Published in final edited form as:
Vox Sang. 2014 November ; 107(4): 333–342. doi:10.1111/vox.12182.

A PILOT EXTERNAL QUALITY ASSURANCE STUDY OF TRANSFUSION SCREENING FOR HIV, HCV AND HBSAG IN TWELVE AFRICAN COUNTRIES

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Abstract

Background and Objectives—Serologic screening for the major transfusion transmissible viruses (TTV) is critical to blood safety and has been widely implemented. However, actual performance as measured by proficiency testing has not been well studied in Sub-Saharan Africa. Therefore, we conducted an external quality assessment of laboratories engaged in transfusion screening in the region.

Materials and Methods—Blinded test panels, each comprising 25 serum samples that were pedigreed for HIV, HBsAg, HCV and negative status, were sent to participating laboratories. The panels were tested using the laboratories' routine donor screening methods and conditions. Sensitivity and specificity were calculated and multivariable analysis was used to compare performance against mode of testing, country and infrastructure.

Results—A total of 12 African countries and 44 laboratories participated in the study. The mean (range) sensitivities for HIV, HBsAg and HCV were 91.9% (14.3-100), 86.7% (42.9-100) and 90.1% (50-100), respectively. Mean specificities for HIV, HBsAg and HCV were 97.7%, 97% and 99.5% respectively. After adjusting for country and infrastructure, rapid tests had significantly lower sensitivity than enzyme immunoassays (EIA) for both HBsAg ($p<0.0001$) and HCV ($p<0.05$). Sensitivity also varied by country and selected infrastructure variables.

Conclusion—While specificity was high, sensitivity was more variable and deficient in a substantial number of testing laboratories. These findings underscore the importance of proficiency testing and quality control, particularly in Africa where TTV prevalence is high.

*see Appendix

Keywords

Blood transfusion; laboratory proficiency testing; Africa; HIV; Hepatitis B surface antigens; Hepatitis C antibodies

INTRODUCTION

Proficiency testing is critical to ensure that laboratory test results are indeed valid; this is particularly important to blood banking. The importance of an external quality assessment (EQAS) of laboratory performance is evident in the World Health Organization's (WHO) recommendation that proficiency testing be implemented globally [1]. This has already been adopted in high and middle-income countries where laboratory accreditation is often contingent upon an external evaluation of laboratory performance.

In contrast, there are limited examples of proficiency testing in Africa, particularly related to blood transfusion. Instead, proficiency testing in Africa has largely focused on clinical infectious disease testing such as examination of peripheral blood smears for detection of malaria and other blood-borne parasites, serological testing for HIV, laboratory diagnosis of tuberculosis and staining techniques for identification of bacteria [2-4]. Barriers to wider implementation of proficiency testing in Africa include cost, logistics, a lack of skilled personnel and the required infrastructure to establish systems of external evaluation [5, 6].

Over the past decade, there has been considerable external funding and technical assistance for transfusion services in Africa. Both the President's Emergency Plan For AIDS Relief (PEPFAR) and the World Health Organization's (WHO) regional strategy of "Safe Blood by 2012" have been catalytic in this regard. [7] The latter identified key areas of deficiency in blood safety: national oversight and policy, donor recruitment, laboratory testing and appropriate clinical use of blood [8]. In addition both hemovigilance and external quality assessment are key –albeit neglected- elements for the safe functioning of a transfusion service. This is pertinent in Africa, given the high prevalence of the major transfusion transmitted viruses (TTV) [HIV, HBV and HCV] in both the general and blood donor populations.

Following the report of two recent EQAS studies[9, 10] in Francophone Africa, we sought to evaluate test performance at laboratories in Anglophone and Lusophone African countries so as to document and contrast performance across Sub-Saharan Africa (SSA).

MATERIALS AND METHODS

We conducted a cross-sectional assessment of test performance using a convenience sample of laboratories that presently conduct transfusion screening in Africa, using a standardized and blinded test panel. Seventeen countries in SSA were invited to participate in the study. Countries that had participated in the prior Francophone African study were excluded from the new study. We identified national coordinators in each of the countries that agreed to participate, who in turn identified laboratories that conduct in-country transfusion-related screening and were willing to participate in the study.

Panels

The panels were prepared at Institut National de la Transfusion Sanguine (INTS) in Paris, France; each panel comprised 25 samples that included 8 negative samples, 5 HIV (four HIV-1 and one HIV-2), 4 HCV, 5 HBsAg positives (confirmed by neutralization assay) and three mixed samples to mimic co-infections (HCV/HIV, HBsAg /HCV, and one HBsAg/ HIV; Appendix Table A). All samples (except S3) were obtained through dilution with a negative sample in order to obtain a range of the antigen or antibody concentrations. Each sample was pedigreed in the French Laboratory Reference with the following enzyme immunoassays (EIAs): Vidas HIV DUO Ultra (BioMérieux, Craponne, France), Genscreen HIV Ag/Ab Ultra (Bio-Rad, Marne la Coquette, France), PRISM HIV (Abbott, Rungis, France), for HIV; ETI MAK4 (Dia Sorin, Saluggia, Italy), PRISM HBsAg (Abbott), for HBsAg; Monolisa HCV Ag/Ab Ultra (Bio-Rad), Monolisa HCV Ab plus v2 Ultra (Bio-Rad), PRISM HCV(Abbott), for HCV. Moreover, positive confirmatory results for HIV and HCV were obtained with WB HIV (HIV blot 2.2, Abbott) and RIBA HCV (Ortho Clinical Diagnostic, Issy, France). The assays were performed in accordance with the manufacturer's instructions. The panel was distributed in a coded fashion and tubes within each panel were numbered uniquely to allow for blinded testing.

In-country Workflow

The panels were couriered to a major international airport that was logistically closest to the national coordinator. The coordinator was tasked with retrieval and redistribution to the participating laboratories, which were located in different parts of the country. The panels were shipped frozen at a minimum of ≤-20°C with strict attention to maintenance of the cold chain during both international and in-country shipment; this was monitored during the study. One panel was lost during shipment and was not replaced.

Upon receipt at each laboratory, the designated peripheral coordinator communicated the panel number to Blood Systems Research Institute (BSRI). A corresponding data collection sheet was relayed to the peripheral laboratory. with instructions to perform routine testing using standard methods and under conditions normally applied to transfusion samples. After testing, the results were e-mailed back to BSRI using the prescribed data collection form for subsequent analysis. Upon receipt of the results form at BSRI, a questionnaire was relayed to the peripheral coordinator to collect data on the laboratory infrastructure and the mode of testing.

Definitions

For the purposes of the study, we designated the category of Enzyme Immunoassay (EIA) to include those automated or semi-automated assays that were able to detect antibodies (in the case of HIV and HCV) or antigens (in the case of HbsAg). We recognize that some EIAs are indeed chemilumiscent assays rather than true enzyme-based assays. We defined combo tests as automated or semi automated assays, which were able to capture both antibodies and antigens. Rapid tests refer specifically to manual, point of care tests.

We referred to HIV, HBsAg and HCV yet acknowledge that antibody (e.g. Anti-HIV or anti-HCV) or antigen may be targeted, depending on which assay is employed. Specifically, combo tests are able to capture both antigen and antibodies.

Statistical Analysis

Test sensitivity, namely the proportion of true positives that were correctly identified as positive, and test specificity, namely the proportion of true negatives that were correctly identified as negative, were calculated for each virus, by laboratory. There were a total of 7 HIV (4 samples mono-infected with HIV 1, 1 mono-infected with HIV2 and 2 mixed samples), 6 HCV (4 mono-infected and 2 mixed samples) and 7 HBsAg (5 mono-infected and 2 mixed samples) and 8 negative “gold standard” results based upon pedigree testing at our central laboratory. The primary outcome variable in all subsequent bivariate and multivariate analyses was sensitivity expressed as a number from 0 to 1. An initial bivariate analysis compared sensitivity separately by country and by test type using the PROC GENMOD procedure. In order to maintain confidentiality, the countries were assigned random codes that do not correspond to the order of countries in Table 1. For each virus, additional correlations between sensitivity and the following variables were examined using ANOVA (PROC GLM): infrastructure (capabilities to produce blood components), number and type of staff (dedicated versus non-dedicated), percentage of voluntary non-remunerated blood donors (VNRBD), highest qualification of laboratory/center director, total number of refrigerators, year of the newest refrigerator and frequency of electricity blackouts. Finally, for each virus, a separate multivariate model was constructed with PROC GENMOD with sensitivity as the outcome variable. The “stepwise” option for independent variable selection and a p value ≤ 0.1 for retention led to a different set of predictor variables for each model. All analyses were performed using SAS 9.3 (SAS Institute Inc., Cary, NC).

RESULTS

Among the 17 invited countries, a total of 12 countries and 44 screening laboratories participated in the study: Botswana (n=2 laboratories), Cape Verde (n=2), Ghana, (n=3). Kenya (n=9), Lesotho (n=1), Mauritius (n=1), Nigeria (n=7), South Africa (n=3), Tanzania (n=7), Uganda (n=6), Zambia (n=2) and Zimbabwe (n=1) (Figure 1). Reasons for non-participation were not specified.

Infrastructure and tests performed (Table 1)

Seventy one percent of participating laboratories reported some level of interruption of electricity. Seventy six percent of blood centers were able to produce blood components. Twenty four percent transfused RBCs only or, alternatively, whole blood only. An average of 50% of blood was collected from VNRBD (range 6%-100%); the remainder was collected from family replacement donors. No paid donation was reported. Forty seven percent of laboratories had a medical director with a medical and/or a doctoral level education (MD or PhD). The median number of collections was 14,531 units per year (range 862-595,000 units). The median number of collections tested annually at the participating centers was 15,427 (range 1,313-580,000).

The number of laboratories that performed rapid testing was as follows: 3 (6.98%) for HIV, 2 (4.88%) for HBsAg, and 2 (4.88%) for HCV (Appendix Table B). The number of laboratories performing combo (Ag/Ab) testing was 35 (81.40%) for HIV and 6 (14.63%) for HCV. Only three of the participating laboratories performed nucleic acid testing (NAT) routinely; only the serological findings are reported in this manuscript.

Proficiency Testing

The mean sensitivity for HIV, HBsAg and HCV was 91.9%, 86.7% and 90.1%, respectively. Sensitivity of 100% was attained for HIV, HBsAg, and HCV in 29 (66%), 24 (55%), and 28 (64%) laboratories (Figure 2). The mean specificity for HIV, HBsAg and HCV was 97.7%, 97% and 99.5%, respectively. Specificity of 100% was attained for HIV, HBsAg and HCV and HIV in 34 (77%), 31 (70%) and 41 (93%) laboratories (Figure 2).

In the bivariate model, when evaluating the sensitivity of detection by mode of testing test (combo [Ag/Ab] or rapid testing as compared to the use of EIA), the sensitivity was lower with rapid tests than with EIA for both HIV (P=0.007) and HBsAg (p=0.001)(Table 2). There was no significant difference in sensitivity between HIV and HCV combo (Ag/Ab) testing compared to EIA. Evaluation of sensitivity by country demonstrated, significantly reduced sensitivity in countries #3 and #8 for HBsAg, #7 and #8 for HCV and #3 and #10 for HIV.

In the multivariate model (Table 3), sensitivity was significantly lower for HBsAg and HCV using rapid testing as compared to EIA. In contrast, the detection of HIV using rapid testing was not statistically different from EIA. There was lower sensitivity for HCV and higher sensitivity for HIV using combo (Ag/Ab) testing as compared to EIA yet these did not reach statistical significance. In the multivariate analysis, country #8 continued to show a reduced sensitivity for both HBsAg and HCV; only country #7 displayed reduced sensitivity for HIV after controlling for mode of testing and infrastructure.

Other significant findings in the multivariate model include an increased sensitivity for the detection of HBsAg in laboratories that reported 100% VNRBD. There was also an increased sensitivity for detection of HCV where the laboratory director had a doctoral degree or if the laboratory employed a dedicated rather than rotational staff. Lastly, laboratories that reported the ability to produce platelets rather than whole blood or red cells alone, were shown to have a significantly increased sensitivity for HIV

DISCUSSION

These results suggest that the sensitivity of operational TTV testing is deficient in a significant number of laboratories engaged in transfusion screening in SSA. Of the 44 laboratories that were surveyed, approximately 40% demonstrated some level of deficiency in detection of at least one of the three major TTVs (HIV, HBV and HCV). The mode of testing, country in which the laboratories were located and certain aspects of infrastructure were all shown to have an effect on sensitivity for detection of TTVs. The use of rapid tests in particular correlated with poor sensitivity of detection as compared to EIAs or combo Ag/Ab assays, even after controlling for country and infrastructure. Our study also showed

that despite the logistical challenges, EQAS is important and feasible in under-resourced settings.

Deficiencies in sensitivity and specificity represent independent blood safety hazards. Our major focus was that of sensitivity where a deficiency poses risk of an infectious unit entering the blood supply. In contrast, although a deficiency in specificity poses less of an immediate risk to patients, it incurs wastage through unnecessary disposal of non-infectious units and deferral of eligible blood donors. Sensitivity of detection was impacted by three key variables: the mode of testing, the country in which the laboratories were located and the infrastructure at the index laboratory. Infrastructure was evaluated using several surrogate measures such as the ability to produce components other than red cells or whole blood, the staffing, the level of qualification of the laboratory director and the proportion of blood that was collected from VNRBD.

Although the use of rapid testing was shown to affect detection of TTVs adversely, rapid tests are often employed out of necessity rather than choice and have an important role in areas with limited infrastructure. Importantly, rapid tests have demonstrated good efficacy when operated correctly [11, 12]. This has been exemplified in voluntary testing and counseling centers (VCT) where rapid testing offers a critical access point to prevention and treatment, particularly in remote areas [13-15]. Furthermore, the study was designed as a means to identify potential areas of deficiency, rather than to establish cause. There are multiple reasons that impact performance of rapid tests such as the storage conditions, environment (e.g. heat and humidity), input volumes, incubation time, operator training and interpretation of the test results that warrant investigation [16]. Furthermore, deficiencies in quality assurance with point of care testing are common and may contribute to suboptimal performance. This is particularly problematic in Africa where the transfusion service may not control the procurement of the test kits and suppliers vary between consignments.

Nonetheless, the comparatively poor performance of rapid testing was consistent with that reported in two studies in Francophone Africa [9, 10]. The first, a pilot study of six laboratories reported significantly lower performance for rapid testing as compared to EIA[10]. An expanded follow-up study, which used similar methods to our study, evaluated fifty-one laboratories representing 17 countries, demonstrated respective sensitivity and specificity of detection of 81.4% and 99.6% for HIV, 75.6% and 94.5% for HBsAg and 80.0% and 98.1% for HCV. In contrast, the reported sensitivities for rapid testing were 72.4% for HIV, 47.4% for HBsAg and 63.7% for HCV [9].

Even after controlling for modality of testing and infrastructure, a minority of participating countries still maintained significant deficiencies for both HBsAg and HCV. This suggests a systemic problem across all laboratories in those countries that might require an assessment and intervention at the national level. The HIV sensitivity was not shown to be significantly affected by country, which may be ascribed to comparatively greater investment in HIV testing as part of a broader HIV prevention strategy. For example, the WHO program of “Safe Blood by 2012” targeted universal blood screening for HIV, and PEPFAR, an HIV focused program, has been prominent in supporting blood safety in SSA.

The data on transfusion infrastructure offers further insight into blood banking capacity in SSA and attests to the diversity in size and concomitant level of infrastructure. Of note, over two thirds of laboratories reported electricity outage at least once per month and almost a fifth reported daily interruptions. Notably, there was significantly increased sensitivity for the detection of HCV in laboratories that had a director with a doctoral degree or a staff of dedicated rather than rotating technologists; this likely reflects general human capacity in those laboratories. We also found that laboratories that produced components (specifically platelets) as opposed to whole blood alone had a significantly increased sensitivity for HIV. Indeed, the ability to produce components, a surrogate of blood center infrastructure, was the only variable that was shown to have a significant effect on sensitivity of detection for HIV.

The major strength of the study was its focus on a neglected area of public health in Africa. Proficiency testing specific to blood transfusion is lacking, despite the high prevalence of TTVs in Africa [17-19]. There is recognition that viral marker screening is critical to mitigation of TTV risk; however, in the absence of quality assurance, such screening offers false assurance. While we had expected greater reservation to participate in this study, the regional transfusion services (with few exceptions) offered strong support. A secondary gain of the study has been the establishment of a regional transfusion-focused research network to conduct both a follow-up EQAS as well as to support independent transfusion-related research. This could serve to influence, positively, clinical practice and blood safety in the future.

There are several limitations of the study. First, the observed step-like drop off in sensitivity and specificity (Figure 2) is due to the small number of positive samples in a given panel. Thus, a single error incurs a relatively large decrease in sensitivity, potentially misrepresenting the true performance characteristics at a given laboratory. This limitation is shared with other proficiency testing studies using pedigreed panels of modest size, and may be offset by a positive bias from laboratory awareness that an EQAS panel is being tested. Second, the preparation of the samples is another potential limitation. Specifically, some of the samples were diluted and may approximate low level infection rather than samples that might be more typically encountered in donors with unrecognized infection i.e. moderate level antibody or HBsAg. However, low titer samples are encountered in daily practice and still pose risk of TTI. Third, the low number of participating laboratories that used rapid testing limits the generalizability of our findings, despite being consistent with previous studies [9, 10]. Fourth, due to our use of a convenience sample of both countries and laboratories within each country, selection bias could have led to either over- or underestimation of performance. Specifically, five countries elected not to participate; reasons for non-participation were not communicated to the research team. Finally, because of its scope, the study did not include an on-the-ground assessment of the procedures at each laboratory and is therefore unable to determine the cause for the observed deficiencies. However, root cause analysis and remediation has been initiated at some of the laboratories following the study.

In conclusion, this study supports the implementation of EQAS for transfusion infectious disease screening in SSA. The findings highlight deficiencies that could be remedied by

improved quality assurance and validation of laboratory screening. Following communication of the results to participating laboratories, we received positive feedback with a number of requests for follow-up investigation; some laboratories have expressed an interest in participating in ongoing proficiency testing. Therefore, we encourage the adoption of ongoing EQAS in Africa, ideally facilitated by the World Health Organization (WHO) and/or the Centers for Disease Control and Prevention (CDC), both of which have expressed their support for continued activities. Implementation of quality assurance systems is feasible, even in remote settings [20].

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

We are grateful to Safe Blood for Africa Foundation for assistance in identifying and facilitating the participation of a number of laboratories and to the Institut National de la Transfusion Sanguine (INTS), Paris, France for serving as our central laboratory and especially Françoise Bouchardeau and Isabelle Houdoin who prepared the panels. The authors are also grateful to Drs. Daniel Kimani at the Centers for Disease Control and Prevention in Kenya, Peter Mwamba at University of Nairobi and Leslie Tobler for their invaluable contribution.

Funding: Blood Systems Research Institute, Institut National de la Transfusion Sanguine and NHLBI career development award K24-HL-75036 to Dr. Murphy

APPENDIX

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Figure 1. Map of Countries that have participated in the African Proficiency testing Studies

Map of Africa that shows Anglophone and Lusophone African countries (dark grey), which participated in the African Proficiency Testing Study (n=12). Countries that participated in the previous proficiency testing study in Francophone Africa are displayed in light grey (n=17). The participating laboratories are indicated with black dots dots (n=44).

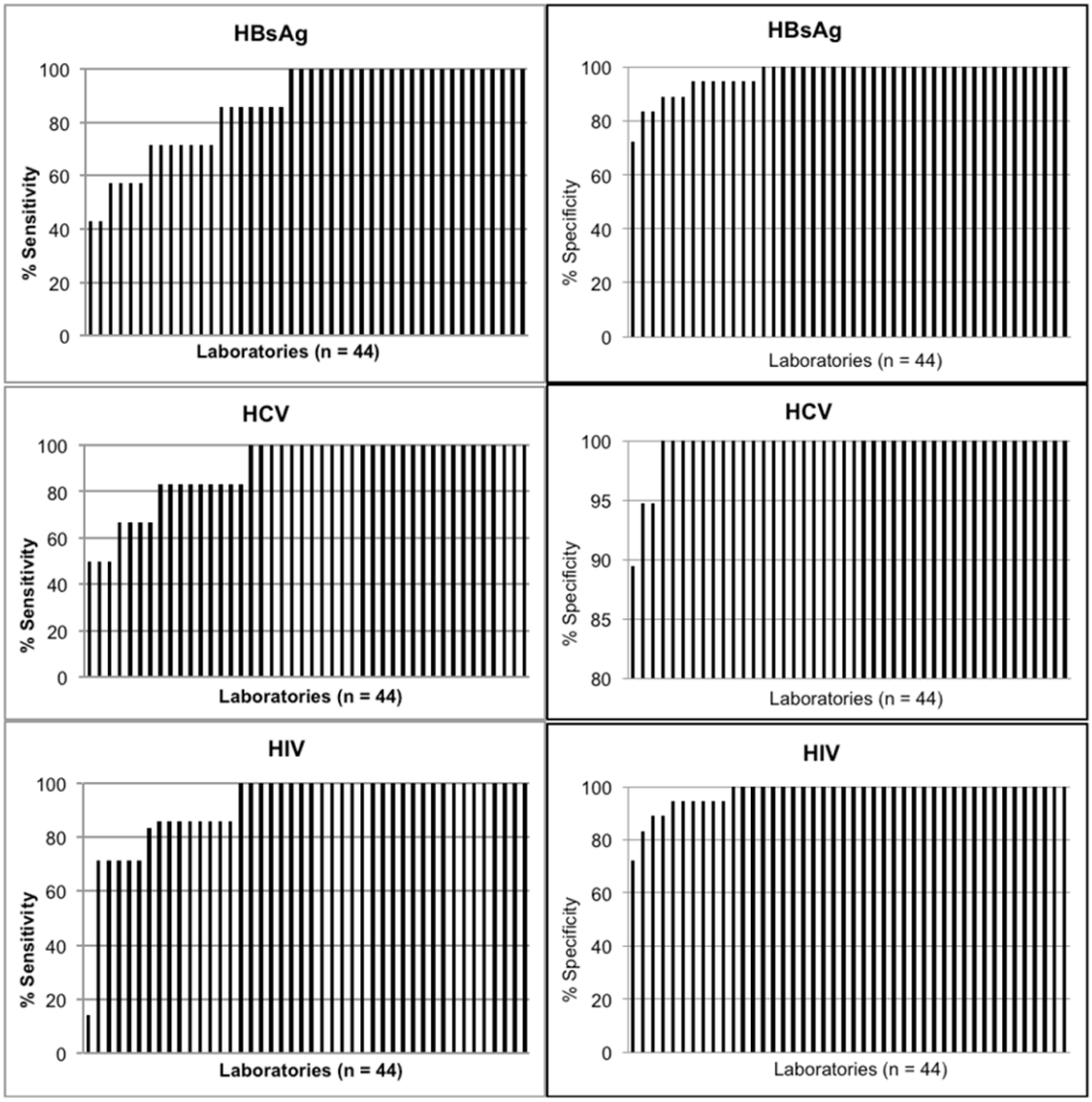

Figure 2.

Sensitivity & Specificity by laboratory for HBsAg, HCV & HIV. In each graph, laboratories are sorted in order of increasing sensitivity or specificity.

Table 1

Demographic Data on participating countries and Collection Infrastructure

Country and Number of Centers/Laboratories	n	%	
Botswana	2	4.5	
Cape Verde	2	4.5	
Ghana	3	6.8	
Kenya	9	20.5	
Lesotho	1	2.3	
Mauritius	1	2.3	
Nigeria	7	15.9	
South Africa	3	6.8	
Tanzania	7	15.9	
Uganda	6	13.6	
Zambia	2	4.5	
Zimbabwe	1	2.3	
Electricity Outage (n=42)			
At least Once a year/Never	12	28.6	
At least Once a month	11	26.2	
At least Once a week	11	26.2	
At least Once a day	8	19	
Infrastructure (n=42)			
Produce Components incl. Platelets	32	76.2	
Produce RBCs only/ No Components at all	10	23.8	
Staff Breakdown (n=41)			
Dedicated	33	80.5	
Rotational/Mixed	8	19.5	
Qualification of Director of Center (n=40)			
Doctoral (MD/PhD/equivalent)	19	47.5	
Non-Doctoral	21	52.5	
% VNRBD * (n=42)			
<75%	11	26.2	
76-99%	10	23.8	
100%	21	50	
Number of Refrigerators (n=42)			
0-5	23	60.5	
=>6	15	39.5	
Other	**Mean**	**Median**	**Range**
No of Collections	385053	14531	862-595000

Country and Number of Centers/Laboratories	n	%	
No of Collections Tested	38705	15427	1313-580000
% VNRBD *	83.3	99.5	6-100
Number of Staff	9.74	6.5	2-30
No of Refrigerators	7.9	5	2-100
Year of Newest Refrigerator	NA	NA	1999-2011

* VNRBD: voluntary non-remunerated blood donors

Table 2

Bivariate Model of Sensitivity for Detection HBsAg, HCV and HIV by Mode of Testing using an EIA reference. The reference category for mode of testing is EIA; a negative parameter indicates worse sensitivity and a positive one indicates better sensitivity.

Virus and Mode of Testing[1]	Parameter Estimate	95% CI	p-value
HBV			
Rapid test	-0.47	(-0.66, -0.27)	<0.001
HCV			
Ag/Ab Combo test	0.08	(-0.06, 0.21)	0.248
Rapid test	-0.06	(-0.28, 0.16)	0.586
HIV			
Ag/Ab Combo test	-0.01	(-0.14, 0.12)	0.894
Rapid test	-0.28	(-0.48, -0.08)	0.007

Table 3

Multivariate model of Sensitivity for the Detection of HBsAg, HCV and HIV*. For each variable, the reference category is indicated in the footnotes; a negative parameter indicates worse sensitivity and a positive one better sensitivity. Variables included in each model differed; those not shown were not significantly associated with sensitivity.

HBsAg			
Variable	**Parameter**	**95% CI**	**p value**
Test category[a]			
Rapid test	-0.52	(-0.73, -0.30)	**<0.0001**
Country[b]			
Country #8	-0.20	(-0.34, -0.05)	**0.0077**
Infrastructure[c]			
Produces components including Platelets	-0.10	(-0.25, 0.05)	0.1821
% Voluntary Donors[d]			
76%-99%	0.03	(-0.08, 0.14)	0.5687
100%	0.11	(0.09, 0.20)	**0.0335**
HCV			
Test category[a]			
Ag/Ab Combo test	-0.19	(-0.38, 0.01)	0.0619
Rapid test	-0.30	(-0.50, -0.09)	**0.0047**
Country[b]			
Country #8	-0.33	(-0.49, -0.16)	**0.0001**
Qualification of Director[e]			
Doctoral	0.15	(0.04, 0.25)	**0.0060**
Staff Breakdown[f]			
Dedicated	0.12	(0.03, 0.21)	**0.0089**
Number of staff[g]			
6-10	0.08	(-0.00, 0.16)	0.0586
>10	0.05	(-0.07, 0.17)	0.4016

HBsAg			
Variable	**Parameter**	**95% CI**	**p value**
% Voluntary Donors[d]			
76%-99%	-0.09	(-0.19, 0.01)	0.0710
100%	-0.03	(-0.12, 0.07)	0.5737
HIV			
Test category[a]			
Ag/Ab Combo test	0.06	(-0.14, 0.27)	0.5508
Rapid test	-0.09	(-0.34, 0.16)	0.4610
Country[b]			
Country #7	0.22	(-0.02, 0.46)	0.0727
Infrastructure[c]			
Produces components including Platelets	0.28	(0.12, 0.44)	**0.0005**
Number of staff[g]			
6-10	0.06	(-0.03, 0.15)	0.1670
>10	0.04	(-0.08, 0.15)	0.5494
% Voluntary Donors[d]			
76%-99%	0.03	(-0.07, 0.14)	0.5484
100%	0.05	(-0.07, 0.16)	0.4157

Reference Category

[a] EIA

[b] Country #0

[c] Produces RBCs only/No components

[d] <75% Voluntary donors

[e] Non-doctoral qualification

[f] Rotational

[g] 2-5 staff