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Editorial

Africa Sanguine: Coming of Age

Barrett C
Editor-in-Chief

As 2019 draws to an end, we celebrate the successful publication of 21 volumes. With this comes a time of introspection; the opportunity to reflect on the last two years of publication.

Africa Sanguine is dedicated to increasing publication of quality transfusion data from and for Africa. In order to promote the publication of local data, we have approached the organisers of blood transfusion congresses in Africa and with the support of the authors and congress organisers, we have been able to print selected abstracts from these congresses. Volume 20 was dedicated to the Africa Society for Blood Transfusion Congress (AfSBT) held in Arusha (2018), in 21(1) we published selected abstracts from the ECOWAS congress held in Accra (2018) and in 21(2) we published oral abstracts from the South African National Blood Transfusion Congress held in Sun City (2019). Researchers on the African continent do fantastic work, yet this work is not always published. My challenge to the authors of these abstracts is to publish the full manuscript, either in *Africa Sanguine*, or another appropriate transfusion journal.

In the last 18 months, we have produced 4 issues. Excluding congress proceedings, 15 original research submissions were received; eight were accepted for publication, one is pending revision and six were rejected. Accepted research articles were from the following countries: Cameroon (1), Congo (1), Madagascar (2), Malaysia (1), Nigeria (2) and South Africa (1). Submissions that were suitable for publication fell into two categories; blood donors (3) and transfusion transmissible diseases (5). Blood transfusion is frequently described as a "vein to vein" process, yet we do not receive many contributions in the other domains of blood transfusion. My challenge is for researchers to collaborate and investigate all aspects of the vein to vein process. Africa has its own story to tell about transfusion and patient blood management. Our challenges are not limited to availability of safe blood for transfusion, but extends to novel methods for delivery of blood, plasma fractionation, transfusion education and clinical practice. We should describe other aspects related to our field, such as the management and outcomes for those in need of transfusion, but for whom blood was not immediately available, to review progress within blood services participating in the AfSBT Step-wise Accreditation Programme, to focus on haemovigilance, look-back and patient blood management. We should not adopt data from other parts of the world, without validating our own findings in Africa.

In this issue, we reprint the article, *Transfusion Safety: Lessons Learned In Ibero-America And Considerations For Their Global Applicability*, with special permission from Dove Medical Press Ltd., the original publisher of the work.[1] Cruz emphasises universal timely access to safe blood products as a priority. In the African context, access to safe blood may be dependent on voluntary non-remunerated blood donors, the estimation of transfusion requirements followed by appropriate adjustment of collection, processing and distribution. Interestingly, this research showed no correlation between human health index (HHI) and blood collection rates in the 29 African countries for which red cell data was available. The red cell use correlates directly with HHI and inversely with maternal and infant mortality rates in Africa. Cruz concludes that in the Africa context, national blood sufficiency needs should be assessed according to transfusion rates, rather than collection rates.

Members of AfSBT, we have come of age! I challenge you as a scientist working in the field of blood transfusion or transfusion medicine, to ask a locally relevant transfusion-related research question, take hands with supportive researchers and collaborators, and then develop a method to answer your research question. Importantly, publish your work. This is the essence of transfusion safety.

Reference:

1. Cruz JR. Transfusion Safety: Lessons Learned In Ibero-America And Considerations For Their Global Applicability. *International Journal of Clinical Transfusion Medicine* 2019;7:23-37 (Available at https://www.dovepress.com/transfusion-safety-lessons-learned-in-ibero-america-and-considerations-peer-reviewed-article-IJCTM. Accessed 23 December 2019)

Editorial

Afrique Sanguine: l'âge adulte

Barrett C
Éditeur en chef

A la fin de cette année 2019, nous célébrons la réussite de la publication de 21 volumes. Avec cela vient un temps d'introspection; l'occasion de réfléchir sur les deux dernières années de publication

Africa Sanguine est engagé à l'augmentation de la publication de données de qualité dans le domaine de la transfusion en provenance et pour l'Afrique. Afin de promouvoir la publication de données locales, nous avons contacté les organisateurs de congrès sur la transfusion sanguine en Afrique et, avec le soutien des auteurs et des organisateurs de congrès, nous avons pu imprimer des résumés sélectionnés de ces congrès. Le volume 20 était consacré au Congrès de la Société Africaine de Transfusion Sanguine qui s'est tenue à Arusha (2018). Dans le volume 21 (1), nous avons publié des résumés sélectionnés du congrès de la CEDEAO tenu à Accra (2018) et dans le 21 (2), nous avons publié des résumés de communication orale du Congrès national sud-africain sur la transfusion sanguine tenu à Sun City (2019). Les chercheurs du continent africain font un travail fantastique, mais ce travail n'est pas toujours publié. Le défi que je lance aux auteurs de ces résumés est de publier le manuscrit complet, soit dans Afrique Sanguine, soit dans un autre journal de transfusion approprié.

Au cours des 18 derniers mois, nous avons publié 4 numéros. En excluant les travaux du congrès, 15 travaux de recherches originales ont été soumis ; huit ont été acceptés pour publication, un est en attente de révision et six ont été rejetés. Les articles de recherche acceptés provenaient des pays suivants: Cameroun (1), Congo (1), Madagascar (2), Malaisie (1), Nigeria (2) et Afrique du Sud (1). Les soumissions qui convenaient à la publication appartenaient à deux catégories; donneurs de sang (3) et maladies transmissibles par la transfusion (5). La transfusion sanguine est souvent décrite comme un processus «de veine à veine», mais nous ne recevons pas beaucoup de contributions dans les autres domaines de la transfusion sanguine. Mon défi est que les chercheurs collaborent et étudient tous les aspects du processus de veine à veine. L'Afrique a sa propre histoire à raconter sur la transfusion et la gestion du sang des patients. Nos défis ne se limitent pas à la disponibilité de sang sûr pour la transfusion, mais s'appliquent également aux nouvelles méthodes de délivrance du sang, de fractionnement, d'éducation à la transfusion et de pratique clinique. Nous devons décrire la gestion et les résultats des patients nécessitant une transfusion, mais pour qui le sang n'est pas immédiatement disponible, mesurer nos progrès dans le programme d'accréditation par étapes de la SATS, l'hémovigilance, la recherche rétrospective et la gestion des patients transfusés. Nous ne pouvons pas adopter des données provenant d'autres continents sans valider ces résultats sur le nôtre.

Dans ce numéro, nous avons réimprimé l'article intitulé «Sécurité transfusionnelle: leçons apprises en Amérique latine et considérations relatives à leur applicabilité mondiale», avec l'autorisation spéciale de Dove Medical Press Ltd., l'éditeur original de l'œuvre[1]. Cruz met l'accent sur le fait que l'accès universel en temps opportun aux produits sanguins est une priorité. Dans le contexte africain, l'accès au sang sûr peut dépendre de donneurs de sang volontaires non rémunérés, l'estimation des besoins en transfusion étant suivie d'un ajustement approprié de la collecte, du traitement et de la distribution. Fait intéressant, cette recherche n'a montré aucune corrélation entre l'indice de santé humaine (ISH) et les taux de collecte de sang dans les 29 pays africains pour lesquels des données sur les globules rouges étaient disponibles. L'utilisation des globules rouges est en corrélation directe avec l'ISH et inversement avec les taux de mortalité maternelle et infantile en Afrique. Cruz conclut que, dans le contexte africain, les besoins nationaux en sang devraient être évalués en fonction des taux de transfusion, plutôt que des taux de collecte.

Chers membres de la Société Africaine de Transfusion Sanguine, nous avons atteint la majorité! Je vous mets au défi de poser une question de recherche sur les transfusions pertinentes au niveau local, de s'associer avec des chercheurs et des collaborateurs qui apportent leur soutien et de développer une méthode pour répondre à votre question de recherche. Surtout, publiez votre travail. C'est l'essence même de la sécurité transfusionnelle.

Références:

1. Cruz JR. Transfusion Safety: Lessons Learned In Ibero-America And Considerations For Their Global Applicability. *International Journal of Clinical Transfusion Medicine* 2019;7:23-37 (Disponible à https://www.dovepress.com/transfusion-safety-lessons-learned-in-ibero-america-and-considerations-peer-reviewed-article-IJCTM. Accédé 23 December 2019)

Original Research

Screening for Syphilis Among Blood Donors in Nigeria: Application of General Quality Principles

Dépistage de la Syphilis chez les Donneurs de Sang au Nigéria: Application des Principes Généraux de Qualité

Shittu AO[1], Fadeyi A[2], Olawumi HO[1], Babatunde AS[1], Omokanye KO[3], Ogunfemi MK[3]

[1]Department of Haematology, University of Ilorin, Ilorin, Nigeria

[2]Department of Medical Microbiology, University of Ilorin, Ilorin, Nigeria

[3]Department of Haematology and Blood Transfusion, University of Ilorin Teaching Hospital, Ilorin, Nigeria

Corresponding author: Dr Shittu AO, MBBS, FMCPath (drakeem06@yahoo.com,)

Conflict of Interest: The researchers do not report any conflict of interest

Key Words: Syphilis, Screening, Quality, Principles

ABSTRACT

Background: Safety of blood for transfusion is a global concern. WHO and Africa Society for Blood Transfusion require a minimum of antibodies to *Treponema pallidum* or VDRL or RPR test on all donated blood units before transfusion. Application of general quality principle in screening for Transfusion Transmissible Infections, syphilis inclusive is a major determinant of safety of blood transfusion.

Methods: Forty-eight health care facilities were recruited for the study between January and June 2018. A self-administered structured questionnaire, physical interactions and telephone calls were employed to collect all relevant data on quality measures, types of blood donors, total number of blood units screened and reactivity to syphilis screening tests.

Results: Venereal Disease Research Laboratory method was used to screen all donations for syphilis at 81.3% of the facilities screened. Twenty seven of the 39 facilities that screened for syphilis validated their test kits, 24 facilities had written SOPs and quality control system while 33 and 6 facilities procured syphilis screening reagents through Hospital Managements and Departments. A total of 98 478 blood units were collected and screened for syphilis. Of the 831 samples found reactive, 405, 408 and 18 were obtained from tertiary, secondary and private hospitals and 384, 381 and 66 of the samples were from family replacement, paid and voluntary non-remunerated blood donors respectively.

Conclusion: Majority of the facilities studied screened for syphilis using non-specific method and most employed general quality

RÉSUMÉ

Contexte: La sécurité transfusionnelle est une préoccupation mondiale. L'OMS et la Société Africaine de Transfusion Sanguine recommandent au minimum le dépistage d'anticorps anti-Treponema palladium par le VDRL ou RPR sur toutes les unités de sang provenant de dons avant la transfusion. La mise en œuvre du principe général de la qualité dans le dépistage des infections tranmissibles par tsransfusion, y compris la syphilis, est un facteur déterminant de la sécurité des transfusions sanguines.

Méthodes: Quarante-huit établissements de santé ont été recrutés pour l'étude entre Janvier et Juin 2018. Un questionnaire structuré auto-administré, des interactions physiques et des appels téléphoniques ont été utilisés pour recueillir toutes les données pertinentes sur le système de la qualité, les types de donneurs de sang, le nombre total d'unités de sang dépistées et le taux de réactivité aux tests de dépistage de la syphilis.

Résultats: Une méthode de laboratoire de recherche sur les maladies vénériennes a été utilisée pour dépister tous les dons pour la syphilis dans 81,3% des installations dépistées.Vingt-sept des 39 établissements qui dépistaient la syphilis ont validé leurs kits ; 24 disposaient de procédures opératoires standardisées et d'un système de contrôle de la qualité, tandis que 33 et 6 établissements avaient acheté des réactifs pour le dépistage de la syphilis par l'intermédiaire des directions et des services hospitaliers. Au total, 98 478 unités de sang ont été collectées et testées pour la syphilis. Sur les 831 échantillons trouvés réactifs, 405, 408 et 18 provenaient d'hôpitaux tertiaires, secondaires et privés respectivement, et 384, 381 et 66 des échantillons provenaient respectivement

principles that conform to National and Africa Society for Blood Transfusion guidelines. Syphilis sero-prevalence of 0.84% was recorded in this study.

de donneurs de remplacement familial, de donneurs de sang payés et de donneurs volontaires.

Conclusion La majorité des établissements dépistaient la syphilis en utilisant une méthode non spécifique et la plupart des principes de qualité généraux employés étaient conformes aux directives de la AfSBT. Une prévalence de 0.84% pour la syphilis a été enregistrée dans cette étude.

INTRODUCTION

Safety of blood and blood products for transfusions has being a concern globally and particularly for African countries. The HIV/AIDS pandemic has awaken attention on the importance of preventing transfusion-transmitted infections (TTIs). Up to 3% of HIV infections worldwide are transmitted through transfusions of contaminated blood and blood products. Many more recipients of blood products may have been infected by hepatitis B and C viruses, syphilis and other infectious agents. The global burden of diseases due to unsafe blood transfusions can be eliminated or substantially reduced through several integrated strategies for blood safety.[1]

Appropriate recruitment and selection of blood donors together with pertinent and precise laboratory screening for TTIs are major determinants of blood safety. WHO recommends screening tests for TTIs including syphilis to be done according to the quality system requirements.[2] Immunological test for syphilis is part of the mandatory recommended tests for blood donors in Nigeria.[3] Screening for syphilis is used as either a surrogate of viral TTI which are regularly transmitted sexually in the general population or, to actually prevent transfusion of *Treponema pallidum*-contaminated blood and blood products[4]. The serological tests that are available for blood donor screening may detect antibodies against treponema antigens (specific) such as Treponema Pallidum Haemaglutination Assay (TPHA) and Treponema Pallidum Particle Agglutination Assay (TPPA) or non-treponema antigens (non-specific) such as Venereal Disease Research Laboratory (VDRL) and Rapid Plasma Reagin (RPR). Those that are *T. pallidum*-specific require infrastructure that may not be available in some laboratories in remote areas of some African countries and, therefore, rapid, non-specific methods are used. Both non-specific and specific assays detect antibodies but not the infectious treponemes. Rapid non-specific tests have also been reported to be highly sensitive and specific.[5] The WHO reported sensitivities of 84.5-97.7% and specificities of 92.8-98% for eight syphilis rapid screening tests (VDRL inclusive) when compared to the TPHA/TPPA reference standard.[6,7] Rapid non-specific syphilis tests have advantages of minimal cost, minimal training and equipment requirements and results availability within 15-20 minutes.

Because of the serious implications of screening tests, blood transfusion services need to eliminate potentials for false positive or false negative results. Application of quality principles like standard operating procedures, adequate in-laboratory quality controls, correct reagents storage, handling and application, training laboratory personnel and avoidance of clerical errors are measures that contribute to correct screening results.

Screening for syphilis as recommended by WHO has been questioned by so many authors.[8] This is because of the belief that *Treponema pallidum* does not survive the cold storage temperature of blood bank (2-6^{O}C) and many syphilis antibodies found in most donors are as a result of previous infections or an unspecific reaction.[9] This theory may not be applicable in developing countries where blood bank storage temperature can hardly be maintained and also because transfusion of Fresh Whole Blood (FWB) units has completely replaced transfusion of platelets concentrate and Fresh Frozen Plasma due to lack of facilities to prepare these blood products.[10] To compound the problem, family replacement (FRDs) and paid blood donors (PDs) constitute 75-80% of blood donors in developing countries, Nigeria inclusive.[11]

Studies done locally and internationally, have indicated varying prevalence levels for syphilis among healthy blood donors.[12,13] The prevalence was reported to be as low as 0.1%[14] and as high as 3.6%[15] among blood donors in Nigeria, hence the need for routine screening for syphilis among blood donors. The last case of syphilis acquisition through blood and blood products transfusion in the developed world was in the United State in 1966[16] while the developing world still battles with the scourge.[3]

In Nigeria as in other developing countries, hospital-based blood transfusion services still predominate where blood for transfusions are collected from all types of blood donors. The largest percentage of these blood donors in Nigeria are FRDs and PDs,[11,17,18] despite reported higher syphilis sero-prevalence among FRDs[19]. This contrast with what obtains in centralized blood transfusion services where voluntary non-remunerated blood donors (VNRDs) predominate. Also in hospital-based transfusion services, equipment and reagents are procured by individual hospitals based on their availability and affordability as against central or regional procurement recommended by WHO for its cost effectiveness and safety. There

is a strong but unsubstantiated believe that screening for syphilis in Nigeria may be poorly regulated and may lack general quality principles.

It was in the light of these that we decided to study the mode of screening for syphilis in our health facilities in all the six geo-political regions of the country with a view to assessing our compliance with Nigerian National Blood Transfusion Service (NBTS) guidelines [20] and Africa Society for Blood Transfusion (AfSBT) Step-Wise Accreditation Standard[21]. National syphilis sero-reactivity amongst blood donors was also determined.

METHODOLOGY

Study Location:
Health care facilities (HCF) that are involved in blood transfusion services in all the six geo-political regions of the country were selected for this study.

Study Population:
The Heads of Department (HOD) of Haematology and/or the Chief Medical Laboratory Scientists of the selected blood banks.

Study Size:
Forty-eight HCFs completed the questionnaires and responded to telephone calls within the study period of 6 months and were recruited for the study. This included 18 tertiary HCFs, 18 secondary HCFs and 12 private HCFs. Tertiary HCFs comprises of Teaching Hospitals and Federal Medical Centers, while secondary HCFs are State government owned General Hospitals.

Inclusion Criteria:
Health Care Facilities that were involved in the collection, processing and transfusion of blood and blood products.

Exclusion Criteria:
Health Care Facilities that rely wholly on NBTS for supply of blood and blood products for transfusions and those that did not give consents.

Methods:
A self-administered and structured questionnaire, physical interactions and telephone calls to the aforementioned study population were employed to collect all relevant data which included kit validation, existence of standard operating procedures, use of quality control programs and methods of reagent procurement as proxy indicators of global best practice, methodologies used for syphilis screening and laboratory results among blood donors. Most of the target population was approached at national conferences and meetings. Communications through telephone calls and sending the questionnaire through e-mail, which were cost effective, were also employed to get all the data where the target population was not met at conferences and meetings.

Data Analysis:
This was done using Software Package for Social Sciences version 20. Results were presented as proportions and analyzed by Chi square tests. Level of significance was set at $p \leq 0.05$.

Funding: This study was funded by the researchers.

RESULTS

Forty-eight HCFs, 18 each of tertiary and secondary and 12 private HCFs participated in the study, out of which, 39 (81.3%) screened for syphilis in all donated blood units. Twenty-seven (69.2%) [12 each of tertiary and secondary and 3 private] of the 39 facilities that screened for syphilis validated their test kits. Twenty-four (61.5%) [12 tertiary, 9 secondary and 3 private] of the 39 facilities had written Standard Operating Procedures (SOPs). Twenty-four (61.5%) [9 tertiary, 12 secondary and 3 private] of the facilities had quality control. Thirty-three (84.6%) [12 tertiary, 9 secondary and 12 private] of the health facilities procured syphilis screening reagents through hospital management, while 6 [secondary health facilities] procured reagents through their departments. All the blood units collected were screened using non-specific (Venereal Disease Reference Laboratory) syphilis screening method, **Table 1**.

A total of 98 478 blood units were collected and screened for in the study period. Tertiary HCFs collected the largest number, 56 061 (56.9%), followed by secondary, 41,133 (41.8%) and private, 1 284 (1.3%). Family replacement blood donors constituted the largest percentage of all blood donors in all the facilities 84%, followed by VNRDs, 14.6% and PDs, 1.4%. A total of 831 samples (0.84%) were reactive to syphilis, of which 405 (0.72%), 408 (0.99%) and 18 (1.4%) were obtained from tertiary, secondary and private HCFs respectively, **Table 2**.

Of the 831 samples that were found reactive to syphilis, 384 (46.2%), 381 (45.8%) and 66 (7.9%) were from FRDs, PDs and VNRDs respectively. Overall sero-reactivity was higher amongst PDs (28.8%) than FRDs (0.46%) and VNRDs (0.46%). Sero-reactivity was significantly higher amongst PDs (33.7%) at tertiary compared with that of private (2.9%) HCFs, $p<0.05$. Significantly higher sero-reactivity was also noticed amongst FRDs at private (1.12%) and secondary (0.98%) than in tertiary HCFs (0.05%), $p<0.05$. Likewise sero-reactivity was significantly less amongst VNRDs at tertiary (0.10) than in secondary HCFs (1.0), $p<0.05$, **Table 3**.

Table 1. Result of Screening Survey for all HCFs.

		HCFs			
		Tertiary	**Secondary**	**Private**	**Total**
Screening Methods	VDRL RPR TPHA	12/66.7 - -	15/83.- - -	12/100 - -	39/81.3 - -
Facilities that validated test kits (n/%)		12/66.7	12/66.7	3/25	27/69.2
Facilities with written SOP (n/%)		12/66.7	9/50	3/25	27/69.2
Facilities with Quality Control Measures (n/%)		9/50	12/66.7	3/25	24/61.5
Methods of reagents procurement (n/%)	HOSP DEPT	12/66.7 0/0	9/50 6/33.3	12/100 0/0	33/84.6 6/7.7
Total samples screened with specific method		0/0	0/0	0/0	0/0
Total samples screened with non-specific method (VDRL) (n/%)		56 061/100	41 133/100	1 284/100	98 478/100

Abbreviations: HCFs (Health Care Facilities), VDRL (Venereal Disease Research Laboratory), RPR (Rapid Plasma Reagin), TPHA (Treponema Pallidum Haemagglutination Assay), HOS (Hospital), DEP (Department).

Table 2. Results of Syphilis Screening Survey 2017 for all HCFs.

		HCFs			
		Tertiary	**Secondary**	**Private**	**Total**
Number of sites studied		18	18	12	48
Number of sites that screened for syphilis (n/%)		12/66.7	15/83.3	12/100	39/81.3
Total samples screened.		56 061	41 133	1 284	98 478
Number of samples screened according to donor type (n/%)	VNBD FRD PD	8 952/16 45 996/82 1 113/2	5 448/13.2 35 685/86.8 0/0	0/0 1 074/83.6 210/16.4	14 400/14.6 82 755/84 1 323/1.4
Number of samples reactive to syphilis (n)		405	408	18	831
Sero-prevalence		0.72	0.99	1.4	0.84

Abbreviations: HCFs (Health Care Facilities), VNBD (Voluntary non remunerated blood donor), FRD (Family replacement donor), PBD (Paid blood donor), VDRL (Venereal Disease Research Laboratory).

Table 3. Comparing sero-reactivity of syphilis amongst types of blood donors and HCFs.

Facilities	VNBD				FRD				PD			
	TD	TR	Sero-P	p-value	TD	TR	Sero-P	p-value	TD	TR	Sero-P	p-value
Tertiary	8.952	9	0.10	<0.05	45.996	21	0.05	<0.05	1.113	375	33.7	<0.05
Secondary	5.448	57	1.0		35.685	351	0.98		0	0	0	
Private	0	0	0		1.074	12	1.12		210	6	2.9	
Total	14.400	66	0.46		82.755	384	0.46		1.323	381	28.8	

Abbreviations: HCFs (Health Care Facilities), VNBD (Voluntary Non-remunerated Blood Donor), FRD (Family Replacement Donor), PD (Paid Donor), TD (Total units donated), TR (Total units found reactive), Sero-P (Sero-prevalence).

DISCUSSION

Blood transfusion practice still appears poorly regulated in Nigeria, despite establishment of NBTS since 2004. Presently there are seventeen NBTS Centers in Nigeria, with headquarter/ demonstration center at Abuja. The center supplies safe blood and blood products to all HCFs in the country. It also has policy and guidelines for blood transfusion practice in Nigeria. At the centers, testing for antibodies to HIV I and II, Hepatitis B surface antigen (HBsAg), antibodies to Hepatitis C virus, immunological VDRL tests for syphilis and p24 HIV antigens are performed using Enzyme Linked Immuno-sorbent Assay method with all the quality principles in place according to WHO recommendations.

Unfortunately, because the demand for blood and blood products out-stripped supply from NBTS, most health facilities still operate hospital-based blood transfusion service where equipment and reagents are procured by individual hospitals based on their availability and affordability as against central or regional procurement recommended by WHO for its cost effectiveness and safety. Hence screening for syphilis in particular and other transfusion transmissible infections may be compromised and in actual fact it is erroneously perceived as being poorly regulated with no internal and external quality control measures.

Our study revealed that most HCFs (more than two thirds) validated their test kits before being used, have Standard Operating Procedures and have both internal and external quality control measures as recommended by WHO[2] and all employed VDRL screening method. Most of the facilities in this study, 84.6%, procured syphilis screening reagent centrally through Laboratory Revolving Fund of the hospitals. Although this is not as acceptable as national or regional procurement, it is better than procurement by individual or by the departments.

A low syphilis sero-reactivity of 0.84% was recorded in this study which is similar to the findings of other researchers in Nigeria[13,14]. Although all facilities that screened for syphilis in this study used *T. pallidum*-nonspecific screening method, VDRL, it is in keeping with AfSBT recommendations.[21] Africa Society for Blood Transfusion requires a minimum of antibodies to *T. pallidum* or VDRL or RPR test and that non reactive blood donor to non-specific screening method could be considered negative for syphilis infection and the donation be released for transfusion provided it meets all other requirements. Overall syphilis sero-reactivity was highest amongst PDs in tertiary HCFs. This is not unexpected as most PDs are found in tertiary facilities. Family replacement blood donors and VNRDs have the same overall sero-reactivity but lower than that of PDs in this study in contrast with the findings of previous studies that indicated higher sero-prevalence amongst FRDs.[19,22-24]

CONCLUSION

Majority of the facilities studied screened for syphilis using *T. pallidum*-non specific, VDRL screening method. Also most of the facilities conformed to the standard by Nigerian NBTS and AfSBT in terms of test kits validation, use of Standard Operating Procedures, quality control measures and central method of reagents procurement. Low syphilis sero-reactivity was recorded in this study despite widespread practice of hospital-based blood transfusion service. Blood transfusion safety in Nigeria can be improved further if all HCFs adopt centralized blood transfusion service.

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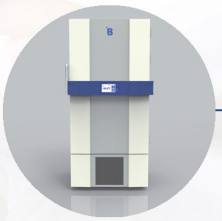

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The True Status of Family Replacement Blood Donors in a Tertiary Hospital Blood Service in Central Nigeria

Le Véritable Statut des Donneurs de Sang Familiaux ou de Remplacement dans un Service de Sang d'un Hôpital Tertiaire au Nigeria Central

Shittu AO[1], Olawumi HO[1], Omokanye KO[1], Ogunfemi MK[1], Adewuyi JO[1]

[1] University of Ilorin Teaching Hospital, Ilorin, Nigeria.

Corresponding author: Adewuyi JO (jamesesie@yahoo.com)

Conflict of Interest: None

Key Words: VNRBD, FRD, PBD, Blood safety, false family donor

ABSTRACT

Background: To make up for the low blood collection from voluntary non-remunerated blood donors (VNRBD), by the blood services in Nigeria, patients' families are often requested to provide substitute blood donors for their family members' usage. However, many so-called family replacement donors (FRDs) are thought not to be true relatives.

Objective: The objective of this study was to establish the true family status of donors presenting as FRDs in a tertiary hospital blood service in central Nigeria.

Methods: Consecutive blood donors were studied with a structured questionnaire immediately after blood donation. The questionnaire contained six pretested, variably discriminatory and revealing questions. Donors' responses to questions about the recipients were verified by cross-checking with hospital records, and also by interviewing recipients. Personal telephone contacts given by the donors were verified by calls to the phone numbers. Donors' responses were scored, and donors scoring below a cut-off point were classified as false relatives.

Results: Seven hundred and sixty consecutive blood donors were recruited for the study. Sixty-seven (8.8%), 673 (88.8%), and 20 (2.6%) of them claimed to be VNRBD, FRD, and paid blood donors (PBDs) respectively. Of the 673 presumed FRDs, 323 (48%) scored below the cut-off mark of 5 points. Hence, 48% of the presumed FRDs were regarded as false family donors.

Conclusion: Significant proportions (48%) of presumed FRDs were found likely to be false family donors. Unquestioning acceptance of such donors may compromise blood safety.

RÉSUMÉ

Contexte: Pour compenser la faible collecte de sang des donneurs de sang volontaires non rémunérés (DVNR) par les services de transfusion sanguine au Nigeria, les familles des patients sont souvent invitées à fournir des donneurs de sang de substitution. Cependant, de nombreux soi-disant donneurs familiaux de remplacement (DFR) ne sont pas considérés comme de vrais parents.

Objectif: L'objectif de cette étude était d'établir le véritable statut familial des donneurs se présentant sous la forme de DFR dans un service de transfusion dans un hôpital tertiaire du centre du Nigéria.

Méthodes: Les donneurs de sang consécutifs ont été étudiés avec un questionnaire structuré immédiatement après le don de sang. Le questionnaire comportait six questions prétestées, discriminatoires et révélatrices. Les réponses aux questions des donneurs concernant les bénéficiaires ont été vérifiées par recoupement avec les dossiers de l'hôpital, ainsi que par des entretiens avec les bénéficiaires. Les contacts téléphoniques personnels donnés par les donneurs ont été vérifiés par des appels téléphoniques. Les réponses des donneurs ont été notées, et les donneurs dont le score était inférieur à un seuil ont été classés dans la catégorie de faux parents.

Résultats: Sept cent soixante donneurs de sang consécutifs ont été recrutés pour l'étude. Soixante-sept (8,8%), 673 (88,8%) et 20 (2,6%) d'entre eux se sont déclarés comme étant des DVNR, DFR et des donneurs rémunérés (DR), respectivement. Sur les 673 DFR présumés, 323 (48%) ont obtenu un score inférieur à la barre des 5 points. Ainsi, 48% des DFR présumées étaient considérées comme de faux donneurs de la famille.

Conclusion: Des proportions significatives (48%) de DFR présumés étaient susceptibles d'être de faux donneurs de la famille. L'acceptation inconditionnelle de tels donneurs peut compromettre la sécurité du sang.

INTRODUCTION

It has been accepted by the World Health Organization (WHO) that blood from voluntary non-remunerated blood donors (VNRBD), especially repeat donors from low-risk segments of the population, is the safest for clinical use.[1] In many countries in the developing world, particularly sub-Saharan Africa (SSA), the rate of collection of donor blood from VNRBDs falls far short of the demand.[2] In order to make up for the shortfall, patients' families are often requested to provide relatives or friends to donate blood for patients' use, or to replace blood that had been borrowed and used for the patients. There are divergent opinions among blood transfusion practitioners as to the safety of blood donated by family members. Some think that family replacement donors (FRDs) are, at least, as safe as first time volunteer donors[3], and can be easily converted to repeat volunteers.[4] It is argued that stigmatizing and rejecting the FRD system is a waste of valuable resources.[5] Other practitioners believe that FRDs are paid blood donors in disguise, and information provided by them at donor selection points may be false. FRD blood may thus not be the safest. This group also thinks that even genuine family donors donate blood under pressure, and are not easy to convert to repeat volunteer donors.[6] While the arguments sound reasonable on both sides, there has been no hard evidence as to the proportion of "true family" and presumably "safe", and "fake family", and presumably "unsafe" donors among the FRDs. There is also no proven mechanism to distinguish one group of donors from the other. The objective of this pilot study is to determine the true family status of FRDs in the blood service of a tertiary hospital in central Nigeria.

METHODOLOGY

Participants

Consecutive blood donors were studied over a period of one month, at the donor clinic of the University Teaching Hospital, Ilorin, Nigeria. A structured questionnaire was designed for the study, and was pretested to reveal inconsistencies in donor's knowledge of the patient, and other donor information and status. The study was approved by the hospital ethics committee. The questionnaire was administered by a member of the research team on every donor, immediately after blood donation. The study was conducted post-donation when, it was thought, the possibility of detection as a commercial donor, and rejection at the screening point would no longer arise. The donor would therefore feel freer to answer questions more truthfully. The questionnaire was anonymous, in order to further put the donor's mind at rest concerning a possible witch-hunt.

Discriminatory questions

Six questions were posed in the questionnaire to establish:

1. Donor's knowledge of the health problem of the patient for which blood had been donated. (such as RTA, peri-natal and surgery)
2. Donor's knowledge of the patient's location in the hospital, (ward, clinic, theatre, emergency)
3. Donor's knowledge of the patient's age group (elderly, adult, youth, child)
4. Donor's knowledge of the patient's gender (male, female)
5. Relationship of the donor to the patient, (family, friend)
6. Telephone number of the donor

Table 1 shows the scores allocated to each question according to their perceived importance, which brought the total obtainable points to 7. If on verification, the donor's responses to at least 4 of the 5 questions about the patient were correct, he would score up to 5 points out of the 7 obtainable. Such a donor was considered likely to be a true family donor. Donors scoring below the cut-off mark of 5 points were considered not to be sufficiently intimate with the patient to be a family member or friend. They were therefore grouped among the false FRD**s**.

Table 1. Questions and point allocation

Question	Point score
Knowledge of patient's health problem	2
Knowledge of patient's age group	1
Knowledge of patient's gender	1
Knowledge of patient's location	1
Relationship to patient	1
Telephone number of donor	1
Total	**7**

Verification of donors' responses

Verification was in the fashion of a detective exercise. The age, gender, health problem, and location of the patient were easily verified from hospital records. The relationship to the patient, as claimed by the donor, was verified by asking the patient, or the visiting relatives, if they knew, by name or by relationship, the person who donated blood on their behalf. If the response was positive, the donor was awarded the full one point for that question. Negative responses by the patient or the relatives attracted a zero score for the donor for that question. It is worthy to note here that many relatives gave the donor's name as the person who was later identified as the "go-between" or syndicate manager. To verify the telephone contact provided by the donor, calls were placed to the given number, ostensibly to check on the post-donation health of the donor. If the person receiving the call confirmed that he recently donated blood at our hospital for a relative or friend, the donor was awarded the full one point for that question. If however the person receiving the call denied having donated blood recently, or the call was repeatedly blocked or truncated by the receiver, or the number was declared invalid by the mobile telecom provider, the donor was judged to have been untruthful

about his telephone contact, and was classified as a false family donor.

RESULTS

Table 2 shows the distribution of donors by category. The vast majority of donors, (673/88.6%), claimed to have donated their blood freely on behalf of a family member or friend. Twenty donors (2.6%) admitted that they donated blood on behalf of a patient for a fee, and were classified as paid donors. The remaining 67 donors (8.8%) had no recipient in mind, and were classified as VNRBDs. **Table 3** shows the results of the verification exercise. Donors scoring up to the cut-off level of 5 points, or above, were 350 or 52%, while donors scoring below the cut-off level of 5 points were 323 (48.0%).

Table 2. Distribution of donors by types

Type of donor	Number	%
Voluntary non-remunerated blood donors (VNRBD)	67	8.8
Family replacement donor (FRD)	673	88.6
Paid donor (self-confessed PBD)	20	2.6
Total	**760**	**100.0**

Table 3. Scores by family/replacement donors

FRD scores after verification	Number	%
Number scoring up to cut-off point (5 and above)	350	52.0
Number scoring below cut-off point (below 5)	323	48.0
Total	**673**	**100.0**

DISCUSSION

In this study, nearly half (48%) of the donors who presented themselves as family members or friends, were found not likely to be so. Although this figure was arrived at indirectly, based on seemingly arbitrary assumptions, there is no doubt that a significant number of so-called family donors were false, and not true relatives or friends. Indeed, the finding of 48% false FRDs may be an underestimate. During the period of study, 28 (3.6%) of the prospective donors screened, were rejected due to low haemoglobin. An unknown proportion of them were likely to be commercial donors who were attempting repeat blood donation before full recovery from a previous donation.

On further interaction with the self-confessed paid donors, it was revealed that the false FRD system operates in an organized syndicate fashion. When relatives are requested to provide family donors, and they are unable or unwilling to do so, they get to find out about, and approach, the syndicate managers to recruit paid blood donors. After agreeable negotiations, the managers collect relevant information about the patient. They then select, and mobilize donors from their existing register, equip them with the patient's data, and send them to the blood bank to pose as relatives. After successful donation, the managers pay off the donor, and keep what is their cut of the fees paid by the relatives. These false FRDs may be normal healthy-looking persons, but information about themselves, provided at donor screening, including names, addresses, telephone numbers, and history of risk behaviour may not be truthful. Traceability is thus almost impossible, and the safety of the donated blood is in doubt. An additional dimension, disclosed by a syndicate member on condition of anonymity, was that the syndicate allegedly has on it's payroll, unscrupulous secret collaborators within the blood service, who tutor the false FRDs how to lie about their history, and may even go as far as falsifying haemoglobin screening results in favour of the false FRDs.

On the other hand, 52% of the FRDs in this study were found likely to be genuine family members, and these are the ones that may be suitable candidates for mobilization as repeat voluntary donors. The problem however remains: how are the true FRDs to be distinguished from the false ones.

CONCLUSIONS AND RECOMMENDATIONS

Beneficial as the FRD system may sound, this study has showed that the system has inherent problems of blood safety. Family donations have become necessary, only because blood services are unable to recruit sufficient voluntary donors to meet blood demand. This in turn is due to inadequate investment in blood donor mobilization and recruitment. In the background of widespread unemployment, and pervasive poverty, and corruption, it is not surprising that altruism and morality may become blunted, and blood donation for money may become an attractive source of income for desperate people. If the practice of requesting relatives to provide donors is stopped, the false family donors will be out of business. This may cost patients higher fees for blood service, from which mobilization expenses may be partially recovered. The benefit will be a greater assurance of blood safety. The good news is that blood safety, and sufficiency is doable, without the FRD system, even in Africa. Some countries in Sub-Saharan Africa, through nationally organized, well-funded, and legally backed and regulated systems, have successfully made the transition to full VNRBD. Examples are the Republic of South Africa, Zimbabwe, Botswana, Uganda, Rwanda, and others.[7] School blood donation programmes,[8 9] Club/Pledge 25, which is an indigenous African creation,[10] and community,[11] and religious houses,[12] mobilization, are some of the strategies that have been found useful. Blood from voluntary donors is free, but it is costly to mobilize these donors, and to process the blood into safe products. In two separate surveys of the knowledge and attitudes of secondary school, [13] and

university graduates[14] about voluntary blood donation in Nigeria, the commonest reason given for non-donation was that: "I have never been asked." The bottom line, therefore, is the political and economic will by our governments, with or without external donor assistance, to invest more in blood safety and sufficiency.

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Profil De L'hemogramme Chez Les Donneurs De Sang A L'ouest Du Cameroun

The Full Count Profile In Blood Donors In Two Hospitals In The West Region Of Cameroon

Kourouma K[1], Ndanchi Tiotsia AR[2], Kanmangné FM[1], Fotsing Kwetche P[3], Kouamouo J[1], Kaptue L[1]

[1] Cliniques Universitaires des Montagnes/ UdM, Bangangté, Cameroun/Doyen Faculté de Pharmacie

[2] Université des Montagnes, Bangangté, Cameroun.

[3] Cliniques Universitaires des Montagnes/Laboratoire analyses biologiques

Corresponding author: Kourouma K (Kk_transfusion@hotmail.com)

Conflict of Interest: The researchers do not report any conflict of interest

Key Words: Blood donor, blood count, West Cameroon

Mots clés: Donneurs de sang, hémogramme, Ouest Cameroun

ABSTRACT

This prospective study aims to describe the blood count profile in blood donors collected from two blood banks in Western Cameroon in order to provide the authorities with valid scientific arguments to define the criteria for eligibility to blood donation. A total of 127 blood donors (volunteers and families) were included during the mobile and fixed blood collections carried out by the Bafoussam Regional Hospital (HRB) and the University Mountain Clinics (CUM) from May to October 2013. The blood count was performed using a Hematology Analyzer type URIT-3000Plus Hematology Analyze and data analysis was done on Microsoft Excel 2007. The average donor's age was 31.32 years and the proportion of volunteer donors was 30%. In our study, 28% of donors were anemic and anemia was microcytic hypochromic in 55.6% of case. Overall, there is a trend of anemia among some regular donors of rare phenotypes because of the frequent solicitation of donations and lack of iron replacement. The analysis of white cells showed leukopenia in 14.96% of donors and one case of leukocytosis was observed. As for platelet data analysis, thrombocytopenia was found in 3.14% of donors and thrombocytosis in 8 blood donors (6.29% of cases). We recommend a systematic hemoglobin screening prior to donation that will guide help to refer anemic donors to specialized services for additional analysis.

RÉSUMÉ

Cette étude prospective a pour but d'étudier le profil de l'hémogramme chez les donneurs de sang prélevés dans deux banques de sang de l'Ouest du Cameroun afin de fournir aux autorités des arguments scientifiques valides permettant de compléter par l'hémogramme les critères biologiques d'aptitude au don de sang. Elle concerne 127 donneurs de sang (volontaires et familiaux) rencontrés lors des collectes de sang mobiles et fixes effectuées par l'Hôpital Régional de Bafoussam (HRB) et les Cliniques Universitaires des Montagnes (CUM) de Mai à Octobre 2013. L'hémogramme a été réalisé à l'aide d'un automate d'hématologie de type URIT-3000 Plus Hematology Analyze et l'analyse des données a été faite sur Microsoft Excel 2007. L'âge moyen des donneurs est de 31.32 ans et la proportion de donneurs bénévoles volontaires est de 30% contre 70% de donneurs familiaux. Dans notre série, 28% des donneurs sont anémiés et l'anémie est hypochrome microcytaire chez 55.6% de ces donneurs. Globalement, il y a une tendance à l'anémie chez certains donneurs réguliers de phénotypes rares à cause de la fréquente sollicitation aux dons et d'une absence de prise en charge de la déplétion martiale occasionnée par une telle pratique. L'analyse de la lignée blanche montre une leucopénie chez 14.96% des donneurs et un cas d'hyperleucocytose a été observé. Quant à l'analyse des données sur les plaquettes on remarque une thrombopénie chez 3.14% de donneurs et une thrombocytose chez 8 donneurs de sang (soit 6.29% des cas). Cette étude recommande l'intérêt du dosage systématique de l'hémoglobine pré-don pouvant orienter certains donneurs anémiés vers des services spécialisés pour des examens complémentaires comme l'hémogramme en vue d'une prise en charge spécialisée.

INTRODUCTION

Depuis 2008,[1,2] il a été instauré l'hémogramme pré-don et la réalisation de l'hémogramme de façon périodique chez les donneurs de sang afin non seulement de protéger le donneur de sang mais aussi de fournir un sang de bonne qualité au receveur. Dans certains pays, chaque don de sang est précédé d'un contrôle du taux d'hémoglobine. Ce test permet d'améliorer la qualité des produits sanguins prélevés mais aussi de dépister l'anémie et d'autres hémopathies chez les donneurs de sang. Certes cette nouvelle mesure protège les donneurs et les transfusés, mais elle risque de s'accompagner d'une pénurie des dons dans certaines localités où il n'existe pas un système de recrutement de donneurs performant, comme le Cameroun[1,3]. Cependant, si plusieurs études ont été consacrées aux paramètres érythrocytométriques chez les donneurs de sang en Afrique très peu de travaux font allusion aux lignées leucocytaire et plaquettaire dans cette population[4].

Dans ce cadre, cette étude a pour but d' etudier le profil de l'hémogramme chez les donneurs de sang prélevés dans deux banques de sang de l'Ouest du Cameroun afin de fournir aux autorités des arguments scientifiques valides permettant de compléter par l'hémogramme les critères biologiques d'aptitude au don de sang.

MATÉRIEL ET MÉTHODE

Cadre et méthodologie d'étude

Cette étude prospective a eu pour cadres les banques de sang de deux hôpitaux de la région de l'Ouest-Cameroun: l'Hôpital Régional de Bafoussam (HRB) et les Cliniques Universitaires des Montagnes (CUM). Cent vingt-sept (127) donneurs de sang (Bénévoles et familiaux) ont été prélevés au cours de la période allant de Mai à Octobre 2013. Les donneurs bénévoles étaient tous recrutés parmi les étudiants de l'UDM au cours des quelques rares collectes mobiles organisées par les Cliniques Universitaires des Montagnes.

Les donneurs de sang remplissaient les critères physiques et cliniques requises pour être éligibles comme donneurs de sang après avoir lus et signés une fiche de consentement libre et éclairé élaborée et un questionnaire pré-don conçus à cet effet. Le questionnaire pré-don utilisé comportait l'identification du donneur, l'interrogatoire et les appréciations d'un examen clinico-physique sommaire.

Pour chaque donneur de sang, une moyenne de 7 ml/kg de poids corporel de sang a été prélevé correspondant à 250 ml à 450 ml de sang dans une poche CPDA. Deux échantillons de 10 ml de sang ont été prélevés; un échantillon dans un tube à EDTA pour les examens hématologiques et immunohématologiques (Groupage ABO/Rh D et quelques phénotypages à la demande pour des polytransfusés et un autre échantillon dans un tube sec pour les examens sérologiques courants (Virus de la Inmunodeficiencia Humana [VIH], Virus de l'hépatite B [VHB], Virus de l'hépatite C [VHC] et le Tréponema paludum de la Syphilis). Pour les besoins de l'enquête, les prélèvements pour examens pré-dons se faisaient après le don de sang à partir de la tubulure de la poche clampée. L'analyse pré-don a été évitée au cours de l'enquête pour obtenir des résultats épidémiologiques non biaisées et donner la chance à tous les candidats de faire un don au cours de cette période. La prise en charge était assurée après les analyses post-dons et de façon confidentielle. L'hémogramme a été réalisé à l'aide d'un automate d'hématologie de type URIT-3000 Plus Hematology Analyze. La présentation, l'analyse des données et l'analyse statistique ont été faites sur Microsoft Excel 2007 et le logiciel R Core Team (2013).

Les personnes ayant participé à cette étude étaient des volontaires. La confidentialité des données de l'étude a été préservée par la stricte application des mesures requises pour en garantir le respect. Seul le personnel de l'étude a eu accès aux données de l'étude qui seront par ailleurs conservées dans les archives.

Par contre, l'impact de la sérologie positive pour les marqueurs du VIH, VHC, VHB et de la syphilis n'a pas été cerné dans cette étude. La formule leucocytaire après coloration au MGG pour compléter qualitativement l'hémogramme n'a pas été effectuée.

Définitions opérationnelles des paramètres hématologiques

Globules rouges

- Le taux d'hémoglobine normal varie en fonction du sexe (chez l'adulte) et de l'âge. Le diagnostic positif d'anémie dépendra donc de ces critères. Anémie= Hb inférieur 14 g/dl chez le nouveau-né, inférieur à 13g/dl chez l'homme et inférieur à 12 g/dl chez la femme.
- Anémie microcytaire hypochrome: VGM < 80 fl et CCMH < 30 g/dl ou TGMH < 27 pg/cellule
- Anémie normochrome: CCMH = 30-36%
- Anémie normocytaire: VGM = 80-100 fl
- Anémie macrocytaire: VGM supérieur à 100 fl

Globules blancs

- Lymphocytose: taux de lymphocytes > 4.5 $x10^9$/l
- Lymphopénie: taux de lymphocytes < 1.5 $x10^9$/l
- Leucopénie: GB < 4 $x10^9$/l
- Leucocytose: GB >10 $x10^9$/l
- Polynucléose neutrophile: taux de PN > 7.5 $x10^9$/l
- Neutropénie: taux de PN < 1.5 $x10^9$/l
- Hyper éosinophilie: taux de PE > 0,5 $x10^9$/L

Plaquettes

- Thrombocytose: taux de plaquettes > 450 x10^9/l
- Thrombopénie: taux de plaquettes < 100 x10^9/l

RÉSULTATS

Description des donneurs

Pendant la période d'étude (Mai à Octobre 2013), 127 donneurs de sang ont été prélevés, parmi lesquels il y avait 93 hommes (73.22%) et 34 femmes (26.78%) avec un sexe ratio de 2.7. La prévalence des dons était statiquement plus élevée chez les hommes que chez les femmes (P<0.005). L'âge moyen des donneurs était de 31.32 ans. La répartition des donneurs par type de don montre 89 donneurs familiaux (70%) et 38 donneurs bénévoles (30%). La **figure 1** ci-dessous présente la répartition des donneurs selon le sexe.

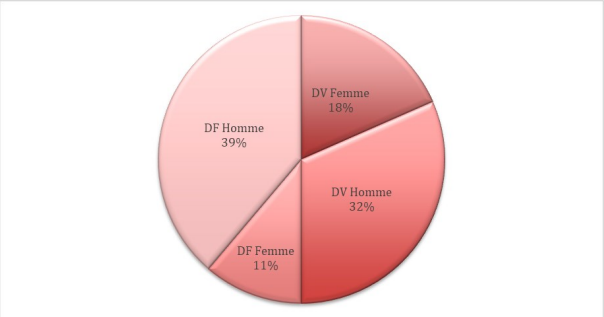

Figure 1. Répartition des donneurs de sang par type de don et par sexe (DV: donneur volontaire, DF: donneur familial)

Caractéristiques de l'hémogramme chez les donneurs

Les t**ableaux 1** et **2** ci-dessous montrent les résultats de l'hémogramme chez les donneurs de sang. On remarque qu'il existe quelques valeurs en deçà et au-delà des valeurs standards.

Tableau 1. Tableau récapitulatif des paramètres de l'hémogramme chez les donneurs de sang.

Parametres	Moy	Max	Min	Med
GB (x10^9/l)	5.38±1.54	11.60	2.60	5.00
LYM (%)	40.40±8.56	65.30	21.50	40.10
MON (%)	10.41±3.56	21.80	2.80	10.30
GRAN (%)	49.19±9.39	73.40	21.40	49.20
LYM (x10^9/l)	2.13±0.65	4.60	0.80	2.00
MON (x10^9/l)	0.56±0.26	1.30	0.10	0.50
GRAN (x10^9/l)	2.68±1.05	5.90	0.80	2.50
GR (×10^6/mm^3)	5.21±0.73	8.010	3.50	5.11
Hb (g/dl)	13.85±1.93	19.40	9.00	14.10
HCT (%)	45.30±0.62	62.00	28.80	45.80
VGM (fL)	87.00±7.42	102.60	66.10	87.90
TCMH (pg)	26.56±2.23	32.70	19.50	26.60
CCMH (g/dl)	30.45±2.14	32.60	12.50	31.00
IDR-CV (%)	11.26±1.46	16.40	8.90	10.90
IDR-DS (fL)	42.06±9.40	67.50	12.70	39.10
PLT (x10^9/l)	202.8±58.47	419.0	47.0	203.0
VPM (fL)	11.88±2.05	14.40	0.26	12.50
IDP (fL)	11.50±2.33	16.50	0.00	10.90
PCT (%)	0.2472±0.11	0.800	0.060	0.240

Tableau 2. Répartition de l'échantillon en fonction des valeurs de référence (VR)

Parametres	VR	< VR	> VR	>VR >
GB (×10^9/l)	4-10	19 (14.96%)	1 (0.79%)	107 (84.25%)
GR (×10^9/l)	3.55-5.5	0 (0%)	49 (38.58%)	78 (61.42%)
Hb (g/dl)	>12 -13*	9 (7.09%)	32 (25.20%)	86 (67.71%)
HCT (%)	36-48	9 (7.09%)	41 (32.28%)	77 (60.63%)
VGM (fL)	80-100	19 (14.96%)	6 (4.72%)	102 (80.32%)
TCMH (pg)	26-32	45 (35.43%)	2 (1.57 %)	80 (63%)
CCMH (g/dl)	30-36	14 (11.02%)	0 (0%)	113 (88.98%)
PLT (×10^9/l)	100-300	4 (3.15%)	8 (6.30%)	115 (0.55%)

GB = Globules Blancs, LYM = lymphocytes, MON = monocytes, GRAN = granulocytes, GR = Globules Rouges, Hb = Hémoglobine, HCT = Hématocrite, VGM = Volume Globulaire Moyen, TCMH = Teneur Corpusculaire Moyenne en hémoglobine, CCMH = Concentration Corpusculaire Moyenne en Hémoglobine, IDR-CV = Indice de Distribution des Rouges-Coefficient de Variation, IDR-DS = Indice de Distribution des Rouges-Déviation Standard , PLT = Plaquettes, VPM = Volume Paquettaire Moyen, IDP = Indice de distribution des plaquettes, TCT = Thrombocrite.

Sur les 127 donneurs de sang et en prenant un taux d'hémoglobine inférieur à 13 g/dl chez l'homme et 12 g/dl chez la femme, nous avons 28.34% d'anémiés dans notre population d'étude soit 36 donneurs de sang. Parmi ces anémiés, 12% (4 donneurs) devraient être d'office écartés du don de sang à cause du taux d'Hb inférieur à 11 g/dl. Ces 36 donneurs anémiés se répartissaient en 29 sujets de genre masculin (81%) et 7 de genre féminin (19 %), soit un sexe ratio de 4.14 en faveur des hommes. Il est remarquable que 21% des femmes donneuses de sang sont anémiées contre 31% d'hommes. L'âge moyen des donneurs anémiés était de 34.5 ans avec des extrêmes allant de 17 à 44 ans. La répartition morphologique des anémies chez les 36 donneurs montre une anémie microcytaire hypochrome chez 20 donneurs (55.6%). Globalement, les caractéristiques morphologiques des anémies chez les donneurs, montre en moyenne une anémie normochrome normocytaire. Dans notre série, les « donneurs dits réguliers » (nombre de dons ≥ à 3 dons) représentaient 26.35% des donneurs anémiés (soit 9 donneurs). Ces donneurs à cause de leur phénotype rare (Facteurs rhésus négatifs notamment) seraient abusivement sollicités par les banques de sang sans tenir compte du délai moyen entre deux dons, occasionnant ainsi une déplétion martiale source d'anémie hypochrome. Les résultats de l'hémogramme ont montré une macrocytose chez 6 donneurs (4.72%) avec une moyenne de VGM de 125 fl. L'analyse du nombre des globules rouges montre des valeurs variant entre 3.5- 8.010 x10^{12}/l avec une moyenne de 5.21 ± 0.73 x10^{12}/l. Une polyglobulie était dépistée chez 49 donneurs (38.58%). L'absence de microcytose et d'hypochromie n'a pas été prouvée chez ces donneurs.

L'analyse de la lignée leucocytaire chez les donneurs de sang montre un taux de globules blancs variant entre 2.60 et 11.60 x10^9/l. Près de 84.25% ont un taux de globules blancs dans les normes.

Des anomalies du taux des globules blancs sont notables chez 15.75 % des donneurs. Il s'agit de leucopénie (14.96%), granulopénie (24.44%), lymphocytose (0.79%) et de leucocytose (0.79%). Cependant l'hémogramme ne signale aucun cas de monocytose, de granulocytose et de lymphopénie dans notre série.

L'étude des plaquettes ne fait ressortir aucun cas d'anomalie chez 90.55% des donneurs. Près de 9.45% présentent des anomalies. Il s'agit de thrombopénie (3.15%) et de thrombocytose (6.30%). Cependant, aucun cas d'ecchymoses et de saignement n'a été signalé par les 4 donneurs chez les quels une thrombopénie a pu être notée.

DISCUSSION

Les paramètres érythrocytaires

L'anémie microcytaire hypochrome chez les donneurs anémiés était de 55.6%. Cela pourrait s'expliquer par l'incidence de pathologie de l'hémoglobinosynthèse (carence martiale, cause inflammatoire, dysérythropoièse). I Keita et coll[4] dans une étude au CNTS de Bamako, trouvent une fréquence de 17.5% de microcytose chez les donneurs de sang. Dans cette étude l'hypochromie était la plus fréquente chez les anciens donneurs (46.4%) comme dans notre étude (44.4%) et la microcytose sans anémie qui a la même orientation diagnostique que l'anémie microcytaire a été retrouvée dans 13.5% des cas.[4] Ces résultats confirment la fréquence élevée des anémies microcytaires chez les donneurs de sang en milieu tropical, probablement due à la déplétion martiale[5] les carences en fer, les pathologies inflammatoires et certaines hémoglobinopathies. Plusieurs auteurs ont rapporté une diminution des valeurs des paramètres érythrocytaires chez les donneurs réguliers de sang.[4-6] Cette diminution par contre serait inversement proportionnelle au nombre de dons dans certaines études.[4] Car si dans la majorité des cas, plus le nombre de dons est élevé, plus on note une tendance à l'anémie, hypochrome et à la microcytose, cette tendance serait statistiquement non significative dans certaines études.[4,7,8]

Les résultats de l'hémogramme ont montré une macrocytose chez 6 donneurs dans notre étude (4.72%). La carence en acide folique par l'alcoolisme serait à la base de certaines macrocytoses. Dans ce cadre, les résultats de certaines études ont été les suivants:

- il n'y avait pas d'influence de la prise d'alcool sur le taux d'hémoglobine ou l'hématocrite;
- il existait une diminution du nombre de globules rouges et une augmentation du VGM dose-dépendantes et significatives même pour une consommation d'alcool occasionnelle[9]

Chez les donneurs de sang, la détermination de l'hémoglobine prédon peut être donc un moyen de dépistage de certaines pathologies érythrocytaires pouvant orienter certains donneurs anémiés vers des services spécialisés pour des examens complémentaires en vue d'une prise en charge adéquate.

L'analyse du nombre des globules rouges montre des valeurs variant entre 3.5-8.010 $x10^{12}$/l avec une moyenne de 5.21 ±0.73 $x10^{12}$/l. Une polyglobulie probablement secondaire à une sécrétion inappropriée d'érythropoïétine était dépistée chez 49 donneurs (38.58%). L'absence de microcytose et d'hypochromie n'a pas été prouvée chez ces donneurs.

L'analyse des paramètres érythrocytaires de l'hémogramme montre dans certaines études, qu'il n'y pas de différence significative quant au nombre de globules rouges (P=0.84) et le taux d'Hb (P=0.07) chez les donneurs de sang. Cependant le taux d'hématocrite était statistiquement différent ainsi que la valeur des constantes de Wintrobe entre les cas et les témoins.[4]

Les paramètres leucocytaires

L'analyse de la lignée leucocytaire chez les donneurs de sang montre un taux de globules blancs variant entre 2.60 et 11.60 $x10^9$/l. Ce taux était normal chez 84.25% de donneurs. Dans la même série, on notait une leucopénie chez 14.96% de donneurs et seulement 0.79% de leucocytose. Dans certaines études[4] les valeurs des paramètres de la lignée leucocytaire étaient globalement plus élevées chez les témoins et cette différence était statistiquement significative pour le nombre des leucocytes, le nombre des polynucléaires neutrophiles et des monocytes.[4] Cependant, les valeurs moyennes des leucocytes n'étaient pas liées au nombre de dons dans cette étude. Notre étude ne rapporte aucun cas de neutrophilie chez les donneurs de sang mais rapporte par contre 24.41% de neutropénie.

Les efforts physiques, la digestion et les stress sont recensés comme causes de polynucléose chez les donneurs de sang.[10,11] Les seules variations nycthémérales qui ont une importance clinique sont celles des différents types de leucocytes. Ces variations peuvent expliquer certaines différences constatées par exemple entre un hémogramme réalisé le matin, et un hémogramme réalisé le soir. Ces données sont en faveur d'un horaire standardisé et a priori matinal pour les prélèvements.[9-11]

Dix-neuf (19) donneurs soit 14.96% ont une leucopénie dans cette étude. Dans la plupart des études, les anomalies les plus fréquentes chez les donneurs sont la leucopénie, la lymphopénie et la neutropénie. Cependant, la neutropénie ethnique est bien établie chez les

inutiles à condition que cette neutropénie, habituellement modérée (PNN<1800/mm3), soit isolée cliniquement, hématologiquement et bien tolérée (pas de notion d'infections sévères ou à répétition).[9]

Le taux des plaquettes

L'analyse des plaquettes fait ressortir que 3.15% des donneurs ont une thrombopénie tandis que 6.29% ont une Thrombocytose. Toutefois, le prélèvement devrait être repris sur un autre anticoagulant tel que le citrate pour écarter une éventuelle fausse thrombopénie liée à l'utilisation de l'EDTA.[10] Le nombre de dons n'aurait pas une influence sur les valeurs moyennes des plaquettes.[4] Il a été cependant rapporté que la production de thrombopoiétine est paradoxalement plus basse chez la femme.[4,5,9] Par ailleurs, nous avons observé trois de cas de malaise (vertiges) après le don dont deux femmes et un homme. Deux de ces cas avaient des valeurs d'hémoglobine et d'hématocrite inférieures à celles requises par l'OMS et l'Organisation Panafricaine de la Santé (OPS) pour donner le sang.[10]

CONCLUSION

Dans cette étude, nous avons déterminé le profil de l'hémogramme chez les donneurs de sang à l'Hôpital Régional de Bafoussam et aux Cliniques Universitaires des Montagnes. Elle révèle particulièrement l'intérêt de la mesure systématique de l'hémoglobine pré-don. Le profil de l'hémogramme nous a permis de déceler les anomalies de globules rouges, de globules blancs, de plaquettes et des constantes érythrocytaires. Si certaines anomalies ont des conséquences immédiates, d'autres cependant peuvent engendrer le dysfonctionnement physiologique à long terme d'où la nécessité de leur dépistage au cours des dons pour préserver la santé du donneur et assurer la qualité des produits sanguins.

Ainsi, au vu de ses multiples indications, le dépistage de l'anémie, le diagnostic d'un syndrome infectieux, le diagnostic d'un syndrome hémorragique et la recherche des atteintes associées des différentes cellules sanguines, l'hémogramme serait une exploration complémentaire à recommander chez certains donneurs de sang en fonction du contexte. A défaut de réaliser systématiquement tous les paramètres de l'hémogramme, le dosage de l'hémoglobine et la mesure de l'hématocrite doivent être faits de façon périodique chez les donneurs réguliers pour la surveillance d'une éventuelle déplétion martiale.

Cette étude recommande un contrôle d'hémoglobine pré-don chez tous les candidats à un don de sang quelle que soit le sexe, le type de don et sa fréquence.

L'hémogramme pourra être recommandé chez le donneur dont le dernier prélèvement analysé laissait apparaitre un taux d'hémoglobine à la limite des seuils, soit 12 et 12.5 g/dl pour les femmes et entre 13 et 13.5 g/dl pour les hommes et le donneur qui, lors de l'entretien médical, révèle une anamnèse clinique en faveur d'une anémie.

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Sécurité transfusionnelle : évaluation du rôle de la sélection médicale des candidats au don de sang dans la prévention des infections transmissibles par le sang au Centre Régional de Transfusion Sanguine Analamanga -Madagascar

Transfusion safety: assessment of medical selection to prevent blood-borne infections at the Analamanga Transfusion Center - Madagascar

Tsatoromila FA[1], Batavisoaniatsy EE[2], Razanadrakoto I[3], Rakoto AO[4], Rasamindrakotroka A[5], Randriamanantany ZA[6]

[1] CRTS Analamanga, HJRA Antananarivo, Madagascar
[2] CHU Anosiala , Ambohidratrimo Antananarivo, Madagascar;
[3] CRTS Vakinankaratra , CHRR Antsirabe , Madagascar
[4] UPFR Hématologie, CHU-JRA Antananarivo, Madagascar
[5] Laboratoire de Biologie Médicale Faravohitra Antananarivo, Madagascar
[6] Direction de la Transfusion Sanguine Madagascar

Corresponding author: Batavisoaniatsy EE (elodie.kwely@gmail.com)

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Key Words: blood donors, infectious risks, selection, transfusion

Mots clés: donneurs de sang, risques infectieux, sélection, Transfusion, Madagascar

ABSTRACT

Introduction: To prevent blood-borne infections, the aim of this study is to evaluate the effectiveness of pre-donation medical screening in the Analamanga Transfusion Center.

Methods: During the 1st term 2019, an observational-prospective study was carried out, by comparing seroprevalence of the 4 infectious agents in both accepted and deferred blood donors. HBs Ag and HCV antibodies were assessed by ELISA technique, while detection of HIV antibodies was performed by immunochromatographic test. The presence of treponemal antibodies was detected by agglutination test. Data were validated and analyzed using Microsoft Excel an Epi Info 7.0.

Results: Medical selection authorised 3638/4228 donors (86.01%). Deferral was more likely in males. All deferred candidates were registered on fixed site, whereby 94.29% were family replacement donors. Sexual behaviors and dermatosis were the leading causes of deferrals. The prevalence was higher in the deferred candidates for HBs Ag (32.86% vs. 2.38%) and HCV antibodies (10% vs. 0.34%) but any HIV infection was registered among them.

Conclusion: Current medical selection is efficient to exclude candidates with risk of HBV and HCV.

RÉSUMÉ

Introduction: Dans la prévention des infections transmissibles par la transfusion, l'objectif de l'étude est d'évaluer l'efficacité de la sélection médicale pré-don chez les candidats au don de sang du CRTS Analamanga.

Méthodes: Une étude prospective observationnelle a été effectuée au premier trimestre de 2019. Il s'agit d'une comparaison des prévalences de 4 agents infectieux transmissibles par la transfusion, chez les donneurs autorisés et les candidats exclus. Un test ELISA a été performé pour l'Ag HBs et les anticorps anti-VHC. Les anticorps anti-VIH étaient screenés par test immunochromatographique. Les tests RPR et TPHA ont été utilisés pour la syphilis. L'analyse statistique a été faite sur Microsoft Excel et Epi Info 7.0

Résultats: La sélection médicale a permis d'autoriser 3638/4228 donneurs soit 86.01%. L'âge moyen est plus élevé chez les donneurs autorisés avec prédominance masculine dans les 2 groupes. Tous les candidats exclus ont été vus en site fixe dont 94.29% étaient des donneurs familiaux de remplacement. Les comportements sexuels à risque et les dermatoses ont été les principaux motifs d'exclusion. La prévalence était plus élevée chez les candidats exclus pour l'Ag HBs (32.86% contre 2.38%) et les anticorps anti-VHC (10% contre 0.34%). Aucune infection par le VIH n'a été retrouvée chez les candidats exclus.

Conclusion: Cette étude a permis de montrer l'efficacité des procédures actuelles de sélection au don, vis -vis du VHB et du VHC. Le faible taux de donneurs bénévoles réguliers demande une sélection médicale plus stricte qui est à balancer avec le risque potentiel de pénurie de donneurs.

INTRODUCTION

Le don de sang reste à présent une source possible de produits sanguins cellulaires et de plasma frais congelé[1]. Les programmes de l'Organisation Mondiale de la Santé (OMS) placent la sécurité transfusionnelle parmi les priorités stratégiques en Afrique.[2,3] Ses objectifs sont axés sur la maîtrise du risque immunologique lié à la transfusion et à la réduction des infections transmissibles par la transfusion[4] L'OMS encourage différentes stratégies dans les pays à ressources limitées comme Madagascar pour assurer la sécurité transfusionnelle. Ces stratégies regroupent la coordination et l'organisation au niveau national d'une politique de sécurité transfusionnelle commune, la promotion du don de sang chez des donneurs réguliers, volontaires et non rémunérés, le dépistage des agents infectieux transmissibles par transfusion, la détermination du groupage sanguin et le bon usage des produits sanguins labiles.[3,5]

Dans les pays occidentaux, une diminution significative de la prévalence des infections virales transmissibles par le sang a été notée depuis quelques décennies. En Afrique par contre, un risque résiduel élevé de leur transmission persiste.[6] La sélection médicale au don est un des moyens avancés pour assurer la sécurité transfusionnelle. Son but est de réduire autant que possible le risque de transmission des infections du donneur vers le receveur[4], en écartant les donneurs de sang en fenêtre sérologique silencieuse.[7] Différents moyens stratégiques sont adoptés par chaque pays: dans les pays développés on peut avoir recours à des auto-questionnaires, des supports audiovisuels et informatiques.[8] A Madagascar, la sélection médicale au don de sang se fait uniquement par un entretien pré- don entre un personnel médical et le candidat. Une fiche de sélection à l'usage des personnels ayant bénéficié d'une formation à la sélection au don de sang comporte les principaux items selon la politique nationale de la transfusion.

Cependant, des candidats à risque infectieux échappent à la sélection médicale, si bien que les examens sérologiques faits sur le don de sang reviennent positifs. A Madagascar, la prévalence des infections virales transmissibles par le sang chez les donneurs de sang varie de 0.47% pour le Virus de l'Immunodéficience Humaine (VIH) à 3.21% pour le Virus de l'Hépatite B (VHB).[9]

OBJECTIFS DU TRAVAIL

Le but de ce travail est d'évaluer l'efficacité de la sélection médicale au don de sang, en comparant la prévalence de 4 agents infectieux transmissibles par le sang : VIH, VHB, Virus de l'Hépatite C (VHC) et l'agent de la syphilis chez deux groupes de population qui sont les candidats exclus et les candidats éligibles au don, au Centre Régional de Transfusion Sanguine (CRTS) Analamanga – Antananarivo.

MATÉRIEL ET MÉTHODE

Une étude prospective observationnelle et analytique a été menée au Centre Régional CRTS Analamanga du 1er Février au 31 Avril 2019.

Nous avons inclus tous les candidats au don ayant passé la sélection médicale faite par le médecin en site fixe ou en site mobile. A l'issue de l'entretien, deux groupes ont été répertoriés : les donneurs autorisés pour lesquels aucun motif d'exclusion n'a été renseigné, et les candidats exclus avec un motif d'exclusion temporaire ou définitif. Un prélèvement de sang veineux sur tube EDTA a été effectué pour la sérologie chez le donneur exclu ayant donné son consentement. Pour les donneurs autorisés, la sérologie a été faite sur les échantillons habituels pour tout donneur de sang.

Les variables étudiées ont été la prévalence e des 4 infections transmissibles par la transfusion : l'infection par le Virus de l'Immunodéficience Humaine (VIH), le Virus de l'Hépatite B (VHB), le Virus de l'Hépatite C (VHC) et la syphilis. La sérologie a été effectuée par technique immuno-enzymatique avec les trousses Rapid Labs® pour la recherche des anticorps anti-VHC et de l'antigène HBs du VHB. De même, la syphilis a été dépistée par le coffret Rapid Plasma Reagin de Rapid Labs®. L'infection par le VIH a été dépistée par un test de diagnostic rapide Alere-Determine™ HIV 1/2.

Les autres variables étudiées ont été le type de don, l'âge et le genre dans chaque groupe. Pour les candidats exclus, le motif d'exclusion sur la fiche de sélection médicale a été enregistré. L'anonymat conformément aux principes éthiques du don de sang en vigueur à Madagascar a été respecté pour les donneurs éligibles au

don, tandis qu'un consentement écrit après explication verbale a été fait pour les donneurs exclus. Les analyses statistiques ont été faites sur Epi Info, en utilisant le test de Chi 2 et analysant l'Odds Ratio pour évaluer le risque entre les deux groupes. L'intervalle de confiance est de 95% et le p-value est significatif s'il est inférieur à 0.05.

RÉSULTATS

Sur une période de 3 mois, 4228 candidats ont été vus au CRTS Analamanga – Antananarivo. La sélection médicale a permis d'autoriser 3638 donneurs soit un taux d'exclusion de 13.95%. Parmi les 590 donneurs exclus, 70 ont donné leur consentement. Parmi les 3638 sélectionnés, nous avons exclus 149 donneurs ayant eu un malaise au cours du prélèvement ou n'ayant pas pu remplir les poches et donc n'ayant pas eu un échantillon pour la sérologie. (Explication: étant donné que notre CRTS travaille encore sur des poches doubles sans le compartiment pour les premiers millilitres, nous n'avons pas pu prélever des échantillons pour la sérologie pour les poches non remplies ou en cas de malaise.)

Au total, 3559 candidats ont été inclus composés de 3489 donneurs autorisés et 70 candidats exclus. L'âge moyen dans chaque groupe a été de 34.87 ±11.33 ans chez les donneurs autorisés contre 29.02 ± 8.90 ans chez les candidats exclus. Une prédominance masculine a été retrouvée dans les deux groupes avec un sex ratio homme/ femme de 2.5 chez les donneurs éligibles et 2.7 chez les donneurs exclus. Les donneurs familiaux de remplacement ont été prédominants pour chaque groupe. Tous les candidats exclus ont été vus en site fixe. Les caractéristiques des deux groupes de candidats sont décrites dans le **Tableau 1**. Pour les candidats exclus au don les motifs d'exclusion ont été principalement dominés par les comportements sexuels à risques (2.,71%) et les dermatoses (11.43%) selon la **Figure 1**.

Les résultats de la sérologie ont montré qu'un des 4 marqueurs infectieux est au moins positif chez 3.26% des donneurs autorisés (114/3489) contre 37.14% chez les candidats exclus au don (26/70). Le candidat exclu présentait 1.54 fois plus de risque de positivité que le donneur autorisé à l'égard des 4 agents infectieux transmissibles par la transfusion sanguine (Odds Ratio=19.28). Aucune co-infection n'a été retrouvée dans les deux groupes. La

Tableau 1. Caractéristiques des deux groupes de candidats au don de sang

	Donneurs autorisés n =3489	Donneurs exclus n =70	Comparaison (p)
Age moyen (ans)	34.87 ±11.33	29.02 ± 8.90	0.009
Minimum	18	19	
Maximum	72	56	
Sex ratio (H/F)	2.5	2.7	0.358
Site de collecte (%)			0.001
Site mobile	8.28	-	
Site fixe	91.72	100	
Type de dons (%)			0.003
Donneurs Bénévoles Réguliers	13.01	1.42	
Nouveaux Donneurs Bénévoles	8.89	4.29	
Donneurs Familiaux	78.10	94.29	

Figure 1. Principaux motifs d'exclusion des candidats au don

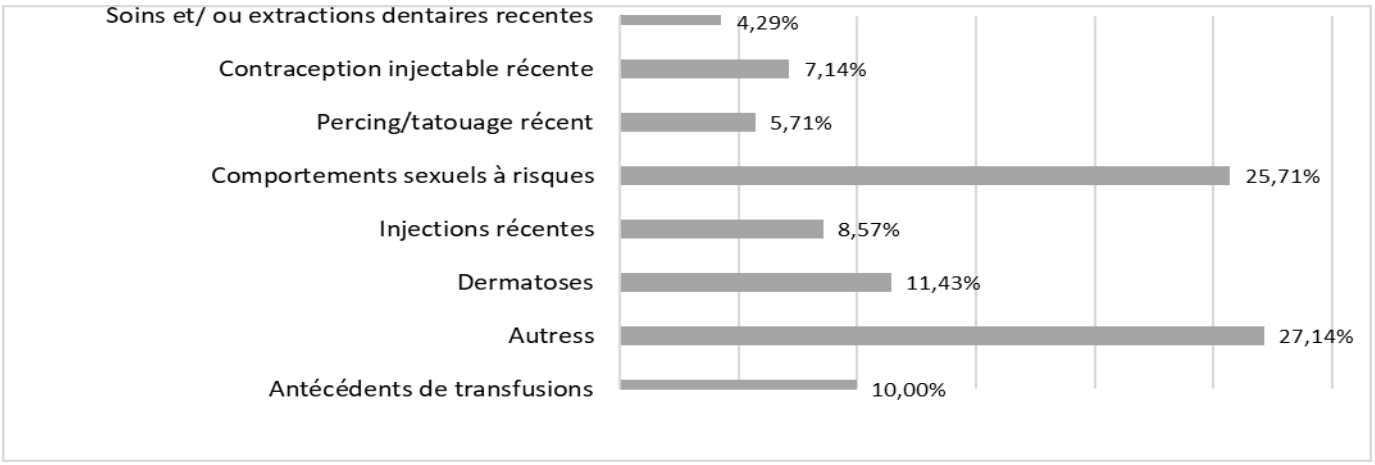

Tableau 2. Comparaison de la prévalence des 4 agents infectieux

Infections	Donneurs autorisés n =3489	Donneurs exclus n =70	Comparaison (p)
Positivité globale (%)	**3.26 (114)**	**37.14 (26)**	0.0001
VHB positif	2.38 (83)	28.57 (2)	0.0001
VHC positif	0.34 (12)	7.14 (5)	0.0001
VIH positif	0.34 (12)	-	0.39
Syphilis positive	0.20 (7)	1.43 (1)	0.07

prévalence était plus élevée chez les candidats exclus pour l'Ag HBs (28.57% contre 2.38% ; *p*=0.0001) et les anticorps anti-VHC (7.14% contre 0.34% ; *p*=0.0001). Tous les cas positifs de l'infection par le VIH ont concerné les donneurs autorisés avec une prévalence de 0.34% (12/3489; *p*=0.39). Un cas de syphilis a été confirmé chez les candidats exclus (**Tableau 2**).

DISCUSSION

Les auteurs ont mené une des premières études sur le rôle de la sélection médicale au don de sang à Madagascar. En effet, la majorité des données relatives au don de sang sont axées sur la prévalence des marqueurs infectieux chez les donneurs autorisés.[9-11] A travers cette étude, nous avons pu soulever les problématiques relatifs à la sélection médicale au don. Si le principal objectif de la sélection est d'exclure les potentiels donneurs à risque de transmission d'infection, sa principale limite réside aussi dans le risque d'exclure des candidats qui , au final ne présente aucune infection transmissible par le sang.[12,13] La hantise serait d'avoir une pénurie de donneurs dans un pays comme le nôtre où le don bénévole régulier ne constitue que 25% des dons de sang.[14]

Au premier trimestre de 2019, la sélection médicale au don au niveau du CRTS d'Analamanga a permis d'exclure 13.95% des candidats au don de sang. Dans le monde, ce taux d'exclusion est variable d'un pays à l'autre, et même au sein des différentes régions du même pays. Le taux d'exclusion à Madagascar est comparable à celui de certains pays africains comme la Tanzanie où il est de 12.7%[12], en Côte d'Ivoire avec 10.8% d'ajournement.[15] Au Zimbabwe, le taux est plus faible avec 7% d'exclusion.[16] Dans différentes régions au Japon, le taux d'exclusion varie de 4.6 % à 30%.[17] Cela s'expliquerait parla variabilité de la prévalence des infections transmissibles par le sang dans les différentes régions du pays. Ainsi, un approfondissement des différents motifs d'exclusion aiderait dans la compréhension de cette variabilité.

Une prédominance masculine a été retrouvée chez les donneurs exclus du CRTS Analamanga, avec un âge moyen de 29.02 ans dont près de 95% sont des donneurs familiaux de remplacement. La même observation est retrouvée en Tanzanie avec un taux d'exclusion de 15% chez les hommes contre 12% chez les femmes.[12] En Afrique, les hommes sont majoritairement sollicités pour le don de sang. En Chine, une prédominance masculine chez les donneurs ajournés est notée notamment dans les tranches d'âge de 18 à 45 ans.[18] La proportion des primo-donneurs de 26 à 55 ans a un fort risque de séropositivité par rapport aux infections transmissibles par la transfusion. A Madagascar, seuls 27.90% des donneurs de sang vus au CNTS Antananarivo sont des femmes[9] ce qui justifierait cette tendance masculine retrouvée chez les candidats ajournés. La forte proportion des donneurs familiaux de remplacement reflète le manque de sensibilisation l'égard du don bénévole régulier dans la population Malagasy; seuls 25% des donneurs à Madagascar sont bénévoles.[14] Cette situation est commune aux pays à ressources limitées. Quelques pays comme le Zimbabwe et la Tanzanie arrivent tout de même à avoir un taux de donneurs bénévoles non rémunérées à 90%.[12,19]

Les comportements sexuels (25.71%) constituent le principal motif d'exclusion à l'issue de l'entretien médical chez les candidats exclus de notre série, suivis des dermatoses (11.43%). Les critères d'exclusion au don se basent sur des paramètres cliniques et épidémiologiques du pays concerné.[1] En Occident, ces motifs d'exclusion sont définis sur base de consensus professionnel national et international. Cette sélection cherche à identifier les affections contre-indiquant le prélèvement par souci de protection du donneur , mais aussi à dépister les infections transmissibles par la transfusion par souci de protection du receveur.[1] Les principaux critères à rechercher sont une séropositivité connue du candidat ou de son partenaire sexuel, des comportements à risque d'exposition aux agents infectieux , les conduites à risque ou l'exposition ponctuelle dans les 4 ou 6 derniers mois ainsi que les expositions nosocomiales.[1]

La positivité globale de la sérologie a été de 37.14% des donneurs exclus contre 3.26% chez les donneurs autorisés (*p*=0.0001). Le candidat exclu a 1.54 fois plus de risque d'être séropositif aux agents infectieux transmissibles par la transfusion. On peut ainsi apprécier l'efficacité de la sélection médicale à exclure les candidats à risque infectieux. Les résultats plus détaillés montrent cette efficacité notamment vis-à-vis du VHB et du VHC. Au Sénégal le

candidat exclu présentait 4.94 fois de risque d'être séropositif pour un des marqueurs sérologiques évalués[20] comparés aux donneurs autorisés. Cela signe une efficacité de la sélection médicale, qui reste une activité importante d'un centre de transfusion sanguine comme le nôtre.[3] En France, l'efficacité de la sélection des donneurs a été appréciée devant la réduction continue, depuis les deux dernières décennies, du risque résiduel et de la faible incidence des infections chez les donneurs de sang par rapport à la population générale.[4] Selon Tagny CT *et al* ,la politique de sécurisation de la transfusion sanguine en Afrique francophone tient compte du grand nombre de donneurs et d'une sélection médicale au don efficace.[6,21] L'impact économique réside dans la limitation du coût des activités transfusionnelles liées à la destruction des poches prélevées mais qui sont séropositives.

L'autre volet de la sélection médicale aussi serait qu'au Sénégal, 84.8% des candidats exclus seraient au final séronégatifs à l'égard de ces infections.[20] Dans notre observation, cette proportion de candidats a été de 62.36%. Il est ainsi nécessaire de faire une révision régulière des questionnaires de sélection pour assurer la sécurité du don mais aussi pour minimiser cette perte de potentiels donneurs. La politique adoptée dans plusieurs pays est actuellement de recruter des donneurs volontaires à faible risque et d'optimiser la sélection médicale. Cela a permis de réduire la prévalence des agents infectieux chez les donneurs de sang.[22] Selon Seck M *et al* , la prévalence du VHB est de 7.35% chez les donneurs de sang contre 14% dans la population générale sénégalaise.[20]

La prévalence de l'Ag HBs chez les candidats exclus était plus importante que chez les donneurs acceptés (28.57% contre 2.38%). Cette forte proportion du portage de l'Ag HBs diffère des antériorités du pays. En effet , la prévalence du VHB chez les donneurs de sang à Analamanga a été de 4.37% en 1993[10] et 3.21% en 2010.[9] Dans la population générale Malgache, le portage aigu ou chronique de l'antigène HBs est estimé à 23% en 2000.[23] Madagascar est ainsi placé parmi les pays à haute endémicité du VHB. La transmission verticale et horizontale sont les principaux modes de transmission décrits rendant 10 à 35% des enfants de moins de 5ans porteurs de l'antigène HBs. Cela pourrait expliquer la forte proportion de positivité de l'infection par le VHB chez nos candidats exclus. L'instauration récente de la vaccination contre le VHB dans le cadre du Programme Elargi de Vaccination pourrait expliquer ce constat, laissant non couverte une tranche d'âge majoritaire de nos donneurs. Une étude de suivi de la prévalence du VHB chez les jeunes Malgaches depuis l'instauration du vaccin obligatoire contre le VHB serait intéressante. Dans le monde, le VHB touche 350 millions d'individus en portage chronique[24] avec une faible prévalence de 0.65% dans les pays occidentaux.

Actuellement, la détection de l'Ag HBs reste le seul moyen permettant de dépister l'infection par le VHB chez les donneurs de sang à Madagascar.

L'efficacité de la sélection pour exclure les porteurs du VHC est tout aussi importante que pour l'infection par le VHB. La prévalence du VHC chez les donneurs exclus est plus importante (7.14%) que chez les donneurs autorisés (0.34%). Cependant, la prévalence du VHC chez les donneurs de sang Malgaches reste faible comparée aux autres pays. En 2010, l'infection par le VHC touche 0.98% des primo-donneurs à Antananarivo.[9] Au Sénégal, aucune différence significative n'a été retrouvée entre les donneurs autorisés et les candidats exclus.[20] Elle concerne 1,4% des donneurs de sang à Dakar.[20] En France, le risque résiduel dans les dons de sang est de 1 don sur 14 millions[5] où la prévalence de la maladie dans la population générale est de 0.84%. Les techniques de dépistage de l'infection par le VHC actuellement sont basées sur les techniques immuno-enzymatiques. Le test ELISA est le test de dépistage le plus utilisé pour le VHC. Elle permet de dépistage un grand nombre d'échantillons dans la pratique quotidienne. Au CRTS Analamanga, cette méthode est bien maitrisée par l'équipe du laboratoire, même si elles sont décrites comme étant d'usage difficile pour les pays à ressources limitées, étant donné leur coût et leur technicité.[25]

Aucune infection par le VIH n'a été retrouvée chez les candidats exclus contre 0.34% chez les donneurs autorisés. Cette différence n'est cependant pas statistiquement significative. Malgré la forte prévalence de l'infection par le VIH en Afrique Subsaharienne, peu de données sur le risque de transmission de cette pathologie par la transfusion sanguine existent.[22] Selon l'OMS, la transfusion sanguine est responsable de 5% de la transmission du VIH en Afrique Subsaharienne.[21] Le risque persistant de transmission est notamment lié aux dons collectés pendant la période de fenêtre sérologique. Ainsi seule la détection du génome viral par la biologie moléculaire permet de les dépister les donneurs. Ceci n'est pas encore le cas de Madagascar. La technique actuellement utilisée est la combinaison des techniques cherchent les anticorps anti-VIH et l'antigène p24 (Ag p24). Ceci permettrait de réduire la fenêtre sérologique mais pas plus que les techniques de biologie moléculaire.[22] La prévalence du VIH chez les donneurs de sang Malgaches reste faible, comparée à celle des autres pays africains, avec 0.34% dans notre observation et 0.47% en 2010[9] chez les premiers dons à Analamanga. En Afrique, l'infection par le VIH touche 1.75% des donneurs de sang au Sénégal,[20] 1.62% au Niger[29] et 1.80% au Burkina Faso.[30] En Europe et les pays occidentaux, le risque résiduel du VIH au cours de la transfusion est devenu extrêmement faible avec un don concerné pour 3.5 millions en 2013.[31]

La syphilis est rare chez les donneurs de sang. Sa prévalence dans notre étude est de 0.20% chez les donneurs autorisés contre 1.43% chez les donneurs exclus. En 1993, la syphilis touche 7.31% des dons de sang vus à Antananarivo.[10] Cette proportion a nettement diminué en 2010 qui est de 1.18%[9] ce qui est comparable à notre observation. Aucun cas de co-infection n'a été observé dans notre étude. La présence de telle co-infection est associée à un risque d'accélération de l'évolution de la maladie. Les études sur ces co-infections sont rares. En Inde la co-infection concerne 0.05% des donneurs de sang en 2017 dont la principale association touche le VHB et le VHC.[32]

CONCLUSION

Notre étude a permis d'évaluer l'efficacité de la sélection médicale au don à exclure les candidats à risque pour le VHB et le VHC. Dans la prévention du risque infectieux lié à la transfusion, il est tout de même important d'adapter régulièrement les critères de sélection en fonction de nos données épidémiologiques. Les autres stratégies de prévention du risque infectieux sont aussi importantes notamment l'usage de nouvelles techniques de qualification biologique des dons et les techniques de réduction des pathogènes. La sécurité infectieuse de la transfusion reste un challenge continu, nécessitant d'études plus approfondies.

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Transfusion Safety: Lessons Learned In Ibero-America And Considerations For Their Global Applicability

Sécurité transfusionnelle: Leçons Apprises en Amérique Latine et Considérations Relatives à Leur Applicabilité Mondiale

Cruz JR[1]

[1] Independent Consultant, Ashburn, VA. USA

Corresponding author: Jose Ramiro Cruz (jcruz62004@aol.com)

Key Words: blood safety, transfusion safety, blood donors, Human Health Index, Ibero-America

ABSTRACT

The safety of blood used for transfusions has historically been the main focus of the international health community. In the Americas, during the first decade of the 21st Century, the attention switched to the patients who need transfusions and to the individuals who donate blood, that is, to transfusion safety. Timely and universal access to blood components implied adequate availability to sufficient blood components by patients who require transfusions in every hospital of every country. Clinical conditions and local non-medical factors influence decisions to admit and transfuse ill individuals. Locally-developed pertinent transfusion guidelines contribute to better estimate blood needs. Replacement blood donation hinders access to blood stocked in the hospitals blood banks and results in excessive component expiry and financial losses. Focusing on patient transfusion needs and on patient outcomes permits implementing national blood collection, processing and distribution, in consonance with the national health system. Analyses of general health conditions, by using the national Human Health Indexes, and the operational characteristics of blood services, by using the blood center density index, permit identification of locally pertinent interventions to improve transfusion safety. For this article, the analytical approaches used in Ibero-America were applied to blood data from South-East Asian and African countries. Data collection and validation were identified as priorities for Asian countries. Estimating blood component requirements at the local level and adjusting blood collection, processing and distribution systems are important in Africa.

RÉSUMÉ

La sécurité du sang utilisé pour les transfusions a toujours été la principale préoccupation de la communauté internationale de la santé. Dans les Amériques, au cours de la première décennie du 21e siècle, l'attention s'est portée sur les patients qui ont besoin de transfusions et sur les donneurs de sang, c'est-à-dire sur la sécurité transfusionnelle. L'accès universel et opportun aux composants sanguins impliquait une disponibilité suffisante en suffisamment de composants sanguins pour les patients nécessitant une transfusion dans chaque hôpital de chaque pays. Les conditions cliniques et les facteurs non médicaux locaux influencent les décisions d'admettre et de transfuser des personnes malades. Les directives pertinentes en matière de transfusion développées localement contribuent à une meilleure estimation des besoins en sang. Le don de sang de remplacement empêche l'accès au sang stocké dans les banques de sang des hôpitaux et entraîne une péremption excessive des composants et des pertes financières. Se concentrer sur les besoins des patients en matière de transfusion et sur leurs résultats permet de mettre en place une collecte, un traitement et une distribution du sang au niveau national, conformément au système de santé national. Les analyses de l'état de santé général, en utilisant les index nationaux de la santé humaine, et les caractéristiques opérationnelles des services de transfusion sanguine, en utilisant l'indice de densité du centre du sang, permettent d'identifier des interventions localement pertinentes pour améliorer la sécurité transfusionnelle. Pour cet article, les approches analytiques utilisées dans la région ibéro-américaine ont été appliquées aux données sur le sang de pays d'Asie du Sud-Est et d'Afrique. La collecte et la validation des données ont été identifiées comme une priorité pour les pays asiatiques. L'estimation des besoins en composants sanguins au niveau local et l'ajustement des systèmes de collecte, de traitement et de distribution du sang sont importants en Afrique.

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INTRODUCTION

The international health community has historically focused on reducing the infectious potential of blood for transfusions, that is, on blood safety. The first World Health Assembly (WHA) resolution on blood services, adopted in 1975, sought to curtail commercial blood collection and plasmapheresis in developing countries. The concerns of the WHA were the possible negative consequences of such activities for donors' health and for the safety of the resulting products.[1, 2] The 1975 resolution urged countries to instead promote blood services based on voluntary blood donation (VBD) and to protect the health of both blood donors and recipients. It was not until 1987 that the WHA discussed blood safety issues again, as part of the global strategy for AIDS prevention and control,[3] approach that persisted within the World Health Organization (WHO) for two decades.[4-6] The strategy for AIDS control laid the groundwork for the Global Safe Blood Initiative and provided the framework for initial actions to strengthen blood services by the WHO African Region[7, 8] and the Pan American Health Organization[9] (PAHO). During the first decade of the 21st century, the WHA established a global plan for universal access to safe blood[10] with five components: a) development of nationally coordinated blood transfusion services, b) exclusive collection of blood from VBD, c) quality-assured laboratory testing, d) reduction of inappropriate transfusions, and e) implementation of quality blood collection and distribution systems.

In the Americas, by contrast, the First Pan American Conference on Blood Safety, held in 2003, developed an innovative plan to improve transfusion safety in the Region by 2010[11] through: a) proper collection and preparation of sufficient blood components, b) timely access to blood components for patients, c) highest level of safety for blood products, d) appropriate transfusion practices, and e) efficient use of national resources. The strategies were: a) planning and management of the national blood network system, based on local needs b) promotion of VBD, through user-friendly blood collection services, c) quality assurance based on locally pertinent standards, and d) appropriate use of blood and blood components based on hospital-adapted transfusion guidelines. This article reviews lessons learned from the implementation of the Regional Plan for Transfusion Safety in Ibero-American countries and provides insights on how those lessons may be applicable in other regions of the world. The article takes as points of departure the following key concepts:

Global blood safety is not a measure of the risk of transmission of infectious agents through transfusion, but actually the goal of attaining the safest possible blood for every patient in every country blood from voluntary altruistic donors only, to carry out universal, pertinent and precise laboratory blood testing, and to protect blood components from contamination during their preparation and storage. Local surveillance of transfusion-transmissible infections (TTI), training of blood service staff, national oversight by health authorities and collaboration among stake holders are considered basic in the quest for global blood safety.[12]

VBD is that which is made with the purpose of contributing to the national sufficiency and general timely access to blood, without the intention of benefiting a specific patient. Voluntary donors do not profit by collecting either money or other material benefits.[13]

Replacement blood donation (RBD) is that which is made on behalf of a specific patient in response to a hospital requirement and prior to that patient being admitted, treated or discharged by the hospital. The patients or their family members are responsible for recruiting replacement donors.[14]

Transfusion safety is the expression of the pursuit of global blood safety in a given population while ensuring the protection of both the individuals who donate blood and those who receive it, and also making efficient use of local resources. Maximum transfusion safety can be achieved when ethical principles, locally pertinent clinical guidelines, and quality assurance measures are applied.[15]

COUNTRY DATA

The 2016 WHO Global Status Report on Blood Safety and Availability [16] was used as the source of all country data for 2013. This publication contains information collected from 178 countries as part of the Global Data Base on Blood Safety. The national data are presented in 12 annexes which detail for each nation the numbers of blood centers, of whole blood donations from VBD, RBD and paid donors, and of apheresis donations, methods and coverage of TTI screening, prevalence of TTI markers, numbers of blood components prepared and transfused, and indicators of policy, governance and quality assurance. The IBCO data from the PAHO report on the Supply of Blood for Transfusion in Latin American and Caribbean Countries 2012-2013[17], published in 2015, are part of the Global Database and are usually included in the WHO Global Reports. Post-2013 national information for IBCO was obtained from a 2017 report on blood supply for the Americas[18], while that for specific blood services was provided by IBCO national health authorities, as indicated in each corresponding table.[19-21]

LESSONS

National Requirements For Blood Components Are Determined Locally And Cannot Be Estimated Using Generic Global Indicators

Accurate estimates of patient needs are essential if blood services are to provide sufficient components for all who need transfusions[22] and to achieve the goal of universal access to blood.[23] Indicators that have been proposed for estimating yearly requirements at the national level include (a) 1-5% of the population,[23-25] (b) the number of hospital beds multiplied by 5-15[26] and (c) 0.40 units/patient admitted to hospitals.[27] Recently, the Lancet Commission on Global Surgery recommended that countries collect at least 15 units/1 000 population in order to provide adequate surgical care.[28]

In 2013, IBCO had 600 304 000 inhabitants and 1 211 353 hospital beds. Based on an annual collection rate equal to 3% of the population—considered sufficient by WHO to cover all needs—the estimated requirement was 18 009 120 units, equivalent to 226% of the actual documented collection of 8 337 141 units. The latter figure is 98% of the estimate that would be obtained by multiplying the number of hospital beds by seven, or 8 479 471. The similarity between these two numbers suggests that estimates based on hospital beds might be sufficiently accurate to guide annual collection. Examining the individual country donation rates proves this conclusion incorrect: national collection rates based on units/hospital bed were 4.44-13.92 (median=9.61), and only three countries collected 7 units/bed/year; those with collection rates below 7/bed discarded 10-33% of their red blood cells (RBC), suggesting that hospitals beds do not provide a valid criterion to either estimating needs or assessing sufficiency of blood for transfusion in IBCO.

Table 1 lists IBCO according to their Human Health Index (HHI, range 0.727-0.992, median 0.843), which is a composite of life expectancy at birth[29] and provides more meaningful context for health issues than national income. Blood collection rates are expressed as units/10 000 inhabitants. According to this indicator (range 66.52-365.52, median 129.35), Cuba collected 5.5 times more blood than Peru, three countries had rates above 200, and four had rates below 100. Units collected/physician ranged from 5.20 to 22.42 (median 7.45). The numbers of blood units collected/hospital bed were independent of HHI (r_s=-0.294, p=0.221193), numbers of units/physician were inversely correlated with HHI (r_s=-0.594, p=0.009411) and collections per 10 000 inhabitants were directly correlated with HHI (r_s=0.4609, p=0.04751). The proportions of RBC discarded (range 4.10-33.25, median 14.66) did not correlate with units collected/population (r_s=-0.2179, p=0.3866), indicating that RBC disposal was not due to excessive collection by those countries with more blood available. Six countries, including two with collection rates below 100/10,000 population, discarded more than 20% of their RBC. The national rates of RBC used/10 000 population (range 52.26-350.53, median 110.41) not only correlated more strongly with HHI (r_s=0.4917, p=0.03238) than the corresponding collection rates but also demonstrated that only two countries utilized more than 200 units/10 000 inhabitants and eight used less than 100.

In order to estimate blood needs, it is important to understand how blood is used in clinical settings. In Guatemala, two national high-complexity reference hospitals in the capital city transfused 40 and 72 units/1 000 admissions, respectively; eight regional reference hospitals transfused 8-51; 16 provincial hospitals used 7-40; and two district hospitals transfused 13 and 16 units/1 000 patients.[15] Overall, in Guatemala's 33 national hospitals, 45% of all patients were cared for at the emergency wards. Wide variations, up to five-fold, were seen in the annual use of RBC among hospitals of the same level of complexity when admissions and emergencies combined were used as the denominator.[15]

Observations in Nicaragua[30] showed significant monthly variations in hospital admissions, in the proportion of those who receive RBC, and in the numbers of RBC units administered. In addition to the patients' clinical condition, doctors' decisions to admit and/or transfuse patients were also influenced by factors such as distance, travel time and expenses involved in reaching the hospital, and the potential of losing patients to follow-up, indicating that the application of pertinent locally developed transfusion guidelines facilitates more reliable estimation of blood needs.

The Development Of Blood Services Depends On The General Development Of The National Health System

In the Region of the Americas, the national availability of blood for transfusions, expressed as units/10 000 population, is inversely correlated with national maternal mortality ratios (MMR).[31] National rates of RBC use/10 000 population correlate directly with HHI (rs=0.4917, p=0.032384), and higher utilization of RBC is associated with lower MMR and infant mortality rates[15] (IMR). There is a direct correlation between MMR and IMR (r_s=0.8064, p=0.000093). National rates of blood collection per physician are directly correlated with both national MMR (range: 16.0-229.0, median 61.6; r_s=0.5996, p=0.008479) and IMR (range: 4.2-24.8; median 14.6; r_s=0.6118, p=0.011874), suggesting that the higher collection rates reflect shortages of physicians in deficient health care facilities rather than augmented blood collection. This would explain why transfusion rates in IBCO tend to be lower in those

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Table 1. Blood collection and use in Ibero-American countries, 2013

Country	HHI	Annual blood collection				Rate of RBC discard (%)	Rate of RBC use/10 000
		Number	Rate/10,000	Rate/bed	Rate/physician		
Costa Rica	0.992	68 209	138.13	12.56	5.50	21.55	108.36
Chile	0.992	229 911	129.35	5.88	7.11	9.95	116.48
Cuba	0.912	411 545	365.52	7.17	5.22	4.10	350.53
Panama	0.885	53 529	136.34	5.93	8.58	14.97	115.93
Mexico	0.885	1 364 395	110.21	7.35	5.20	14.88	93.81
Uruguay	0.880	99 151	290.00	11.60	6.17	9.08	263.73
Ecuador	0.869	229 018	143.20	9.61	9.02	9.38	129.04
Argentina	0.866	966 059	231.10	4.72	6.08	33.25	154.26
Nicaragua	0.844	72 658	118.74	13.92	14.13	4.23	113.72
Peru	0.843	204 871	66.52	4.44	6.55	21.43	52.26
Venezuela	0.841	340 345	110.32	12.26		10.33	98.92
Colombia	0.831	740 173	151.27	10.08	9.00	14.66	129.05
Brazil	0.830	2 969 204	146.97	6.39	9.69	24.87	110.41
Honduras	0.828	69 082	83.62	11.94	9.95	16.92	69.49
Dominican Republic	0.822	110 780	105.21	6.58	6.88	8.89	95.86
El Salvador	0.809	98 088	153.65	13.97	6.68	10.70	137.24
Paraguay	0.804	86 056	126.20	9.70	7.79	28.14	90.68
Guatemala	0.802	121 921	78.87	12.81	10.38	25.29	58.92
Bolivia	0.727	102 146	94.16	8.56	22.42	12.72	82.12

Notes: Adapted with permission from Cruz JR. Satisfacción de los requerimientos de hemocomponentes [Satisfaction of the requirements for blood components]. In: Cortes-Buelvas A, Cabezas-Belalcazar AC, García-Castro Gutiérrez M, Urcelay-Uranga S, editors. Promoción de la donación voluntaria de sangre en Iberoamérica. *Cali, GCIAMT*. 2017:61-70.[15] Data obtained from these studies.[16, 17]
: Not available. HHI/Collection rate per 10,000 correlation: r_s=0.4609, p=0.04751. HHI/collection rate per physician correlation: r_s= -0.5940, p=0.009411. HHI/RBC use rate correlation: r_s=0.4917, p=0.003238.
Abbreviations: HHI, Human Health Index; RBC, red blood cells.

countries with less access to renal and liver transplants and with lower numbers of diagnosed cases of hemophilia.[15] In Guatemala, intra-hospital maternal deaths associated with bleeding commonly occur during weekends and national holidays, and in high-risk remote areas (**Table 2**). During working days, deaths are more likely to occur between 11 pm and 5 am. In Bolivia, mothers with delivery complications did not have access to blood units stored in the hospitals because they were deposited for specific patients as a requisite for elective surgery (aka, replacement donation).[32] This phenomenon results not only in poor patient management but also inefficient use of dedicatedly stocked blood. In two consecutive years, 131 mothers died due to peripartum hemorrhage in 32 Guatemalan hospitals where 6 401 RBC units, or 49 units per deceased woman, were discarded during the same period.[19, 20] Focusing on patient transfusion needs and patient outcomes is necessary for implementing adequate national blood collection, processing and distribution processes.

More Blood Banks Do Not Result In Better Availability Or Access To Blood Components

In 2015, there were 2 254 blood processing centers in IBCO.[18] Fifteen countries had fewer than 100 such centers while the four nations with federal-type government -Argentina, Venezuela, Brazil and Mexico-had 259, 339, 530 and 572 centers, respectively (**Table 3**), a result of the blood services being set up and managed by each autonomous state/province. The mean number of blood units processed annually per center in each country varied from 884 to 37 477 (median 4,478, **Table 3**). Given that smaller centers are more prone to producing inaccurate laboratory testing results[33, 34] and to being financially inefficient,[35] assessing the availability of blood and the operational efficacy of such processing systems is important. Using the number of blood processing centers/100 000 inhabitants as an indicator, it becomes clear that countries with blood center density indexes (BCDI) higher than the median process fewer units per center, have lower proportions of VBD, defer

Table 2. Maternal deaths due to hemorrhage in public hospitals of Guatemala, 2015-2016

Type of hospital	Number of hospitals with deaths	Number of deaths	Deaths on weekends and holidays		Number of RBC units discarded
			Number	Proportion	
National reference	2	20	4	20%	2 482
Regional	8	52	25	48%	1 769
Provincial	9	41	18	44%	1 935
District, Contingency, Health Center	13	18	12	67%	215
Total	**32**	**131**	**59**	**45%**	**6 401**

Note: Data obtained from these studies.[19,20]
Abbreviation: RBC, red blood cells

more prospective donors, have higher prevalence of TTI markers, prepare fewer components per unit, and discard more RBC due to expiry as compared to countries with indexes lower than the median (**Table 3**, Chi^2=14.93, p<0.0001). The BCDI show no correlation with national rates of RBC use (r_s=0.0754, p=0.760329), indicating that more blood processing centers do not result in increased availability of or access to blood components.

In Guatemala, just five of the existing 60 blood centers processed 42% of all the units collected in the country (**Table 4**).[20] In Honduras, the three blood centers managed by the Red Cross accounted for 50% of national blood collection in 2018. Processes and operational results differed among the three Honduran centers (**Table 5**), a finding that led to closure of the smallest center in 2019. [21]

These data, and the impact of reducing the processing centers from 37 to two in Nicaragua,[14] demonstrate that planning and implementing national blood systems with the suitable number of centers can result in optimum availability of blood components and efficient use of national resources, including blood.

Regular Voluntary Donation Is A Major Contributor To Transfusion Safety

During 2015, there were 4.9 million VBD and 6.7 million RBD in IBCO.[18] The respective deferral rates were 15.5% and 24.4%, amounting to 2.4 million individuals. Limited-scope observations point to low hemoglobin and risk behaviors for infectious disease transmission as major causes of deferral in both VBD and RBD. Unjustified deferral reasons include lipemic plasma, inappropriate veins, recent food intake, menstruation and over-stocked blood type.[35,36] Despite these common factors, VBD were deferred in lower proportions (range: 4.63-23.57; median: 17.98) than RBD (Range: 7.97-33.01; Median 23.29). Lower deferral rates translate into more blood available and more efficient use of the resources to register and screen donors. With the pre-donation interview lasting 15 minutes, the 2 380 501 deferrals represent 316.5 full-time employees. The 57% excess associated with RBD compared to VBD equals 124 full-time jobs. Once allowed to donate, VBD, especially those who have donated before, are less likely to have adverse reactions to donation[37-40] and markers for TTI.[41,42] The attributable monetary loss of 323 013 TTI-reactive donations in 2015 is US$40.85 million.

Blood components derived from units that are not deposited for specific patients are available to any person in need of a transfusion. RBD not only limits access to available blood but also deters VBD, as the public is inclined to save their blood for family members or friends who may call on them as RBD.[11] Eliminating the requirement for blood replacement is the most important intervention to achieve universal VBD, as has been shown in Nicaragua and Buenos Aires.[12,14]

In 2008, PAHO recommended that blood systems managers educate regular blood donors and to have them donate twice a year [43]. The purpose of the education process should be to provide the individuals with the capacity and competences to decide to become blood donors, to protect their health, to understand why their blood donations are important for society, and to donate blood repeatedly[3]. Limiting regular donations to two annually allows groups of females and males to donate together, reduces the risk of draining hemoglobin to unacceptable levels in repeat donors, and facilitates programming extramural collections. Additionally, should unforeseen circumstances suddenly deplete the RBC stock, there would be enough eligible regular donors to replenish it. The initiative "Pledge2 save lives" was created with those considerations in mind.[43]

National Blood Systems Based On Consolidated, Stand-Alone Blood Processing Centers Which Focus On Serving Blood Donors And Satisfying Patient Needs Are More Effective And Contribute To Public Health

Considering that blood components for transfusion are essential medicines and prepared locally using biological materials obtained from multiple individuals, PAHO proposed that consolidated

Table 3. Operational indicators of blood centers, Ibero-American countries, 2015

Country	Blood processing centers		Donors			Viral TTI markers	Separation index	RBC expiry
	Number	Density/100,000	Per center	Voluntary	Deferred			
Nicaragua	2	0.0320	37 477	100	9.0	0.61	2.12	2.18
Paraguay	6	0.0853	14 353	10.2	7.7	0.93	2.50	15.48
Chile	17	0.0948	14 091	28.5	22.3	0.06[a]	2.62	7.18
Ecuador	22	0.1365	11 222	68.3	15.7	0.85	2.40	6.21
Bolivia	18	0.1633	6 007	40.9	29.4	0.85	2.43	9.00
Colombia	83	0.1675	9 588	91.1	18.0	0.70	2.35	7.50
Honduras	19	0.1899	4 478	18.6	15.7	0.65	1.83	9.78
El Salvador	13	0.2013	7 145	17.0	25.0	0.35	2.72	7.74
Brazil	530	0.2602	5 848	61.3	19.3	0.77	2.30	17.1
Peru	89	0.2856	2 302	4.6	29.7	1.17	2.32	13.03
Guatemala	60	0.3691	2 104	5.4	25.9	1.16	1.82	12.16
Cuba	46	0.4089	9 064	100	4.6	1.78	1.53	10.96
Mexico	572	0.4567	3 794	3.8	28.5	0.87	2.27	9.02
Panama	22	0.5517	2 560	7.0	23.0	0.73	2.09	14.75
Argentina	259	0.6143	3 965	45.7	14.2	1.06	2.20	7.30
Costa Rica	32	0.6397	2 367	60.4	22.5	0.45	2.83	14.35
Dominican Republic	71	0.6665	1 106	11.2	23.0	1.27	0.57	15.37
Venezuela	339	1.0833	884	5.8	19.6	0.98	2.36	12.07
Uruguay	54	1.5743	1 679	51.4	23.4	0.53	1.90	20.56

Notes: [a] Confirmed testing results.[16] "Poor outcomes" in relation to the median values are shaded.[29]
Abbreviations: TTI, Transfusion-transmitted infections; RBC, red blood cells

Table 4. Blood processing in Guatemala, 2016

Institution	Larger centers		Smaller centers		Institutional mean number of units
	Number	Total units	Number	Total units	
Ministry of Health	2	30 089 (34%)	31	57 353 (66%)	2 650
Social Security	2	17 560 (67%)	3	8 552 (33%)	5 224
Private sector	1	7 636 (41%)	21	10 970 (58%)	846
All	5	55 285 (42%)	55	76 875 (58%)	
Annual mean		11 057		1 398	2 203

Note: Date obtained from this study.[20]

Table 5. Blood collection and processing, Honduran Red Cross National Program, 2018

Blood center	Donors		Units		Separation Index	RBC expiry
	Voluntary	Deferred	Collected	TTI markers		
CENASA	6 446 (34%)	2 436 (11%)	18 837	441 (2.34%)	2.34	338 (1.84%)
CERESA	4 969 (23%)	3 622 (15%)	21 175	861 (4.07%)	2.40	66 (0.32%)
CESAAT	0	1 255 (22%)	4 489	229 (5.1%)	1.79	0
All	11 415 (26%)	7 313 (14%)	44 501	1 531 (3.44%)	2.31	404 (0.94%)

Note: Data obtained from this study.[21]

processing facilities be responsible for distributing sufficient blood components to predetermined hospitals.[42] Fewer processing centers are easier to oversee and make it easier to standardize operating procedures, implement quality assurance, hire specialized personnel, purchase and maintain equipment, procure consumables, acquire automated technology, manage donor and product information, reduce inequity in access to blood, and interact with public health and plasma fractionation institutions.[33-35]

The lessons described above are likely applicable in other parts of the world.

In 2013, 53 low- and lower-middle-income countries (LLMC) — 41 AFCO, 8 SECO and 4 IBCO—- collected only 24% of the global blood supply and discarded the highest proportion of RBC among all income groups.[16] These nations often fail to provide adequate, equitable, consistent, safe and timely blood supplies to their populations.[44,45] Lack of government oversight, inadequate resources and fragmented national systems are some of the factors identified as responsible for poor access to safe blood,[46,47] which in turn leads to poor patient outcomes.[48,49] Recognizing regional heterogeneities,[50] identifying gaps within each country, focusing attention at the local levels, and using successful experiences as models[51-54] have been suggested as the basis for improving transfusion safety in LLMC. **Table 6** summarizes the major health indicators for the three geographically distinct groups of countries. HHI ($p \leq 0.0023$) is highest in IBCO, while both MMR and IMR are highest ($p<0.0001$) in AFCO. All values for SECO are intermediate. The general main causes of death are infectious in AFCO, a mix of infectious and non-infectious in SECO, and non-infectious, including violence and road accidents, in IBCO. Understanding that the level of development of blood services depends on the general development of the health systems, it is not surprising that blood collection rates are lowest in AFCO, intermediate in SECO and highest in IBCO ($p=0.0668$); the prevalence of viral TTI markers among donors follows the reverse pattern ($p \leq 0.0588$, **Table 6**).

Table 7 shows HHI, main causes of death, MMR, IMR, proportion of births attended by skilled personnel, blood collection rates, and the estimated RBC transfusion rates in SECO. Maldives, Thailand, and Sri Lanka have the highest HHI and are also countries with upper-middle income. The Democratic Republic of Korea and Nepal, with low income, fall in the middle of the table. HHI is inversely correlated with both MMR ($p=0.008516$) and IMR ($p=0.000145$), confirming that HHI is a more valid reference for health issues than national income. IMR is inversely correlated with skilled attendance at birth ($p=000544$), and IMR and MMR are positively correlated ($p=0.000672$), indicating that the level of health care determines both MMR and IMR and affects neonatal preterm mortality. “Poor outcomes” by all measures, including blood collection rates, are more likely to occur in countries with lower HHI. These rates seem to be lower than expected in at least five countries and in agreement with the assessment that SECO have an 11% deficit of blood based on the distribution of the global population.[18] Reliable RBC transfusion rates could not be estimated for all countries.

Table 6. Major health indicators of Ibero-American, African and South-East Asian countries, 2013

Countries	Main causes of death	Indicator						
		Measure	HHI	Maternal mortality ratio	Infant mortality rate	Blood collection/10 000	Viral TTI makers (%)	RBC use/10 000
African	LRI, malaria, HIV, diarrhea	Median	0.597	492	48.5	50.64	7.800	49.79
		Range	0.393 0.848	42 1 360	12 96	2.44 391.66	0.35 22.62	3.18 369.36
South-East Asian	IHD, stroke, neonatal conditions, LRI	Median	0.769	166	30	90.79	0.980	86.17
		Range	0.695 0.891	21 291	9 47	18.82 184.99	0.32 6.82	16.89 180.05
Ibero-American	IHD, violence, stroke, road accidents	Median	0.843	66.6	14.6	129.35	0.835	110.40
		Range	0.727 0.992	16 229	4.2 24.8	66.52 365.52	0.34 1.82	52.26 350.53

Abbreviations: HHI, Human Health Index; TTI, transfusion-transmissible infections; RBC, red blood cells; LRI, lower respiratory infections; IHD, ischemic heart disease

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Table 8 shows HHI, main causes of death, MMR, IMR, proportion of births attended by skilled personnel, blood collection rates, and the estimated RBC transfusion rates in AFCO. Cape Verde, Mauritius, and Seychelles, with HHI above 0.800, have low-medium, upper-medium and high income, respectively, and, together with upper-middle-income Algeria, show the lowest MMR and IMR of all 48 AFCO. There is no correlation between HHI and blood collection rates. The rate of RBC use correlates directly with HHI (p=0.03108) and inversely with both MMR (p=0.00031) and IMR (p=0.00067), supporting the idea that estimating national needs and assessing sufficiency of blood by using blood transfusion rates is more appropriate than using collection rates. Reliable data on RBC use were available for only 29 AFCO. Skilled attendance at birth correlates inversely with IMR (p=0.000735), and IMR and MMR are directly correlated (p<0.000001). In general, "poor outcomes" on all measures are more likely to occur in the 24 countries with lower HHI (p=0.0001), corroborating that HHI segregates countries in a manner that facilitates understanding the relationships between national health services and local transfusion safety.

Table 7. Human Health Index, mortality, and patient care, South-East Asian countries, 2013

Country	HHI	Mortality			Patient care		
		Main causes	Maternal mortality ratio	Infant mortality rate	Skilled- attended births	Blood collection rate/10 000	RBC transfusion rate/10 000
Maldives	0.891	IHD, Congenital	70	9	100	146.75	141.41
Thailand	0.837	IHD, Stroke	21	10	99	90.79	61.77
Sri Lanka	0.835	IHD, Self-harm	32	9	100	184.99	180.05
Indonesia	0.782	Stroke, IHD	140	25	93	108.03	
Bangladesh	0.779	Stroke, IHD	201	33	50	37.68	
Dem Rep Korea	0.769	Stroke, IHD	87	18	100	40.72	39.70
Nepal	0.745	LRI, IHD	291	33	58	71.87	
Bhutan	0.743	NN preterm, IHD	166	30	89	115.89	110.57
Timor Leste	0.731	LRI, NN preterm	248	47	57	18.82	16.89
India	0.714	HID, NN preterm	189	39	81	77.81	
Myanmar	0.695	Stroke, LRI	189	44	60	51.81	

Notes: "Poor outcomes" in relation to the median values are shaded. : Not available. HHI/Maternal mortality ratio correlation: r_s=-0.697, p=0.017032. HHI/Infant mortality rate correlation: r_s=-0.8859, p =0.000283. Maternal mortality ratio/Infant mortality rate correlation: r_s=0.8604, p=0.000672. Infant mortality rate/skilled-attended births correlation: r_s=-0.8664, p=0.000544. HHI/collection rate correlation: r_s=0.5364, p=0.04423.

Abbreviations: HHI, Human health index; RBC, red blood cells; IHD: ischemic heart disease; NN, neonatal; LRI, lower respiratory infections.

Table 8. Human Health Index, mortality, and patient care, African countries, 2013

Country	HHI	Mortality			Patient care		
		Main causes	Maternal mortality ratio	Infant mortality rate	Skilled attended births	Blood collection rate/10 000	RBC transfusion rate/10 000
Cape Verde	0.848	LRI, Stroke	42	19	92.3	61.65	58.82
Mauritius	0.825	IHD, Diabetes	53	13	99.8	391.66	369.36
Seychelles	0.818	IHD, LRI	57	12	99.0	176.92	152.20
Algeria	0.785	IHD, NN preterm	144	22		125.43	109.69
Sao Tome & Principe	0.713	LRI, NN sepsis	156	29	92.5	48.11	41.72
Benin	0.695	Malaria, LRI	405	69	77.2	75.36	
Madagascar	0.688	LRI, Diarrhea	353	37	44.3	9.78	
Namibia	0.684	HIV, LRI	265	37	88.2	118.74	112.02
Botswana	0.683	HIV, TB	129	35	99.9	93.20	80.79
Rwanda	0.678	LRI, HIV	290	35	90.7	37.96	
Ethiopia	0.671	LRI, Diarrhea	353	48		8.14	
Gabon	0.669	HIV, Malaria	291	39		99.19	74.49
Senegal	0.668	Diarrhea, LRI	315			46.62	
Eritrea	0.659	Diarrhea, LRI	501	36	34.1	16.61	14.74
Sudan	0.647	NN preterm, congenital	311	48		50.20	
Kenya	0.642	HIV, Diarrhea	510	37		34.49	
United Republic of Tanzania	0.639	HIV, LRI	398	44	48.9	31.33	25.48
Mauritania	0.639	LRI, NN sepsis	602	58	65.1	26.79	24.20
Ghana	0.633	Malaria, LRI	319	43		58.45	49.79
Comoros	0.629	LRI, Diarrhea	335	58	82.2	33.33	29.77
Liberia	0.624	LRI, Malaria	225	63	61.1	60.60	
Zimbabwe	0.613	HIV, Diarrhea	443	45	80.0	36.96	35.65
Uganda	0.603	HIV, LRI	343	43		52.26	
Congo	0.597	HIV, Malaria	442	39	94.4	103.62	93.89
Gambia	0.597	LRI, NN sepsis	706	45	57.2	52.46	51.09
Niger	0.591	Malaria, Diarrhea	553	56	29.3	39.68	34.87
Zambia	0.586	HIV, LRI	224	48	64.2	72.59	61.99
South Africa	0.568	HIV, Violence	138	34	94.3	173.80	169.05
Togo	0.562	Malaria, HIV	368			57.40	
Burkina Faso	0.559	Malaria, LRI	371	58		57.27	43.13
Guinea	0.556	Malaria, LRI	679	64	45.3	35.34	28.81
Malawi	0.543	HIV, Malaria	634	46		34.52	18.30
South Sudan	0.543	Diarrhea, LRI	789	63	17.2	2.44	3.18
Mali	0.539	Malaria, Diarrhea	587	73	57.1	27.08	18.59
Somalia	0.539	Diarrhea, LRI	712	89		20.96	
Cameroon	0.539	HIV, Malaria	596	62	64.7	20.50	17.68
Guinea Bissau	0.528	LRI, Diarrhea	549	64	45.0	27.26	23.22
Burundi	0.525	LRI, Diarrhea	712	51		56.28	51.24
Nigeria	0.500	Malaria, Diarrhea	814	73		7.09	
Angola	0.491	LRI, Malaria	477	64	46.7	57.32	
Chad	0.480	Diarrhea, LRI	856	80	24.3	51.05	40.63
Cote D'Ivoire	0.473	Malaria, HIV	645	71		59.039	
Mozambique	0.465	HIV, Malaria	725	61	54.3	43.73	
Central African Republic	0.464	Malaria, HIV	882	96		35.30	
Democratic Rep of the Congo	0.461	Malaria, LRI	693	78	80.1	59.042	50.01
Lesotho	0.453	HIV, Diarrhea	487	72	77.9	37.24	
Eswatini	0.446	HIV, LRI	389	49	88.3	106.20	93.43
Sierra Leone	0.393	Malaria, LRI	1,360	96	59.7	61.13	58.10

Notes: "Poor outcomes" in relation to the median values are shaded. ■ : Not available. HHI/collection rate per population , Correlation: r_s=0.2252, p=0.1232. MMR/IMR correlation: r_s=0.8036, p<0.00001. RBC use/MMR correlation: r_s=-0.6044 p=0.00031. RBC use/IMR correlation: r_s=-0.577, p=0.00067. IM/Skilled-attended births correlation: r_s=-0.5655, p=0.000735. Skilled-attended births/RBC use correlation: r_s=0.7723, p=0.000001.
Abbreviations: HHI, Human Health Index; RBC, Red blood cells; IHD, ischemic heart disease; NN, Neonatal; LRI: lower respiratory infections.

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Table 9. Operational indicators of blood centers, South-East Asian countries, 2013

Country	Blood centers		Blood collection		Voluntary donation	Viral TTI markers	Whole blood separation
	Number	Density	N units	per center			
Indonesia	375 (321)[a]	0.1448	2 722 758	8 482	84.72	2.110	60.4
India	2 760 (2 545)	0.1990	9 949 012	3 909	85.00	1.600	60.0
Bangladesh	327	0.2075	593 774	1 816	29.64	0.976	18.7
Thailand	170	0.2495	618 675	3 639	100	0.480	96.4
Nepal	100 (86)	0.3573	201 122	2 339	87.79	0.570	25.6
Sri Lanka	90	0.4272	380 808	4 231	100	0.324	100
Maldives	2	0.5038	5 826	2 913	29.54	0.920	100
Timor Leste	6	0.5068	2 227	372	33.15	6.820	74.7
Myanmar	334 (145)	0.6491	266 540	1 838	76.86	3.210	79.5
Dem Rep Korea	188 (12)	0.7524	101 742	8 479	100	0.920	70.0
Bhutan	27	3.5340	8 854	328	63.12	1.180	50.8

Notes: [a]Numbers of blood centers which provided information "Poor outcomes" in relation to the median values are shaded.

Abbreviation: TTI, transfusion-transmissible infections.

Table 9 shows operational indicators of blood centers in SECO, with a caveat: only 6 of the 11 countries included all their centers in their reports. The BCDI shown were calculated using the number of centers that exist in the country, while the mean blood collection by center was estimated based on the number of centers included in the WHO report.[17] Taking into consideration that lower BCDI regularly result in more units processed by each center, in the case of SECO a better approximation to operational efficiency may be achieved by examining the number of units collected per center in the six countries with complete data. Sri Lanka and Thailand, with the largest number of units collected per center, have 100% VBD, have the lowest prevalence of TTI markers, and separate over 95% of their units into components. Maldives, with only two centers, processes all its units into components and shows the third lowest prevalence of TTI markers despite having only 29.54% VBD. Bangladesh, Timor Leste, and Bhutan reported the highest TTI prevalence rates and the lowest separation of blood into components. Total RBC discard was estimated at 31.2% and, as a consequence, 68% of RBC collected were actually transfused. Implementing universal VBD in SECO would result in improved availability and safety of blood. Nevertheless, in order to better understand the status of transfusion safety in SECO, the first priority should be the systematic local collection, validation, and analysis of data from blood centers and hospitals. Regulation and inclusion understand the status of transfusion safety in SECO, the first priority should be the systematic local collection, validation, and analysis of data from blood centers and hospitals. Regulation and inclusion of unbanked directed blood transfusion[47] and unlicensed blood brokers[49] requires special attention by health authorities, since they may manage up to 25% of the blood transfused in SECO. [851]

Table 10 shows operational indicators of the blood centers in AFCO. The BCDI fluctuate between 0.0134 and 1.2072 (median 0.1173). The number of blood units processed/center annually varies from 489 in the Democratic Republic of Congo to 86,172 in South Africa. There are 7 AFCO with VBD below 20%; 17 of them collect more than 90% of their units from VBD, with 9 having universal VBD. Prevalence rates of viral TTI markers vary from 0.35 in South Africa to 22.62 in Mali. Seychelles, Mauritius, Namibia, and Algeria report viral TTI prevalence under 1.00; 16 countries find more than 10% of their donations reactive for viral TTI. Twenty-two countries prepare components from less than 50% of the units collected. Eighteen of 29 AFCO with data discard more than 10% of the RBC they prepare. It was estimated that 11.6% of the collected RBC were discarded and, as a consequence, 88% of the RBC collected during 2013 were transfused. Operational "poor outcomes" are more likely among the 24 AFCO with BCDI above the median (p=0.0001). Eritrea, Namibia, Eswatini, Mauritius, Sao Tome and Principe, and Seychelles have only one blood center. Countries with two centers may want to keep them both as part of a contingency plan and because of the size of territory and transportation facilities. Independent of the BCDI, understanding where, when, and how many blood components are

Table 10. Operational indicators of blood centers, African countries, 2013

Country	Blood centers		Blood collection		Voluntary donation	Viral TTI markers	Whole blood separation	Rate 0f RBC discard (%)
	Number	Density	N units	per center				
Tanzania	7	0.0134	163 645	23 378	84.59	6.22	23	18.67
South Sudan	2	0.0173	2 812	1 406	2.31	19.91	0	
Eritrea	1	0.0191	8 692	8 692	92.48	3.18	92.6	11.26
South Africa	11	0.0202	947 890	86 172	99.96	0.35	99.7	2.73
Malawi	4	0.0234	48 579	12 145	30.09	7.80	6.9	46.49
Nigeria	43	0.0244	125 101	2 909	42.98	8.50		
Ethiopia	25	0.0257	79 274	3 171	67.72	5.50	30.8	
Niger	5	0.0261	75 977	15 195	33.91	12.28	1.6	12.12
Togo	2	0.0277	41 488	20 774	95.35	5.35	66.4	
Zimbabwe	5	0.0324	56 958	11 392	100	1.33	95.8	31.54
Uganda	14	0.0360	202 935	14 495	100	3.64	60	
Namibia	1	0.0422	28 143	28 143	100	0.89	99.8	5.66
Sierra Leone	30	0.0423	43 273	1 442	10.00	15.27	0	4.95
Rwanda	5	0.0441	43 074	8 615	100	3.30	100	
Central African Republic	2	0.0443	11 423	5 712	98.92	17.10		
Sudan	20	0.0529	189 432	9 472	17.11	7.45		
Mali	9	0.0530	45 932	5 104	30.60	22.62	55.9	31.35
Zambia	9	0.0576	113 386	12 598	100	10.50	10.6	14.60
Burundi	7	0.0708	55 666	7 952	99.97	10.52	39.8	8.95
Eswatini	1	0.0786	13 498	13 498	100	4.63		12.02
Mauritius	1	0.0794	49 349	49,349	84.36	0.40	49.9	5.69
Cote D'Ivoire	23	0.1021	133 023	5 784	100	7.75	94.5	
Gabon	2	0.1067	18 598	9 299	68.30	6.41	97.3	24.90
Kenya	54	0.1173	158 742	2 940	100	2.32	60.7	
Senegal	21	0.1444	67 815	3 229	94.23	10.09	51.8	
Lesotho	4	0.1864	7 988	1 997	96.62	4.95	43.4	
Madagascar	47	0.1992	23 075	491	18.60	4.89	35.8	
Somalia	31	0.2294	28 330	914	35.00	4.09	0	
Burkina Faso	43	0.2445	100 716	2 342	67.55	16.74	91.4	24.69
Cameroon	55	0.2473	46 483	845	8.14	11.52	0	13.76
Botswana	6	0.2767	20 207	3 368	100	1.96	100	13.31
Guinea Bissau	5	0.2898	4 703	941	28.79	18.94	0	14.82
Mauritania	13	0.3199	10 886	837	25.21	16.86	100	9.67
Guinea	38	0.3219	41 718	1 098	11.10	11.40	0.8	18.48
Mozambique	153	0.3676	119 003	778	43.87	9.54	100	
Ghana	103	0.3820	160 295	1 556	33.00	11.50	16.6	14.82
Benin	40	0.3889	77 510	1 938	95.49	14.18		
Chad	56	0.4127	69 265	1 237	6.22	15.15	1.9	20.46
Algeria	200	0.5113	490 633	2 453	31.28	0.54	92.4	15.55
Angola	139	0.5163	154 300	1 110	14.75	7.23	10.5	
Sao Tome & Principe	1	0.5236	919	919	65.29	12.96	75.0	13.28
Congo	29	0.5954	50 472	1 740	38.54	10.38	53.8	9.39
Gambia	12	0.6260	10 057	838	21.50		0	
Comoros	5	0.6588	2 530	506	11.46	5.14	0	10.68
Liberia	40	0.9112	26 602	665	26.31		0	
Seychelles	1	1.0990	1 610	1 610	50.93	0.00*	1.1	13.97
Cape Verde	6	1.1407	3 243	540	85.17	1.81	98.9	4.59
Democratic Rep of Congo	890	1.2072	435 275	489	35.70	6.24	75.0	15.30

Notes: "Poor outcomes" in relation to the median values are shaded. : Not available. Prevalence of "poor outcomes" higher in countries with blood center density > 0.13085; $Chi^2 = 14.42$, $p = 0.0001$

Abbreviations: TTI, transfusion-transmissible infections; RBC, red blood cells.

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needed is essential to plan adequate blood collection, preparation and delivery to hospitals before patients' medical conditions indicate transfusions. A national plan to avoid excessive discard of RBC will result in considerable financial savings.

FINAL REMARKS

Important lessons were learned from efforts to improve transfusion safety in IBCO during the last 25 years. Initial work focused on prevention of TTI. The systematic communication among national blood programs to assure valid data on TTI facilitated the establishment of a quality-controlled blood processing information system and solid collaboration among stakeholders. Delayed, deficient or lack of provision, however, called for securing timely access to blood by patients. The negative consequences of RBD as a requirement for patient treatment at hospitals became obvious. The pursuit of universal VBD was hindered by unawareness of time- and space-driven requirements for blood components at hospitals, and the preference among the public to save their blood for a relative potentially in need of RBD. Review of transfusion practices showed poor record keeping and variable patient management. It was understood that only hospital-based clinical guidelines provide a valid framework for estimating future patterns of blood needs. Blood donors were recognized as vital for achieving blood sufficiency and timely access to transfusions; therefore, nurturing donors became a central strategy. Recognizing that blood transfusion services are part of the national health system is indispensable for self-sufficiency and timely access to blood. The application of lessons learned in IBCO may allow countries of other parts of the world to improve their blood safety in the near future.

ABBREVIATIONS

AFCO: African countries. BCDI: Blood center density index. HHI: Human Health. Index. IBCO: Ibero-American countries. IMR: Infant mortality rate. LLMC: Low- and lower-middle income countries. MMR: Maternal mortality ratio. PAHO: Pan American Health Organization. RBC: Red blood cells. RBD: Replacement blood donation. SECO: South-East Asian countries. TTI: Transfusion transmissible infections. VBD: Voluntary blood donation. WHA: World Health Assembly. WHO: World Health Organization.

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DATA AVAILABILITY

Pan American Health Organization. Supply of blood for transfusion in Latin American and Caribbean countries 2012 and 2013. http://iris.paho.org/xmlui/bitstream/handle/123456789/28420/9789275118672_eng.pdf?sequence=1&isAllowed=y. World Health Organization 2016 Global Status Report on Blood Safety and Availability. https://apps.who.int/iris/bitstream/handle/10665/254987/9789024115654 31-eng.pdf?sequence=1. Pan American Health Organization. Supply of blood for transfusion in Latin American and Caribbean countries 2014 and 2015. http://iris.paho.org/xmlui/bitstream/handle/123456789/34083/9789275119587-eng.pdf?sequence=1&isAllowed=y.

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The author was Regional Advisor on Laboratory and Blood Services (1994-2011) and Senior Advisor on Health Technologies for Quality of Care (2009-2011), Pan American Health Organization, Regional Office for the Americas, World Health Organization. He was also a member of AABB Global Standards Committee (2015-2017). He is an honorary member of Grupo Cooperativo Ibero-Americano de Medicina Transfusional (GCIAMT, 2013-present), a member of Education Committee of the African Society for Transfusion Medicine (2017-present). The author reports no other conflicts of interest in this work.

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35th South African National Blood Transfusion Congress, 5 —8 August 2019
Oral Abstracts

The impact of Infection Prevention and Control (IPC) on the Rate of Bacterial Contamination of Apheresis Platelets

Malema H, Jentsch U, Swanevelder R

Background: The residual risk of bacterial contamination of platelets remains a global problem. Platelets are susceptible to bacterial contamination as they are stored at 20 to 24°C, which is conducive for bacterial growth. In countries where standardized bacterial screening procedures are in place, the risk of bacterial contamination of platelets is reported as 1/ 000 to 1/3 000. A recent publication on bacterial surveillance of apheresis platelets (AP) at SANBS has shown that the average bacterial contamination between 2011 and 2016 was 2.7% with a peak in 2015 and 2016.

Aim: The aim of the study was to assess if (IPC) interventions and improvements in microbiological processes implemented in 2017 have reduced the rate of bacterial contamination of apheresis platelets.

Materials and Methods: A retrospective review of laboratory data review was performed comparing the rate of bacterial contamination of AP between Jan 2015 to December 2016 to the rate from January 2017 to December 2018. Enhanced IPC measures were introduced in 2017 focussing on hand and environmental hygiene and the implementation of 0.5% chlorhexidine (CHX) / 70% isopropyl alcohol (IPA) as a hand sanitizer. AP samples were collected from 14 apheresis clinics across South Africa, except the Western Cape. They were transported at room temperature and processed 24 to 48 hours after collection. Between 2015 and 2016, 2 ml of platelet product was inoculated aseptically into an aerobic and anaerobic culture bottles (Bact/ALERT BPA and BPN or BACTEC Standard Aerobic F and Anaerobic F medium) and incubated for 14 days. Cultures giving a positive signal had a Gram stain performed, culture and identification was done using standard microbiological procedures. Microbiological culture improvements from 2017 included increasing the culture volume to 4 ml in an aerobic medium only and reducing the incubation time to 7 days.

Results: In 2015 and 2016, 2826 and 2918 AP samples were tested respectively, with a positive rate of 5.3% in both years (n=302/ 5744). In 2017, 4% (n=116) of the 2892 samples tested positive for bacterial contamination while in 2018, 3366 were tested of which 42 (1%) tested positive with an average positive rate for 2017/18 of 2.5%. The change in bacterial contamination rate from 5.3% in 2015/16 to 2.5% in 2017/18 was highly significant ($p<0.0001$). A total of 440 bacteria were cultured from the 460 positive signals. Coagulase Negative Staphylococci (CNS) (n=131; 29%), Cutibacterium acnes (n=129; 28%), and Micrococcus species (n=63; 14%) were the most frequent isolates for both periods.

Discussion: Implementation of IPC and improved microbiological processes has reduced bacterial contamination rates from 5% to 1%. The majority of bacteria identified were common skin commensals indicating that the skin flora remains the biggest source of contamination.

Conclusion: While on-going monitoring is required, replacing the 70% IPA swabs used for cleaning of donor skin with a 2% CHX/70% IPA combination product to reduce skin colonization more effectively should be investigated. The introduction of additional interventions such as pathogen inactivation may further reduce the residual risk of bacterial contamination.

Seroprevalence of Human T-cell Lymphotropic Virus-1/2 Among Blood Donors in Uganda

Ayikobua R

Background: HTLV-1/2 causes serious diseases in humans and is transmittable by blood transfusion. The need to screen for these viruses in the donated blood remains a concern for blood transfusion services and to ensure the safety of the blood recipient, its prevalence in a given population must be known.

Aims: Assess the seroprevalence of HTLV-I/2 among blood donors in Uganda.

Methods: The study was a cross sectional one, which enrolled 1,294 randomly selected healthy blood donors, with age ranging from 17 – 54 years. These donors were from six regional blood banks in Uganda and were screened for HTLV-I/2 using a chemiluminescence micro particle immunoassay technique to test the serum samples.

Results: HTLV-I/2 antibodies were present in 13/1294 (1%) of the blood donors. The highest HTLV1/2 seropositivity was found in the Gulu regional blood bank center (7 of 146, 4.7%, P<0.039, OR 5.31). The results also showed a slight variation in the prevalence of sero-positivity between female (4/459, 0.9%) and male donors (9/835, 1.1%). The prevalence also varied among the various types of blood donors, with the highest sero positivity (7/628, 1.1%) among first-time donors. The presence of some risk factors was associated with relatively higher rates of HTLV 1/2, but these associations were not statistically significant in the population tested.

Conclusion: The HTLV-1/2 sero-prevalence found in blood donors in Uganda is relatively high, when compared to other regions endemic for these viruses (South America, Japan, and Caribbean region) and points to the need of screening for HTLV-1/2 in blood donated in Uganda. More studies are necessary to understand the risk factors associated with HTLV in the country.

Seroprevalence of the Human T-cell Lymphotropic Virus Types 1 and 2 Among First-time Blood Donors in the Western Cape, South Africa

Cable R

Background: Human T-cell Lymphotropic Virus type-1 (HTLV-1) is considered a major health challenge in endemic areas. The virus is associated with severe diseases, such as adult t-cell leukaemia/lymphoma and HTLV-1-associated myelopathy/tropical spastic paraparesis. One of the known routes of transmission is through blood transfusion. The aim of this study was to determine the seroprevalence of HTLV in the new/first-time donor population of the Western Cape, South Africa. In South Africa, HTLV screening is not mandatory for blood services.

Methods and Materials: New donors were targeted as they tend to have higher prevalences for all routine infectious markers screened at the Western Cape Blood Service (WCBS). Based on the results of a previous HTLV seroprevalence study at the South African National Blood Services (SANBS), a low overall prevalence was expected and the highest risk group was the black population. The black race group at WCBS forms a small percentage (~5%) of the total donor population, therefore new and repeat/regular black donors were selected for this study. Donor samples were screened on the Cobas e801 analyser, which uses electrochemiluminescence technology (ECL). Repeat reactive samples were further tested on the Architect i1000 analyser, which uses microparticle immunoassay technology (CMIA). Sero-positive samples were confirmed by Inno-LIA HTLV-1/2 Score, which distinguishes between HTLV-1 and HTLV-2, and further tested by HTLV-1-specific PCR.

Results: Of the 9758 donors screened, 12 (0.12%) donors were repeatedly reactive on the Cobas e801. Only four of the 12 were repeat reactive on the Architect i1000. Of those four, only two were PCR and Western Blot positive (HTLV-1). Calculated specificity of the Cobas HTLV-1/2 assay was 99.86% (99.76% to 99.92%: 95% CI). Two donors were found to be HTLV-1 positive. Both were female,

repeat donors and from the black race group. They were 34 and 16 years old at the time of donation. This represents 0.02% of all donors tested, or 0.05% of all black repeat donors tested. During the study period, there were 67 Hepatitis B, 28 HIV and 3 Hepatitis C confirmed positive donors. None were co-infected with HTLV-1/2.

Conclusion: Migration from HTLV-endemic African countries to South Africa, and Cape Town specifically, is on the rise. The risk of HTLV transmission by blood transfusion is a concern, which requires further investigation.

HBV infection rates in South African National Blood Service (SANBS) Donors Born Before and After the Implementation of Universal HBV Vaccination

Skyes W, Coleman C, van den Berg K, Vermeulen M

Background: Hepatitis B (HBV) is endemic in South Africa (SA) with more than 70% of the population exposed. Even though it is a vaccine preventable disease, it remains one of the main causes of liver related disease. In April 1995, SA introduced universal hepatitis B vaccination for newborns as part of the Expanded Programme of Immunisation. Infants vaccinated in 1995 became eligible to donate blood in 2011 at the age of 16. The aim of this study was to compare the prevalence of HBV in first time blood donors < 20 years of age in 2015 to 2010 to determine whether the introduction of universal HBV vaccination translated to a decrease in the observed HBV prevalence among blood donors. Secondary aims were to compare Occult HBV infection (OBI) and vaccine breakthrough rates.

Methods: All donations were screened for HBsAg (Abbott Prism) and HBV DNA (Procleix TIGRIS Hologic). The Ultrio assay was used in 2010 and the Ultrio Plus assay (with improved HBV sensitivity) in 2015. HBV prevalence was analysed by age, gender and population group in first time donations from 2010 (probable non-vaccinated) and 2015 (probable vaccinated). Significance was determined using Chi square statistics.

Results: Of 91,540 donations from first time donors < 20 years of age in 2010 and 2015, 223 (0.24%) tested HBV positive; 201 were confirmed positive (HBV DNA+/HBsAg+), 18 NAT yields (NY) – (HBV DNA+/HBsAg-) and four serology yields (HBV DNA-/HBsAg+). HBV prevalence decreased by 69% from 0.377% in 2010 to 0.117% in 2015 ($p<0.0005$). HBV prevalence decreased by 71% in males (0.471% to 0.134%) ($p<0.0005$) and 64% in females (0.285% to 0.103%) ($p=0.00001$). There was a 5-fold insignificant decrease in HBV prevalence in White donors (0.032% to 0.006%) ($p=0.21$) and a 4 fold significant decrease in both Black (0.787% to 0.201%) ($p<0.0005$) and Coloured donors (0.467% to 0.110%) ($p=0.031$). OBI (HBV DNA+/HBsAg-/anti-HBc+) accounted for 57% of NYs in 2010 but only 18% in 2015 ($p=0.23$). While there were no presumed vaccine breakthroughs in first time donors <20 years old in 2010, 45% of HBV NYs in 2015 were attributed to presumed vaccine breakthrough (DNA+/HBsAg-/anti-HBs+ with rising titre on follow up) ($p=0.12$).

Discussion/Conclusions: HBV prevalence in first time blood donors < 20 years decreased significantly from 2010 (probable non-vaccinated) to 2015 (probable vaccinated) indicating vaccine efficacy. The decrease in HBV rate in male donors was greater than in female donors, which could indicate that the program had a higher impact on male donors for reasons that are not yet apparent. The decrease was slightly greater in White donors as compared to Black and Coloured donors however insignificant due to small sample size. An increase in vaccine breakthroughs was observed in donors who had probably been vaccinated (2015) while OBI decreased in these donors even when a more sensitive assay for OBI was used. Additional anti-HBs titre and anti-HBc testing on HBsAg+ and HBV DNA- donors is required to confirm the decline in young blood donors is due to vaccine efficacy.

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Syphilis testing in the South African National Blood Service - January 2010 to December 2018

Skyes W, Coleman C, van Emmenis T, Mmenu C, Govender N, Vermeulen M

Background: The South African National Blood Service (SANBS) tests all donations for HIV, HCV, HBV and Syphilis. Syphilis is a highly contagious sexually transmitted bacterial infection caused by Treponema pallidum (TP). As there has been no reported cases of transfusion-transmitted (TT) syphilis globally for many decades, a number of blood services have questioned the utility of TP screening considering the number of false positives detected and positive test results after successful treatment. The aim of the study was to determine donor demographics associated with incident Syphilis in SANBS blood donors to improve education of donor's pre donation. This information could be used to educate donors during the 1:1 interview so that donors self-exclude if at risk.

Study design: Screening for TP antibodies is performed using a TP Haemaggluttination (TPHA) reagent on the Beckman Coulter PK7300 instrument. Confirmatory testing is performed on all reactive samples on the Cobas e411 analyser and a Carbon antigen Venereal disease Research Laboratory (VDRL) test is performed to distinguish between past and current infections. For the purposes of this study, TPHA positive repeat donors and VDRL positive first time donors were considered to be incident infections and potentially infectious.

Donations from January 2010 to December 2018 were analysed and data compared using Chi Square statistics to assess significance.

Results: Of 7,423,405 donations tested (2010-2018), 19,388 (0.26%) were TPHA confirmed positive and 5,158 (0.07%) were VDRL positive. During the period there were 5,765,971 repeat donors and 948,994 first time donors. 7,855 (0.12%) incident infections were detected of which 4324 (0.08%) were TPHA positive repeat donors and 3,531 (0.37%) were VDRL positive first time donors ($p<0.0001$).

The rate of incident infections was higher in female (0.14%) than in male donors (0.10%) ($p<0.0001$) and in donors over 40 years of age (0.15% vs 0.09%) ($p<0.0001$). Black donors were 8 fold more likely to have an incident syphilis infection than Asian, Coloured or White donors (0.16%, 0.08%, 0.008%, 0.05% respectively) (OR 8.18, 95%CI 7.73 – 8.87, $p<0.0001$). Mpumalanga had the highest rate of incident infections (0.15%) as compared to Egoli that had the lowest rate (0.1%) (OR 1.49 95% CI 1.37 – 1.61, $p<0.0001$).

Discussion/Conclusion: The rate of potentially infectious incident syphilis infections was significantly higher in first time donors, females, Black donors and donors older than 40 years of age. A number of factors may reduce the risk of TT syphilis. These include storage of blood and blood products that may inactivate the spirochete in red cells, toxicity to TP due to oxygen flow levels in platelet storage bags, clinical symptoms that accompany infectious stages of syphilis leading to donor exclusion and hospital patients receiving antibiotics as part of their treatment that may prevent syphilis infection following a blood transfusion. These factors together with improved donor education could potentially make testing for syphilis redundant and further work is required using antibiotic use and age of blood when transfused, to model the residual risk of TT Syphilis.

Evaluation of the Abbott Alinity S and the Roche Cobas e801 for Virology Screening at the South African National Blood Service

Coleman C, Jaza J, Machaba S, Vermeulen M

Background: The South African National Blood Service (SANBS) test all donations for Human Immunodeficiency Virus (HIV), Hepatitis C (HCV) and Hepatitis B (HBV). Nucleic Acid Testing (NAT) and Viral Serology Testing (anti-HIV, anti-HCV and HBV Surface Antigen (HBsAg)) are performed. Viral Serology was performed on the Abbott Prism for the past 15 years at SANBS. The aim of this study was to evaluate two new viral serology systems namely Abbott Alinity S (Alinity) and Roche Cobas e801 (Cobas).

Methods: Approximately 200-300 first time donor specimens from Johannesburg and Durban Donation Testing laboratories were tested daily between December 2017 and May 2018. All discordant reactive samples were confirmed using the NAT result (Procleix ULTRIO

Elite) or confirmatory testing for anti-HIV (Biorad Geenius), HBsAg (Roche e411 neutralization) or anti-HCV (Roche e411 HCV and Innogenetics HCV INNO LIA Score). Specificity was determined (HIV N=3953, HCV N=3899 and HBsAg N=3953) as per calculation True Negatives (TN) / (False Positives + TN) x 100. Sensitivity was evaluated by comparing confirmed positive donations and a panel of HIV NAT yields. The Chi-squared test was used to test for statistical significance. The coefficient of variation (%CV) was calculated from inter (x30) - and intra-run repeats (10x across 3 runs) of custom quality controls. Instrument failures were recorded.

Results: A specificity of, 1) HIV was 99.95% (CI 99.80-99.99%) and 99.97% (CI 99.86-100%) (p=0.57), 2) HBsAg was 99.95% (99.78-99.98%) and 99.90% (CI 99.71-99.96%) (p=0.49), 3) HCV was 99.77 (99.57-99.90%) and 99.90% (CI 99.74-99.97%) (p=0.17) for Cobas and Alinity respectively. The sensitivity on donor samples for anti-HCV, HIV Ag/Ab and HBsAg were all 100%. Sensitivity determined by p24 antigen positive confirmed NAT yield samples was 95% (19/20) on both Cobas and Alinity. The sample not detected by both had a viral load of 37,537 copies per mL with a p24 antigen positive result S/Co ratio of 1.56. Sensitivity determined by p24 antigen negative HIV confirmed NAT yields was 4/19 (21%) on Cobas and 5/19 (26%) on Alinity (4/5 positive by both systems and one detected by Alinity only). Inter-and intra-run repeatability were 100% with the %CV on Cobas and Alinity at 3.1% and 6.71% respectively. No failures occurred on Cobas whereas one failure (not leading to downtime) occurred on Alinity.

Conclusion: The Abbott Alinity S was selected by SANBS mainly due to specificity criteria. Specificity has a direct impact on the number of available units for transfusion and the amount of confirmatory work required. The largest specificity difference was on anti-HCV. The total difference in specificity across all markers of 0.15% in favor of Alinity was considered. With a collection target of 900,000 units per annum, 1350 less donors would be deferred and the loss of units valued at R2, 521,800 per annum would be avoided. The sensitivity and reproducibility criteria was met by both Cobas and Alinity. Both system showed robustness with little downtime occurring.

Syphilis and Viral Co-infections in the Western Cape Donor Population. A 7-year Review

Valensky S, Bird A

Background and Aim: Syphilis screening of blood donors is common practice worldwide. At WCBS, the Treponema pallidum haemagglutination assay (TPHA) is used routinely to determine the reactive status of syphilis in donors. A study to assess the prevalence of syphilis in the donor population, including the co-infections with other Transfusion Transmissible viral markers ie: Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Human C Virus (HCV) was performed.

Method: A cross-sectional retrospective study of blood donors at WCBS was conducted over a seven year period (Jan 2012 – Dec 2018). All donors included in this study, donated at least once in this period. The routine serologic test for syphilis was TPHA, performed on the Beckman PK7300 blood grouping platform. Confirmatory testing included manual TPHA and the Rapid Plasma Reagin (RPR) quantitative test. Syphilis and viral marker results were tabulated according to gender, age, race and donation status i.e. first time or a repeat donor.

Results: 145 280 individual donors were screened during this period. 586 (0.4%) were confirmed syphilis reactive (VDRL ≥4, TPHA confirmed reactive). The prevalence of syphilis reactive donors within the donor population by age group is <20 (0.22%), 20 – 29 (0.48%), 30 – 39 (0.62%), 40 – 49 (0.35%), 50 – 59 (0.28%), 60+ (0.11%) and by race group is White (0.10%), Asian (0.31%), Black (0.78%) and Coloured (0.80%). There was no significant difference in prevalence according to gender or between first time and repeat donors. Of the 586 donors with syphilis, the prevalence of co -infections with HIV, HBV and HCV were calculated and these were 44 (7.51%), 35 (5.97%) and 3 (0.51%) respectively. A total of 82 donors presented with syphilis and viral co-infections. 9 donors found to be TPHA reactive on one donation were found to be NAT reactive for HIV or hepatitis B or hepatitis C on the following donation. In all of these cases, the time between donations exceeded one year.

Conclusion: The data indicated that there is an association between donors confirmed as syphilis-reactive, and other viral markers, which should be explored further. The highest prevalence of syphilis was found in the age group 30 – 39 and in the coloured and black population. The 9 donors that later became NAT reactive is possibly indicative of recurrent high risk behaviour, and test seeking behaviour. Although the overall syphilis reactive rate of 0.4% is low, it remains an area of concern and continued testing for syphilis remains appropriate. In addition, donors found syphilis reactive are referred for treatment, which contributes to improving public health care and reducing the spread of this infection.

Use of a Limiting Antigen Avidity Assay to Determine HIV Incidence in South African First-Time Blood Donors

Vermeulen M, Chowdury D, Brambilla D, Beck G, Busch M, Custer B, Jentsch U, Murphy E

Background: In the South African general population, 2016 HIV prevalence was 19% among adults and 2012-2015 HIV incidence has been estimated at 12 to 13 per 1,000 person-years (PY) (UNAIDS and Statistics South Africa). Incident infections pose the greatest risk to blood safety. Although first time (FT) donor incidence has been estimated using parallel HIV antibody and nucleic acid testing (NAT) with a 15.4 day RNA to antibody window, a limitation of this method is that relatively few NAT yield (RNA+, Antibody -) donors are detected per year.

Aims: We applied a new antibody recency assay to detect the much larger number of recent (within 4 months) incident infections, allowing more precise time trend and subgroup analyses for FT donors.

Methods: Plasma samples from HIV seropositive FT donors during calendar years 2012 through 2016 were tested with a limiting antigen avidity (LAg) assay (Sedia Biosciences, Portland OR). We used a cutoff of 1.50 normalized optical density units corresponding to an incidence "window" of 129 days. Incidence was calculated as cases/1,000 PY of which numerator cases were recent infections as classified by the LAg assay. Each uninfected donor contributed the full 129-day person-time to the denominator while recently infected donors contributed half that. We used multiple imputation to adjust incidence for missing LAg results for 414 (7%) confirmed HIV-positive donors. Donors classified as longstanding HIV were excluded from both the numerator and denominator. 95% confidence intervals were calculated using the Poisson method.

Results: Among 513,896 donations by FT donors in 2012-2016, 5763 (1.12% tested HIV seropositive. Of these and after imputation, a total of 857 were classified as recent incident infections and the denominator consisted of approximately 179,738 PY. Overall incidence per 1,000 PY was 4.77 (95% CI 4.66-4.89) and declined from 4.88 in 2012 to 4.35 in 2016 (p trend < 0.0001). By age, HIV incidence was 8.03 in those aged 20-25 years, 5.28 in those 26 and older and 3.2 in those aged 16-19. By sex, HIV incidence was 6.36 in females and 2.78 in males. By race/ethnicity, incidence was 8.44 among Black, 2.00 among Colored, 0.27 among White and 0.20 among Asian donors. By province, incidence ranged from a high of 8.27 in Mpumalanga, 6.47 in Free State and 6.23 in Kwa-Zulu Natal to a low of 2.33 in the Northwest.

Summary/conclusions: In South Africa, HIV incidence among FT donors was high but two- to threefold lower than general population estimates and is declining over time. Incidence is highest in the 20-25 year age group, twice as high in females compared to males and highest in Mpumalanga province followed by Kwa-Zulu Natal and Free State provinces, consistent with public health data. Because we could not control for undisclosed antiretroviral therapy among HIV positive donors, resultant false recency on the LAg assay may have caused a small over-estimation of incidence. The use of antibody recency assays is an important new tool and future research will compare these results to those obtained using other incidence methods.

The prevalence of HIV, HBV AND HTLV, in Patients Receiving Blood from the South African National Blood Service

Reynier W, Grobler C, Vermeulen M

Introduction: Transfusion of the human T-cell lymphotropic virus (HTLV) is the most infectious mode of transmission as it often delivers a large viral dose, resulting in seroconversion rates of 44–63%, in addition the interval from infection to disease is shortened. HTLV may be detrimental to an HIV-infected individual, with increasing risk for development of neurologic complications including Tropical spastic paraparesis HTLV-1 associated myelopathy, leukaemia, and lymphoma. HTLV Tax protein up-regulates both HIV expression, as well as

the expression of various cytokines and cytokine receptors involved in T-cell activation. This creates a favourable milieu for the HI-virus and exacerbates the cytopathic effects of HIV that accelerate the clinical progression to AIDS in individuals co-infected with HIV and HTLV. A 2013 cross sectional study of 46,752 South African blood donors confirmed an overall HTLV prevalence of 0.062%. We aim to determine the prevalence of HIV, HBV and HTLV among blood transfusion recipients receiving blood products from the South African National Blood Service (SANBS).

Methods: Patient specimens collected for compatibility testing were separated and frozen. The number of samples was matched to the number and proportion of patient samples received per blood bank nationally to enable the estimation of a national prevalence. The ABBOTT Alinity S® Immunochemiluminescent system was used to serologically test for HTLV, HIV and HBV. Samples testing initial reactive were repeated in duplicate and repeat reactive samples were confirmed using the Roche cobas® 8000 Electrochemiluminescence system. Chi-square statistics were performed and a p value <0.05 was determined significant.

Results: Of the 7015 patient samples tested, each zone contributed the following: Egoli 1764 (25.14%), Northern 1694 (24.15%), KwaZulu Natal 1254 (17.88%), Vaal 930 (13.26%), Eastern Cape 516 (7.36%), Free State and Northern Cape 429 (6.12%) and Mpumalanga 428 (6.10%). The overall prevalence of HIV, HBV and HTLV was 40.24%, 7.73% and 0.71% respectively. HIV, HBV and HTLV prevalence was highest in the Mpumalanga (53.60%; 9.81%, 0.93%), and KwaZulu Natal zones (44.9%; 8.93%, 1.2%). HIV and HBV prevalence was lowest in the Northern zone (35.48%; 7.14%) and HTLV prevalence was lowest in the Vaal (0.22%) zone. The HIV prevalence was significantly higher in female transfusion recipients (42,75%) compared to males (33,76%) (p<0.0001), in contrast the HBV prevalence was significantly higher in males transfusion recipients (8,78%) compared to females (6,85%) (p=0.004). Females (0,84%) had a twofold non-significant (probably due to the low number of positive samples) higher prevalence of HTLV than in males (0,48%) (p=0.09).

Conclusion: Our study confirmed an overall high prevalence of HIV and HBV infections among patients receiving blood products from SANBS. Unlike HBV and HTLV, the prevalence of HIV among the general population is well known. Compared to the general population, the HIV prevalence in blood recipients was two-fold higher. This may be due to HIV positive patients becoming anaemic and requiring blood transfusions, increasing their risk of acquiring HTLV through transfusion. Patients receiving blood transfusion from SANBS have high rates of HIV, HBV and HTLV which should be taken into consideration when determining donor screening strategies.

The Impact of the HBS100 Marker on HBV NAT Yields at the South African National Blood Service

Jacobs G

Introduction: According to the South African National Blood Service (SANBS), only 1% of the South African population are blood donors. The country is also endemic for Hepatitis B (HBV) infection, with a prevalence of 9% of people exposed to HBV. To ensure the safety of the blood supply, SANBS employs ultrasensitive nucleic acid testing (NAT) and serological assays to screen out infected donations. The unavoidable consequence is the increased deferral of blood donors who have been exposed to HBV in the past but may not be infectious. In an effort to minimise the deferral of blood donors, SANBS reviewed its deferral strategy for confirmed HBV NAT yield donors in April 2015. Donors who, on a follow up sample, test negative for NAT, HBsAg, and anti-HBc IgM with only anti-HBc total as the sole positive marker (indicating past HBV infection) remain active and their future blood donations are utilised for transfusion if the anti-HBs titre is >100 IU/L. High levels of anti-HBs have a protective role against levels of HBV DNA below the limit of detection of ID-NAT. An HBs100 marker is added to the donors Meditech record which flags subsequent donations for repeat testing of anti-HBs titre to ensure consistent protective levels. This study describes the impact of this implemented change amongst confirmed HBV NAT Yield (NY) donors, who would otherwise have been permanently deferred from blood donation.

Methods: We performed a retrospective, cohort study of all donors classified as an HBV NAT Yield (NAT positive, HBsAg negative) who donated between April 2015 and March 2018. Serological HBV markers of the index and subsequent follow up specimen donations were analysed. Microsoft Excel spreadsheets and Pivot tables were used to analyse the data.

Results: There were 528 HBV NAT Yield donors identified over 3 years. 244 (46%) donors returned for follow up testing, of which 14 (5.7%) tested negative for all HBV viral markers. Of the 230 (94.3%) follow up donors that tested positive for at least one HBV viral marker, 111 (48.3%) donors were anti-HBc positive only), 80 had anti-HBs levels >100 IU/L (72%) and 31 had anti-HBs levels <100 IU/L

(28%). The average time between index donation and follow up specimen for anti-HBs >100 IU/L in the HBc positive only group was 207 days. Females were more likely to have increased levels of anti-HBs than males (80% vs 60%) even though the rate of past HBV infection was higher in males (59% vs 41% for females).

Discussion: The implementation of the HBs100 marker has resulted in the retention of 80 donors, who would otherwise have been lost. Measures to improve the return rate of donors for follow up testing could synergise this intervention. Current HBV NAT Yield donors are not advised to return within a pre-defined period. A 6-month deferral period for HBV NAT Yield donors is recommended to accommodate the resolution of acute HBV infection along with protective levels of anti-HBs.

Conclusion: Blood transfusion services with limited donor resources benefit from exploring alternative donor deferral strategies.

Investigation into the Role Environmental Factors Play in Bacterial Contamination in Platelets

Walker G

Background: Apheresis platelets contaminated by bacteria are a serious risk for platelet recipients. During 2016, 2,858 platelet products were tested for bacterial contamination at the South African National Blood Service (SANBS). Of these, 141 (5%) were found to contain bacteria. Most of the bacterial isolates were indicative of hand flora, suggesting poor hand hygiene. SANBS embarked on an organization wide program to strengthen hand hygiene procedures, introduced an improved hand sanitizer and emphasized aseptic technique during collection. Apheresis sites in the Vaal Zone showed an improvement after these changes but were still finding contaminated units.

Aim: This study aimed to determine the association between contamination from environmental sources and the sterility of apheresis platelet products.

Materials and methods: Interventions to reduce contamination from the environment included environmental fogging, changing airflow in the clinic, and changing the floor cleaning process. Three different sites were selected to test each treatment. Site A underwent environmental fogging which involved deep cleaning, followed by sealing off the site and spraying it with disinfectant gas. The floor cleaning process was changed at Site B. This involved mopping the floor, waiting an hour and then disinfecting the work areas. This change was done to allow any contamination that was present on the floor to first settle before disinfection was done. For site C the airflow was changed by moving the air conditioner intake away from the bleeding area to the entrance. Impact was measured by assessing the number of platelet units which had positive bacterial growth for the period between November 2016 and November 2018 (November 2017 excluded as these changes were done at that time)

Results:

Site A: Before the change 656 units bled with 210 tested for sterility 203 negative and 7 positive (96.67% compliance). After the change 875 units bled with 194 tested, 193 Negative and 1 positive (99.48% compliance). This was not statistically significant (p=0.097)

Site B: Before the change 572 units bled with 195 tested, 179 negative and 16 positive (91.79% compliance). After the change 610 units bled with 192 tested, 190 Negative and 2 positive (98.96% compliance). This was statistically significant (p=0.012)

Site C: (From May 2017 until May 2018 excluding November 2017) Before the change 138 units bled with 75 tested, 72 Negative and 3 positive (96% compliance). After the change 225 units bled with 106 tested, 103 Negative and 3 positive (97.17% compliance). This was not statistically significant (p=0.622)

Discussion: Changing the sequence was the only process to show a statistically significant improvement (p=0.012). This also had no cost element and no downtime, as such it is the better process to be used. Whereas fogging requires deep cleaning, there is a yearly cost element to maintain, and there are 2 days downtime. Changing the airflow did not show a significant improvement and therefore is not an effective treatment.

Conclusion: Environmental hygiene has an effect on reducing bacterial contamination of apheresis platelets, it is essential to ensure a high quality, safe product and provides a good return on investment.

Management of Highly Infectious Blood Specimens– are we Doing Enough to Protect Laboratory Staff?

Meaker J, van den Berg K

Introduction: Viral Haemorrhagic Fevers (VHF) are highly contagious blood borne diseases associated with very high rates of morbidity and mortality. Blood bank staff are at significant risk when handling specimens from patients with VHF. The South African National Blood Service (SANBS) launched a project to raise awareness, reduce exposure and implement a rapid communication strategy to alert relevant stakeholders of suspected cases. VHF often presents with vague symptoms complicating early diagnosis. Crossmatch requests are sometimes received in SANBS blood banks without full diagnostic information, resulting in staff following routine crossmatch procedures. Specimens are sent to the National Institute of Communicable Diseases (NICD) for confirmation of possible VHF, however, SANBS is not informed of the pending diagnosis. Doctors and NICD operate independently, leaving SANBS out of the communication, thus placing staff at risk of exposure.

Design and Methodology: In November 2017, a task team was formed comprising clinical, occupational health and laboratory stakeholders from SANBS, NICD and Western Cape Blood Service. A cascading communication system was established whereby all parties are notified as soon as a suspected VHF specimen is received by any stakeholder. This creates an alert, preventing crossmatching procedures being performed on suspected VHF specimens. Universally compatible uncrossmatched products are issued instead. Systems within the blood banks, together with the existing procedure for managing VHF specimens were reviewed and areas for improvement identified. A database of suspected VHF cases was developed recording patient details, admitting hospital, provisional and final NICD diagnosis, diagnosis indicated on blood request form, crossmatch performed/not, and type of blood products issued.

Results: The active communication cascade generated a rapid response to potential cases, resulting in all stakeholders being informed of suspected cases on a near real-time basis. Of the 22 suspected cases reported to the NICD during November 2017 to March 2019, 7 occurred in 2017, 11 in 2018 and 4 in 2019. 6 cases were confirmed VHF. In 50% of the cases (11), no blood products were ordered. Of the 11 cases where blood products were ordered, 6 (55%) did not indicate 'suspected VHF' as the diagnosis. 2 of the confirmed positive cases requested blood products, and VHF was stated on the requisition. Of these 11 cases, crossmatches were performed on 2, of which one in 2017 indicated VHF on the requisition. Subsequently, no crossmatches have been performed on cases with VHF-related diagnosis on the requisition form.

Discussion: This project has improved communication and raised awareness amongst staff regarding the risks associated with working with specimens from patients with VHF. While the framework for reducing potential exposure is in place, gaps and areas of improvement still exist. A significant gap is a possible lack of awareness on the part of doctors and blood bank staff.

Conclusion: Training for blood bank staff and doctors is required to improve awareness on VHF and the associated risks for all involved.

The Implementation of Platelet Additive Solution in Buffy Coat Platelet Concentrates at the Western Cape Blood Service.

Sutton S, Bellairs G

Background: Buffy coat (BC) platelet concentrates (PCs) suspended in 100% plasma was introduced at WCBS in 2005. Whole blood was centrifuged at high speed, resulting in sedimentation of cells according to relative density. Four BCs of the same ABO group with similar collection times and one corresponding plasma was pooled in a platelet kit. Pooled BCs with plasma underwent a second soft centrifugation. Platelet-rich plasma was transferred into a platelet storage bag and residual red cells discarded.

Platelet additive solution (PAS) is a substitute medium for plasma in PC and has advantages:

- Increased plasma for fractionation
- Reduced risk of adverse patient plasma associated reactions
- Improved PC storage conditions, reduced platelet activation
- Reduced photochemical absorption times in pathogen inactivation technology.

An evaluation was done to determine if PAS with 30 – 40% plasma carryover was a suitable replacement for 100% plasma in BC PCs. Platelet specifications for quality i.e. volume, platelet count and pH were monitored.

Method: Three PAS types were selected for the evaluation. A total of 48 PCs were made, 12 for each PAS type and 12 for platelets in 100% plasma. Plasma PCs were centrifuged at 830 relative centrifugal force (RCF) for 8,5 minutes, and PAS PCs spun at 630 RCF for 6,5 minutes. PCs were weighed to calculate the final volume. Samples were taken on day 1, 5 and 7 for haematocrit (Hct), platelet counts and pH testing.

Calculations used to determine the percentage of plasma carryover:

- Red cell concentrate (RCC) = Hct x volume
- Plasma amount = Volume – RCC – PAS
- Percentage plasma carryover = amount of plasma/ (plasma+PAS)

Results: Average percentage plasma carryover was 38% in PAS PCs. Average platelet recovery for PAS 1, 2 and 3 was 74%, 72% and 73% respectively, compared to the 81% recovery in plasma. Volume averages for PAS PCs were 336 ml and plasma PCs 340 ml. One plasma PC failed to meet pH specification of >6,4 @ 20 - 24°C. All PAS PCs met the pH requirement. Four of the 36 PAS PCs failed the platelet specification of 2,4 x 10^{11}, and no failures seen in plasma PCs.

Day 5 average platelet count:

- PAS 1 3,7 x 10^{11}
- PAS 2 3 x 10^{11}
- PAS 3 2,8 x 10^{11}
- Plasma 3,5 x 10^{11}

Conclusion:

- The evaluation showed a >80% quality control (QC) pass rate on day 5 of PCs in PAS.
- The 3 PAS types compared well.
- PAS was implemented in October 2017.

Following implementation, < 80% platelet count QC was passing the required standard. The evaluation was done using 4 BCs, it was considered the PC sample size was too small to detect a failing trend. PAS with anticoagulant has a dilution effect causing a loss of platelet numbers during storage which could account for failures. From February 2018, WCBS increased from 4 to 5 BC in PCs, and to date has experienced a 96% platelet count and 100% pH QC pass rate.

Risk Factors for Recently Acquired HIV infection in Blood Donors in South Africa

Van den Berg K, Vermeulen M, Jacobs G, Swanevelder R, Hemmingway-Foday JJ, Creel D, Jentsch U, Murphy EL, Custer B

Background: Recruiting safe blood donors amongst the largest HIV-positive population in the world is a major challenge for South African blood transfusion services. South African donor deferral criteria and deferral periods for perceived high risk activities have evolved over time, but current risk factors for infection have not been formally assessed. In addition, most studies have reported risk factors for prevalent HIV infection whereas risk behaviours for incident infection are more informative as donations with these infections could occur during the window periods of available screening assays.

Aims: To identify the demographic and behavioural risk factors associated with incident HIV infection among blood donors in South Africa.

Methods: We conducted a case-control study with incident HIV-infected blood donors compared to infectious marker negative controls. Incident HIV cases and controls seronegative for HIV, hepatitis B and C viruses and syphilis were accrued from a donor pool covering 8 of 9 provinces in South Africa. Controls were frequency matched at a 3:1 ratio to cases on race, age and geography. Incident HIV-infections were HIV RNA positive by individual donation nucleic acid amplification testing (ID-NAT; Procleix, Grifols) but antibody (Ab) negative (PRISM, Abbott) as well as those RNA+/Ab+ donors with recently-acquired HIV based on Limiting Antigen Avidity (LAg) assay results with normalized optical density values of <1.5. Eligible cases and controls completed a confidential audio computer assisted structured interview (ACASI) on motivations for blood donation and behavioural factors, including behaviours in the 6 months before donation. Frequencies and measures of statistical association for risk behaviours comparing cases and controls are reported after adjusting for multiple comparisons.

Results: From November 2014 to January 2018, we enrolled 323 incident HIV cases and 877 controls; 202 (62.5%) cases and 544 (62%) controls were ≤29 years old. There were significantly more female cases 230 (71.2%) than female controls 439 (50.1%) ($p<0.0001$). Significant HIV risk factors (all $p<0.0001$) reported within the 6-months before donation included: having a primary sex partner who is male; reporting increasing numbers of male sexual partners for both females and males; frequency of vaginal sex; frequency of vaginal sex without condoms; use of methods to clean, dry, or tighten one's anus before sex; and having visited a traditional healer for medical care. Lack of medical aid (private health insurance) and reports of injury or accident with blood loss were also associated with an incident HIV infection.

Conclusion: Our study has identified a set of novel, putative risk factors for incident HIV infection among South African blood donors while confirming a number of previously known sexual risk behaviours. Not having private health insurance and being injured may be markers of socio-economic context that place individuals at higher risk rather than behaviours that directly increase HIV transmission risk. The detection of risk behaviours by ACASI in donors who passed pre-donation questionnaires and interviews suggests that ACASI has the potential to improve risk behaviour identification.

Five Years of Routine Experience using INTERCEPT Platelets with Storage up to 7 Days in Switzerland

Benjamin RJ, Infanti L, Holbro A, Passweg J, Lin JS, Corash L, Buser A

Background: Universal use of amotosalen/UVA (INTERCEPT™ Blood System for Platelets) pathogen reduced (PR) apheresis (80-90%) and pooled buffy-coat (10-20%) platelet components (PC) was introduced in Switzerland in 2011. PC's are stored in platelet additive solution (Intersol) for up to 7 days. The study evaluated the impact of pathogen reduction and storage age on the efficacy of PR-PC under routine-use conditions comparing two 5-year periods.

Methods: Platelet and recipient characteristics of all PC transfusions were prospectively captured by storage day from 01/02/2006-01/09/2011 for conventional PC (C-PC) and 01/10/2011-05/17/2016 for PR-PC. PR-PC were stored for up to 7 days and transfused for all indications with routine collection of pre- and 1-4-hour post-transfusion platelet counts. PCs were transfused on a first in, first out basis. The risk of hemostasis failure was assessed by the need for additional PC or RBC transfusion on the day of or the day following an index PC transfusion.

Results: 14,181 C-PC up to 5-days old and 22,579 PR-PC up to 7-days old were transfused to 2,036 and 2,809 general hospital patients, respectively. PR-PC dose was 3.0 ± 0.4 x1011 with a storage age of 4.2 ±1.4 days. 3,750/22,579 PR-PC (16.6%) were >5 days old at transfusion. Wastage was reduced from 8.7%% to 1.5% with 7-day storage. Overall, the mean corrected count increment (CCI) with PR-PC was 22.6% lower than C-PC over 5-days of storage ($p<0.001$), and decreased in a linear fashion with increasing age. The proportion of transfusions requiring additional PC or RBC transfusion on the same or next day was not different with increasing storage age (Table shows data for PR-PC). The median time to the next PC transfusion was ≤1.0 day for Day ≤2 PR-PC and 1.0 days for older PR-PC. The incidence of all transfusion reactions; febrile non hemolytic transfusion reactions and allergic reactions was not different for PR-PC ≤5 or >5 days-old. Hematology/oncology and hematopoietic stem cell transplant (HSCT) patients comprised 982 (34.9%) of the transfused population and used 77.6% of PR-PC. Mean number of PC used per patient; days of PC support; proportion of patient requiring RBC transfusion and mean number of RBC transfused were not different in these patients compared to the prior 5-year period when C-PC were utilized.

Age of PR-PC	≤2 days	3 days	4 days	5 days	6 days	7 days
Mean CCI (x103)	9.1	8.4	8.0	7.6	6.4	5.9
% needing additional PC on same or next day	63.2%	60.4%	60.8%	62.0%	62.3%	61.7%
% needing RBC on the same or next day	52.7%	48.8%	47.3%	49.4%	47.5%	47.7%

Conclusion: Transfusion of PR-PC older than 5 days was safe and effective and did not affect hemostasis as assessed by the need for additional PC or RBC transfusions on the day of, or the day following an index PC transfusion. The use of PR-PCs did not increase platelet requirements in hematology/oncology and HSCT patients.

The Prevalence of Non-Disclosure of Antiretroviral use Among HIV-Positive Donors in South Africa

van den Berg K, Vermeulen M, Murphy EL, Maartens G, Busch M, Hughes S, Louw VJ

Background: Non-disclosure of ARV use among HIV-positive donors who tested HIV antibody (Ab) positive but RNA negative (Ab+/RNA-), so-called False Elite Controllers, was previously described. Concerns were raised of a more wide-spread problem when a further subset of HIV Ab+/RNA+ donations with low viral loads also had high rates of ARV non-disclosure. In a country with a growing treated HIV population, ARV non-disclosure at time of donation represents a significant risk to the safety of the blood supply.

Aims: To establish the prevalence of ARV non-disclosure among HIV-positive donors and the demographic factors associated with such non-disclosure.

Methods: Blood donations previously confirmed as HIV-positive were further classified as acute (Ab-/RNA+), recent (AB+/RNA+, LAg recent), longstanding (Ab+/RNA+, LAg longstanding) and potential Elite Controller (Ab+/RNA-) HIV cases through HIV antibody (PrISM, Abbott), HIV RNA individual donation nucleic acid testing(NAT) (Procleix, Grifols) and LAg avidity testing. Stored plasma of these donations were tested for four ART drugs using qualitative liquid chromatography-tandem mass spectrometry (sensitivity 0. 0.02 µg/mL). Chi-square tests were used to assess the association of gender, ethnicity, age, geographic area, donor type, donor clinic type and HIV case type with ARV non-disclosure.

Results: During 2017, a total of 1226 donors tested HIV-positive of which 1218 were tested for the presence of ART. The overall prevalence of non-disclosed ARV use was 4.6% (n=56) with Efavirenz most frequently detected (50), followed by Lopinavir (4) and Nevirapine (2). There was no association with gender, ethnicity, geographic area and donor clinic type and non-disclosed ARV use. However, older donors aged 35 to 64 years (7.2%) were significantly more likely to test positive for ARV compared to younger donors aged 15 to 34 (3.9%; p=0.0216). Non-disclosed ARV use was significantly more frequent among New (42, 6.5%) than Lapsed (8, 3.0%) and Repeat (6, 2.0%) donors (p=0.0032). Ab+/RNA- HIV (serology yield) cases had the highest non-disclosed ARV use prevalence (2, 100%), followed by donors with longstanding (37, 4.9%) and recent (17, 4.8%) HIV. These differences were highly significant (p<0.0001).

Conclusion: Although lower than the previously reported 67% non-disclosed ARV use among HIV Ab+/RNA-) donors in South Africa, a prevalence of 4.6% non-disclosed ARV use among HIV-positive South African blood donors is an alarming finding. Higher rates of non-disclosure among New donors was expected, but non-disclosure among repeat and lapsed donors is concerning as it speaks to significant failures in donor education, recruitment and selection. The non-disclosure rate in Ab+/RNA- HIV cases is in-line with previous finding, but the 4.7% prevalence among concordant positive HIV cases suggests sub-optimal viral suppression which has significant public health implications. None of the 78 acute (Ab-/RNA+) HIV cases tested positive for ARV's, however, this may, in part, be due to the not testing for Tenofovir, the most common drug used in pre-exposure prophylaxis. Donor motivation for ARV non-disclosure at time of donation needs urgent exploration as early ARV initiation is associated with waning Ab titres or even Ab reversion, which, combined with suppressed viral loads could result in failure to detect HIV-positive donation.

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Implementation of a Script for Pre-Donation Interviews: Impact on HIV Risk in South African Blood Donors

Mitchel J, Custer B, Kaidarova Z, Murphy E, van den Berg K

Introduction: Donor selection plays a crucial role in ensuring blood safety. Since the emergence of the HIV epidemic, selection strategies are focussed on preventing window period infections by deferring donors who engaged in recent high risk behaviour. Strategies used include donor education, direct and indirect questioning of the donor regarding risk behaviour. 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. Use of these approaches is widely accepted, often as precautionary measures, but evidence of efficacy is limited. 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. We evaluated the impact on HIV risk of using a scripted interview to conduct one-on-one donor eligibility assessments in South African blood donors.

Methods: We conducted a pre-post implementation cross-sectional evaluation study to determine the impact of using a scripted interview on pre-donation high risk deferral (HRD) and recently acquired HIV (RAH) infections among accepted blood donors. We compared two 18 -month periods before (unscripted period, November 2013 to April 2015) and after the implementation of the interview script (scripted period, June 2015 to November 2016). Recently acquired HIV infections were identified as either HIV NAT yields or Lag-Avidity EIA recent (<= 1.5 OD). Chi-square tests were used for statistical significance assessment, and multivariable models were developed to determine odds ratios separately for each outcome (HRD and RAH) while adjusting for covariates, including sex, age, race, collection zone, and donation history.

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. 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). 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. The odds of RAH were higher among females (OR: 2.06; 95%CI: 1.85-2.29) compared to males and among Black (OR: 26.91; 95%CI: 21.35-33.93) and Coloured (OR: 7.33 95%CI: 5.23-10.26) donors compared to White donors. Significant differences by collection zone were evident.

Discussion: 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.

The Unexpected Benefits of Participating in Collaborative Research: A Novel Experience for the Virology Reference Laboratory at SANBS

Jacobs G

Introduction: In 2011, SANBS started its journey with the Recipient Epidemiology and Donor Evaluation Study III (REDS III), collaborating with scientists from the University of California San Francisco (UCSF) and Vitalant Research Institute (VRI) in San Francisco. The Virology Reference Laboratory (VRL) played a key role in the various arms of the study.

Nature of the problem: REDS III was the first collaborative research program of its kind for SANBS, bringing both unique opportunities and challenges to the various role-players. The aim of this study was to describe the challenges and highlight the benefits gained by the

VRL as it navigated its way through this novel experience.

Design and Methodology: We performed a retrospective, descriptive study of the primary activities performed by the VRL between November 2014 and December 2018 for the Incident HIV / HBV Case Control (CACN), and Monitoring & Acute Treatment of HIV (MATHS) studies. Data was retrieved from the Study Management System and laboratory records. Employee perspectives on challenges and benefits were sourced from a semi-structured interview.

Results: The CACN and MATHS studies ran concurrently for a period of 2 years (each study ran for 3 years) with 4 permanent and 1 temporary lab staff which fluctuated throughout the studies. Approximately 29 506 working hours were dedicated to the studies in addition to routine lab work. There were 1 464 participant visits over a period of 208 weeks. 7 374 whole blood specimens and 67 leukapheresis units were processed. 8 644 Peripheral Blood Mononuclear Cell (PBMC) aliquots yielding approximately 330 billion (329 111 x106) cells; and 6 092 plasma and serum aliquots were harvested and made available for research assays. Challenges were described as: intense workload requiring immediate attention, working extended hours, acclimatizing to new team members and communicating across various teams, high performance expectations for new processes with limited time available for development of mastery, complex procedures prone to error initially; and managing a research study of this scale alongside routine responsibilities. Benefits highlighted were: gaining new technical laboratory skills, seeking alternative ways of doing work, strengthened interpersonal skills, a broader understanding of HIV and current interventions for treatment, appreciation for diversity through inter-cultural interactions, effective planning, variety in scope of work outside routine job specifications, greater understanding of team dynamics; and ability to work under pressure. Unexpected benefits were an increase in confidence, willingness to take risks, increase in likelihood to volunteer for other studies, international training opportunities; and fostering of good relationships. Other unforeseen outcomes were the addition of anti-retroviral drug testing to the SANBS Operations Testing algorithm and an increasing interest in PBMC harvesting services from potential customers.

Discussion: Although research studies have distinct objectives related to their aims, participating in collaborative research has supplementary benefits that manifest en voyage with sometimes far reaching consequences. REDS III has been one of those journeys for SANBS and the VRL in particular.

Conclusion: Participating in collaborative research is challenging but may have surprising benefits. We hope that our experience will encourage other aspiring researchers.

Baseline Sterility Testing of Platelet Products at the Western Cape Blood Service, South Africa

Sutton S, Hilton C

Introduction: Bacterial contamination of platelet products remains a significant transfusion safety risk. A study was conducted at the Western Cape Blood Service to determine the prevalence of bacterial contamination of single-donor platelet (SDP) and random-donor platelet (RDP) products in order to establish a baseline for haemovigilance reporting and ascertain the need for implementation of additional safety measures.

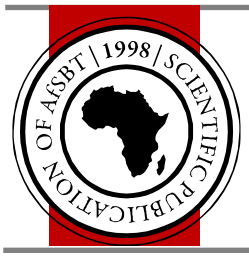
Method: The study aimed at collection of 1500 SDP and 1500 RDP products as per Council of Europe recommendations for establishment of quality control sterility programmes. The BacT/Alert® system was selected, which uses a colourimetric method and reflective light to detect carbon dioxide produced by proliferating micro-organisms. Samples of ≥ 4 ml were taken from the sample pouch of the platelet storage bags whilst maintaining a closed system. These samples were inoculated into aerobic BacT-Alert® culture bottles using sterile technique under laminar flow, 24 hours after the time of donation. The culture bottles were sent to the National Health Laboratory Service for incubation and result reporting.

Initial positive results were cultured according to gram type, and species identification was performed. If no growth occurred within five days, the result was regarded as negative. During the study period, platelet and other products linked with the positive sample donation were removed from the general stock and either retested or discarded, depending on the product. In the event of the product/s already having been transfused, the WCBS Transfusion Medical Specialist informed the relevant clinician of the results.

Results: A total of 3028 platelet products were included in this study (1521 RDP and 1507 SDP units). Three RDP units were found to be

culture positive (0.2%), all of which grew Gram Positive cocci (coagulase negative Staphylococcus, Staphylococcus epidermidis and Staphylococcus aureus). The positivity rate for SDP units was slightly higher at 0.33% (five positive units) and only Gram positive organisms were cultured (Bacillus species, Micrococcus species, Coagulase Negative Staphylococcus, Micrococcus species and Staphylococcus hominis subspecies hominis).

Discussion: The baseline sterility testing of platelet products at WCBS has established a benchmark value for our service. All organisms grown in this study were skin commensal bacteria that were likely introduced at the time of donor venepuncture or during the inoculation process. There were no cases of septic transfusion reactions reported during the study period, although under-reporting of adverse events is acknowledged in our setting. Despite this, there are several infection-control areas at WCBS that should be further investigated to mitigate the risk of potential septic transfusion reactions from bacterially contaminated products. These include improvements to donor arm cleansing, routine bacterial detection of platelet products by culture or point-of-care testing, and the implementation of pathogen reduction technology.



The Importance of Infection and Prevention Controls (IPC) in Blood Product Processing. A Case Study

Du Plessis R, Jentsch U, Niekerk T

Introduction: Pathogen inactivation/reduction (I/R) aims to reduce the risk of, among others, bacterial contamination in the product being treated. There are currently two systems available to inactivate/reduce pathogens and bacteria in plasma and platelet products which were evaluated for possible use at the South African National Blood Service (SANBS). However, manipulation of products to obtain samples for Quality Control (QC) testing during the pathogen I/R process may inadvertently introduce bacterial contamination.

Nature of the Problem: Two pathogen I/R systems were evaluated for use in pooled platelet products at two Processing sites (Site 1 and Site 2) between April and July 2017. 30 pooled platelets were produced at each site. These products were sampled for Quality Control (QC) testing according to the applicable standard operating procedures, which includes the use of a sterile welding device (SWD). The QC sampling was performed at the processing sites. The platelet products were sampled, at both sites, on day one of production, pre- and post-pathogen I/R, and on day six of storage. The actual platelet products were sampled by the QC department on day eight. Bacteriology was performed by inoculating aerobic and anaerobic culture bottles and incubating for 14 days. Site 1 yielded positive sterility results for 9 pooled platelet products, both pre- and post-pathogen I/R and one positive result for one pooled platelet product on day 6. Site 2 products yielded one positive bacterial growth pre-pathogen I/R and one negative result post pathogen I/R. The high number of positive results obtained at Site 2 was not in line with the specifications from the manufacturers of these systems. An investigation was launched to determine the root cause.

Body of Work: The QC department performed environmental screening on all equipment, wash basins and the work surfaces before and after cleaning and disinfection. Staffs' hands were swabbed pre- and post-washing. High levels of bacterial growth were obtained pre-disinfection for most of the equipment, the wash basin and the preparation area around the platelet agitator. Post-cleaning indicated sparse growth in the centrifuge drum only. The rest of the results indicated no bacterial growth. Results received for the hand swabs from staff pre and post-hand washing indicated heavy bacterial growth for all staff members. The bacteriological results pointed to inadequate hand and environmental hygiene.

Closing remarks: The actual pooled platelet products sampled by the QC department on day eight did not reveal any growth. This sampling takes place under a laminar flow hood. This investigation suggests that IPC was neglected at the time of the sampling the pooled platelet products in the processing area. Following this event effective hand sanitisation and good laboratory practice was strengthened. The critical importance of having an effective IPC program was across the SANBS value chain was emphasized and policies and procedures regarding IPC principles have been implemented.

Donors with Altered Donor Questionnaires: An Unexplored Risk?

Duncan D, van der Bergh K, Heine A

Introduction: Historically, donor questionnaires have been shown to contribute to the safety of a country's blood supply. At the South African National Blood Service (SANBS), blood donors are required to complete a donor questionnaire prior to the medical assessment and interview before proceeding to donate any blood products. Donors answers questions regarding their demographics, health and lifestyle. The lifestyle questions ask about any skin penetrating wounds, for example needle stick injuries and piercings, or markings such as tattoos and scarification. In addition, there are questions relating to the donors' and their partners' sexual lifestyle and history. In some instances, donors may answer affirmative to a question but under direct questioning change their response. The extent to which such changes are associated with potential risk is not clear.

Methods: For this retrospective study, an inspection of over 44,000 donor forms took place during the months of October to December 2017 to identify forms where changes to lifestyle questions were made.

The use of retrospective collections and HIV count data obtained from the Business Intelligence (BI) system made this study possible. The donor forms were separated into the five Collections Branches, namely Egoli Central, Egoli South, Egoli East, Egoli West and Egoli North.

Results: We identified 4,697 donor forms where donors changed answers to the lifestyle questions and who were accepted to donate blood, of whom 20 (0.43%) tested positive for HIV. Of the donors who did not make changes to the donor form and were accepted for donation 53 (0.12%) of the 42,612 tested positive for HIV. The unadjusted odds of testing HIV positive when making changes to the lifestyle questions of the donor form was 3.4 (95% CI 2.05 – 5.75) times higher than donors who did not make any changes. The highest percentage of donors making changes to the donor form and testing HIV positive occurred in the Egoli East and Egoli South Collections branches at 0.61% and 0.57% respectively. The lowest percentage of donors making changes to the donor form and then testing HIV positive occurred in the Egoli Central and Egoli North Collections branches at 0.28% and 0.25% respectively. However, the highest percentage of donors not making changes to the donor form and then testing HIV positive also occurred in the Egoli East and Egoli South Collections branches at 0.17% and 0.28% respectively. The lowest percentage of donors not making changes to the donor form and then testing HIV positive occurred in the Egoli Central and Egoli North Collections branches at 0.07%.

Discussion: We confirmed that donors who made changes to their donor forms during the interview process before being accepted to donate blood had a 3.4 times greater odds of testing HIV positive than those who did not make any changes. The differences in the geographic distributions may indicate confounding and further analysis should be considered. Despite potential confounding, donor staff who question donors about their answers should take care to ensure donors are provided a safe space within which to answer honestly when questioned further.

Blood Donor, Component, and Recipient Factors in Patient blood Management Strategies for Red Blood Cell Transfusion

Roubinian N, Murphy E, Plimier C, Busch M

Background: The shortage of blood for transfusion is a contributory factor to mortality in resource-limited settings. We sought to understand how blood donor, component, and recipient factors could be used to optimize transfusion efficacy for red blood cell (RBC) transfusion.

Materials and Methods: We conducted a linked analysis of blood donor and component data with patients who received single-unit RBC transfusions between 2008 and 2016. Studied exposures included donor factors: sex, age, and body mass index; component factors: blood collection method, gamma irradiation, and storage duration; and recipient factors: age, gender, body mass index, and pre-transfusion

hemoglobin levels. We analyzed hemoglobin levels prior to and after RBC transfusions. Linear regression was used to examine changes in hemoglobin level following RBC transfusion, and multivariable logistic analysis to adjust for recipient sex, age, and estimated blood volume.

Results: We linked data on 23,194 transfusion recipients who received one or more single-unit RBC transfusions (n=38,019 units) to donor demographic and component characteristics. Median blood donor age was 47 years (IQR: 29-58), and 57% of transfused RBC units were from male donors. All units were leukoreduced, and the median storage age of RBC units prior to transfusion was 26 days (IQR 20-32). Median recipient age was 72 years (IQR: 61-81). The mean pre-transfusion hemoglobin levels was 8.00 g/dL (SD: 0.88) and hemoglobin increment was 1.04 g/dL (SD: 0.89). Donor and recipient gender, collection method, gamma irradiation, recipient age and body mass index, and pre-transfusion hemoglobin levels were significant predictors of hemoglobin increments in univariate and multivariable analyses ($p<0.01$). The effects of individual donor, component, and recipient characteristics were additive with lower increments observed in male recipients of apheresis units from female donors (0.74 g/dL) compared to female recipients of whole blood units from male donors (1.23 g/dL).

Discussion: Blood donor, component, and recipient characteristics are significant predictors of hemoglobin increments after red blood cell transfusion. Collectively, these factors account for much of the variation observed in practice and allow prediction of changes in hemoglobin with RBC transfusion.

Conclusion: Blood donor, component, and recipient factors have utility in predicting expected hemoglobin increments with red blood cell transfusion and could be used to optimize blood allocation as part of patient blood management strategies.

Deterrents to Regular Blood Donation Among Blood Donors in the Port Elizabeth Branch of the South African National Blood Service

Harris M

Background: Collecting blood from repeat blood donors is sustainable and cost effective. At the end of 2012, 84% of the SANBS donor panel were inactive. There is a lack of research available on lapsed donors in South African and available research is mostly quantitative. The purpose of the study was to explore and uncover deterrents to continued blood donation. The study focuses on lapsed donors to understand why their initial motivation to donate blood changed.

Methods: The sample population included donors who donated blood in 2012 at permanent blood donor centres in Port Elizabeth (PE), and did not return in 2013. Eleven lapsed donors who were randomly selected participated in a two-hour face-to-face interview. A comparative analysis was done against different communication and marketing theories. The theories analysed include Harzberg's Two-Factor Theory, The Social Penetration Theory, Hawthorne Experiments, Theory of Planned Behaviour, Verderber's Transactional Model of Communication and the AIDA Marketing Model.

Results: There were 10 062 donors who donated blood at PE donor centres in 2012 and 4 923 lapsed during 2013. Analysis of sub groups showed a higher proportion of donors who lapsed in the following sub-categories: new donors (95%), re-joined donors (64%), black donors (63%), donors younger than 40 (61%), female donors (52%). Peer Pressure was highlighted as the biggest motivator. As Peer Pressure declined due to changing jobs or other reasons, commitment to blood donation was negatively affected. Poor customer service, convenience, location, communication and reminders, bad or hurtful previous donation experiences was not mentioned as a deterrent. Participants felt that SANBS staff was competent and professional. All participants showed a high intention to donate blood again, and within a month after the interviews, 18% of the participants donated blood again.

Discussion: Of the six communication theories applied, The Social Penetration Theory highlighted the cost-minus-benefit ratio which played a big role in these donor's motivation and decision to return. The AIDA Marketing Model described lapsed donor behaviour most comprehensively, although one critical step was omitted through an application of Grounded Theory. An additional fourth step was identified and called "Action Motivator". "Action Motivators" should result in the desired "Action" as the existing fifth step which in the blood service's context would refer to increased blood collections, improved blood donation frequency and a reduction in lapsed donors. The 18% of participants that returned to donate blood after the interview, confirm the power of the Social Penetration Theory were closeness is

regulated, on the basis of rewards and cost. The depth of professional interaction with blood donors play a big role in retention and personalising recruitment efforts and messages becomes critical.

Conclusion: Donors lapse due to a lack of an "Action Motivator". "Action Motivator" is the critical missing step in the AIDA model and provides creative opportunities to improve donor retention. Recruitment efforts should be strategically planned in line with existing theories. Combining the AIIDA Model with the Social Penetration Theory in donor recruitment can yield excellent results if applied correctly and consistently.

A Two-Year Retrospective Review of Adverse Events in Patients Receiving Clinical Apheresis Provided by SANBS

Anderson L, Strydom C, Poole C, van Wyk E, Mills L

Background: Clinical apheresis procedures are used for the management of a growing number of diseases. The South African National Blood Service (SANBS) uses a mobile clinical apheresis system to maximize coverage in 8 of the 9 provinces of South Africa. The aim of this retrospective study was to review the adverse events experienced by patients during clinical apheresis in a real world patient population in South Africa. The procedure types reviewed include therapeutic plasma exchange (TPE), peripheral blood stem cell collection (PBSC), leucopheresis and red blood cell exchange (RBCX).

Material and Methods: A retrospective descriptive review of all clinical apheresis intra-procedure adverse events logged on the SANBS SAP notification system was performed for the period June 2016 to June 2018 and verified against the clinical apheresis procedure worksheets. The apheresis procedures were performed using a continuous flow centrifugation platform. The number and type of adverse events, type of procedure, replacement fluid (TPE) and disease indication for the procedure were recorded.

Results: A total of 3724 therapeutic apheresis procedures were performed on 828 patients at 18 hospitals in South Africa during the study period. Of these 3060 (82.2%) were TPE, 505 (13.5%) were PBSC, 144 (3.9%) were Leucopheresis and 15 (0.4%) were RBCX. A total of 229 (6.1%) adverse events were recorded. Of all adverse events, 78% (n-179) were associated with TPE, 15% (n=35) were associated with PBSC, 7% (n=15) were associated with leucopheresis and none with RBCX. Leucopheresis had the highest percentage of procedures with adverse events (15/144, 10.4 %), followed by HPC-A (35/505, 6.93%) and TPE (179/3060, 5.85%). For leucopheresis, the most common disease indications were hyperleukocytosis requiring leukopheresis in Chronic Myeloid Leukaemia (CML) and Acute Myelod Leukamia (AML) patients and the average incident total white cell counts was 291.2 x 10^9 cells /L (107-525 x 10^9 cells /L). Among the 179 TPE, during which adverse events were reported, the replacement fluids utilised and the percentage of adverse events reported were FFP 94 (53%), albumin-saline 4% solution 70 (39%) and cryopoor plasma 15 (18%). The patient population treated were mainly HIV positive, antiretroviral treatment naïve patients with at least one other co-morbidity other than HIV and TTP. There was 1 death during procedure that occurred and according to the managing clinician was attributed to the underlying disease.

Discussion: The overall adverse event percentage of 6.1% compares favourably with both published multicenter (4.8%) and single centre (36%) studies from the USA. No fatalities were directly ascribed to clinical apheresis; the overall procedure mortality rate was 1:3724. This is compared with a French clinical apheresis registry study reported overall mortality range of 1:5000 to 1:10 000 and the Swedish apheresis registry study value of none in 20 485 procedures. The patient population treated were mainly HIV positive, antiretroviral treatment naïve patients with at least one other co-morbidity other than HIV and TTP.

Conclusion: For the study period, therapeutic apheresis procedure using continuous flow centrifugation platforms have an acceptable percentage of adverse events and no deaths ascribed to the procedure.

Do Once-Off Annual Campaigns Influence Donor Return Rate and Interval to Return?

Mitchel J, Vermeulen M

Introduction: Blood donor recruitment and retention is an important key factor in ensuring a sustainable blood supply. Once-off annual campaigns are often used to create public awareness and get more people to donate blood. While these campaigns are usually successful in increasing blood collections on the day, it is not known if the donors would continue to donate blood on a regular day. On March 21, 2018, the South African National Blood Service hosted a nationwide campaign, #Thumamina, urging the whole nation to donate blood. The campaign was successful and brought in an excess of 5400 units of blood on the day. The aim of this study was to determine whether campaigns have a better return yield than routine days.

Methods: First time donors who donated on #Thumamina were analysed and compared to a control group of first-time donors who donated the week before, from March 12-15, 2018 (Non-#Thumamina). We used data from the SANBS Business Intelligence to assess return rate, interval to return and number of subsequent donations. Chi-square and Odds Ratios were used to determine statistical significance.

Results: Of the 2713 first time donors in the study, 1207(44.5%) donated on #Thumamina. The mobile blood drives accounted for 771 (63.9%) and the majority of the donors were Black 704(58.3%). More female donors 694(57.5%) donated compared to males. Of the 1207 #Thumamina first time donors, 632(52.4%) returned compared to 855(56.8%) for the non #Thumamina first time donors (OR: 0.80; 95% CI: 0.72-0.92). There was no difference between the two groups for most donor demographic characteristics except there was a significantly lower odds of returning from the #Thumamina donors for males (OR: 0.76; 95%CI: 0.59-0.97), White donors (OR: 0.70; 95%CI: 0.50-0.96) and >= 40 age group (OR: 0.60; 95%CI: 0.40-0.90) when compared with the same donor characteristics in the non #Thumamina donors. There was no significant difference between the two group's return rate in Eastern Cape, Egoli, Mpumalanga, Northern and Vaal zones. However, in the Kwa-Zulu Natal and Free-State zones, first time donors from #Thumamina were less likely to return compared to non #Thumamina (p=0.02 and 0.03 respectively). There was no significant difference with regards to interval to return between the two groups, however, #Thumamina donors were less likely to give two subsequent donations (p<0.00001) but more likely to give four (p<0.00001) subsequent donations.

Discussion: The study found that, first time donors who donated during the #Thumamina campaign were less likely to return compared to non #Thumamina donors. The lower return rate amongst #Thumamina donors could be attributed to inadequate donor education and the hype of the day. While we found no difference in interval to return, it was surprising to find that #Thumamina donors who did return were more likely to give four subsequent donations compared to non #Thumamina donors. This finding suggests that as the donors become familiar with blood donation and receive more education, they may be more committed to donating blood regularly.

Assessment of Major Motivational and Inhibitory Factors for Voluntary Non-Remunerated Blood Donors in Zimbabwe.

Mutenherwa M

Background: In the whole world, human blood is the only source of blood that is required to correct deficiency of blood components in humans. Zimbabwe is one country in the world that conforms to the WHO recommendation of obtaining safe blood from voluntary non-remunerated blood donors (VNRBD). The donor recruitment process is a difficult task that requires proper strategic planning with knowledge of the factors that motivate VNRBD in order to sustainably maintain stocks of blood that is adequate to meet patient needs. This study was carried out to assess the motivational and inhibitory factors for VNRBD in Zimbabwe.

Methods: The study was a desktop review retrospective survey that analysed secondary data collected by NBSZ through self-administered questionnaires that are completed by the NBSZ mobile team leader, the Head or contact person of a panel and the NBSZ Planning and recruitment officers. The study was done from May to June 2018. The study population was all panels that NBSZ visits. The sample was all panels visited by NBSZ mobile teams in 2015. The sampling technique was convenient sampling. All the mobile team time sheets reports and mobile team time sheets were gathered from January 2015 to December 2015. For the mobile team time sheet reports, data on all areas that needs improvement was captured in excel categorised into either motivator or inhibitor of blood donors or blood donation and qualitatively analyses. All the comments by the PROs on the mobile team time sheets reports were captured in excel, interpreted and categorised as motivator, inhibitor balanced and no comment. These were semi-quantitatively analysed.

Results: The NBSZ mobile teams visited 194 panels in 2015. The expected number of comments was 388. Overall, the motivators were 52% (168/323), the inhibitors were 23% (74/323), and the balanced were 25% (81/323). The probability that a VNRBD will be motivated is twice the likelihood that the donor will be inhibited. The major motivational factors for VNRBD in Zimbabwe include: peer promotion, incentives, refreshments, regular donation, lack of disturbances, regular visits, cooperation, donor mobilisation, service quality, awareness, noble cause, posters, motivational talk, willingness, gender, reception, staff, bereavement, sms, no incidences, professionalism, innovation, media campaigns, peer education, churches, ethical conduct, punctuality and donor turn out. The major inhibitory factors for VNRBD in Zimbabwe include: weather conditions, examinations, booking, holidays, retrenchment, talks, under age, competition, absenteeism, incentives, authorisation, student behaviour, venue, bereavement, association, vehicles, talk, schedule fulfilment, competition, distance from the NBSZ mobile fixed centre, fear, lack of variety and innovation, attitude of staff, financial status, teachers, reminder, leave, lack of banners, staff shortage, sports, preparedness, poster strategies, staff efficiency, convenience, lack of support, change process, donor education channels, donor health status, donor population composition, incentives, competing priorities, ethics, blood component utilisation, counselling, refreshments and competition.

Conclusions: VNRBD do not expect payment in return for donating blood. The refreshments that are offered by NBSZ influence VNRBD to give blood.

The Effectiveness of Introducing a Donor Representative Points-Based programme

Salie A

Background: A donor representative plays an important role in establishing a business relationship between the organisation he/she represents and the Western Cape Blood Service (WCBS); they are relied on to organise and promote blood donation clinics. As members of WCBS, donor representatives are the voice for a panel of blood donors at their organisation and have voting rights at the Service's Annual General Meeting (AGM). In the past, donor representative's efforts in promoting blood were recognised by inviting them to a year-end recognition function, and a small gift was awarded to them as a gesture of appreciation for their work throughout the year. Due to the low attendance of these functions, as well as the cost and time in organising such a function, it was decided to trial a different appreciation strategy.

Method: In February 2018, a donor representative points-based rewards programme was introduced through e-mail communication, explaining the dynamics of the programme. Each donor representative would start off with a standard gift voucher with a base amount of R100. An opportunity to increase the voucher amount was based on their participation in certain activities and tasks. Each activity successfully achieved equated to 10 points, equivalent to R10, added to the voucher. The programme was implemented throughout the Service, but results are only presented for the Cape Town metropole.

Results: Of the 367 Cape Town Metropole donor representatives who had performed their duties for more than six months, 350 (95%) participated in the awards programme and scored according to the following activities:

• 86% hosted more than four clinics in 2018.

• 85% had no clinic cancellations during the year – re-scheduling to an alternative date was permitted.

• 66% of clinics increased their donor base by 10%: the base set was captured in February and measured against the November statistics.

• 15% of donor representatives attended the AGM or managed to send a completed proxy form.

• 96% of donor representatives updated their clinic scheduling requirements and contact information via the Annual Clinic Review Form.
• 31% of donor representatives accommodated extra awareness activities.
The total costs for gift vouchers in 2018 amounted to R47 890, while the event and a small gift for donor representatives added up to R60 206.

Conclusion: A points-based recognition programme has shown to be effective in not only showing recognition and appreciation to donor representatives but also act as a cost-effective incentive to encourage their buy-in and participation in activities benefiting the Service. Also, all donor representatives are now recognised based on their efforts, as opposed to only a small percentage that attended the function in the past.

Battle of the Blood Donors: A Marketing Campaign at Educational Institutions in the Western Cape

Gevers M

Background: Schools compete in various fields such as academics, culture, chess, choir and sport. Based on this spirit of competitiveness, the Battle of the Blood Donors campaign was created by the Western Cape Blood Service (WCBS) where schools would compete against each other to increase blood donations. The battle took place in the first two months of the second term in both 2018 and 2019. Blood donor clinics at educational institutions were invited to take part in this campaign and were nominated to challenge one or more schools. The winner of each challenge was determined by a pro-rata formula looking at the potential eligible donors, the number of new donors, attendance and units collected at the clinic. An overall winner was also selected from all the winning schools. Each school was responsible for coming up with creative initiatives to promote their respective blood donation clinics. WCBS Promotions Officers assisted with normal promotional material and Blood Buddy, our mascot, was offered to make appearances at the clinics. Members of the public, parents and surrounding schools were invited to donate; inter-class and grade competitions were held; presentations were held in assembly; flyers were distributed to the community; the schools' social media platforms were used and one school even advertised on a local radio station. The purpose of this study was to determine whether the Battle of the Blood Donors was an effective recruitment and blood collection campaign for educational institutions in the Western Cape.

Method: The total number of units collected and new donors in 2017, when no specific campaign was held, was compared to the same period in 2018 and 2019.

Results: Comparing data from 2017 to 2018, there was a 9% increase in total units collected and a 10% increase in new donors. Comparing 2018 with 2019 there was an increase of 28% in units collected and a 15% increase in new donors.

Conclusion: The Battle of the Blood Donors campaign met its overall objectives of increasing new donors, attendance and units collected over the campaign period in 2019 and 2018 compared to 2017. This campaign encouraged camaraderie amongst members of the community and in the educational institutions, and inspired them to come up with great initiatives to promote their blood donation clinics, even after the campaign. It also created a platform for WCBS to provide additional education and blood donation promotion than normally allocated, as educational institutions were invested in the competition. This campaign created a great stepping stone from which we will build upon and host our next battle in 2020.

Review of the Guidelines for Medical Assessment of Donors

Rapodile T, van den Berg K

Introduction: The South African National Blood Service (SANBS) which services 8 of the 9 provinces in South Africa, has in recent years struggled to maintain its blood stock above a 3-day supply, a level generally considered the minimum at which to ensure security of supply. Strict deferral criteria aimed at ensuring the safety of both blood donors and recipients are thought to contribute to the difficulty in maintaining a sufficient blood supply.

Nature of the problem: In 2018, these strict deferral criteria resulted in a 20% deferral rate with one out of every five potential donors being turned away. Deferred donors have lower return rates and if they do return take longer to do so. The need to balance the demand and safety of the blood supply has led to an in-depth review of the SANBS Donor Selection Guide.

Design and Methodology: An extensive literature review was performed, comparing SANBS criteria to those of the World Health Organisation, United Kingdom (UK), American Red Cross and Canadian Blood Services. Areas of discrepancy were reviewed and in general alignment with the UK and Canadian guidelines was reached. Where SANBS practice did not align with these services, an assessment of the South African context in relation to the particular practice was performed. Opinion with supporting evidence was sought from experts within SANBS, and local and international organisations and societies. All changes were collated and presented to the business, the Medical Director and the SANBS Clinical Governance Committee for consensus agreement.

Results: In total, 192 changes were made to the guidelines of which 91 (47%) related to medical conditions, 46 (24%) to high risk exposures and 16 (8%) to medical procedures and investigations. Overall, 93 (48%) conditions had a reduction in their deferral periods with most of the remaining conditions being internally aligned to ensure that similar conditions had the same deferral period. Requirements for doctors' letters for 39 conditions were removed resulting in only 10 conditions for which such letters are still required; a 78% elimination of such letters.

Discussion: The majority of the changes made fell into four major categories: a 3-month decrease (from 6 months) for high risk exposures; a similar decrease for major medical procedures and a decrease from 3 months to 2 weeks for minor medical procedures; removal of the requirement for doctors' letters for certain conditions and an increase in the upper age limit from 65 to 75 years for first time donors. In addition, the simplification and standardisation of the deferrals have enabled non-healthcare professionals to assist with donor assessment, addressing a major cause of bottlenecks in the donation process. The more efficient donor assessment process should improve the donation experience and in turn lead to improved donor retention.

Conclusion: The simplified guidelines will provide a best-practice, simplified tool to SANBS staff with which to assess donors. Careful, continuous monitoring of the impact of these changes on donor and recipient safety are required to ensure that any negative impact is identified early and responded to rapidly.

Blood Donor Satisfaction – A Four Year Review

Van Schalkwyk I

Background: Without the continued altruism of blood donors, supplying sufficient, safe blood products would be impossible. Retaining blood donors depends on meeting and exceeding their expectations. Donors are more likely to make repeat donations and recommend blood donation when they have had positive experiences. The Western Cape Blood Service recognises the necessity to regularly review our understanding of the needs and interests of our biggest stakeholder, our blood donors. This is done through an annual donor satisfaction

survey, the results of which steer our strategy review and business planning process. The results of the 2015 to 2018 surveys are presented here.

Method: Within a 12-month interval, one month is selected when all active donors are sent an SMS with a link to the survey via a digital platform, Mobiz. Donors are asked to rate their satisfaction of ten aspects of their recent blood donation process on a Likert scale of 1 to 5 where 1 is "very poor", and 5 is "excellent". They also have the option to include comments or suggestions. The participating donor receives an SMS thanking them for their participation. Results are collated and presented at a meeting with the relevant WCBS departments where the outcomes are discussed and analysed. The target outcome is to obtain a score of 3 or more by 80% of the respondents. Any score below this is investigated, corrective actions are taken, and additional training is done on aspects that need to be reinforced. Teams are informed of any positive feedback received.

Results: The study included 578 participants in 2015, 748 in 2016, 571 in 2017 and 1 683 in 2018. An average of 39% of donors that received the SMS clicked through to the survey link, and 20% of donors went on to complete the survey. The average results over four years with a maximum score of 100% (equivalent to 5 on the Likert scale) were the following:

- Communication prior to donation/recruitment – 92.8%
- Visibility of the clinic (directional and promotional signage) – 85.2%
- Reception and greeting on arrival – 89.6%
- Professional appearance of staff – 84.5%
- Friendliness and helpfulness of staff - 95.8%
- Professional appearance and cleanliness of donation area – 94.7%
- Refreshments offered after donation – 91.6%
- Post-donation advice given and thanked for donation – 90.55%
- The time it took to make your donation - 94.4%
- The likeliness that you will recommend blood donation based on your experience – 96.2%

Conclusion: With a 93% overall score over the four years, donors are generally very happy with the service they receive. It is positive that 96% of donors would recommend WCBS to people considering donating blood. Consistent areas for improvement (90% and below) have been the visibility of clinics/signage, as well as reception and greeting on arrival. The comments section offered valuable insights and suggestions for improvement. The annual donor satisfaction survey gives a good overview of customer service at all WCBS blood donor clinics. It ensures that customer service is measured by donors and that staff are held accountable.

The Rare Donor Program at SANBS: Achievements and Future Plans

Van Nierke LN, Jentsch U, McLinden D

Background: The South African Rare Donor Program (SARDP) is a collaborative program between the South African National Blood Service (SANBS) and the Western Cape Blood Service (WCBS) to identify rare donors and obtain their donations for storage and issue when required. Donors are considered rare if they lack antigens present in 99% of the population, or if they are negative for high frequency antigens. Natural attrition of donors has led to a decline of the active rare donor database and the use of a manual system for the tracking of incoming and outgoing rare donations made assessment of the status of the rare donor program difficult. In order to re-establish a younger, active donor pool, an urgent donor screening program was implemented. The objectives of this study were to analyse the outcome of the rare donor screening program implemented by SANBS in January 2016 through to October 2018, to describe the number and type of new rare donors identified, and to list the rare types most frequently issued.

Methods: A retrospective review using frequency analysis of laboratory data was performed. Batch screening of random donor samples was performed to identify rare types, using extended phenotyping by manual tube indirect antiglobulin and enzyme techniques. Results were captured on Meditech, the SANBS operating platform, and extracted to the SANBS Business Intelligence System.

Screening outcome was assessed by comparing the number of donors screened to the number of rare donors identified. Rare units issued by the SARDP from January 2016 to October 2018 are presented, along with an analysis of the number of the active donors.

Results: From January 2016 to October 2018, 11712 random donor samples were screened. This resulted in the identification of 90 rare donors, a success rate of 0.8%, increasing the SARDP by 38%. Types identified were: 40 hrB-, comprising 44% of the newly identified rare donors, 17 U-:19%, 14 Js(b-):16%, 9 hrS-:10%, 7 U variant: 8%, 1 Lan-, 1 Do(b-) and 1 kk, each comprising 1% of new types found. The following rare units were issued from the SARDP over the same period: 65 hrB-, 23 U-, 18 hrS-, 7 Lu(b-),6 kk, 6 Js(b-), 4 Oh, 3 Yt(a-), 4 Lan- 2 Kp(b-), and 2 Tja-.

Conclusion: SANBS currently has 129 donors contributing to the SARDP. The most frequently issued rare types are hrB-, hrS- and U-. These issues are supported by 80 donors and their donations make up approximately 36% of the frozen units available in the repository. The SANBS rare donor screening program has successfully identified donors with rare types, however, long-term screening is unsustainable due to limited availability of the rare reagents required. Future plans for the rare donor programme include the sourcing of alternate supplies of rare reagents, validation of different screening methods as well as the introduction of a family studies programme, for the identification of rare blood types within the families of rare patients and donors.

Is the Increase in the Group O Day's Cover Bloodstock a Result of a Focused Goal that was Displayed on a Visible Scoreboard and Instilled Accountability and Responsibility?

Duncan D, van den Berg K

Background: The South African National Blood Service (SANBS) measures the availability of blood by using the "Day's Cover" at the zonal and at national level which is based on what the estimated daily patient issue requirements are, and what the available stock levels of the blood group specific blood products in the inventory departments are. The requirement of zero cutbacks has become the singular most important ethical goal in ensuring that patient demand is fully met. In "The 4 Disciplines of Execution: Achieving your Wildly Important Goals", McChesney, Covey and Huling explain how to achieve effective execution of goals using 4 key disciplines of execution, namely the discipline of focus, leverage, a compelling scoreboard and accountability to produce outstanding results.

Methods: Nationally, the SANBS Operations Management created a clear focus by setting a clear goal of achieving a 4-days blood stock level to mitigate the need to perform cutbacks due to constant low stock levels. We leverage additional budget allocations to employ 101 new staff members and procure extra equipment. A compelling scorecard was initiated on 20 December 2018; a WhatsApp group for Bloodstock Emergency Response Team (BERT) report was created. Zone Donor Managers (ZDM) were required to report on collections versus target for the previous day, the shortfall if present and action plans to correct the shortfall. The members of this WhatsApp group include Senior Management, the Chief Operations Officer, the ZDM and the Head of Donor Relations. Accountability was instilled through the BERT report in that the ZDM were held accountable for achieving the daily targets. Retrospective data obtained from the SANBS Business Intelligence system were used to analyse changes in Group O blood stock levels.

Results: In 2018 for the 3 months prior to December and implementation of the BERT report the Group O blood stock levels were 2.7, 3.2 and 3.0 days. The goal of 4 days cover was not achieved.

Average Group O blood stock levels of unfiltered reds cells per month in 2019 were 2.9, 4.7 and 5.4 days for January, February and March respectively, achieving the 4-days cover goal 66% of the time. In contrast, the days cover for the same months in 2018 were 3.1, 3.4 and 3.7 respectively.

Conclusion: An analysis of the methods used to increase the Group O blood stock levels showed that all four of the Covey disciplines were used with remarkable success. A comparison of the results for 2019 and the same period in 2018, and a comparison for the 3 months in 2018 prior to the introduction of the four disciplines when compared to the 2019 results shows that there was an increase in the Day's Cover for Group O once the BERT report was introduced. Implementing the four disciplines have led to an increase in the Group O bloodstock levels because of the focused goal, leveraging resources, requirement to submit daily focused reports and the accountably to address any shortfalls. SANBS should consider replicating this mechanism for ensuring the achievement of strategic goals.

Collection of Hyperimmune Rabies Plasma at University of Pretoria Onderstepoort Faculty of Veterinary Science Campus

Van Der Merwe W

Introduction: In the recent past the South African National Blood Service (SANBS) has not been able to supply the National Bioproducts Institute (NBI) with the annual required 2300 litres of hyperimmune Rabies plasma. The plasma is used to make Human Rabies Immunoglobulin, a product critical to the treatment of people exposed to rabid animals.

Nature of the case: At the beginning of 2017 a SANBS task team investigated possible interventions to increase the volume of hyperimmune Rabies plasma collected. The decision was made to target the University of Pretoria Onderstepoort Faculty of Veterinary Science Campus (UP Onderstepoort). This would be done by running an awareness and education campaign for students and staff and thereafter administering vaccinations and performing plasmapheresis procedures on campus. The main reason for this decision was that students and staff at the campus receive anti-Rabies vaccines as a requirement for their studies and therefore potentially could qualify to become plasma donors without SANBS having to start the vaccination programme. The campus management has also previously indicated their willingness to assist and participate in programmes related to the fight against Rabies.

Body of work: Discussions with the management at the UP Onderstepoort campus started during July 2017. The initiative was launched with an awareness campaign and event on the campus for students and staff on 18 September 2017. Stakeholders from SANBS, NBI and the National Institute for Communicable Diseases were involved in the event. Thereafter a permanent venue on campus was provided to SANBS which was used to take samples, vaccinate and perform plasmapheresis procedures. Immediately it was apparent that students and staff at Onderstepoort would support the initiative. Plasmapheresis procedures were started on a small number of students whose antibody titre levels were sufficient during November 2017. SANBS staff were available on campus initially one day a week which was increased to three days a week from May 2018. Two days for performing procedures and the third to administer vaccinations and take samples. A Special Projects Coordinator role was created and filled to run the project, administer vaccinations and perform plasmapheresis procedures from April 2018. From February 2018 to February 2019 a total of 310.8 litres of plasma have been collected through 787 plasmapheresis procedures. On average 60 procedures were performed per month for this period. The number of procedures and volume collected have been steadily increasing with a peak seen in October 2018, during which 127 procedures were completed, yielding 50.8 litres of plasma.

Closing remarks: The initiation of hyperimmune Rabies plasma collections at UP Onderstepoort has contributed significantly to the increase in this type of plasma supplied to NBI. For the period March 2018 to February 2019, 136 more plasmapheresis procedures were performed at UP Onderstepoort than any other SANBS site. There is however still potential to substantially increase the volume collected at UP Onderstepoort. The frequency of visits to the campus and increasing resources allocated for this purpose will be adjusted to facilitate this.

GRID - The Global Registration Identifier for Stem Cell Donors - Is it different from ISBT 128 Donation Identification Number (DIN)?

Ward J, Ingram C, Schlaphoff T

Background: GRID stands for Global Registration Identifier for Donors. The GRID project was initiated after a patient was transplanted with stem cells from an incorrect donor (0/10 match) due in large part to the inappropriate use of a supposedly unique donor identifier. Donor registries facilitate the exchange of stem cell products throughout the world. To improve communication across national and international borders, and to prevent errors in identification of donors, a system to uniquely and consistently identify potential donors and

product on a global scale is needed. The European Union Regulations require all blood products to be distributed internationally must carry a unique identifier. To this end, the World Marrow Donor Association (WMDA) is working in collaboration with ICCBBA (formally the International Council for community in Blood bank Automation) to develop and implement GRID. GRID assures that every donor is assigned a globally unique identifier; thus reducing the risk of misidentification. GRID will eliminate the possibility of two donors having the same identifier across the global network.

Implementation: GRID is a nineteen-character identifier composed of three elements: a four digit Issuing Organization Number (ION); a thirteen-character Registration Donor Identifier assigned by the Issuing organization; and a two-digit checksum. ISBT 128 DIN for Blood Donation is a thirteen-character identifier composed of a five-digit facility identification number (FIN). The Implementation plan for GRID is made up of six steps:

Step A – Start of the implementation of GRID completion date 31 December 2018

Step B - Donor files submitted to the Search & Match Service show the old as well as the GRID donor ID, completion date 01 January 2019

Step C 1 - Organisations start to use the new GRID ID in their IT communications between organisations, completion date 29 April 2019

Step C 2 - Organisations must use the new GRID ID in all international (IT & Operational) communication between organisations, completion date 01 July 2019

Step D - Use the new GRID donor ID as the main donor identifier, completion date 17 December 2019

Step E - Fully implemented the new GRID donor ID, completion date 15 December 2020.

Conclusion: It is believed that the GRID will improve electronic communication, traceability, and accuracy in unambiguously identifying potential donors by standardizing systems of donor identification across the globe. The steps taken and path of implementation taken by SABMR to comply with regulations and international standards will be presented.

ABO Next Generation Sequencing (NGS) – An Exploratory Study of Common and Rare ABO Sub-Types at the South African National Blood Service

Govender L, Moonsamy A, Jentsch U

Background: In blood transfusion, the gold standard serological phenotyping method is used to complete ABO blood grouping in 90% of cases. The remaining 10% of complex and/or inconclusive serology ABO cases are resolved by red cell genotyping. Molecular red cell genotyping uses DNA extracted from blood samples to identify the genes coding for the ABO red cell antigens present in individuals. However, red cell genotyping for the ABO blood group is limited to the gene and allele coverage of the commercial kit. Further, rare and novel alleles may not be covered by the kit and may be missed. South African individuals have several rare ABO subtypes such as the Abantu, Bombay Oh, Parabombay, Ael, Ax that cannot be identified by the current red cell genotyping kit. This prompted the requirement to evaluate commercial red cell next generation sequencing (NGS) assays. Red cell sequencing allows for massive, parallel sequencing of genes coding for ABO antigens. This exploratory study was to review, interpret and analyse the sequences that arise from testing common and rare ABO blood types.

Methods: A panel of 15 samples comprised of Group A1, A2, B, O, AB and a further 10 samples that were either identified serologically as either weak/inconclusive/rare were tested using the Omixon Monotype ABO NGS kit on the Illumina/MiSeq instrument. The sample DNA was extracted using the Maxwell AS2000 instrument and 50ng/ul DNA was used to complete the Omixon ABO NGS assay over 2 days. The Micro 300 cycle cartridge was loaded on the MiSeq and results were interpreted on the HLA Twin software on Day 3.

Results: The standard Group A1, A2, B, AB and Group O ABO NGS results correlated 100% with the known red cell genotyping results. The rare ABO NGS results correlated with the known red cell genotyping results at the broad gene level. Interrogation of sequences at the allele level showed the differences between a common versus rare ABO group.

Discussion: The HLA Twin analysis software uses the reference ABO sequences obtained from the dbRBC (database red blood cell) that contains gene sequences from a number of databases including the Blood Group Antigen Gene Mutation Database (BGMUT). However, this database is comprised of sequences obtained from completed international studies and therefore is not a fully comprehensive database. For this reason, many ambiguous results were obtained at both alleles in this study. One benefit of NGS is that high resolution results were obtained to the 6th digit level allowing for interrogation of exons and flanking introns. However, until more experience is gained in analysis of NGS results, the real benefit and value-add of the detailed sequencing results will not be realised.

Conclusion: Red cell sequencing is new to users at SANBS and experience in reviewing bulk data produced by NGS will assist in creating a database of ABO sequences amongst the different ethnicities in South African blood donors. This new technique will be used to upskill staff and more importantly assist with identifying rare and novel ABO blood types.

KIR Genotyping at the South African National Blood Service (SANBS) – First Steps and Looking Ahead

Govender L, Moonsamy A, Jentsch U

Background: Human natural killer (NK) cells have the ability to lyse target cells without prior sensitization (hence termed 'natural killer' cells). NK cells are important in the innate immune system as the first line of defence against infectious agents where they kill virus-infected and malignant cells. Families of antigen receptors control the functions of natural killer cells, prominent amongst these receptors are the Killer cells Immunoglobulin-like Receptors (KIR). KIR cells thus regulate the activity of the NK cells. The KIR family consists of 15 distinct KIR genes 2DL1, 2DL2, 2DL3, 2DL4, 2DL5, 2DS1, 2DS2, 2DS4, 2DS3, 2DS5, 3DL1, 3DS1, 3DL2, 3DL3 and 2 pseudogenes

2DP1, 3DP1 located on chromosome 19q13.4. The KIR genes are differentiated into two haplotypes, Haplotype A (inhibitory) and Haplotype B (activating).

Methods: A known KIR panel of 30 samples was sourced from University of California, Los Angeles. The DNA was diluted to 50ng/ul for use with the Innotrain KIR Ready-Gene genotyping assay. The assay mastermix was prepared and added to plates containing pre-aliquoted primers, followed by the addition of DNA. Amplification was completed on the 9700 thermal cycler. Visualisation of bands was by gel electrophoresis using a 2% agarose gel. The size of bands against the reference KIR decode was used for interpretation of the KIR genotypes.

Results: The inhibitory KIRs 3DL1, 3DL2, 2DL1, 2DL2, 2DL3 was positive in 63% (19/30) of the panel. The activating KIRs 3DS1, 2DS1, 2DS2, 2DS3, 2DS4, 2DS5 was present in 13% of the panel (4/30). The sum of inhibitory KIRs being weaker than the activating KIRs was noted in 7% (2/30) samples and the sum of activating KIRs were weaker than inhibitory KIRs in 20% (6/30) samples. KIR2DL1, KIR3DL3 and KIR3DP1 was present in 100% of the samples.

Discussion: In individuals where the sum of inhibitory KIR signals are weaker than the activating KIR signals then target cells such as tumour cells will be lysed. Inhibitory KIRs 3DL1, 3DL2, 2DL1, 2DL2/3 are associated with HLA-Bw4, HLA-A3/A11, HLA-C2 and HLA-C1. Activating KIRs 3DS1 and 2DS1-5 are associated with HLA-B*57:01 and HLA-C. Combinations of these HLA variants and KIR correlate with not only the outcome of haematopoietic stem cell transplants but also with autoimmunity (rheumatoid arthritis), virus infections (HIV, HCV) and pregnancy complications. In this study, KIR2DL1, KIR3DL3 and KIR3DP1 was present in all samples and therefore is not informative as a marker of clinical outcome.

Conclusion: While there have been great advances in KIR genetics, knowledge of basic KIR biology (expression, specificity, function) lags well behind. This is partly due to the difficulties in developing specific reagents for proteins with a high degree of similarity. One of the first large studies identified that KIR2DL3, when present on a homozygous ligand background (HLA-C1/C1), was associated with spontaneous resolution of HCV infection. In another study, KIR3DL1 modified the HLA-B*57 protection against HIV-1. The next step from this study will be to explore the value of KIR testing in the SA environment, possibly looking at KIR-HLA-HIV associations.

Onsite Evaluation of Two Automated Blood Grouping Analysers: Zimbabwe Experience

Mavunganidze G, Nkomo SZ

Background: The National Blood Service Zimbabwe (NBSZ) automated its donations blood grouping in the year 2011 adopting Bio-Rad's Tango Optimo (TO) for its routine testing. Prior to that, the conventional tube test (CTT) was being used, and continued being used for confirmatory purposes upon move to automation. All donations are from voluntary non-remunerated blood donors and routine Transfusion Transmitted Infectious (TTI) diseases and donor blood group testing is performed on all donations. Annual national blood donations for 2019 is estimated at 108 400 donations. Due to the very poor throughput of Tango Optimo, it was not possible to perform routine antibody screening on all donations. The CTT method proved to be faster than TO, hence all gains for automated immunohematology were not realized with TO. In time there developed a need for a higher throughput analyser and two automated immune-haematological systems were considered.

Aims: To evaluate the performance, and efficiency of two fully automated immuno-haematological systems; and assess their role in donor blood group and antibody screening at NBSZ, with the intention of selecting one for routine use

Methods: Two automated analyser systems (Qwalys 3 (eythro-magnetic technology) and NEO IRIS (Solid phase red cell adherence)) were compared with current system (TO confirmed by CTT) in ABO/RhD typing and antibody screening. Operational performance was assessed on throughput, loading options reagent shelf life and instrumentation errors.

Results: The NEO IRIS showed a concordance in results for 5982/6012 (99.5%) samples tested for ABO blood grouping and 5967/6012 (99.25%) for RhD. There were 64/6012 (1.1%) samples with initially un-interpretable results. The Qwalys 3 showed a concordance in results for 5734/6118 (93.7%) samples tested for ABO, and 5708/6118 (93.3%) samples for RhD samples whilst 384/6118 (6.3%) were un-interpretable. A total of 198 samples were tested for weak D on the NEO IRIS and there was a concordance of results among 196/198

(98.99%) samples with a discordance in 1/198(0.5%) sample and an un-interpretable result on 1/198(0.5%) other sample. On the Qwalys 3, 22 samples tested for weak D and there was a concordance of results in all 22/22 (100%) samples tested.

Summary/Conclusions: Both analyzers proved to be easy to operate and have complete walk away capability. They all have alarm systems to notify the user when user intervention is needed. Based on: the high concordance of ABO/Rh results and lesser un-interpretable results encountered, higher throughput and turnaround time and more flexibility in assay ordering and adjustment of workflow; the NEO IRIS from IMMUCOR was selected for routine use for blood donor grouping and antibody screening by the National Blood Service Zimbabwe. The high proportion of uninterpretable results reflected some of the problems encountered during collection of samples into vacutainers where blood might not be mixed uniformly.

A Comparison of 5 years' Experience with the Tigris and Panther Analysers

Pistorius C, Cable R

Background: Western Cape Blood Service (WCBS) performs stringent testing for transfusion-transmissible infections on blood donations. In the Virology laboratory, routine screening includes testing for HIV, hepatitis B (HBV) and hepatitis C (HCV). Individual donation nucleic acid testing (ID-NAT) is performed on the Panther system (Grifols) using the Ultrio Elite assay. From 2005 until 2013 ID-NAT was performed using the Tigris analyser. WCBS screens approximately 160 000 donations per annum. WCBS is a non-profit, independent organisation and is driven to improve and streamline processes and procedures in order to decrease costs, without compromising the safety of the blood supply.

Aim: To compare the Panther instrument to the Tigris instrument with reference to: Ease of use and robustness, assay specificity, controls and calibration, efficiency, and going green.

Methods: Historical data from the Tigris was reviewed for a 5-year period from January 2009 to December 2013 and historical data from the Panther was reviewed for a 5- year period from April 2014 to March 2018. During the review period, 722 431 donations were tested on the Tigris analyser and 770867 donors were tested on the Panther analyser.

Results:

Ease of use and robustness: Since the introduction of the Panther analyser, WCBS has seen a reduction in errors (both instrument and staff) from 27226 to 20738 for the respective review periods. The Tigris analyser operates as a batch system while the Panther analyser allows random access.

Assay specificity: False initial reactive rates were 0.05% on Tigris and 0.04% on Panther. The specificity on Tigris was 99.99% and 100.00% on Panther.

Controls and calibration: Calibration of reagents on the Panther is valid for 24 hours and no controls are required. Each sample is validated against an internal control. During the review period, the Panther analyser used 47641 tests (5.5% of total Ultrio Elite tests used) for calibrations. In comparison, calibration and controls are required for every batch of samples run on the Tigris analyser. During the review period, the Tigris analyser required 99889 tests (11.43% of total Ultrio Plus tests used) for calibrators and controls.

Efficiency: Turn-around-times (TAT) to the first result is shorter on the Panther than on the Tigris (3.5 hrs vs 5 hrs). Reagents can be loaded on the fly and sample access is random, i.e. no batch testing required. This has resulted in increased efficiency resulting in decreased TAT for urgent samples and a reduction in staff shifts.

Going green: Tigris analyser was unable to support PDF printing - as a result, 32735 pages were printed – equivalent to approximately 4 trees worth of paper. The Panther analyser allows PDF printing, therefore, results are transmitted from the analyser through the middleware (eL@bs), through validation software and uploaded to the network, all electronically and automatically. The system is completely paperless.

Conclusion: The migration from the Tigris to the Panther analyser has greatly decreased the turnaround time of urgent samples, increased efficiency, increased specificity, and decreased the carbon footprint of the Virology laboratory resulting in cost and resource benefits.

Review of Internal Proficiency Testing Using Inter-Laboratory Comparison

Adams F

Background: The aim of internal proficiency testing (PT) in a laboratory setting is to assess the performance of technical staff against pre-established criteria using routine manual, semi-automated or automated procedures. This is to maintain and improve the analytical quality of staff in order to reduce laboratory errors and to produce accurate patient or donor test results. PT review reports may also alert management and staff to non-conforming trends relating to testing and/or staff. While the assessment of staff competency is a continuous process, PT is only one indicator of overall laboratory performance and should therefore be regarded in conjunction with other Quality Management System indicators. PT was introduced at WCBS in 1994. The South African National Accreditation System (SANAS) issued WCBS with a non-conformance for not having a structured PT programme in place in 2013 and another in 2015 due to lack of information recorded on the PT report, as indicated per SANAS R-80 document. The Standard Operating Procedure (SOP) for PT was updated and the internal PT programme improved.

Objective: The purpose of this study is to review the assessment methodologies used for internal PT conducted by the Professional Development and Training Department (PD&T), including the evaluation of inter-laboratory comparisons for routine testing performed, the limitations and areas of improvement.

Methods: Data from Proficiency Tests completed from 2010 to 2017 were evaluated as well as inter-laboratory performance in conjunction with Quality Management System regulations.

Results: The competency of the technical staff for a routine test such as ABO grouping varied from 83%, 38%, 94% and 97% during the 2010 to 2013 period respectively. The low percentage attained may be attributed to staff being on long leave or not completing the initial or repeat PT due to staff constraints. However, the staff competency for the same test remained at 100% from 2014 to 2017 and this improvement may be attributed to amendments made to the SOP for PT as well as other related SOPs. Similar improvements are observed for other routine tests.

Conclusion: A PT programme not only assures technical competence of staff and laboratories while maintaining quality output but also provides a measure of laboratory confidence to clients and higher authorities. Currently, the internal PT programme consists of issuing a PT form with corresponding sample number to the intended PT participant. The completed form is returned to the PD&T department where results are assessed and results are recorded with a PT report issued to all supervisors of the participating laboratories. The PD&T department has liaised with the IT department at WCBS to complete an online PT programme where only samples will be issued to the participants for routine testing. The test results will be furnished by the participants, evaluated by the PD&T department and reports issued to the supervisors of the participating laboratories using the online system. *This work was presented as a poster at the Africa Society for Blood Transfusion (AfSBT) Congress held in Arusha, Tanzania, June 2018.*

Advantages of Service Process Automation in Supporting Blood Transfusion Services

Van der Walt N, Singh A

Introduction: Information Communication Technology (ICT) forms the backbone of several business processes within The South African National Blood Service. In 2016 SMART Service desk was implemented for the management of ICT related incidents, requests and changes. What started out as an ICT Service Desk tool rapidly evolved into a Service Management tool for other business units within SANBS.

This has proved to be a digital transformation from manual to automated processes.

Nature of the problem: The use of the service delivery system and its influence on customers' perceived service quality was a key objective. Manual and paper based processes are a challenge in organisations because of the time and effort taken to complete and track tasks. Automation and digitization of forms reduces these challenges by eliminating the need for paper documents, manually completing forms, signatures, loss of documents, time and effort. Using the Quality Systems Management Review report (QSMR) as an example, the manual process required one individual in the Quality Systems department to consolidate a large number of documents into one report and to manually populate and design graphs. This took approximately four days to complete and one day to format. The aim of automating the QSMR report was to enhance and automate current manual processes and workflows as a service quality improvement initiative.

Design and Methodology: ICT engaged with the various support divisions and gathered requirements for the specification and design of the system. The design consists of four related components, namely the Service Requirements, Service Performance Standards, Customer Expectations and Customer Experience. Where paper based forms where being used these were digitised to form part of the automation with the focus on a more effective robust process for reporting and management of internal customer needs. Examples include but were not limited to the QSMR. For the QSMR report a portal for each business unit's requirements were designed and developed.

Results: Eight business processes on SMART Service Desk were automated electronically removing paper-based systems. The most complex being the QSMR. The automated process makes each business unit owner responsible for their own report. Upon completion, consolidation and formatting of graphs, data and text occurs using workflows when the report is exported. The consolidation and formatting has reduced from 5 days in the manual report to less than 1 minute on the automated platform.

Discussion: The automation and digitalisation of paper-based documents and reports has reduced the need for paper thus reducing cost and time associated with printing and transporting documents. The decreased time required to consolidate the QSMR reduces the number of human resource hours required enabling the more efficient use of such human resources. In addition, automation provides real time monitoring and reporting for service level agreements and audit requirements which allows a more stringent and controlled environment within which to manage customer satisfaction and expectations.

Conclusions: SMART has enabled Support Service business units to have an improved overview through the facilitation of automated management of activities, call logging, tracking, and reporting.

Dried Blood or Plasma Spot Testing – The Answer for Making Blood Transfusion Testing Safer in Africa?

Pistorius C

Introduction: Africa has a unique set of challenges regarding safe blood transfusion. Two of the largest contributing factors are the most common disease states in Sub-Saharan Africa (SSA) e.g. Malaria, require large amounts of blood as lifesaving interventions and the highest burden of infectious diseases transmissible through blood transfusion is found in SSA. This has often led to the binary donor base that exists in SSA, consisting of Voluntary Non-remunerated Blood donors (VNBD) and family or replacement donors (FRD) as transfusion centres are unable to supply the demand when relying only on VNBD. Nucleic Acid Testing (NAT) in conjunction with serological testing is the gold standard for Transfusion Transmitted Infection (TTI) testing. However vast distances and high temperatures of Africa makes transport of traditional blood samples a logistical challenge. Many publications evaluating the stability, suitability, and ease of use of dried blood spots (DBS) for NAT have been published. Results have shown to be comparable to traditional blood samples. DBS are being used successfully in early infant diagnosis (EID) programs for HIV by means of Polymerase Chain Reaction (PCR) testing, especially in Africa.

Method: To demonstrate that DBS or dried plasma spot (DPS) is suitable for blood donor screening. 900 negative new donor samples and 100 confirmed positive donor samples, as defined by routine screening done at Western Cape Blood Service, were screened using a DBS/ DPS as the sample type. After routine testing was completed, one DBS sample and one DPS sample for each negative blood donor sample (one DPS and where possible one DBS for each positive sample) was prepared and analysed with the Ultrio Elite Assay (Grifols Diagnostic Solutions Inc, Spain) on the Panther analyser (Grifols, CA, USA). Each reconstituted DBS/DPS sample consisted of 2000 µℓ of sample transport buffer (Gen-Probe, San Diego, CA, USA) and two DBS/DPS spots per donor. Sensitivity and specificity of using DBS/ DPS

samples was determined when compared to using routine plasma samples.

Results:

Ultrio Elite (Multiplex qualitative assay)

Invalid rate: 5 DBS invalids 0.56 %

Specificity (n=900)

- DBS: 100 %
- DPS: 100 %

Sensitivity (n=100)

Human immunodeficiency Virus (HIV)

- DBS (n=30): 96.67 %
- DPS (n=40): 97.50 %

Hepatitis B (HBV)

- DBS (n=33): 57.58 %
- DPS (n=50): 58.00 %

Hepatitis C (HCV)

- DBS (n=2): 100 %
- DPS (n=10): 100 %

Overall Accuracy: 98 %

Conclusion: DBS/DPS can be used as a sample for screening blood donors as the invalid rate was 0.56%, and only found with DBS samples. Logistically DBS/DPS is well suited for resource-poor countries as samples are:

1. Easy to obtain (fingerpick samples could be used.)
2. Transport is simplified as samples will not leak or haemolyse due to high temperatures.
3. Samples can be stored at room temperature

DBS/DPS demonstrated acceptable specificity. The Ultrio Elite performed well with regards to HIV and HCV sensitivity. Sensitivity with regard to HBV was not as high but this could be due to very low and erratic viral loads and further investigations should be performed.

DEGREE DAYS and COLD CHAIN: Novel Metrics to Obtain Meaningful Information as an Aid in the Development and Validation of Cold Chain Systems

Scanes T, du Plessis L

Background: The Standards for Blood Transfusion in South Africa require that whole blood (WB) be transported, after an initial 8-hour cooling period, at between 18ºC and 24ºC for no longer than 24 hours. To minimise product loss, systems must be extensively validated. Effective validation is best achieved using a simulation-based, limit-testing approach in which summer and winter validation runs are performed under extreme conditions. There are, however, theoretical (selection of suitable ambient validation temperatures) and practical (simulation of diurnal temperature variation is often not available) difficulties in employing these principles and the authors would suggest the novel use of Degree Days (DD), a system widely used in the architectural and agricultural fields, in which an approximation of the area under the time/temperature curve is used to model the relationship between energy consumption and ambient air temperature.

Aims: The study was carried out in an attempt to mathematically define the relationship between duration (DUR), the time products are maintained within specified limits, and DD, in cold chain systems and to determine whether metrics derived from this relationship could be utilised in the development and validation of cold chain systems.

Methods: Hourly temperature records, from 2013 to 2015 for the 5 Branches of the Freestate and Northern Cape Zone of the South African National Blood Service were obtained from the South African Weather Service (SAWS) and used to determine base 18ºC DD (DD_{18}) for the hottest and coldest days of the 3-year period. WB cold chain system validation runs were performed according to SANBS protocol at simulated summer (40ºC) and winter (10ºC) ambient temperatures with time and temperatures continuously recorded using the I-button

system. These time and temperature data were used to calculate the following novel metrics; DD_{18}, Corrected Duration (cDUR), Optimum Validation Ambient Temperature (Tvalid) and Efficacy Specification (Espec). Standard Excel Office 365 mathematical and statistical functions were utilised in data analysis. Levels of 0.05 were used to judge statistical significance.

Results: Regression analysis of DUR and DD_{18} showed a significant positive correlation (n =19, r=0.77, t=5.04, P=0.00). Analysis of the SAWS data indicated the hottest day to be at Upington on 18/12/2015 (mean 33.1ºC, max 41.6ºC, min 20.5ºC, DD_{18} -18.5) and the coldest in Bethlehem on 8/7/2014 (mean -0.1ºC : max 9.2ºC : min -9ºC : DD_{18} 21.1). Corrected DUR indicated that, had summer validations been performed under hottest day conditions, the original 18-hour DUR would have been extended by 10 hours to a cDUR of 28 hours while the winter DUR of 8 hours would have shortened by 4 hours to a cDUR of 4 hours. Calculations indicated the optimal validation ambient temperature (Tvalid) to be 33ºC for summer and 0ºC for winter. The Espec of 0.97 hours/DD_{18} could be used as a performance specification measure allowing comparison of efficacy of this system with that of other systems.

Conclusion: The significant linear relationship between DUR and DD_{18} allows the calculation of several novel parameters, the use of which could assist in the development and validation of cold chain systems.

National Quality Assessment Scheme for Hospital Blood Banks in Malawi

Ndhlovu DB, M'baya B

Introduction: External Quality Assessment (EQA) is an important part of the overall quality system that should be in place in any blood bank. There are many benefits for participating laboratories and for patients. EQA schemes can drive forward quality where quality systems are not in place and help awareness of quality issues and need for quality systems. A good EQA scheme will include a 'training 'element aimed at addressing weakness identified by the Scheme.

Background: In 2007, MBTS with funding from Center for Disease Control and Prevention (CDC) initiated the national quality assessment scheme for Hospital Blood Banks (NQAS) in blood grouping and crossmatching in order to improve laboratory performance and transfusion practice in Malawi. To date, all (87) hospital blood banks that carry out blood transfusions in Malawi have been enrolled in the program. Panel samples are distributed twice per calendar year to participating hospital blood banks. The scheme is supported by the Ministry of Health. Training for hospital blood bank staff is a key activity in the strategy.

Activities: A Hospital Blood Bank (HBB) is enrolled in the NQAS after one of its staff members has attended a training course. By the end of 2018, 24 exercises had been distributed. Each exercise consisted of 3 whole blood samples and one serum plasma, prepared at MBTS Laboratories in Blantyre and distributed to HBBs by local courier service to arrive within 72 hours. Certificates of participation are issued to HBBs that participate both exercises each year.

Results: With one exception the samples distributed were of good quality and survived the rigors of transportation. On average 100% of hospitals got the ABO and RhD typing correct while 97% of the hospitals got the correct crossmatch results in 2018. 87 hospital blood banks were sent proficiency testing panels to test in the 2018. And of these; 60 (69%) of the hospitals returned results. 47 (54%) of the 87 hospital blood banks were issued with a certificate of participation in 2018.

Conclusion: The NQAS-HBB scheme has been a success. Although the results to date might, to some in countries with more developed services, seem poor; the aim of the national strategy of which the scheme is a part, is to improve transfusion practice. WHO Guidelines state that EQA schemes are essential for driving forward improvements and this relatively simple and inexpensive scheme is helping to do just that.

A Descriptive Overview of the Omixon Holotype HLA 11 Loci Next Generation Sequencing Workflow

Moonsamy A, Govender L, Jentsch U

Background: The Human Leukocyte Antigen (HLA) complex is the most polymorphic region in the human genome. Due to its complexity, classic first line low-resolution HLA typing methods cannot comprehensively resolve HLA ambiguities and therefore reduces the probability of finding compatible donor/recipient matches. HLA next generation sequencing (NGS) methods overcomes these challenges by providing high-resolution HLA results. HLA NGS was implemented at SANBS in the Tissue Immunology laboratory in 2016. Several new NGS technologies offering the benefit of an improved workflow and extended loci coverage have been introduced in the transplant field. One of these workflows is the Omixon Holotype HLA 11 loci NGS assay described in this overview.

Methods: Sequencing was performed using the Omixon Holotype HLA 11 loci kit on the Illumina/MiSeq platform. The parameters for a comparative, descriptive study of the Omixon Holotype HLA assay to the previously NGS method were as follows: extended HLA loci coverage, streamlined workflow processes, reduced turnaround time (TAT), ease of analysis, cost-effectiveness.

Results: Omixon Holotype HLA assay covers HLA-A, HLA-B, HLA-C, HLA-DRB1, HLA-DQA1, HLA-DQB1, HLA-DPB1, HLA-DRB3/4/5 and HLADPA1 as compared to HLA-A, HLA-B, HLA-C, HLA-DRB1 and HLA-DQB1. Pooling of all samples into one tube occurs prior to size selection step as compared to after size selection resulting in a more streamlined workflow. There are six stopping points in the Omixon assay as compared to two stops at the Library preparation step. There was a reduction in assay turnaround time to 2 days as compared to 3 days. Analysis of results is an automated process in Omixon but still a manual step in the previous assay. The HLA Twin analysis software offers 2 independent algorithms for sequence alignment. Omixon Holotype HLA is more cost effective as it offers more loci coverage at a lower cost due to all assay reagents being contained all in the one kit.

Discussion: The additional high-resolution HLA loci coverage of the Omixon Holotype kit increases the chances of finding suitable bone marrow recipient/donor matches. More 'safe stopping points' prevents the loss of an entire run as testing could resume from the last step that was successful. A shorter assay time and automated sequencing analysis provides a reduction in turnaround time. The Omixon HLA Twin analysis software offers 2 independent analysis algorithms based on 'de novo' and reference alignment and analysis against the IMGT (IMmunoGeneTics) database. No capital outlay was required in implementing the Omixon Holotype as the Illumina MiSeq was already in use at SANBS.

Conclusion: This comparative overview has proven that the Omixon Holotype HLA NGS assay offers a more cost-effective HLA NGS assay at a competitive price. A high-resolution HLA database unique to the South African population is currently being developed. In addition, several novel alleles have been identified and the resolution of null alleles, which is an EFI requirement, is possible and takes SANBS closer to achieving EFI accreditation. This will allow us to offer this service with more confidence to our stakeholders such as the South African Bone Marrow Registry and Sunflower Fund.

A series of Cases Demonstrating Unusual Pan C HLA Antibody Patterns

Nelson D, Zwane N, Jentsch U

Introduction: The Tissue Immunology laboratory at the South African National Blood Service (SANBS) provides HLA diagnostics to support organ transplantation and blood transfusion related investigations. HLA antibodies are developed in response to sensitisation events where the patient is exposed to 'non-self' human leucocyte antigens (HLA). HLA antibody identification is critical to ensure that transplanted organs are not rejected. The testing also facilitates finding compatible platelet products for patients who are refractory to platelet

transfusions and to minimise serious transfusion related disorders such as TRALI. Literature describes the identification of HLA antibodies as a 'minefield' as various factors complicate testing, such as non-HLA antibodies, autoantibodies, non-compliment binding antibodies, IgM antibodies and varying levels of antibody titres.

Nature of Case: Recently we have investigated four cases demonstrating unusual HLA antibody profiles of the C locus. These patterns are very similar to the known pan-DR antibody reactivity where the DRB antibodies are assumed to react to denatured antigens on the surface of the Single Antigen beads in the LabScreen procedure. There is however, currently not much literature published on cases related to positive antibody reactivity patterns in the C-locus. We describe 4 cases, where patients' serum samples demonstrated unusual HLA C locus antibody reactivity patterns.

Body of Work: HLA antibody identification testing is performed using DTT treated serum samples on One Lambda's LabScreen Single Antigen assay. This assay leverages on the Luminex® bead-based multiplexing technology. Additional testing was performed using the LabScreen PRA kits. It is important to note that the beads from these two kits have different compositions of antigens. Microbeads from the PRA kits are coated with HLA antigens purified from human cell lines while Single Antigen Beads are coated with individual recombinant antigens. Four cases were investigated. These samples originated from adult patients awaiting kidney transplantation. The results of these four cases demonstrated positive reactions to all the C locus antigens in the panel including the patients' own C antigens using the LabScreen Single Antigen beads. However, when re-tested using the LabScreen PRA kits negative results were obtained. These samples were sent to a reference laboratory in the USA, who were able to duplicate our results and confirm the false positive pan C antibody reactivity patterns.

Closing Remarks: The negative results obtained from the LabScreen PRA kit have confirmed the phenomenon of the pan C antibody reactivity pattern observed using the Single antigen assay.

Lyophilized Growth Factors in the Management of a Chronic Post-Operative Non-Healing Venous Ulcer: A Case Study

Fahmy H, Diab AA

Introduction: This case of a 70-year-old female patient who underwent a coronary artery bypass using a saphenous vein graft, illustrates the growing importance of the use of platelet derived growth factors as adjunct therapy in modern regenerative medicine.

Nature of the problem/case: Although the procedure was successfully carried out with excellent prognosis the patient was left with a post -operative non-healing wound at the site of the venous graft harvesting. The lesion, measuring 15 cm x 7 cm, and 2 cm deep, showed limited healing response after 4 weeks of conventional treatment with local topical antibiotics and chemical debridement.

Body of work: On initial examination the ulcer appeared to consist largely of devitalised tissue with no signs of infection and was judged to be a venous ulcer suitable for management using platelet derived lyophilized growth factors (LGF). Initially the patient had two injections of LGF, 1 week apart, into the borders and at the base of the ulcer. This resulted in substantial tissue growth from the wound periphery towards the centre of the wound and healthy granulation tissues tarting to fill the cavity. The second step in management of this ulcer, was the application of bioactive degradable hydrophilic foams enriched with LGF in the cavity. This was undertaken twice a week for three weeks. At the completion of the second stage treatment the wound was completely covered with healthy granulation tissue and epithelial creeping. The plastic surgeon's decision was to leave it under strict observation for spontaneous fibrosis and healing.

Closing remarks: This case illustrates that LGF can play an important role in the management of wounds recalcitrant to conventional therapies. LGF appears to be a more feasible option when compared to conventional non-lyophilised platelet rich plasma (PRP) in that LGF is available immediately and would not require multiple venesections from the patient over an extended period of time. The treatment would be useful in anaemic patients where autologous PRP would be contraindicated. While PRP is currently considered a well established modality in regenerative medicine, there is still some controversy, and even disappointment as regards results obtained in it's clinical use. The main reason for this could be lack of standardization due to in variations in methods of preparation or in initial platelet count. Lyophilized Growth Factors is an advanced refined form of PRP that is efficacious, safe and easy to use. LGF could be described as a virally inactivated, pathogen free, standardized and lyophilized platelet releasate obtained from healthy tested donors and presented as an over the shelf product.

The Monocyte Monolayer Assay – A Case Study

McLinden D, van Niekerk L

Introduction: The Monocyte Monolayer Assay (MMA) is an in vitro assay considered to be representative of the in vivo survival of sensitized red blood cells (RBC) and is used to predict the clinical severity and significance of RBC alloantibodies. MMA results are calculated as a percentage reactivity (%R) of RBC vs monocytes: the higher the %R, the greater the predicted risk of a transfusion reaction and/or of decreased in vivo survival of the RBC. The percentage of reactive vs non-reactive monocytes determines the predicted severity of a transfusion reaction and therefore the clinical significance of the antibody. Guidelines are applied as follows: %R = ≤ 5%: incompatible blood may be given with little risk to the patient; %R = 5.1 – 20%: 33% of patients may have clinical signs of a reaction; %R = >20%: 64% of patients may have clinical signs of a reaction.

Nature of the case: Following successful validation of the MMA, a request for blood for Patient X was received in the Reference Laboratory. Patient X is a 75-year old male, group O negative, on dialysis for chronic renal failure with previously identified anti-D, -C, -E, -K, -Fya, and –Yta antibodies. Prior transfusions of D, C, E, K and Fya antigen negative, but Yta positive units were well tolerated by Patient X in spite of the Yta incompatibility. It was therefore anticipated that he would demonstrate a low MMA %R for similar units.

Body of Work: Patient X's plasma was used to sensitize two different donor samples of group O RBC: Cell 1 being Yta antigen positive, but D, C, E, K and Fya negative (serologically incompatible), and Cell 2 being D, C, E, K, Fya and Yta negative (serologically compatible). Monocytes were isolated from a fresh whole blood sample. The monocytes were incubated on a chamber slide, creating a cell layer on the slide with which the sensitized RBC were subsequently incubated, facilitating binding between the two cell types. Thereafter, unbound cells were removed from the slide by washing, the slide stained and read microscopically. D positive cells with anti-D were used as a positive control, and D negative cells with anti-D, as a negative control. The positive and negative controls yielded MMA %R of 50.5% and 7% respectively. Patient X's MMA %R with Cell 1 was 13.5% and with Cell 2 was 8%.

Closing remarks: The %R of the negative control and Cell 2 suggests non-specific background reactivity of donor monocytes to the sensitized RBC. Control results may be unpredictable due to unknown reactivity between the RBC and monocytes; thus MMA results must always be interpreted alongside control results. The actual %R of Cell 1 could therefore not be determined, however, the %R of these incompatible cells demonstrates that Patient X's anti-Yta is of low severity. This is consistent with his tolerance to previous Yta incompatible transfusions. Should this patient require transfusion in the future, Yta positive RBC may again be considered.

Irregular Red Cell Antibodies in Antenatal Patients: A 5-year Review

Moloi M, McLinden D

Background: The Red Cell Serology Laboratories (RCS) routinely test antenatal samples, performing confirmatory RhD typing and irregular antibody screening tests to identify the presence of irregular red cell antibodies. Antibody identification tests are performed on screen positive samples. Irregular red cell antibodies that are IgG in nature are considered obstetrically significant due to their ability to transverse the placenta as opposed to IgM antibodies, which do not. The objective of this retrospective study was to analyse data obtained from RCS Constantia Kloof from January 2014 to December 2018, to list the number and type of irregular red cell antibodies found, and to describe the number of obstetrically significant and insignificant antibodies identified.

Materials and Methods: Antibody screening and identification, and RhD typing is performed by automated gel column agglutination technique on the Erytra Instrument, and confirmatory RhD typing by manual tube indirect antiglobulin technique (IAT), using an anti-D Blend reagent. Obstetrically significant antibodies are titrated by IAT. Sample numbers and Rh results were extracted from the SANBS Business Intelligence system and percentages were calculated from this data using Microsoft Excel. Antibody specificity data was obtained by manual reviewing of laboratory records.

Results: From January 2014 to December 2018, 10713 antenatal samples were tested in RCS. Of the tested samples, 8829 (82.4%) were Rh negative and 1884 (17.6%) were Rh positive. Irregular antibodies were present in 661 (6.2%) of these. Specificities identified were: 501 (76%) anti-D; 25 (4%) anti-Lea; 19 (3%) anti-M; 13 (2%) anti-K and 1 (0.2%) anti-Leb. In addition, the following multiple specificities were identified: 80 (12%) anti-D, -C; 12 (2%) anti-D, -C, -E; 3 (0.5%) each of anti-D, -E and anti-D; -C, -E, -S; 2 (0.3%) anti-D, -C, -Jkb: and 1 (0.2%) each of anti-D, -C, -Jka and anti-D, -E, -Fya. Of these cases, the anti-Lea, -Leb and –M antibodies, 45 in total, were IgM type antibodies, and deemed not obstetrically significant. These comprised 7% of all antenatal antibodies. The balance of 616 (93%), were all considered obstetrically significant.

Discussion: This study shows that 93% of the antibodies identified in antenatal patients tested were obstetrically significant. Of these, by far the most prevalent was anti-D, implicated in 91% of antenatal cases and 6% of all antenatal samples tested.

Conclusion: The disproportionate number of Rh negative to Rh positive samples observed is not representative of the general population, but rather, indicates selective submission of Rh negative samples to RCS. This explains the high incidence of anti-D seen within the sample group, however, the presence of this antibody is concerning, as anti-D is largely a preventable antibody with the effective implementation of an antenatal anti-D prophylaxis programme. This study has therefore highlighted the need for a greater emphasis on the prevention of anti-D maternal alloimmunisation within the healthcare sector.

Blood Group Frequencies in the Western Cape Blood Donor Population - A Brief Synopsis

Fillander C, Valensky S

Introduction: Published recent data regarding blood group frequencies in the Western Cape is limited and as a result, WCBS uses the current edition of the AABB Technical Manual as a reference.

Considering the diverse population of the Western Cape, using the AABB Manual as a reference may not be ideal, as it may not reflect the local situation. In 2005 WCBS embarked on a program to extend routine testing and include Kell and Rh phenotype (C, E, c, e) on all donors, which enables an analysis of blood group frequencies over a period of time.

Method: Extended blood group test results (performed on the Beckman PK7200/ 7300 blood group analyser) were extracted and categorised by race . Analysis of the active donor base (n=145 278) enabled an understanding of the frequencies of ABO and Rh groups by race. Of the 145 278 donors, a subset of 135 682 (93.4%) have had extended phenotyping performed, and the Rh and Kell phenotype frequencies were computed.

Results: The WCBS donor base is comprised as follows: 1.33 % Asian, 7.93% Black, 35.32% Coloured and 55.42% White. Overall, the ABO blood groups are divided as follows: Group AB (4.99%), Group B (16.01%), Group A (33.81%) and Group O (45.19%). The prevalence of Group O is different between the race groups 47,87%, 44.53%, 41.37% and 38.83% for White, Black, Coloured and Asian respectively. Group B is more common amongst Asian (29.19%) and Coloured (21.67%) donors. Group A is more common amongst White (36.58%) and Black (31.36%) donors. The prevalence of Group AB appears to be the least common among White (3.87%) donors. The data from the AABB Technical Manual is as follows: Group O 45%, 49% for European Ethnicity and African Ethnicity respectively. Group B is more common amongst African (20%) Group A is more common amongst European (40%). Group AB is 4% European and 4% African. These are the findings for the Rh phenotype in WCBS: 13.96% are D+C-E-c+e+ (R0r), primarily in the Black (64%) population. 17.20% are D+C+E-c-e+ (R1R1) and found predominantly in the Asian (40%) population. The data from the AABB Technical Manual: D+C-E-c+e+ (R0r), primarily in the Black (44%) and D+C+E-c-e+ (R1R1) is predominantly Asian (70%).

Discussion: The distribution of ABO between race groups and Rh distribution does not correlate well with the AABB Technical Manual. Antibodies against Rh antigens are the most common cause of alloimmunisation in multitransfused patients with thalassemia and Sickle Cell Disease. Transfusion of Rh antigen matched blood will prevent alloimmunisation. An understanding of the distribution of Rh phenotype among different race groups is advantageous when selecting blood for patients with multiple antibodies.
Conclusion: This data analysis has provided valuable information regarding frequencies of ABO and Rh phenotypes amongst blood donors in the Western Cape. This information assists with finding compatible units of blood for transfusion and assists with finding appropriate units for extended phenotyping within specific race groups. Further data analysis is being undertaken to include Fya, Fyb, Jka, Jkb, S and s.

An Investigation into Leadership Factors Affecting Employees in SANBS

Bisnath M

Introduction: Empirical studies on leadership, leadership style, behaviours and leadership factors affecting employees in an organisation is a continuous process. International and national organisations are investing large amounts of time and money to improve the leadership skills of team leaders and managers. This type of research serves the purpose of a self-examination of one's own leadership style and behaviours, as well as triggers for self-development. Secondly draws awareness of organisations to re-assess the leadership styles and behaviours of their leaders and facilitates development of these skills. We investigated the leadership styles, behaviours and leadership factors of a leader responsible for managing employees that enable good outcomes for the leader, employee and the organisation.
Methods: A quantitative study was conducted with a sample size of 130 participants randomly selected from the South African National Blood Service (SANBS). A structured, self-administered questionnaire containing questions with guided responses in a Likert scale of 1 to 5 was completed by the participants. The questionnaire covered three domains. The demographics did not form part of the purpose of the study, however the data set was utilised to evaluate for any influence on the research findings. Section B comprised questions on Leaders' Effectiveness Factors and behaviours. Section C comprised questions on Leadership Styles. All questions were retained as data was reliable as shown by the reliability co-efficient which was very high (0.990), strongly affirming to the reliability, validity and consistency of the questions. The results in the survey were analysed with IBM SPSS version 17.0 statistical software.
Results: We had a response rate of 64% (84) of the 130 questionnaires that were sent. "Focus on results," had an overall positive response for accountability, ethics, motivation and recognition. "Cultivate capabilities" indicated a positive response for managing performance, however career development for employees seemed to have been overlooked in a small proportion. "Establish trust and Demonstrate Integrity" indicated positive behaviours for authenticity, honesty, communication, interaction and matters of principle. However, a response of 42% and 56% for disagreeing and agreeing respectively on "appropriately and effectively setting direction"; 58% agreeing for "consistent, clear and compelling oral and written communication"; 54% disagreeing for "assignments and career development", may indicate a minor gap in effective communication, guiding towards goals and provision for development. Leaders demonstrated Laissez-faire leadership, transactional and transformational leadership with idealized influence being common.
Discussion: Our study confirmed factors of effectiveness, leadership style and behaviours were frequently employed by SANBS leaders. Factors as communication, setting direction appropriately and effectively, and providing assignments and experience for career development required additional consideration. Responses on leadership styles indicated a need to employ a mix of transformational and transactional leadership style with transformational being dominant to be an effective leader.
Conclusion: Leaders should endeavour to create a learning organisation by developing opportunities for learning. SANBS as an organisation should invest in the development of its leaders if it is to ensure that each employee operates to their highest potential.

Antenatal Blood Transfusion in South Africa: Indications and Practice in a High HIV Prevalence Setting

Murphy E, Hull J, Bloch E, Fawcus S, Anthony J, Green-Thompson R, Ingram C, Crookes R, Courtney L, Jauregui A, Hilton J

Background: Hemorrhage and anemia during pregnancy are common indications of need for maternal blood transfusion. However there is limited information on antenatal transfusion practice in South African women, including differences by HIV status.

Methods: We studied transfusion indications, underlying obstetric conditions and transfusion practices among South African women who were transfused during pregnancy. We performed a cross-sectional study of women who were transfused during pregnancy, in 2014 – 2015, at two urban South African hospitals with large obstetric populations. Female inpatients receiving a transfusion of red cells, platelets or plasma during pregnancy but more than 48 hours before anticipated delivery were approached. Following discharge, trained obstetric research nurses used a standardized form to abstract data from the participant's medical record on demographics, current and previous pregnancies, HIV status and treatment, and indications for hospitalization and blood transfusion by trimester.

Results: A total of 560 transfused women were enrolled, 371 in Soweto and 189 in Durban. Mean age was 28 years, 98% were of black African ethnicity and 28% were HIV+, of whom 42% were taking therapeutic antiretroviral medication. At the time of transfusion, 48%, 32%, and 16% of women were in trimesters 1, 2, and 3, respectively, and 3%, 18%, and 86% had received antenatal care. Hemorrhage was noted in 63% of women, with causes including incomplete/threatened abortion (n=265; most in trimesters 1 and 2) and/or ectopic pregnancy (n=114; most in trimester 1). Chronic anemia was noted in 50% of women and was associated with HIV infection (OR=2.39, 95% CI 1.36-4.20). Most transfusions included red blood cells (median, 2 units); 14% of women were transfused with fresh frozen plasma (median, 2 units) and 2% with platelets. Mean pre- and post-transfusion hemoglobin levels were 6.7 g/dL and 9.0 g/dL, respectively, representing an increment of 1.0 g/dL per RBC unit transfused (1.09 g/dL in Soweto and 0.83 g/dL in Durban). Indications for transfusion included obstetric hemorrhage (31%), chronic anemia (29%), surgery or anesthesia (13%), other (9%) and not specified (17%). Transfusion for chronic anemia (vs. hemorrhage) was associated with gestation ≥26 weeks (odds ratio=7.07, 95% confidence interval 3.52-14.24). Surgical blood loss was a common indication in trimester 1 (21%) that declined to 7% then 1% in trimesters 2 and 3.

Conclusions: Hemorrhagic complications accompanying spontaneous abortions and ectopic pregnancies in the first and second trimesters were the most common reasons for antenatal transfusion. However chronic anemia was a frequent and potentially preventable indication in this South African setting, particularly during third trimester pregnancies. HIV infection was associated with anemia but not with transfusion indication. Transfusion practice appears, in general, to be appropriate, although a higher hemoglobin increment suggests over-transfusion at one hospital. *[pending poster presentations at RCOG World Congress 2019, and ISBT Regional Congress 2019]*

Blood Usage Practice for Coronary Artery Bypass Surgery at Two Medical Centres in the Western Cape

Wolmerans D

Background: International studies have documented variation in transfusion practice for Coronary Artery Bypass (CABG) surgery, despite widespread availability of guidelines on clinical blood product use. Optimally, Patient Blood Management systems (PBM) seek to streamline utilization, focusing on patient care and outcome as well as potential waste and cost of blood. The purpose of this study was to audit blood product utilization for CABG surgery at two hospitals in the Western Cape.

Methods: An observational prospective audit was conducted at two medical centres in the Western Cape. The participating centres completed a data sheet of fifty consecutive patients undergoing isolated, elective CABG surgery. A total of 100 patient's forms were analyzed.

Data recorded included age, gender, weight, co-morbidities, pre and post-operative International normalization ratio (INR), Haemoglobin (Hb), Platelet count, serum creatinine, operative details, use of anticoagulants as well as transfusion history.

Results: The two institutions were coded hospital P (HP) and hospital T (HT). The transfusion rate at HP (56%) was significantly lower than at HT (92%). The mean pre-operative haemoglobin (Hb) for patients at HP was 14.07 g/dL compared to 13.79 g/dL at HT. HP transfused an average of 2 RBC units whilst HT transfused an average of 3 RBC units. Of the 100 patients reviewed for this study, 84% were male and 16% female. The males had a lower transfusion rate (69%) than the females (100%). Females received more RBC units than males, 3.5 compared to 2.4. The mean age of transfused patients was 56,36 years which was significantly lower than non-transfused patients age of 60.38 years. Patients weighing less than 70 kg received on average 3.6 units of blood, compared to patients weighing more than 70 kg who received on average 2.4 units of blood. The majority of patients had no history of cardiac surgery (43/50 = 86% at HP and 41/50 = 82% at HT). This group received on average 2.5 units of blood. Patients who had previous histories of cardiac surgery, received on average, 3.3 units of blood.

Conclusion: The transfusion rate for the two hospitals for CABG surgery was significantly different although both were well within the wide ranges documented in the literature. Numerous studies however support a guideline transfusion "trigger" of 10 g/dL for CABG. With a post-operative Hb of 11.15 g/dL for HP and 14.75 g/dL for HT this study would conclude that this transfusion trigger is considerably higher at these two institutions. Increased knowledge, through training, with regard to the optimal transfusion at these centres may prove beneficial.

The Impact of a Well-Functioning Hospital Transfusion Committee at a Tertiary Hospital in the Eastern Cape Province of South Africa

Bayata V, Mgwigwi N

Background: After several previous failed attempts driven by the South African National Blood Service (SANBS) to establish a Hospital Transfusion Committee (HTC) at the Nelson Mandela Academic Hospital, a hospital management led initiative recently succeeded in establishing an HTC comprising of the Heads of Departments and senior consultants. The main premises of the HTC were a) patients would benefit from a restrictive transfusion policy and b) the hospital would benefit financially from such a conservative approach. The HTC acts as a hospital-based peer review mechanism to ensure implementation of evidence-based restrictive guidelines while monitoring patient safety. We evaluated the impact of the newly established Nelson Mandela Academic HTC by comparing blood ordering patterns pre- and post its establishment.

Methods: We performed a retrospective analysis of the blood ordering patterns for two similar 6-month periods (September 2017 to February 2018 and September 2018 to February 2019) pre- and post the establishment of the HTC. Data on the number of requisitions received, red blood cell products ordered and issued, the type-and-screens (TSH) ordered and converted and patient haemoglobin (Hb) levels pre-transfusion were extracted using the SANBS Business Intelligence System and analyzed in Microsoft Excel.

Results: In total, 5 651 requisitions were received during the two periods under review, 3 084 (55%) during the pre-HTC period and 2567 (45%) in the post-HTC period. The number of units ordered (7 497 vs 5 842) decreased by 22%, the number of units issued (4 603 vs 3 942) decreased by 14%, and the number of units ordered per requisition (2.42 vs 2.28) decreased by 6% in the post HTC compared to the pre-HTC period. These differences were all statistically significant ($p<0.001$). The number of TSH requested decreased significantly by 1202 (78%) requests from 1544 in the pre-HTC period to 342 in the post-HTC period with an increase in converted requests from 14% in the pre- to 19% in the post-HTC periods ($p<0.001$). The number of requisitions without a reported Hb decreased from 47% in the pre-HTC era to 24% in the post-HTC era. There was significant decline ($p<0.001$) in the pre-transfusion Hb in the post-HTC period where 50% of requisitions had an Hb of less than 7 g/dL compared to 29% in the pre-HTC period.

Conclusion: Our review confirms a significant decline in the number of requisitions received, the number of units ordered per requisition, the number of units ordered and the hemoglobin levels as transfusion triggers, suggesting a significant uptake of the proposed restrictive transfusion policy. The absence of any untoward patient outcomes reported to the HTC supports the beneficial impact of the HTC policies. The reduction in RBC products and TSH ordered had a positive impact on the hospital's financial expenditure. A senior-management hospital-driven HTC can significantly influence hospital blood ordering patterns.

The Knowledge of Transfusion and Related Practices Amongst Doctors Working at a Tertiary Academic Hospital in South Africa

Mphahlele K, Khunoua I, Joubert G, Mkwanazi T, Moshoeshoe P, Mabine M, Wessels PL, Setlogelo O, Barrett CL

Background: Patient blood management is a growing field of interest. Although blood transfusions are one of the most commonly used therapies, many prescribing doctors do not have appropriate knowledge regarding blood transfusion or transfusion alternatives. Inappropriate blood transfusion may lead to increased patient morbidity and mortality. It is unknown what doctors employed at the local academic hospital complex know about patient blood management.

Objective: The purpose of this research project was to evaluate the knowledge of transfusion and related practices amongst doctors working at an academic hospital complex in the Free State, South Africa.

Method: A cross sectional descriptive study was performed using a questionnaire. Clinicians from family medicine, medical, surgical and anaesthetic disciplines from the three hospitals in the academic complex were selected to participate. Non-clinical disciplines and paediatrics were excluded from the study.

Results: Questionnaires of 152 participants were suitable for analysis. Most (31.5%) of the particpants were medical officers with less than 5 years experience, follwed by specialists (19.9%). Interns and community service medical officers made up 12.5% and 4.8% of participants respectively. Although prescribing habits varied, 43.3% of participants prescribe blood at least weekly. A haemoglobin based transfusion trigger is used by 76.2%. of respondents, with 67.3% using a haemoglobin of < 7g/dL as the transfusion trigger, the remainder used higher transfusion triggers. Almost 80% of respondents reported using a single unit of blood followed by clinical reassessment before ordering a second unit. Of note, 8.6% of respondents reported that if they were ill, they would prefer to be transfused to maintain a haemoglobin of 10g/dL. Cost of laboratory investigations and lack of human resources were the main obstacles to adequately investigating anaemia. Twenty nine percent reported that transfusion of red cells decreases length of hospital stay and 32.2% reported that transfusion reduces serious morbidity. The main causes of blood wastage were reported to be blood issued where blood on returnable basis would have been preferable (52.7%), blood being removed from cold chain for too long (36.7%) and patient dying before transfusion (21.3%). Interestingly, 87.5% of respondents reported that tracing donor triggered look-back cases is the responsibility of the blood transfusion service.

Conclusion: In a tertiary hospital where blood is frequently transfused, knowledge of some basic patient blood management principles are lacking. Regular transfusion training is necessary to ensure compliance with best practice and to improve patient care.

Congress Attendance and its Predictive Value for Future Congress Contribution

Coleman C, Nelson E, Vermeulen M

Introduction: The South African Society for Blood Transfusion congress is hosted bi-annually in South Africa. Selection of attendees from the South African National Blood Service (SANBS) are based on congress contribution through presentation, chairing of sessions, previous attendance, position held, quotas allocated per department and budget allocated. Congress attendance provides a unique learning opportunity and has the potential to motivate attendees to do research in their own areas and develop scientific skills for personal development and to the benefit of SANBS. The aim of this study is to describe previous congress attendance and evaluate if congress attendance is a predictor for contribution to future congresses through presentation or related contributions.

Methods: Congress attendance data for three consecutive congresses (2013, 2015 and 2017) were analyzed per zone, department and gender. Previous attendance and subsequent presenter status were noted. Chairing a session or being part of the organizing committee was

classified as a contribution similar to presentation. Statistical significance were analyzed using the chi-square test.

Results: Total congress attendance from SANBS was 146 delegates in 2013, 190 in 2015 and 177 in 2017. Approximately a third of attendees were from Head Office Constantia Kloof (29%, 31% and 32%) followed by KwaZulu-Natal (KZN) (19.2%, 16.8% and 16.9%). The Donor department had the highest representation (33.6%, 36.8 and 38.4%) followed by the Technical department (29.5%, 32.1%, 27.1%). No department showed a significant increase over time. Within the Donor division, KZN and Northern Zones had the highest average representation of 18.7% followed by Egoli (16.6%). Within the Technical division, this trend continued with the Northern zone averaging 18.4%, KZN 17.8% and Egoli 17.1%. Two thirds (62.3%, 62.1% and 59.9%) of attendees were female which did not change significantly over the three congresses ($p=0.96$). The total attendance over three years was 513 of whom 86 attendees presented. A significant proportion (51) of the 86 presenters, attended a previous congress compared to 22 of 427 attendees who were not presenting ($p<0.0001$). Of the 86 presenters, 29 females vs 22 males attended a previous congress compared to 19 females vs 16 males who did not previously attend which was not significantly different ($p=0.81$).

Discussion: This analysis showed a significant association between previous congress attendance and future congress participation; however, it has the limitation of not taking into account other motivators for presenting at congress and does not aim to answer this question in full. A bias exists related to the congress attendance selection as most delegates who attended a previous congress will not be selected to attend the next congress unless they were presenting. Congress attendance could be used as an important development tool to be included in personal development plans. Contribution through presentation at a national congress can be seen as an important first step towards development of personal scientific analysis and writing skills which can increasingly contribute to developing a much-needed scientific skill base within the organization.

A Five-Year Review of the Staff Health Department at the Western Cape Blood Service

Hilton C

Background and Aim: The Western Cape Blood Service (WCBS) has a staff health department run by a dedicated professional nurse. The functions of the staff health department include entry, routine and exit medical examinations of staff members, medical management and documentation of injuries on duty, the dispensation of Department of Health regulated contraception, and provision of medication for minor ailments during working hours. Owing to the exposure of WCBS staff to potentially virally contaminated blood, regular testing for Human Immunodeficiency Virus (HIV), Hepatitis B and Hepatitis B antibody screening is performed for susceptible staff members using nucleic acid and serological testing. The purpose of this study is to review aspects of the workload and costs of the department over five years (2014-2018) to identify areas to improve efficiencies in terms of Lean Management/Continuous Improvement principles.

Methods: A retrospective review of data collected by the WCBS Staff Health Department and Virology Department has been performed.

Results: The number of medical examinations performed per year has declined from a maximum of 395 in 2015 to 245 in 2018. An average of 36.8 incidents of occupational exposure to blood through needlestick injuries or eye splashes have occurred over the past five years, with no cases of seroconversion. The cost of viral marker testing for both routine staff medications and occupational blood exposure investigations has steadily risen from R29 781 in 2014 to R39 841 in 2018. The number of COID injuries ranged from 39-67 incidents per year during the period under review of which between 19.5-41% required formal referral to a doctor for management, and 12.2-30.8% resulted in one or more day's sick leave from work. The Disabling Injuries Incidence Rate (DIIR) has ranged from 2.2 to 0.76 DI per 200 000 working hours. An average of 215.6 doses of government regulated contraception was administered to staff members over the five years. The most commonly dispensed medications from the staff health department were Panado®, Histacon®, Brufen®, Napacod® and Gastron®.

Conclusion: This study has been a useful investigation into the functioning and costs of the staff health department at WCBS. Numerous areas of improvement have been identified, such as a revision of the frequency of routine medical examinations for staff members, removal of uncommonly used medications from the dispensary as a cost-saving measure, and addressing new topics for staff health awareness campaigns. This exercise has also highlighted the number of working hours spared through the provision of on-site medication and basic first aid management for the staff based at the Headquarters facility, and the potential influence of staff health awareness campaigns in the reduction of occupational injuries seen over the past two years.

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REDS-III Partnership was Instrumental in Building Research Capacity in South Africa

Jentsch U, Swanevelder R

Introduction: The South African National Blood Service (SANBS) participated in the Recipient Epidemiology and Donor Evaluation Study –III (REDS III) multicentre study between 2011 and 2019. The goal of this partnership was to perform cutting-edge research in Transfusion Medicine (TM) while also building local research capacity.

Nature of the Problem: TM research in low to middle-income countries such as SA is challenging due to multifactorial reasons ranging from inadequate scientific, research methodology and project management skills, as well as lack of sustainable financial resources and possibly also language and cultural factors. The aim of the collaborative research project was to develop a high level of local research capacity at SANBS.

Methods: To achieve this goal four clinical / epidemiological REDS III projects provided opportunities for research output. Research capacity-building initiatives included research-training courses in South Africa and longer-term research training in San Francisco for promising junior South African investigators under separate (non-REDS) programs. In addition, junior researchers were provided with ongoing mentorship and collaborative interactions with experienced researchers. Research outputs directly and indirectly linked to REDS include; research-based qualifications attained, training provided, articles published and other research exposure and investment.

Results: Over a nine-year period, the following REDS-III related research output was accomplished: Seven young investigators were mentored to perform an active role within the four studies ranging from development of databases to performing of specialized laboratory tests to project management. Three PHD's are in progress and four mini-grants were provided to allow training in research internationally, in addition to 34 SANBS staff receiving training locally. Six REDS-III manuscripts have been published in reputable journals on transfusion related topics and an additional 13 publications are planned. All REDS-III collaborative SANBS staff have had exposure to international research collaboration, working group meetings and networking opportunities, grant management, research ethics and conduct. Most staff have had opportunities to attend or present at international conferences. Proficiency training in specialized HIV diagnostic assays has resulted in performing of research tests locally rather than shipping samples to international laboratories. Indirect output in one SANBS department has resulted in 22 publications of which eight were primary author publications, 24 posters or presentations at international conferences of which 3 directly related to REDS-III. This foundation has led to the establishment of a Translational Research Unit to ensure that research initiatives mature and are sustained.

Discussion: Significant research capacity was built by collaboration with a reputable research institution and highly experienced researchers who were committed to share their knowledge, provide direct mentorship and training over an extended period. Ongoing active searching and applying for suitable research grants is required to ensure sustainability of being a recognized blood transfusion research institution in Africa and beyond its borders

Conclusion: Grant funded research with a capacity building focus in a resource-limited country such as SA is possible and can yield significant return on investment in terms of research output and human resource development by expanding the local research knowledge base, facilitating the attainment of higher qualifications and international recognition.

Implementation of a Bursary Scheme for the BHSc Qualification

Breuninger M

Introduction: In 2010 the Cape Peninsula University of Technology (CPUT), which is the primary source of Western Cape Blood Service (WCBS) laboratory staff, implemented the Bachelor of Health Sciences (BHSc) Degree and phased out the National Diploma of Biomedical Technology (NDBMT). Candidates studying for this qualification are required to find employment in their chosen specialist discipline for a period of 1 year prior to writing the final assessment in that discipline.

Nature of the problem: Many of the graduates are interested in specialising in clinical pathology or a specialist discipline that would make them more marketable, as earning a good salary is an important factor for these graduates. Blood transfusion (Immunohaematology) is not a popular choice as a specialist discipline, as it is limiting in that it only allows graduates to work for the Blood Services (WCBS or SANBS), whereas with a clinical pathology registration, graduates have a wider choice of laboratories where they can work. Due to the high turnover of laboratory staff, WCBS needs to replace a minimum of 10 staff members annually. In order to attract graduates and make Blood Transfusion a more popular choice as a company to work for, it was decided that a form of 'enticement' was needed.

Design and methodology: As a recruitment strategy, in 2013, a bursary scheme was implemented which offered financial assistance for students' 4th year of study to cover academic fees and the final summative assessment (FSA). A stipend for reimbursement of some expenses is also paid to the students during their 4th year.

Results: As a result of this assistance, if has been observed that students are no longer applying to the Blood Service as a last resort to obtain their qualification. Since implementing the bursary scheme in 2014 to 45 students, 36 have qualified. The students' work has been found to be of a high standard and they have attained excellent results in the board exams and final summative assessments. Of the 45 students that have received a bursary, 9 students still need to complete their FSA in November 2019. The 36 students who have written so far, have achieved a 100% pass rate. This includes 7 distinctions and 1 candidate who received a Cum Laude for the qualification.

Discussion: When a student is offered a bursary, they sign a contract which is in place to protect the investment which WCBS has made in them. On completion of the qualification, students are appointed as permanent staff members but if they should leave the Service within 2 years, they are responsible for repaying a pro rata portion of the academic fees and stipend received.

Conclusion: Offering final year BHSc students a bursary, has improved WCBS pool of prospective new laboratory personnel as more students are selecting immunohaematology as a discipline due to the financial assistance in their final year.

Designing a New Staffing Model for Processing Sites in SANBS

Du Plessis R

Introduction: The South African National Blood Service (SANBS) had a staffing model for processing sites with a baseline calculation of 10 minutes work being equivalent to one work unit. This baseline formula was applied to all processes and tasks performed and the number of staff required was calculated. This model was used during a time when the alignment of processes and procedures across the processing sites was still being finalised and the seven-day workweek schedule for laboratories was being implemented.

Nature of the problem: Once the processes and procedures had been aligned and the seven-day work schedule was implemented the model had to be updated.

Design and Methods: The required hours per month were calculated using a 40-hour work week scheduled over seven days, which, for example in January, translated into 5.7 hours per day accumulating into 177 hours for the month. Time and motions studies were performed for all the tasks and processes for all the departments in a processing site. As an example, it took 4.32 minutes to filter a red blood cell product (RBC). This total time was made up of 10 tasks that were individually timed. The number of whole blood collections and the subsequent blood products that were processed on a monthly basis was determined using the annual collection targets and information retrieved from the Business Intelligence system. These numbers were entered into the model. The required monthly time was divided into the total time it takes to complete all the tasks and processes in a month. The model included a calculation for the number of relief positions required to cover for staff taking annual leave and sick leave.
Results: The staffing model indicated the number of staff required for each department as well as the number of staff required per month according to the number of days in the month. For example, the Egoli Zone processes 17 430 units of whole blood collections per month and all the processes take 2 052 hours per month to complete; therefore, for the month of January, 12 staff members are needed.
Discussion: The model is currently designed in an EXCEL template which allows new tasks and/or processes to be timed and added as and when required. The model is in the process of being validated by each department and when this is completed the model will be rolled out and implemented.
Conclusion: The model is simple to use and has background formulas that that will automatically update when the volume of work is changed. The model will assist with scheduling the appropriate number of staff required to perform the required tasks for the month and will assist the line managers to determine their manpower plans during the annual business planning sessions. There may be an opportunity to automate the model and the BI specialists will be approached to investigate the possibility of creating such a report.

An Innovative Approach to Stakeholder Management: Managing Relationships with Blood Drive Controllers

Pillar T

Introduction: The South African National Blood Service (SANBS) collects 850 000 units of blood annually from voluntary non-remunerated blood donors. We supply blood products and services to more than 600 hospitals in eight of the nine provinces in South Africa. An integral part of the SANBS Donor Services function is to constantly focus on the relationships formed between the SANBS and supporting organizations, media partners and donors. Blood drive controllers (Controllers), as critical stakeholders, assist the SANBS to set up blood drives in an attempt to collect sufficient blood. It is imperative that SANBS establish and maintain excellent relationships with Controllers to ensure that they receive effective support to gain commitment and success for all blood drives planned. In 2018, SANBS Benoni branch introduced a new approach to stakeholder management with the intention of improving stakeholder relationships with Controllers.
Methods: A pilot study was implemented to evaluate the impact of enhancing stakeholder relations in order to increase engagement and commitment. The study incorporated traditional controller functions, taking the form of an evening event vs individual stakeholder meetings, limited to corporate blood drives, focused on joint planning and getting commitment at the strategic level to increase commitment and improve success in the blood drives anticipated. The traditional functions had limited opportunity for networking and sharing of ideas and were restricted to Controllers. The individual stakeholder meeting, in comparison, allowed for senior decision makers to get involved. Five organisations were identified and individual stakeholder meetings and planning sessions were held with their Controllers at the beginning of the year (2018). These individual meetings created a platform to share ideas and suggestions, and allowed for confirmation of support from senior management. The SANBS team explained the importance of increasing collections to achieve targets to meet demand. The requisite commitment and support from these organisations was attained prior to blood drive dates being agreed. Thereafter, additional partnerships and promotional events for the year were discussed and confirmed.
Results: Five organisations that had repeat blood drives held during 2017 participated in the study. The total number of collections from these blood drives in 2017, were 1071 units. The blood drives held at the same organisations during 2018, yielded 1773 units. In 2017, these organisations held blood drives 4 times with a total of 22 blood drives and in 2018 they held 6 times with a total of 29 blood drives.

These five blood drives collectively increased their collections by 65% contributing a total of 702 additional units. The percentage increase in collections at the individual organisation level ranged from 23 to 178.

Conclusion: The implementation of the stakeholder management approach enhanced commitment and stakeholder engagement with Controllers, allowing SANBS to hold more blood drives. The positive impact of this approach was seen in the increased collections achieved at the participating blood drives of the Benoni branch of the SANBS. A further positive spin-off of the increased engagement, for the Benoni branch, was the securing of two additional promotional blood drives and one CSI partnership initiative.

Case Studies of Incidental Finding of Secondary Polycythaemia due to Hookah Pipe Use in Regular Blood Donors at the Western Cape Blood Service, South Africa

Boniface V, Hilton C

Introduction: Blood donors at the Western Cape Blood Service (WCBS) undergo routine point-of-care haemoglobin testing using a quantitative haemoglobin screening device (Hemocue®). In the event that their haemoglobin levels are well above the upper limit of the normal range, they are flagged for review by the Transfusion Medical Specialist and Therapeutic Phlebotomy Clinic staff. An elevated haemoglobin level can be caused by primary disorders of the bone marrow, or due to secondary conditions that result in overstimulation of red blood cell production through erythropoietin production by the kidney, such as smoking or testosterone use. A high haemoglobin and haematocrit (percentage of red cells in the blood) increases a person's risk for life-threatening thrombotic complications, such as strokes or heart attacks. This can be managed with therapeutic venesections to reduce the red cell mass. Hookah (also known as arguileh or shisha) refers to the smoking of tobacco using a waterpipe that originated in the Eastern Mediterranean region, which has become a very popular social practice amongst young people throughout the world. A common misconception exists that hookah smoking is safer than cigarette use as the tobacco smoke moves through a column of water prior to being inhaled. However, a literature review performed as part of this study highlights significant health risks posed to hookah users.

Methods: This is a summary of five case studies where regular blood donors were discovered to have significant secondary polycythaemia at routine blood donation screening due to hookah pipe usage.

Results: Five cases were earmarked over a three-year period all of whom were male donors between the ages of 26 to 35 years. Their initial haemoglobin values were all above 20.3 g/dl (normal range 13.5 – 17.5 g/dl) with haematocrit readings ranging from 0.53 to 0.67 (normal range 0.45 - 0.52). Each person was interviewed telephonically by the WCBS Therapeutic Phlebotomy Clinic staff and referred to their own doctor for further investigation. Of the five donors referred to the therapeutic phlebotomy service, two donors defaulted further management, one donor started therapeutic venesections but did not return after three donations, one donor is currently on a monthly bleeding interval and another donor is being further investigated by his own doctor.

Conclusion: These case studies demonstrate the health risks posed to hookah pipe users, as found on incidental screening of haemoglobin levels of regular blood donors. Although the blood collection services should not be regarded as diagnostic facilities, the promotion of donor health is very important. This study highlights the value of increasing public awareness regarding the health risks of hookah pipe smoking, as well specific questioning regarding this practice in blood donor's with high haemoglobin values.

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