghvai, 2017). Additionally, no researchers have examined the association between gender, age groups, ethnicity, year, serology, discard factors, and the availability of the donated blood supply throughout the New Orleans region. In this research, I filled this gap in understanding by specifically investigating variables that may have contributed to the reduction of the available donated blood supply. The information that I obtained from

this research can be used by blood centers in developing practices that would maintain a satisfactory blood inventory to meet routine and emergency demands.

Purpose of the Study

The purpose of this quantitative, cross-sectional, epidemiological study was to examine the association between a set of factors and the availability of the donated blood supply throughout the New Orleans region. It was unclear why there is a decreasing trend in blood collection. Therefore, identification of these contributing factors may result in understanding the reasons for the reduction of the donated blood supply. I obtained secondary data from The Blood Center (TBC) of New Orleans, Louisiana to determine the association between the independent variables of gender, age group, ethnicity, year, serology, and discard factors and the dependent variable: available blood. I used bivariate logistic regression to analyze the association between the independent variables and the dependent variable. This project is unique because I addressed an area in research that has not been investigated.

Conceptual Framework

Many different models and frameworks are used to describe public health and the ways in which the health of the population is shaped (Kelly et al., 2009). Because this study was a natural science/epidemiology study and not a social science study, the usual public health social science theories, such as theory of planned behavior, health belief model, social cognitive theory, and so forth were not appropriate for this study. The main emphasis in this study was on natural/environmental factors, which include

contamination, leakage, and improper storage. As such, the conceptual base for this study was the donated blood supply chain model.

The donated blood supply chain is widely used to demonstrate the process of managing blood and blood components (Osorio et al., 2017). The model involves four stages: collection, production, storage, and distribution of donated blood and blood components (Osorio et al., 2017). Within each stage, the model highlights major discard factors, which consist of insufficiently filled, clotted, air contaminated, and expired blood components (Osorio et al., 2017). The model also underscores additional discard factors comprised of blood units with abnormal temperatures and miscellaneous aspects, which includes leakage and burst units (Osorio et al., 2017). Identification and examination of these discard factors will provide insight into the barriers affecting the availability of the donated blood supply. Therefore, the donated blood supply chain has not only served as a guide to discovering these factors, it has also been used in developing ways to effectively increase the donated blood supply. Because blood cannot be manufactured and can only come from volunteer donors (Osorio et al., 2017; Shahshahani & Taghvai, 2017; Yazer et al., 2016), this conceptual framework is often used in public health literature to help illustrate the journey that blood components undergo to ensure that the blood supply is safe and helps as many people as possible.

The following figure illustrates the independent and dependent variables that I investigated to determine its association with available blood:

Figure 1

Independent and Dependent Variables

Independent Variables	Dependent Variable
1. Gender • Male; Female	1. Available Blood • No, blood is not available for use; Yes, blood is available for use
2. Age Group • 16–96 years	
3. Ethnicity • Black; White; Asian; Other; Unknown	
4. Year • 2008–2017	
5. Serology • Bacterial Contamination; Chagas Disease; Hepatitis B; Hepatitis C; HIV; HTLV-I/II; Syphilis; West Nile Virus	
6. Discard Factors • Abnormal temperature; Air contaminated; Bloody; Broken; Clotted; Expired; Miscellaneous; Quantity Not Sufficient	

Research Questions and Hypotheses

Research Question 1 (RQ1): Is there an association between gender and available blood?

Null Hypothesis 1 ($H_0$1): There is no statistically significant association between gender and available blood.

Alternate Hypothesis 1 ($H_1$1): There is a statistically significant association between gender and available blood.

Research Question 2 (RQ2): Is there an association between age group and available blood?

Null Hypothesis 2 ($H_0$2): There is no statistically significant association between age group and available blood.

Alternate Hypothesis 2 ($H_1$2): There is a statistically significant association between age group and available blood.

Research Question 3 (RQ3): Is there an association between ethnicity and available blood?

Null Hypothesis 3 ($H_0$3): There is no statistically significant association between ethnicity and available blood.

Alternate Hypothesis 3 ($H_1$3): There is a statistically significant association between ethnicity and available blood.

Research Question 4 (RQ4): Is there an association between year and available blood?

Null Hypothesis 4 ($H_0$4): There is no statistically significant association between year and available blood.

Alternate Hypothesis 4 ($H_1$4): There is a statistically significant association between year and available blood.

Research Question 5 (RQ5): Is there an association between serology and available blood?

Null Hypothesis 5 ($H_0$5): There is no statistically significant association between serology and available blood.

Alternate Hypothesis 5 ($H_1$5): There is a statistically significant association between serology and available blood.

Research Question 6 (RQ6): Is there an association between discard factors and available blood?

Null Hypothesis 6 ($H_0$6): There is no statistically significant association between discard factors and available blood.

Alternate Hypothesis 6 ($H_1$6): There is a statistically significant association between discard factors and available blood.

Research Question 7 (RQ7): Is there an association between gender, age group, ethnicity, year, serology, discard factors and available blood?

Null Hypothesis 7 ($H_0$7): There is no statistically significant association between gender, age group, ethnicity, year, serology, discard factors and available blood.

Alternate Hypothesis 7 ($H_1$7): There is a statistically significant association between gender, age group, ethnicity, year, serology, discard factors and available blood.

Nature of the Study

I used a quantitative, cross-sectional study design to assess the association between gender, age group, ethnicity, year, serology, discard factors and available blood collected between January 1, 2008 to December 31, 2017. I used a quantitative approach

to determine differences and patterns between each independent variable. I used this design to establish whether there has been an increase or decrease in the number of blood donors, discarded units, and infectious diseases detected among the blood supply. By detecting trends and changes, I identified factors that have attributed to the availability of the donated blood supply in the New Orleans region.

Definitions

I used the following key terms in this study:

Age group: Corresponds to an ordinal variable for individuals who have donated blood between 2008 and 2017 at TBC. I created subgroups of the age group variable and coded them as: 0 = 16–26 years; 1 = 27–34 years; 2 = 35–44 years; 3 = 45–54 years; 4 = 55–64 years; 5 = 65–96 years.

Available blood: Is a dichotomous, categorical variable that categorizes whether donated blood units were available for use. I coded this variable as: 0 = No, blood is not available for use; 1 = Yes, blood is available for use.

Ethnicity: A categorical variable that corresponds to participant's race/ethnicity. I used four ethnicity groups in this study, which I coded as: 0 = White/Caucasian; 1 = Black/African American; 2 = Asian; 3 = Other; 4 = Unknown.

Gender: A nominal variable that identifies the study population as either male or female. I coded this variable as: 0 = Male; 1 = Female.

Major discard factors: A nominal variable that corresponds to the reasons blood units were rejected or discarded. I coded this variable as: 0 = Abnormal temperature; 1 =

Air contaminated; 2 = Bloody; 3 = Broken; 4 = Clotted, 5 = Expired; 6 = Miscellaneous; 7 = Quantity Not Sufficient.

Serological tests: Refers to the federal-regulated tests that are conducted on all blood units prior to distribution. In this study, this variable was measured as a nominal. I coded the subgroups of the serological tests variable as: 0 = Bacterial Contamination; 1 = Chagas Disease; 2 = Hepatitis B; 3 = Hepatitis C; 4 = HIV; 5 = HTLV-I/II; 6 = Syphilis; 7 = West Nile Virus.

Year: A categorical variable that refers to the year in which an individual donated a unit of blood at TBC between the period of January 1, 2008 to December 31, 2017. I coded the subgroups of this variable as: 0 = 2008; 1 = 2009; 2 = 2010; 3 = 2011; 4 = 2012; 5 = 2013; 6 = 2014; 7 = 2015; 8 = 2016; 9 = 2017.

Assumptions

I assumed that data collected from TBC's BECS were reliable and possessed strong internal validity at the time of primary data collection. I also assumed that the data gathered were representative of the New Orleans population as well as the general blood donor population. To the best of my knowledge, the participants answered their medical history questionnaires honestly, the results of their laboratory testing was precise, data entry was accurate, and confidentiality was maintained. These assumptions were necessary to the context of this study because the instruments that I used to collect and store data were validated and confirmed to meet U.S. Food and Drug Administration (FDA) standards.

Scope and Delimitations

The scope of this study was defined by several variables that would identify factors associated with the availability of donated blood supply. My focus was on specific variables, such as gender, age group, ethnicity, year, serology, and discard reasons, which were previously studied by researchers to determine their relationship with blood collection and wastage (Collins et al., 2015; Khurram et al., 2016; Kurup et al., 2016; Shahshahani & Taghvai, 2017). Therefore, I addressed the internal validity through the examination of the association between the specific independent variables and available blood. I minimized threats to internal validity by excluding unknown or missing variables. For example, I excluded data with missing or inconclusive laboratory results. This study was limited to allogeneic blood donors who donated whole blood or blood components at TBC between January 1, 2008 and December 31, 2017.

I initially reviewed Ajzen's theory of planned behavior (TPB) as a possible theoretical framework for this study because it was found to be a useful predictor of donation behavior (Sardi et al., 2019). However, this theory was not appropriate for this study because I did not investigate behavior. I examined natural factors such as contamination, clotting, and leakage. Therefore, to address the issue of external validity, I used donated blood supply chain as the model for this study, as it was the most suitable. The results from this study maybe generalized to the New Orleans population.

Limitations

The current study was subject to limitations. First, the available secondary data set determined the specific factors that could be investigated. Although more factors

affecting the available donated blood supply may be present, I did not explore these variables due to limited information provided from the dataset. Secondly, the FDA guidance states that donation facilities are required to perform a serological screening test on each donation of blood. However, false-positive test results are a typical challenge among blood donation facilities. From 1995 to mid-2008, approximately 64,000 allogeneic donors at the American Red Cross (ARC) were deferred based on false-positive enzyme immunoassay results, representing 130,000 U.S. donors (Vo et al., 2015). False-positive test results could inflate the actual number of true positive test results, which presents a continued loss of both donors and blood products.

Significance

The findings of this study included information regarding the challenges associated with the donated blood supply. Blood centers may use these findings to enact changes in their practices to improve efficiency and increase productivity to meet the needs of the community. Blood is a perishable, scarce, and highly essential commodity (Najafi et al., 2017). Blood products have been used to address major public health challenges, such as national and international epidemics, pandemics, domestic threats, and natural disasters. Therefore, the insights from this research should be used by public health practitioners to understand the barriers that are affecting the donated blood supply, and furthermore, make quality changes that would reduce the quantity of discarded blood and maintain a satisfactory blood inventory to meet routine and emergent demands. This study may be used to create social change through information for blood center practitioners who could change or enhance their current work practices and ultimately

increase the donated blood supply. Additionally, the establishment of public health interventions that would increase individual blood donation efforts would benefit the New Orleans community.

Summary

Findings from national surveys have indicated a continued decline in both blood collection and blood utilization (Chung et al., 2016; Ellingson et al., 2017; Jones et al., 2020). The literature reveals a gap in understanding the factors that may contribute to the possible reduction of the donated blood supply. I conducted a natural science, cross-sectional study to identify the variables associated with the availability of the donated blood supply. The findings from this study could be used to create changes to current blood center practices, increase awareness of wastage issues, and influence the development of public health interventions geared towards increasing the donated blood supply.

In this chapter, I provided a description of the topic of study, a brief summarization of the literature related to barriers affecting blood availability, the problem statement, purpose of study, research questions and hypotheses, the conceptual framework, the nature of the study, definitions, assumptions, scope and delimitations, limitations, significance, and a summary. In Chapter 2, I will provide details of previous studies relative to the decreasing trend in blood collection and usability.

Chapter 2: Literature Review

Introduction

Blood and blood components are essential commodities of public health practice. The national blood supply is mostly comprised of units of RBCs, PLTs, and plasma, which are derived from WB after donation or collected as separate components by apheresis methods (American Red Cross, 2017; Ellingson et al., 2017). In the United States, more than 35,000 units of blood are drawn daily and 12 million red-cell units are provided annually to support patients and aid in emergencies and disasters (Klein et al., 2017). According to Klein et al. (2017), blood is transfused in 10 to 15% of all hospitalizations. In addition, more than 16% of Medicare claims include blood use (Klein et al., 2017). As such, blood maintains a special role within the public health arena. Nevertheless, the national blood supply has declined precipitously during the past decade (Klein et al., 2017).

Between 2009 and 2016, the number of blood units collected by the American Red Cross decreased by 26.4% (Klein et al., 2017). Findings from national surveys also indicate a continued decline in both blood collection and blood utilization (Chung et al., 2016; Ellingson et al., 2017; Jones et al., 2020). For instance, the Office of the Assistant Secretary for Health launched the biennial NBCUS, which was administered by the AABB and subsequently by the Centers for Disease Control and Prevention (CDC) (Ellingson et al., 2017). The findings of the 2017 NBCUS revealed a 3.0% decline in RBC and WB collections compared with declines from 2015 (Jones et al., 2020). However, the 2015 NBCUS revealed a 10.2% decline in the total number of whole blood

units available after excluding units that were rejected than in 2013 (Ellingson et al., 2017). Likewise, the results of the 2013 NBCUS showed an 8.2% decline in the total number of whole blood units available after excluding units that were rejected compared to 2011 (Chung et al., 2016). Because a sufficient supply of blood products is needed to meet disaster preparedness and other public health challenges (Chung et al., 2016; Ellingson et al., 2017; Jones et al., 2020, Whitaker et al., 2016), this slow decline in blood collections poses a considerable public health concern.

Although much is known about the decreasing trend in blood collection, to my knowledge no previous researchers have examined factors that affect the availability of the donated blood supply throughout the New Orleans region. Therefore, the purpose of this epidemiological study was to examine factors, such as gender, age group, ethnicity, year, serology, and discard factors that were associated with the availability of the donated blood supply throughout the New Orleans region.

In this chapter, I discuss the major findings regarding the declining blood supply. The chapter begins with an overview of the search strategies used to find articles and studies pertaining to the national blood supply. Specifically, I describe the scope of the literature review in its relation to the decreasing trend in blood collection and usability in this chapter. In addition, I describe the conceptual framework as well as its practical application and relation to the current study. I conclude the chapter with synthesized findings from various researchers in relation to the independent and dependent variables of the current study to identify the gap in the literature, which justified the need to examine factors associated with the availability of the donated blood supply.

Literature Search Strategy

I performed a search for this literature review using PlosOne, Google Scholar, ScienceDirect, and SAGE Journals. I also used several additional database searches, such as ProQuest and Walden University's Thoreau Multi-Database. Additionally, I searched the FDA, CDC, AABB, American Red Cross, and TBC's websites to access valuable information regarding blood products and collections.

Key search terms that I used to generate results included: *blood collection*, *blood utilization*, *blood shortage*, *blood wastage*, *blood inventory*, and *blood supply chain*. I also used advanced search to include peer-reviewed articles. I then filtered the results to include studies conducted within the last 5 years. The results generated over 100 relevant articles that were reviewed and used in this study.

Conceptual Framework

The DBSC was the conceptual model best suited for this epidemiological natural science study. Like other commodities, blood has its own supply chain (Najafi et al., 2017). The DBSC details the path of a single unit of blood from the time of its procurement to its distribution (Pirabán et al., 2019). The purpose of the DBSC is to guarantee that blood products are available when required by a patient (Pirabán et al., 2019). This implies that availability of blood products is critical because lives can be lost if no blood products are available when needed. Hence, the DBSC is more than just a blood management model, but rather a public health model since it aids in promoting and protecting the health of people. The model consists of four individual echelons or stages

that involves the collection, production, storing, and distribution of blood and its components (Osorio et al., 2017).

Donated Blood Supply Chain Model

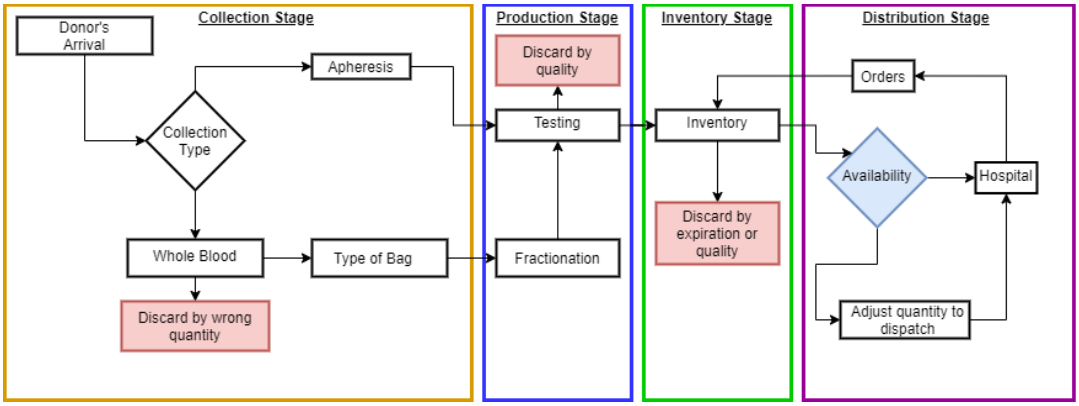
The DBSC framework is based on the following criteria (Najafi et al., 2017):

- *Collection*: Blood is first collected from donors either at a blood center or at a mobile collection site that forwards the donated blood to the blood bank.
- *Testing*: The blood bank laboratory performs several regulatory tests to meet legal requirements, specifically infectious agents and transmissible diseases, and the determination of blood group.
- *Production*: The whole blood units are then separated into various components, such as RBCs, PLTs, and plasma. These components are then placed into quarantine until all laboratory testing are validated and the products are considered safe for use.
- *Storage and Distribution*: The blood components are either stored or transferred to a hospital based on orders.
- *Discard*: Unfortunately, not all blood collected can be used. There is considerable variability within the DBSC model which illustrates the points in which blood products may be discarded.

An illustration of each echelon is depicted in the advanced model of the DBSC (Figure 2).

Figure 2

Donated Blood Supply Chain



Note. The DSBC is a model of the process of blood production through four stages: collection, production, inventory, and distribution. It also considers the areas in which units may be discarded which affects availability. I retrieved the original DSBC model from Osorio et al. (2017) and modified its content for my study.

Collection Stage

The objective of the collection stage is to obtain an ample quantity of blood products to supply the public demand (Pirabán et al., 2019). The supply of blood is irregular and there are several factors that affect blood product availability, such as the number of altruistic allogeneic donors in a region and donation campaigns (Pirabán et al., 2019). In addition, prospective donors in the United States must meet strict federal regulations to be eligible to donate blood (Nagurney & Dutta, 2019). For instance, donors must be at least 17 years old to donate to the general blood supply or 16 years of age with parental/guardian consent (American Red Cross, 2017; The Blood Center, n. d.). In addition to meeting the age criteria, prospective donors must also meet weight,

temperature, pulse, blood pressure, and hemoglobin/hematocrit level requirements (American Red Cross, 2017; The Blood Center, n. d.). Donors are also screened for disease risk factors and may become deferred for reasons such as, exhibiting signs and symptoms of colds or flu, and/or relevant transfusion-transmitted infectious diseases like HIV, viral hepatitis, syphilis, and so forth (American Red Cross, 2017; The Blood Center, n. d.). As a result, only 38% of the U.S. population is eligible to donate at any given time (Nagurney & Dutta, 2019). Nevertheless, less than 10% donate blood annually (Nagurney & Dutta, 2019).

There are two collection methods: WB donation (in single, double, triple, or quadruple collection containers) and a collection of RBCs, plasma, or PLTs by apheresis (Osorio et al., 2017; Pirabán et al., 2019). For whole blood collection, the blood stored as WB is collected in single bags and is used for trauma and surgery (American Red Cross, 2017; Pirabán et al., 2019). The blood to be separated into components is collected in double, triple, or quadruple bags (Pirabán et al., 2019). A double bag yields RBCs and plasma, while a triple bag yields RBCs, PLTs/cryoprecipitate (cryo), and plasma (Pirabán et al., 2019). RBCs are used for trauma, surgery, anemia, and blood loss (American Red Cross, 2017). The major uses of PLTs are for cancer treatments and organ transplants (American Red Cross, 2017). In addition, plasma is used to treat burn patients and those with bleeding disorders, whereas cryo is used to treat those suffering with blood disorders such as, hemophilia and von Willebrand disease (American Red Cross, 2017). Quadruple bags generate RBC, plasma, and buffy coat (PLT and WBCs) (American Red Cross, 2017).

The yield of blood products by apheresis is considerably greater than that of the whole blood collection (Pirabán et al., 2019). For instance, only two tablespoons of PLTs are collected from a WB donation (American Red Cross, 2017). Six WB donations must be separated and pooled to provide a single PLT transfusion (American Red Cross, 2017). However, one apheresis donation provides enough PLTs for one complete transfusion, which is equivalent to six times the amount collected from a WB donation (American Red Cross, 2017).

During the collection stage, the discard rate for WB units is accounted for before fractionation, since errors can result in blood units that do not meet the volume requirements (Osorio et al., 2017). Therefore, blood units that do not meet the mandated weight requirement of a minimum of 450 ml are either discarded during procurement or during the production stage (Osorio et al., 2017). Products obtained by apheresis do not need fractionation; however, discarding can still be applied if the proper volume is not obtained (Osorio et al., 2017). Units and blood products that are discarded during the collection stage are not considered to be a part of the available blood supply. These discards, however, need to be reviewed to ensure that additional staff training or machine maintenance is not warranted, as this could affect the availability of the donated blood supply.

Production Stage

The production stage includes testing and fractionation processes. During the collection stage, sample tubes are also drawn along with the collection unit during the donation process for regulatory testing to ensure blood safety (Pirabán et al., 2019). The

sample tubes and blood units are then forwarded to the blood bank's laboratory. Once at the blood bank, the units are placed in quarantine, which is where the products are isolated while samples are tested in order to identify diseases and other defects.

Testing is a rigorous process to ensure blood safety, as described by Pirabán et al. (2019). First, the blood type (O^+, O^-, A^+, A^-, B^+, B^-, AB^+, and AB^-) of each product is determined. Then the products are tested to ensure that they are disease-free. Those that fail the infectious-disease testing process are removed from quarantine and discarded. However, the approved WB is either stored for transfusion directly or mechanically separated into components. Products obtained by apheresis do not need fractionation, but still go through the production stage for testing and quality control purposes (Osorio et al., 2017). Collected blood is also discarded during the production phase due to substandard quality, such as clotted, burst, or air contaminated units. Hence, discards rendered during the production stage also need to be reviewed as this could affect available blood.

Inventory Stage

In the inventory stage, the daily operation of the inventory levels for each product is represented. After the production phase is complete, products are added to the inventory and are available for use. On a daily basis, all outdated units of each product are removed from the inventory to be discarded (Osorio et al., 2017).

Distribution Stage

Finally, distribution is the last stage represented on the DBSC model. During this phase, blood products are released from inventory and distributed to meet orders that

come from hospitals and other agencies of transfusion in to meet their demand. However, in some instances, units are returned to the blood bank from the hospital. In these cases, the returned blood is discarded through an incineration process (Osorio et al., 2017).

Syntheses of Primary Writings

Many researchers have focused on augmenting the efficiency of blood products within specific areas of the DBSC. Several authors have suggested that the study of the DBSC began in the early 1960's and peaked during the late 1970's to the beginning of the 1980's (Najifi et al., 2017; Pirabán et al., 2019). It is believed that van Zyl (1964) initiated research relative to supply chain management of perishable blood products in general (Nahmias, 1982). However, the first framework used to promote blood optimization is presented in Jennings's study (1973). In this early work, the whole blood inventory problem was classified by hierarchy level (strategic – tactical – operational) and showed the impact of the application of different blood inventory policies (Jennings, 1973). Cohen and Pierskalla (1979) published fundamental literature geared towards hospital and regional blood banks. These researchers used the DBSC model to identify areas of shortages and wastage of blood products to obtain an optimal inventory level to meet daily demand. During the 1980's, comprehensive reviews were produced by Nahmias (1982) who focused on the theory of perishable commodities, and Prastacos (1984) who focused on blood bank policy management and decision-making. Since then, the body of literature on blood supply optimization using the DBSC have greatly increased over the years.

Key Statements and Definitions

The key statements and definitions inherent in the DBSC model were included herein:

Allogeneic donation: Typically referred to as whole blood donation, is the process of voluntarily donating a unit of blood (which is around a 450mL) for the available blood supply (American Red Cross, 2017; The Blood Center, n. d.).

Apheresis: Apheresis is an automated process in which the whole blood of a person is passed through an apparatus that separates out a particular blood component (i.e., red blood cells, plasma, or platelets) and returns the remainder to the donor (American Red Cross, 2017; The Blood Center, n. d.).

Autologous donations: Blood donations that individuals give for their own use, usually for an upcoming elective surgery (American Red Cross, 2017).

Directed donation: The donation of blood or blood products that is designated for a specific patient (American Red Cross, 2017; The Blood Center, n. d.).

Fractionation: Blood fractionation is the process of fractionating whole blood or separating it into its component parts. This is typically done by centrifuging the blood (Osorio et al., 2017).

Replacement: Blood or blood products donated to support patients with pre-existing illnesses. For each pint of blood donated as a replacement for a specific patient, TBC issues a monetary contribution directly to the patient (The Blood Center, n. d.).

Replenishment: Similar to a replacement, blood and blood products are donated to replenish the community blood supply, usually after the occurrence of a catastrophic event (The Blood Center, n. d.).

Therapeutic phlebotomy: A blood draw procedure usually prescribed by a physician as a part of a treatment of various medical conditions associated with the accumulation of excess red blood cells. This blood is normally discarded during the production stage (The Blood Center, n. d.).

Whole blood (WB): Blood drawn directly from the body from which none of the components, such as red blood cells, plasma, or platelets, has been removed (American Red Cross, 2017; The Blood Center, n. d.).

Application of the DBSC

Several studies have been published covering distinct aspects of the DBSC. Additionally, many authors have used the DBSC as a foundational guide for their research. However, literature related to blood supply optimization has received a considerable amount of attention (Osorio et al., 2018). Recent research in this area includes Beliën and Forcé (2012) whose work provided a comprehensive review of blood product inventory and supply-chain management. The authors classified 98 manuscripts according to 8 criteria: blood products, solution methods, hierarchical levels of decision-making, problem types, stochastic and deterministic approaches, optimization problems, performance measures, and practical implementations and case studies (Beliën & Forcé, 2012). Their work facilitated the tracing of published work in relevant fields, identified trends, and exposed areas subject to future research (Beliën & Forcé, 2012). Osorio et al.

(2015) presented a structured review on quantitative modeling of the blood product supply chain. The models proposed in the literature were broken down into five categories: collection, production, inventory, delivery, and integrated models (Osorio et al., 2015).

Regarding the supply and demand of blood products, some researchers examined the use of simulation techniques to amplify blood inventory levels (Duan & Liao, 2014; Kopach, 2008; Rytilä & Spens, 2006). Conversely, Pierskalla (2005) and Hemmelmayr et al. (2009) used mathematical programming to solve blood product inventory and distribution issues. Ramezanian and Behboodi (2017) applied a mixed integer linear programming (MILP) optimization to a deterministic location-allocation model to increase utility and motivate blood donors to donate blood. Sarhangian et al., (2017) examined the performance of threshold-based allocation policies designed to reduce the age of transfused RBCs without compromising their availability.

Some researchers have developed and presented various optimization models designed to enhance the DBSC. Fortsch and Khapalova (2016) addressed major challenges within the DBSC and introduced practical methods for forecasting blood demand, thus allowing for lowering of costs, reduction of blood wastage, and conservation of limited resources. Nagurney et al. (2012) developed a generalized network optimization model to capture many of the critical issues associated with DBSC while satisfying the uncertain demand for blood products. El-Amine et al. (2017) developed a robust solution that would minimize the risk of a transfusion-transmittable infectious donation being released into the blood supply. Ayer et al. (2019) also sought to

optimize blood collection while minimizing collection cost by determining when and from which mobile collection sites to collect blood for cryo production. The authors further developed a decision support tool to help the American Red Cross select cryo collection sites, which resulted in a successful increase in production at a lower collection cost (Ayer et al., 2018).

Since managing blood products in the DBSC is a task, some investigators used stochastic approaches to optimize blood inventory and minimize blood shortage and wastage (Dillon et al., 2017; Zahiri & Pishvaee, 2017). For instance, Osorio et al. (2018) investigated different blood collection methods and presented a multi-objective stochastic optimization model to aid blood banks in collection strategy planning. Salehi et al. (2017) focused on the demands for blood units during a natural disaster and developed a robust stochastic model for the blood supply chain.

Perishability of blood and wastage due to outdating is another common issue in blood supply chains and, hence, has been incorporated into some studies (Chazan & Gal, 1977; Nagurney & Masoumi, 2012; Nagurney et al., 2012; Wang & Ma, 2015). Najifi et al. (2017) used the DBSC model to investigate major challenges within a hospital's blood inventory and identify areas of shortages and wastage of blood products. The researchers further developed a mathematical model to manage blood ordering and issuance (Najifi et al., 2017).

In much of the recent work on DBSC, researchers focused on the optimization of the blood inventory at the hospital and blood bank levels as well as on the optimization of the shipment of blood from the blood banks to the hospitals (Gunpinar & Centeno, 2015;

Wang and Ma, 2015). For instance, Hosseinifard and Abbasi (2018) considered the effect of a centralized hospital inventory and demonstrated how it could increase the sustainability and resiliency of the blood supply chain. However, according to Pirabán et al. (2019) very few studies have investigated the entire DBSC to identify areas of shortages and wastage of blood products due to its complexity. In their literature review, Osorio et al. (2015) cited a few studies on integrated models or models that included all stages of the DBSC (Delen et al., 2011; Katsaliaki & Brailsford, 2007; Nagurney et al., 2012). Pirabán et al. (2019) referenced two additional studies that were devoted to all echelons of the DBSC in their review (Eskandari-Khanghahi et al., 2018; Heidari-Fathian & Pasandideh, 2018).

My study benefits from this framework because it highlights the areas that affect blood availability. As shown in Figure 1, the DBSC includes the areas in which units may be discarded. Since the main emphasis of my study is on the natural/environmental factors affecting the available blood supply, such as contamination, leakage, and improper storage, the DBSC aided in identifying these issues and provided insight into the barriers affecting the availability of the donated blood supply.

Literature Review Related to Key Variables and/or Concepts

My review of literature on barriers affecting availability of blood and blood components revealed a focus on the continuous decline of the national blood supply and minimizing wastage to maximize availability. Although the reduction of discarded blood could increase the efficiency of blood inventory within blood banks, and furthermore, improve productivity, little is known about the quantity and availability of donated blood

products. Additionally, no researchers have examined factors that have contributed to the availability of the donated blood supply throughout the New Orleans region. Several researchers have presented factors that may have contributed to its decline; however, Klein et al. (2017) indicated that more information remains to be collected to better understand the vulnerabilities of the U.S. blood system. There is a gap, then, in understanding the potential declines in the amount of available blood once donated, and variables that may contribute to the possible reduction of the donated blood supply.

Chung et al. (2016) estimated the number of blood and blood components collected and transfused in the United States based on data obtained from the 2013 NBCUS. Their main purpose was to report the findings of the 2013 NBCUS into peer-reviewed literature and their main objective was to estimate, with 95% confidence intervals (CIs), the number of blood and blood components collected and transfused in the U.S. The researchers indicated that The Department of Health and Human Services electronically disseminated an 83-question survey on general facility information; blood collections, processing, and testing; blood and blood component transfusions; modification of components; and prices paid by hospitals for blood components to hospitals and blood collection centers throughout the United States (Chung et al., 2016). Chung et al. (2016) found a 4.4% decline in both blood collection and utilization compared to the 2011 NBCUS results. Chung et al.'s national estimation of collections and utilizations was effective in revealing recent blood collection and utilization trends for the current study.

Collins et al. (2015) sought to identify the extent and causes of blood product wastage. They also examined interventions aimed to address the causes of wastage. RBC, PLT, and plasma wastage data was analyzed over a course of 16 months at eight hospitals. Multiple waste reduction interventions were then implemented across the eight hospital systems. Collins et al. (2015) evaluated the impact of the waste reduction interventions on reducing RBC, PLT, and plasma wastage. Using a Chi-Square test, the authors discovered a decrease in the RBC (0.67% to 0.56%; $p = .001$) and PLT (3.71% to 2.81%; $p < .001$) wastage rates, but conversely an increase in the plasma wastage rate (1.14% to 1.40%; $p < .001$) (Collins et al., 2015). Research by Collins et al. was useful in explaining some causes and benefits of reducing blood wastage.

Ellingson et al. (2017) described the findings from the 2015 NBCUS. Since the 2011 and 2013 NBCUS revealed declines in blood collection and utilization in the United States, the researchers sought to confirm whether this trend has continued. Electronic surveys consisting of 42 questions were distributed intermittently to blood collection centers and transfusing hospitals to assess supply and demand throughout the United States. Ellingson et al. (2017) indicated a higher response rate for blood collection centers (78.4%) and transfusing hospitals (73.9%) compared to 2013 NBCUS response rates. Their results showed a consistent decline in demand for blood and blood products in 2015, which could have resulted in fewer units collected and distributed. Ellingson et al.'s national estimation of collections and utilizations was useful in revealing current and projected demands for blood products.

Jones et al. (2020) described the results of the 2017 NBCUS. The authors additionally sought to evaluate the declining trend in blood collection and utilization in the United States. Survey questionnaires consisting of 48 questions, including 20 questions applicable to blood collection centers and 28 questions applicable to transfusing hospitals were administered to 65 community-based and 108 hospital-based blood collection centers, and 2,214 transfusing hospitals. Jones et al. (2020) indicated a higher survey response rate for community-based blood centers (94%, *n* = 61), hospital-based blood centers (85%, *n* = 92), and transfusing hospitals (86%, *n* = 2435) compared to the 2015 survey responses. The researchers' findings revealed that 12,211,000 (95% CI, 11,680,000-12,742,000 units) WB and apheresis RBC units were collected in the U.S in 2017. The authors explained that the total amount of WB and apheresis collected in 2017 reflected a 3.0% decline in RBC collections since 2015, when 12,291,000 RBC units were collected. The researchers further indicated that in the United States, the rate of whole blood and RBC units collected per 1000 population decreased from 60.4 units in 2015 to 58.2 units in 2017 (Jones et al., 2020). The findings posed by Jones et al. (2020) raises concerns regarding the sustainability of the national blood system and its ability to maintain resilience.

Khurram et al. (2016) studied the frequency and reasons for donor deferral prior to the blood donation process. The researchers conducted a cross-sectional study at the National Institute of Blood Disease and Bone Marrow Transplantation in Karachi, Pakistan between 2012 and 2014 and documented the deferrals of all potential blood donor candidates between the study period. They found that out of a total of 25,901

attempted donations, 280 candidates were permanently deferred, while 2,876 individuals were temporarily deferred. History of hepatitis B infection and low hemoglobin levels were the most common factors for permanent and temporary deferrals (Khurram et al., 2016). Khurram et al.'s study was useful in defining and establishing factors for the continual decline in blood collections.

Kurup et al. (2016) analyzed the usage and wastage of blood and blood products at the Georgetown Public Hospital Cooperation (GPHC) in Guyana. A retrospective study was conducted on data retrieved from the hospital's laboratory blood banking information system on usage and wastage of blood products during 2012-2014. Out of a total of 16,426 units of blood, 25% (n = 4,167 units) were wasted due to various reasons. Kurup et al. (2016) concluded that the major reason for wastage was due to how the blood units were handled after collection. They further recommended that interventions through raising awareness among medical staff were needed to reduce blood wastage. Kurup et al.'s study was also useful in determining factors that contribute to the continual decline in blood quantity.

Shahshahani and Taghvai (2017) sought to determine the rate of blood component wastage before and after interventions were implemented at Yazd Blood Transfusion Center. The interventions included regular monitoring of blood component wastage, training sessions for staff, continual educational programs, calibration and validation of equipment, and the implementation of policies geared toward wastage management. Wastage data was obtained from all four echelons of the DBSC – collection, production, inventory, and distribution (Shahshahani & Taghvai, 2017). Discard rates of blood

components in the three years after interventions (2013-2015) were compared with the discard rates in the three years before interventions (2010-2012). Shahshahani and Taghvai (2017) found that after the implementation of multiple interventions, the wastage of blood components was significantly reduced (RBCs: from 9.7 to 2.9, $p < 0.001$; PLT: from 18.5 to 10.6%, $p < 0.001$; and plasma: from 5.4 to 2.3%, $p < 0.001$). This study was used to highlight the importance low-cost interventions to optimize blood availability and reduce wastage.

Whitaker et al. (2016) summarized data from the 2013 AABB (formerly known as the American Association of Blood Banks) Blood Collection, Utilization, and Patient Blood Management Survey (AABB Blood Survey). The researchers described the difficulty in obtaining an accurate national picture of blood collection and transfusion activity due to the diverse nature of the U.S. blood system. As such, a Web-based survey was conducted to capture quantitative data on blood collection, utilization, and patient blood management (PBM) activities among AABB blood centers and hospitals. Results of the survey were then compared to findings obtained from the 2013 NBCUS. Whitaker et al. (2016) indicated a significant decline in both blood collections and transfusions. However, the authors also revealed a decrease in the number of outdated and wasted components by hospitals which suggests improvements in product and inventory management. The findings from this study could be used to assist in understanding blood collection and utilization trends in the United States.

Strengths and Weaknesses of the Researchers' Approaches

Chung et al. (2015), Ellingson et al. (2017), and Jones et al. (2020) presented findings from the 2013, 2015, and 2017 NBCUS, which revealed declines in both blood collection and utilization. Although the researchers provided a viable estimate of the national blood collection and utilization, their studies were not void of limitations. First, the NBCUS is a cross-sectional survey of all U.S. blood collection centers and hospitals. However, according to Chung et. al. (2015), approximately one-third of the study participants' responses may not have been analyzed. Nevertheless, the researchers found that reporting bias was most likely to be minimal (Chung et. al., 2015). On the contrary, Ellingson et. al. (2017) indicated that their methodology and findings were more robust than that of Chung et al. (2015); however, Jones et al. (2020) explained that imputation and weighting were used to generate national estimates and comparisons with previous years could have been affected by differences in sampling and response rates. Additionally, Jones et al. (2020) indicated that several smaller hospitals, military hospitals, and outpatient facilities were excluded which may have resulted in underestimates.

The Whitaker et al. (2016) study was similar to the studies conducted by Chung et al. (2015), Ellingson et al. (2017), and Jones et al. (2020). The difference is that Whitaker et at. (2016) obtained information from AABB-member institutions only. Therefore, the findings from this study are predictive of AABB-member activity and not necessarily of the overall U.S. (Whitaker et al., 2016). The researchers' findings were compared to the 2013 NBCUS, in which they also discovered a descending trend in blood collections

(Whitaker et at., 2016). Therefore, despite the limitation, the comparisons were statistically robust and reflected U.S. collections in 2013 (Whitaker et at., 2016).

Collins et al. (2015), Kurup et al. (2016), and Shahshahani and Taghvai (2017) presented various causes of blood wastage and the benefits of reducing blood product wastage through multiple interventions. All investigators agreed that low-cost interventions could greatly reduce blood product wastage; however, since multiple inventions were examined, it was difficult to identify which intervention had the greatest impact (Collins et al., 2015; Kurup et al., 2016; and Shahshahani & Taghvai, 2017). Collins et al. (2015), Kurup et al. (2016), and Shahshahani and Taghvai (2017) used retrospective data; hence, their information was limited to the data available. Shahshahani and Taghvai (2017) found that expiry and preparation were major factors for blood wastage. Kurupt et al. (2016) also discovered that expiration was a major cause of blood wastage. On the other hand, Collins et al. (2015) indicated that a low-level of outdating of components in the blood bank is acceptable due to the inherent need to maintain inventory, and often the unpredictable demands on the inventory.

The study conducted by Khurram et al. (2016) was useful in defining and establishing factors for the continual decline in blood collections. However, researchers used a cross-sectional study design which only captured a specific point in time (Khurram et al., 2016). Nevertheless, the authors indicated that their results were consist with current literature (Khurram et al., 2016). The researchers further indicated that only 6.2% of their sample were volunteer (allogeneic) blood donors while others were

replacement (family) donors (Khurram et al., 2016). Their lack of allogeneic donors highlighted the need for more effective recruitment measures.

Literature Related to the Research Questions

I developed descriptive and inferential research questions to investigate trends and examine the association between gender, age group, ethnicity, year, serology, discard factors, and available blood collected between 2008–2017. The following research questions were presented:

RQ1: Is there an association between gender and available blood?

$H_0$1: There is no statistically significant association between gender and available blood.

$H_1$1: There is a statistically significant association between gender and available blood.

RQ2: Is there an association between age group and available blood?

$H_0$2: There is no statistically significant association between age group and available blood.

$H_1$2: There is a statistically significant association between age group and available blood.

RQ3: Is there an association between ethnicity and available blood?

$H_0$3: There is no statistically significant association between ethnicity and available blood.

$H_1$3: There is a statistically significant association between ethnicity and available blood.

RQ4: Is there an association between year and available blood?

$H_0$4: There is no statistically significant association between year and available blood.

$H_1$4: There is a statistically significant association between year and available blood.

RQ5: Is there an association between serology and available blood?

$H_0$5: There is no statistically significant association between serology and available blood.

$H_1$5: There is a statistically significant association between serology and available blood.

RQ6: Is there an association between discard factors and available blood?

$H_0$6: There is no statistically significant association between discard factors and available blood.

$H_1$6: There is a statistically significant association between discard factors and available blood.

RQ7: Is there an association between gender, age group, ethnicity, year, serology, discard factors and available blood?

$H_0$7: There is no statistically significant association between gender, age group, ethnicity, year, serology, discard factors and available blood.

$H_1$7: There is a statistically significant association between gender, age group, ethnicity, year, serology, discard factors and available blood.

Independent Variables

Gender/Age Group. The issue of gender and age differences in blood donation has received little attention in the literature. However, researchers have indicated that women are under-represented among allogeneic blood donors (Misje et al., 2010; Royse & Doochin, 2005; Ferdández-Montoya et al., 1998; James & Matthews, 1996; Ringwald et al. 2007). This may be because women experience up to 70% more exclusions from blood donation than men, due to higher rates of anemia, other health problems and adverse reactions (Newman, 2002; Newman et al., 2007). According to AABB, nearly 60% of blood donations come from people over the age of 40 years, and nearly 45% come from people older than 50 years (Whitaker et al., 2016). In the current study, I investigated the most prevalent gender and age groups among the blood donor population in New Orleans.

Race/Ethnicity. Researchers have shown that although the U.S. population has diversified, minorities are under-represented in the blood donor population. White donors constitute most of RBC donors and donations (Yazer et al., 2017). Yazer et al. (2017) noted that 86.7% of U.S. donors were White/Caucasian, 5.8% were Black/African American, 3.5% were Hispanic, 2.3% were Asian, and 1.7% were of other race/ethnicity. According to the U.S. Census Bureau (2019), African Americans constitute for 59.7% of the New Orleans population, whereas Caucasians, Hispanics, and Asians make up 34.0%, 5.5%, and 2.9% of the region, respectively. Since minorities represent the bulk of the New Orleans population, I examined their presence among the blood donor population.

Year. On August 23, 2005, the city of New Orleans was devastated by a Category 5 storm named Hurricane Katrina (American Red Cross, 2015). Hurricane Katrina's fury contributed to the loss of more than 1,800 lives and more than $81 billion in destruction and damages across the Gulf Coast region. The storm forced the evacuation of the entire New Orleans metropolitan area, and survivors were dispersed to various states. The population of New Orleans fell from 484,674 individuals before Hurricane Katrina (April 2000) to 230,172 individuals after Hurricane Katrina (July 2006) (Plyer, 2016). In 2007, the population slowly increased to 239,759 individuals (U.S. Census Bureau, 2017). Yet, in 2008, the population jumped to 264,976 individuals, and has continued climbing rapidly ever since (U.S. Census Bureau, 2017). As the population increased, the need for safe blood and blood products also increased. Therefore, to obtain a more current picture and trend of the available blood supply throughout the New Orleans region, I examined a 10-year period beginning January 1, 2008 to December 31, 2017 to determine the factors associated with the availability of the donated blood supply.

Serological Test. All blood for transfusion is tested for evidence of certain infectious disease pathogens. The government-mandated serological tests include hepatitis B and C viruses, Human Immunodeficiency Virus Types 1 and 2 (HIV), Human T-Lymphotropic Viruses Types 1 and II (HTLV-I/II), syphilis, West Nile Virus (WNV), Chagas disease, and bacterial contamination (Ellingson et al., 2017). In a review of the literature concerning serological tests, researchers have indicated that discard rates due to reactive infectious tests vary widely among blood centers (Shahshahani & Taghvai, 2017). In a study of blood services in Uganda, the investigators found that the discard

rate due to infectious tests reactivity was nearly 6% (Shahshahani & Taghvai, 2017). An analysis of reasons for discarding blood components in central India showed that 1-2% of blood components were discarded due to seropositivity for transfusion-transmissible infections (TTIs) (Shahshahani & Taghvai, 2017). The total blood discard rate due to positive serology in a blood center in Brazil was 5% (Monich et al., 2017). Researchers conducting screening test results for TTIs in The Netherlands and the Australian Red Cross Establishment revealed that the average for repeatedly reactive donations was approximately 0.1% (DeKort et al., 2016). Results of the 2017 NBCUS revealed, of whole blood and apheresis RBC units rejected after collection in 2017, 11.7% (78,000 units; 95% CI, 70,000-87,000 units) were rejected upon testing for transfusion-transmissible infections (Jones et al., 2020). In the current study, I examined the total blood discard rate due to positive serology as a whole and the rate of each test individually to determine which infectious disease was most predominant.

Major Discard Factors. Blood units can be discarded at any phase of the DBSC due to abnormal quality and/or quantity. The major discard factors that were examined in my study were defined as abnormal temperature, air contaminated, bloody, broken, clotted, expired, quantity not sufficient, and miscellaneous. In a review of the literature concerning major discard factors, researchers revealed that in 2017, a total of 666,000 whole blood and apheresis units were rejected after collection in the United States. Of the total blood units rejected, 88.3% (587,000 units; 95% CI, 539,000-635,000 units) were excluded for discard reasons, such as insufficient volume or a broken bag (Jones et al., 2020). Although a considerable amount of discarded blood is inevitable due to TTIs and

expiry, in the current study I reviewed trends to determine if there had been a decline or increase in the number of outdated and wasted components.

Dependent Variable

Available Blood. In a review of the literature, researchers have revealed a continued decrease in the amount of available blood. Jones et al. (2020) explained that the total WB and RBC supply available in 2017 after excluding units that were rejected was 11,545,000 units (95% CI, 11,034,000-12,057,000 units), a 4.0% decrease compared with 2015 (*n* = 12,028,000.). Chung et al. (2016) and Ellingson et al. (2017) also displayed trends that illustrated constant declines of the available blood supply. In addition, Whitaker et al. (2016) demonstrated declining blood supply trends among AABB blood centers and hospitals. However, these researchers focused solely on the national blood supply and not specifically the New Orleans area. My objective in this study was to investigate the amount of available blood within this region and establish trends.

Summary and Conclusions

The purpose of my study was to examine factors that were associated with the availability of the donated blood supply throughout the New Orleans region. Several researchers have acknowledged that there is a continuous decline of the national blood supply (Chung et al., 2016; Ellingson et al., 2017; Jones et al., 2020); however, there is a gap in understanding the contributing factors influencing the decline of the available blood supply (Klein et al., 2017). As such, I aimed to fill this gap in the literature by not

only identifying the barriers to blood availability, but also recommending initiatives to minimize wastage and optimize blood inventory.

In Chapter 3, I further delineate the research study design and methodology, including sampling procedures, instrumentation, and data analysis. I address any threats to the validity of the current study. Finally, in Chapter 3, I conclude with a description of measures taken to protect the rights of the study participants.

Chapter 3: Research Method

Introduction

The purpose of this quantitative, cross-sectional, epidemiological study was to examine factors associated with the availability of the donated blood supply throughout the city of New Orleans and its surrounding areas. Researchers have detected a national decline in blood collection in the United States (Chung et al., 2016; Ellingson et al., 2017; Jones et al., 2020). Nevertheless, the causes of this reduction are unclear. Klein et al. (2017) indicated that more information remains to be collected to better understand the vulnerabilities of the U.S. blood system. As such, I provided insight into the barriers affecting the availability of the donated blood supply through the identification of the factors contributing to this decline. I used bivariate logistic regression analysis to examine the association between gender, age group, ethnicity, year, serology, discard factors and available blood.

In this chapter, I explain the study's research method. I begin this chapter with a brief introduction of the purpose of the study. I proceed to highlight the study's research design and rationale as well as methodology. I discuss a detailed description of the study's target population along with sampling and sampling procedures. Although secondary data from TBC was used, I thoroughly explain the procedures for recruitment of participants and their eligibility for participation. In addition, I address threats to validity of the data and ethical considerations of the study. I conclude this chapter with an overall summary of the research methods used in this study.

Research Design and Rationale

I used a quantitative cross-sectional study design to analyze the secondary data retrieved from TBC's database. My focus in this study was to identify the factors associated with blood availability. Therefore, I examined several variables. The independent variables were gender, age group, ethnicity, year, serology, and discard factors. The dependent variable was available blood. The research questions and the null and alternate hypotheses in this study are as follows:

RQ1: Is there an association between gender and available blood?

$H_0$1: There is no statistically significant association between gender and available blood.

$H_1$1: There is a statistically significant association between gender and available blood.

RQ2: Is there an association between age group and available blood?

$H_0$2: There is no statistically significant association between age group and available blood.

$H_1$2: There is a statistically significant association between age group and available blood.

RQ3: Is there an association between ethnicity and available blood?

$H_0$3: There is no statistically significant association between ethnicity and available blood.

$H_1$3: There is a statistically significant association between ethnicity and available blood.

RQ4: Is there an association between year and available blood?

$H_0$4: There is no statistically significant association between year and available blood.

$H_1$4: There is a statistically significant association between year and available blood.

RQ5: Is there an association between serology and available blood?

$H_0$5: There is no statistically significant association between serology and available blood.

$H_1$5: There is a statistically significant association between serology and available blood.

RQ6: Is there an association between discard factors and available blood?

$H_0$6: There is no statistically significant association between discard factors and available blood.

$H_1$6: There is a statistically significant association between discard factors and available blood.

RQ7: Is there an association between gender, age group, ethnicity, year, serology, discard factors and available blood?

$H_0$7: There is no statistically significant association between gender, age group, ethnicity, year, serology, discard factors and available blood.

$H_1$7: There is a statistically significant association between gender, age group, ethnicity, year, serology, discard factors and available blood.

Quantitative research is used to quantify a problem by way of generating numerical data or data that can be transformed into usable statistics to formulate facts and uncover patterns in research, as indicated by Burkholder et al. (2016). It is most useful in testing and validating theories. By contrast, a qualitative study is suitable for such data as opinions, behaviors, values, and social context of a population (Creswell, 2009). As such, a qualitative approach was not suitable for this study due to the type of numerical data that I collected from TBC's Blood Establishment Computer System (BECS). Unlike qualitative research, which is characterized by queries that ask *why* or *how*, in quantitative research the researcher asks questions that pertain to what, where or when. Given my research questions and problem statement, a quantitative approach was most suitable for this study. I chose a quantitative method to explore the associations between gender, age group, ethnicity, year, serology, discard factors and available blood. I used quantitative analysis tools to answer the research questions by analyzing the associations between categorical independent variables on a dichotomous dependent variable.

Creswell (2009) explained that a cross-sectional design involves collecting data from a population at a specific point in time. As such, I chose a cross-sectional design for this study. Cross-sectional studies provide a snapshot of the frequency of a disease or other health-related issues in a population at a given point in time. Because data are collected within a certain period, a cross-sectional design is susceptible to biases. Despite this limitation, a cross-sectional design was most suitable for investigating factors associated with blood availability. Other quantitative designs, such as case-control or experimental were not appropriate for this study. Case-control design provides data on

specific people within a population with certain characteristics, whereas experimental design evaluates the utility of a proposed new drug, treatment, or program (Aschengrau & Seage, 2014). By using a cross-sectional design, this allowed me to estimate the prevalence of factors in the sample and make proper inferences that will benefit the general population. In this study, I investigated barriers to blood availability in a representative sample of the New Orleans blood donor population using data from TBC collected between January 1, 2008 and December 31, 2017.

Methodology

Population

I obtained secondary data from TBC of New Orleans, Louisiana. Founded in 1960, TBC is responsible for blood collection, processing, testing, and distribution of blood and blood products. Its facility is one of the largest blood centers in the New Orleans area and the primary supplier of blood, blood components, and plasma derivatives to local hospitals throughout South Louisiana and parts of the Mississippi Gulf Coast. In addition, TBC collects and stores demographic and laboratory results on blood donors who have donated with their establishment in their secured computer database. Accredited by the AABB and licensed by the Food and Drug Administration, the information obtained from TBC meets federal regulations and guidelines.

The primary target population consisted of healthy male and female blood donors who donated whole blood or blood components at TBC's mobile or donor center collection site between 2008 to 2017. The sample was comprised of 286,625 allogeneic blood donors aged 16 years and greater. Other donation criteria included a weight of

more than 110 lbs. if 17 years of age or greater, or 130 lbs. if 16 years of age; hemoglobin greater than 12.5 g/dl for women and 13.0 g/dl for men; pulse ranging between 50-100 bpm, and; blood pressure ranging between 90–180 for systolic and 50–100 for diastolic. Regarding race/ethnicity, the blood donors were diversified into the categories of Black/African American, White/Caucasian, Asian, or Other.

Sampling and Sampling Procedures

I used a simple random sampling technique to select the study participants. Simple random sampling involves drawing a sample so that individuals in the population of interest have an equal likelihood of selection (Babbie, 2017). One advantage of simple random sampling is that it creates samples that are highly representative of the population. However, this process is extremely cumbersome and time consuming, especially when creating larger samples.

Sampling Frame

I selected the sample based on their health status, age, weight, and ability to meet eligibility rules established by the FDA. Blood donors were in good general health (i.e., not ill and were able to carry out normal daily activities), weighed at least 110 pounds, and was at least 16 years old. Blood donors were excluded if they met the following criteria:

- Had tested positive for hepatitis B or hepatitis C, co-habited or had sexual contact within 12 months with anyone who had hepatitis B or symptomatic hepatitis C.
- Had ever had a positive test for the HIV/AIDS virus.
- A male who had sex with another male since 1977.

- Used injectable drugs, including anabolic steroids, not prescribed by a physician.
- Engaged in prostitution.
- Had or been treated for syphilis or gonorrhea within 12 months.
- Had a tattoo within 12 months or received a blood transfusion within 12 months.
- Had an accidental needle-stick or came in contact with someone else's blood within 12 months.
- Lived in or visited the United Kingdom for 3 months or more cumulatively between 1980 and 1996.
- Spent a cumulative total of 5 years or more in Europe between 1980 to the present.
- Resided on a military base in Europe for 6 months or more between 1980 to 1996.
- Traveled or lived in a malaria-endemic area.
- Had cancer during the last year unless localized and treated.
- Taken medications known to cause fetal abnormalities and certain vaccinations/immunizations.
- Had ever received a dura mater (brain covering) graft.
- Had ever been diagnosed with Creutzfeldt-Jakob Disease (CJD), variant CJD (vCJD), or had a blood relative diagnosed with genetic CJD.
- Pregnant women and incarcerated individuals were also excluded from the sample.

Power Analysis. A power analysis is conducted to help the researcher determine the smallest sample size that is suitable to detect the effect of a given test at the desired

level of significance (Sullivan & Feinn, 2012). If the sample size is too small, the results may be inconclusive. I conducted the power analysis to increase the likelihood that the null hypothesis was correctly rejected. For example, a study that has an 80% power means that the study has an 80% chance of the test having significant results. Hence, it is important for a researcher to perform a power analysis before beginning research. My preferred determined alpha level for this study was set at 0.05. Adding more restriction, such as setting the alpha level at 0.01, would increase the probability of a Type II error, failing to reject the null hypothesis. As such, setting the alpha at 0.05 was a good balance between avoiding both Type I and Type II errors.

Power Analysis Justification. I used G*Power 3.1.9.2 to determine a suitable sample size for this study. I also used a bivariate logistic regression analysis along with an A priori power analysis to analyze the research questions. Considering a confidence level of 95% ($\alpha = 0.05$), a power of 0.95, and a binomial distribution, I calculated the total minimum sample size needed to achieve 95% power as 3,651 persons. However, my study consisted of 286,625 participants, which exceeded the minimum requirements needed to detect significance and enhance the validity of the study.

Procedures for Recruitment, Participation, and Data Collection

TBC staff used planned and ad hoc approaches to recruit the sample, which consists only of volunteer blood donors. It is unacceptable to provide volunteer blood donors with monetary compensation, hence the act of blood donation in the United States is voluntary (Zegler et al., 2007). To appeal to extrinsic donors (donors who respond to incentives), TBC advertised FDA-approved donation incentives such as t-shirts, cups,

membership in a blood assurance program, non-redeemable gift cards, event tickets, and paid time off from work. However, Zegler et al. (2007) suggested that the most successful approach to recruitment of volunteer blood donors has been an appeal to community responsibility. As such, TBC staff also used this approach and informed donors of the need for donation through public service announcements and appeals for blood from newspapers, radio, email, billboards, and television. Other donors became aware of the importance of blood donation when transfusions were needed for family, friends, or themselves. In addition, telemarketers were used whenever there was need for blood of a special blood group or a significant surge in blood demand.

Once the blood donor had been recruited, TBC workers followed a screening protocol to ensure that the donation process was safe not only for the donor but also for the intended recipient. Per federal guidelines and regulations, the prospective donor was initially provided information regarding the criteria for blood donation eligibility and the process itself. Prospective donors were provided with informed consent. In the latest revision of the International Society of Blood Transfusion (ISBT) Code of Ethics published in 2017, it is required that such contribution should be respected, the donor should be advised of all risks associated with blood donation, and all reasonable steps must be taken to protect the donor's health and safety. Practitioners are advised to maintain anonymity and confidentiality of all donors and recipients.

The screening protocol consisted of a medical health history questionnaire that was designed to find medical conditions and behaviors that might make the donation unsafe for the donor or recipient. If no disqualifying information was discovered during

the screening process, a brief physical examination that consisted of the measurement of the prospective donor's hematocrit or hemoglobin, pulse rate, blood pressure, and body temperature followed. Information concerning the prospective donor's age, weight, and an examination of the antecubital area of their arms was also conducted and documented on the questionnaire. Once the screening process was completed, the prospective donor then proceeded to the phlebotomy area. In the phlebotomy area, the donor's arms were re-assessed for veins suitable for venipuncture using a tourniquet or blood pressure cuff. If the donor's veins were not found to be suitable for venipuncture, the individual was deferred from donating blood. However, if found suitable, venipuncture was performed. A pint of blood from the donor was then collected, tested, and processed for distribution. The private nature of TBC data required a special release agreement between the Chief Executive Officer (CEO) of the organization and any researchers. Both verbal and written permission was obtained from the facility's CEO, William "Billy" Weales.

Instrumentation and Operationalization of Constructs

TBC staff used a wide variety of instruments to collect data. Blood donor information was captured using blood establishment computer software (BECS). BECS is used in the manufacture of blood and blood components to assist in the prevention of infectious disease in humans (Food and Drug Administration [FDA], 2013). Its major functions are to identify ineligible donors by preventing the release of unsuitable blood and blood components for transfusion or for further manufacturing into products for human treatment or diagnosis. Staff also conduct compatibility testing between the donor

and the recipient and perform positive identification of patients and blood components at the point of transfusion to prevent transfusion reactions.

Although the blood donors' information was stored in BECS, a confidential donor history questionnaire (DHQ) was also used to capture relevant information concerning the donor to determine eligibility. The DHQ consisted of a standardized set of questions used by most blood centers in the U.S. to screen volunteer blood donors. It included all the questions that must be asked of U.S. blood donors, but also flowcharts outlining the steps to take depending on a donors' answer to a question, educational materials for donors, and a list of medications that lead to donor deferral from donation. Interviews were administered at either a blood collection center or mobile site with trained donor technicians. Additional instrumentation included the use of a calibrated sphygmomanometer and stethoscope, a watch with a second hand, a hemoglobin/hematocrit analyzer, and disposable thermometers to capture the results of the donors' pulse, blood pressure, temperature, and hemoglobin/hematocrit levels during the medical screening process. Following the medical screening process, phlebotomists used a sterile blood collection bag containing anticoagulant and an integrally attached tube and needle to collect the donors' blood. A sample diversion pouch was connected to sequester the first 20-60 ml of blood collected for sample tubes. Trained donor technicians and phlebotomists collected blood samples and units from the participants during the blood donation process. Upon completion of the donation, blood collection units and sample tubes were placed in validated insulated containers for transport to the blood bank's laboratory.

Laboratory technicians performed tests based on the blood donors' eligibility at the time of the interview. The blood samples were assessed for various indicators, such as blood type (ABO group) and Rh type (positive or negative), as well as certain proteins and antibodies that may cause adverse reactions in a person receiving a blood transfusion (Ellingson et al., 2017). The samples were also tested for infectious disease pathogens transmissible by blood transfusion, such as hepatitis B virus (HBV), hepatitis C virus (HCV), Human Immunodeficiency virus Types 1 and 2 (HIV), Human T-Lymphotropic virus Types I and II (HTLV), *Treponema pallidum* (syphilis), West Nile virus (WNV), Zika virus (ZIKV), Trypanosoma cruzi (Chagas disease), Cytomegalovirus (CMV), and bacterial contamination (platelet donations only). The instruments used to conduct these tests were the NEO and ECHO (ABO/Rh and antibody identification and CMV), Cobas 6800 (WNV, ZIKV, HBV, HIV, and HCV), PK 7300 (syphilis), Ortho Summit Processor (HIV, hepatitis B surface antigen (HBsAG), HTLV, hepatitis B core (HBCore), HCV, and Chagas disease), BioRad PhD (Ebstein-Barr virus (EBV) and Toxoplasmosis). All laboratory testing instruments were not only used by multiple U.S. blood banks, but were also calibrated, validated, and approved by both AABB and FDA.

When test results were received, units suitable for transfusion were labeled and stored. Red cells were stored in refrigerators at 6ºC for up to 42 days. Platelets were stored at room temperature in agitators for up to five days. Plasma and cryo products were frozen and stored in freezers for up to one year. Upon hospital request, the units were then shipped in validated insulated containers to a specified facility.

Figure 3 shows the study variables and their operationalization.

Figure 3

Variables and Operationalization

Conceptual Framework Title: Donated Blood Supply Chain	Proposed Study Title: Barriers to Blood Availability Within the New Orleans Area	Variable Nature/Coding Scheme
1- Collection	1- Gender, Year	Gender: (Independent variable) Nominal; 0 = Male; 1 = Female Year: (Independent variable) Ordinal; 0 = 2008; 1 = 2009; 2 = 2010; 3 = 2011; 4 = 2012; 5 = 2013; 6 = 2014; 7 = 2015; 8 = 2016; 9 = 2017
2- Collection	2- Age Group, Year	Age Group: (Independent variable) Ordinal; 0 = 16–26 years; 1 = 27–34 years; 2 = 35–44 years; 3 = 45–54 years; 4 = 55–64 years; 5 = 65–96 years. Year: (Independent variable) Ordinal; 0 = 2008; 1 = 2009; 2 = 2010; 3 = 2011; 4 = 2012; 5 = 2013; 6 = 2014; 7 = 2015; 8 = 2016; 9 = 2017
3- Collection	3- Ethnicity, Year	Ethnicity: (Independent variable) Nominal; 0 = White/Caucasian; 1 = Black/African American; 2 = Asian; 3 = Other; 4 = Unknown Year: (Independent variable) Ordinal; 0 = 2008; 1 = 2009; 2 = 2010; 3 = 2011; 4 = 2012; 5 = 2013; 6 = 2014; 7 = 2015; 8 = 2016; 9 = 2017

3- Production	4- Serology, Year	Serology: (Independent variable) Nominal; 0 = Bacterial Contamination; 1 = Chagas Disease; 2 = Hepatitis B; 3 = Hepatitis C; 4 = HIV; 5 = HTLV I/II; 6 = Syphilis; 7 = West Nile Virus. Year: (Independent variable) Ordinal; 0 = 2008; 1 = 2009; 2 = 2010; 3 = 2011; 4 = 2012; 5 = 2013; 6 = 2014; 7 = 2015; 8 = 2016; 9 = 2017
4- Inventory	5- Discard Factors, Year	Discard Factors: (Independent variable) Nominal; 0 = Abnormal temperature; 1 = Air contaminated; 2 = Bloody; 3 = Broken; 4 = Clotted; 5 = Expired; 6 = Miscellaneous; 7 = Quantity Not Sufficient Year: (Independent variable) Ordinal; 0 = 2008; 1 = 2009; 2 = 2010; 3 = 2011; 4 = 2012; 5 = 2013; 6 = 2014; 7 = 2015; 8 = 2016; 9 = 2017
5- Distribution	6- Available Blood, Year	Available Blood: (Dependent variable) Dichotomous; 0 = No, blood is not available for use; 1 = Yes, blood is available for use. Year: (Independent variable) Ordinal; 0 = 2008; 1 = 2009; 2 = 2010; 3 = 2011; 4 = 2012; 5 = 2013; 6 = 2014; 7 = 2015; 8 = 2016; 9 = 2017

Reliability and Validity

TBC staff took numerous steps to ensure reliability and validity of the data collected. First, all equipment used for collection of blood donations were regularly calibrated, maintained, and serviced, as required. Such equipment included but were not limited to computers, blood pressure monitors, hemoglobin/hematocrit analyzers, scales, donor chairs, blood collection monitors, blood bag tube sealers, blood transportation boxes, sample tube testing equipment, centrifuges, rotators, and blood bank refrigerators. Second, all donor technicians involved in interviewing and sample collection went through an extensive 12-week training program which involved appropriate interviewing, computer, phlebotomy, donor confidentiality, and cardiopulmonary resuscitation. Additionally, clear instructions and manuals were provided on proper collecting, labeling, and processing units. Third, all laboratory personnel underwent certified training in laboratory practices and safety. Technologists processing the samples and involved in other areas of sample collection held degrees and certifications in medical technology. Standard operating procedure manuals were also provided on proper testing, labeling, processing, and distribution of samples and units. Fourth, the laboratory results were directly entered into BECS. All entries were verified for a second time by an experienced TBC staff person. Fifth, annual performance evaluations were conducted on all TBC staff. Finally, all areas of TBC were internally and externally audited by Quality Assurance, AABB, FDA, and other regulatory agencies on a periodic basis to ensure accuracy and completeness of processes and data entries.

Threats to Validity

According to Patino and Ferreira (2018), the validity of a research study refers to how well the results among the study participants represent true and accurate findings among similar individuals outside the study. The validity of a research study includes both internal and external validity. Internal validity is the extent to which the observed results accurately represent the condition of the population, and therefore, are not due to methodological errors. The internal validity of a study can be threatened by many factors, including errors in measurement or in the selection of participants in the study. While internal validity relates to how well a study is conducted, external validity relates to how applicable the findings are to other people, settings, situations, and time periods. Threats to external validity include selection bias and situational factors, such as time and location, that may affect the generalizability of findings.

Mertler (2016) explained that all types of quantitative research designs are subject to threats of internal and external validity. These threats must be controlled, or accounted for, so that the potential error they might introduce into the research study does not jeopardize the legitimacy and accuracy of the research findings and conclusions. The FDA has issued a guidance to assist blood establishments in developing a blood establishment computer system validation program, consistent with recognized principles of software validation, quality assurance, and current good software engineering practices. As such, the TBC's BECS has undergone extensive testing and met the validity, reliability, and accuracy standards as defined by the FDA guidelines. Threats to validity were controlled through the extensive training of individuals conducting the

interviews, collecting the blood, performing the laboratory testing and analyzing the findings, and processing and distributing the units of blood. Minimizing threats to validity was also maintained by automated and computerized data entry of results, certified phlebotomy and laboratory technicians, and by only using forms approved by the AABB, FDA, and other various ethical committees.

Potential Bias

Despite the rigorous training of TBC personnel and strict ethical standards of the organization's processes, limitations and information bias did exist. Information bias, also known as measurement bias or misclassification bias, is a distortion in the measure of association caused by a lack of accurate measurements of key study variables (Szklo & Nieto, 2014). Information bias results when key study variables, such as exposure, health outcome, or confounders are inaccurately measured or classified. Regardless of the reason, the information collected is not accurate and could therefore introduce bias into the analysis. TBC's donor medical screening and laboratory processes were subject to three different types of information bias: recall bias, interviewer bias, and measurement variations.

Recall bias occurs when participants erroneously report data. Recall bias was minimized by probing questions that detected irregularity in responses. Interviewer bias occurs when interviewers record inaccurate data into BECS or pose questions in a way to elicit a specific favorable response. This type of bias was reduced by using standardized questions and multiple reviews of data entry by supervisors and quality control personnel. Measurement variations can occur when performing laboratory testing. Measurement

variations and interviewer bias were minimized through extensive training of field staff, and standard operating procedures that reviewed responses and testing results. Annual training, refresher courses, and quality assurance programs enhanced the reporting of accurate and reliable data from BECS.

Ethical Procedures

Due to the private nature of the secondary archived data, special authorization was required from TBC. I obtained both verbal and written agreements from the organization's Chief Executive Officer, Billy Weales. Data were downloaded into a password-protected personal computer accessed by the researcher of this study. The data were then downloaded and converted into SPSS format for analysis.

Federal regulations require that the identity of all blood donors be masked prior to testing. Therefore, all participants' information remained confidential and protected in accordance with federal laws, i.e. the Code of Federal Regulations, Title 21, Volume 7 (21CFR630.15). Donor demographics, blood collection samples, and blood units were coded with unique bar-coded numbers in place of names or other personal identifiers.

TBC's mission is to provide a quality supply of blood components to meet the needs of the communities served by the organization, and to provide the technical support needed by the blood banking profession to achieve the highest safety and ethical standards. As such, informed consent was obtained pre-donation. All participants were provided with privacy statements concerning their rights for review and consideration. The following information was provided to participant prior to blood donation:

- Educational materials regarding the blood donation process and potential adverse donor reactions
- The tests that were conducted (transfusion-transmissible infections, blood group serology, etc.) on the samples taken from the donated blood and the reasons for these tests
- Notice of confidentiality of all personal information, including test results
- The mode of communication with the donor about unusual or abnormal test results
- A notice stating that a sample of the donated blood unit may be used for additional tests, quality assurance, or research purposes

Donors were also allowed an opportunity to ask questions and withdraw their participation at any stage of the donation process. Additionally, TBC personnel were extensively trained on how to ensure privacy of blood donors and confidentiality of donors' personal information and test results. In addition to being an ethical obligation, maintaining confidentiality and privacy contributes to a safe blood supply. Therefore, all personal information revealed to TBC staff was protected and not shared with any unauthorized person. Once stored in BECS, only authorized personnel, such as TBC managers, directors, vice presidents, and medical directors had access to the participants' personal information.

Other Ethical Issues

The information obtained for this study was obtained from my own work setting. As such, there were several consents and precautions that were mandated by the

Institutional Review Board (IRB) prior to research study. First, the secondary analysis of data was generated as a byproduct of normal organizational practices (Walden University, n. d.). Since infectious disease testing is considered a normal work practice as it is conducted on all donated blood products, the dataset met this IRB criterion. Second, no client names or identifiers were recorded in the research documents. As previously mentioned, federal regulations require that the identity of all blood donors be masked prior to testing. Therefore, all client identifiers are currently removed from test results. Finally, a data use agreement releasing the de-identified test results was signed by my organization's chief executive officer. This practice was used to ensure that my organization was aware and in agreement with the research being conducted at their facility. All permissions obtained from TBC's CEO are depicted in Appendices A and B. Additionally, I obtained Walden's IRB approval was before data collection.

This study was conducted to fulfill the requirements for the Doctor of Philosophy, Public Health/Epidemiology program at Walden University. I declare no financial interest was pursued in this study. I also claim no conflicts of interest with other parties.

Summary

The purpose of this quantitative, epidemiological study was to examine factors associated with the availability of the donated blood supply throughout the city of New Orleans and its surrounding areas. I used a cross-sectional research design to assess the association between gender, age group, ethnicity, year, serology, discard factors and the available blood supply. I obtained secondary data from TBC to examine a study population consisting of 286,625 allogeneic blood donors. I discussed instrumentation

that was used to select the sample, as well as collect and process blood samples and units throughout this chapter. Potential threats to the validity of the study included three different types of information bias: recall bias, interviewer bias, and measurement variations. However, I explained the methods used to control and reduce bias. Finally, I concluded Chapter 3 with a description of measures taken to protect the rights of the study participants. I have conducted and presented the data analysis and research results in Chapter 4.

Chapter 4: Results

Introduction

The purpose of this quantitative, cross-sectional, epidemiological study was to provide insight into the barriers affecting the availability of the donated blood. I used descriptive statistics and bivariate logistic regression analysis to determine whether gender, age group, ethnicity, year, serological tests, and discard factors were associated with the availability of the donated blood supply throughout the New Orleans region. The research questions and hypotheses of the study are as follows:

RQ1: Is there an association between gender and available blood?

$H_0$1: There is no statistically significant association between gender and available blood.

$H_1$1: There is a statistically significant association between gender and available blood.

RQ2: Is there an association between age group and available blood?

$H_0$2: There is no statistically significant association between age group and available blood.

$H_1$2: There is a statistically significant association between age group and available blood.

RQ3: Is there an association between ethnicity and available blood?

$H_0$3: There is no statistically significant association between ethnicity and available blood.

$H_1$3: There is a statistically significant association between ethnicity and available blood.

RQ4: Is there an association between year and available blood?

$H_0$4: There is no statistically significant association between year and available blood.

$H_1$4: There is a statistically significant association between year and available blood.

RQ5: Is there an association between serology and available blood?

$H_0$5: There is no statistically significant association between serology and available blood.

$H_1$5: There is a statistically significant association between serology and available blood.

RQ6: Is there an association between discard factors and available blood?

$H_0$6: There is no statistically significant association between discard factors and available blood.

$H_1$6: There is a statistically significant association between discard factors and available blood.

RQ7: Is there an association between gender, age group, ethnicity, year, serology, discard factors and available blood?

$H_0$7: There is no statistically significant association between gender, age group, ethnicity, year, serology, discard factors and available blood.

$H_1$7: There is a statistically significant association between gender, age group, ethnicity, year, serology, discard factors and available blood.

In this chapter, I presented information regarding the data collection process and results of the study. The data collection process includes an account of the time frame in which the data was collected, discrepancies in data collection methods, and a description of the study population. Chapter 4 also includes a descriptive analysis of the variables, and the findings of bivariate logistic regression analysis. This chapter concludes with a summary and a transition to Chapter 5.

Data Collection

After obtaining International Review Board (IRB) approval from Walden University, I extracted data from TBC's database. The IRB approval number for this study is 03-29-21-0697816. I downloaded data from 2008 through 2017 and saved it to a large ZIP file. The data included information on whole blood units collected between January 1, 2008 and December 31, 2017. Due to the enormity of the file, which generated over one million cases, I only included whole blood collections obtained from allogeneic blood donors in this study (n = 889,717 units). As stated in Chapter 3, I only examined allogeneic donations in this study, which excludes therapeutic and autologous procedures. However, I excluded directed, apheresis, replacement, and replenishment donations from the study to minimize the dataset. Despite these omissions, the purpose of the study, which was to examine factors associated with the availability of the donated blood supply, was not altered. I separated the 2008–2017 datasets into individual files. I then

merged each individual dataset into one dataset file and uploaded into SPSS. The total time frame for data collection after IRB approval was approximately 6 weeks.

Results

This section includes the findings of the study, beginning with a descriptive and demographic analysis of the study population followed by the results of each research question. I used bivariate logistic regression analysis to assess the association between the categorical independent variables and the dichotomous dependent variable. I employed the Kolmogorov-Smirnov (K-S) goodness of fit test to test for normality. I also used the odds ratio (OR) to describe the probability of associations between the independent and dependent variables. For comparison of statistical significance, I set a 95% level of confidence and an alpha level of 0.05. The seven assumptions of bivariate logistic regression were met, and I explored the probability and significance of each association.

Descriptive Statistics

TBC's 2008–2017 datasets included a total of 889,717 whole blood donations, which were made by 286,625 allogeneic blood donors aged 16 to 96 years. I generated frequency distribution tables along with charts and graphs to illustrate the counts, frequencies, and percentages of the six categorical independent variables (gender, age group, ethnicity, year, serological tests, and discard factors) and the one dichotomous dependent variable (available blood). Information about the categorical variables for the population is provided in Tables 1–7 and Figures 4–12.

Gender

The gender variable was divided into two subcategories: (a) male, and (b) female. Table 1 shows the frequency distribution and percentage of gender. According to the table, more whole blood units were collected from male blood donors (*n* = 514,813, 57.9%) compared to female blood donors (*n* = 374,864, 42.1%). The bar chart shown in Figure 4 graphically illustrates the frequency and percentage of whole blood donations by gender.

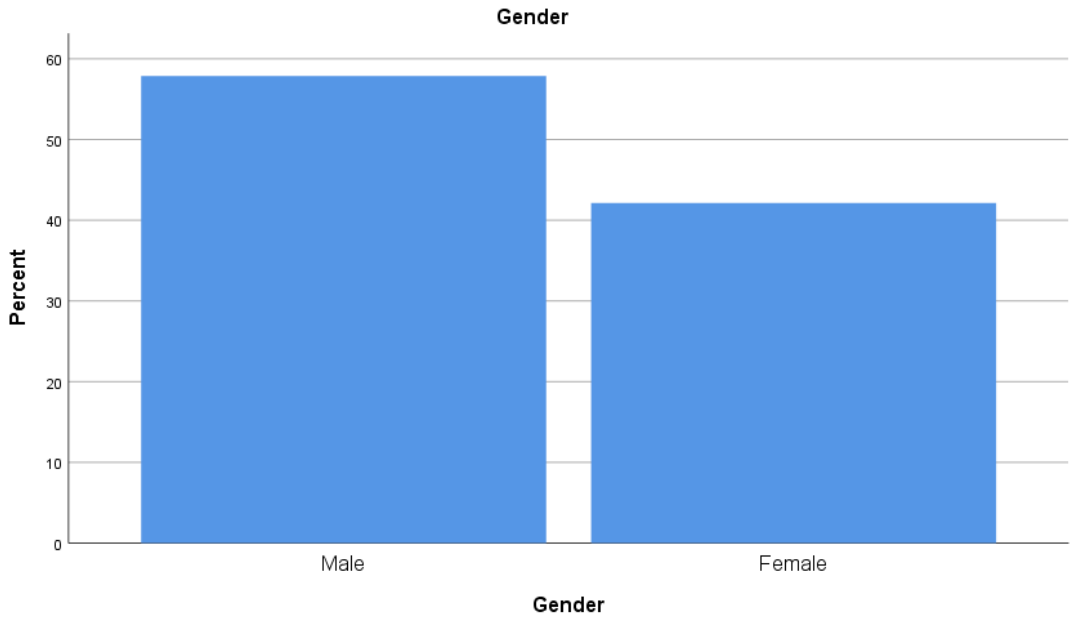
Table 1

Frequency Distribution and Percentage of Whole Blood Units by Gender

Variable	Frequency	Percent
Gender		
Male	514853	57.9
Female	374864	42.1

Figure 4

Simple Bar Percent of Whole Blood Units by Gender



Age Group

The age group variable was subdivided into five categories: (a) 16–26 years, (b) 27–34 years, (c) 35–44 years, (d) 45–54 years, (e) 55–64 years, and (e) 65–96 years. The frequency distribution table (Table 2) shows that 260,388 (29.3%) whole blood units were collected from blood donors between the ages of 16–26 years, 123,014 (13.8%) units between the ages of 27–34 years, 142,029 (16.1%) units between the ages of 35–44 years, 171,440 (19.3%) units between the ages of 45–54, 134,097 (15.1%) units between the ages of 55–64 years, and 57,749 (6.5%) units were collected from blood donors between the ages of 65–96 years. Figure 5 shows a simple bar percentage of whole blood donations by age group. When compared to the other age groups, blood donors in the age

group 16–26 years donated more whole blood units between 2008 to 2017 than the other age groups.

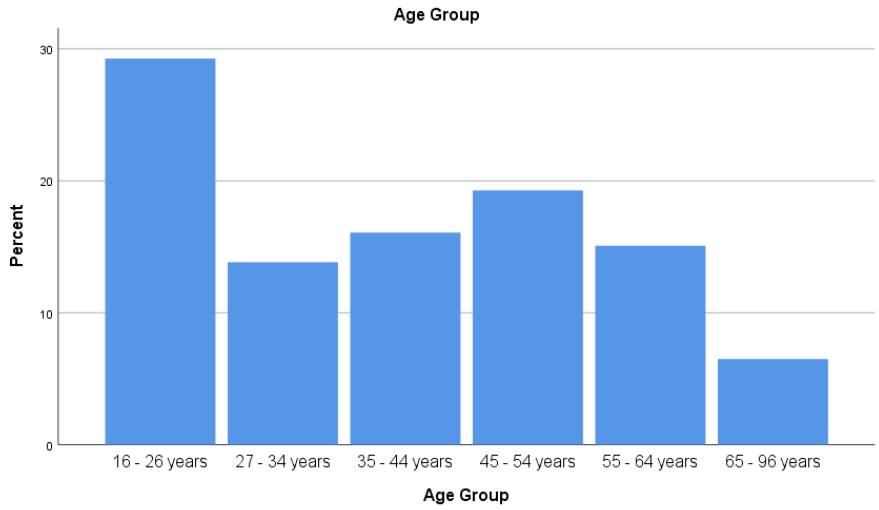
Table 2

Frequency Distribution and Percentage of Whole Blood Units by Age Group

Variable	Frequency	Percent
Age Group		
16 – 26 years	260388	29.3
27 – 34 years	123014	13.8
35 – 44 years	143029	16.1
45 – 54 years	171440	19.3
55 – 64 years	134097	15.1
65 – 96 years	57749	6.5

Figure 5

Simple Bar Percent of Whole Blood Units by Age Group



Ethnicity

Table 3 shows the frequencies and percentages of the ethnicity independent variable. The ethnicity variable was subdivided into five categories: (a) White/Caucasian, (b) Black/African American, (c) Asian, (d) Other, and (e) Unknown. Whole blood donations involved blood donors who were predominantly White/Caucasian, accounting

for 709,381 (79.7%) of the donations. Whole blood donations for minority groups accounted for 132,807 (14.9%), 3,898 (0.4%), and 43,201 (4.9%), for Black/African American, Asian, and Other, respectively. The ethnicity of the remaining (*n* = 430, 0%) whole blood units were unknown. Based on Table 3, Figure 6 shows the percentage of whole blood donations by ethnicity using a simple bar chart.

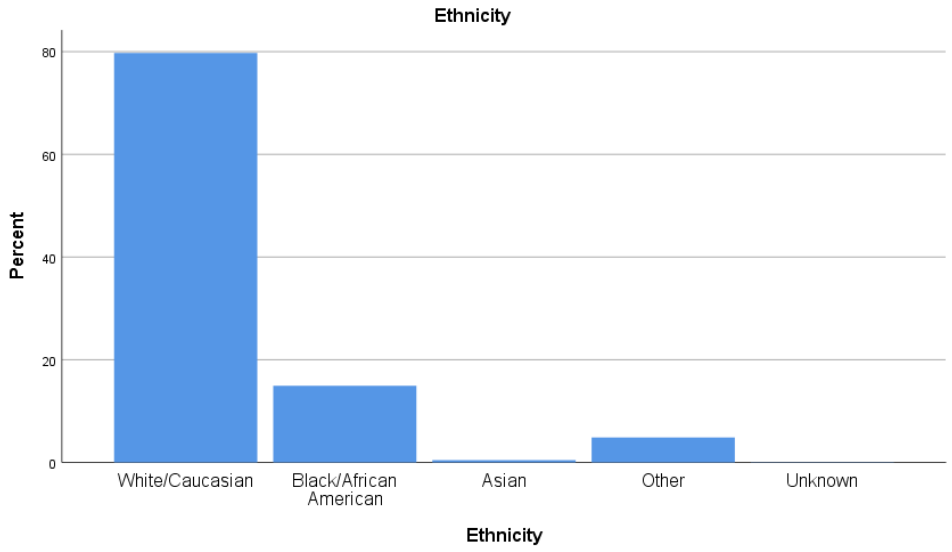
Table 3

Frequency Distribution and Percentage of Whole Blood Units by Ethnicity

Variable	Frequency	Percent
Ethnicity		
White/Caucasian	709381	79.7
Black/African American	132807	14.9
Asian	3898	0.4
Other	43201	4.9
Unknown	430	0.0

Figure 6

Simple Bar Percent of Whole Blood Units by Ethnicity



Year

The year variable was subdivided into ten categories: (a) 2008, (b) 2009, (c) 2010, (d) 2011, (e) 2012, (f) 2013, (g) 2014, (h) 2015, (i) 2016, and (j) 2017. The frequency distribution table (Table 4) shows an increase in whole blood collections between 2008–2010, with a slow decline between 2011–2017. In 2008, 80,544 (9.1%) units were collected, whereas in 2009, 96,784 (10.9%) units were collected. Most whole blood units were collected in 2010, (*n* = 101,955, 11.5%), followed by a decline in 2011 (n = 92,901, 10.4%). Whole blood collections once again increased in 2012 (*n* = 100,252, 11.3%); however, a slow decline followed with 85,160 (9.6%), 84,925 (9.5%), and 79,592 (8.9%) units in 2013, 2014, and 2015, respectively. In 2016, 95,971 (10.8%) units were collected 2016; however, the lowest number of whole blood units were collected in 2017 (*n* = 71,633, 8.1%). Using a simple bar chart, Figure 7 shows the percentage of whole blood donations by year.

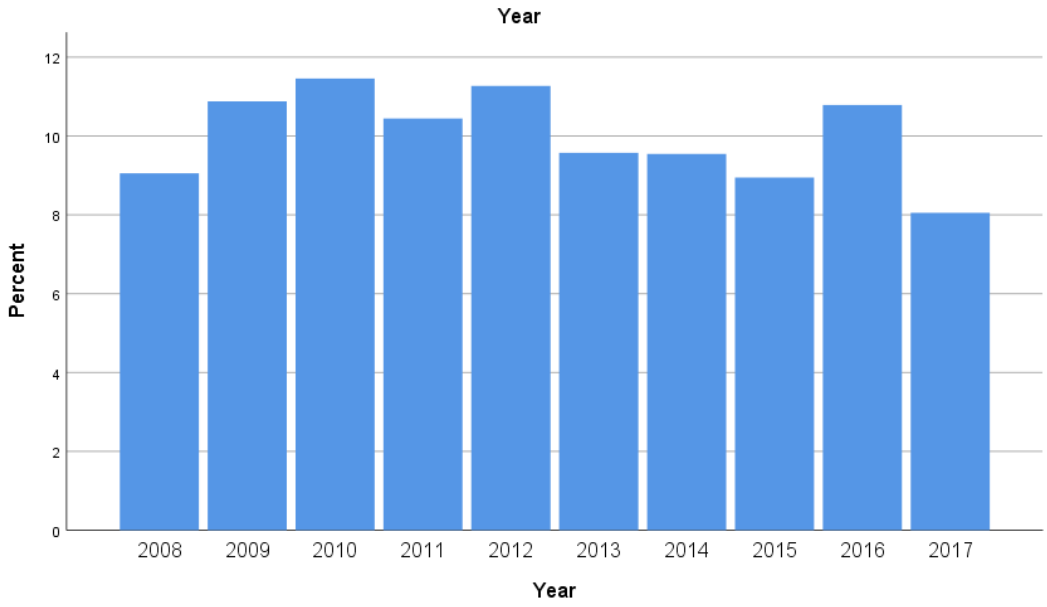
Table 4

Frequency Distribution and Percentage of Whole Blood Units by Year

Variable	Frequency	Percent
Year		
2008	80544	9.1
2009	96784	10.9
2010	101955	11.5
2011	92901	10.4
2012	100252	11.3
2013	85160	9.6
2014	84925	9.5
2015	79592	8.9
2016	95971	10.8
2017	71633	8.1

Figure 7

Simple Bar Percent of Whole Blood Units by Year



Serology

Table 5 illustrates the frequency and percentage of whole blood units that were discarded due to positive serology results. Serology was subdivided into nine categories: (a) bacterial contamination, (b) Chagas disease, (c) hepatitis B, (d) hepatitis C, (e) HIV, (f) HTLV I/II, (g) syphilis, (h) WNV, and (i) negative serology. Table 5 shows that 363 (0.0%) whole blood units were discarded due to bacterial contamination, followed by positive Chagas results (*n* = 76, 0.0%), hepatitis B (*n* = 15,789, 1.8%), hepatitis C (*n* = 5,433, 0.6), HIV (*n* = 1,407, 0.2%), HTLV I/II (*n* = 1,661, 0.2%), syphilis (*n* = 4,181, 0.5%), and WNV (*n* = 139, 0.0%). Overall, a total of 29,049 (3.3%) units over the 10-year time span were discarded due to positive serology results. However, a total of 860,668 (96.7%) whole blood units were not discarded due to positive serology results.

Since categorical variables were examined, both bar graphs and pie charts are most appropriate for illustration as they show descriptive data (Frost, 2018). Like bar graphs, pie charts are best used with categorical data to aid in viewing what percentage of the whole each category constitutes (Frost, 2018). Based on Table 5, Figure 8 uses a pie chart to illustrate the percentage of whole blood units that were discarded due to positive serology as well as those that were not discarded. Figure 9 shows a detailed view of discarded whole blood products due to positive serology results, excluding those with negative serology. As shown, most whole blood units were discarded due to positive hepatitis B results.

Table 5

Frequency Distribution and Percentage of Whole Blood Units by Serology

Variable	Frequency	Percent
Serology		
Bacterial Contamination	363	0.0
Chagas Disease	76	0.0
Hepatitis B	15789	1.8
Hepatitis C	5433	0.6
HIV	1407	0.2
HTLV I/II	1661	0.2
Syphilis	4181	0.5
West Nile Virus	139	0.0
Negative Serology	860668	96.7

Figure 8

Pie Chart Percent of Whole Blood Units by Serology

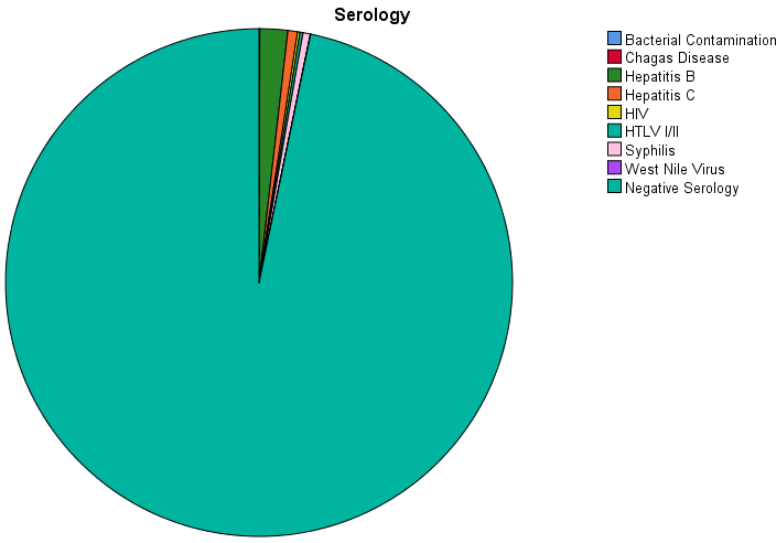
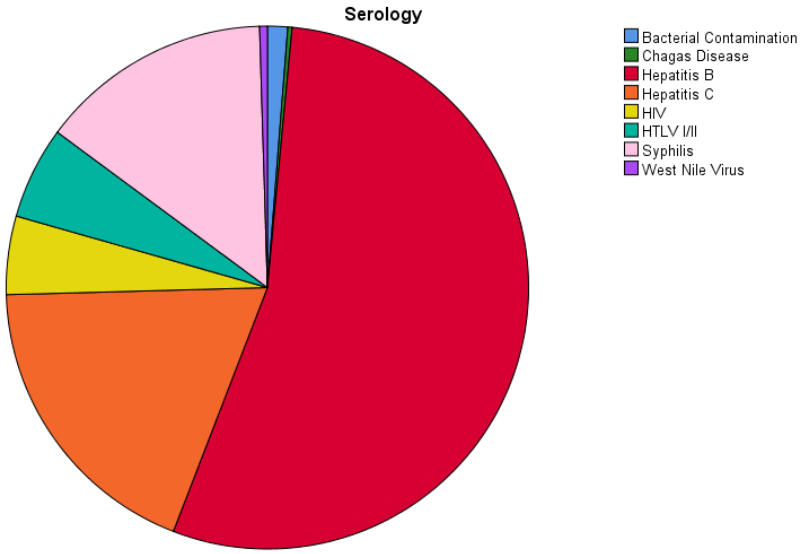


Figure 9

Pie Chart Percent of Whole Blood Units by Serology minus Negative Serology



Discard Factors

Table 6 illustrates the frequency distribution of whole blood units that were discarded due to various discard reasons. The variable, discard factors, was subdivided into nine major discard categories: (a) abnormal temperature, (b) air contaminated, (c) bloody, (d) broken, (e) clotted, (f) expired, (g) miscellaneous, (h) quantity not sufficient, and (i) not discarded. The frequency table showed that 3,442 (0.4%) units were discarded due to abnormal temperature, air contamination (*n* = 6,238, 0.7%), bloody (*n* = 8,617, 1.0%), broken (*n* = 26,297, 3.0), and clotted (*n* = 3,265, 0.4%). Table 6 also revealed that largest number of whole blood units were discarded due to expiry (*n* = 113,504, 12.8%). Miscellaneous reasons, such as lipemia, incomplete medical history, hemolysis, and the presence of red cell antibodies, accounted for 21,203 (2.4%) units of whole blood discards, followed by 46,665 (5.2%) units that were discarded due to insufficient quantity. Although a total of 229,231 (25.8%) whole blood units were discarded between 2008–2017 due to various discard factors, 660,486 (74.2%) units were not discarded. Using a pie chart, Figure 10 shows the percentage of whole blood donations that were discarded due to major discard factors as well as those that were not discarded. Figure 11 illustrates a comprehensive view of units that were discarded due to major discard factors, excluding units that were not discarded. As shown, most whole blood units were discarded due to expiry.

Table 6

Frequency Distribution and Percentage of Whole Blood Units by Discard Factors

Variable	Frequency	Percent
Discard Factors		
Abnormal Temperature	3442	0.4
Air Contaminated	6238	0.7
Bloody	8617	1.0
Broken	26297	3.0
Clotted	3265	0.4
Expired	113504	12.8
Miscellaneous	21203	2.4
Quantity Not Sufficient	46665	5.2
Not Discarded	660486	74.2

Figure 10

Pie Chart Percent of Whole Blood Units by Discard Factors

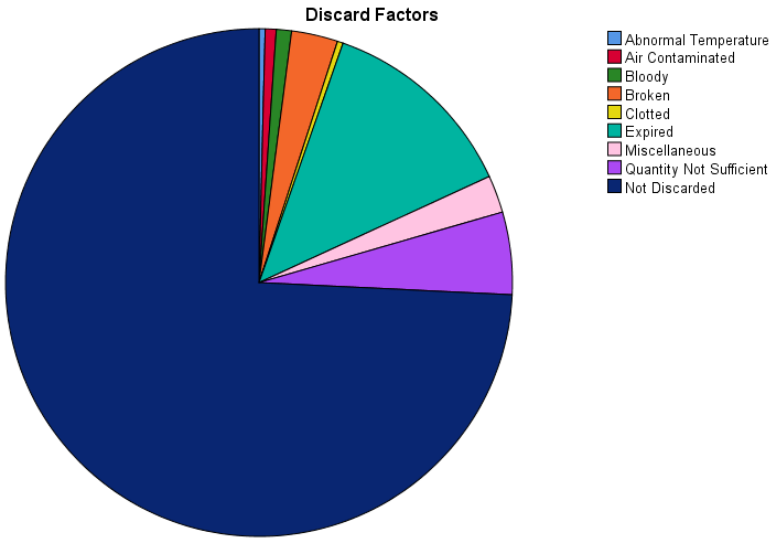
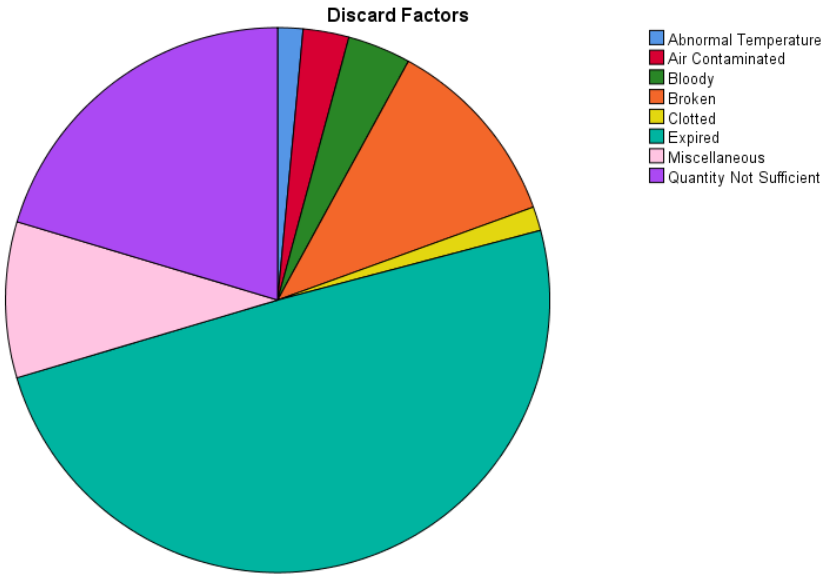


Figure 11

Pie Chart Percent of Whole Blood Units by Discard Factors minus Units Not Discarded



Available Blood

In terms of the dependent variable, available blood, Table 7 illustrates that more whole blood units were available for use (n = 631,437, 71.0%) than those that were not available for use (n = 258,280, 29.0%). The units not available for use includes those that were discarded due to positive serology and discard factors. The frequencies and percentages of available blood are presented in Table 7. Figure 12 shows a simple bar percentage of whole blood units that were available and those that were discarded between 2008 and 2017.

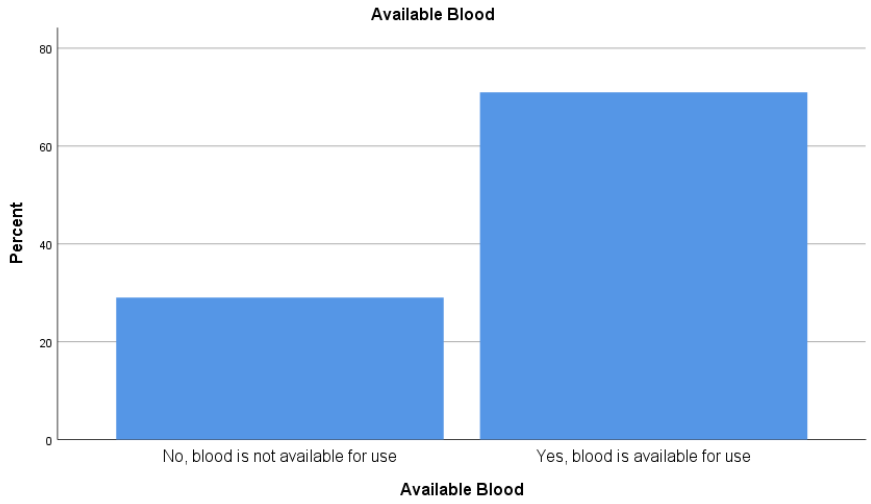
Table 7

Frequency Distribution and Percentage of Whole Blood Units by Availability

Variable	Frequency	Percent
Available Blood		
No, blood is not available for use	258280	29.0
Yes, blood is available for use	631437	71.0

Figure 12

Simple Bar Percent of Whole Blood Units by Availability



Inferential Statistics

Stepwise Regression

Stepwise regression is a method that examines and selects the most suitable independent variables to be used in a regression model (Harrell, 2001). It involves adding or removing independent variables from the model based on its statistical significance. The forward selection approach starts with an empty model and adds in variables individually, keeping those that are deemed most statistically significant. The backward elimination method begins with a model that contains all independent

variables, deleting one at a time, and testing the removed variable for statistical significance.

I used both forward and backward stepwise regression to ensure the proper independent variables were included in the bivariate and multiple logistic regression models. The forward stepwise regression model is shown in Table 8. In all steps, gender, age group, ethnicity, and year were statistically significant, maintaining the same odd ratios throughout the different steps in the analysis. The backward regression model is shown in Table 9. Like the forward regression, the independent variables were statistically significant. The backward regression only produced one step, which indicates all variables in the full model were statistically significant. Therefore, gender, age group, ethnicity, and year are significantly associated with available blood.

Table 8

Forward Stepwise Logistic Regression Analysis of Gender, Age Group, Ethnicity, Year, and Available Blood

								95% C.I.for OR	
		B	S.E.	Wald	df	*p*-value	OR	Lower	Upper
Step 1[a]	**Year**			25744.803	9	.000			
	2009	-.285	.012	575.404	1	.000	.752	.735	.770
	2010	-.056	.012	21.644	1	.000	.945	.923	.968
	2011	-.486	.012	1715.765	1	.000	.615	.601	.629
	2012	-.924	.011	6767.479	1	.000	.397	.388	.406
	2013	-.546	.012	2105.430	1	.000	.580	.566	.593
	2014	-.883	.012	5787.146	1	.000	.414	.404	.423
	2015	-1.165	.012	10089.980	1	.000	.312	.305	.319
	2016	-1.013	.011	8077.057	1	.000	.363	.355	.371
	2017	-.338	.013	716.753	1	.000	.713	.696	.731
	Constant	1.495	.009	26931.871	1	.000	4.459		
Step 2[b]	**Ethnicity**			5525.676	4	.000			
	Black/African American	-.431	.006	4552.847	1	.000	.650	.642	.658
	Asian	-.661	.033	397.852	1	.000	.516	.484	.551
	Other	-.352	.011	1104.492	1	.000	.703	.689	.718
	Unknown	-.111	.106	1.108	1	.293	.895	.728	1.101
	Year			25063.996	9	.000			
	2009	-.288	.012	582.782	1	.000	.750	.733	.768
	2010	-.054	.012	19.535	1	.000	.948	.926	.971
	2011	-.484	.012	1687.324	1	.000	.617	.602	.631
	2012	-.920	.011	6671.217	1	.000	.398	.390	.407
	2013	-.529	.012	1972.033	1	.000	.589	.575	.603
	2014	-.867	.012	5553.194	1	.000	.420	.411	.430
	2015	-1.151	.012	9776.120	1	.000	.316	.309	.324
	2016	-1.002	.011	7845.067	1	.000	.367	.359	.376
	2017	-.325	.013	656.428	1	.000	.723	.705	.741
	Constant	1.577	.009	29316.085	1	.000	4.842		
Step 3[c]	Female	-.246	.005	2639.117	1	.000	.782	.774	.789
	Ethnicity			5433.214	4	.000			

Table 8 Continued

	Black/African American	-.425	.006	4410.710	1	.000	.654	.646	.662
	Asian	-.662	.033	396.324	1	.000	.516	.483	.551
	Other	-.362	.011	1158.467	1	.000	.697	.682	.711
	Unknown	-.097	.106	.843	1	.359	.907	.737	1.117
	Year			24482.688	9	.000			
	2009	-.286	.012	573.440	1	.000	.751	.734	.769
	2010	-.041	.012	11.627	1	.001	.959	.937	.983
	2011	-.465	.012	1555.324	1	.000	.628	.614	.643
	2012	-.900	.011	6362.022	1	.000	.407	.398	.416
	2013	-.513	.012	1844.400	1	.000	.599	.585	.613
	2014	-.849	.012	5303.544	1	.000	.428	.418	.438
	2015	-1.135	.012	9483.112	1	.000	.321	.314	.329
	2016	-.985	.011	7564.042	1	.000	.373	.365	.382
	2017	-.306	.013	579.666	1	.000	.737	.719	.755
	Constant	1.670	.009	31462.728	1	.000	5.312		
Step 4[d]	Female	-.228	.005	2223.988	1	.000	.796	.789	.804
	Age Group			1436.088	5	.000			
	27-34 years	-.008	.008	1.226	1	.268	.992	.977	1.007
	35-44 years	-.005	.007	.436	1	.509	.995	.981	1.010
	45-54 years	.066	.007	86.486	1	.000	1.068	1.053	1.083
	55-64 years	.150	.008	376.364	1	.000	1.162	1.144	1.179
	65-96 years	.355	.011	1021.101	1	.000	1.426	1.395	1.458
	Ethnicity			4590.263	4	.000			
	Black/African American	-.397	.006	3780.574	1	.000	.672	.664	.681
	Asian	-.630	.033	357.713	1	.000	.533	.499	.569
	Other	-.328	.011	942.907	1	.000	.720	.705	.736
	Unknown	-.051	.106	.235	1	.628	.950	.772	1.169
	Year			24751.400	9	.000			
	2009	-.285	.012	571.661	1	.000	.752	.734	.769
	2010	-.040	.012	10.777	1	.001	.961	.938	.984
	2011	-.464	.012	1546.697	1	.000	.629	.614	.643
	2012	-.899	.011	6326.640	1	.000	.407	.398	.416

Table 8 Continued

2013	-.515	.012	1858.019	1	.000	.597	.583	.611
2014	-.854	.012	5351.023	1	.000	.426	.416	.436
2015	-1.146	.012	9628.562	1	.000	.318	.311	.325
2016	-.999	.011	7750.297	1	.000	.368	.360	.376
2017	-.321	.013	636.095	1	.000	.726	.708	.744
Constant	1.606	.010	24365.620	1	.000	4.982		

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

b. Variable(s) entered on step 2: Ethnicity.

c. Variable(s) entered on step 3: Gender.

d. Variable(s) entered on step 4: Age Group.

Table 9

Backward Stepwise Logistic Regression Analysis of Gender, Age Group, Ethnicity, Year, and Available Blood

								95% C.I.for OR	
		B	S.E.	Wald	df	*p*-value	OR	Lower	Upper
Step 1[a]	Female	-.228	.005	2223.988	1	.000	.796	.789	.804
	Age Group			1436.088	5	.000			
	27-34 years	-.008	.008	1.226	1	.268	.992	.977	1.007
	35-44 years	-.005	.007	.436	1	.509	.995	.981	1.010
	45-54 years	.066	.007	86.486	1	.000	1.068	1.053	1.083
	55-64 years	.150	.008	376.364	1	.000	1.162	1.144	1.179
	65-96 years	.355	.011	1021.101	1	.000	1.426	1.395	1.458
	Ethnicity			4590.263	4	.000			
	Black/African American	-.397	.006	3780.574	1	.000	.672	.664	.681
	Asian	-.630	.033	357.713	1	.000	.533	.499	.569
	Other	-.328	.011	942.907	1	.000	.720	.705	.736
	Unknown	-.051	.106	.235	1	.628	.950	.772	1.169
	Year			24751.400	9	.000			
	2009	-.285	.012	571.661	1	.000	.752	.734	.769
	2010	-.040	.012	10.777	1	.001	.961	.938	.984
	2011	-.464	.012	1546.697	1	.000	.629	.614	.643
	2012	-.899	.011	6326.640	1	.000	.407	.398	.416
	2013	-.515	.012	1858.019	1	.000	.597	.583	.611
	2014	-.854	.012	5351.023	1	.000	.426	.416	.436
	2015	-1.146	.012	9628.562	1	.000	.318	.311	.325
	2016	-.999	.011	7750.297	1	.000	.368	.360	.376
	2017	-.321	.013	636.095	1	.000	.726	.708	.744
	Constant	1.606	.010	24365.620	1	.000	4.982		

a. Variable(s) entered on step 1: Gender, Age Group, Ethnicity, Year.

Research Question 1: Is there an Association Between Gender and Available Blood?

Due to the large sample size, I used the Kolmogorov-Smirnov goodness of fit test to test for normality. The test revealed that for the gender group, the dependent variable, available blood, was not normally distributed. As shown in Table 10, the *p*-value of .000 for both men and women also confirmed that the data significantly deviated from a normal distribution. As such, I conducted bivariate logistic regression analysis to assess the association and odds ratio between gender and available blood. The case processing summary revealed that there were 889,717 cases in the dataset and no missing data. The SPSS numerical codes for the two levels of the dependent variable, available blood, were identified as: (a) 0 = No, blood is not available for use, and (b) 1 = Yes, blood is available for use. The omnibus test of model coefficients was statistically significant ($p = .000$), indicating that the model was a better predictor than the baseline model. In Table 11, the Cox & Snell R square value suggested that 0.4% of the variability in available blood was explained by gender, while Nagelkerke R Square suggested that 0.5% of the variability in available blood was explained by gender. Overall, Table 12 showed that gender was positively related to available blood at a statistically significant level, F (*) = 3387.626, $p = .000$, R = .004, and Adj $R^2 = .005$. The output provided the odds ratio of men to women. Therefore, the results indicated that units of blood donated from women in this sample were 76% (OR = .760; 95% CI .753 – .767) less likely to be available for use than units of blood donated from men. Hence, the null hypothesis was rejected, and the alternative hypothesis was accepted.

Table 10

Tests of Normality: Gender

		Kolmogorov-Smirnov[a]		
	Gender	Statistic	df	*p*-value
Available Blood	Male	.460	514853	.000
	Female	.432	374864	.000

a. Lilliefors Significance Correction

Table 11

Model Summary: Gender

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	1068570.483[a]	.004	.005

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

Table 12

Bivariate Logistic Regression: Gender and Available Blood

								95% C.I. for OR	
		B	S.E.	Wald	df	*p*-value	OR	Lower	Upper
Step 1[a]	Female	-.274	.005	3395.732	1	.000	.760	.753	.767
	Constant	1.013	.003	103293.442	1	.000	2.755		

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

Research Question 2: Is there an Association Between Age Group and Available Blood?

Table 13 shows that the Kolmogorov-Smirnov goodness of fit test was used to confirm whether the dependent variable, available blood, was normally distributed among the independent variable, age group. The test revealed that the data significantly deviated from a normal distribution (p = .000). Therefore, I conducted bivariate logistic regression analysis to assess the association and odds ratio between age group and available blood. The regression analysis showed that age group was positively related to available blood at a statistically significant level, F (*) = 2626.363, p = .000, R = .003, and Adj R^2 = .004. The omnibus test of model coefficients was statistically significant, indicating that the model was a better predictor than the baseline model. In Table 14, the Cox & Snell R square and Nagelkerke R Square values suggested that 0.3% and 0.4% of the variability in available blood was explained by age group.

The results, which were displayed in Table 15, indicated that in comparison to individuals aged 16–26 years, units of blood donated from individuals aged 27–34 years were .02% (OR = 1.018; 95% CI 1.003 – 1.033) more likely to be available for use, .08% (OR = 1.079; 95% CI 1.064 – 1.094) of donated blood were more likely to be available for use from individuals aged 35–44 years, 18% (OR = 1.184; 95% CI 1.169 – 1.200) of donated blood were more likely to be available for use from individuals aged 45–54 years, 26% (OR = 1.263; 95% CI 1.245 – 1.282) of donated blood were more likely to be available for use from individuals aged 55–64 years, and 55% (OR = 1.554; 95% CI 1.522 – 1.588) of donated blood were more likely to be available for use from individuals

aged 65–96 years. The results also showed that for every increase in age group, more blood was available for use. This was evident by the positive β values and the odds ratio >1. Based on the findings, the null hypothesis was rejected, and the alternative hypothesis was accepted.

Table 13

Test of Normality: Age Group

		Kolmogorov-Smirnov[a]		
	Age Group	Statistic	df	*p*-value
Available Blood	16 - 26 years	.437	260388	.000
	27 - 34 years	.439	123014	.000
	35 - 44 years	.445	143029	.000
	45 - 54 years	.455	171440	.000
	55 - 64 years	.461	134097	.000
	65 - 96 years	.479	57749	.000

a. Lilliefors Significance Correction

Table 14

Model Summary: Age Group

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	1069331.746[a]	.003	.004

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

Table 15

Bivariate Logistic Regression: Age Group and Available Blood

							95% C.I. for OR	
		B	S.E.	Wald	df	*p*-value	OR	Lower	Upper
Step 1[a]	Age Group			2559.469	5	.000			
	27-34 years	.018	.007	5.686	1	.017	1.018	1.003	1.033
	35-44 years	.076	.007	111.628	1	.000	1.079	1.064	1.094
	45-54 years	.169	.007	609.672	1	.000	1.184	1.169	1.200
	55-64 years	.234	.007	971.775	1	.000	1.263	1.245	1.282
	65-96 years	.441	.011	1668.065	1	.000	1.554	1.522	1.588
	Constant	.786	.004	34600.773	1	.000	2.195		

a. Variable(s) entered on step 1: 16-26 years.

Research Question 3: Is there an Association Between Ethnicity and Available Blood?

Since the independent variable, ethnicity, was composed of both large and small sample sizes, I used both the Kolmogorov-Smirnov test and the Shapiro-Wilk test to assess for normality between the ethnicity group and the dependent variable, available blood. Both tests revealed that for the ethnicity group, available blood, was not normally distributed. Table 16 also confirmed that the data significantly deviated from a normal distribution ($p = .000$).

I conducted bivariate logistic regression to assess the association and odds ratio between ethnicity and available blood. The results showed that ethnicity was positively related to available blood at a statistically significant level, F (*) = 6142.023, $p = .000$, R = .007, and Adj $R^2 = .010$. The omnibus test of model coefficients was statistically significant, indicating that the model was a better predictor than the baseline model. In Table 17, the Cox & Snell R square and Nagelkerke R Square values suggested that 0.7%

and 1.0% of the variability in available blood was explained by ethnicity. The results in Table 18 indicated that in comparison to White/Caucasian blood donors, whole blood donated from Black/African American, Asian, and blood donors who were identified as Other were 64% (OR = .635; 95% CI .627 – .643), 52% (OR = .635; 95% CI .490 – .556), and 69% (OR = .690; 95% CI .676 – .704) less likely to be available for use, respectively. Blood donors whose ethnicity was unknown in this sample were not positively related at statistically significant levels to available blood. This was evidenced by a 95% CI that ranged between .670 and 1.008. Based on these findings, the null hypothesis was rejected, and the alternative hypothesis was accepted.

Table 16

Tests of Normality: Ethnicity

		Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Ethnicity	Statistic	df	*p*-value	Statistic	df	*p*-value
Available Blood	White/Caucasian	.458	709381	.000			
	Black/African American	.409	132807	.000			
	Asian	.385	3898	.000	.626	3898	.000
	Other	.418	43201	.000			
	Unknown	.438	430	.000	.583	430	.000

a. Lilliefors Significance Correction

Table 17

Model Summary: Ethnicity

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	1065816.086[a]	.007	.010

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

Table 18

Bivariate Logistic Regression: Ethnicity and Available Blood

							95% C.I. for OR	
		B	S.E.	Wald	df	*p*-value	OR	Lower	Upper
Step 1[a]	Ethnicity			6292.629	4	.000			
	Black/African American	-.454	.006	5223.835	1	.000	.635	.627	.643
	Asian	-.650	.033	397.658	1	.000	.522	.490	.556
	Other	-.372	.010	1270.181	1	.000	.690	.676	.704
	Unknown	-.196	.104	3.556	1	.059	.822	.670	1.008
	Constant	.989	.003	137097.954	1	.000	2.688		

a. Variable(s) entered on step 1: White/Caucasian.

Research Question 4: Is there an Association Between Year and Available Blood?

Table 19 shows that the Kolmogorov-Smirnov goodness of fit test was used to confirm whether the dependent variable, available blood, was normally distributed among the independent variable, year. The test revealed that the data significantly deviated from a normal distribution (p = .000). Hence, I conducted bivariate logistic regression to assess the association and odds ratio between year and available blood. The findings revealed that year was positively related to available blood at a statistically significant level, F(*)

= 26607.266, p = .000, R = .029, and Adj R^2 = .042. The omnibus test of model coefficients was statistically significant, indicating that the model was a better predictor than the baseline model. In Table 20, the Cox & Snell R square and Nagelkerke R Square values suggested that 2.9% and 4.2% of the variability in available blood was explained by year.

The results, as displayed in Table 21, indicated that compared to 2008, units of whole blood collected in 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, and 2017 were 75% (OR = .752; 95% CI .735 – .770), 95% (OR = .945; 95% CI .923 – .968), 62% (OR = .615; 95% CI .601 – .629), 40% (OR = .397; 95% CI .388 – .406), 58% (OR = .580; 95% CI .566 – .593), 41% (OR = .414; 95% CI .404 – .423), 31% (OR = .312; 95% CI .305 – .319), 36% (OR = .363; 95% CI .355 – .371), and 71% (OR = .713; 95% CI .696 – .731) less likely to be available for use, respectively. Therefore, between 2009 to 2017, less blood was available for use compared to units of blood collected in 2008, which ultimately revealed a decline in blood availability. Based on the findings, the null hypothesis was rejected, and the alternative hypothesis was accepted.

Table 19

Tests of Normality: Year

		Kolmogorov-Smirnov[a]		
	Year	Statistic	df	*p*-value
Available Blood	2008	.499	80544	.000
	2009	.478	96784	.000
	2010	.495	101955	.000
	2011	.460	92901	.000
	2012	.413	100252	.000
	2013	.454	85160	.000
	2014	.418	84925	.000
	2015	.383	79592	.000
	2016	.402	95971	.000
	2017	.473	71633	.000

a. Lilliefors Significance Correction

Table 20

Model Summary: Year

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	1045350.843[a]	.029	.042

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

Table 21

Bivariate Logistic Regression: Year and Available Blood

								95% C.I. for OR	
		B	S.E.	Wald	df	*p*-value	OR	Lower	Upper
Step 1[a]	Year			25744.803	9	.000			
	2009	-.285	.012	575.404	1	.000	.752	.735	.770
	2010	-.056	.012	21.644	1	.000	.945	.923	.968
	2011	-.486	.012	1715.765	1	.000	.615	.601	.629
	2012	-.924	.011	6767.479	1	.000	.397	.388	.406
	2013	-.546	.012	2105.430	1	.000	.580	.566	.593
	2014	-.883	.012	5787.146	1	.000	.414	.404	.423
	2015	-1.165	.012	10089.980	1	.000	.312	.305	.319
	2016	-1.013	.011	8077.057	1	.000	.363	.355	.371
	2017	-.338	.013	716.753	1	.000	.713	.696	.731
	Constant	1.495	.009	26931.871	1	.000	4.459		

a. Variable(s) entered on step 1: 2008.

Research Question 7: Is there an Association Between Gender, Age Group, Ethnicity, Year, Serology, Discard Factors and Available Blood?

I used multiple logistic regression to assess the association and odds ratio between gender, age group, ethnicity, year, and available blood. I could not conduct statistical analyses to determine the association between serology, discard factors and available blood since there were no observed available blood units in this group. Hence, I excluded the independent variables, serology, and discard factors from the multiple logistic regression analysis.

Before conducting the multiple logistic regression analysis, I analyzed the independent variables to ensure that multicollinearity did not exist. I performed this step to confirm that the degree of correlation between the independent variables was not high

enough to reduce statistical significance between the independent and dependent variables. Multicollinearity was detected using the variance inflation factor (VIF), which measures the correlation and strength of correlation between the independent variables in a regression model. A value less than five is ideal; however, a value greater than five can potentially indicate extreme correlation (Harrell, 2001). It is illustrated in Table 22 that none of the VIF values were greater than five, indicating no multicollinearity. As such, the independent variables were suitable for multiple logistic regression analysis.

Table 22

Variance Inflation Factor Testing for Multicollinearity Among Independent Variables

Independent Variables	Variance Inflation Factor (VIF)
Gender	1.016
Age Group	1.035
Ethnicity	1.022
Year	1.004

a. Dependent Variable: Available Blood

Table 23 and Table 24 illustrate the multiple logistic regression association between the independent variables and the outcome variable. The multiple logistic regression analysis showed that gender, age group, ethnicity, and year were positively related to available blood at a statistically significant level, F (*) = 36125.236, $p = .000$, R = .040, and Adj $R^2 = .057$. The omnibus test of model coefficients was statistically significant, indicating that the model was a better predictor than the baseline model. In Table 23, the Cox & Snell R square and Nagelkerke R Square values suggested that 4.0% and 5.7% of the variability in available blood was explained by the independent variables.

Gender. The output provided the odds ratio of men to women. Therefore, the results indicated that units of whole blood donated from women in this sample were approximately 80% (OR = .796; 95% CI .789 – .804) less likely to be available for use than units of whole blood donated from men. Additionally, the β value (-.228) was negative, indicating decreased odds of available blood.

Age Group. In comparison to individuals aged 16–26 years, units of blood donated from individuals aged 45–54 years were .07% (OR = 1.068; 95% CI 1.053 – 1.083) more likely to be available for use, 16% (OR = 1.162; 95% CI 1.144 – 1.179) of donated blood was more likely to be available for use from individuals aged 55–64 years, and 43% (OR = 1.426; 95% CI 1.395 – 1.458) of donated blood was more likely to be available for use from individuals aged 65–96 years. However, units of blood donated from individuals aged 27–34 years (OR = .992; 95% CI .977 – 1.007) and 35–44 years (OR = .995; 95% CI .981 – 1.010) were not positively related at statistically significant levels to available blood.

Ethnicity. The results indicated that in comparison to White/Caucasian blood donors, whole blood donated from Black/African American, Asian, and blood donors who were identified as Other was 67% (OR = .672; 95% CI .664 – .681), 53% (OR = .533; 95% CI .499 – .569), and 72% (OR = .720; 95% CI .705 – .736) less likely to be available for use, respectively. Blood donors whose ethnicity was unknown in this sample were not positively related at statistically significant levels to available blood (OR = .950; 95% CI .772 – 1.169).

Year. The results indicated that compared to 2008, units of whole blood collected in 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, and 2017 were 75% (OR = .752; 95% CI .734 – .769), 96% (OR = .961; 95% CI .938 – .984), 63% (OR = .629; 95% CI .614 – .643), 41% (OR = .407; 95% CI .398 – .416), 60% (OR = .597; 95% CI .583 – .611), 43% (OR = .426; 95% CI .416 – .436), 32% (OR = .318; 95% CI .311 – .325), 37% (OR = .368; 95% CI .360 – .376), and 73% (OR = .726; 95% CI .708 – .744) less likely to be available for use, respectively.

The results of the model multiple logistic regression analysis are displayed in Table 24. The regression analysis was performed using a standard logistic regression enter method for the independent variables. The analysis revealed a statistically significant association between gender, age group, ethnicity, year, and available blood. Therefore, the null hypothesis is rejected, and the alternative hypothesis is accepted.

Table 23

Model Summary: Gender, Age Group, Ethnicity, Year

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	1035832.872[a]	.040	.057

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

Table 24

Multiple Logistic Regression Analysis of Gender, Age Group, Ethnicity, Year, and Available Blood

								95% C.I.for OR	
		B	S.E.	Wald	df	*p*-value	OR	Lower	Upper
Step 1[a]	Female	-.228	.005	2223.988	1	.000	.796	.789	.804
	Age Group			1436.088	5	.000			
	27-34 years	-.008	.008	1.226	1	.268	.992	.977	1.007
	35-44 years	-.005	.007	.436	1	.509	.995	.981	1.010
	45-54 years	.066	.007	86.486	1	.000	1.068	1.053	1.083
	55-64 years	.150	.008	376.364	1	.000	1.162	1.144	1.179
	65-96 years	.355	.011	1021.101	1	.000	1.426	1.395	1.458
	Ethnicity			4590.263	4	.000			
	Black/African American	-.397	.006	3780.574	1	.000	.672	.664	.681
	Asian	-.630	.033	357.713	1	.000	.533	.499	.569
	Other	-.328	.011	942.907	1	.000	.720	.705	.736
	Unknown	-.051	.106	.235	1	.628	.950	.772	1.169
	Year			24751.400	9	.000			
	2009	-.285	.012	571.661	1	.000	.752	.734	.769
	2010	-.040	.012	10.777	1	.001	.961	.938	.984
	2011	-.464	.012	1546.697	1	.000	.629	.614	.643
	2012	-.899	.011	6326.640	1	.000	.407	.398	.416
	2013	-.515	.012	1858.019	1	.000	.597	.583	.611
	2014	-.854	.012	5351.023	1	.000	.426	.416	.436
	2015	-1.146	.012	9628.562	1	.000	.318	.311	.325
	2016	-.999	.011	7750.297	1	.000	.368	.360	.376
	2017	-.321	.013	636.095	1	.000	.726	.708	.744
	Constant	1.606	.010	24365.620	1	.000	4.982		

a. Variable(s) entered on step 1: Gender, Age Group, Ethnicity, Year.

Deviations from the Data Plan

Due to FDA regulations, blood products resulting with positive serology results are discarded; thus, the available blood with positive serology and positive discard factors resulted in $n = 0$. Therefore, the bivariate logistic regression analysis for Research Question 5 (Is there an association between serology and available blood?) and Research Question 6 (Is there an association between discard factors and available blood?) could not be conducted since there were no observed available blood units in this group. In Chapter 5, the percentage of units discarded due to positive serology and discard factors will be presented and compared to the findings in the current literature.

Overall, the findings of the research questions and hypotheses are summarized and illustrated in Table 25. The null hypotheses were rejected for all research questions except research questions 5 and 6. As previously mentioned, statistical analyses could not be conducted for research questions 5 and 6. Gender, age group, ethnicity, and year were significantly associated with available blood.

Table 25

Research Questions and Hypotheses

Research Questions	Independent Variables	Null Hypothesis
RQ1	Gender	Rejected
RQ2	Age Group	Rejected
RQ3	Ethnicity	Rejected
RQ4	Year	Rejected
RQ5	Serology	Unable to perform statistical analysis
RQ6	Discard Factors	Unable to perform statistical analysis
RQ7	Gender, Age Group, Ethnicity, Year	Rejected

Summary

In this chapter, I used a dataset obtained from TBC to investigate the association between gender, age group, ethnicity, year, serology, discard factors, and available blood. I also used descriptive statistics, which included frequency distribution analyses, percentages, and graphical illustrations to characterize the sample. In addition, I presented the results of the data analyses in this chapter. I used bivariate logistic regression to analyze the associations between the independent and dependent variables. I reported the odds ratios, along with the accompanying confidence intervals and statistical significance of the associations. The results of the bivariate logistic regression analyses showed that gender, age group, ethnicity, and year were statistically significantly

associated with available blood. However, I was unable to conduct statistical analyses on serology and discard factors due to the constant nature of the variables.

In Chapter 5, I interpret and compare the findings in the current literature to the results of my study. I also described the strengths and limitations of my study. I conclude Chapter 5 with recommendations for future research, and the implications for positive social change.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

The need to maintain a safe and adequate supply of blood and blood components is becoming a significant public health concern. Over the past decade, there has been a continued decline in the collection of blood products, which may ultimately pose a risk to both patients and reserves for emergencies and disasters (Chung et al., 2006; Ellingson et al., 2017; Jones et al., 2020; & Whitaker et al., 2016). Findings from empirical studies showed that more information remains to be collected to better understand the vulnerabilities of the blood system and the variables impacting the donated blood supply. Therefore, though this research, I identified and examined barriers affecting the availability of the donated blood supply throughout the New Orleans region. I used secondary data from TBC of New Orleans, Louisiana to examine the independent variables (gender, age group, ethnicity, year, serological tests, and discard factors) and dependent variable (available blood). I also used a quantitative approach with a cross-sectional study design to explore the association between the independent and dependent variables. Key findings revealed statistically significant associations ($p < .05$) between gender, age group, ethnicity, year, and available blood. However, statistical analyses could not be conducted due to the constant ($n = 0$) nature of the independent variables, serology and discard factors. Nevertheless, frequency distributions of the variables revealed discard levels that were consistent with national standards. Identification and examination of these barriers may aid researchers in understanding the reasons for the reduction of the donated blood supply.

Interpretation of the Findings

I analyzed the results from a total of 889,717 whole blood units drawn from 286,625 allogeneic blood donors aged 16 to 96 years for this study. I used bivariate logistic regression analysis to examine the association between the independent and dependent variables. Findings from this research were based on the following variables: gender, age group, ethnicity, year, serology, and discard factors.

Gender

Results from this study revealed that male donors exceeded the number of female donors by 15.8% (*n* = 139,989 male donors), and that blood collected from women was 76% less likely to be available for use as compared to men. These results are consistent with those previously published in the literature in that women were under-represented among allogeneic blood donors (Misje et al., 2010; Royse & Doochin, 2005; Ferdández-Montoya et al., 1998; James & Matthews, 1996; Ringwald et al. 2007). However, contrary to these findings, Madrona et al. (2014) found that women were more altruistically inclined than men to give blood, with the percentages of donors and first-time donors being higher among women. Nevertheless, the researchers also explained that despite the larger number of female blood donors compared to male donors, the total number of units collected were higher among men than women, which is consistent with the current study (Madrona et al., 2014). The reason for the observed differences between male and female blood donors may be that women experience up to 70% more exclusions from blood donation than men (Newman, 2002; Newman et al., 2007). There are restrictions to women giving blood, especially low hemoglobin concentrations, which

reduces the number of female blood donations (Madrona et al., 2014). Women also are more susceptible to vasovagal reactions and experience more difficulty during the blood donation process, which negatively affects their experience as donors (Madrona et al., 2014). As such, measures should be taken to reduce these barriers affecting female donors to improve their donation experiences, thereby increasing the number of regular blood donors, which is a primary factor in maintaining an adequate blood supply.

Age Group

The findings of this study support the findings from existing literature. Increasing age was associated with an increased availability of donated blood. Blood collected from older individuals had a higher probability of being available for use compared to younger blood donors aged 16–26 years. Units of blood collected from individuals aged 27–34 years were .02% more likely to be available for use compared to blood donors aged 16–26 years. The probability increased to .08% for individuals aged 35–44 years, 18% for those that were 45–54 years of age, 26% for individuals aged 55–64 years, and 55% for individuals that were 65–96 years of age compared to younger blood donors aged 16–26 years.

According to current literature, nearly 60% of blood donations come from individuals over the age of 40 years, and nearly 45% come from people older than 50 years (Whitaker et al., 2016). Similarly, the AABB data indicate that the bulk of the U.S. blood supply is contributed by older donors (U.S. Department of Health and Human Services [HHS], 2020). However, the decline in younger donors aged 16–26 and an increase in donors aged 65 and older suggests an increasing reliance upon an aging donor

base. In the BEST collaborative study, researchers reported that while donors older than 70 years of age accounted for only 1.0% to 4.2% of the donor population in each country, they contributed 1.5% to 5.7% of total donations (Goldman et al., 2019). This is consistent with earlier research, as well as my study, showing that older donors make more donations per year than younger donors (Goldman & O'Brien, 2017). As elderly blood donors decline due to health, age, or other factors, younger blood donors are not being added to the donor population at a rate high enough to sustain a stable blood supply (Jones et al., 2020). Hence, there is a need to determine new, innovative ways to engage younger blood donors to steadily maintain a sufficient blood supply to meet the needs of the community.

Ethnicity

Findings from this study indicate that minorities are under-represented in the blood donor population. This is consistent with previously published literature in that White/Caucasian donors provided most of blood donations (Yazer et al., 2017). The research showed that probability of whole blood donated from minority blood donors was significantly lower than White/Caucasian blood donors. Compared to White/Caucasian donors, whole blood donated from Black/African American, Asian, and blood donors who were identified as Other was 64%, 52%, and 69% less likely to be available for use, respectively.

Although African Americans represent most the New Orleans population (59.7%), they only accounted for approximately 15% of the whole blood units collected for this study. Nevertheless, this number exceeds the U.S. national average of 5.8%

(Yazer et al., 2017). Similarly, African American individuals make up 13% of the U.S. population, but less than 3% of blood donors (ARC; American Red Cross, 2017). This may imply that Black/African American donors residing in the New Orleans area are donating at a higher rate than the national average. In addition, Asian and blood donors who were identified as Other represented 0.4% and 4.9% of the whole blood units collected for this study, respectively. However, these percentages do not meet the national average of 2.3% and 5.2%, respectively (Jones et al., 2020). The disproportionately low number of whole blood units donated by donors whose ethnicity was unknown may explain why there is no significant association between unknown ethnicity and available blood. Minority blood donors are essential for a diverse supply of blood because they provide greater access to corresponding phenotypes required for individuals with rare diseases (Spratling & Lawrence, 2019). Nevertheless, minority blood donations have historically been low in the United States (Spratling & Lawrence, 2019; Yazer et al., 2017). Additionally, a decreased proportion of minority blood donors has also been reported in Canada (Charbonneau & Daigneault, 2016) and France (Grassineau et al., 2007). This research underscores the need to develop strategies to increase blood donations among minority populations.

Year

The 2011, 2013, 2015, and 2017 NBCUS all indicated a continued decline in blood products from 2008 to 2017. My findings confirm that between 2009 to 2017, less blood was available for use compared to units of blood collected in 2008, which ultimately reveals a continuing decline in blood availability. The results show that

compared to 2008, units of whole blood collected in 2009 were 75% less likely to be available for use. In 2010, 95% of whole blood units were less likely to be available for use compared to 2008. In 2011, 62% of whole blood units were less likely to be available for use compared to 2008. Compared to 2008, 40% of whole blood units collected in 2012 were less likely to be available for use. In 2013, 58% of whole blood units were less likely to be available for use compared to 2008. In 2014, 41% of whole blood units were less likely to be available for use compared to 2008. Compared to 2008: 31% of whole blood units collected in 2015 were less likely to be available for use, 36% of whole blood units collected in 2016 were less likely to be available for use, and 71% of whole blood units collected in 2017 were less likely to be available for use. Therefore, the results of the analysis are consistent with the literature.

The steady decline in available blood may be due to a corresponding decline in donor base. According to the 2017 NBCUS, from 2015 to 2017, there was a 7.2% decline in the total number of donors presenting to give a volunteer blood donation (Jones et al., 2020). The 2017 NBCUS also reported a decrease in first-time blood donors of 6.6% (Jones et al., 2020). While only 37% of the U.S. population are eligible to donate blood, only 3% donate annually (ARC, 2017). Researchers have suggested that while more people may be eligible to donate because the FDA has relaxed its blood donor eligibility criteria, blood donors are still often confused about their eligibility (Satyavarapu & Wagle, 2020). Hence, new outreach, education, and recruitment efforts are needed to increase the understanding of the need for blood, to maintain a healthy donor base, thus increasing blood availability. Researchers have also indicated that the U.S. blood supply

is reaching a point of instability (Klein, Hrouda, & Epstein, 2017). This may be a result of an increased demand of blood products due to population growth (Satyavarapu & Wagle, 2020; Fortsch, & Khapalova, 2016). However, research focusing on understanding blood donor motivation could improve retention rates and blood donation frequency.

Serology

I could not conduct bivariate logistic regression analysis to determine the relationship between serology and available blood. Units that test positive for infectious disease are not available for use, being discarded per FDA regulations. Therefore, there was no association between serology and available blood. However, a review of the literature concerning serological tests has shown that discard rates due to reactive infectious tests vary widely among blood centers (Shahshahani & Taghvai, 2017). Results of the 2017 NBCUS revealed, of whole blood and apheresis RBC units rejected after collection in 2017, 11.7% (78,000 units; 95% CI, 70,000-87,000 units) were rejected upon testing for transfusion-transmissible infections (TTIs; Jones et al., 2020). In a study of blood services in Uganda, the investigators found that the discard rate due to infectious tests reactivity was nearly 6% (Shahshahani & Taghvai, 2017). Researchers in India showed that 1 to 2% of blood components were discarded due to seropositivity for TTIs (Shahshahani & Taghvai, 2017). Borelli et al. (2013) reported that the blood unit discard rate in Brazil ranged between 10% and 20% of which infectious diseases were the main cause of this percentage. However, Monich et al. (2017) indicated that the total blood discard rate due to positive serology in a blood center in Brazil was 5%. My findings

reveal that over a 10-year period, 3.3% of whole blood units were discarded due to positive serology. Of the 3.3%, 1.8% were due to hepatitis B. Khurram et al. (2016) discovered that hepatitis B infection was a common factor of blood donor deferrals. Increased knowledge of hepatitis B vaccination can not only prevent individuals from contracting this potentially serious liver infection, but also reduce the amount of blood products discarded due to positive serology.

Discard Factors

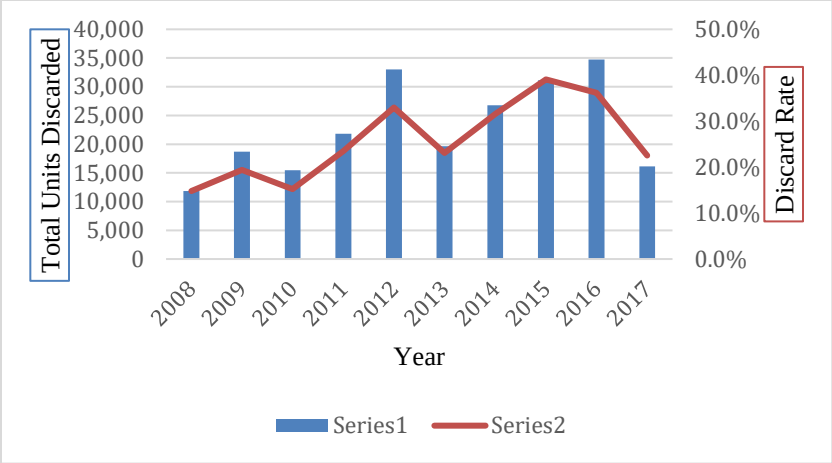
Units that are discarded are not available for use. Therefore, there was no association between discard factors and available blood and I could not perform a bivariate logistic regression analysis. The research findings indicate that a total of 229,231 (25.8%) whole blood units were discarded between 2008–2017 due to various discard factors (i.e., abnormal temperature, air contamination, bloody, broken, clotted, expired, miscellaneous, and quantity not sufficient). However, a look at the discard rate per year shows an increase in wastage percentage (Figure 13). In 2008, a total of 11,834 (14.8%) units were discarded due to various discard factors. However, in 2009, the total amount of discards increased to 18,721 (19.4%) units. In 2010, 15,488 (15.2%) whole blood units were rejected due to discard factors. Yet in 2011, the discard rate increased to 23.5% (n = 21,801 units). In 2012, a total of 33,001 (33.0%) whole blood units were discarded; however, in 2013, the total number of units discarded due to discard factors decreased to 19,663 (23.1%) units. In 2014, 2015, and 2016, the total number of units rejected due to discard factors increased to 26,758 (31.6%); 31,133 (39.1%); and 34,722 (36.2%) units, respectively. However, in 2017, the total number of discards decreased to

16,110 (22.5%) whole blood units. These findings indicate that of the 25.8% of discarded whole blood units, nearly half (12.8%) were due to expiry.

A review of the previous literature concerning major discard factors revealed that in 2017, a total of 587,000 (4.81%) whole blood and apheresis units were excluded for discard reasons, such as insufficient volume or a broken bag (Jones et al., 2020). Other research findings revealed whole blood discard rates ranging between 2.3% to 22.45% (Kanani et al., 2017; Kumar et al., 2014). Researchers have indicated in previous literature that expiry and preparation were major factors for blood wastage among blood centers (Shahshahani & Taghvai, 2017; Kurupt et al., 2016). Nevertheless, Collins et al. (2015) suggested that a low-level of outdating of components in the blood bank is acceptable due to the inherent need to maintain stock, and often the unpredictable demands on the inventory. Although a considerable amount of discarded blood is inevitable due to expiry and various discard factors, the average discard rate for whole blood in the present study was slightly higher than the average discard rates presented in previous literature. Therefore, effective interventions and strategies are needed to minimize blood wastage.

Figure 13

Discard Factors



Note. The graph illustrates the total number of whole blood units discarded from 2008 to 2017. The discard rate as a percentage shows an ascending trend from 2008 to 2015, and a descending trend from 2016 to 2017.

Conceptual Framework

The DBSC served as the conceptual framework for this study. The model involves four stages: collection, production, storage, and distribution of donated blood and blood components (Osorio et al., 2017). Within each stage, the model highlights specific areas in which barriers to blood availability could occur. The collection echelon includes gender, age group, and ethnicity. My study indicates that the largest percentage of available blood was donated by White/Caucasian males aged 65 years and older. By contrast, the smallest percentage of available blood was donated by women, minorities, and young blood donors aged 16–26 years. In the production echelon, hepatitis B, a sub-category of serology, was the most prevalent barrier to blood availability. My study also

shows that in the inventory echelon, expiry was the most common barrier to blood availability. As such, the DBSC data identified the areas in which blood wastage was most frequent and where effective interventions were of the greatest need.

Limitations of the Study

Although my study possesses many strengths, such as a very large sample and reliable data, it is subject to limitations. First, the findings are only generalizable to New Orleans, Louisiana, and its surrounding areas. Nevertheless, the results were consistent with data derived from national studies. Secondly, the available secondary dataset determined the specific factors that could be investigated. Although more factors affecting the available donated blood supply may be present, I could not explore these variables due to limited information provided from the dataset.

Thirdly, the FDA guidance explains that donation facilities are required to perform a serological screening test on each donation of blood. However, false-positive test results are a typical challenge among blood donation facilities. From 1995 to mid-2008, approximately 64,000 allogeneic donors at the American Red Cross were deferred based on false-positive enzyme immunoassay results, representing 130,000 U.S. donors (Vo et al., 2015). False-positive test results could inflate the actual number of true positive test results, which presents a continued loss of both donors and blood products. Fourthly, all allogeneic donations collected between January 1, 2008 and December 31, 2017 were not included in the study. Directed, apheresis, replacement, and replenishment donations were excluded. Despite these omissions, the ability to identify barriers to blood availability was not seriously altered.

Another limitation of my study is that the information provided was solely based on the data entered in the blood establishment computer system by TBC's staff. As such, there is the possibility of information bias as the variables may have been misclassified. Lastly, this study's cross-sectional design limits its ability to allow for causal inference.

Recommendations

In this study, I identify and examine barriers to blood availability within the New Orleans region. The findings indicate a statistically significant relationship between gender, age group, ethnicity, year, and available blood. Future studies should be conducted at various blood centers throughout different regions to determine if similar findings are discovered. This would provide greater validity to the results of this study.

My study does not include all allogeneic donation types. Future research should be conducted to include directed, apheresis, replacement, and replenishment donation types. A large portion of the donated blood inventory is obtained through apheresis donations. Exclusion of these blood components may have introduced bias in the current analysis that could be evaluated in a future study.

Additionally, I solely focus on eligible blood donors. However, the lack of eligibility among prospective blood donors greatly affects blood availability. Researchers conducting future studies should also examine ineligible blood donors and the prevalence and causes of donation deferrals.

Implications

The results of my study can influence positive social change at both the individual and organizational levels. Age group was significantly associated with available blood,

with older individuals having a higher probability of donating blood that was available for use. This knowledge presents an opportunity to develop targeted educational strategies geared towards encouraging younger blood donors to donate blood and increasing awareness among blood center staff on the need to proactively recruit this specific demographic.

My results also showed that compared to women, whole blood donated from men was more likely to be available for use. Previous published researchers indicated that compared to men, women possessed a higher rate of adverse reactions, such as dizziness and fainting, due to lower weight (Newman, 2002; Newman et al., 2007). Therefore, awareness of this finding can encourage the development of recruitment strategies that have been documented to be effective in reducing adverse reactions, thereby improving the quality of the experience of donating blood.

Additionally, my research findings show a significant association between ethnicity and available blood, with minorities having a lower probability of donating blood that is available for use, compared to their White/Caucasian counterpart. The results bring an awareness to this disparity, which can promote the development of incentive programs and recruitment campaigns to encourage blood donations from minority populations. In addition, partnerships with health care professionals and faith-based organizations may also be used to increase blood donations from minority populations and improve the probability of donors returning to make further donations. These efforts can have major consequences for increasing blood availability, especially in communities with a large or a majority minority population.

The findings from my study also bring an awareness to the need to minimize wastage of blood and blood products. Process improvements, such as continued medical education for technical staff to improve phlebotomy practices, prevent contamination of blood components, and avoid adverse reactions during the donation process will reduce blood wastage. Additionally, guidelines and policies can be updated to ensure proper processing and preparation of the blood components, which will further help in reducing the discard rate. Overall, positive social change implications from this study stimulate new approaches that would increase individual blood donation efforts, and ultimately benefit the New Orleans community.

Positive Social Change

My study fills a gap in understanding by identifying the factors that have contributed to the reduction of the available donated blood supply. As such, this research can be used as a framework for the development of public health initiatives and policies. Having a sustainable donor base and blood supply will require investment in research, strategy development, legislative action, and funding (HHS, 2020). Therefore, positive social change implications from this study can influence policymakers to develop legislation that would encourage investments in research and development by sustaining or expanding government investments in blood-related programs geared towards improving donor retention, recruitment, and understanding blood donor motivation. These policies can ultimately promote positive behavioral and lifestyle changes that would maintain a stable donor base and increase the available blood supply.

Conclusion

In this study, I explore the barriers affecting the donated blood supply throughout the New Orleans region. While findings from previous literature have indicated a continued decline in both blood collection and blood utilization (Chung et al., 2016; Ellingson et al., 2017; Jones et al., 2020), my study provides insight into the factors contributing to the reduction of the donated blood supply. My results reveal a statistically significant association between gender, age group, ethnicity, year, and available blood. Whole blood donated from White/Caucasian individuals were more likely to be available for use compared to the minority population. Members of minority groups donated a small percentage (15%) of the total available blood collected although they comprised nearly 60% of the New Orleans population. Higher odds ratios of available blood were observed among men compared to women. Also, increasing age was associated with an increased availability of donated blood. My findings reveal a need to implement process improvement strategies to minimize wastage to maintain optimal blood inventory levels. Based on the knowledge gained from my study, I encourage the development of educational strategies geared towards proper recruitment of target demographics and policy enhancements to minimize wastage.

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Appendix A: Data Use Agreement

DATA USE AGREEMENT

This Data Use Agreement ("Agreement"), effective as of March 2, 2021 ("Effective Date"), is entered into by and between Tishawn M. Francis ("Data Recipient") and The Blood Center ("Data Provider"). The purpose of this Agreement is to provide Data Recipient with access to a Limited Data Set ("LDS") for use in research in accord with the HIPAA and FERPA Regulations.

1. Definitions. Unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the "HIPAA Regulations" codified at Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time.

2. Preparation of the LDS. Data Provider shall prepare and furnish to Data Recipient a LDS in accord with any applicable HIPAA or FERPA Regulations.

3. Data to be included in the LDS. **No direct identifiers such as names may be included in the Limited Data Set (LDS).** The researcher will not name the Data Provider in the doctoral study that is published in Proquest unless the Data Provider makes a written request for the researcher to do so. In preparing the LDS, Data Provider or designee shall include the **data fields specified as follows**, which are the minimum necessary to accomplish the research:

1) Gender, age group, ethnicity, and total number of all individuals who presented and actually donated blood (excluding special procedures: autologous, therapeutic, directed, etc.) between January 1, 2008 and December 31, 2017.
2) The amount of available blood collected between January 1, 2008 and December 31, 2017.
3) The amount of blood that was discarded each year between January 1, 2008 and December 31, 2017 due to positive serology results (HIV; HTLV-I/II; Hepatitis B; Hepatitis C; Syphilis; West Nile Virus; Chagas disease, and; Bacterial contamination).
4) The amount of blood that was discarded each year between January 1, 2008 and December 31, 2017 due to various discard factors (Clotted; Air contaminated; Insufficiently filled; Expired; Abnormal temperature, and; Miscellaneous).

4. Responsibilities of Data Recipient. Data Recipient agrees to:

a. Use or disclose the LDS only as permitted by this Agreement or as required by law;

b. Use appropriate safeguards to prevent use or disclosure of the LDS other than as permitted by this Agreement or required by law;

c. Report to Data Provider any use or disclosure of the LDS of which it becomes aware that is not permitted by this Agreement or required by law;

d. Require any of its subcontractors or agents that receive or have access to the LDS to agree to the same restrictions and conditions on the use and/or disclosure of the LDS that apply to Data Recipient under this Agreement; and

e. Not use the information in the LDS to identify or contact the individuals who are data subjects.

5. Permitted Uses and Disclosures of the LDS. Data Recipient may use and/or disclose the LDS for its research activities only.

6. Term and Termination.

a. Term. The term of this Agreement shall commence as of the Effective Date and shall continue for so long as Data Recipient retains the LDS, unless sooner terminated as set forth in this Agreement.

b. Termination by Data Recipient. Data Recipient may terminate this agreement at any time by notifying the Data Provider and returning or destroying the LDS.

c. Termination by Data Provider. Data Provider may terminate this agreement at any time by providing thirty (30) days prior written notice to Data Recipient.

d. For Breach. Data Provider shall provide written notice to Data Recipient within ten (10) days of any determination that Data Recipient has breached a material term of this Agreement. Data Provider shall afford Data Recipient an opportunity to cure said alleged material breach upon mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within thirty (30) days shall be grounds for the immediate termination of this Agreement by Data Provider.

e. Effect of Termination. Sections 1, 4, 5, 6(e) and 7 of this Agreement shall survive any termination of this Agreement under subsections c or d.

7. Miscellaneous.

a. Change in Law. The parties agree to negotiate in good faith to amend this Agreement to comport with changes in federal law that materially alter either or both parties' obligations under this Agreement. Provided however, that if the parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either Party may terminate this Agreement as provided in section 6.

b. Construction of Terms. The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.

c. No Third Party Beneficiaries. Nothing in this Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

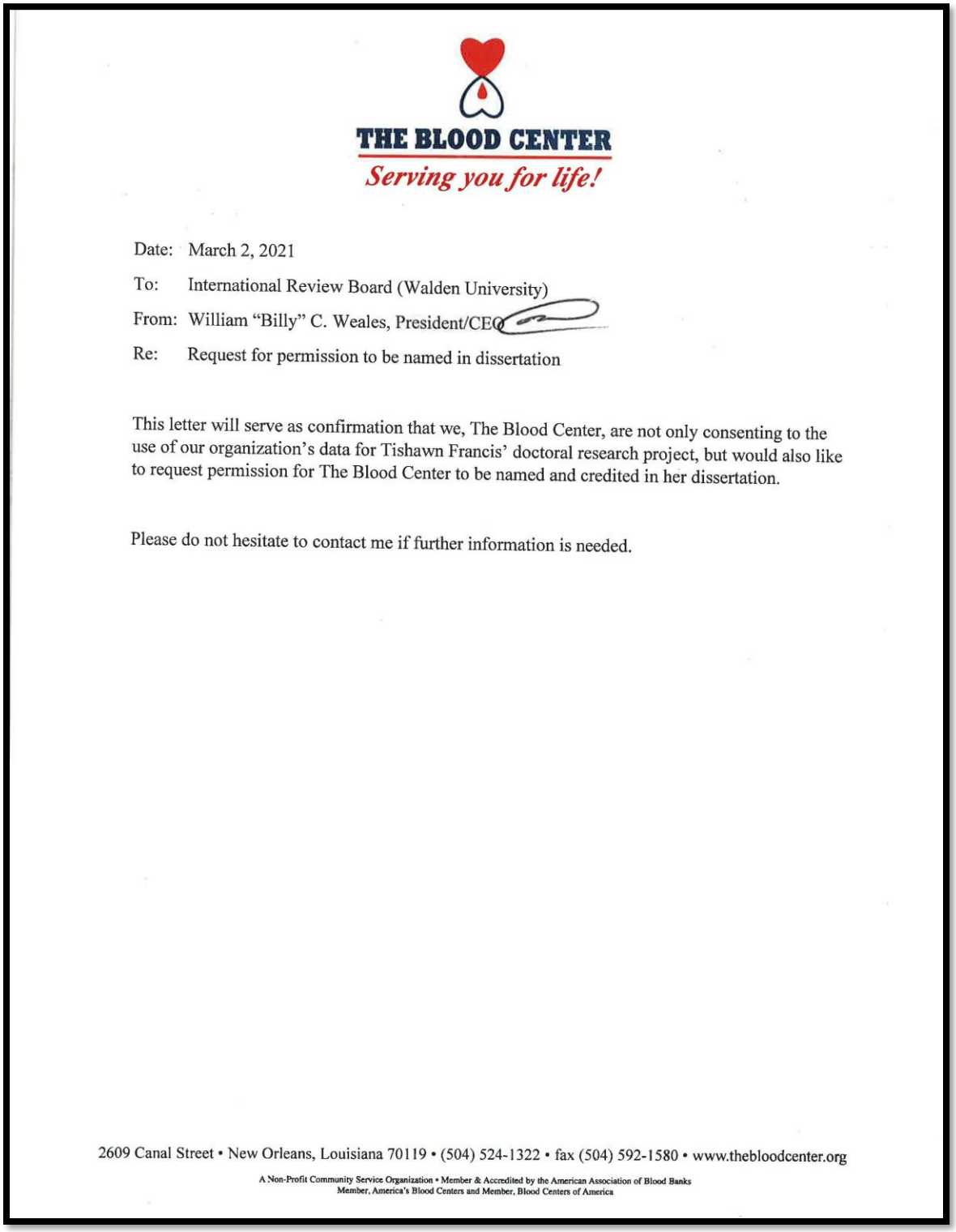
d. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

e. Headings. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Agreement.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

DATA PROVIDER		**DATA RECIPIENT**	
Signed:		Signed:	
Print Name:	William "Billy" C. Weales	Print Name:	Tishawn M. Francis
Print Title:	President/CEO of The Blood Center	Print Title:	Donor Services Training Specialist/Candidate for Ph.D. Public Health/Epidemiology

Appendix B: TBC Request for Permission



THE BLOOD CENTER

Serving you for life!

Date: March 2, 2021

To: International Review Board (Walden University)

From: William "Billy" C. Weales, President/CEO

Re: Request for permission to be named in dissertation

This letter will serve as confirmation that we, The Blood Center, are not only consenting to the use of our organization's data for Tishawn Francis' doctoral research project, but would also like to request permission for The Blood Center to be named and credited in her dissertation.

Please do not hesitate to contact me if further information is needed.

2609 Canal Street • New Orleans, Louisiana 70119 • (504) 524-1322 • fax (504) 592-1580 • www.thebloodcenter.org

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Member, America's Blood Centers and Member, Blood Centers of America