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IMPLEMENTATION OF A SCRIPT FOR PRE-DONATION INTERVIEWS: IMPACT ON HIV RISK IN SOUTH AFRICAN BLOOD DONORS

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Abstract

Background: The way in which the donor history questionnaire is conducted plays a crucial role in the self-disclosure of behavioural risk factors for HIV infection by prospective donors. The South African National Blood Service changed its policy on the process of donor assessment in May 2015 by implementing a compulsory interviewer script used to assess donor eligibility.

Study design and Methods: A pre- and post-evaluation study to determine the impact of scripted interviews on high risk deferrals and recently acquired HIV infections. We used historical data to compare 18 months before and after the implementation of the script.

Results: We recorded a total of 3,169,656 donor presentations during the two 18-month periods, of which 52.2% (1,655,352) were made during the scripted period. A multivariable logistic regression analysis adjusting for donor and demographic characteristics, found the odds of high risk deferral to be slightly greater (OR: 1.06; 95%CI: 1.05 – 1.07) during the scripted period. A separate multivariate logistic regression model, also adjusting for donor and demographic characteristics, showed the odds of recently acquired HIV infection, were significantly lower (OR: 0.88; 95% CI: 0.79 – 0.97) during the scripted period.

Conclusion: This study showed that implementation of a scripted interview was associated with increased HIV risk deferral and decreased recent HIV infection. This study indicates potential improvement in blood safety with the implementation of a scripted donor interview and has relevance to blood safety in other sub-Saharan African countries.

Keywords

blood donors; risk factors; surveys and questionnaires; blood safety; South Africa

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Introduction

Blood donor selection is one of the key factors in determining the safety of a country's blood supply[1]. Donor self-disclosure of behavioural risk factors and the way in which the face to face interviews are conducted play a crucial role in the selection of suitable donors[2,3]. In an effort to improve pre-donation screening methods, changes are continuously made to the deferral policies, the content of the donor health questionnaire and the approach in which questions are posed to donors[2,3]. As a result, donor selection strategies have become multi-layered and more stringent over the years[4]. Despite these interventions, non-compliance with donor deferral criteria and unreported deferrable risk behaviours associated with transfusion transmissible infections continue to be reported and impact on blood safety[5–7].

In SANBS, changes in pre-donation screening methods are often made with the hope to elicit more truthful responses from donors, thereby increasing high risk deferrals with the hope that this will translate to a safer blood supply. Several studies reported an increase in high risk deferrals associated when conducting face-to-face interviews[8,9], while other studies reported no impact[10]. Although face to face interviews have been associated with some improvement in deferring donors with high risk behaviours, it was also shown that some people might be less truthful due to lack of privacy since most of the questions are of a sensitive nature[10,11]. In addition, the form in which interviews are conducted can be affected by the interviewer's lack of experience and discomfort when asking sensitive questions[12,13]. More recently, Blayta et al.[3] have shown improved disclosure of high risk behaviours when audio computer-assisted self-interview methods are used to interview donors.

In South Africa, all donors self-complete a donor health questionnaire and undergo a face-to-face interview every time they present to donate blood. The South African National Blood Service (SANBS), covering 85% of blood donations in South Africa, changed its policy on the process of donor assessment in May 2015 by implementing a compulsory interviewer script used to assess donor eligibility. The main aims of this change was to ensure donor interviews were conducted consistently and that supplemental education was provided on the donors' understanding of the risk of window-period donations.

Although several studies have used the frequency of high risk deferrals[8,10,14] and recently acquired HIV infections[915,16] as indicators of improvement in blood safety, these have mainly been in developed settings, with a paucity of data from research constrained in settings such as South Africa and elsewhere in Africa. We therefore conducted a study to evaluate the impact of using a scripted donor interview on high risk deferrals and recently acquired HIV infections among South African blood donors.

Materials and Methods

Settings:

SANBS is a non-profit organisation of 100% voluntary non-remunerated blood donors. We collect over 800 000 units of blood annually and issue blood products to both public and private hospitals in eight provinces of the nine provinces in South Africa. The eight provinces are divided into 7 operational units, which are referred to as zones. Donations

from all the zones are managed using the same standard policies and procedures and records are maintained electronically on a central operating platform.

Overall study design:

We conducted a pre-post evaluation of the impact of implementing a script to assess donor eligibility on high risk deferrals and recently acquired HIV infections among blood donors in SANBS.

Study subjects:

All donors who presented to donate blood from November 2013 to April 2015 and June 2015 to November 2016 were included in the study. A script (Appendix 2) to assess the donor's eligibility to donate was implemented in May 2015. The interviews were conducted by nursing staff and qualified registered phlebotomists, who were trained and found competent by observing them while conducting the donor interview, before implementation. Historical data extracted from the SANBS donation database were used to analyse two periods representing 18-months prior (November 2013 to April 2015) and 18-months post-implementation (June 2015 to November 2016) of the script. Figure 1 illustrates the distribution of donor presentations and donations for the unscripted and scripted periods.

Donor assessment and deferral

On presentation, prospective donors complete a pen and paper donor questionnaire, which is self-administered privately. The donor questionnaire addresses areas of donor health, life style and potential high risk behaviours and/or exposures. In addition to the donor questionnaire, a face-to-face interview is conducted in private by a qualified nursing staff or a registered phlebotomist. Prior to May 2015, the face-to-face interview was unstructured and the approach was left to the individual staff member. A script for conducting the interview was introduced in an attempt to ensure consistency in the execution of the interviews and to emphasize to donors, the risks related to donations made during the window period of viral infections. The interviewer reviews with the donor their answers to confirm understanding and to ensure that all questions were answered. The interviewer specifically asks the donor to explain their own understanding of the window period and how it relates to blood donation. The interviewer then follows with a detailed explanation of the window period and importance of donor honesty. The interviewer orally questions the donor regarding the risk behaviour or exposure. Donors who report engaging in risk behaviour or having had high risk exposure in the preceding six months, either on the donor questionnaire or during the one-on-one interview, are deferred by the interviewer.

Blood donation screening

All blood donations were routinely screened in parallel for HIV RNA as well as anti-HIV antibodies. HIV RNA testing was performed through individual donation nucleic acid testing (ID-NAT) using the Procleix Ultrio assay on the Tigris platform (October 2005 – December 2015) and the Ultrio Elite assay on the Procleix Panther platform (January 2016 to date) (Grifols Diagnostics). HIV antibody testing was done with the Abbott Prism HIV 1/2 antibody assay on the Prism platform (Abbott Diagnostics, Delkenheim, Germany).

Donations found ID-NAT and anti-HIV antibody positive were further assessed for recency of HIV infection using a single-well limiting-antigen avidity enzyme immunoassay (LAg-Avidity EIA), Duong et al, 2012). For this study, recently acquired HIV infections were classified as either HIV NAT yields (donations that are positive on ID-NAT HIV RNA, but negative for anti HIV 1 and 2) or Lag-Avidity EIA recent (<= 1.5 OD).

Measurements

Historical data on the following variables were extracted from the SANBS donation database: high risk deferrals (a deferral due to high risk behaviour or exposure), HIV testing results and demographic data which included gender, population group (categorised as Asian, Black African, Coloured and White), donor type (categorised as first presentation, first time, lapsed and repeat donors), clinic type (categorised as fixed site, mobile drive and other (unallocated and any site other than fixed site or mobile drive)) age and zone (based on geographical location).

The rate of high risk deferrals was measured as the total number of donor presentations that resulted in a deferral for high risk behaviour and/or exposure as a proportion of total donor presentations for the periods under review. Recently acquired HIV infections were measured as the total number of donations found to be positive for recently acquired HIV as a proportion of the total number of donations for the periods under review.

Statistical Analysis

The data were compared for the unscripted and scripted periods to assess if there was evidence of statistical differences in demographic characteristics between the two periods, primarily using Chi-Square comparisons. These results were used to develop two multivariable models of the factors associated with high risk deferral and, separately, recently-acquired HIV infection using generalized estimating equation (GEE) methods to account for repeated measures in the same donors.

To conduct these analyses we assumed an exchangeable correlation structure and modelled the association between binary response variables of high risk deferral (yes or no) and recently-acquired HIV infection (yes and no) with the primary predictor variable (script versus unscripted period) and the additional explanatory variables which were thought to either confound the relationship between the two outcome variables and the primary predictor or which were considered to be important independent predictors of their own. The factors we included in the multivariable models are: sex, population group, age group, donor type, clinic type, and geographical/zone within SANBS. Odds ratios and 95% confidence intervals for each predictor are reported with $p < 0.05$ considered significant. The statistical package SAS 9.3 (SAS Institute, Cary NC) was used for data analyses.

Ethical issues

The study was performed under the Donor-Donation REDS-III ethics clearance certificate number: 2011/07.

Results

We recorded a total of 3,169,656 donor presentations during the two 18-month periods, of which 52.2% (1,655,352) were made during the scripted period (Table 1). There was a small but significant increase in the proportion of presentations from female donors, from 47.8% to 49.2% ($p < 0.0001$) during the scripted period. The distribution by race group differed significantly between the two periods ($p < 0.0001$) with presentations from Black African donors increasing from 31.0% to 34.6%. Small, but significant differences in distribution were also observed for age, geographical location, donor type and clinic type ($p < 0.0001$). There was no significant difference in the proportion of overall HIV positive cases ($p = 0.59$) and recently acquired HIV infections between the two periods ($p = 0.41$).

Overall, 3.0% of donor presentations during the scripted period resulted in high risk deferrals compared to 2.9% during the unscripted period ($p < 0.0001$) (Table 1). The greatest increase in the proportion of high risk deferrals during the scripted period was observed is the category “New /Multiple sex partners”, from 1.8% to 2.0% ($p < 0.0001$). A small but significant increase (0.05% to 0.06%; $p < 0.0001$) was also observed in the category “HIV positive donors/ Partners of HIV positive persons / Anti-retroviral drug use”, Appendix 1. There was a significant decrease in the proportion of high risk deferrals due to “Tattoos/ Traditional/Tribal cutting/Scarification/Circumcision”, “Body piercing” and “Male to male sex” ($p < 0.0001$).

A multivariable logistic regression analysis, which adjusted for gender, race, age, geographical location, donor and clinic type, found the odds of high risk deferral to be 6% greater (OR: 1.06; 95%CI: 1.05 – 1.07) during the scripted period (Table 2). When compared to male donors, female donors had 31% lower odds of high risk deferral (OR: 0.69; 95%CI: 0.68–0.70). Compared to White donors, Black African donors had the greatest odds (OR: 1.48; 95%CI: 1.46–1.50), of high risk deferral, followed by Coloured donors (OR: 1.12; 95%CI: 1.08–1.16), while Asian donors had lower odds (OR: 0.89; 95%CI: 0.85–0.92) of high risk deferral. After the age of 30, the odds of high risk deferral decreased with increasing age with the highest odds observed among the 21–30 age group (OR: 8.38; 95% CI: 7.99–8.80). Geographically, all zones other than the Vaal zone, had lower odds of high risk deferrals when compared to Egoli zone, with the lowest odds in Kwazulu-Natal (OR: 0.63; 95%CI: 0.62–0.65). First time donors had 7 times greater odds (OR: 7.55; 95%CI: 7.42–7.69) of high risk deferral, followed by lapsed donors (OR: 1.46; 95%CI: 1.42–1.50) when compared to repeat donors. Donors at mobile drives had slightly higher odds (OR: 1.10; 95%CI: 1.08–1.13) of high risk deferral compared to those at the fixed sites.

A separate multivariate logistic regression model, also adjusting for gender, race, age, geographical location, donor and clinic type, showed the odds of recently acquired HIV infection, were significantly lower (OR: 0.88; 95% CI: 0.79 – 0.97) during the scripted period (Table 3). Female donors had twice the odds (OR: 2.07; 95% CI: 1.86–2.3) of recently acquired HIV compared to male donors. When compared to White donors, Black African donors had 27 times greater odds of recently acquired HIV (OR: 27.01; 95% CI: 21.42–34.06) followed by Coloured donors with 5 times greater odds (OR: 7.34; 955 CI: 5.24–10.27). Compared to donors 51 years or older, the odds of recently acquired HIV

infection was highest in donors 21–30 years of age (OR: 3.25; 95% CI: 2.47– 4.26). There were significant differences across the zones, with the highest odds of recently acquired HIV observed in Mpumalanga zone (OR: 2.11; 95% CI 1.77–2.51). Both the first time (OR: 0.1.63; 95% CI 1.44 – 1.84) and the lapsed donors (OR: 1.70; 95% CI 1.48 – 1.95) had greater odds of recently acquired HIV when compared to repeat donors. There was no significant difference in the odds of recently acquired HIV infection when comparing mobile drives (OR: 1.02; 95% CI: 0.90–1.14) to fixed sites.

Discussion

Using a large donor-donation database, we demonstrated that there was a significantly increased odds of high risk deferral and a concomitant significant reduction in recently acquired HIV infections during a period with a scripted interview compared to the period before the script was used. This result suggests that using a script during the face-to-face interviews was successful in drawing the attention of the donors to potential high risk behaviours and encouraged disclosure. But it also may have had the effect of reminding the staff to ask relevant questions that they might not consistently done before. Regardless of the specific effect, use of the script resulted in a small increase in high risk deferral. In addition, the script has standardised the process of conducting donor interviews, which may result in improved confidence among interviewers to address sensitive life style and risk exposure questions.

Our study supports the findings from previous studies which reported an increase in high risk deferral associated with a change in the way in which questions were asked during the face-to-face donor interviews[8,9]. Disclosure of high risk behaviours increased significantly among the “New /Multiple sex partners” and “HIV positive donors/ Partners of HIV positive persons / Anti-retroviral drug use” deferral categories during the scripted period. This might be due to donor’s improved understanding and comprehension of risk behaviours and the importance for honesty, following explanation by the interviewer. Although there is clear evidence of an increase in these specific sexually related high risk deferrals, we cannot fully ascertain the impact of these deferrals on the incidence of recently acquired HIV infections since we did not test these deferred donors for HIV infection.

Along with the increase in high risk deferral, an approximately 12% decrease in recently acquired HIV infections was observed. This result strongly suggests that the use of the script contributed to the deferral of donors with recently acquired HIV infection. Even so, there are other potential explanations for these findings. While unlikely, it is possible that changes in the donor recruitment strategies may have resulted in the recruitment and presentation of a greater number of potential donors who have engaged in risk behaviours. Our use of multivariable modelling to adjust for donor demographics and the finding of fewer deferrals for piercings and tattoos do not support this hypothesis. It is more likely that the structured interview process elicited better probing for risk, more disclosure and therefore lower HIV incidence in those eligible to donate. Although the adjusted rate of recently acquired HIV infection decreased, the unadjusted rate remained stable. This indicates that with the changing donor demographics the rate of recently acquired HIV infections would have increased if the script was not implemented. The lower rate of recently acquired HIV may in

part be due to downward secular trend of HIV incidence in South Africa. Self-deferral due to growing awareness of high-risk deferrals amongst potential and repeat donors could also have contributed to this.

Other demographic characteristics, specifically gender, some race groups, and age 21 – 30, showed strong associations with high risk deferral and recently acquired HIV infections. This result is in line with a previous study conducted in the same setting[17]. Because of the extent of the HIV epidemic in South Africa with 17.3% of sexually active females being infected[18], this finding might indicate that even apparently low risk women have high rates of recent infection. In other words, a monogamous woman could have a partner with undisclosed risk behaviours and would not be picked up by our donor questionnaire. Another potential explanation for this result is differing societal standards regarding, not only sexual behaviour, but also willingness to disclose such behaviour to others[19] during face-to-face interviews. Subconscious gender profiling by the blood transfusion staff may lead to an expectation of less high risk behaviour among female donors and staff may therefore be less rigorous when interviewing female donors, especially with the tendency to stereotype women as being more altruistic than they actually are[20].

When compared to White donors, there was a 1.5-times greater odds of high risk deferral among Black African donors, but a 27-times greater odds of recently acquired HIV infection. The huge differential is likely due to the background HIV prevalence and incidence in the general population, where HIV disproportionately affect different race groups, particularly, Black Africans, adolescent girls and young women[18]. However, we cannot rule out other factors such as poor literacy[11], historical limited exposure to a blood donation culture and information, and potential language barriers. All these factors could potentially hinder the level of understanding of high risk questions and the subsequent answering thereof among Black African donor candidates, resulting in lower rate of disclosure.

Among younger donors (<21 age group), there were 6.4–times greater odds of high risk deferrals compared to older donors (>50 age group), and yet, only a 1.8-times greater odds of recently acquired HIV infection. This result is contrary to the suggestion that younger donors might find the face-to-face environment to be judgemental, especially is settings with significant age difference between the staff and the young donors[3]. There are multiple explanations that could potentially lead to younger donors being more open to disclose high risk behaviours. These include focussed donor education at schools, where the majority of donors younger than 21 are donating; the younger generation’s willingness to talk more openly about sex and related matters with greater ease than the older generations due, in part, to different educational programs targeted to the youth. Finally, the youth might have engaged in more sexually risky behaviour and thus be deferred but their risky behaviour might have been concentrated within recent birth cohorts at lower risk of HIV[21].

The primary limitation of the study is the use of pre-post comparison rather than a contemporaneous study comparing sites using to sites not using the script, which could lead to confounding by other unmeasured changes between the two periods. The gold standard would have been a cluster randomized trial whereby collection sites were randomized to use

the script or not, however this was not feasible within available resources. At the time of script implementation, no member of SANBS staff were informed of our intent to analyse two comparison periods to assess impact. Another limitation is that data on recently acquired HIV among donors deferred for high risk behaviours were not collected. We are therefore unable to fully comment on a causal link between implementing the scripted interview procedure and behaviours in persons with and without recently acquired HIV. In addition, while staff were trained and instructed to implement the script, the extent to which this was done consistently across sites is not known. Variability in the adjusted odds of high risk deferrals between zones may in part be due to variability in how the script was utilised. Our study also has strengths. Specifically, the use of the large donor-donation database, representing all data from across most of South Africa (except Western Province), limits bias in observations and makes the findings as generalizable as possible to other blood transfusion services operating in high HIV prevalence settings.

In conclusion, this study showed that implementation of a scripted interview was associated with increased HIV risk deferral and decreased recent HIV infection. This result has led to the retention of the scripted interview within our blood service. To fully assess the efficacy of high risk deferrals among donors, a study investigating the HIV incidence and prevalence among donors deferred for high risk behaviour should be considered. While other potential unmeasured confounding factors cannot be excluded, this study indicates potential improvement in blood safety with the implementation of a scripted donor interview and has relevance to blood safety in other sub-Saharan African countries.

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Appendix 1:: Distribution of high risk deferrals by deferral codes for unscripted versus scripted period as a proportion of all donor presentations, N = 3,169,656

		Unscripted		Scripted		
Deferral Codes	**Deferral Description**	**N**	**%**	**N**	**%**	**p value**
Total presentations		1,514,304	47.78	1,655,352	52.22	<0.0001
All high risk deferrals		43,566	2.88	49,917	3.02	<0.0001
BPG	Body piercing	5,857	0.39	5,409	0.33	<0.0001
BTAB	Blood transfusion recipients and their partners/Accidental blood exposure	792	0.05	858	0.05	0.9500

		Unscripted		Scripted		
Deferral Codes	**Deferral Description**	**N**	**%**	**N**	**%**	**p value**
HOVA	High Risk: Unclassified / other/HIV vaccine trials	97	0.01	131	0.01	0.0817
HSTD	HIV positive donors / Partners of HIV positive persons / Anti-retroviral drug use	770	0.05	984	0.06	0.0011
IVDU	Intravenous drug use	219	0.01	184	0.01	0.0133
MSM	Male to male sex	76	0.01	14	0.00	<0.0001
NMSP	New/Multiple sexual partners	27,144	1.79	33,600	2.03	<0.0001
SAT	Sexual Assault	122	0.01	160	0.01	0.1826
TATC	Tattoos/Traditional/tribal cutting/scarification/circumcision	8,051	0.53	8111	0.49	<0.0001
TSX	Transactional sex	438	0.03	466	0.03	0.4886

Appendix 2:: Script used to interview blood donors to assess eligibility to donate blood in SANBS- Implemented in May 2015

SCRIPT FOR PRE-DONATION ASSESSMENT

Good day Mr/ Ms _____.

My name is _____ and I will be doing your pre-donation assessment today.

Thank you for taking the time to save a life today.

The mission of the South African National Blood Services is ultimately to give all patients safe, quality products. We rely on our donors for their honesty in order to provide this to the patients.

Have you been well since your last donation?

In order for our test result to be accurate, I would like you to relax while I go through your form to make sure that you can donate blood today.

Address any anomalies on the donor form according to *Assessment of Blood Donors* (SOP-DSC-003).

New/ Lapsed donors:

What made you decide to donate blood today? I hope that the experience of saving a life will be amazing and that we will see you donating on a regular basis.

All Donors:

It is very important for us to ensure that our blood donors return to donate after their first donation, in order for us to build a history of your donations. After your 3rd donation, all the components of the blood can be used. You can donate once every 28 days for Platelet donations, once every 56 days for whole blood donations, once every 112 days for double red cell donations and once every 14 days for Hyperimmune Plasma

I need to confirm your responses to some of the lifestyle questions.

Are there any questions you would like to ask about the questionnaire?

Have you read the pamphlet “are you donating blood for the right reasons?” Do you have any questions around the pamphlet?

Please tell me what you know about the window period and how it relates to blood donation.

The window period is the time, from when someone is infected with a virus, until the virus is picked up in the blood tests. While a person is in the window period, blood tests will still show negative, but the person is already capable of infecting others, (This includes blood tests done by SANBS). There is no specific time period attached to the window period, as every person’s immune response differs when being exposed to viruses. Therefore it is of utmost importance for our donors to be honest whilst completing the donor questionnaire, as any risk behaviour can put the life of the patient receiving the unit of blood at risk, which could be a baby, a child or one of your family members.

During this procedure, we will be doing your blood pressure, determining your haemoglobin level by doing a finger prick procedure, inserting a needle into a vein in your arm to obtain 470 – 500 ml of blood. You will be required to sit on the donor chair for 10 minutes after your donation, to ensure that you do not have adverse effects associated with blood donation. This whole process will take about 30 minutes.

As a voluntary donor, you have the option to withdraw from the process at any stage.

Some of the adverse effects of blood donation can include:

- Dizziness and fainting.
- Haematoma formation (bruise on the arm where the needle was inserted).

When donating on any apheresis procedure:

- Citrate toxicity.
- Red cell loss if the procedure has to be aborted and it is considered unsafe to return the red cells.
- Chilling on reinfusion.

Do you have any other questions relating to adverse reactions?

Have you read through the declaration, and do you understand that your blood will be tested for certain infections?

We take blood samples to test for HIV/AIDS, hepatitis B and C and syphilis. These diseases can be passed to a patient if the donor’s blood is infected.

Address any anomalies on the Self-exclusion questionnaire according to SOP-DSC-003.

May I sign with you where you state you consider your blood to be safe?

I am going to do your blood pressure, and it is important for you to please keep still whilst the machine takes the reading, as movement can have an effect on the reading. The acceptable range for the blood pressure is 60–100 mmHg for the lower reading, and 100 – 180 mmHg, for the higher reading, to donate blood. There are many variables that can have an influence on your blood pressure.

Your blood pressure is: ___ mmHg, which is normal/ high/ low for your age.

I am going to check your Haemoglobin level. This is done by pricking your finger, and obtaining blood into a capillary tube. We use Copper Sulfate as the reagent to screen for the Haemoglobin level. In order for you to donate blood, your Haemoglobin level needs to be 12,5g/dl or higher for whole blood donation (14,5g/dl for double red cells)."

When donating blood, you need to replace the iron lost by your body, as blood donation can result in iron stores being lost over time. The following foods contain high levels of iron, meat, green leafy vegetables. Iron needs Vitamin C to be absorbed by the body, thus it is important that you eat vegetables and fruit with your protein source of iron, so that the maximum amount of iron is absorbed. Do not drink milk with your main meals, as calcium blocks iron absorption. As a blood donor, it is important for SANBS that you look after your health.

Your Haemoglobin level is ___ g/dl. This means that you are able/ not able to donate blood today.

Able to donate: Please proceed through to the donor chair where _____ will assist you with your donation.

Not able to donate: Thank you very much for taking the time to come to our donor centre / blood drive. The reason why you are unable to donate today, is because _____. Defer the donor from *Guidelines for medical assessing of blood Donors* (INF-MLD-004), by looking up the deferral and showing it to the donor.

You can return on ____ (date) for further assessment. Hand the donor the appropriate pamphlet, whether it be on general deferrals or the Iron pamphlet. Where applicable, hand the donor *Request for permission to donate blood* (FRM-DSC-003), to obtain permission from their treating physician to donate blood. Explain to the donor, that on their return, the SANBS Medical Officer will evaluate the request to donate blood, and make a decision based on the information supplied by their physician, and the SANBS guidelines.

Revision Summary

VERSION NUMBER	REVISION DETAILS
0	• New Document. • The staff must be found competent on this procedure.
1	• The following paragraph was added: During this procedure, we will be doing your blood pressure, determining your haemoglobin level by doing a finger prick procedure, inserting a needle into a vein in your arm to obtain

VERSION NUMBER	REVISION DETAILS
	470ml – 500ml of blood. You will be required to sit on the donor chair for 10 minutes after your donation, to ensure that you do not have adverse effects associated with blood donation. This whole process will take about 30 minutes. As a voluntary donors, you have the option to withdraw from the process at any stage. Some of the adverse effects of blood donation can include: • Dizziness and fainting • Haematoma formation (bruise on the arm where the needle was inserted) When donating on any apheresis procedure: • Citrate toxicity • Red cell loss if the procedure has to be aborted and it is considered unsafe to return the red cells. • Chilling on reinfusion. Do you have any other questions relating to adverse reactions?

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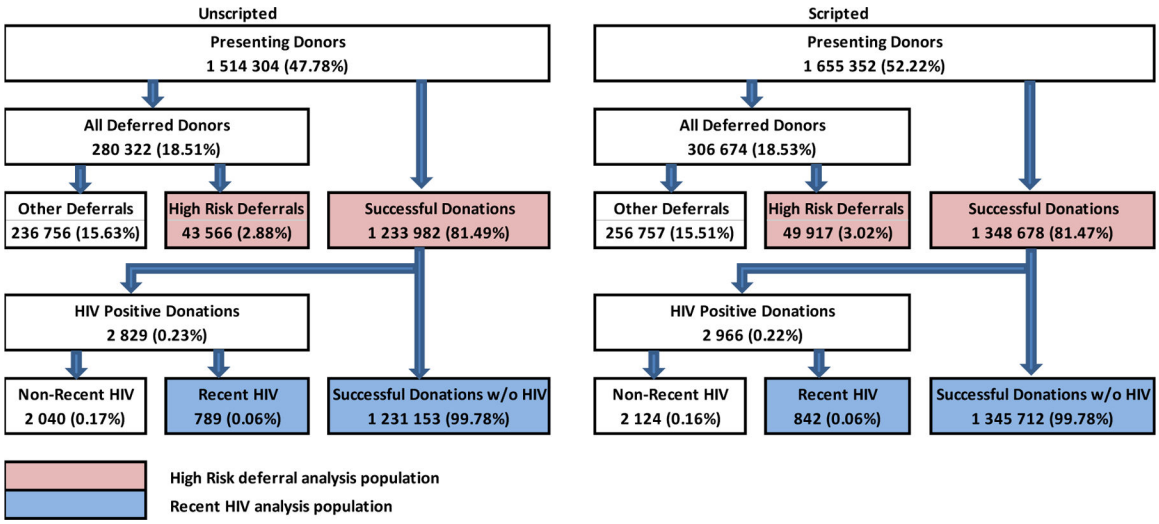

Figure 1:

Schematic illustration of distribution of donor presentations for unscripted versus scripted periods, N= 3,169,656

Table 1:

Distribution of donor presentations by demographic characteristics for unscripted versus scripted period, N= 3,169,656

		Unscripted		Scripted		
Parameter	**Categories**	**N**	**%**	**N**	**%**	**p value**
Total		1,514,304	47.78	1,655,352	52.22	<0.0001
Gender	M	790,270	52.19	840,723	50.79	<0.0001
	F	724,025	47.81	814,621	49.21	
	Unknown	9	0.00	8	0.00	
Race group	White	829,298	54.76	853,390	51.55	<0.0001
	Asian	114,231	7.54	116,945	7.07	
	Black African	469,708	31.02	572,866	34.61	
	Coloured	81,921	5.41	89,816	5.43	
	Unknown	19,146	1.27	22,335	1.35	
Age (years.)	< 21	319,274	21.08	344,495	20.81	<0.0001
	21–30	344,557	22.75	376,953	22.77	
	31–40	283,169	18.70	313,400	18.93	
	41–50	276,346	18.25	301,820	18.23	
	>=51	290,958	19.21	318,684	19.25	
Geographical area/Zone	Egoli	325,244	21.48	358,407	21.65	<0.0001
	Eastern Cape	141,420	9.34	152,231	9.20	
	Free State/Northern Cape	123,380	8.15	134,453	8.12	
	KwaZulu Natal	273,319	18.05	287,608	17.37	
	Mpumalanga	135,795	8.97	152,961	9.24	
	Northern	303,825	20.06	331,192	20.01	
	Vaal	211,319	13.95	238,490	14.41	
Donor type	Repeat	1,053,834	69.59	1,171,980	70.80	<0.0001
	Lapsed	186,031	12.28	192,972	11.66	
	First Time	274,439	18.12	290,400	17.54	
Type of donation site	Fixed Site	634,001	41.87	682,584	41.23	<0.0001
	Mobile Drive	853,455	56.36	939,485	56.75	
	Unclassified	26,848	1.77	33,283	2.01	
Deferrals	Any deferral	280,322	18.51	306,674	18.53	<0.0001
	High risk deferral	43,566	2.88	49,917	3.02	<0.0001
All HIV positive cases[†]	Positive	2,829	0.23	2,966	0.22	0.5875
Recently acquired HIV[†]	Positive	789	0.06	842	0.06	0.4045

[†]Overall HIV prevalence and recently acquired HIV prevalence were calculated as percentage of total donations for which testing results were available.

Table 2:

Multivariable logistic regression analysis for association with high risk deferral. The model included our primary predictor, donation during scripted vs. unscripted period, as well as relevant demographic and blood donation characteristics.

Parameter	Categories	Odds Ratios	95% CI	p value
Scripted period	No	1		
	Yes	1.06	1.05 – 1.07	<0.0001
Gender	M	1		
	F	0.69	0.68 – 0.70	<0.0001
	Unknown	1.52	0.52 – 4.47	0.4476
Race group	White	1		
	Asian	0.89	0.85 – 0.92	<0.0001
	Black African	1.48	1.46 – 1.50	<0.0001
	Coloured	1.12	1.08 – 1.16	<0.0001
	Unknown	1.28	1.22 – 1.35	<0.0001
Age (years.)	< 21	6.44	6.13 – 6.76	<0.0001
	21–30	8.38	7.99 – 8.80	<0.0001
	31–40	3.88	3.69 – 4.08	<0.0001
	41–50	2.19	2.07 – 2.31	<0.0001
	>=51	1		
Geographical area	Egoli	1		
	Eastern Cape	0.91	0.89 – 0.94	<0.0001
	Free State/Northern Cape	0.96	0.93 – 0.99	0.0101
	KwaZulu Natal	0.63	0.62 – 0.65	<0.0001
	Mpumalanga	0.90	0.88 – 0.93	<0.0001
	Northern	0.96	0.94 – 0.98	<0.0001
	Vaal	0.99	0.96 – 1.01	0.2472
Donor type	Repeat	1		
	Lapsed	1.46	1.42 – 1.50	<0.0001
	First Time	7.55	7.42 – 7.69	<0.0001
Type of donation site	Fixed Site	1		
	Mobile Drive	1.10	1.08 – 1.13	<0.0001
	Unclassified	4.07	3.90 – 4.24	<0.0001

Table 3:

Multivariable logistic regression analysis for association with recent HIV infection. The model included our primary predictor, donation during scripted vs. unscripted period, as well as relevant demographic and blood donation characteristics.

Parameter	Categories	Odds Ratios	95% CI	p value
Scripted period	No	1		
	Yes	0.88	0.79– 0.97	0.0074
Gender	Male	1		
	Female	2.06	1.85– 2.29	<0.0001
Race group	White	1		
	Asian	1.43	0.84– 2.44	0.1887
	Black African	27.01	21.42–34.06	<0.0001
	Coloured	7.34	5.24–10.27	<0.0001
	Unknown	8.31	4.96–13.92	<0.0001
Age (years.)	>=51	1		
	< 21	1.82	1.37– 2.42	<0.0001
	21–30	3.25	2.47– 4.26	<0.0001
	31–40	2.19	1.65– 2.91	<0.0001
	41–50	1.53	1.12– 2.09	0.0070
Geographical area	Egoli	1		
	Eastern Cape	1.53	1.26– 1.86	<0.0001
	Free State/North Cape	1.45	1.16– 1.81	0.0011
	KwaZulu Natal	1.79	1.54– 2.09	<0.0001
	Mpumalanga	2.11	1.77– 2.51	<0.0001
	Northern	0.96	0.80– 1.14	0.6083
	Vaal	1.36	1.14– 1.62	0.0006
Donor type	Repeat	1		
	Lapsed	1.70	1.48– 1.95	<0.0001
	First Time	1.63	1.44– 1.84	<0.0001
Type of donation site	Fixed Site	1		
	Mobile Drive/Unclassified	1.02	0.90– 1.14	0.7882