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LABORATORY SCREENING FOR INFECTIOUS DISEASES AMONG BLOOD DONORS: A SYSTEMATIC REVIEW

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Abstract

Background: Transfusion-transmissible infections (TTIs) is a critical threat to blood safety. Recent screening combines serology with nucleic acid testing (NAT) to shorten diagnostic window periods and detect occult infection. **Objectives:** To synthesize recent evidence on laboratory screening strategies in blood donors, serology (HBsAg, anti-HCV, anti-HIV, syphilis) and NAT (HBV DNA, HCV RNA, HIV-1 RNA), and to summarize prevalence, NAT yield, and implementation outcomes. **Methods:** We followed PRISMA guidance. We included ten original studies that evaluated donor screening outcomes in routine blood-bank settings in Africa, the Middle East, and Asia. Data extracted included setting, assays, sample size, TTI prevalence, and NAT yield or incremental detection. **Results:** Seroprevalence in included studies varied by region; HBsAg ranged from 2–10% in African settings and 0.5–2% in parts of Asia, with lower anti-HIV and variable anti-HCV rates. Studies implementing ID-NAT, MP-NAT reported additional yield over serology alone, particularly for HBV DNA in HBsAg-negative donations and early HCV infection. Adoption studies also described feasibility at national or tertiary-centre scale. **Conclusions:** Combining serology with NAT improves detection of window-period and occult infections and enhances blood safety. Programs should tailor panels to local epidemiology, consider anti-HBc policies where HBV is endemic, and evaluate cost-effectiveness for national scale-up.

Keywords: Blood Donors; Transfusion-Transmissible Infections; Nucleic Acid Testing; Seroprevalence; Screening; Occult Hepatitis B.

INTRODUCTION

Ensuring the safety of blood components requires minimizing residual risk from TTIs such as HBV, HCV, HIV, and syphilis. Serologic screening iss foundational, but residual risk persists due to diagnostic window periods, immune escape, and occult infections, especially occult HBV (OBI) in HBsAg-negative individuals in intermediate to high HBV prevalence regions [1–3]. The most widely adopted adjunct is NAT, which detects viral genomes and shortens the window period for HBV, HCV, and HIV-1; global surveys describe substantial international heterogeneity in NAT adoption, configuration (minipool vs individual donation), and panels beyond viruses (malaria, Babesia in selected geographies) [2].

Systematic reviews in specific regions highlight how local epidemiology should guide screening menus. For example, a meta-analysis from Egypt underscores non-trivial OBI prevalence in blood donors and high-risk populations and argues that HBV NAT and, or

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anti-HBc policies can meaningfully mitigate risk in HBsAg-negative donations [3]. In Sub-Saharan Africa, reviews and policy analyses emphasize large between-country variation in TTI burdens and the need to consolidate voluntary non-remunerated donor bases, strengthen quality systems, and progressively add NAT as infrastructure and financing allow [1]. In Southeast Asia, real-world program data show post-implementation declines in transfusion-associated HCV when NAT is added to screening algorithms [4].

Recent national and international syntheses also compare ID-NAT with MP-NAT, noting trade-offs between sensitivity and cost, and describe regional differences in NAT yield rates and residual risk estimates after implementation [2,5]. In parallel, country-focused reviews outline practical enablers, platform selection, centralized vs decentralized testing, and integration with hemovigilance and donor epidemiology surveillance, to prioritize incremental risk reduction where it matters most [6]. We present a focused synthesis of ten original studies from Africa, the Middle East, and Asia assessing donor screening outcomes using serology with or without NAT, and we discuss the findings in light of recent review evidence.

METHODS

Design and registration: Systematic review conducted in accordance with PRISMA 2020. Eligibility criteria. We included observational original studies of blood donors that evaluated laboratory screening for TTIs (HBV, HCV, HIV, syphilis and malaria), using serology (HBsAg, anti-HCV, anti-HIV, treponemal testing) and, or NAT (HBV DNA, HCV RNA, HIV-1 RNA). Outcomes included any of: seroprevalence, NAT yield, incremental detection over serology, or programmatic implementation metrics. Populations were allogeneic blood donors (first-time or repeat) in blood-bank settings.

Information sources and search: Bibliographic databases (PubMed, Medline, Scopus, Web of Science) and reference lists were searched from 2015 to 2025. Two reviewers screened titles, abstracts and full texts; disagreements were resolved by consensus. Only ten original articles were included in Results.

Data extraction: Using a standardized form, we captured country, setting, period, donor numbers and type (voluntary, replacement), assays (ELISA, CLIA, rapid; ID-NAT, MP-NAT and platform), prevalence (%) for HBsAg, anti-HCV, anti-HIV, syphilis (and malaria where available), NAT positivity and incremental yield over serology, and key implementation notes.

Risk of bias: We qualitatively appraised cross-sectional studies using accepted domains (sampling frame, representativeness, test validity, and completeness of outcome data). NAT implementation reports were judged on clarity of algorithms, verification testing, and denominator integrity.

Synthesis: We narratively summarized in regions and assay strategies. Given heterogeneity in design and reporting, no meta-analysis was attempted. Numeric values reported below are those explicitly provided by the included articles.

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RESULTS

Study Settings and Designs

Ten original studies include Sudan (Port Sudan), India (metropolitan hospitals and tertiary centres; serology and NAT), Egypt (Suez Canal University Hospital; ELISA vs NAT and a focused HBsAg-negative cohort), Saudi Arabia (national multi-centre analysis), Yemen (national donor network), and Nigeria (Lagos donor base). Designs were predominantly cross-sectional prevalence assessments, with several NAT implementation, evaluation studies (minipool and individual-donation formats).

Sudan (Port Sudan Central Blood Bank, 2016–2018): Cross-sectional of 5,429 donors; overall TTI 13.1% (HBsAg 8.2%, anti-HCV 3.2%, anti-HIV 0.2%, syphilis 1.5%). Replacement donors predominated; higher TTI than voluntary segment. India (metropolitan hospital, 2008–2014): Large cross-sectional series characterizing magnitude and trends in TTIs in donors with routine serology; decreasing trends over time from early to late period, varying by marker. India (New Delhi tertiary centre, 2008–2014): Parallel evaluation of routine ELISA and NAT introduction; design enabled comparison of incremental detections attributable to NAT (early infection, occult). India (Jaipur, ID-NAT evaluation): Observational assessment of NAT yield in donors; NAT identified additional viremic donations beyond serology, supporting routine ID-NAT in high-throughput centres.

Egypt (Suez Canal University Hospital): Comparative study of NAT vs ELISA during 2019–2022; NAT detected additional HBV; HCV infections otherwise missed by serology alone. Egypt (HBsAg-negative donors): Focused ID-NAT screening in HBsAg-negative donors quantified HBV DNA–positive occult infections, illustrating the specific contribution of NAT within HBV-endemic settings. Saudi Arabia (nationwide, 2011–2016): Population-level donor TTI surveillance showing geographic heterogeneity and sustained burden of HCV relative to HIV; provides a baseline for NAT policy evaluation. Yemen (national network, 2019–2020): multi-centre donor seroprevalence with differential risk in regions and donor types, emphasizing contextual tailoring of screening algorithms. Nigeria (Lagos): Donor TTI prevalence analysis, with syphilis and HBV as leading markers; adds West-African contrast to Middle-East, North-African data.

Serology Outcomes

Where reported, HBsAg prevalence in donors ranged widely: 8.2% in Port Sudan (mixed donor base) with lower HIV reactivity (0.2%) and moderate anti-HCV (3.2%); syphilis was 1.5% [7]. In Yemen, national level serology confirmed region-specific patterns consistent with broader Arabian Peninsula epidemiology [11]. Saudi multicentre data (2011–2016) documented low HIV, non-trivial HCV, and variable HBsAg by province, useful for prioritizing targeted enhancements to screening [12]. Indian metropolitan cohorts (2008–2014) showed downward trends in sero reactivity in markers over time, in line with strengthened donor selection and testing algorithms [8,9]. Nigerian data echo a pattern of HBV predominance over HCV and HIV, plus measurable treponemal reactivity [16].

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NAT Adoption and Incremental Yield

Multiple included studies evaluated NAT's added value. The Suez Canal Egypt comparison found that NAT detected additional viremic donations missed by ELISA, an effect driven largely early HBV, HCV infection and occult HBV in HBsAg-negative samples [10]. A Jaipur ID-NAT series similarly reported NAT-only detections over serology and documented operational feasibility in a large tertiary-care workflow [9]. Targeted HBsAg-negative donor screening in Egypt shows HBV DNA positivity in HBsAg-negative donations, highlighting OBI relevance and the unique contribution of HBV NAT beyond anti-HBc policies in endemic settings [13]. These observations align with international experience that ID-NAT increases sensitivity (vs larger minipools) at higher cost, with adoption patterns varying by resources and epidemiology [2,5].

Implementation and Program Impact

At the program level, Indonesia's clinical experience, while recipient-focused, showed 0% anti-HCV in the NAT era vs 3.3% in the pre-NAT era in multi-transfused children, consistent with upstream risk reduction from donor NAT [4]. The Saudi multicentre dataset provides a baseline against which incremental benefits of NAT could be modeled; areas with higher HCV serology would predict higher NAT yield [12]. The Yemeni network underscores how donor type (replacement vs voluntary) and regional epidemiology shape expected yield and cost-effectiveness if NAT is introduced [11].

Table 1: Characteristics of included original studies

Study, country	Period	Assays	Primary markers	Key note
Port Sudan, Sudan [7]	2016–2018	Serology (ELISA, rapid)	HBsAg, anti-HCV, anti-HIV, syphilis	Overall TTI 13.1%, HBsAg 8.2%, higher in replacement donors.
India (metro hospital) [8]	2008–2014	Serology	HBV, HCV, HIV, syphilis	Declining TTI trends over time.
New Delhi, India [9]	2008–2014	Serology + NAT	HBV, HCV, HIV	Evaluation of NAT vs ELISA, incremental NAT detection.
Jaipur, India [9]		ID-NAT	HBV, HCV, HIV	NAT-only yield beyond serology, operational feasibility.
Suez Canal, Egypt [10]	2019–2022	ELISA vs NAT	HBV, HCV, HIV	NAT detected additional viremic donations.
HBsAg negative donors, Egypt [13]	NR	ID-NAT	HBV DNA	OBI detection in HBsAg-negative donors.
Saudi Arabia (nationwide) [12]	2011–2016	Serology	HBV, HCV, HIV, syphilis	Regional heterogeneity, HCV notable.
Yemen (national) [11]	2019–2020	Serology	HBV, HCV, HIV, syphilis	Regional differences, donor-type effects.
Nigeria (Lagos) [16]		Serology	HBV, HCV, HIV, syphilis	HBV predominant, treponemal reactivity present.
India (ID-NAT early implementation) [14]	2015	ID-NAT	HBV, HCV, HIV	Early Indian ID-NAT experience and role in safety.

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Table 2: Selected quantitative outcomes reported in included studies

Outcome	Study, setting	Finding
Overall TTI prevalence	Port Sudan (Sudan)	13.1% overall, HBsAg 8.2%, anti-HCV 3.2%, anti-HIV 0.2%, syphilis 1.5%. [7]
NAT incremental detection vs ELISA	Suez Canal University (Egypt)	NAT detected additional HBV; HCV infections missed by ELISA. [10]
ID-NAT yield over serology	Jaipur (India)	NAT-only reactive donations identified, supports routine ID-NAT. [9]
OBI in HBsAg-negative donors	Egypt cohort	HBV DNA-positive donations in HBsAg-negative donors detected via ID-NAT. [13]
Post-implementation impact (recipient cohort)	Indonesia (children with bleeding disorders)	Anti-HCV 0% after NAT adoption vs 3.3% before, supports upstream donor NAT benefits. [4]

DISCUSSION

The included original studies show that adding NAT to serology captures early-window and occult infections missed by antibody, antigen assays, most prominently HBV DNA in HBsAg-negative donations and early HCV [2,3,5,10]. Global survey data confirm heterogeneous NAT adoption and configuration; ID-NAT generally yields more window-period detections than larger minipools but at higher per-donation cost, and both strategies reduce residual risk versus serology alone [2,5].

The Egyptian OBI meta-analysis show why HBV presents a special case in endemic regions: donors may be HBsAg-negative while viremic at low levels, underpinning the argument for HBV NAT and, or anti-HBc policies in addition to HBsAg to secure the supply [3]. Country-level implementation experiences (Indonesia's NAT roll-out) underscore downstream benefits, with recipient cohorts showing lower HCV reactivity after NAT adoption in upstream donor screening [4]. This is directionally consistent with broader programmatic evaluations and modeling of residual risk post-NAT [2,5].

Regional reviews emphasize aligning screening menus with local epidemiology and donor mix. Where replacement donors predominate and HBV prevalence is higher, the incremental yield of HBV DNA NAT (and potential anti-HBc deferral) is likely to be greater; where HCV iss a burden, HCV RNA NAT deliver similar dividends [1,2,5,6]. The Gabon synthesis (Sub-Saharan Africa) highlights variability in TTI prevalence and health-system capacity, reinforcing the importance of phased adoption with robust quality systems [1]. In India, recent systematic syntheses show increasing NAT penetration and document yield estimates that can inform pool size and test menu decisions [5].

Reviews advise attention to workflow integration, confirmatory algorithms, and cost-effectiveness. The choice between MP NAT and ID-NAT hinges on expected yield, throughput, and budget; several analyses favor starting with MP-NAT then migrating to

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ID-NAT in higher-risk settings as resources allow [2,5,6]. Expansion beyond HBV, HCV, HIV (malaria, Babesia where relevant) is being explored within NAT frameworks in selected countries and seasons [2].

Implications: For countries represented in our included studies (Sudan, Egypt, Yemen, Saudi Arabia, India, Nigeria), priorities include consolidating voluntary non-remunerated donors, maintaining highquality serology, and layering NAT (starting with HBV, HCV, HIV) where predicted yield and budget align. In HBV-endemic contexts, anti-HBc policy plus HBV-DNA NAT should be considered to mitigate OBI risk.

CONCLUSION

Laboratory screening of blood donors built on serology plus NAT meaningfully reduces residual TTI risk by detecting window-period and occult infections. The ten original studies here, spanning Africa, the Middle East, and Asia, collectively show added yield from NAT and context-dependent seroprevalence patterns that should guide local menus. Recent reviews reinforce that NAT configuration (ID-NAT vs MP-NAT) and HBV-focused strategies (including anti-HBc) must be tailored to epidemiology, donor mix, and resources. Strengthening donor selection, quality systems, and surveillance alongside stepwise NAT adoption offers the most practical path to safer transfusion.

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