Original Research Article

LATERAL FLOW ASSAY AND ENZYMATIC DETECTION OF VIRAL TRANSFUSION TRANSMISSIBLE INFECTIONS (TTIs) AMONG BLOOD DONORS IN FEDERAL MEDICAL CENTER KEFFI, NASARAWA

Commented [DO1]: Suggested topic: Detection of Viral Transfusion-Transmissible Infections Among Blood Donors Using Lateral Flow Assay and ELISA at Federal Medical Center Keffi, Nasarawa.

ABSTRACT

Background: Transfusion-transmissible infections (TTIs) pose a significant risk to blood transfusion safety, making early detection through reliable diagnostic methods crucial for reducing transmission rates. This study aimed to determine the prevalence of viral TTIs among blood donors at Federal Medical Centre, Keffi, Nasarawa State, Nigeria, using the lateral flow assay technique (Rapid Diagnostic Test (RDT)) and enzymatic detection (Enzyme-Linked Immunosorbent Assay (ELISA)).

Method: An institution-based cross-sectional study was conducted from March to September 2024, involving 240 blood donors, where all samples were initially screened using RDT. The RDT-negative samples were further analysed using ELISA. A questionnaire was used to inquire about social demographics and risk factors.

Results: The RDT Seroprevalence rates were 3.8% for HBV, 3.3% for HCV, and 1.6% for HIV, while ELISA detected additional cases, leading to final seroprevalence rates of 4.6% for HIV, 9.6% for HBV, and 5.0% for HCV with an overall TTI prevalence of 19.2%. Males had a higher overall TTI prevalence than females, however, the gender difference was not statistically significant ($P > .05$). Single donors had a higher prevalence of HIV 6.5% and HCV 7.5% compared to married donors, 3.0%, respectively. HBV seroprevalence was 9.7% for married donors and 9.3% for single donors ($P > .05$). There were no cases of co-infection among the blood donors in this study.

Conclusion: Using the ELISA technique to confirm the presence of TTIs among blood donors is highly recommended.

Commented [DO2]: Clarification Needed: Why only RDT-negative samples were tested with ELISA? This could lead to missed cases among RDT-positives and may bias the sensitivity comparison.

Commented [DO3]: State inclusion/exclusion criteria, and clarify if donors were first-time or repeat donors.

Commented [DO4]: Report actual prevalence rates by gender for transparency.

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Keywords: Transfusion-Transmissible Infections (TTIs), Blood Donors, Rapid Diagnostic Test (RDT), Enzyme-linked Immunosorbent Assay (ELISA).

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1.0 Introduction

Transfusion Transmissible Infection (TTIs) is a virus, parasite, or other potential pathogen that can be transmitted in donated blood through a transfusion to a recipient (Yadav *et al*., 2018). The term is usually limited to known pathogens, but also sometimes includes agents such as simian foamy virus, which are not known to cause disease (Pinto-Santini *et al*., 2016). Transfusion transmissible infections agents such as Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Syphilis/Veneral Disease of Research Laboratory (VDRL) are among the greatest threat to blood safety and pose a serious public health problem (Deshmukh *et al*., 2024; Habibu *et al*., 2025). The high prevalence of HIV, HBV, HCV, and VDRL has heightened the problem of blood safety and continuous monitoring of the magnitude of TTIs in blood donors is important for estimating the risk of transfusion and optimising donor recruitment strategies to minimise infectious disease transmission (Deshmukh *et al*., 2024). There is a rising threat resulting from the transfusion of infected blood, with consequences, not only for the recipients themselves, but also for their families, their community and the wider society. This threat is higher in developing countries, including Nigeria (Aliyo *et al*., 2022; Durowade *et al*., 2023). Only continuous improvement implementation of donor selection, sensitive screening tests and effective inactivation procedures can ensure the elimination, or at least reduction of the risk of acquiring TTIs (Emadi *et al*., 2021). Rapid advances and continuous improvement in serology assays and Enzyme-Linked Immunosorbent Assay (ELISA) have reduced the risk of transfusion-transmitted infections (TTIs) (Gao *et al*., 2019). In addition, the use of molecular screening methods would stimulate the development and use of increasingly sophisticated molecular methods to confirm initial screening results. This study aimed to detect viral transfusion-transmissible infections (TTIs) among blood donors at the Federal Medical Centre, Keffi, Nasarawa State, Nigeria, using the lateral flow assay and enzymatic detection method.

2.0 Place and Duration of Study: The study was carried out at Federal Medical Centre Keffi, Nasarawa State, Nigeria, from March 2024 to September 2024.

3.0 Materials and Methods

3.1 Study Design: This study was an institution-based cross-sectional study which involved 240 blood donors between the ages of 18 to 65 years. Donors who met the inclusion criteria were selected at intervals from the donor registry until the required sample size of 240 blood donors was achieved.

3.2 Study Area and Population: This study was conducted Keffi from March 2024 to September 2024. Keffi is located in Nasarawa state, North Central, Nigeria (Figure 1). It is 68km from Abuja, the Nation's Federal Capital Territory and 128 km from Lafia, the Nasarawa State capital. Keffi is located between Latitude 8°50′47″ N and Longitude 7°52′24″ E with an elevation of 321 m above sea level. The 2006 National Census reported that Keffi has an estimated population of 92,664 (NPC, 2006; Hassan *et al*., 2018).

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Figure 1. Map of Nasarawa State Showing Keffi LGA (Abiola *et al*., 2016).

3.3 Study Participants: The study population consisted of blood donors at the Blood Bank of the Medical Laboratory Department, Federal Medical Centre (FMC), Keffi, Nasarawa State, Nigeria. The donors, comprising male and female individuals aged 18 to 65 years who met the eligibility criteria, were included in the study.

3.4 Inclusion and Exclusion Criteria: Donors that were 18-65 years, weighting at least 50 kg with a hemoglobin level of 12.5 g/dl for males and 13.0 g/dl for males without any history of chronic or recent infection while those that did not meet the criteria were excluded. All the participants gave written consent.

3.5 Sample Size Determination: The formula described by Sadiq *et al*. (2024) was used for calculating sample size as follows:

$$N = \frac{Z^2pq}{d^2}$$

Where:
N= Minimum sample size
Z= Standard normal distribution at 95% confidence interval 1.96
P= Prevalence of HBV in previous studies = 17% (0.17) (Oti *et al*., 2021).
q= (1 - p) = 0.83
d= precision or margin of error = 5% (0.05)
To substitute the values of the formula $N= Z^2pq / d^2$ will mean

$$N= \frac{1.962 \text{ X } 0.17 \text{ X } 0.83}{0.05^2}$$

N = 216.82
Adding 10% attrition of 216.82 = 21.68, 216.82+21.68 = 238.5
N = 238.5
Approximately 240 samples.

3.6 Data Analysis: Statistical analysis of the data was conducted to evaluate the significance of variables, with the Chi-square test employed to assess relationships between categorical variables. Descriptive statistics, like percentages, were used to summarise the collected data effectively.

3.7 Specimen Collection: Blood samples were collected from consenting study participants who came to donate blood at the Blood Bank of the Federal Medical Centre, Keffi. The venipuncture method (WHO, 2010) was employed to aseptically collect blood samples from each participant, such that the arm of the individual was tied with a tourniquet and the position of the vein was disinfected using cotton wool soaked in methylated spirit. Using a disposable sterile needle and 5ml syringes for each blood donor, 5ml of blood sample was collected and then transferred into a labelled Ethylene Diamine Tetracetic Acid (EDTA) blood sample tube and centrifuged at 1500 rpm for 15 minutes to obtain plasma. The plasma was dispensed into labelled microtubes and stored at 8 °C until ready for use. Socio-demographic information of the donors was obtained by the use of well-structured questionnaires.

3.8 Test Procedure:

The rapid tests for TTIs were conducted using the lateral flow immunochromatographic assay for quantitative detection of antibodies following the manufacturer's instructions. The following rapid test kits were used in this study: Abbott Determine HIV-1/2, DIALAB DIAQUICK HBsAg and HCV dipstick rapid screening kits (DIALAB Austria), while the ELISA quantitative analysis was done using the DIALAB HIV, HBsAg, and HCV ELISA test kit (DIALAB Austria) on samples that were negative from the RDT test.

4.0 Results

4.1 Seroprevalence of Transfusion-Transmissible Infections (TTIs) Using Rapid Diagnostic Test (RDT) and Enzyme-Linked Immunosorbent Assay (ELISA)

The seroprevalence of transfusion-transmissible infections (TTIs) detected using the Rapid Diagnostic Test (RDT) among the 240 blood donors as well as those who tested negative that were further screened using ELISA is shown on Table 1 where Hepatitis B Virus (HBV) had the highest prevalence, with 9 cases (3.8%), followed by Hepatitis C Virus (HCV) with 8 cases (3.3%). Human Immunodeficiency Virus (HIV) had the lowest prevalence, with 4 cases (1.6%) using RDT. However, more cases were detected after screening with ELISA as follows: HBV 6.0% (14/231), followed by HIV at 3.0% (7/236), while HCV had the lowest prevalence at 1.7% (4/232).

Table 1 Seroprevalence of Transfusion-Transmissible Infections (TTIs) Using Rapid Diagnostic Test (RDT) and Enzyme-Linked Immunosorbent Assay (ELISA)

Test	RDT		ELISA	
	No. of Sample (N)	Seroprevalence (%)	No. of Sample (N)	Seroprevalence (%)
HBV	240	9 (3.8)	231	14 (6.0)
HCV	240	8 (3.3)	232	4 (1.7)
HIV	240	4 (1.6)	236	7 (3.0)

4.2 Combined Seroprevalence of Transfusion-Transmissible Infections (TTIs) from Both RDT and ELISA

Table 2 represents the overall seroprevalence of TTIs, 19.2% (46/240) detected using both Rapid Diagnostic Test (RDT) and Enzyme-Linked Immunosorbent Assay (ELISA) among the 240 blood donors. This table reflects the final prevalence after confirming additional cases with ELISA among RDT-negative samples. Hepatitis B Virus (HBV) had the highest prevalence of 9.6% (23/240), followed by Hepatitis C Virus (HCV) at 5.0% (12/240), while the Human Immunodeficiency Virus (HIV) had the least prevalence of 4.6% (11/240).

Table 2 Combined Seroprevalence of Transfusion-Transmissible Infections (TTIs) Using RDT and ELISA

Test	No of Sample (N)	Seroprevalence (%)
HIV	240	11 (4.6)
HBV	240	23 (9.6)
HCV	240	12 (5.0)
Total	240	46 (19.2)

4.3 Seropositivity Regarding Some Sociodemographic Variables of the 240 Blood Donors After Testing Using RDT and ELISA.

Regarding the age group of the blood donors, there was varying seroprevalence of the viral TTIs screened with no statistical association observed (*P*> .05). For instance, those aged 21-25 age group 17.9%, had the highest seropositive for HBV while for HCV, it was higher, 13.1% among blood donors aged 36-40. For HIV it was highest 10.5% amongst donors aged 41-45 years (Table 3).

Based on gender of the blood donors screened (Table 3), females had a seroprevalence of 12.5% for HBV compared to males 9.4%. For HCV, the seroprevalence was 5.1% in males, while no cases were detected in females, while for HIV, the seroprevalence was higher in females 12.5% compared to males 4.3% though there was no statistical association (*P*> .05).

With regards to the marital status of the blood donors, the seroprevalence was slightly higher 9.7% among married donors compared to 9.3% among single donors, while for HCV it was higher among single donors 7.5% compared to married donors 3.0%. Finally, for HIV, it was higher among single donors 6.5% compared to married donors 3.0% (*P*> .05) Table 3.

Table 3 Seroprevalence of Viral TTIs Regarding Some Sociodemographic of Donors Using RDT and ELISA.

Age Category	Frequency (N= 240)	HBV Seropositive (%)	*P*-Value	HIV Seropositive (%)	*P*-Value	HCV Seropositive (%)	*P*-Value
21-25	39	7 (17.9)	0.154	3 (7.7)	0.287	1 (2.2)	0.708
26-30	59	2 (3.4)		0 (0.0)		5 (8.5)	
31-35	58	5 (8.6)		4 (6.9)		2 (3.5)	
36-40	53	8 (15.1)		1 (1.9)		3 (13.1)	
41-45	19	1 (5.3)		2 (10.5)		0 (0.0)	
46-50	11	0 (0.0)		1 (9.1)		1 (9.0)	
51-55	1	0 (0.0)		0 (0.0)		0 (0.0)	
Gender							
Male	232	22 (9.4)	0.988	10 (4.3)	0.819	12 (5.1)	0.986
Female	08	1 (12.5)		1 (12.5)		0 (0)	
Marital Status							
Married	133	13 (9.7)	0.322	4 (3.0)	0.322	4 (3.0)	0.200
Single	107	10 (9.3)		7 (6.5)		8 (7.5)	

5.0 Discussion

The current study assessed the prevalence of viral transfusion-transmissible infections (TTIs) among blood donors at Federal Medical Centre, Keffi, Nasarawa State, using Rapid Diagnostic Test (RDT) and Enzyme-Linked Immunosorbent Assay (ELISA). HBV was found to be 9.6%, HCV 5.0%, and HIV 4.6%, indicating a significant burden of TTIs among blood donors in the study area. Zakari *et al*. (2022), Durowade *et al*. (2023), Singogo *et al*. (2023), Hadfield *et al*. (2024), Cwinyaai *et al*. (2024), and Mengjiao *et al*. (2024) reported a similar trend. These studies consistently demonstrate that HBV remains more prevalent than HCV and HIV across different populations. The higher HBV prevalence may be attributed to its high infectivity, varied transmission routes, including perinatal transmission, unsafe injections, and unprotected sexual contact (Doosti-Irani *et al*., 2017; Habibu *et al*., 2025; Jaldo *et al*., 2025). An overall prevalence of 19.2% was observed in this study, which was comparatively lower than 21.0%, reported by Zakari *et al*. (2022) in Nigeria and by Walana *et al*. (2023) in Ghana, respectively, while Hadfield *et al*. (2024) reported 31.4% also in Ghana. On the contrary, lower prevalence has been reported in Nigeria and globally. Obeagu *et al*. (2020) reported an overall prevalence of 8.57%. Also, Durowade *et al*. (2023) reported 11.3% while Jacob *et al*. (2023) reported 3.3%. In Tanzania, Mremi *et al*. (2021) reported 10.1%, Bartanjo *et al*. (2019) reported 14.1% in Kenya, 13.8% by Cwinyaai *et al*. (2024) in Uganda, and 10.7% reported by Singogo *et al*. (2023) in Malawi. Interestingly, in Rwanda, a much lower prevalence of 2.1% by Nsekuye *et al*. (2023) and 2.99% by Dahie *et al*. (2024) was found in Somalia. In India, 1.46% was reported by Deshmukh *et al*. (2024), while Almajid (2020) reported 0.7% in Saudi Arabia.

The differences in the overall prevalence of TTIs reported globally could be attributed to differences in geographical location, sample size, sample population, cultural practices, and level of healthcare delivery (Pessoni *et al*., 2019; Dahie *et al*., 2024; Hadfield *et al*., 2024; Thakur *et al*., 2025).

The findings of this study, based on some social demographic characteristics, show that out of 240 blood donors, male donors accounted for 96.7%, while females accounted for 3.3%. This gender disparity is consistent with other studies in-country and globally (Bartanjo *et al*., 2019; Chang *et al*., 2019; Fasakin *et al*., 2022; Nsekuye *et al*., 2023; Habibu *et al*., 2025). Several factors, including the perception that male donors are healthier than females, male donors present more often, physiological factors such as menstruation, pregnancy, childbirth, breastfeeding, and anaemia contribute to low participation of females (Pessori *et al*., 2019; Kasraian *et al*., 2021; Narayanan *et al*., 2023; Dahie *et al*., 2024; Hadfield *et al*., 2024; Thakur *et al*., 2025). However, the differences between male and female seroprevalence in this study were not statistically significant ($P > 0.05$), indicating that both genders are at risk of TTIs.

The seroprevalence regarding the age distribution of the blood donors was also assessed, revealing that the majority of participants were between 26 and 30 years (24.6%) and 31 and 35 years (24.2%), followed by those aged 36 to 40 (22.1%). The lowest proportion was observed in the 51-55 years category, accounting for only 0.4% of the participants. Nsekuye *et al*. (2023), Sabir *et al*. (2023), and Ngomtcho *et al*. (2024) reported a similar trend, where most donors were aged between 26 and 35 years. On the contrary, the prevalence of TTIs among donors aged 45 and above has been reported (Siraj *et al*., 2018; Keleta *et al*., 2019; Dahie *et al*., 2024).

The age group differences in the prevalence of TTIs have been attributed to factors like sexual activity, socioeconomic status, risky behaviour, such as unsafe body modifications, drug abuse (Bartanjo *et al*., 2019; Cwinyaai *et al*., 2024; Gebreyes *et al*., 2025).

Regarding marital status, 55.4% of the donors were married, while 44.6% were single. The relatively higher number of married donors may reflect a demographic trend in voluntary blood donation patterns within the study population. A similar trend has been reported by Akpan *et al*. (2022) in Nigeria, Teferi *et al*. (2021) in Ethiopia, and Daneshi *et al*. (2021) in Iran. Single donors had a higher prevalence of HIV (6.5%) and HCV (7.5%) compared to married donors (3.0% each), suggesting that unmarried individuals may engage in higher-risk behaviours, such as unprotected sexual activities and unsafe body modifications. Married donors have a greater sense of responsibility, family ties, knowledge, and positive attitude towards blood donation (Etete & Inya, 2021; Saeed *et al*., 2024).

5.1 Conclusion

This study confirms that HBV, HCV, and HIV remain significant transfusion-transmissible infections among blood donors in the study area, with HBV having the highest prevalence. The findings highlight the importance of integrating ELISA into routine donor screening to improve diagnostic accuracy and reduce the risk of Viral TTIs. Strengthening public health interventions, expanding hepatitis B vaccination, and enforcing stringent blood safety measures are crucial in mitigating the risk of transfusion-related infections.

Consent

Written consent was obtained from all subjects after explaining the entire research protocol.

Ethical Approval

Institutional ethical approval was obtained from the Health Research Ethics Committee of the Federal Medical Centre Keffi, Nasarawa State (FMC/KF/HREC/02644/24).

Disclaimer (Artificial intelligence)

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc.) and text-to-image generators have been used during the writing or editing of this manuscript.

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