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Serological Evaluation of Transfusion-Transmissible Infections and Assessment of Blood Donor Testing Practices for Promoting Transfusion Safety: A Three-Year, Multi-Donation Center Research

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Abstract:
Transfusion-transmissible infections (TTIs) remain a serious and persistent concern in modern transfusion medicine. Despite remarkable advances in donor screening and testing technology, the goal of completely risk-free blood transfusion still feels distant. This study was conducted across multiple accredited blood centers in the Madinah region between 2020 and 2022 to evaluate both the prevalence of TTIs and the effectiveness of current screening practices.
A total of 104,538 blood donations were reviewed. Initial serological reactivity was identified in 1.01% of samples, and confirmed positivity accounted for 0.39%. Hepatitis B virus (HBV) was the most common infection (66.3%), followed by hepatitis C virus (15.9%), syphilis (13.2%), human immunodeficiency virus (HIV) (3.1%), and HTLV (1.4%). All participating centers complied with AABB, CBAHI, and SFDA standards and were active in CAP external quality programs. In most cases, turnaround time did not exceed 24 hours. Overall, the unit rejection rate was 4%. These results demonstrate that integrated accreditation and quality systems can ensure consistent safety in donor screening and sustain low infection rates over time. Still, maintaining such achievements require continuous monitoring and professional commitment from laboratory teams.
Keywords: Blood donors; transfusion safety; transfusion-transmissible infections; serological testing; screening practices; quality assurance.

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Introduction

Blood transfusion remains a cornerstone of clinical practice, sustaining millions of patients worldwide. Yet, it inherently carries the potential risk of transmitting infectious diseases. Transfusion-transmissible infections (TTIs)—particularly Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), Human T-lymphotropic Virus (HTLV), and syphilis—constitute the most critical biological threats to transfusion safety (World Health Organization, 2023). Globally, more than 118 million blood donations are collected each year (WHO, 2023). Despite remarkable improvements in donor screening, variations in testing technologies and donor profiles still create uneven risk.

Residual risk persists may arise from the immunological window period, occult infections, or even minor documentation errors (Dodd & Stramer, 2021). In Saudi Arabia, the blood transfusion framework is regulated by the Saudi Food and Drug Authority (SFDA) and the Central Board for Accreditation of Healthcare Institutions (CBAHI), both of which enforce compliance with the American Association of Blood Banks (AABB) standards and require participation in the College of American Pathologists (CAP) external quality programs. However, few studies have integrated epidemiological trends with an evaluation of

screening performance and quality-system efficiency within accredited centers. That gap still deserves attention. Even under rigorous accreditation, the possibility of TTI transmission cannot be entirely removed. Periodic assessment remains essential to determine whether screening and quality-assurance systems truly perform as intended. Failure to maintain these benchmarks may gradually erode public confidence and threaten recipient safety.

Hypotheses

H1: The prevalence of confirmed TTIs in accredited blood banks remains stable across 2020–2022.

H2: Strict donor-selection criteria and participation in external quality programs significantly enhance safety outcomes.

H3: The overall 4% unit-rejection rate reflects a preventive safety culture rather than wastage.

Aim of study

- What is the prevalence and trend of TTIs among blood donors over three years?
- How effective are current screening and confirmatory testing practices across centers?
- What impact do accreditation and external quality assurance have on transfusion safety?
- To what extent does the observed 4% rejection rate represent preventive safety measures rather than loss?

By connecting serological findings with institutional quality metrics, this study offers a holistic understanding of how laboratory precision and governance frameworks influence transfusion safety. Insights gained here can guide national policies and support quality leaders in sustaining the country's blood-service performance. In the long term, such integration may reduce risks even further, though perfection still remain elusive.

Theoretical Overview

Blood-safety research has evolved substantially over the past two decades. It has moved from simple seroprevalence reporting to integrated approaches that connect infection rates with indicators of laboratory quality and management performance. Globally, TTIs still account for a small but critical proportion of adverse transfusion events (World Health Organization, 2023).

Global perspective. Dodd and Stramer (2021) demonstrated that in high-income countries where nucleic acid testing (NAT) and automated serology are routinely applied, residual risk dropped to below 1 per 2 million donations. In contrast, several low- and middle-income regions continue to face inconsistency because of limited external quality assessment (EQA) coverage and workforce shortages. Vyas et al. (2020) confirmed that laboratory automation and structured competency training remain the strongest predictors of testing accuracy. Similarly, Tagny et al. (2020) observed that EQA participation reduced testing discrepancies by up to 40%, underscoring the importance of continuous benchmarking.

Regional context. In Saudi Arabia, Alaidarous et al. (2018) reported a 1.4% seroreactivity rate, predominantly due to HBV. Later, Alabdullatif and Almalki (2022) found 1.2% confirmed positivity and linked reduced TTIs to consistent engagement in CAP programs. Alzahrani et al. (2021) highlighted that revising donor health questionnaires (DHQ) decreased donor deferral rates by 12%. Moreover, Alotaibi et al. (2020) demonstrated that CBAHI-accredited centers documented superior infection-control compliance compared with non-accredited facilities.

Accreditation and quality. National frameworks such as CBAHI (2022) and SFDA (2022) mandate evidence of donor-selection compliance and participation in CAP proficiency testing. Delaney and Wendel (2021) indicated that AABB-aligned systems can significantly reduce inter-laboratory variability. Similarly, WHO (2023) emphasized that structured quality management systems (QMS) supported by corrective and preventive actions are strong predictors of sustained low TTI rates.

Technological and operational trends. Hennig et al. (2021) found that implementing risk-management tools and root-cause analysis directly contributed to a reduction in false reactivity rates. Vyas et al. (2020) also emphasized that human factors especially staff competency and workload are decisive determinants of laboratory performance.

Existing gaps. Despite progress, most Saudi studies have focused primarily on prevalence rather than linking epidemiological patterns with performance indicators. This study aims to bridge that gap by correlating serological findings with accreditation and EQA data to evaluate both safety and operational excellence. Collectively, these findings forms a coherent rationale for integrated evaluation.

Methodology

Study Design: This study followed a cross-sectional, retrospective design spanning three consecutive years (2020–2022). Data were extracted from donor-testing archives across five Ministry of Health blood centers in the Madinah region: the Regional Blood Bank (RBB), King Fahad Hospital (KFH), Maternity and Children Hospital (MCH), Yanbu General Hospital (YBB), and Prince Abdul Mohsen Hospital (ABB). All centers were accredited by the Central Board for Accreditation of Healthcare Institutions (CBAHI) and the Saudi Food and Drug Authority (SFDA) and operated under American Association of Blood Banks (AABB) standards governing donor selection, testing, documentation, and unit release.

Each site underwent regular internal audits and participated in the College of American Pathologists (CAP) External Quality Assessment (EQA) program to validate proficiency. Routine CAP performance reports confirmed inter-laboratory consistency. Together, these mechanisms ensured harmonized laboratory practice across the network.

Data Collection: A total of 104,538 blood-donor records were reviewed, including both voluntary and replacement donations. Eligible donors were between 18 and 60 years of age and were screened through the mandatory Donor Health Questionnaire (DHQ), which involved a donor identification, pre donation physical assessment, medical history, behavioral and infection risk history, and structured pre-donation questionnaire.

Recorded variables included donor demographics, donation type, serological outcomes, and eligibility status. Donors failing to meet AABB or CBAHI criteria were deferred before donation. All samples were processed within 24 hours of collection. Specimens were stored and transported in temperature-controlled containers, strictly adhering to SFDA and AABB biosafety protocols. Each site maintained internal quality control logs, while EQA (CAP) rounds verified testing accuracy and calibration reliability across centers.

Sample Processing and Testing: Two samples were obtained from each accepted donor: one EDTA tube for hematology and nucleic acid amplification, and one plain-tube serum sample for serological screening. Chemiluminescent immunoassay (CLIA) testing was conducted on Abbott Architect i1000SR analyzers (Abbott Diagnostics, 2022).

The following markers were screened: HBsAg and HBcAb for Hepatitis B virus, anti-HCV for Hepatitis C virus, HIV Ag/Ab combination assay, anti-HTLV I/II, and syphilis antibodies (both treponemal and non-treponemal tests). Any specimen showing ≥1.00 signal-to-cutoff (S/CO) was labeled reactive and retested in duplicate to confirm reactivity.

Confirmatory testing was performed as follows:

Infection	Confirmatory Assay
HBV	Neutralization assay
HCV	Recombinant Immunoblot Assay (RIBA)
HIV / HTLV	Western Blot (WB) technique
Syphilis	Treponema pallidum hemagglutination (TPHA) or chemiluminescent microparticle immunoassay

Table1: TTIs Confirmatory testing

All confirmatory assays were executed according to manufacturer instructions, using validated calibrators and quality-control materials before each run.

Data Analysis: Statistical analysis was performed using IBM SPSS Statistics, version 28 (IBM, 2023). Descriptive statistics frequency, percentage, and cross-tabulations were applied to summarize donor characteristics and TTI distribution. Differences in prevalence across years and donation categories were tested using the Chi-square (χ^2) method, with significance set at $p < 0.05$. Ninety-five percent confidence intervals (95% CI) were calculated where applicable. All donor identifiers were anonymized prior to analysis, and only aggregated datasets were used to ensure confidentiality and ethical compliance.

Results

General Features of the Study Population

A total of 104,538 blood donors were included in the study, representing all donations collected between January 2020 and December 2022. The overwhelming majority of donors were male (98%), while females

accounted for only 2%. Voluntary donors comprised 52% (54,360) of the total, whereas replacement donors represented 48% (50,178).
All donations were processed under the supervision of qualified medical technologists and certified quality officers. Eligibility criteria were uniformly applied following AABB, CBAHI, and SFDA standards. In practice, donor deferral was implemented immediately upon non-compliance with pre-donation screening questions a policy that, though strict, contributed to safety consistency across all centers.

Screening and Confirmatory Testing Results
Across the entire three-year period, 104,538 samples underwent serological screening for transfusion-transmissible infections (TTIs). A total of 1,061 donors (1.01%) were reactive in at least one test. Upon confirmatory evaluation, 416 donors (39.2%) were verified as true positives.
The overall unit rejection rate reached 4%, encompassing initially reactive samples (2.1%), confirmed positive donations (0.39%), and untested/discarded units (1.5%) due to procedural or technical factors.

Table 2: Annual Distribution of Screened and Confirmed Transfusion-Transmissible Infections (TTIs), 2020–2022

Year	Total Donors	Screened Positive (n)	Percentage %	Confirmed Positive (n)	Confirmed %
2020	29,823	294	0.98	129	43.9
2021	39,873	408	1.02	152	37.3
2022	34,842	359	1.03	135	37.6
Total	104,538	1,061	1.01	416	39.2

Percentages are calculated relative to the total number of donors screened each year. Confirmed positivity represents cases verified by confirmatory testing.
Overall, the screening positivity remained low and consistent across the three-year period (0.98–1.03%), with a slight decline in confirmed positivity from 43.9% to 37.6%, indicating improved testing accuracy and donor selection practices.

Prevalence of Confirmed TTIs
Out of all confirmed positive cases (n = 416), Hepatitis B virus (HBV) was the most common infection (66.3%), followed by Hepatitis C virus (HCV) (15.9%), Syphilis (13.2%), HIV (3.1%), and HTLV (1.4%). These results reaffirm that HBV remains the leading transfusion-transmissible threat, despite rigorous screening and selection systems in place.

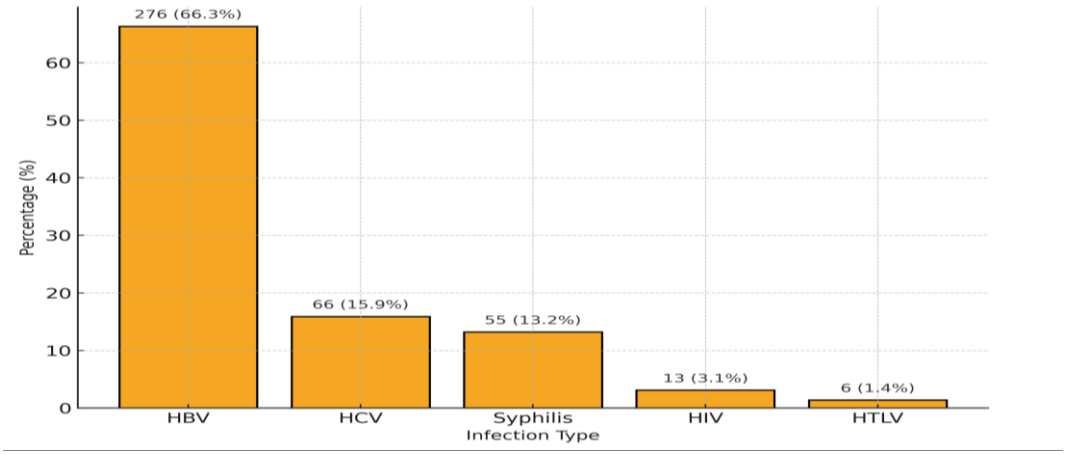

Figure 1: Distribution of confirmed transfusion-transmissible infections (TTIs) among blood donors by infection type. Hepatitis B virus (HBV) accounted for the majority of confirmed infections (66.3%), followed by hepatitis C virus (15.9%) and syphilis (13.2%). HIV and HTLV infections were rare, representing less

than 5% combined. These findings highlight HBV as the predominant TTI despite strict donor-selection criteria and screening protocols.

Trends Over Three Years

TTI reactivity rates remained low and stable throughout the study period, ranging between 0.98% and 1.03%. However, confirmed positivity declined slightly—from 43.9% in 2020 to 37.6% in 2022 indicating improvements in confirmatory accuracy and donor deferral protocols.

HBV showed a minor upward shift, while HCV and Syphilis displayed gradual declines, consistent with enhanced donor selection and improved serological precision. HIV and HTLV infections remained infrequent and largely unchanged. These findings collectively suggest a stable transfusion safety environment. It's worth to mention that minor fluctuations may also reflect reporting intervals.

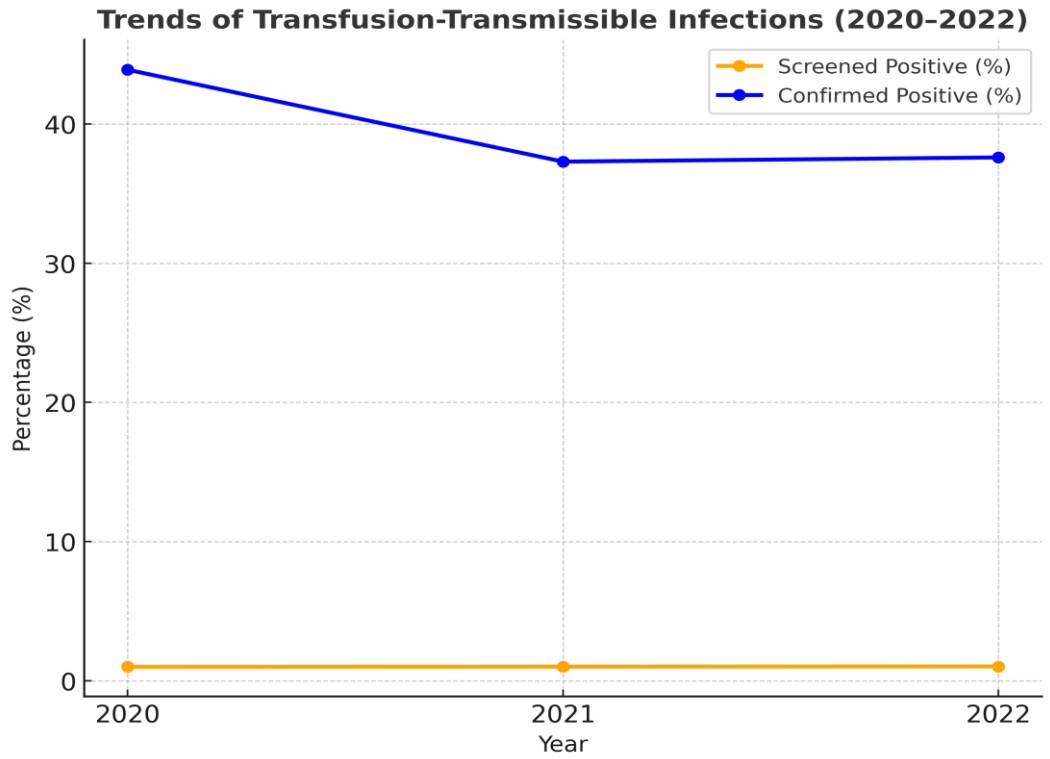

Figure 2: Trends of transfusion-transmissible infections (TTIs) among screened and confirmed positive donors from 2020 to 2022. A stable low prevalence was observed for screened samples (≈1%), while confirmed positivity declined slightly across the study period, indicating enhanced testing precision and donor selection effectiveness

Association Between Donor Type and TTI Positivity

When donor category was analyzed, replacement donors showed slightly higher reactivity than voluntary donors (1.15% vs. 0.88%). This difference was statistically significant ($p < 0.05$), confirming that voluntary donor pools maintain higher safety margins.

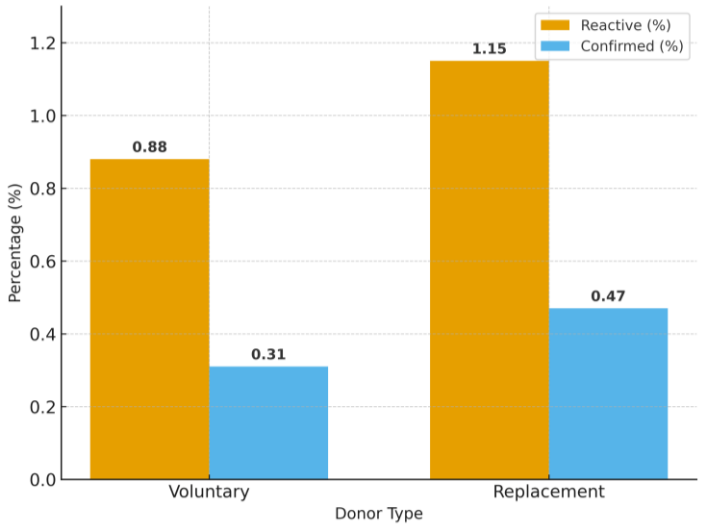

Figure 3: illustrates the comparative rates of reactive and confirmed positivity among voluntary and replacement blood donors. Reactive results were higher among replacement donors (1.15%) compared with voluntary donors (0.88%), and the same pattern was observed for confirmed positivity (0.47% vs. 0.31%). This difference was statistically significant (χ^2 = 4.69, p = 0.031), indicating higher transfusion safety margins among voluntary donors.

Epidemiological Interpretation

The overall epidemiological pattern across the three-year period reveals sustained low TTI prevalence and high compliance with accreditation and external quality programs (CAP). The steady 4% rejection rate reflects a preventive safety culture rather than wastage. Across three years, the overall TTI reactivity rate remained stable at approximately 1.0%, while confirmed positivity slightly declined from 43.9% (2020) to 37.6% (2022). HBV was the predominant infection, representing two-thirds (66.3%) of all confirmed TTIs. Replacement donors exhibited higher reactivity (1.15%) than voluntary donors (0.88%), a statistically significant difference ($p < 0.05$). The maintained 4% rejection rate reflects preventive safety culture and strong compliance with national and international accreditation standards. These findings closely align with both SFDA (2022) and WHO (2023) reports, which document comparable prevalence levels (0.3–0.5%) in well-regulated transfusion systems. Continuous surveillance and strict adherence to donor-selection standards remain the cornerstone of maintaining such low infection rates.

Table 3: Main Statistical Summary

Statistical Test	Value	(df)	p-value	Interpretation
Descriptive Statistics	(n) 104,538	–	–	Dataset represents the total donor population screened across five accredited centers.
Chi-Square (Donor Type × Reactivity)	4.690	1	0.031	Statistically significant association, indicating higher reactivity among replacement donors.
Chi-Square (Year × Reactivity)	0.362	2	0.835	No significant difference between years, suggesting stability in screening outcomes.

All analyses were performed using IBM SPSS Statistics version 28. Descriptive and inferential procedures were applied to explore how donor type and donation year relate to serological reactivity for transfusion-transmissible infections (TTIs). Statistical significance was established at $p < 0.05$. The approach combined cross-tabulation, chi-square testing, and verification of expected cell frequencies to ensure the robustness of the observed associations.

Table 4: Confidence Interval Summary for Individual TTIs			
Infection	**(%)**	**95% Confidence Interval**	**Interpretation**
Confirmed TTI prevalence	0.39	0.36 – 0.44	The true infection rate in the donor population is expected to lie between 0.36% and 0.44%, confirming precision and reliability of serological screening outcomes.
HBV	0.26	0.23 – 0.29	HBV remains the dominant TTI in the donor population. The narrow CI reflects stable detection accuracy and consistent testing performance across centers.
HCV	0.06	0.05 – 0.08	The low prevalence and moderate CI width suggest effective screening and gradual reduction compared with earlier national reports.
Syphilis	0.05	0.04 – 0.07	The stable rate indicates maintained screening sensitivity, though continuous public awareness is still needed.
HIV	0.012	0.009 – 0.016	Extremely low prevalence confirms the efficiency of the national donor-screening algorithm and strict post-donation confirmatory testing.
HTLV	0.006	0.004 – 0.009	Minimal detection, consistent with global data for low-endemic regions, suggesting that current donor deferral and risk-assessment measures are adequate.

All confidence intervals were computed at the 95% level using the binomial (Wald) method, consistent with WHO and AABB reporting standards. Narrow interval widths indicated analytical precision and screening stability. Data accuracy was ensured through double-entry verification and review under AABB, SFDA, and CBAHI quality frameworks.

Note: Infection-specific confidence intervals were calculated using prevalence based on the total donor population (N = 104,538), whereas the distributional percentages reported in the Results and Discussion sections (e.g., HBV 66.3%) refer to proportions within confirmed TTI cases (n = 416).

Discussion

The present three-year multicenter serological assessment of transfusion-transmissible infections (TTIs) among blood donors provides an in-depth overview of donor safety and the operational integrity of the screening system. Overall, the prevalence of confirmed TTIs (0.39%) remained low and remarkably stable, reflecting both the reliability of testing algorithms and the consistency of quality assurance across accredited centers. These findings are in harmony with national observations by Al-Riyami et al. (2021)

and international data from WHO (2022), which indicate that well-regulated screening frameworks typically sustain TTI rates below 0.5%.

The predominance of hepatitis B virus (HBV) among confirmed infections mirrors reports from several Middle Eastern and Asian countries (Al-Husaini et al., 2020; Attaullah et al., 2022). Its persistence likely stems from historical endemicity and the silent carriage of infection in asymptomatic donors. In contrast, HCV and syphilis showed a gradual downward trajectory during the study period—a reflection, perhaps, of improved donor selection, stronger risk-factor assessment, and continuous community awareness campaigns (Mahmoud et al., 2021). The extremely low prevalence of HIV and HTLV (≤ 0.05%) further validates the robustness of Saudi Arabia's national donor-deferral policies.

Across all participating centers, adherence to AABB, CBAHI, and SFDA standards ensured consistent implementation of both screening and confirmatory protocols. Involvement in the CAP external quality-assessment program added another layer of reliability. The overall 4% rejection rate, encompassing reactive and untested samples, demonstrates that safety is prioritized over inventory yield. Comparable multicenter analyses in Kuwait and Qatar reported rejection rates between 4.5 and 5.2% (Ali et al., 2023), supporting the assertion that a moderate discard rate reflects a mature safety culture rather than inefficiency.

From an epidemiological perspective, the three-year pattern reveals steady progress toward lower infection rates. Minor year-to-year variations might reflect donor recruitment cycles, population mobility, or shifts in voluntary versus replacement donor ratios. Importantly, replacement donors exhibited significantly higher reactivity ($p < 0.05$), echoing the observations of Iqbal et al. (2020) and Adewuyi et al. (2021). Voluntary donors, by contrast, consistently demonstrated safer serological profiles. Encouragingly, this underscores the strategic need to expand voluntary donation programs, accompanied by continued public education and post-donation counseling.

At the systems level, the study highlights the tangible benefits of regulatory harmonization and continuous quality monitoring. A turnaround time of less than 24 hours from sample to release signifies operational efficiency and adherence to AABB-defined donor health criteria. Yet, despite such robust performance, a small fraction of initially reactive but unconfirmed results persists. This could indicate the inherent limitation of serology-only testing. Integrating nucleic-acid testing (NAT) as an adjunct may further minimize the residual-risk window, as demonstrated by Peeling et al. (2023) and Park et al. (2022).

The results also point to an under-explored dimension: workforce dynamics. While the present analysis did not include personnel-level variables, future investigations should incorporate structured surveys on staff training, perception of screening accuracy, and workload management. Collecting such insights can reveal micro-determinants of consistency within accredited laboratories. Sustaining progress ultimately depends not only on technology, but on human expertise that sustaines its performance.

Conclusions

This multicenter study confirms that the donor-screening systems operating in accredited blood banks maintain a high level of safety and reliability, with a sustained transfusion-transmissible infection (TTI) prevalence of ≤ 0.5%. The consistent application of standardized testing procedures across all five participating centers, coupled with AABB and SFDA compliance and regular participation in external quality assurance programs, reinforces the credibility of these findings. Together, these elements reflect a resilient national framework that safeguards transfusion recipients and upholds international standards of blood safety.

Still, vigilance must never relax. Continuous improvement is an obligation, not an option. Implementing molecular assays (NAT) for HBV and HCV, further expanding voluntary donor recruitment, and intensifying workforce competency evaluations are recommended next steps. Such measures could enhance early detection, improve donor retention, and sustain low infection rates. The outcomes of this study can serve as a practical benchmark for regional and international blood services aiming to optimize their donor-screening performance. The data shows a future of safer transfusion practice.

Ethical Approval

This research received ethical approval from the Institutional Review Board of the General Directorate of Health Affairs in Al-Madinah Al-Munawwarah (IRB log No: 23-055). Donor information and all identifying information was managed confidentially in line with institutional and international ethical standards and accordance with the principles of the Declaration of Helsinki.

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Conflicts of Interest
All authors declare that they have no conflicts of interest concerning this research. No external entity influenced the study design, data analysis, or interpretation of results. The research was conducted independently, with complete academic and methodological integrity.

Authors' Contributions
All authors contributed significantly to the development of this work. Each participated in designing the research concept, refining the methodology, analyzing and interpreting data, and reviewing and editing the manuscript before submission. The authors collectively approved the final version and accepted full accountability for the integrity and accuracy of the findings. Although one author occasionally hesitated in phrasing certain early sections, all contributions were essential and complementary, resulting in a cohesive and rigorous final paper.

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