DEMOGRAPHIC CORRELATES OF LOW HAEMOGLOBIN DEFERRAL AMONG POTENTIAL BLOOD DONORS IN SOUTH AFRICA

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19 October 2015

DECLARATION

I, Farisai Kuonza (student number 880911) am submitting my research report in partial fulfilment of the requirements of Master of Science in Epidemiology in the field of Epidemiology and Biostatistics at the University of Witwatersrand, School of Public Health. I declare that all materials presented in this report are my own work and have not been submitted before for any degree at any other University. Where I used materials/thoughts from other sources, I have properly acknowledged through the conventional referencing.

..... 19 October 2015

Signature Date

DEDICATION

I dedicate this work to my parents for always encouraging and supporting me to achieve more in life

ABSTRACT

Introduction

Blood transfusion is important in the management of many diseases. Approximately 20% of all potential blood donors are deferred from giving blood for various reasons. Low haemoglobin potential donor deferral is the single major cause of donor deferral and it accounts for about 10% of all deferrals (1). Understanding factors associated with low haemoglobin potential donor deferral could help in reducing deferrals and increase blood supply. Literature on correlates of low haemoglobin deferral is sparse in South Africa. The aim of the study was to determine the prevalence of low haemoglobin deferral among potential donors, proportion of low haemoglobin deferral among deferred donors and to identify factors associated with low haemoglobin donor deferral in potential blood donors in eight provinces of South Africa in 2013.

Methods

The study was a cross sectional analysis of secondary data collected from eight South African provinces in 2013. There were a total of 996 060 attempted blood donations from 471 126 potential donors. Analysed sample consisted of 8056 random sampled donors (representing 2% of the potential blood donors aged 18 and above). Prevalence of low haemoglobin donor deferral among potential donors and proportion of low haemoglobin donor deferral among deferred donors were estimated. Binomial and multinomial logistic regression analyses were used to identify the factors associated with low haemoglobin donor deferral.

Results

Among the 8056 potential donors, 51.9% were females and the overall median age of all potential donors was 32 years (IQR: 23-45). About half (49.3%) of all the potential donors were repeat donors, 26.4% were re-join and 24.3% were first time donors. The potential donors

of blood group O were 43.8% of the population, followed by blood group A (29.4%) while blood group B and AB were 14.9% and 4.4%, respectively.

The overall prevalence of donor deferral was 22.7% (95% CI: 21.8-23.7), while the prevalence of deferral due to low haemoglobin was 6.7% (95% CI: 6.1-7.2). Potential donors of female gender, 18-25 age group, Black race, first time donors and those that donated in Kwa-Zulu Natal had the highest low haemoglobin prevalence. The proportion attributable to low haemoglobin among potential donors was 0.29. In adjusted analysis the factors associated with low haemoglobin deferral were sex (P<0.001), donor type (P<0.001), province (P<0.001) and race (P<0.001).

Conclusion

The prevalence of low haemoglobin donor deferral obtained was 6.7%. The proportion of deferral due to haemoglobin among deferred donors was 0.29 and the identified correlates are sex, donor type, province and race. The identified correlates could be used when deciding which potential donors to invite for a blood donation after each inter-donation interval has elapsed and blood supply could be increased.

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I am indebted to my husband Lazarus, and my two sons who never understood why I had no time for them and to God who makes all things possible.

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CI:	Confidence Intervals
Hb:	Haemoglobin
IQR:	Interquartile Range
SANBS:	South African National Blood Services
<:	Less than
>:	More than
OR:	Odds ratio
RR:	Relative risk
HIV:	Human immunodeficiency virus
HDI:	Human Development Index
WPBTS:	Western Cape Blood Transfusion Service

CHAPTER 1: INTRODUCTION

The chapter begins with an explanation of the need of blood donation and transfusion and outlines the importance of ensuring safety of blood donors and recipients. The causes of deferral are also explored and low haemoglobin is highlighted as major cause of deferral among deferred donors. Statement of the problem, a description of the aims and objectives of the study, followed by the justification and the chapter ends with a critical review of the available literature on low haemoglobin potential donor deferral.

1.1 Background

Blood transfusion is an essential part of the medical care system due to its importance in the management of many diseases and conditions (2). Blood is transfused to patients as red cells, whole blood, platelets or plasma products (3,4). The nature of medical problem a patient has determines the blood product that they are transfused with. The conditions that require blood transfusion are mostly surgical, medical and obstetric and gynaecological. Bleeding from the gastro intestines, primary haematological disorders and non-haematological cancers are some of the many medical disorders that require blood transfusion (5). Severe postpartum haemorrhage or uterus rupture in obstetrics and gynaecology, require rapid replacement of lost blood through transfusion (6). In surgery, cardiac operations require most blood transfusions because there is severe bleeding (7). Blood transfusion is also crucial in cases where there are road traffic accidents and victims lose a lot of blood (5).

The basic goal of any blood facility is to improve the safety of blood donor and blood recipient. Blood donor selection criteria policies are modelled to protect both the donor and the recipient. This is attained by continual and consistent efforts to upgrade the standards of blood transfusion services. Although, blood services aim to supply safe blood products, it is not possible to have a transfusion that is totally free from risk of transfusion transmissible diseases

(8). Blood for transfusion is usually collected from voluntary donors and in some countries, by replacement system where donors give blood when their friends or family require a blood transfusion (9).

The risk of transmission of disease by donated blood varies by type of donation (voluntary vs. replacement) and donation history (first-time attempt vs. repeat) (10). Repeat and voluntary donors are regarded to be safer donors. Eligibility criteria also differ across nations due to variations in transfusion-transmitted infection prevalence, diseases related to different ethnic population groups and other factors (11). Transfusion transmissible diseases are those infections that are spread when infected blood is transfused into a patient and they develop the disease for instance HIV, Hepatitis, Syphilis and Malaria (12).

It is therefore critical to select donors using rigorous screening procedures that assess their health and thereby reduce disease transmission (8). The eligibility criteria for blood donation is determined by known socio behavioural risk factors that attribute risk of transfusion-transmissible infections. The potential donor is deferred from donating if they are suspected to have transfusion transmissible diseases, have low body weight or have low haemoglobin and many other possible deferral reasons (11). Donor deferral can be through self-deferral by the donor or by the blood centre based on information revealed by potential donor (13). Potential blood donor deferral occurs as it is believed that a donor's exposures, history and behaviour represents an increased risk to the safety of blood supply or the donor.

Donor deferral has negative influence on donor recruitment, retention, and capacity to fulfil the increasing demands on the blood reserves (14). Potential blood donors are deferred either temporarily or permanently due to several reasons. Deferrals can be temporary or short term, long term, and permanent (15). Many potential donors are deferred temporarily due to anaemia

or low haemoglobin which is an easily correctable cause. Permanent deferral occurs as a result of presence of incurable transfusion transmissible diseases such as HIV in donor blood.

Measuring haemoglobin level before blood donation is a global safeguarding requirement against inappropriate donation (16). The haemoglobin test ensures that it is safe for the potential donor to give blood without compromising their own health and that there are sufficient red cells in donated blood for the recipient (17). If a recipient were to receive blood with low haemoglobin it would not resolve their medical condition thus it will be a wasted blood donation and transfusion.

Generally 8% to 12% of donor deferrals are due to low haemoglobin each year at blood collection sites (18). The haemoglobin level of potential blood donors is measured by different methods (17). Commonly used methods for haemoglobin estimation in blood donors are the Copper sulphate and Hemocue methods. A potential donor can only donate blood if their haemoglobin level is 12.5g/dL or above. A low haemoglobin level results in temporary deferral from donating blood and advice is given to come at a later date to attempt to donate again hoping that haemoglobin level will be normal (19). Other tests that are done in the laboratory after blood donation but before blood transfusion include tests for HIV, Hepatitis B and C and Syphilis. If blood is found to be reactive to any of these, it is not suitable for transfusion and is discarded (20).

Low haemoglobin (anaemia) among potential donors due to malnutrition is a worldwide problem, especially in developing countries where due to poverty, people are unable to acquire foods rich in essential nutrients that are necessary for haemoglobin formation (21). Iron and folate deficiency are the most common nutritional deficiency cause of low haemoglobin. In young women, low haemoglobin is usually due to menstruation and pregnancy. Excessive bleeding during menstruation, physiological changes in pregnancy and too much blood loss

whilst giving birth can result in low haemoglobin (1). Pregnant women are at risk of anaemia because they require more nutrients than usual due to their condition. In older women 50 years and above, the most frequent cause of low haemoglobin is persistent gastrointestinal bleeding from non- parasitic causes, such as duodenal ulcers, gastrointestinal cancers or gastric ulcers and HIV infection (22).

Chronic iron deficiency anaemia which results in low haemoglobin is a known complication of frequent blood donation (19). Regular blood donors develop iron deficiency anaemia because a lot of iron is removed from the donor during blood donation and the 56-day inter-donation interval may be insufficient for haemoglobin and iron stores recovery for some donors. Other than iron-deficiency anemia, heamoglobinopathies may occur in blood donors. Haemoglobinopathies lower the level of blood haemoglobin by destroying blood cells (23). The timely diagnosis of these blood diseases is beneficial to both blood donors and blood recipients. It is beneficial to donors as they become aware of the disease and can rapidly correct iron deficiency, and recipients by not being transfused with blood of low quality.

Certain medications used for the treatment of cancer for instance chemotherapy or radiation exposure may also result in decrease in haemoglobin by supressing the bone marrow which produces haemoglobin (24). Diseases like aplastic anaemia cause the body to make abnormal red cells. Other causes of low haemoglobin include kidney problems, blood loss from trauma, bleeding wounds, bleeding from digestive or urinary tracts, nose bleeds, surgery and red blood cell synthesis problems as in bone marrow and genetic disorders (23). Low haemoglobin level could also be caused by malabsorption or high loss of iron from the body due to malaria or hookworm infestation (25). Methods for haemoglobin measurement have poor accuracy and reproducibility and are also instrumental to donor deferral thus any haemoglobin measurement below 12.5mg/dl should be repeated to avoid unnecessary deferrals (26).

1.2 Statement of problem

Approximately 12% of all attempted blood donations in South Africa are deferred for various reasons (SANBS, April 8, 2014). The percentage of donor deferral due to haemoglobin at South African National Blood Service (SANBS) has been steadily increasing since 2010 (4.8% in 2010 and 5.7% in 2012) with proportionate decline in successful donation (SANBS, April 8, 2014). This could adversely affect blood supply.

In South Africa, there is usually an increase in demand for blood during the holidays because of increases in the number blood transfusions related to injuries resulting from road traffic accidents which often results in acute shortages of blood (27). It is therefore necessary to find ways to decrease deferral among potential donor population so as to increase blood supply.

Previous studies done in other countries (India, Japan) have shown that low haemoglobin level is the greatest single factor that causes the highest number of donor deferrals among potential blood donors (13,28,29).

The study by Hillgrove (30) done in Australia also showed that donors deferred due to low haemoglobin have up to 30% less donations in the following 4-5 years after being deferred than they would have donated have they not been deferred. This may well be the case in South Africa. Since blood donors deferred due to low haemoglobin represent a significant percentage of all the potential blood donors, identifying the risk factors for low haemoglobin deferrals is important for improving the wellbeing of blood donors and increasing blood availability in South Africa.

Further, any potential donor that is deferred add to South African National Blood Service (SANBS) costs in terms of time spent interviewing them and the costs of testing of haemoglobin or haematocrit.

1.3 Study aims and objectives

The overall aim of the study is to determine the prevalence of and identify factors associated with low haemoglobin donor deferral in potential blood donors in eight provinces of South Africa. The specific objectives are:

1. Determine the prevalence of low haemoglobin levels among potential blood donors in eight provinces of South Africa in 2013.
2. Determine the proportion of donor deferral due to low haemoglobin among deferred donors in eight provinces of South Africa in 2013.
3. Identify factors that are associated with low haemoglobin levels among potential blood donors in eight provinces of South Africa in 2013.

1.4 Justification of the study

Research on potential blood donors is limited in South Africa. The available information on the prevalence, patterns and contributing factors to donor deferral are often from personal communication. Many studies done outside South Africa have concentrated on potential donor characteristics and deferral patterns and there is a gap in existing literature regarding donor deferrals related to low haemoglobin (9,13,28). When the deferral data is collected, analysed systematically and interpreted, it may help to put in place interventions to reduce donor deferral, and thus improve blood supply.

Estimation of the prevalence and identification of predictors of low haemoglobin deferral in the South African potential donor population is crucial for the design of effective potential donor deferral preventive strategies. This study will add to current knowledge regarding donor deferral in South Africa. Its findings may also help to reduce the rate of donor deferral in the country and increase blood donations and supply.

Key definitions

Potential donors: men and women who attempted to donate blood at any SANBS donation site whether the donation was successful or not.

Deferred donors: all potential donors that attempted to donate but failed to, for any reason as per South African National Blood Services (SANBS) standard operating procedure.

Deferred donors due to low haemoglobin: all potential donors that attempted to donate but failed because their haemoglobin was less than 12.5g/dL as per SANBS standard operating procedure using the Hemocue /Copper sulphate test.

Other Deferral reasons: All other deferral reasons other than low haemoglobin. These are the other 162 reasons that results in attempted blood donation being unsuccessful including but not limited to: Blood pressure/pulse issues, hepatitis exposure, high risk behaviours, malaria, medical diagnosis/procedure, occupational exposure, infections, body piercing, pregnancy, surgery/trauma, tachycardia, and transfusion/transplant issues.

1.5 Literature review

1.5.1 Prevalence of donor deferral

Many studies done in different settings have reported the prevalence of donor deferral due to various reasons to be between 11% and 17% (13,28,29) and low haemoglobin has been reported as the main cause of deferral among all potential donors (23,31). Studies have reported varying reports on donor deferral rates in males and female donors. Mangwana et al (32) in a study done in India found that more males were deferred than females (79.58% vs 20.42%) whilst Ngoma et al (28) in Japan found that the overall proportion of donor deferral was higher among females than males.

1.5.2 Prevalence of low haemoglobin donor deferral

About 10% of all attempted whole blood donations in the United States of America are deferred due to low haemoglobin and it is usually a result of iron deficiency (23,33). Low haemoglobin has been reported as the single leading cause of deferral among all donors and mostly among female potential donors compared to male potential donors (68.01% in females versus 14.82% in males) (30).

1.5.3 Causes of low haemoglobin donor deferral

Female donors have been reported to be deferred more for low haemoglobin than their male counterparts. This has been explained by the fact that women lose blood during menstruation and pregnancy and they depend on iron absorption to replete loss due to blood donation whereas men have large iron stores that can be used to produce new red blood cells after multiple blood donations (13).

Studies have shown that it is donation interval that results in low haemoglobin not donation frequency (30,34,35). Donation interval is the time between two consecutive blood donations whilst donation frequency is the number of donations per given time which could be a year. Donation interval determines frequency that is why it is most important. Another study done in Brazil has shown that most deferrals due to low haematocrit/ haemoglobin are more prevalent in repeat donors. This might be due to shorter donation intervals (36).

Baart et al (37) in study done in Germany showed that haemoglobin measured at previous donation attempt visit, time since previous donation attempt visit, deferral at previous visit and the total number of whole blood donations, to be strong predictors for presence of low haemoglobin in a prospective donor at next donation visit and thus resulting in deferral. These strong predictors have been found useful in selecting potential blood donors for invitation for a donation attempt by the blood services.

A study has examined the causes of low haemoglobin in non-frequent and non-menstruating deferred donors. Most of the reasons for having low haemoglobin after seeking medical advice were due to serious diseases like cancers and gastrointestinal bleeding (39). Another study has shown that most cases of low haemoglobin occurred often in potential donors on their first attempt to donate and this was the frequent reason for deferral of blood donors (23).

A systematic review by Smith et al (40) has linked low haemoglobin to low iron levels. Iron-related parameters have been shown to be significantly influenced by a donation frequency of more than twice a year. Donor deferral may result due to low haemoglobin due to iron deficiency if more phlebotomies are done without giving them enough time to be restored.

Discrepancies among screening methods for haemoglobin measurement have been found consequently resulting in false low haemoglobin and haematocrit levels and consequently potential donors being deferred unnecessarily (23). It has been recommended that all low haemoglobin measurements be confirmed by use of other alternative tests before potential donors are deferred due to anaemia as it may increase blood supply in blood banks.

1.5.4 Causes of low iron stores

Depletion of iron has been noted with frequent blood donations and iron repletion was found necessary for donor welfare. An association between incidence of iron deficiency anaemia and increase in number of blood donations has been demonstrated (21). High levels of iron deficiency among repeat donors has been reported by a recent multicentre study done in a number of American States and more women than men were found to be iron deficient (41).

Custer et al (42) in Hong Kong did an investigation to assess the pre-donation haemoglobin and iron status of prospective blood donors. The results were consistent with other studies as they observed that there was increasing prevalence of reduction of iron stores with increasing frequency of blood donations among Chinese blood donors and this was more common in

female donors than male donors. Similar to other studies, iron deficiency was present in 65.3% of female donors and 35.1% of male donors and more women were found to be deficient of iron though their pre-donation haemoglobin was within acceptable range for blood donation (43,44). Nutritional deficiency also causes low iron stores thus it is recommended that donors consume a well-balanced iron rich diet although diet alone may not replace all the iron lost from blood donation (40).

1.5.5 Demographic factors for low haemoglobin deferral

Sex has been regarded as one of the main determinants of low haemoglobin deferral among potential donors. In their investigation Mast et al (1) in United States found that females were deferred more than men (17.1% vs 1.6%) in terms of donation attempts. In a study done previously demonstrating low haemoglobin as the most common reason for deferral in prospective whole blood donors, females have been observed as the most anaemic indicating the extensive anaemia problem in general female population (43). A study has shown that donor deferral varies by repeat donor status vs first time donor, race and sex. Most deferrals occurred in females, first time Asian donors and the least deferrals occurred in repeat, male white donors (45). It has also been shown that there is no difference in potential donor deferral in voluntary and replacement donors with regards to low haemoglobin (13).

Low haemoglobin donor deferral can also be associated with low body weight in both males and females (1) but in another study, an inverse relationship was found between body weight and low haemoglobin deferral among males and not among females (40). Increasing age in men has been shown to be associated with deferral due to low haemoglobin. Post-menopausal women between 51-60years have been found to have the least low haemoglobin deferral rates. After that age the rate increases progressively due to aging and becomes similar to that of men

(1). Donors of Hispanic or African descent, high body temperature and short inter-donation interval have also been associated with low haemoglobin donor deferral (1,40).

It has also been shown that in most countries the minimum haemoglobin threshold for donating blood is the same for males and females. Since reference range for females is lower than that of men, most females with normal haemoglobin thus, fall into the low haemoglobin range. It has been suggested that new haemoglobin criteria should be set for donor deferral and this should be done according to the reference range of that specific population and should be sex specific (45). Causes of high haemoglobin in males include higher levels of testosterone that increases haemoglobin production (46). Studies have also shown that smoking is associated with increased haemoglobin levels and smoking is more common in males than in females (47,48).

A study by Madrona et al (49) in Spain showed that females were more likely to give blood than males as percentages of first time donors were found to be higher among females but at the same time they were prone to low haemoglobin thus the numbers of successful donations by females were reduced significantly.

1.5.6 Other factors associated with low haemoglobin deferral

A relationship between low haematocrit/haemoglobin deferral among prospective blood donors with mean monthly temperature has been observed in the United States (50). The seasonal pattern affected all age groups and both genders equally and most haematocrit/haemoglobin deferrals occurred in summer. Oliviera et al (51) in their study done in Minas Gerais State, Brazil showed that areas that had low Human Development Index (HDI) had high prevalence of low haemoglobin deferral among potential blood donors compared to those that had high HDI and low haemoglobin deferral was more prominent among females

and non-white donors from northern part of Brazil. They also reported differences in deferral rates among different geographic regions within the Minas Gerais State, Brazil.

CHAPTER 2: METHODS

2.0 Introduction

This chapter presents the study design, setting, population and data management. Definitions of study variables and eligibility criteria are described in depth. The South African National Blood Service (SANBS) dataset used for analysis is also outlined here, and so are the measures taken to ensure data quality. This chapter ends with a description of methods used for data analysis and ethical considerations.

2.1 Study design

This is a cross sectional study of secondary data collected by South African National Blood Service (SANBS) on potential blood donors. The exposures and outcome variables were collected from potential donors at the same time when they visited SANBS donation sites in eight of South Africa's provinces in 2013 in an attempt to make a blood donation.

2.2 Study Setting

South Africa is located in the southern part of Africa and has an area of 1,221,037 km². It has 2,798 km of coastline which stretches along the Indian Ocean and Atlantic Ocean. On dry land, South Africa shares borders with Namibia, Botswana, Zimbabwe, Swaziland and Mozambique to the east, and lastly surrounds Lesotho before rejoining Mozambique's southern border (52).South Africa has an estimated population of 58 million (53). The country is divided into 9 provinces which are Limpopo, Gauteng, North West, KwaZulu Natal, Eastern Cape, Mpumalanga, Northern Cape, Free State and Western Cape. Each province has its own provincial government, with legislative and executive power vested in a provincial premier. Gauteng is the smallest and most crowded province though it is highly urbanized and Northern Cape is the largest but arid and empty. Northern Cape takes up almost a third of South Africa's total land area. Provinces vary by race, culture, religion and socioeconomic issues (52).

There are 11 official languages recognized within South Africa which are Afrikaans, English, Ndebele, Northern Sotho, Sotho, Swazi, Tswana, Tsonga, Venda, Xhosa and Zulu. About 80 percent of South Africans are Blacks, about 9% are Whites and the Asians and Coloured races form the minority of the population (53).

2.3 Study population

The data was collected in South Africa in 2013 from eight of the nine provinces. The provinces included in the study are Limpopo, Gauteng, North West, Kwa-Zulu Natal, Eastern Cape, Mpumalanga Northern Cape and Free State. Western Cape Province was excluded from analysis because it works independently and is covered by a different blood service provider. The data set comes from the SANBS. SANBS is rated amongst the best in the world in supplying blood and blood products (54). There are ninety fixed sites around the eight provinces and 4000 mobile donor sites that collect blood. The mobile donor sites target shopping malls, educational institutions and other places where there may be reasonable donations. Potential donors are required to complete a pre-donation questionnaire. The questionnaire collects demographic, health, sexual and lifestyle information.

The potential donors are then tested for the level of haemoglobin before they are eligible to donate blood at each attempted donation visit. Low haemoglobin is defined as a haemoglobin of less than 12.5mg/dl as per SANBS standard operating procedure. A potential donor has to weigh at least 50kg, and be between 16 and 65 years of age (65 if it is a first time donor and above 65 if it is a repeat donor provided they bring a medical certificate every 2 years which states they are in good health). It is information extracted from the questionnaire and the haemoglobin level that determines if a potential donor is eligible to donate blood. Whether the potential blood donor successfully donates blood or not is also captured on the questionnaire. The information on questionnaire is then captured onto the Medical information

technology (MEDITECH) system of the SANBS. It is the captured information that was used in the current study.

2.4 Study Eligibility criteria

2.4.1 Inclusion criteria

- All potential donors aged 18 and above that attempted to donate blood and resided in any of the eight provinces of South Africa in 2013 were included into the study.

2.4.2 Exclusion criteria

- All potential donors that were below 18 years of age were excluded from the study as per National Health Act (section 71 of the National Health Act of 2003) which states that parental consent is required when research is done on minors.

2.5 Sampling strategy

In 2013, there were 996 060 attempted blood donations by 471 126 potential donors in the eight provinces (Limpopo, Gauteng, North West, Kwa-Zulu Natal, Eastern Cape, Mpumalanga, Northern Cape and Free State) of South Africa. For the purpose of this study, the last donation attempt by each potential donor in 2013 was considered as the donation visit of interest for potential donors that made multiple attempted donations in 2013. This was a recommendation from SANBS as they use last donation attempt for all the research work. Figure 1 shows the selection of participants that were included in the analysis sample of this study. Of the 471 126 people that attempted to donate blood in 2013, 68 326 were below 18 years of age and thus were excluded. As large sample size would yield statistically significant results for all variables, descriptive analysis of basic characteristics was done for the 100%, 5%, 2% and 1% samples of the 402 800 potential donor population. The results were consistent across the samples (see Appendix A to C for this result) and the 2% sample was chosen for use in this study.

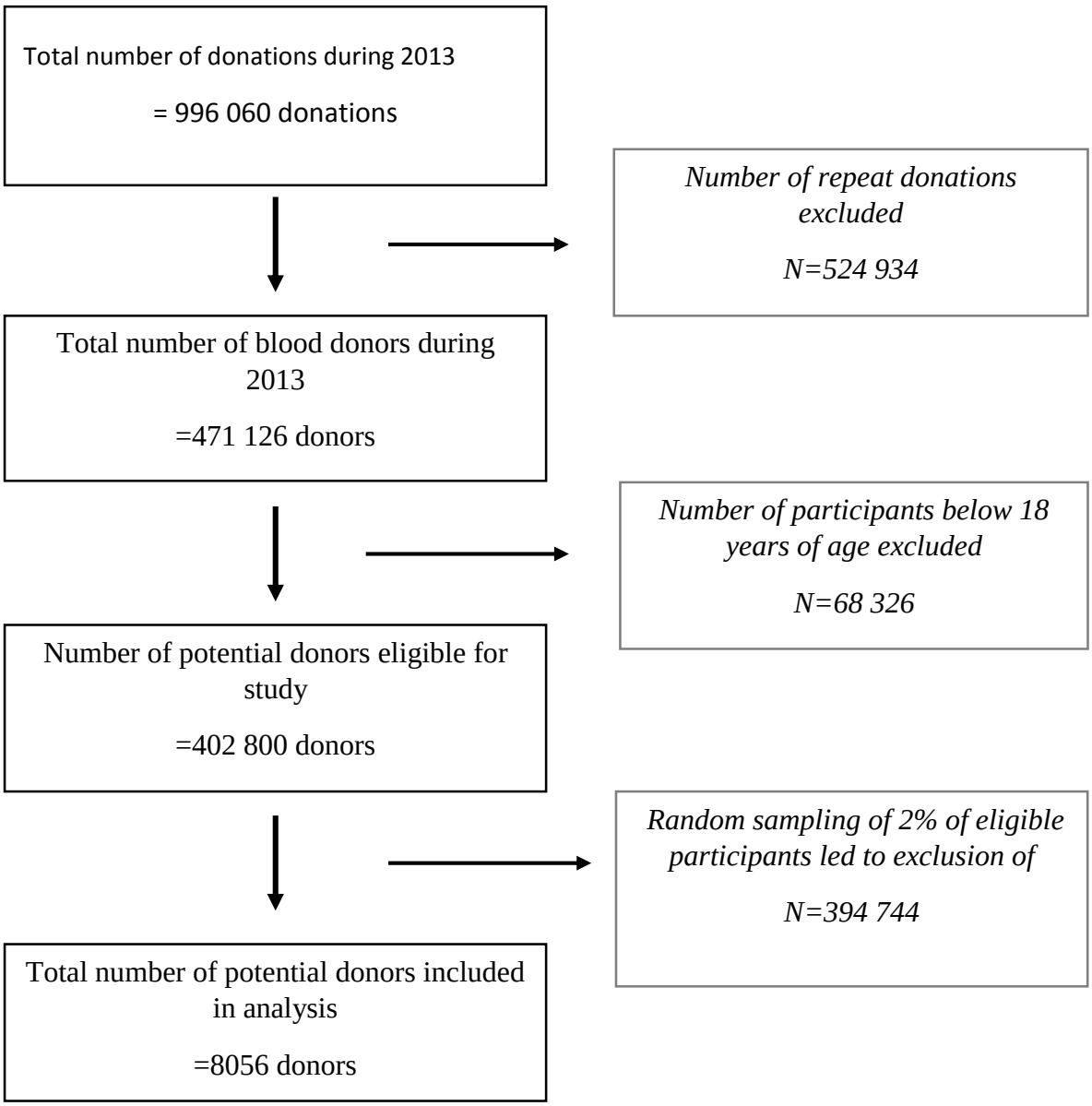

Figure 1: Flow chart of potential donors

2.6 Definition of variables

2.6.1 Outcome variable

Donation status: Two variants of this variable were used in our analysis. The first one (donation status 1) has two categories: deferred donation due to low haemoglobin (1), otherwise, 0 (this comprises of successful donation and those deferred due to other reasons). As the population in the comparison group coded (0) may be very different, further analysis using three categories of the outcome variable was done. To achieve this, the outcome variable 'donation status 2' was categorized as follows: successful donation (1), deferred due to low haemoglobin (2) and deferred due to other reasons (3).

2.6.2 Explanatory variables

Age: refers to age of potential donor at time of donation in years and was categorised as 18-25 (0), 26-35 (1), 36-45 (2), 46-55 (3) and above 55 (4).

Sex: refers to the biological sex of potential donor [male (0) or female (1)].

Race: ethnicity of potential donor defined as Black (0), Asian (1), Coloured (2), White (3) and Unknown (4).

Blood group: blood group of potential donor categorised as O (0), A (1), AB (2), B (3) and Unknown (4).

Province: province where potential donor attempted to donate blood. Gauteng (0), Eastern Cape (1), Free State (2), Kwa-Zulu Natal (3), Limpopo (4) Mpumalanga (5), North West (6), Northern Cape (7).

Donor type: There are four categories of donor as classified by SANBS. These are:

- New- A potential donor with at most one successful donation within the previous 12 months. The donor may also have been deferred during the period if multiple attempts were made.
- Join- A potential donor that presented at any SANBS donation site for the first time in attempt to make a blood donation and was deferred.

For the purposes of the study and to enable robust statistical analysis, the join donors were combined with new donors and referred to as "First time donors".

- First time donor (0) - A potential donor with at least one successful donation within previous 12 months or a potential donor that presented at any SANBS donation site for the first time in attempt to make a blood donation and was deferred.
- Re-join (1) - A potential donor that has donated blood more than once previously and did not present to donate within previous 12 months or was deferred temporarily that presents at any SANBS donation site in attempt to make a blood donation. The donation can be successful or deferred.
- Repeat (2) - A potential donor that has had successful blood donations previously that presents at any SANBS donation site in attempt to make a blood donation. The donation can be successful or deferred.

2.7 Data cleaning and quality checks

All data analyses were done in STATA 13. Variables were tabulated which also allowed us to check for missing data. Inconsistencies in the data were checked in terms of misclassification of donor type as some were not consistent with the definitions of the categories and these were clarified using source documents. Data cleaning included applying the inclusion and exclusion criteria, while data management included coding/recoding of variables in preparation for analysis.

2.8 Data Analysis

Bivariate descriptive analysis of potential donor characteristics was done by "donation status 2" (successful donation/ deferred due to low haemoglobin/ deferred for other reasons). Chi-squared tests were also done to establish the association between donation status and individual characteristics of the potential blood donors. Frequency table was used to display the percentage distribution and the chi square statistics were also reported in the table.

To achieve objective 1 of the study *(determination of the prevalence of low haemoglobin deferral among potential blood donors)*, prevalence of low haemoglobin was computed as a percentage of the total number of donors that attempted to donate blood whether successful or deferred. This is analytical cross tabulation of donation status by the various characteristics. The prevalence was also estimated by sex, age group, blood group, race, donor type and province.

To achieve objective 2 of the study *(determination of the proportion of donor deferral due to low haemoglobin among deferred blood donors)*, proportion of donor deferral due to low haemoglobin was computed as a ratio of the total number of deferred donors that attempted to donate blood. The proportion of low haemoglobin is technically a ratio and the denominator was taken into account in estimating the confidence intervals. The ratio was also estimated by sex, age group, blood group, race, donor type and province.

To achieve objective 3 of the study *(identification of the factors that are associated with low haemoglobin levels among potential blood donors)*, three models were run. The first model was a binomial logistic regression using the two-category outcome variable (comparing deferral due to low haemoglobin to other potential donors). The second and third models made use of the three-category outcome variable. In this regard, multinomial logistic regression was done with successful donors as the base category for the second model and other deferrals as

the base category for the third model. Essentially, a comparison of deferral due to low haemoglobin and successful donation in the second model and a comparison of deferral due to low haemoglobin and other deferrals in the third model. The second and third models are actually the same model, except for the different parameterizations used corresponding to two alternative choices for the base category.

Donor blood group was only used in descriptive analysis and omitted in statistical analysis.

2.8.1 Binomial logistic regression

$$logit(p) = b_0 + b_1X_1 + b_2X_2 + b_3X_3 + \ldots + b_kX_k$$

Where p is the probability of presence of the characteristic of interest (successful donation), b_0 is the intercept and $b_1 \ldots b_k$ are the slopes and $X_1 \ldots X_k$ are the explanatory variables. The logit transformation is defined as the logged odds:

And

$$logit(p) = \ln\left(\frac{p}{1-p}\right)$$

Taking the exponential of both sides of the regression equation, it becomes:

$$odds = \frac{p}{1-p} = e^{b_0} \times e^{b_1X_1} \times e^{b_2X_2} \times e^{b_3X_3} \times \ldots \times e^{b_kX_k} \quad (55)$$

2.8.2 Multinomial logistic regression

The model involves categorical-dependent variable "donation status" with three possible outcomes: "successful donations (1)", "deferred for low haemoglobin (2)", "deferred for other reasons (3)" recorded in y and the explanatory variables X (55). A set of coefficients $\beta^{(1)}$, $\beta^{(2)}$, and $\beta^{(3)}$ corresponding to each outcome are estimated.

$$\Pr(y = 1) = \frac{e^{x\beta(1)}}{e^{x\beta(1)} + e^{x\beta(2)} + e^{x\beta(3)}}$$

$$\Pr(y = 2) = \frac{e^{x\beta(2)}}{e^{x\beta(1)} + e^{x\beta(2)} + e^{x\beta(3)}}$$

$$\Pr(y = 3) = \frac{e^{x\beta(3)}}{e^{x\beta(1)} + e^{x\beta(2)} + e^{x\beta(3)}}$$

Setting β (1) = 0, the equations become

$$\Pr(y = 1) = \frac{1}{1 + e^{x\beta(2)} + e^{x\beta(3)}}$$

$$\Pr(y = 2) = \frac{e^{x\beta(2)}}{1 + e^{x\beta(2)} + e^{x\beta(3)}}$$

$$\Pr(y = 3) = \frac{e^{x\beta(3)}}{1 + e^{x\beta(2)} + e^{x\beta(3)}}$$

The models provide estimates for the effect that each explanatory variable has on the response. The effect of the explanatory variables can be assessed for each logit model.

2.9 Ethical Considerations

The study is a secondary data analysis of anonymized data from South African National Blood Service (SANBS). Written permission to use the data was requested for and obtained from the SANBS. Ethics clearance to conduct the study was sought from South African National Blood Service Ethics Committee (see Appendix D) and the Faculty of Health Sciences Research Ethics Committee of the University of Witwatersrand (see Appendix E) and it was granted. As a means of maintaining confidentiality, the data for the study was password protected, and was only available to the two supervisors and the investigator.

CHAPTER 3: RESULTS

3.0 Introduction

This section provides the results of the analyses carried out to achieve the objectives of the study. The chapter begins with a description of potential donor characteristics by donation status: successful donation, deferred for low haemoglobin and deferred for other reasons. This is followed by the presentation of the prevalence of low haemoglobin deferral among potential donors and proportion of low haemoglobin deferral among deferred donors by selected potential donor characteristics. The chapter ends with presentation of the factors associated with low haemoglobin donor deferral.

3.1 Description of potential donor characteristics

Table 1 shows the percentage distribution of the potential blood donors by selected characteristics. Of the 8056 potential donors, 51.9% were females and 48.1% were males. Most potential donors (33.2%) were in the age group 18-25years and as age increased, the number of potential donors decreased with the least number (8.8%) of potential donors being above 55 years of age. The median age of all potential donors was 32 years (IQR: 23-45).

The race with the highest proportion of potential donors was the White race (49.9%), closely followed by those of Black race (34.6%). The potential donors of Asian and Coloured race constituted 8.1% and 5.4%, respectively. About half (49.3%) of all the potential donors were repeat donors, 26.4% were re-join and 24.3% were first time donors. The blood group with highest proportion of potential donors was blood group O (43.8%) followed by blood group A (29.4%). Potential donors of blood group AB and B constituted 4.4%, and 14.9% respectively.

Most of the potential donors (45.9%) attempted to give blood in Gauteng province followed by KwaZulu Natal (18.8 %). Eastern Cape and Mpumalanga had similar percentages of potential donor attempted donations (8.9% and 8.6%) respectively. Potential donors from Free State and

Table 1: Percentage distribution of potential donors by selected characteristics

Characteristic	Total	Donated	Deferred low haemoglobin	Deferred for other reasons	P value
Total	8056	6225	536	1295	
Sex					
Males	48.1	54.2	3.7	37.1	
Females	51.9	45.8	96.3	62.9	<0.001
Age group					
18-25	33.2	31.1	46.5	37.8	
26-35	23.8	23.7	21.6	25.5	
36-45	19.5	20.3	16.4	17.0	
46-55	14.2	15.1	10.1	11.5	
> 55	8.8	9.8	5.4	8.2	<0.001
Median age (IQR)	32(23-45)	33(23-45)	27(20-40)	30(22-42)	
Race					
Black	34.6	30.9	59.5	41.9	
Asian	8.1	8.0	11.6	6.9	
Coloured	5.4	5.5	6.0	4.3	
White	49.9	53.6	19.2	44.7	
Unknown	2.1	1.9	2.1	2.2	<0.001
Donor type					
First time	24.3	18.9	44.2	42.2	
Re-join	26.4	24.6	24.6	35.4	
Repeat	49.3	56.4	31.2	22.5	<0.001
Blood group					
O	43.8	47.4	29.5	32.7	
A	29.4	32.3	20.0	19.5	
AB	4.4	4.6	3.5	3.3	
B	14.9	15.7	12.7	12.3	
Unknown	7.4	0.0	34.3	32.2	<0.001
Province					
Gauteng	45.9	44.6	38.4	55.1	
Eastern Cape	8.9	9.0	10.8	7.9	
Free State	6.0	5.8	5.0	7.0	
KwaZulu Natal	18.8	18.0	33.4	16.5	
Limpopo	3.6	3.8	3.4	2.7	
Mpumalanga	8.6	9.9	3.5	4.9	
North West	5.5	5.9	3.2	4.3	
Northern Cape	2.7	3.0	2.2	1.5	<0.001

P value for chi squared test for categorical variable

North West constituted 6.0% and 5.5%, respectively. The provinces with the least attempted donations were Limpopo (3.6%) and Northern Cape (2.7%). All the explanatory variables were statistically significantly associated with donation status.

3.2 Prevalence of low haemoglobin donor deferral among potential donors

The overall prevalence of donor deferral was 22.7% (95% CI: 21.8-23.7). The second column in Table 2 shows the prevalence of donor deferral due to low haemoglobin by selected potential donor characteristics. The prevalence of haemoglobin donor deferral among potential donors was 6.7% (95% CI: 6.1-7.2). Females had higher prevalence for haemoglobin deferral 12.3% (95% CI: 11.4-13.4) compared to males 0.5% (95% CI: 0.3-0.8). The potential donors of 18-25 year age group had the highest prevalence 9.3% (95% CI: 8.3-10.5) and the potential donors that were above 55 years had the lowest prevalence 3.9% (95% CI: 2.7-5.5). The prevalence in the 26-35 and the 36-45 year age groups were similar 6.0% (95% CI: 5.1-7.2) and 5.6% (95% CI: 4.6-6.8), respectively. The potential donors between 46 and 55 years of age had a low haemoglobin donor deferral prevalence of 4.7% (95% CI: 3.6-6.1).

Potential donors of the Black race had the highest prevalence of low haemoglobin donor deferral 11.4% (95% CI: 10.3-12.7) followed by those of the Asian race 9.6% (95% CI: 7.5-12.1). The Coloureds had a prevalence of 7.4% (95% CI: 5.3-10.3). Those of the White race had the least prevalence 2.6% (95% CI: 2.1-3.1). First time potential donors had the highest prevalence of low haemoglobin deferral 12.1% (9% CI: 10.7-13.6) and repeat donors had the lowest prevalence 4.2% (95% CI: 3.6-4.9) whilst those of re-join category had a prevalence of 6.2% (95% CI: 5.3-7.3).

Kwa-Zulu Natal had the highest prevalence of haemoglobin donor deferral 11.8% (95% CI: 10.3-13.6) followed by Eastern Cape 8.1% (95% CI: 6.3-10.3) and Mpumalanga province had the least 2.7% (95% CI: 1.7-4.2). Free State and Gauteng had the same prevalence (5.6%) for

Table 2: Prevalence of donor deferral due to low haemoglobin among potential donors.

Characteristic	Prevalence of low haemoglobin deferral in potential donors (%) (95% CI)	Prevalence of deferral for other reasons in potential donors (%) (95% CI)	Prevalence of successful donations in potential donors (%) (95% CI)
Overall Prevalence	6.7 (6.1-7.2)	16.1 (15.3-16.9)	77.2 (76.3-78.2)
Sex			
Males	0.5 (0.3-0.8)	12.3 (11.4-13.5)	87.1 (86.0-88.1)
Females	12.3 (11.4-13.4)	19.4 (18.3-20.7)	68.2 (66.7-69.6)
Age group			
18-25	9.3 (8.3-10.5)	18.3 (16.9-19.8)	72.4 (70.7-74.1)
26-35	6.0 (5.1-7.2)	17.2 (15.6-19.0)	76.7 (74.8-78.6)
36-45	5.6 (4.6-6.8)	13.9 (12.4-15.8)	80.4 (78.4-82.3)
46-55	4.7 (3.6-6.1)	13.0 (11.2-15.1)	82.3 (79.9-84.3)
> 55	3.9 (2.7-5.5)	14.3 (12.0-17.0)	81.8 (78.8-84.3)
Race			
Black	11.4 (10.3-12.7)	19.5 (18.0-20.9)	69.1 (67.4-70.8)
Asian	9.6 (7.5-12.1)	13.7 (11.3-16.6)	76.7 (73.3-79.8)
Coloured	7.4 (5.3-10.3)	13.0 (10.1-16.4)	79.6 (75.6-83.2)
White	2.6 (2.1-3.1)	14.4 (13.4-15.5)	83.0 (81.8-84.2)
Unknown	11.7 (7.7-17.6)	17.1 (12.1-23.5)	71.2 (63.9-77.5)
Donor type			
First time	12.1 (10.7-13.6)	27.8 (25.9-29.8)	60.1 (57.9-62.2)
Re-join	6.2 (5.3-7.3)	21.6 (19.9-23.4)	72.2 (70.3-74.1)
Repeat	4.2 (3.6-4.9)	7.3 (6.6-8.2)	88.5 (87.4-89.4)
Province			
Gauteng	5.6 (4.9-6.4)	19.3 (18.1-20.6)	75.1 (73.7-76.5)
Eastern Cape	8.1 (6.3-10.3)	14.1 (11.8-16.9)	77.8 (74.6-80.7)
Free State	5.6 (3.9-8.1)	19.0 (15.7-22.7)	75.4 (71.4-79.1)
KwaZulu Natal	11.8 (10.3-13.6)	14.1 (12.5-16.0)	74.1 (71.8-76.2)
Limpopo	6.2 (3.9-9.6)	12.0 (8.8-16.3)	81.8 (76.9-85.8)
Mpumalanga	2.7 (1.7-4.2)	9.2 (7.3-11.6)	88.1 (85.4-90.2)
North West	3.9 (2.4-6.1)	12.5 (9.7-15.9)	83.6 (79.9-86.8)
Northern Cape	5.5 (3.1-9.4)	9.1 (6.0-13.7)	85.4 (80.1-89.5)

low haemoglobin deferral.

3.3: Proportion (ratio) of donor deferral due to low haemoglobin among deferred donors

The second column of Table 3 shows the proportions of low haemoglobin donor deferral among deferred donors. The overall proportion of low haemoglobin donor deferral among all deferred donors was 0.29 (95% CI: 0.27-0.31).Among female potential donors that were deferred, 0.38 (95% CI: 0.36-0.41) of them were deferred due to low haemoglobin and the proportion of their male counterparts was 0.04 (95% CI: 0.02-0.06). The highest proportion of haemoglobin deferrals among deferred donors was among the 18-25 age group 0.34 (95% CI: 0.30-0.37). The least proportion were among the potential donors that were above 55 years of age 0.21 (0.15-0.29). The 26-35 age group 0.26 (95% CI: 0.22-0.30), the 36-45 age group 0.29 (95% CI: 0.24-0.34) and the 46-55 age group 0.28 (95% CI: 0.21-0.33) had similar low haemoglobin donor deferral proportions among deferred donors.

Deferred potential donors of Asian race had the highest proportion of low haemoglobin deferral 0.41 (95% CI: 0.33-0.49). The proportions of deferral attributable to low haemoglobin for Blacks and Coloureds were 0.37 (95% CI: 0.34-0.40) and 0.36 (95% CI: 0.27-0.47) respectively. The deferred White potential donors had the least proportion 0.15 (95% CI: 0.13-0.18). Deferred repeat potential donors had the highest proportion of low haemoglobin deferral 0.37 (95% CI: 0.32-0.41) followed by first attempt potential donors 0.30 (95% CI: 0.27-0.34). The re-join potential donors had the least proportion 0.22 (95% CI: 0.19-0.26).

Kwa-Zulu Natal had the highest proportion of potential donors that were deferred due to low haemoglobin among the deferred donors 0.46 (95% CI: 0.41-0.51) followed by Northern Cape Province 0.38 (95% CI: 0.23-0.55). Gauteng province had the least proportion for low haemoglobin donor deferral 0.22 (95% CI: 0.20-0.25).

Table 3: Proportions (ratios) of donor deferral due to low haemoglobin among deferred donors

Characteristic	Proportion of low haemoglobin deferral in deferred donors (95% CI)	Proportion of deferral for other reasons in deferred donors (95% CI)
Overall proportion	0.29 (0.27-0.31)	0.71 (0.68-0.72)
Gender		
Males	0.04 (0.02-0.06)	0.96 (0.93-0.97)
Females	0.38 (0.36-0.41)	0.62 (0.58-0.63)
Age group		
18-25	0.34 (0.30-0.37)	0.67 (0.62-0.70)
26-35	0.26 (0.22-0.30)	0.74 (0.69-0.77)
36-45	0.29 (0.24-0.34)	0.72 (0.66-0.76)
46-55	0.28 (0.21-0.33)	0.73 (0.66-0.79)
> 55	0.21 (0.14-0.28)	0.79 (0.71-0.84)
Race		
Black	0.37 (0.34-0.40)	0.63 (0.60-0.66)
Asian	0.41 (0.33-0.49)	0.59 (0.51-0.67)
Coloured	0.36 (0.26-0.46)	0.64 (0.53-0.73)
White	0.15 (0.12-0.18)	0.85 (0.82-0.87)
Unknown	0.41 (0.27-0.55)	0.59 (0.45-0.72)
Donor type		
First time	0.30 (0.27-0.33)	0.70 (0.66-0.73)
Re-join	0.22 (0.19-0.26)	0.78 (0.74-0.81)
Repeat	0.36 (0.32-0.41)	0.63 (0.59-0.68)
Province		
Gauteng	0.22 (0.20-0.25)	0.78 (0.75-0.80)
Eastern Cape	0.36 (0.29-0.44)	0.64 (0.56-0.84)
Free State	0.23 (0.16-0.31)	0.77 (0.75-0.80)
KwaZulu Natal	0.46 (0.41-0.51)	0.54 (0.50-0.59)
Limpopo	0.34 (0.23-0.48)	0.66 (0.52-0.78)
Mpumalanga	0.23 (0.15-0.33)	0.77 (0.67-0.85)
North West	0.24 (0.15-0.35)	0.76 (0.65-0.85)
Northern Cape	0.38 (0.23-0.55)	0.62 (0.45-0.78)

3.4 Factors associated with low haemoglobin donor deferral

Two models were run in this regard, a binomial and multinomial model. The binomial logistic regression model was run using the two-category outcome variable (deferral due to low haemoglobin and other potential donors). The multinomial logistic regression model was run using two different parameterization corresponding to two alternative choices of the base categories. Firstly it was run with successful donors as the base category and then, other reasons for deferrals as the base category. The last model enabled comparison of deferral due to low haemoglobin with other reasons for deferral.

3.4.1 Binomial Logistic Regression

As shown in Table 4 second column; sex, age group, race, donor type and province were significant in the unadjusted bivariate analysis. Females were more likely to be deferred for low haemoglobin compared to the males (unAOR=27.1). Potential donors aged above 25 years of age were less likely to be deferred low haemoglobin. White and Coloured potential donors were less likely to be deferred for haemoglobin compared to Black potential donors. Re-join and repeat potential donors were less likely to be deferred for low haemoglobin (unAOR=0.5) and (unAOR=0.3), respectively compared to a first time potential blood donor.

Compared to potential donors from Gauteng, those from Eastern Cape and Kwa-Zulu were significantly more likely to be deferred for low haemoglobin (unAOR=1.5, unAOR=2.3 respectively) while potential donors from Mpumalanga compared to those of Gauteng were significantly less likely to be deferred for low haemoglobin (unAOR=0.5) .In the adjusted model (Table 4, column 3), the adjusted overall effect of gender is still statistically significant ($P < 0.001$) whilst the adjusted overall effect of age is no longer statistically significant ($P=0.719$). The adjusted effect of race and type of donor remains statistically significant ($P < 0.001$). The adjusted effect of province remains statistically significant ($p<0.001$).

Table 4: Unadjusted and adjusted ORs for the binomial logistic regression analyses examining associations between donation status and selected potential donor characteristics (Model 1).

Variable	Unadjusted OR (95% CI)	P value	Adjusted OR (95% CI)	Overall p value
Sex	***	P < 0.001		P < 0.001
Males	1.0		1.0	
Females	27.1 (17.3 - 42.5)***		27.1 (17.2-42.6)***	
Age group	***	P < 0.001		0.719
18-25	1.0		1.0	
26-35	0.6 (0.5-0.8)***		0.7 (0.6-0.9)*	
36-45	0.6 (0.5-0.7)***		0.9 (0.7-1.2)	
46-55	0.5 (0.4-0.7)***		0.9 (0.6-1.3)	
Above 55	0.4 (0.3-0.6)***		1.0 (0.7-1.6)	
Race	***	P < 0.001		P < 0.001
Black	1.0		1.0	
Asian	0.8 (0.6-1.1)		0.9 (0.6-1.2)	
Coloured	0.6 (0.4-0.9)*		0.6 (0.4-0.9)*	
White	0.2 (0.1-0.3)***		0.3 (0.2-0.4)***	
unknown	1.0 (0.6-1.7)		0.9 (0.5-1.4)	
Donor type	***	P < 0.001		P < 0.001
First time	1.0		1.0	
Re-join	0.5 (0.4-0.6)***		0.7 (0.6-0.9)***	
Repeat	0.3 (0.2-0.4)***		0.7 (0.5-0.9)***	
Province	***	P < 0.001		P <0.001
Gauteng	1.0		1.0	
Eastern Cape	1.5 (1.1-2.0)*		1.5 (1.1-2.0)*	
Free State	1.0 (0.7-1.5)		1.2 (0.9-2.3)	
KwaZulu Natal	2.3 (1.8-2.8)***		2.4 (1.9-3.1)***	
Limpopo	1.1(0.7-1.8)		1.1 (0.7-1.9)	
Mpumalanga	0.5 (0.3-0.8)**		0.7 (0.4-1.1)	
North West	0.7(0.4-1.1)		1.2 (0.7-2.0)	
Northern Cape	1.0(0.5-1.8)		1.6 (0.8-3.0)	

P < 0.05 *, P < 0.01 **, P < 0.001***

3.4.2 Multinomial Logistic Regression

Low haemoglobin vs Successful donation

The second column of Table 5 shows the likelihood of haemoglobin deferral compared to having successful donation was greater among females than males (RR=29.7). Potential donors of age 26-35 were less likely to be deferred for low haemoglobin than those aged 18-25years. The potential donors of White race compared to those of Black and Coloured race were significantly less likely to be deferred for low haemoglobin than have successful donations (RR=0.3 and RR=0.6) respectively. Compared to first time potential donors, re-join (RR=0.6) and repeat (RR=0.5) were less likely to be deferred for low haemoglobin relative to having successful donations. Potential donors from Kwa-Zulu Natal compared to those of Gauteng were significantly more likely to be deferred for low haemoglobin relative to having successful donations (RR=2.2). Potential donors from Mpumalanga compared to those of Gauteng were significantly less likely to be deferred for low haemoglobin relative to having successful donations (RR=0.6).

Deferred for other reasons vs successful donations

The third column of Table 5 shows that compared to males, females were more likely to be deferred for other reasons relative to being successful donors (RR=1.7). Potential donors of above 55 years of age (RR=1.3) compared to the 18-25 age group were significantly more likely to be deferred for other reasons relative to being successful donors. There was no clear significant relationship between potential donors of all races compared to Black race in relation to deferral for other reasons compared to being successful donors. Re-joined and repeat potential donors compared to first time potential donors were significantly less likely to be deferred for other reasons relative to being successful donors (RR=0.7) and (RR=0.2) respectively.

Table 5: Adjusted relative risk ratios (and 95% confidence intervals) from multinomial logistic regression analyses examining associations between donation status and selected potential donor characteristics.

Independent variables	Model 2		Model 3
	Low haemoglobin vs successful donation	Other deferral reasons vs successful donation	Low haemoglobin vs other deferral reasons
Sex			
Males	1.0	1.0	1.0
Females	29.7 (18.8-46.6)***	1.7(1.5-1.9)***	17.7 (11.0-28.0)***
Age group			
18-25	1.0	1.0	1.0
26-35	0.7 (0.6-0.9)**	0.9 (0.8-1.1)	0.8 (0.6-1.0)
36-45	0.9 (0.7-1.2)	0.9 (0.7-1.1)	1.0 (0.8-1.4)
46-55	0.9 (0.6-1.3)	1.0 (0.8-1.2)	0.9 (0.7-1.4)
Above 55 years	1.1 (0.7-1.7)	1.3(1.1-1.7)*	0.8 (0.5-1.3)
Race			
Black	1.0	1.0	1.0
Asian	0.8 (0.6-1.2)	0.9 (0.6-1.2)	0.9 (0.6-1.4)
Coloured	0.6 (0.4-0.9)*	0.8 (0.7-1.0)	0.8(0.4-1.2))
White	0.3 (0.2-0.4)***	0.9 (0.8-1.1)	0.2 (0.1-0.3)***
Unknown	0.8 (0.5-1.5)	0.9 (0.6-1.3)	0.9 (0.5-1.6)
Donor type			
First time donor	1.0	1.0	1.0
Re-join	0.6 (0.5-0.8)***	0.7 (0.6-0.8)***	0.9 (0.7-1.2)
Repeat	0.5 (0.4-0.6)***	0.2 (0.1-0.3)***	2.7 (2.0-3.5)***
Province			
Gauteng	1.0	1.0	1.0
Eastern Cape	1.4 (0.9-2.0)	0.7 (0.6-0.9)*	1.8 (1.3-2.7)**
Free State	1.3 (0.8-1.9)	1.2 (0.9-1.5)	1.3 (0.8-2.0)
KwaZulu Natal	2.2(1.7-2.8)***	0.7 (0.6-0.9)**	3.0 (2.2-3.9)***
Limpopo	0.9 (0.5-1.6)	0.5 (0.3-0.8)**	1.9 (1.1-3.6)*
Mpumalanga	0.6 (0.3-0.9)*	0.5 (0.4-0.7)***	1.4 (0.8-2.4)
North West	1.0 (0.6-1.8)	0.6 (0.5-0.9)**	1.7 (0.9-3.1)
Northern Cape	1.4 (0.7-2.6)	0.6 (0.4-0.9)*	2.6 (1.2-5.6)*
N=8056 X^2(df=44)=3018.79 Pseudo R = 0.2782			

The top entries are multinomial logit relative risks. Confidence intervals in parentheses
P < 0.05*, P < 0.01 **, P < 0.001***

The likelihood of being deferred for other reasons compared to being a successful donor for potential donors of Eastern Cape, Kwa-Zulu Natal, Limpopo, Mpumalanga, North West and Northern Cape was lower than those of Gauteng province (RR=0.7, RR=0.7, RR=0.5, RR=0.5, RR=0.6 and 0.6 respectively).

Low haemoglobin vs other reasons of deferral

The forth column of Table 5 shows that compared to males potential donors, females potential donors (RR=17.7) were significantly more likely to be deferred for low haemoglobin relative to being deferred for other reasons. Compared to Black potential donors, potential donors of White race (RR=0.2) were significantly less likely to be deferred for low haemoglobin relative to being deferred for other reasons. Repeat potential donors (RR=2.7) compared to first time donors were significantly more likely to be deferred for haemoglobin compared to being deferred for other reasons. Compared to potential donors of Gauteng, potential donors from Eastern Cape (RR=1.8), Kwa-Zulu Natal (RR=3.0), Limpopo (RR=1.9) and Northern Cape (RR=2.6) were significantly more likely to be deferred for low haemoglobin relative to other reasons.

CHAPTER 4: DISCUSSION

4.0 Introduction

The study aimed to determine the prevalence of low haemoglobin donor deferral among potential blood donors, the proportion of low haemoglobin deferral among deferred donors and identify the correlates of low haemoglobin donor deferral among potential blood donors. The study findings are discussed below.

4.1 Characteristics of potential donors and deferred donors

The number of women who attempted to donate was slightly higher than the number of males (51.9% female vs 48.1% male). This finding agrees with a study done by Bani et al in Europe which showed that women were more likely to attempt to give blood compared to men (56). Females are thought to believe strongly about the humanitarian aspects of giving blood and the possibility of saving lives compared to their male counter parts. Whilst women attempt to donate blood more than men, they tend to be deferred more. In the current study, 68.2% of the women successfully donated compared to 87.1% for men and the rest were deferred. A study done by Sundar et al in India also reported higher deferral rate among females than males (29).

In this study most potential donors were of the White race (49.9%) followed by Black (34.6%). According to the 2011 census report of South Africa (57), the majority of the population (79.2%) are of the African descent and the White population (8.9%) form the minority group. Thus there is a mismatch in blood donation between the ethnic groups. Willingness to attempt to donate blood varies within different ethnic groups and it has been linked to differences in religion/spirituality (58). Some religions do not accept blood transfusions, donation or storing of one's own blood for transfusion later if there is need. In South Africa, any racial differences are likely to be a legacy of apartheid which might be related to where fixed donation sites are located or areas where the mobile sites visit. Most potential donors were young people of age

group 18-25 (33.2 %) and as age increased the number of potential donors decreased. This might be because South African National Blood Service (SANBS) targets schools and colleges more when attempting to recruit potential donors.

The potential donors that attempted to donate blood most were repeat donors (49.3%) and the least were the first time potential donors. It is within the standard operating procedures of most blood services to notify and invite repeat donors after the elapse of 56 days minimal inter-donation interval. The repeat donors usually honour the invitation whilst the first time potential donors are a cohort of potential donors that want to find out if they are eligible to give blood thus their small numbers. The frequencies of potential donors per province do not reflect the populations of the different provinces with Gauteng having similar population with Kwa-Zulu Natal yet Gauteng provides 45% of the potential donors whilst Kwa-Zulu Natal provides only 18% (53). This provincial imbalance in favour of Gauteng could also be explained by the racial imbalance in Gauteng as far greater of its population is White compared with that of Kwa-Zulu Natal.

4.2 Prevalence of low haemoglobin donor deferral among potential donors

Many different studies done on potential donor cohorts, have reported varying prevalence of donor deferral including deferral due to low haemoglobin (1,9,13,25). The overall prevalence of donor deferral in the analysed population was 22.7% (95% CI: 21.8-23.7). This is higher than the 9% reported by Bahadur et al (59) in India probably because of stringent donor selection criteria in South Africa. However, the overall prevalence of 6.7% (95% CI: 6.1-7.2) for deferral due to low haemoglobin among potential donors found in this study was lower than the 10% reported in the United States of America (1).

The prevalence of deferral due to low haemoglobin was much higher in females (12.3%) than the males (0.5%) and suggests gender differences in terms of low haemoglobin prevalence in

the population. Jashnani et al (60) in their study done in United States reported that the majority of deferrals for low haemoglobin occur in women because of menstruation and blood loss at when they give birth. Our findings showed that prevalence of low haemoglobin deferral gradually decreases with increasing age, with the highest prevalence found within the 18-25 age group (9.3%) and lowest among those above 55 years of age (3.9%). Younger age groups include women who are still in the reproductive stage and lose blood during menstruation and child birth thus their prevalence for low haemoglobin deferral is high. Compared to other donor types, first time donors had the highest prevalence.

Potential donors of Black race had highest prevalence and Whites had the least prevalence of deferral due to low haemoglobin. Differences in prevalence of low haemoglobin deferral across different provinces were noted in this analysis with the highest prevalence in Kwa-Zulu Natal (11.8%). Province specific differences may be as a result of procedural factors, such as differences in staff training to perform haemoglobin testing and equipment calibration (1). Regional variation in haemoglobin values within South Africa could also explain for differences in haemoglobin deferral rates. Regional differences in cigarette smoking was not accounted for in this analysis and may have influenced haemoglobin values (61). Lifestyle and diet may affect haemoglobin levels although these were not tested in the study.

4.3 Proportion of low haemoglobin donor deferral among deferred donors

In this study the overall proportion of haemoglobin deferral among deferred donors was 0.29 (95% CI 0.27-0.31) depicting that almost a third of all deferrals were due to low haemoglobin. Haemoglobin has been found to be the single most important factor that causes the most blood donor deferrals as reported by Mangwana et al (32) in India . They reported that haemoglobin deferral accounted for 68.01% in female donors versus 14.82% in male donors thus reflecting the overall higher prevalence of low haemoglobin in women. This finding was similar to this study as the proportions of low haemoglobin deferral were higher in females than in males

(0.38 vs 0.04) and among the youngest age group (18-25years) than the above 55years of age (0.33 vs 0.21). In young females, it is due to blood loss at births and menstruation and old females are in menopause phase so their haemoglobin levels tend to be normal.

The proportion of low haemoglobin deferral was highest among the repeat donors compared to all other donor types. Studies have shown that donors lose a substantial amount of iron per every blood donation (22,41). Iron is important for blood synthesis. Despite efforts by other blood services to give blood donors iron supplements, most repeat donors have depleted iron stores which need more than 56 day inter-donation interval to be replenished. It may also be difficult to verify if potential donors take the iron supplements provided for them. Those that were re-joining the donor pool had the least prevalence. These donors had been temporarily deferred before the visit of interest or delayed their donation attempt. They have had sufficient time for restoration of their haemoglobin to normal levels before attempting to donate blood thus they were unlikely to be deferred for low haemoglobin.

The proportion of the Asian, Black and Coloured races were comparable but much higher than those of White race. Eastern Cape, Kwa-Zulu Natal and Northern Cape had the highest proportion and Free State and Gauteng and Mpumalanga had the lowest.

4.4 Factors that are associated with low haemoglobin levels among potential blood donors

Significant demographic factors for low haemoglobin donor deferral in bivariate analysis were; sex, age, donor type, race and province and these were included in multivariate analysis.

4.4.1 Sex

Sex was the main determinant of low haemoglobin donor deferral. The prevalence of low haemoglobin donor deferral was higher among female potential donors than male potential donors so was the proportion attributable to low haemoglobin among the deferred donors. Of all potential donors deferred due to haemoglobin, 96.2% of them were females. In the analysis,

women had on average 27.1 times higher odds for a low haemoglobin deferral compared to men.

These results are higher than those by Mast et al (1) in United States who found women to have on average 11 times higher odds for low haemoglobin deferral than men. Low haemoglobin has been linked to low iron stores in women as a result of pregnancy and menstruation on the other hand, men usually have up to four times bigger iron stores that is used in haemoglobin synthesis after numerous blood donations. Increased levels of testosterone in men (46) also produces increased haemoglobin and high prevalence of cigarette smoking among men also causes higher haemoglobin levels (61).

Another possible cause why female potential donors are deferred more than male potential donors for low haemoglobin could be use of one cut off limit for eligibility to donate blood for both females and males (12.5mg/dL) but clinically haemoglobin cut off values for presence of anaemia are different for males and females with that of males being higher than that of females. The current system may have allowed for anaemic males to donate blood whilst deferring for low haemoglobin females who are non-anaemic. Clinically, men and women have different reference ranges for haemoglobin and ironically they have the same reference range with regards to blood donation

4.4.2 Age

As age increased the prevalence of low haemoglobin decreased and proportion of deferral due to low haemoglobin also decreased. In bivariate analysis, there was a progressive decrease in odds of low haemoglobin deferral as age increased. In the study we tested sex by gender interaction but the results were statistically not significant. In women this has been explained by decrease in child births and menopause as age increases. A study done by Mast et al (1) in United States on comparison of donor deferral in men and women as age increased has shown

different low haemoglobin deferral characteristics as age increased. It showed that in men there was a continuous increase in the odds for low haemoglobin deferral with increasing age whilst in women the age effect on low haemoglobin deferral was insignificant.

4.4.3 Race

Potential donors of White race had the lowest prevalence of haemoglobin deferral and lowest proportion of deferral attributable to low haemoglobin. In logistic analysis, White potential donors were significantly less likely to be deferred for low haemoglobin. The prevalence of low haemoglobin was highest among Blacks (11.4%). This is similar to a study by Custer et al (60) done in United States which found that Blacks, compared to Whites were more likely to be deferred for low haemoglobin. The study also suggested that the normal range for haemoglobin was not applicable to all races as presence of low haemoglobin among potential donors varied with the different races.

Blacks have been found to have lower mean haemoglobin values than Whites but a universal reference range was being used so blacks tended to be deferred more than Whites. Low haemoglobin in Blacks as a result of high prevalence of alpha-thalassemia (blood disorder that suppresses the production of haemoglobin) that accounts for about one-third of the difference in the haemoglobin levels between Blacks and Caucasians and resulted in Blacks being deferred more (62). Blacks also have anaemia of unknown origin probably due to multiple genetic factors that contribute to lower haemoglobin (63).

4.4.4 Donor type

The prevalence for low haemoglobin deferral was highest among first time donors and the proportion of deferral due to haemoglobin was highest among the repeat donors. One of the reasons for the proportion of low haemoglobin being high among repeat donors is that the overall number of deferrals in this group is low. In unadjusted and adjusted analysis, repeat and

re-join potential donors were less likely to be deferred for low haemoglobin. These findings are opposite to a study by Almeida et al done in Brazil which found that potential donor deferral due to low haemoglobin levels in repeat blood donors was highly prevalent in Brazil (64). Donation intensity by the repeat donors was not explored due to cross sectional nature of this study.

4.4.6 Province

Kwa-Zulu Natal and Eastern Cape had the highest prevalence of low haemoglobin deferral and Kwa-Zulu Natal had the largest proportion of deferral attributable to low haemoglobin among all deferred donors. In multivariate analysis, potential donors from Kwa-Zulu Natal and Eastern Cape were significantly more likely to be deferred for low haemoglobin. Unadjusted analysis showed an association between low haemoglobin deferral and the province where potential donor attempted to donate blood. There was variation between provinces after adjustment of other factors. Odds ratios varied from 0.7 to 2.4. Site or centre differences may be due to differences in race, culture and religion distribution within provinces.

4.5 Limitations

This was a cross sectional study using secondary data collected routinely before potential donors qualify to donate blood and as such, only pre-collected and captured data was available for analysis. At South African National Blood Service, not all variables collected on the pre-donation questionnaire are captured on their MEDITECH system. Other important variables and that might have had influence on low haemoglobin deferral (for instance nutrition, weight, blood pressure, comorbidities, level of education and occupation level as an indicator of social economic status) could not be controlled for in analysis. In this study, multiple donation attempt data, whether successful or not for the same individual were not be utilized.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.0 Introduction

This chapter presents the conclusions of the study findings and recommendations.

5.1 Conclusions

This analysis which was based on the pre-donation potential donor data, showed a 6.7% prevalence of donor deferral due to low haemoglobin among potential donors and a 0.29 overall proportion of low haemoglobin deferral among deferred donors in eight provinces of South Africa in 2013. In adjusted analysis the factors associated with low haemoglobin deferral were sex ($P<0.001$), donor type ($P<0.001$), province ($P<0.001$) and race ($P<0.001$).It was not clear why there was variation in low haemoglobin deferral among the provinces. This study could assist in generating hypotheses for research on the possible causes of low haemoglobin in various defined groups of potential donors.

5.2 Recommendations

The study has shown high prevalence of donor deferral due to low haemoglobin. Deferred potential blood donors might never return to attempt to donate blood due to low morale. The identified correlates could be used when deciding which potential donors to consider for a blood donation after each inter-donation interval has elapsed.

Given the high prevalence of low haemoglobin deferral, we recommend that all blood donors be given iron supplements to help with haemoglobin replenishing that would have been removed from the body after each donation. This could reduce incidence of iron deficiency anaemia among donors and increase successful donations. Potential donors should also be made aware of the need for iron and folate rich diets to avoid developing anaemia and thus deferral from donating blood. It should be the mandate of blood services to educate these potential donors on foods rich in these essential nutrients.

Most potential donors that were deferred due to low haemoglobin were females. We recommend that the current 56 day inter-donation interval be increased for females to allow for sufficient time for haemoglobin synthesis and recovery. Women lose blood due to delivery and menstruation so they would greatly benefit from longer inter-donation intervals. In South Africa the minimum cut off for haemoglobin for donation eligibility is 12.5mg/dl for both men and women. Clinically it has been shown that the reference ranges for men and women are different with that of women being lower than for men (65). We recommend SANBS to have different cut of limits for males and females as a large proportion of females with haemoglobin of between 12-12.5mg/dl who are clinically not anaemic could donate blood thus increase blood supply as is the practice with Western Cape Blood Transfusion Service (WPBTS) which supplies blood to the Western Cape Province (66) and works independent of SANBS.

More studies involving strict screening criteria and on populations with more parameters are required for the improvement of the successful blood donation rate and quality. It is suggested that future studies take into account the longitudinal nature of repeat visits by same donor, donation intensity and donation interval so as to get as much information as possible from the influence of these variables on low haemoglobin donor deferral. We also recommend that more information on donor characteristics is collected and captured by SANBS as it will result in better analysis of potential donor attributes.

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APPENDICES

Appendix A: Percentage distribution of potential donors by selected characteristics (100%)

Characteristic	Total	Donated	Deferred low haemoglobin	Deferred for other reasons	P value
Total	402 800	317 165	25 574	60 061	
Sex					
Male	49.1	54.2	4.9	40.8	
Female	50.9	45.8	95.1	59.2	<0.001
Age group					
18-25	34.3	32.6	49.1	37.1	
26-35	22.9	22.5	19.9	26.1	
36-45	20.0	20.6	17.4	18.0	
46-55	14.1	14.9	9.6	11.7	
> 55	8.8	9.5	4.0	7.2	<0.001
Median age (IQR)	32(23-44)	33(23-45)	26(20-39)	30(22-42)	
Race					
Black	35.0	31.5	63.1	41.1	
Asian	8.6	8.6	10.7	7.7	
Coloured	5.3	5.4	5.1	4.8	
White	49.3	52.8	18.9	44.2	
Unknown	1.8	1.7	2.1	2.3	<0.001
Donor type					
First time	24.6	19.7	42.6	42.7	
Re-join	25.0	23.4	24.3	33.7	
Repeat	50.4	56.9	33.1	23.6	<0.001
Blood group					
O	44.5	47.5	33.1	33.9	
A	29.0	31.6	20.1	19.0	
AB	4.3	4.6	3.3	3.0	
B	15.0	15.9	12.4	11.5	
Unknown	7.2	0.5	31.1	32.6	<0.001
Province					
Gauteng	45.5	44.5	40.2	53.2	
Eastern Cape	9.1	9.4	8.9	7.6	
Free State	6.2	6.0	4.8	7.4	
KwaZulu Natal	19.3	18.8	31.8	16.6	
Limpopo	3.2	3.2	4.5	2.9	
Mpumalanga	8.7	9.5	4.7	5.2	
North West	5.2	5.4	3.9	4.5	
Northern Cape	2.8	3.1	1.6	2.8	<0.001

Appendix B: Percentage distribution of potential donors by selected characteristics (5%)

Characteristic	Total	Donated	Deferred low haemoglobin	Deferred for other reasons	P value
Total	20140	15 964	1 224	2 952	
Sex					
Male	48.8	53.3	5.8	42.0	
Female	51.2	46.7	94.2	58.0	<0.001
Age group					
18-25	32.8	31.4	47.8	34.3	
26-35	24.1	23.7	21.2	27.1	
36-45	20.1	20.6	17.0	18.6	
46-55	14.2	14.9	10.3	12.3	
> 55	8.9	9.5	3.7	7.7	<0.001
Median age (IQR)	32(23-44)	33(23-45)	26(20-38)	31(23-43)	
Race					
Black	33.8	30.6	62.0	39.3	
Asian	8.6	8.6	10.6	7.7	
Coloured	5.2	5.4	5.0	4.1	
White	50.8	53.8	20.2	47.0	
Unknown	1.7	1.6	2.2	1.9	<0.001
Donor type					
First time	23.6	19.0	41.3	40.8	
Re-join	26.1	24.2	26.5	35.8	
Repeat	50.4	56.8	32.3	23.4	<0.001
Blood group					
O	44.7	47.2	34.9	35.5	
A	29.0	31.8	18.1	18.3	
AB	4.3	4.7	2.5	2.7	
B	15.2	16.0	13.0	12.1	
Unknown	6.8	0.4	31.4	31.4	<0.001
Province					
Gauteng	46.1	44.9	41.2	54.6	
Eastern Cape	8.9	9.2	7.8	7.4	
Free State	6.3	6.1	6.1	7.8	
KwaZulu Natal	18.8	18.2	32.4	16.4	
Limpopo	3.4	3.4	4.0	2.7	
Mpumalanga	8.9	9.9	3.8	5.5	
North West	4.9	5.2	3.6	4.0	
Northern Cape	2.7	3.0	1.4	1.6	<0.001

Appendix C: Percentage distribution of potential donors by selected characteristics (1%)

Characteristic	Total	Donated	Deferred low haemoglobin,	Deferred for other reasons	P value
Total	4 028	3 176	244	608	
Sex					
Male	48.9	54.1	5.7	39.0	
Female	51.1	45.9	94.3	61.0	<0.001
Age group					
18-25	32.8	31.4	53.3	31.7	
26-35	23.6	23.5	18.4	26.0	
36-45	21.0	21.1	17.6	21.4	
46-55	13.7	14.2	74	13.7	
> 55	9.1	9.9	3.3	7.2	<0.001
Median age (IQR)	32(23-44)	33(23-45)	24.5(19-38)	31(23-43)	
Race					
Black	34.8	31.1	68.4	41.0	
Asian	8.5	8.7	8.6	7.1	
Coloured	5.3	5.5	5.0	4.9	
White	49.6	53.1	16.4	44.5	
Unknown	1.8	1.6	1.6	2.5	<0.001
Donor type					
First time	24.4	19.2	45.5	42.6	
Re-join	27.0	25.7	23.8	35.4	
Repeat	48.6	55.1	30.7	22.0	<0.001
Blood group					
O	43.4	46.2	27.9	35.4	
A	30.0	33.0	20.9	17.9	
AB	4.0	4.4	2.9	2.0	
B	15.1	15.9	13.1	12.2	
Unknown	7.4	0.5	35.3	32.6	<0.001
Province					
Gauteng	47.9	46.9	42.2	55.6	
Eastern Cape	8.1	7.9	9.4	8.2	
Free State	6.2	6.2	5.3	6.4	
KwaZulu Natal	18.8	18.4	29.9	16.5	
Limpopo	3.0	3.0	4.1	3.0	
Mpumalanga	8.2	9.2	3.3	5.3	
North West	5.3	5.7	4.5	3.3	
Northern Cape	2.6	2.8	1.2	1.8	<0.001

Appendix D: Ethics Approval Letter (SANBS)

SOUTH AFRICAN NATIONAL BLOOD SERVICE NPC

Human Research Ethics Committee

SANBS
South African National Blood Service

Association Incorporated Under Section 21
Registration No. 2000/026390/08

OHRP Number : IORG0006278
FWA Registration Number : IRB00007553
SA NHREC Registration Number : REC-270606-013

Secretariat: Tel: 011 761 9135 | Fax: 011 761 9137 | Cell: 0842453455 | thandiwe.matsoso@sanbs.org.za

To: Farisai Kuonza
E-mail:fksuonza@gmail.com

Dear Farisai Kuonza

DATE OF COMMITTEE MEETING:	**11 September 2014**
PROJECT TITLE:	**Demographic correlates of low haemoglobin deferral among potential blood donors in South Africa**
DECISION OF THE COMMITTEE:	**Approved**
CLEARANCE CERTIFICATE NO:	**2014/11**

- Execution of the study must be compliant with applicable guidelines and policies.
- Any amendment, extension or other modifications to the protocol must be submitted to this Ethics Committee for approval prior to implementation.
- The Committee must be informed of any serious adverse event, planned and unplanned termination of the study.
- A progress report should be submitted yearly for long-term studies and a final report at completion of both short term and long term studies.
- Kindly refer to the SANBS HREC clearance certificate number on all future correspondence on this study to the HREC secretariat.
- This approval is valid for 5 years from the date stated above.

COMMITTEE GUIDANCE DOCUMENTS:

- International Conference on Harmonization (ICH) Good Clinical Practices (GCP) Guideline (ICH, 1996), Ethics in Health Research: Principles, Structures and Procedures (SA Department of Health, 2004); Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (SA Department of Health, 2006); Ethical Principles for Medical Research Involving Human: Declaration of Helsinki (World Medical Association, 2013); Reviewing Clinical trials: A Guide For Ethics Committees (Karlberg and Speers, 2010)

In the event that the Investigator fails to adhere to the above, the Committee reserves the right, at any time hereafter, to: (1) cancel; or (2) suspend its approval granted herein, provided that such right is exercised in writing.

_____ _____

CHAIRPERSON: Prof J.N. Mahlangu **DATE**

Appendix E: Ethics Approval letter (University of Witwatersrand)

R14/49 Mrs Farisai Susan Kuonza and Tshilidzi Muthivhi

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M140916

NAME: (Principal Investigator)	Mrs Farisai Susan Kuonza and Tshilidzi Muthivhi
DEPARTMENT:	School of Public Health
PROJECT TITLE:	Demographic Correlates of Low Haemoglobin Deferral among Blood Donors in South Africa
DATE CONSIDERED:	03/10/2014
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Latifat Ibisomi
APPROVED BY:	Professor Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	12/11/2014

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES