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Supply Effects of Implementing Donor Interval Strategies to Prevent Iron Deficiency in Blood Donors

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SUPPLY EFFECTS OF IMPLEMENTING DONOR INTERVAL STRATEGIES TO PREVENT IRON DEFICIENCY IN BLOOD DONORS

BY

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A doctoral project submitted to the faculty of the Medical University of South Carolina in partial fulfillment of the requirements for the degree Doctor of Health Administration in the College of Health Professions

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Chairperson: Kit N. Simpson, DrPH
Committee: John Armitage, MD
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Iron depletion in blood donors has been a topic of concern for the AABB over the past couple of years. In March 2017 the AABB published bulletin #17-02 recommending blood collection facilities implement additional actions to limit or prevent iron deficiency in blood donors. Three of the recommended strategies were to limit the donation interval for all individuals to two times in a 12-month period, limit 16–18 year olds to one donation in a 12-month period, and to limit pre-menopausal woman to one donation in a twelve month period. With a declining donor pool, the focus of this study is on additional effects of implementing the three aforementioned strategies on the blood supply of a southeastern community blood collection facility. My findings suggest that if any of the three donation interval changes were implemented, there would be additional reductions in the blood supply.

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INTRODUCTION

Background

One of the physical screening practices required for donating blood in the United Sates is the measurement of hemoglobin or hematocrit prior to phlebotomy. A male donor is considered eligible if he has hemoglobin ≥ 13.0 g/dL or a hematocrit ≥ 39%. A female donor is considered eligible if she has hemoglobin ≥ 12.5 g/dL or a hematocrit ≥ 38% (Fung, 2017). During the donation process, a donor loses approximately 500 ml of blood volume, containing an estimate of 200–250 mg of iron (Bialkowski et al., 2015). Despite the current practices of hemoglobin/hematocrit screening to protect the health of blood donors, one of the consequences of blood donation is iron depletion.

The recommendations from the AABB, in its published bulletin #17-02 on March 16, 2017, requested that blood collection establishments take additional voluntary actions to monitor, limit, or prevent iron deficiency in blood donors (Szczepeorkowski & Hopkins, 2017). Currently, the stipulations in the 30th edition of the *Standards for Blood Banks and Transfusion Services* only require donor centers to provide blood donors with education materials, which includes the risks of post donation iron deficiency that can be found in standard 5.2.1.5. (Ooley, 2016). The donors only need to acknowledge that they have received the materials with signature. Ooley (2016) outlines three additional iron mitigation recommendations along with strategies and interventions. The bulletin includes recommendations that blood establishments voluntarily implement one of the following strategies:

1. Development of a program to provide replacement iron in absence of ferritin measurements.

2. Measurement of serum or plasma ferritin.
3. Evidence-based lengthening of donation interval, or restrict number of donations per year.

Under strategy number three, the lengthening interval and/or decreasing the number of donations per year provides three additional options. Option one limits whole blood donations to two times in a 12-month period, or one 2-unit collection in 12-month period. Option two limits the number of whole blood collections from 16–18 year olds to one time in a 12-month period because of the higher documented rates of iron deficiency in young donors. Option three limits whole blood collections from premenopausal women to one donation in a 12-month period (Szczepeorkowski & Hopkins, 2017).

Throughout history, physicians have used blood and its components to treat a variety of ailments ranging from blood loss to autoimmune diseases. The first recorded blood transfusion occurred in England in 1665 between two dogs, but it was not until 1818 that a successful human blood transfusion occurred. In 1914, Adolf Hustin discovered that sodium citrate could be used as an anticoagulant and could be stored for transfusions for patients on the battlefield. This led to the first blood bank established at a Leningrad hospital in Russia in 1932. Eight years later, the United States established a nationwide blood collection program, and in 1970, the collection program became an all-volunteer donor base. In 1949, the total United States blood collection system consisted of 1,500 hospital blood banks, 46 community blood centers, and 31 American Red Cross regional blood centers. Through consolidation currently there are approximately 67 community blood centers in the United States including the Southeast Community Blood Center (pseudonym) whose data was used for this research project.

National Data

The United States has a volunteer-based donation program comprised of community- and hospital-based blood collection centers. Their mission is to collect, process, and distribute blood and blood products. For the purpose of this study, the blood product I will focus on is red blood cells processed from whole blood donors. It is imperative that our national blood supply meet the needs of the hospitals routine and emergency requests.

In 2003, the Office of the Assistant Secretary for Health developed a National Blood Collection and Utilization Survey (NCBUS) administered by the Centers for Disease Control and Prevention (CDC) and the AABB (Ellingson, 2017). Since 2011, the NCBUS has identified a continuous decline in red cell collections and utilization. Data from the 2015 NCBUS indicates an 11.2% decrease in allogeneic non-directed whole blood collections from 2013. Figure 1 illustrates how the gap between collections and transfusions per 1000 population continues to narrow. Data shows 60.4 collections per 1000 collected, compared to 35.3 per 1000 units transfused. The NCBUS data also identified a 14.3% national blood collection deferral rate with almost half due to low hemoglobin.

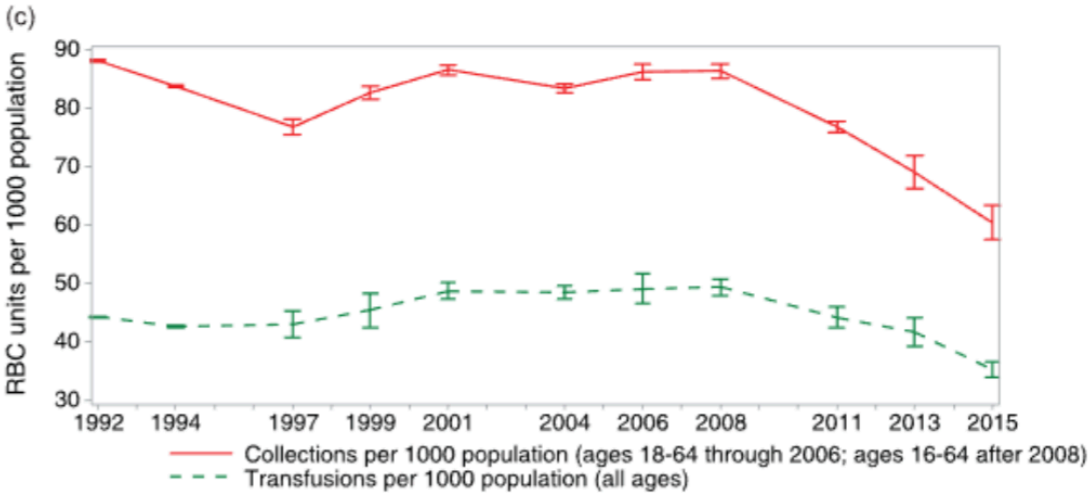

Figure 1. RBC Collections Compared to Transfusions

Source: Ellingson, K., Sapiano, M., Haass, K., Savinkina, A., et al. (2017). Collection Transfusion Graph. National Blood Collection and Utilization Survey Report

Local Data

Red blood cells collected by one local blood center in the southeast went from 33,032 units collected in 2015 to 30,208 collected in 2016, which is a decrease of 8.7%. The organizations deferral rate (donors who were told they could not donate) was 16% with 9% the result of low hemoglobin.

Problem Statement

It is unclear how each of the AABB strategies for the prevention of iron deficiency in blood donors may affect the blood supply of an individual local southeast community blood center.

Research Question

What is the estimated differential impact on the local blood supply if a southeastern community blood center implements the AABB recommendation of lengthening the donor interval, and/or decreasing the number of donations per year.

Research Hypothesis

I expect that the impact of the different strategies will be influenced by a center's donor age and sex distribution and by total volume of annual collections.

Study Objective

The study's objective is to develop and deploy an analytical response to historical data from a blood center to compare the expected effects of different AABB prevention strategies on the overall U.S. blood supply.

Population

I extracted de-identified data from a southeastern community blood center's central computer system for the population that donated blood for the 2016 calendar year. The donor population is diverse, consisting of 17,462 donors with a minimum age of 16 years old, a median age of 47 years old with no upper age limit.

Assumption

The data extracted from the Blood Bank Computer System (BBCS) for the 2016 calendar year is adequate for representing donor behavior in future years.

LITERATURE REVIEW

Chapter Two consists of a review of related research on the relevance of using hemoglobin/hematocrit screening for qualifying blood donors and how it relates to the identification of iron deficiency. The chapter will also describe the AABB recommendations and what researchers have discovered about iron depletion within the donor population. The review will include the current status of the donor population along with a review of the sustainability of the blood supply. Ultimately, the aim of this chapter is to expose and interrogate the reasoning behind the AABB's recommendations to lengthen the donor interval, and/or decrease the number of donations per year on the study site, a local southeastern blood center.

Hemoglobin/Hematocrit Screening

Hemoglobin is a protein found in red blood cells and is a combination of a hem protein and an iron molecule. The main function of hemoglobin is to carry oxygen from the lungs to body tissue. Hemoglobin levels less than 12 gm% may indicate the individual is in a state of anemia (Rudmann, 1995). Iron is stored in the body in the form of ferritin and circulates in the blood. Ferritin is an important component of the human body system because it combines with molecules that aid in cellular respiration and metabolism. Figure 2 represents a hemoglobin molecule found in red blood cells.

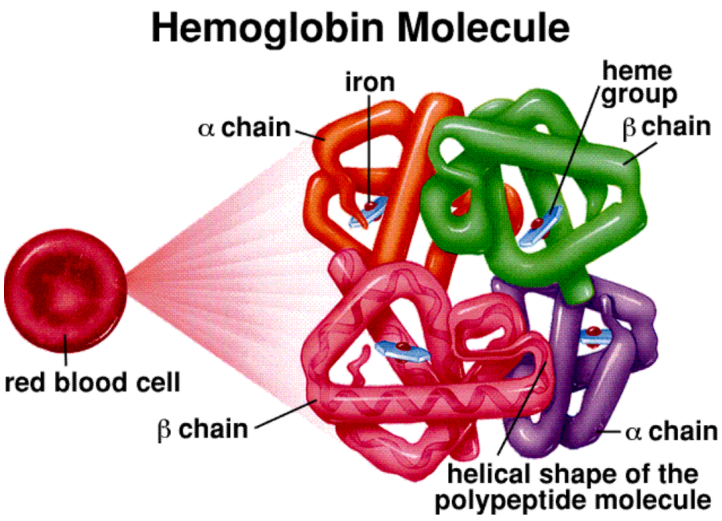

Figure 2. Hemoglobin Molecule

Source: Sylvia M. (1997), Hemoglobin Molecule, Inquiry into Life, 8th edition

A male donor is eligible to donate whole blood if his hemoglobin measurement is ≥ 13.0 g/dL or the hematocrit is ≥ 39%. A female donor is eligible to donate whole blood if she has a hemoglobin measurement ≥ 12.5 g/dL or the hematocrit is ≥ 38% (Fung, 2014).

The Food and Drug Administration (FDA) allows for the measurement of either hemoglobin or hematocrit to determine donation eligibility. There is no clinical difference between the two measurements and allowing both types of test enables blood centers to choose a method that matches with preferred internal process (Food and Drug Administration, 2015). When calculating hemotocirit you can you can multiply hemoglobin by three.

Iron is an important nutrient required for the body to function. The total iron found in the body is estimated at 3.9 g while 2.5 g is found in hemoglobin. Hemoglobin thus accounts for approximately 70% of the body's total iron. The other 30% can be

found in the heart (500 mg), liver (250 mg), bone marrow (150 mg), muscles, in the form of myoglobin (300 mg), enzymes in the body (150 mg), and plasma, which carries 5 mg bound to transferrin protein (Camaschella, 2011). Figure 3 diagrams the uptake of daily iron within the human body.

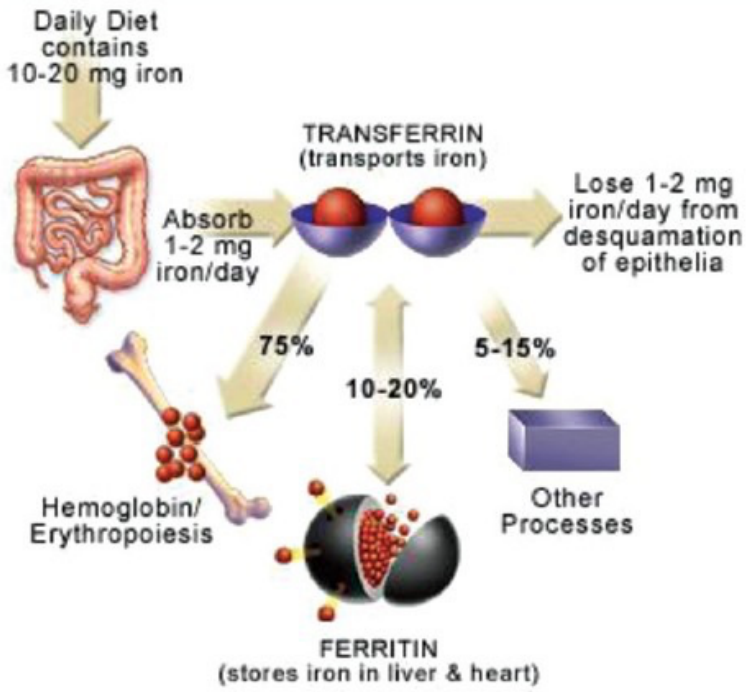

Figure 3. Iron Metabolism

Source: Abbaspour N, Hurrell R, Kelishadi R. (2014). Iron Transport System diagram. Licensed under Open Access Res Med Sci Journal

Iron Deficiency in Blood Donors

The objective of the REDS-II Donor Iron Status Evaluation (RISE) was to determine the optimal laboratory measures to identify iron deficient erythropoiesis (IDE), or absent iron stores (AIS) in blood donors and the ability of hemoglobin to identify iron depletion in presenting donors. Iron deficiency moves through three stages: the first stage is iron depletion while red cell morphology and hemoglobin levels remain normal;

second stage is IDE, with the red cell morphology and hemoglobin levels remaining normal; and the third stage is iron deficiency anemia indicated by abnormal red cell morphology and a decreased hemoglobin level. Kiss et al. (2013) concluded that red blood cell indices hypochromic mature RBCs (HYPOm), content of reticulocyte (CHr) correlate with AIS and IDE better than the hemoglobin measurement, but are not sensitive or specific enough to be used as a diagnostic test for blood donors.

Studies have shown that blood donation may result in depleted iron stores for donors with normal pre-donation hemoglobin values. Mobilizing iron stores in the form of ferritin makes up the iron loss. Men usually have the most dramatic drop in ferritin levels because of higher iron stores before donation. In one study in Australia, researchers found that about 19% of female blood donors were iron deficient at a hemoglobin level of 12.5 g/dL, while about 5% of male donors were iron deficient at a level of 13.5 g/dL (Lucky et al., 2014).

Up to two-thirds of young women in developing countries suffer from iron deficiency. However, it is not only a phenomenon of developing nations, with prevalence rates between 10% and 20% in the United States and Europe. Latent iron deficiency, also known as IDE, is characterized by individuals having serum ferritin ≤ 20 ng/mL and hemoglobin > 12 g/dL . Iron-deficiency anemia is the most severe form of iron deficiency and is characterized by having hemoglobin ≤12 g/dL in addition to having low serum ferritin (Falkingham et al., 2010).

A study performed by Bialkowski et al. (2016) to analyze strategies to reduce iron deficiency (STRIDE) demonstrated that providing 19 mg or 38 mg of iron daily or iron status information (donor brochures) after ferritin testing was effective and mostly

equivalent in mitigating post-donation iron deficiency. One of the limitations of the study was that it was randomized, meaning it may not represent the way donors behaved at community blood centers. A finding of particular interest is that de-enrollment for donors receiving tablets was higher within 60 days. Reasons for the de-enrollment included gastrointestinal symptoms and rash formation indicating side effects of taking iron supplements.

Another study enrolled males and females 18 years old and older from four U.S. blood donor centers. Donors were separated into two groups based on their ferritin tests (> 26 ng/mL and less than 26 ng/mL). The subjects either received 37.5 mg of oral ferrous gluconate for 24 weeks daily or no supplementation. Results indicated that levels in both the high and low ferritin groups, donors given the iron supplements returned to 80% pre-donation ferritin. The Hemoglobin Iron Recovery Study (HEIRS) also concluded that donors taking iron supplementation recovered to their baseline in 11 weeks compared to more than 24 weeks for individuals who did not take iron supplementation (Kiss et al., 2015).

An Australian study analyzed female whole blood donors who were given iron directly or given advice on taking iron supplements. Eighty-eight percent of the donors given the iron directly maintained ferritin levels and did not experience a decline. Forty-four percent of the donors complied with the recommendation but most donors failed to maintain ferritin levels. The screening process was extended by one to five minutes and adverse effects were common but mild (Pasricha, Marks, & Salvin, 2017).

Iron supplementation in individuals with normal iron stores has several potentially harmful side effects and is not recommended. Overload may lead to secondary

hemochromatosis, increased oxidative stress, and production of free radicals (Nowsheen et al., 2009). Researchers have shown that oxidative stress plays a role in causing cancer. When treating for iron deficiency the intention is to "first do no harm" (Zoller & Vogal, 2004).

Restless legs syndrome (RLS) is a neurological sensorimotor disorder and has been associated with iron deficiency anemia. A Danish blood center enrolled 13,448 blood donors and found that 7.2% woman and 4.5% men were classified with RLS. Researchers concluded that the disorder was not related to reduced plasma ferritin, employment status, or income level (Didriksen et al., 2017).

The 30th edition of the *Standards for Blood Banks and Transfusion Services* includes reuiquirements that donor centers provide blood donors with educational materials that includes information about the risks of post-donation iron deficiency, which can be found in standard 5.2.1.5. (Ooley, 2016). According to recommendations, patients must acknowledge receipt of this educational information. Figure 4 is an example of the information form used by Shepeard Community Blood Center.

A WORD ABOUT
IRON

Prepare to donate blood by eating iron rich foods. In order to donate, blood donors must meet the minimum Hematocrit/ Hemoglobin levels listed below:

- Males - 39 Hematocrit/13.0 Hemoglobin
- Females - 38 Hematocrit/12.5 Hemoglobin

This high standard is to ensure your well-being since donating blood temporarily lowers your iron count. Below is a list of some of the iron rich foods commonly eaten:

VEGETABLES

Bean Sprouts	Beets	Broccoli	Brussels Sprouts
Tomato Juice	Greens	Kale	Sweet Potatoes
Sauerkraut	Peas	Potatoes	

WHOLE GRAINS AND BEANS

Enriched Pasta	Whole Grain Bread	Whole Grain Cereal
Dry Beans	Dry Peas	Lentils
Nut Butters	Soy Flour	Tortillas
Bran	Brown Rice	Wheat Germ
Green Beans	Lima Beans	

FRUIT

Apricots	Berries	Dried Fruit
Grapes	Grapefruit	Oranges
Plums	Prunes	Raisins
Watermelon		

MEAT AND SEAFOOD

Lean Beef	Clams	Crab
Fish	Hearts/Kidneys	Lamb
Oysters	Poultry	Sardines
Shrimp	All liver except fish*	

*Liver should only be eaten once a week

SHEPEARD COMMUNITY BLOOD CENTER

For more information about iron, Please contact the Director of Donor Services 706.737.4551 www.shepeardblood.org

REV. 1/2/18

Figure 4. Iron Information Handout

The AABB bulletin #17-02, published on March 16, 2017, recommended blood collection establishments take additional voluntary actions to monitor, limit, or prevent iron deficiency in blood donors (Szczepeorkowski & Hopkins, 2017). The bulletin outlines three additional recommendations along with strategies and interventions. Blood establishments voluntarily should implement one of the following strategies:

1. Development of a program to provide replacement iron in absence of ferritin measurements.
2. Measurement of serum or plasma ferritin.
3. Evidence-based lengthening of donation interval, or restrict number of donations per year.

Under strategy number three, the lengthening interval and/or decreasing the number of donations per year includes three further options. The first limits whole blood donations to two times in a 12-month period, or one two-unit collection in a 12-month

period. The second limits whole blood collections from 16–18 year olds to one time a year in response to higher documented rates of iron deficiency in young donors. The third limits whole blood collections from pre-menopausal women to one donation in a 12-month period (Szczepeorkowski & Hopkins, 2017).

Donor Population

Riley, Schwei, and McCullough (2007) concluded that the United States' conventional method for determining donor eligibility was out of date and suggested a new method. This propsal changed the potential eligible population in the United States from 60.2% to 37.8%. The new method formula is:

> Total eligible donor population = (Total population-Age exclusions) - (Total population-Age exclusions) x (Adjusted prevalence – overlap adjustment). It is important to note that the model was lacking additional exclusions such as vaccinations, recent blood donations (within 8 weeks), transplant, transfusion, piercing, or certain prescription medications as well as sociologic determinants.

In Australia, Lucky et al. (2014) expanded the 31 donor exclusion factors to 70 factors. Their refined method attempted to predict more accurately the donor-eligible pool. According to their study, 67% of the population between the ages of 16 and 18 was excluded from donating blood. Of the 33% of the population eligible to donate blood in Australia, only about 5.6% donate annually. Accounting for repeat donations, the calculated number is 12.2 units of blood collected per 100 potential donors.

Whole blood collection and transfusions continue to decline based on the 2015 National Blood Collection and Utilization Survey (NBCUS). The United States collected 12,056,000 whole blood units excluding autologous collections and rejected units, which

was a decline of 10.2 % from 2013. Red blood cell transfusions also declined 14% from 2013 to 2015, with a 2015 total of 11,330,000. The hospitals outdated 186,000 red blood cell units and blood centers outdated 414,000 red cell units (Ellingson, 2017).

Blood Supply Sustainability

In 2016, American Blood Centers (ABC) an organization representing all community blood centers in the Unites States partnered with the U.S. Department of Health and Human Services (HHS) to fund a study to analyze the United States' blood supply and its current sustainability. The study cost approximately $1.2 million and was performed by the RAND Corporation and released in December of 2016. The researchers attempted to describe the current system and employed a mixed-method approach, using available data and interviews with stakeholder groups. The purpose of the study was to inform federal policymakers about the current environment and the future regarding blood supply, payment for services, and corporate investment regarding innovation (RAND Corporation, 2016).

The RAND report had the following recommendations meant to improve the sustainability of the U. S. blood system (RAND Corporation, 2016, p. xvi–xvii):

1. Collect data on blood use and financial arrangements – While stakeholders have access to statistics on blood use and transactions related to their individual organizations, the U.S. government currently does not have access to comprehensive data describing the performance of the blood system as a whole.
2. Develop and disseminate a vision for appropriate levels of surge capacity – Describing a desired level or surge capacity from public health and

preparedness perspective will help stakeholders and policy makers plan and estimate the costs associated with maintaining surge capacity in the blood system aside from the usual transaction-based arrangements between blood centers and hospitals.

3. Subsidize blood centers' ability to maintain surge capacity – Surge capacity to respond to serious events and emergencies falls outside the typical financial arrangements between hospitals and blood centers. In the current environment of falling demand for blood and resulting excess supply, centers have shown some surge capacity to meet emergency needs. However, once the industry has adjusted to lower demand, there is no guarantee that this surge capacity will remain. If blood centers are asked to retain excess staff, collection capabilities, or stock for any reason other than meeting the current demand for blood from hospitals, there is a strong argument that the government should separately finance this surge capacity.
4. Build relationships with brokers and other entities to form a blood "safety net" – HHS should build ongoing relationships with the American Red Cross (ARC) the Armed Services Blood Program (ASBP), and brokerage entities that would commit to procuring and delivering blood at the request of HHS to address short-term and local shortages. A well-established set of relationships can reduce response times in the case of shortages.
5. Build and implement a value framework for new technology – RAND recommended that HHS invest in health technology assessment research for existing technologies with low adoption rates and for technologies on the

horizon. These analyses should distinguish between costs and benefits accruing to blood centers and hospitals and costs and benefits from the broader societal perspective. For technologies with significant costs and benefits from the societal perspective but not from the blood center and hospital perspective, policy intervention could encourage adoption.

6. Pay directly for new technologies for which there is no private business case for adoption – Decisions to adopt some tests that are now industry standards are difficult to justify from the business perspectives of blood centers and hospitals. However, these technologies often have clear public health and preparedness benefits, so policy makers may want to require or at least encourage adoption. In these cases, U.S. government financing of technology acquisition costs might be appropriate.
7. Implement emergency use authorization and contingency planning for key supplies and inputs – HHS could through the FDA to implement emergency use authorizations for replacement supplies and other inputs in the event of a shortage.

Researchers performed a stock and flow simulation at a national and inter-regional level for a pandemic and a mass casualty emergency event on the blood supply system. Results indicated that the variables used in the model are highly customizable and can be manipulated depending on current data and or situation. Simonetti et al. (2017) discovered that no shortage of blood occurred in either scenario, indicating the blood system was robust enough if blood is moved from region to region within a centralized blood transfer system.

Klein, Hirouda, and Epstein (2017) described the current blood system as being in danger of a major disruption. As blood usage and collections decline the cost of producing a unit of red blood cells has increased for the blood center as hospital reimbursements have declined. The combination of the two resulted in an estimated 90% of blood centers providing red blood cells below cost. They concluded that "outwardly the blood-delivery system appears to be functioning effectively but evidence that a once-reliable system is faltering is unmistakable" (p. 1488).

Monte Carlo Simulation

The Monte Carlo method is a technique that approximates solutions to quantitative data by translating uncertainties in model inputs into uncertainties in model results. The result of a single simulation represents a qualified statement, but the result of a Monte Carlo simulation is a quantified probability. The simulation runs a great number of times and the output results are probability distributions (GoldSim, 2017).

The simulation works by selecting a random value for each task. The model is calculated based on this random value. The result is displayed and the process is repeated hundreds or thousands of times depending on the circumstances. When complete, the results are used to describe the likelihood or probability of reaching various results. The Environmental Protection Agency (EPA) uses Monte Carlo simulation in risk assessments but must ensure they include single-point risk estimates prepared under current EPA guidelines (Smith, 1994).

Summary

Chapter Two provided some insight to the the AABB's decision to publish bulletin #17-02. As the research and analysis to potentially protect the blood donor

continues, the impact on supply of blood in an already declining collection population must be discussed. The risk of lengthening the donor interval, and/or decreasing the number of donations per year on the blood supply must be quantified to understand the true impact of the decision for southeastern community blood centers. After consultation and review, the Monte Carlo simulation will not provide the essential predictability matrix; therefore, it should not be used to estimate the reduction in blood collections.

METHODOLGY

Research Design

The research design for this study is a descriptive study using quantitative data from blood donors who donated whole blood from January 1, 2016–December 31, 2016 at a southeast community blood center. Statistical analysis will be used for each of the following three options:

1. Limit whole blood donations to two times in a 12-month period, or one 2-unit collection in 12-month period .
2. Limit whole blood collections from 16–18 year olds to one time a year.
3. Limit whole blood collections from pre-menopausal women to one donation in a 12-month period.

A reduction in donors will directly correlate to a reduction in the collection of red blood cells. With the manipulation of some of the variables, the final result would be to produce a predictability chart that the donor center could use in determining the impact of the three options based on their data.

Data Set Description

I gathered data from the Southeast Community Blood Center's Blood Bank Computer System database, which contains 17,462 donors for fiscal year 2016. The data set does not contain names of the donors and was compiled into excel for analysis. The fixed data fields were separated into the following columns:

1. donor number
2. gender
3. age
4. birth year
5. birth month
6. birth day
7. blood type
8. race
9. Hgb/HCT
10. number of donations

Using the above data, calculations were made by limiting individuals to donating only two times in a 12-month period, limiting donors 16–18 years old to donating only one time in a 12-month period, or limiting pre-menopausal woman to only one donation in a twelve month period.

Data Analysis

The Statistical Analysis System (SAS) software was used to analyze the data set for for the three donor interval options:

For the option of limiting whole blood donations to two times in a 12-month period, or one 2-unit collection in 12-month period, I will use the following calculation:

% Loss = Total Products – Total Products (removing donor collections > 2 donations in a 12-month period / Total Products x 100.

For the option to limit whole blood collections from 16–18 year olds to one time in a 12-month period, the calculation is:

% Loss = Total Products – Total Products (removing donor collections ≥ 2 from 16–18 year olds in a 12-month period / Total Products x 100

For option three, limiting whole blood collections from premenopausal women to one donation in a 12-month period, I will use the calculation:

% Loss = Total Products – Total Products (removing donor collections ≥ 2 from females < age 50 in a 12-month period / Total Products x 100

Each of the three scenarios will reveal the percentage changed in the number of red cell units collected.

Limitations

The data extracted was a point in time in the 2016 calendar year and does include fluctuations that occur year to year based on external factors such as natural disasters, community health outbreaks, additional mandated testing, and the state of the economy. Demographics differ from region to region; therefore, other community blood centers' donor mix of age and gender may not correlate exactly with the Southeast blood center's database.

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