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Orapuh Journal

ORIGINAL ARTICLE

Journal of Oral & Public Health

Evaluation of biological qualification by rapid diagnostic tests of transfused blood units in Isiro, DRC: Case of major virological markers

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ARTICLE INFO

Received: *07 March 2025*
Accepted: *28 March 2025*
Published: *07 May 2025*

Keywords:
Blood, biological qualification, transfusion, Isir, DRC

Peer-Review: *Externally peer-reviewed*

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To cite:
Matimada, G. M., Sumbu, B. M. M. M., Misingi, P., Muamba, C. M., Gamani, D. S., Mazoba, T. K., Masika, L. H., & Muwonga, J. M. (2025). Evaluation of biological qualification by rapid diagnostic tests of transfused blood units in Isiro, DRC: Case of major virological markers. *Orapuh Journal*, *6*(4), e1237
https://dx.doi.org/10.4314/orapj.v6i4.37

ISSN: *2644-3740*

Published by Orapuh, Inc. (info@orapuh.org)

Editor-in-Chief: Prof. V. E. Adamu
Orapuh, Inc., UMTG PMB 405, Serrekunda, The Gambia, editor@orapuh.org.

ABSTRACT

Introduction

Ensuring blood recipient safety during transfusion requires systematic screening for transfusion-transmissible infections (TTIs). In Isiro, this screening is performed using single-unit, operator-dependent rapid diagnostic tests (RDTs).

Purpose

This study aimed to evaluate the virological qualification of transfused blood units in healthcare facilities in Isiro, Haut-Uélé Province, Democratic Republic of the Congo.

Methods

A descriptive and analytical cross-sectional study was conducted from August 14, 2023, to September 13, 2023, across five major healthcare facilities in Isiro that perform blood transfusions. A counter-analysis was conducted at the National Blood Transfusion Center (CNTS) using the Architect i1000 automated system, which operates based on chemiluminescence, on samples collected in dry tubes. The intrinsic performance metrics, including sensitivity (Se) and specificity (Sp), as well as extrinsic performance measures such as positive predictive value (PPV) and negative predictive value (NPV), were estimated for the main virological markers (HIV, HBV, and HCV). Cohen's Kappa coefficient was used to assess the reliability of RDTs compared to the Architect i1000.

Results

A total of 148 samples were collected during the study period. The mean age of the study population was 32.92 ± 8.43 years, with a modal age of 28 years. The minimum and maximum ages recorded were 18 and 55 years, respectively. Most donors were family donors, with a male-to-female sex ratio of 1.85. The frequency of infectious markers for HIV, HBV, and HCV was 2%, 3.4%, and 4.1%, respectively. The sensitivity of RDTs was low. The agreement between RDTs and the Architect i1000 was assessed as moderate (56.1%), good (65.6%), and moderate (42.9%) for HIV-1/2 antibodies, HBs antigen, and HCV antibodies, respectively.

Conclusion

Blood qualified using RDTs in Isiro exposes recipients to a risk of contracting TTIs. Further studies to better understand the problem, additional training for healthcare providers, and more effective tests are necessary to prevent contamination through blood transfusions.

INTRODUCTION

Blood transfusion (BT) is a therapeutic procedure that involves administering blood or one of its components (red blood cells, platelets, granulocytes, plasma, proteins) from one or more donors to one or more recipients (Zmouli & Seghier, 2014; Goita et al., 2019). It saves lives and improves health, but many patients in need do not have timely access to safe blood (Baweld & Patassi, 2024; Weaver et al., 2023). Therefore, the World Health Organization (WHO) has identified transfusion safety as a public health issue that must be treated as a health priority (Abdelrazikam & Ahmed, 2016). Blood donation biological qualification laboratories are required to implement human, technical, material, IT, and organizational resources to ensure the reliability of results (Ferdowsi et al., 2023).

Despite the ever-growing mastery of the transfusion chain, from donor selection to patient transfusion, and the progressive improvement of analytical performance of different generations of serological tests in terms of sensitivity and specificity, the risk of infectious agent transmission through BT remains, and it cannot yet be considered null for all pathogens (Barlet, 2011; Pozzeto & Garrand, 2011).

Several studies on BT have demonstrated a significant residual infectious risk related to the use of serological tests, which at times are unable to detect the presence of antibodies during the pre-detectability period known as the "serological window" (Zhuh et al., 2024). The duration of this serological window is estimated to be 22 days for HIV, 56 days for HBV, and 66 days for HCV when using serological tests (Pozzeto & Garrand, 2011).

In Africa, several studies have revealed a high frequency of infectious agents among blood donors (Kashosi et al., 2018; Pruett et al., 2015). In the city of Isiro in Haut-Uélé Province, no health structure has a functional blood bank meeting standards. Therefore, blood supply is only available in large health structures via predominantly family donors, and more rarely, via voluntary donors. Donor selection is carried out by technicians or nurses working in the laboratory without prior documented medical interviews. Moreover, the supply of reagents does not follow a formal circuit and is not guaranteed. This makes it difficult to comply with rules, particularly regarding test quality, adherence to analysis procedures, and management of cases positive for certain markers.

As a result, the qualification of blood units for transfusion in Isiro health structures is carried out using unitary serological tests for markers of HIV infection, hepatitis B and C, and syphilis. However, these serological tests have detection limitations reflected in the "serological window" (Weimer et al., 2019). The serological window, which lasts from a few days to a few weeks, is the period between the time of contact with the infectious agent (contamination) and the point at which antibodies can be detected in the bloodstream (World Health Organization [WHO], 2019).

In light of the above, we asked ourselves the following questions: Does the virological qualification of blood units transfused in Isiro health structures in Haut-Uélé Province meet the quality standards set by the CNTS? Does this process guarantee the prevention of infectious agent transmission? Therefore, the objective of this study was to evaluate the virological qualification of blood units transfused in Isiro health structures in Haut-Uélé Province while describing the sociodemographic, clinical, and biological characteristics of blood donors and conducting quality control (QC) of transfused blood for virological infectious markers.

METHODS

Type and Study Sites

A descriptive and analytical cross-sectional study was conducted from August 14, 2023, to September 13, 2023, in five major healthcare facilities in the city of Isiro (University Clinics of Uélé, Isiro General Referral Hospital, Clinique de l'Est, TULUBA Health Center, and MAYOGO Health Center) in Haut-Uélé Province. The choice of these healthcare facilities was justified not only by their relatively high patient attendance but also by the fact that they practice blood transfusion (BT).

Study Population

The study population consisted of blood donor candidates who presented themselves at the selected facilities during the data collection period. We selected the following sociodemographic parameters and clinical variables: age, sex, length of donation, and category of blood donor

candidate. The biological variables included the results of HIV, HBV, and HCV serology tests performed using rapid tests by laboratory personnel at the target facilities.

Additionally, quality control tests were conducted on the same samples by the research team at the CNTS/Kinshasa laboratory. Data collection for blood donor candidates was conducted as they arrived at the laboratory for blood donation. A 5 ml blood sample was drawn into a dry tube for biological qualification in the respective laboratories. After centrifugation, the serum collected from each sample was divided into aliquots in two cryotubes. These were placed in an isothermal container and transported to the Expanded Program on Immunization (EPI) office in Isiro, where they were stored in a freezer at -20°C while awaiting transfer to the CNTS laboratory in Kinshasa. This process adhered to the cold chain and the principle of triple packaging for quality control.

Laboratory Analyses

In the main healthcare facilities of the city of Isiro, analyses were performed by site personnel using serum collected from candidate donors. The detection of infectious markers (anti-HIV1 and 2 antibodies for HIV, HBs antigen for HBV, and anti-HCV antibodies) was conducted using rapid diagnostic tests based on the principle of immunochromatography.

For quality control at the CNTS laboratory in Kinshasa, the samples were thawed and brought to room temperature before analysis. For the three virological markers, retesting was conducted using the Architect i1000 automated analyzer, which operates on the principle of chemiluminescence (CLIA), considered the gold standard in this study.

Statistical Data Analysis

The data collected using a data collection form (attached in the appendix) were recorded, entered, and pre-coded using Excel 2016. All statistical analyses were performed using IBM SPSS Statistics (The Statistical Package for the Social Sciences) version 20.0 for Windows. The variables were presented in tabular form. The results of the various rapid tests used for virological qualification of blood units (screening for virological markers of HIV, HBV, and HCV) were compared with the results obtained at CNTS/Kinshasa using the Architect i1000 automated system.

The intrinsic performance measures, specifically sensitivity (Se) and specificity (Sp), as well as the extrinsic performance measures, particularly the Positive Predictive Value (PPV) and the Negative Predictive Value (NPV) of each rapid diagnostic test (RDT), were estimated for each virological marker. The confidence interval (CI) was set at 95%, and the significance level (p) was fixed at 0.05. Binary concordance was estimated using Landis and Koch's Kappa agreement measures. The reference values of Landis and Koch were applied, with corrected concordance categorized as excellent (k ranging from 0.81–1.0), satisfactory (k ranging from 0.61–0.80), moderate (k ranging from 0.41–0.6), and low (k ranging from 0.21–0.4). Sensitivity (Se) expressed the proportion of true positives (TP) and was calculated as follows:

$$Se = \frac{VP}{VP + FN}$$

Where: FN = false negatives, meaning a positive result detected by the Architect i1000 but missed by the RDT.

Specificity (Sp) estimated the proportion of true negatives (TN), i.e., non-reactivity of the RDT to a sample confirmed by the Architect i1000, and was calculated as follows:

$$Sp = \frac{VN}{VN + FP}$$

Where: FP = false positives, meaning a reactive sample on the RDT that was not confirmed by the Architect i1000. PPV and NPV were also calculated using the following formulas:

$$VPP = \frac{VP}{VP + FP}$$

$$VPN = \frac{VN}{VN + FN}$$

Ethical Considerations

The study protocol was submitted for review and approval to the National Health Ethics Committee and

received a favorable approval recorded under No. 619/CNES/BN/PMMF/2025 on 06/01/2025.

RESULTS

A total of 148 blood donors were recorded in this study. The mean age of the study population was 32.92 ± 8.43 years, with a modal age of 28 years. The age range extended from 18 to 55 years. The most represented age group (36.5%) was 26–35 years, followed by the 36–45-year age group, which comprised approximately 32% of the donors. The majority (64.2%) of the study population was male, resulting in a male-to-female sex ratio of 1.85. More than half (56.1%) of the participants were recruited from the Uélé University Clinic (25.7%) and the Isiro General Reference Hospital (30.4%). The vast majority (72.3%) were family donors (FD), with nearly 56% being first-time blood donors.

Table 1:
General characteristics of blood donors

Variables	Frequency *(n)*	Percentage (%)
Age		
18–25	35	23.6
26–35	54	36.5
36–45	48	32.4
46–55	11	7.4
Gender		
Male	95	64.2
Female	53	35.8
Blood Drive Site		
CE	23	15.5
CS Mayogo	14	9.5
CST	28	18.9
CUU	38	25.7
HGR	45	30.4
Donor Category		
DB	41	27.7
DF	107	72.3
Donation Status		
New	83	56.1
Regular	65	43.9

Legend: CE: Clinique de l'Est; CS: Centre de Santé Mayogo; CST: Centre de Santé Tuluba; CUU: Clinique Universitaire de l'Uélé; HGR: Hôpital Général de Référence.

Table 2:
Prevalence of HIV, HBV, and HCV among blood donors based on RDT and reference method (Architect i1000)

Variable	Modality	Architect *n (%)*	RDT *n (%)*
HIV	Negative	145 (98.0)	144 (97.3)
	Positive	3 (2.0)	4 (2.7)
HBV	Negative	143 (96.6)	144 (97.3)
	Positive	5 (3.4)	4 (2.7)
HCV	Negative	142 (95.9)	145 (98.0)
	Positive	6 (4.1)	3 (2.0)

A total of 148 blood donation samples were analysed during the study period. The frequency of HIV, HBV, and HCV using rapid diagnostic tests (RDTs) was 2.7% (n = 4), 2.7% (n = 4), and 2.0% (n = 3), respectively. Conversely, using the reference method (Architect®), the prevalence was 2.0% (n = 3), 3.4% (n = 5), and 4.1% (n = 6) for HIV, HBV, and HCV, respectively (see Table 2).

Table 3:
Intrinsic performance of RDTs for detecting virological markers compared with Architect

Virus	RDT Result	Architect Positive n (%)	Architect Negative n (%)	Total n (%)
HIV	Positive	2 (66.7)	2 (1.4)	4 (2.7)
	Negative	1 (33.3)	143 (98.6)	144 (97.3)
HBV	Positive	3 (60.0)	1 (0.7)	4 (2.7)
	Negative	2 (40.0)	142 (99.3)	144 (97.3)
HCV	Positive	2 (33.3)	1 (0.7)	3 (2.0)
	Negative	4 (66.7)	141 (99.3)	145 (98.0)

Among samples reactive for HIV, HBV, and HCV using the reference method (Architect®), 66.7%, 60.0%, and 33.3% were also reactive on RDTs, respectively, indicating low sensitivity (Table 3). Furthermore, 98.6%, 99.3%, and 99.3% of non-reactive samples on Architect® were similarly non-reactive on RDTs for HIV, HBV, and HCV, respectively, indicating high specificity. However, 33.3%, 40.0%, and 66.7% of Architect-positive samples for HIV, HBV, and HCV, respectively, were not detected by RDTs.

Table 4:
Extrinsic performance of RDTs in the detection of virological markers compared with Architect i1000

Virus	RDT Result	Architect Positive *n (%)*	Architect Negative *n (%)*	Total
HIV	Positive	2 (50.0)	2 (50.0)	4
	Negative	1 (0.7)	143 (99.3)	144
HBV	Positive	3 (75.0)	1 (25.0)	4
	Negative	2 (1.4)	142 (98.6)	144
HCV	Positive	2 (66.7)	1 (33.3)	3
	Negative	4 (2.8)	141 (97.2)	145

The positive predictive values (PPVs) for RDTs were 50.0%, 75.0%, and 66.7% for HIV, HBV, and HCV, respectively. In contrast, the negative predictive values (NPVs) were 99.3%, 98.6%, and 97.2% for HIV, HBV, and HCV, respectively (see Table 4).

Table 5:
Measure of Kappa Agreement in Relation to the Diagnostic Performance of RDT versus Architect®

Test	Area under the ROC Curve	Standard Error	*p*-value	95% CI Lower	95% CI Upper	Sensitivity *(%)*	Specificity *(%)*	PPV *(%)*	NPV *(%)*	Kappa
HIV RDT vs. HIV Architect®	0.826	0.167	0.053	0.500	1.000	66.7	98.6	50.0	99.3	0.561
HCV RDT vs. HCV Architect®	0.797	0.137	0.024	0.528	1.000	60.0	99.3	75.0	98.6	0.656
HBV RDT vs. HBV Architect®	0.663	0.137	0.177	0.395	0.932	33.3	99.3	66.7	97.2	0.429

The Kappa coefficients calculated for the agreement between rapid diagnostic tests (RDTs) and the reference Architect® test for HIV, HBV, and HCV were 0.561 (56.1%), 0.656 (65.6%), and 0.429 (42.9%), respectively. Based on these values, the concordance was considered moderate for HIV, good for HCV, and fair for HBV (McHugh, 2012).

No statistically significant differences were observed between RDT and Architect® results for the detection of HIV (p = 1.00), HBV (p = 1.00), and HCV (p = 0.375), based on McNemar's test (Field, 2013).

DISCUSSION

Despite the benefits of blood transfusion, it carries a significant risk for recipients: the transmission of bloodborne infectious diseases. Therefore, transfusion safety requires systematic and mandatory screening for infectious markers of HIV, HBV, HCV, and syphilis in all potential blood donors (World Health Organization [WHO], 2010).

Sociodemographic Characteristics and Categories of Blood Donors

The mean age of the study population was 32.92 ± 8.43 years, with a modal age of 28 years and age extremes of 18 and 55 years. The male-to-female sex ratio was 1.85.

Our findings regarding the most represented age group are similar to those of Ngama et al. (2016), who reported a mean age of 31.59 ± 8.2 years among blood donors in the University Clinics of Lubumbashi. This may be explained by the youthful demographic structure of African populations and the common practice of recruiting younger individuals for blood donation, especially during family emergencies.

Our sex ratio results are also comparable to those of Ngama et al. (2016), Siraj et al. (2018), and Mayaki et al. (2013), who also reported a predominance of male donors. This gender disparity may be attributed to several sociocultural and physiological factors limiting women's participation in blood donation, including pregnancy, breastfeeding, childbirth, and menstruation.

Most of our study population was recruited from the University Clinics of Uélé and the General Referral Hospital of Isiro. This is likely because these are the two largest healthcare facilities in the area, with adequate infrastructure to accommodate high patient volumes and a significant number of healthcare professionals.

Family donors represented the majority of the study population (72.3%), while voluntary blood donors (VBDs) accounted for only 27.7%. These findings are consistent with those of Ngama et al. (2016), who also observed a predominance of family donors. However, they contrast with Siraj et al. (2018), who reported a predominance of voluntary donors.

Prevalence of Infectious Markers

Several studies have reported a high prevalence of transfusion-transmissible infections (TTIs) among blood donors in sub-Saharan Africa. In our study, the prevalence rates of HIV, HBV, and HCV were 2%, 3.4%, and 4.1%, respectively, using the Architect® i1000SR immunoassay system.

These results are consistent with those of Goita et al. (2019), who reported prevalence rates of 1.9% for HIV and 3% for HCV, and with Ngama et al. (2016), who found 2.6% for HIV and 2.67% for HCV in Lubumbashi. However, our rates are higher than those reported by Siraj et al. (2018), who found a prevalence of only 0.1% for all TTIs. This discrepancy may be due to differences in sample size and study duration, as their study involved a larger and more representative sample.

Regarding the performance of rapid diagnostic tests (RDTs) used for screening infectious biomarkers in Isiro, our results indicate that blood deemed qualified through RDTs alone carried a considerable risk of transmitting infections to recipients. The intrinsic performance of the RDTs was limited due to low diagnostic sensitivity. The WHO recommends the use of RDTs with ≥99.5% sensitivity and specificity to minimise the risk of TTIs and ensure transfusion safety (WHO, 2010).

In our study, the sensitivity of the RDTs was 66.7% for HIV, 60% for HBV, and 33.3% for HCV. These values are low, particularly for blood transfusion purposes where undetected infections pose significant risks. However, these results are comparable to those from Ethiopia, where Dessie et al. (2008) reported a sensitivity of 60.5% for the Determine HIV-1/2 test. Similar findings were reported by Angandji Tipane et al. (2024), who found sensitivities of 46.2% for HIV RDTs, 66.7% for HBsAg, and 58.8% for anti-HCV antibodies. In the Democratic Republic of the Congo, Kashosi et al. (2018) reported RDT sensitivity values of 57.14% for HIV, 50% for HCV, and 25% for HBV, all lower than ELISA results.

The low diagnostic sensitivities observed may be due to factors such as testing during the seroconversion period, the presence of viral variants or mutants not detected by the tests, improper storage conditions, noncompliance with test procedures, and operator-dependent errors in test interpretation. In contrast, other African studies have reported relatively high RDT sensitivity and specificity (Pruett et al., 2015), highlighting variability in test performance across different contexts.

CONCLUSION

The transmission of transfusion-transmissible infections remains a major complication of blood transfusion. In Isiro, screening for infectious biomarkers using rapid diagnostic tests demonstrated significant limitations in sensitivity, increasing the risk of undetected infections in donated blood. These findings call for further studies to better understand the issue, increased training for healthcare providers, and commitment from authorities to provide more accurate testing technologies to prevent transmission of infections through transfusion.

Authors' Contributions

- **Matimada, G. M.**[1,3]: Principal author; study design, data collection, interpretation, manuscript writing.
- **Sumbu, B. M. M. M.**[1]: Statistical analysis.
- **Misingi, P.**[2]: Provided authorisation for analyses at the CNTS/Kinshasa laboratory.
- **Muamba, C. M.**[3], **Gamani, D. S.**[1], **Masika, L. H.**[1]: Data collection at various facilities.
- **Mazoba, T. K.**[4]: Statistical revision, English translation.
- **Muwonga, J. M.**[1]: Study design, supervision, manuscript writing.

Ethical Approval: The study protocol was submitted for review and approval to the National Health Ethics Committee and received a favorable approval recorded under No. 619/CNES/BN/PMMF/2025 on 06/01/2025.

Conflicts of Interest: None declared.

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