

From Donation to Distribution: The Regulatory Anatomy of India's Blood Bank EcoSystem

Gloria Venissa Quadros¹, Deepak Paliwal²

¹Assistant Professor, Blood Centre Medical Officer, Yenepoya Medical College,

<https://orcid.org/0000-0002-8662-4994>

²Research Scholar, Department of Business Administration, Mangalore University,

<https://orcid.org/0009-0000-4417-8853>

Abstract:

Blood transfusion services in India have evolved from the first wartime blood bank in 1942 to a complex, digitally enabled network of over 4,200 licensed centres, yet continue to grapple with a national shortfall of 3–4 million units annually. Through a comprehensive review of historical records, regulatory texts, policy documents, and peer-reviewed literature, this study maps key milestones—from the enactment of the Drugs and Cosmetics Act (1940) to the launch of the E-RaktKosh portal (2016) and the 2022 National Standards for Blood Centres. Advanced screening techniques such as nucleic acid testing and hemovigilance programs have markedly improved safety, while component separation units and automation have enhanced clinical utility and traceability. However, fragmented oversight across multiple agencies (CDSCO, NBTC, NACO, SBTCs), regional infrastructure deficits, and persistent ethical barriers—especially gender exclusion and identity-based donor deferrals—undermine equity and supply resilience. The study concludes that achieving universal, safe, and timely blood access demands a unified National Blood Law, mandatory adoption of advanced screening (NAT/PRT), expansion of voluntary non-remunerated donation, and investment in cold-chain logistics and digital infrastructure.

Keywords: Blood Bank, National Blood Policy, E-RaktKosh, Hemovigilance

Introduction

Blood transfusion is a cornerstone of modern healthcare, saving millions of lives in contexts ranging from surgery and trauma care to chronic disease management. In India, with its vast and diverse population, blood banks are a critical infrastructure essential for equitable access to safe blood and components. Despite substantial progress in the last several decades, achieving universal and safe blood availability remains a formidable challenge due to persistent supply-demand gaps, regulatory complexities, and evolving ethical issues. This article offers a comprehensive account of the evolution of blood banks in India, the regulatory and legal frameworks guiding their operation, the infrastructure and policy innovations shaping their future, and the persistent and emerging challenges facing the sector. The analysis is anchored in the most recent data, national regulatory updates, government initiatives, technological advances, and a nuanced understanding of India's unique healthcare context.

Methodology

This study employs a mixed-methods narrative review and policy analysis to evaluate India's blood banking ecosystem across historical, regulatory, technological, and ethical dimensions.

Data Sources

Primary legislation and regulations: Drugs and Cosmetics Act 1940; Drugs and Cosmetics Rules 1945; National Blood Transfusion Services Act 2007; 2020 Second Amendment Rules; National Blood Policy 2002 (MoHFW).

Institutional reports and portals: National AIDS Control Organisation (NACO) publications; National Blood Transfusion Council (NBTC) guidelines; E-RaktKosh usage and performance data; Hemovigilance Programme of India records.

Peer-reviewed literature: Academic studies on transfusion-transmissible infection screening (ELISA, NAT), hemovigilance outcomes, and component therapy efficacy.

Industry and think-tank analyses: NITI Aayog reports on rural blood deserts; Health Technology assessments on pathogen reduction and automation; digital health white papers on Ayushman Bharat Digital Mission integrations.

Media investigations and NGO surveys: Documented instances of forced donations, LGBTQ+ donor deferrals, and replacement-donor prevalence.

Analytical Framework

Historical Mapping: Chronological synthesis of foundational milestones from 1942 through key legislative amendments, Supreme Court directives, and policy initiatives.

Regulatory Analysis: Comparative examination of central (CDSCO/DCGI, NACO, NBTC) versus state (State Blood Transfusion Councils, State FDAs) oversight structures, licensing requirements (Form 27-C), and accreditation standards (NABH, EQAS).

Technological Assessment: Evaluation of screening modalities (TTI panels, NAT adoption), component separation automation (RFID, temperature monitoring), and digital platforms (E-RaktKosh, Blood Bank Discovery Service).

Ethical and Equity Review: Identification of barriers to voluntary non-remunerated blood donation, gender and identity exclusions, donor notification practices, and black-market blood risks.

Supply-Demand Gap Analysis: Synthesis of annual collection versus demand figures to quantify shortfalls and regional disparities; assessment of cold-chain and transport bottlenecks.

Triangulation and Validation

Quantitative data (collection volumes, TTI prevalence, inventory metrics) were cross-validated with official government dashboards and peer-reviewed studies. Qualitative insights (policy effectiveness, ethical debates, system fragmentation) were corroborated through stakeholder interviews documented in published NGO and think-tank reports.

Historical Development of Blood Banks in India

Early Years: From Wartime Necessity to Institutional Beginnings

The genesis of blood donation and banking in India can be traced back to the exigencies of World War II in 1942, when the need for blood for injured soldiers catalysed the establishment of the country's first blood bank in Kolkata at the All India Institute of Hygiene and Public Health, managed by the Red Cross. The initial wave of voluntary donors included government employees and the Anglo-Indian community, motivated by humanitarian ideals^[1].

However, after the war, voluntary enthusiasm waned, and blood donors had to be paid, a practice that would persist for decades. The period after 1949 saw slow growth, with Bombay (now Mumbai) emerging as a hub for the voluntary movement due to the efforts of Mrs Leela Moolgaokar, who began organising donation camps from 1954 onwards. She was later recognised with the Padma Shri for her pioneering work^[1].

Expansion and Institutionalisation

The 1960s and 1970s marked the expansion of blood banks in multiple Indian cities, with significant contributions from medical societies and social activists. The Indian Society of Blood Transfusion and Immunohaematology, led by Prof. J.G. Jolly, declared October 1 as National Voluntary Blood Donation Day in 1975, further galvanising the movement^[2]. Noteworthy figures such as MsKanta Sarup Krishen and Dr Shanthi Ranganathan established and led blood banks and donor societies in Chandigarh and Madras (Chennai), respectively, emphasising voluntary, non-remunerated blood donation.

Public Health Crises and Regulatory Awakening

The HIV/AIDS pandemic in the 1980s was a watershed moment for transfusion safety. With cases of HIV transmission via blood transfusion, the Indian government established the National AIDS Control Organisation (NACO) in 1992 to set policy and improve blood safety and screening protocols^[3]. NACO's creation was closely followed by the 1996 Supreme Court judgment in the Common Cause vs Union of India case, which mandated the creation of the National Blood Transfusion Council (NBTC) and State Blood Transfusion Councils (SBTCs). This ruling also drove the removal of professional (paid) blood donation, effectively outlawing the practice by 1998.

Modernisation and Policy Initiatives

Entering the new millennium, efforts intensified to systematise, modernise, and regulate India's fragmented blood banking ecosystem. Key milestones included the adoption of the WHO Guidelines on Clinical Use of Blood by NACO in 2002 and the launch of the National Blood Policy, which set forth a

framework for safe, accessible, and adequate blood supplies nationwide^[4]. Laws such as the National Blood Transfusion Services Act 2007 criminalised paid blood donation.

In recent years, the sector has seen a wave of digital transformation, notably the launch of the E-RaktKosh portal in 2016, which connects thousands of blood banks through a centralised platform, and the integration of rare blood donor registries to enhance access for patients with uncommon blood types^[5].

Evolution of Operations and Technology in Indian Blood Banks

Advancements in Blood Typing and Screening

From the early reliance on crude or manual blood typing, India has progressively integrated advanced methods in transfusion medicine, benefiting from landmark discoveries such as the ABO and Rh blood group systems. Today, all blood units are routinely screened for Transfusion-Transmissible Infections (TTIs), including HIV, hepatitis B and C, syphilis, and malaria, using techniques ranging from ELISA to highly sensitive Nucleic Acid Testing (NAT)^[6,7]. The introduction of NAT over the past decade, spurred by pilot programs in Delhi and recommended across the country, significantly reduced the “window period” during which infections could escape detection.

Component Therapy and Automation

The rise of component therapy transformed Indian blood banking, moving from whole blood transfusion to the preparation and storage of specific components such as packed red blood cells, plasma, platelets, and cryoprecipitate. The proliferation of component separation units (CSUs) has helped maximise the clinical utility of each donated unit, which is in line with international best practices. Automation in component preparation and storage, such as the use of RFID tagging, real-time temperature sensors, and automated inventory management, has markedly improved safety and traceability^[8].

Digitalisation and Data Management

The digital transformation of blood banks accelerated with the roll-out of systems like E-RaktKosh and, more recently, the Blood Bank Discovery Service linked to citizen-facing apps under the Ayushman Bharat Digital Mission. These platforms provide real-time inventories, enable cross-institutional coordination, facilitate emergency requests, and integrate with health records for seamless patient management^[9,10].

Hemovigilance and Quality Assurance

Another significant stride was the launch of national haemovigilance programs, beginning in 2012, which enable systematic monitoring of adverse transfusion reactions at both the donor and recipient ends.^[2,6] These surveillance systems, supported by digital reporting tools, are essential for improving standards, identifying systemic risks, and informing policy.

Recent Technological and Policy Innovations

Technologies under exploration and adoption include pathogen reduction technologies (PRT), cryopreservation for long-term storage of rare types, and, in select centres, artificial blood substitutes and 3D bioprinting research. India's integration of rare blood donor registries with digital inventory systems is an emerging best practice, particularly significant for patients with hemoglobinopathies and rare antigen profiles^[10]. The use of predictive analytics, cloud-based management, and blockchain for inventory and supply chain transparency has also begun to impact operational efficiency and data integrity^[11].

Government Involvement, National Organisations, and Programmatic Initiatives

Establishment of National Bodies and Policy

Governmental engagement in blood banking, initially limited, became assertive through multi-tiered institutional mechanisms over the last three decades. The following entities now form the backbone of India's policy, technical oversight, and operational guidance:

- **National Blood Transfusion Council (NBTC):** Apex technical and policy-formulating authority, responsible for standards, guidelines, and quality systems at the national level. The NBTC oversees the development of the National Blood Policy and is the principal driver for programmatic improvements and interventions^[4,12].
- **National AIDS Control Organisation (NACO):** Initially under the Ministry of Health and Family Welfare, NACO has played a leading role in supporting blood banks, enforcing screening protocols, funding infrastructure, and promoting voluntary blood donation^[12].
- **State Blood Transfusion Councils (SBTCs):** These bodies coordinate implementation, oversight, and public engagement at the state level.

Key National Initiatives and Schemes

- **Model Blood Banks and Component Separation Units:** Established as demonstration and training centres to elevate transfusion standards and increase voluntary donation rates.
- **Voluntary Blood Donation Drives:** Major thrusts around World Blood Donor Day (June 14) and National Voluntary Blood Donation Day (October 1), accompanied by mass media campaigns and public awareness initiatives^[13].
- **Digital Connectivity and Real-Time Inventory:** The E-RaktKosh portal, supporting over 4,263 licensed blood centres by 2024, provides seamless national coverage, live inventory updates, and is expanding to include rare donor data and emergency locator services^[14,5].
- **Blood Bank Discovery Service:** Launched in 2025, this integration under the National Health Authority leverages real-time data to help hospitals, patients, and citizen-facing apps identify and access nearby blood units swiftly in emergencies^[5].
- **Hemovigilance and Donor Surveillance:** The Hemovigilance Programme of India and National Blood Donor Vigilance Programme enable systematic monitoring of adverse events and quality assurance^[15].

Special Focus Initiatives

- **Plasma Policy (2014):** Aimed at optimal utilisation and fractionation of plasma to produce essential blood-derived medicines domestically.
- **Integration with Rare Donor Registry:** Facilitates faster, more precise matching for patients with complex blood requirements or rare types^[10].

Legal and Regulatory Framework Governing Blood Banks

Drugs and Cosmetics Act and Rules

The foundation of legal regulation is the Drugs and Cosmetics Act of 1940 and the accompanying Drugs and Cosmetics Rules, 1945. Human blood is legally defined as a “drug,” making blood banks subject to stringent licensing, inspection, and quality standards^[16,17].

Licensing and Compliance

Blood banks must secure a manufacturing license (under Form 27-C) granted by the State Drug Controller, following thorough inspection and documentation. Key requirements include:

- Qualified technical staff (at least one full-time medical officer with relevant experience).
- Adherence to infrastructure and equipment standards.
- Documented SOPs for all operations, storage, and quality control.
- Separate approvals from SBTCs for non-governmental or voluntary organisations^[18].

Licenses are valid for five years and require timely renewal; operation without a license is a criminal offence.

Amendments and Modernisation

The legal framework has evolved through major amendments:

- **1999 Amendment:** Defined blood bank operations and staff qualifications, banned professional donation, and mandated safe disposal of biomedical waste.
- **2020 Second Amendment Rules:** Adopted the term “blood centre,” further specified equipment, credentials for technical staff, and operational protocols (e.g., minimum space, air conditioning for component areas, new technologies for plasma and platelet processing)^[19].

National Blood Policy and Quality Standards

The National Blood Policy (2002, updated periodically) provides a comprehensive strategic and operational roadmap, from ensuring voluntary, non-remunerated blood donation to national clinical guidelines and quality assurance schemes^[6].

Quality, Accreditation, and Standards

- All blood centres must maintain robust quality systems, SOPs, regular audits, and participate in External Quality Assessment Schemes (EQAS).

- Compliance is benchmarked against the National Standards for Blood Centres & BTS, first published in 2007 and updated in 2022, which codify requirements for staff, equipment, screening protocols, biosafety, and waste management^[6].
- Accreditation by the National Accreditation Board for Hospitals and Healthcare Providers (NABH) reinforces adherence to scientifically validated procedures and is increasingly sought by both public and private centres^[20,21].

Table 1: Major Regulatory Milestones and Corresponding Impacts

Year	Regulatory Milestone	Impact
1940	The Drugs and Cosmetics Act was enacted	Legal recognition of blood as a drug; standards for blood banks
1945	Drugs and Cosmetics Rules	Detailed procedures and licensing
1992	Formation of NACO	Centralised AIDS/blood safety program
1996	Supreme Court Judgment (Common Cause)	NBTC/SBTC established; ban on professional donors
1999	Drugs & Cosmetics (2nd Amendment) Rules	Defined donor types, staff qualifications, and safe waste disposal
2002	National Blood Policy, WHO Guidelines adopted	Strategic framework for safety, quality, and voluntary donation
2007	National Blood Transfusion Services Act	Criminalised paid donation, enforced safety
2012	Launch of National Haemovigilance Programme	Monitoring of transfusion safety and reactions
2015	National Blood Donor Vigilance Programme	Focus on donor safety and reporting
2020	Drugs & Cosmetics (Second Amendment) Rules	Updated definition to 'Blood Centre', stricter standards for centres
2022	Second Edition, National Standards for Blood Centres	Incorporated the latest regulatory and scientific developments
2024	Rollout of Blood Bank Discovery Service under ABDM	Digital real-time inventory and access
Ongoing	E-RaktKosh upgrades, RDRI integration, universal NAT adoption	Centralised digital inventory, rare donor access, improved safety

This table synthesises key milestones, reflecting regulatory tightening, technological modernisation, improved surveillance, and strategic government engagement^[22,4,10,5].

Institutional and Operational Oversight

Both federal and state agencies share regulatory responsibility (dual licensing). The Central Drugs Standard Control Organisation (CDSCO) and the Drug Controller General of India (DCGI) lead at the central level; state FDAs manage on-ground enforcement and licensing. NBTC develops policy and technical standards, while NACO (now under the Directorate General of Health Services) channels programmatic funding and technical support^[23].

Accreditation and Quality Standards in Indian Blood Banks

NABH Accreditation

Blood banks increasingly aspire to accreditation under the NABH. Accredited centres must demonstrate:

- Evidence-based donor screening, component processing, testing, storage, and distribution protocols.
- Stringent document control and traceability at each step.
- Internal audits, continuous quality improvement mechanisms, and participation in EQAS^[20,21].

Benefits include higher clinical reliability, legal compliance, preferred partner status for hospitals, and enhanced trust among patients and stakeholders.

National and International Benchmarking

National Standards for Blood Centres and BTS (2022 Edition) set forth requirements for:

- Legal identity and organisational structure.
- Infrastructure (minimum space, air conditioning, dedicated rooms for processing/collection/testing).
- Mandatory testing protocols-universal screening for TTIs, NAT adoption, quality control of blood components (e.g., hematocrit, sterility, platelet count).
- Robust waste management, biosafety, and infection control protocols, in line with Biomedical Waste Management Rules (2018)^[6].

Supply Chain Management and Blood Shortages

Demand-Supply Dynamics and Regional Disparities

India's annual demand for blood is unparalleled, estimated at 15 million units per year. Yet, the voluntary donation rate has historically lagged below the WHO-recommended threshold of 1% of the population; blood collection remains at around 11 million units, yielding an annual shortfall of 4 million units in 2025^[24].

- Voluntary donations now contribute about 60-80% of the total supply, with the remainder still from replacement donors. Other countries reaching 100% voluntary status, such as Switzerland or Japan, demonstrate better supply equilibrium^[25].

Regional disparities persist. Urban centres have higher densities of blood banks and better access, while “blood deserts” in rural and underserved states, such as Bihar, Jharkhand, and parts of the North East, struggle with dire shortages^[26]. Over 60 districts reportedly have no blood banks.

Infrastructure and Logistical Challenges

Critical bottlenecks include:

- **Storage and Cold Chain:** Many primary health centres (over 80%) lack blood storage facilities or reliable cold chains, risking spoilage and wastage^[27].
- **Transport:** Only a fraction of India’s blood banks are equipped with specialised vans and insulated transport boxes for safe, timely delivery to remote centres^[3].
- **Real-Time Inventory Coordination:** Until recently, the lack of central inventory and communication meant patients had to approach multiple centres manually, often in emergencies.

Innovations and Best Practices

The implementation of E-RaktKosh and nationwide push for digital inventory management, predictive stock analytics, automated alerts for expiry and low stock, and cloud-based dashboards have improved efficiency, transparency, and readiness in emergencies^[14,5]. Studies suggest these innovations have reduced wastage by up to 15% and decreased blood shortages by 25% in major cities post-implementation^[28].

Nonetheless, real-time systems face operational issues in rural areas due to connectivity gaps, staff training deficiencies, and integration challenges with existing hospital IT systems.

Supply Chain and Inventory Management

Adopting practices like Just-In-Time (JIT) replenishment, first-in-first-out (FIFO) stock rotation, and automated demand forecasting can further reduce wastage and stockouts^[28]. Communication and coordination between donor organisations, blood banks, and hospitals is recognised as a critical success factor in maintaining optimal inventory levels and rapid emergency response.

Ethical Concerns and Donor Issues

Voluntary vs. Replacement and Paid Donations

India’s transition from a paid donor system to voluntary, non-remunerated blood donation, catalysed by Supreme Court interventions and public health imperatives, has generally reduced the transmission of TTIs, as voluntary donors are less likely to hide risk factors^[25,29]. Yet gaps remain:

- **Replacement Donation:** Persisting especially in rural and tertiary hospitals, replacement donation is discouraged due to increased risks and the potential for coercion, undermining the central policy thrust towards VNRBD (Voluntary Non-Remunerated Blood Donation).
- **Donor Eligibility and Deferral:** Anaemia, especially among women, remains the leading cause of deferral (up to 77.9% in females), accounting for the woeful under-representation of female donors, who comprise less than 10% of the nationwide donor base^[25].

Gender, Discrimination, and Human Rights

Women's participation is limited by physiological, cultural, and socio-economic barriers. Novel initiatives such as the Swasth Nari, Sashakt Parivar Abhiyaan campaign (2025) specifically target anaemia screening, empowerment, and blood awareness among women^[13].

A separate but increasingly urgent ethical concern is the government's continued lifetime ban on blood donation by men who have sex with men (MSM), transgender individuals, and sex workers, as per NBTC/NACO 2017 guidelines. This blanket exclusion has been challenged before the Supreme Court and criticised by LGBTQ+ advocates, clinicians, and international human rights observers for perpetuating stigma rather than focusing on behaviour-based risk assessment, especially as several other countries now allow donations from LGBTQ+ persons provided enhanced screening and testing are in place^[30].

Donor Notification and Confidentiality

While TTIs can only be detected reliably through post-donation screening, India faces ethical dilemmas around donor notification: blood banks are mandated to inform donors testing positive for TTIs, but often lack counsellors and confidential processes. This creates situations in which donors remain unaware of their infectious status, or conversely, are exposed to social stigma due to breaches of confidentiality^[31]. Properly managed, confidential post-test counselling and referral recommended by WHO, is crucial for donor and public health protection.

Forced or Coerced Donations and Black Market Blood

In rare but serious cases, forced extraction rings have been documented, particularly in poorer, high-need states. While law enforcement and monitoring have reduced these abuses, vigilance is needed to prevent coerced or black-market blood activity, particularly amidst acute shortages^[12].

Safety, Screening, and Protocols

Rigorous Mandatory Testing

Indian regulations prescribe the following mandatory screening of every donated unit:

- **HIV 1 & 2**
- **Hepatitis B (HBsAg) and C (anti-HCV)**
- **Syphilis**
- **Malaria**

Many of the leading centres employ fourth-generation ELISA testing, chemiluminescent immunoassays, and, increasingly, NAT to cover the "window period" and reduce residual risk^[7].

Universal NAT and Component Safety

National standards now recommend (though not yet mandate universally) NAT for all blood units. Pathogen reduction technologies are being evaluated to further mitigate emerging risks, including bacterial contamination, especially in platelets^[7].

Traceability, Recall, and Hemovigilance

Robust traceability protocols and hemovigilance are now standard. Digital record-keeping, barcoding of units, and participation in sentinel surveillance aid both infection control and rapid response to adverse reactions or quality failures. ^[15]

Comparative Analysis: Public vs. Private Blood Banks

Distribution and Roles

India's blood banking network comprises four principal categories:

- **Government/Public Blood Banks (≈46%)**
- **Private Blood Banks (≈33%)**
- **Charitable/NGO-run Blood Banks (≈18%)**
- **Red Cross Blood Banks (≈1%)**

Charitable and public centres predominate in rural and tier 2/3 cities, while major urban areas feature a higher density of private hospitals and blood banks.

Regulation and Regulatory Compliance

Both public and private centres are equally subject to licensing and regulatory standards under the Drugs and Cosmetics Act. However, anecdotally and as per periodic audits, compliance rates and infrastructure quality are often higher in larger, government-run or NABH-accredited urban centres.

Access and Equity

- **Rural Bias:** Public/charitable banks are more likely to serve rural populations, but also suffer the most from infrastructural and resource deficits.
- **Urban Bias:** Private banks, often better-funded, may provide superior technology and storage but are less equitably distributed and may charge higher processing or service fees.
- **Cord Blood Banks:** India permits both public and private cord blood banks, with ongoing debate about accessibility, long-term viability, and the ethics of commoditising stem cell storage ^[32,33].

Coordination with Digital Platforms

E-RaktKosh and the Blood Bank Discovery Service integrate both public and private centres, but real-time participation and reporting compliance are more robust among larger, corporate hospital chains and Model Blood Banks.

Challenges Facing Blood Banks in India

Supply Shortages

- **Demand-Supply Gap:** Despite progress, an annual shortfall of 1-4 million units persists, aggravated by demographic changes (ageing population), rising demand from chronic disease and trauma, and low donation rates.

- **Geographic Gaps:** 30-40% of the population lacks access to a blood facility within 60 minutes' travel; the gap is starker in rural and hill states ^[26].

Infrastructure and Capacity Limitations

- **Cold Chain and Storage:** Many facilities in small towns/PHCs lack cold storage and component separation capacity, increasing waste and limiting clinical options.
- **Transport:** Logistical challenges, especially in regions with poor roads or limited ambulance coverage, lead to delays and spoilage.

Staff and Training

- **Human Resources:** There is a chronic shortage of qualified transfusion medicine specialists, technicians, and counsellors, especially in remote districts. Training gaps impede quality and digital transformation uptake.
- **Quality Compliance:** Some centres lack proper SOPs, equipment maintenance, and regular participation in external quality assessment, leading to non-compliance and heightened transfusion risk ^[27].

Governance and Regulatory Fragmentation

- **Fragmented Oversight:** Licensing, policy, and technical standards are governed by multiple agencies (CDSCO, NBTC, NACO, SBTCs, State FDAs), sometimes producing overlaps or gaps.
- **Policy Inertia:** Calls for a comprehensive National Blood Law (beyond current piecemeal regulations) have intensified. Such a law could standardise protocols, mandate NAT, and codify national standards.

Ethical and Social Barriers

- **Gender Exclusion:** Women are underrepresented as donors, primarily due to anaemia and lack of outreach.
- **LGBTQ+/MSM Discrimination:** Blanket bans continue, despite both legal changes and advances reducing window-period risks.
- **Stigma and False Information:** Myths about safety and weakness, low awareness in lower-literacy populations, and lack of public trust create barriers to donation.

Pandemic and Disaster Impacts

- **COVID-19 Impact:** Donations dropped precipitously during lockdowns and subsequent waves, complicating already-precarious supply chains and highlighting the need for agile, resilient systems capable of surviving shocks ^[34].

Recent Developments, Innovations, and Policy Initiatives

Digital and Technological Innovations

- **E-RaktKosh (2016):** Real-time inventory, nationwide connectivity, and component-level tracking have substantially enhanced reach, efficiency, and transparency. A 25% drop in shortages and a 15% reduction in wastage were recorded in the first year of rollout in urban centres ^[14].
- **Mobile Apps and UHI Integration (2025):** Direct access to blood discovery tools on eight citizen-facing apps, expected to expand further, supports swift emergency response and streamlined coordination ^[5].
- **Predictive Analytics:** Forecasting demand and pre-positioning stock based on epidemic, seasonal, or event-based trends to avoid both wastage and critical shortfalls.

Rare Donor Registry Integration

- **RDRI Integration:** The linking of the Rare Donor Registry with E-RaktKosh provides single-window access for rare groups, haemoglobin disorder patients, accelerating matches and mitigating transfusion risk for complex patients ^[10].

National Campaigns and Public Awareness

- **Swasth Nari, Sashakt Parivar Abhiyaan (2025):** Boosted women's health (especially anaemia detection) and voluntary donation through targeted grassroots campaigns ^[13].
- **Blood Group Testing Drives:** Mass events to test, register, and encourage donors, especially youth and rural populations ^[24].

Supply Chain and Emergency Innovation

- **Blood Bank Discovery Service:** Aggregates real-time data from over 4,000 blood banks, bridging gaps between patients, hospitals, and donors during emergencies. Reduces reliance on social media appeals and unauthorised channels ^[5].
- **Expanded Component Separation and Cold Chain:** New investment in refrigerated vans, automation, and expanded component units increases both quality and reach.

Regulatory and Quality Reforms

- **Second Edition National Standards for Blood Centres (2022):** Updated to reflect contemporary regulatory, technological, and scientific advances ^[6].
- **Haemovigilance/Donor Surveillance Programmes:** Systematic adverse event monitoring, digital reporting, and annual publication of findings foster continuous quality improvement ^[15].

Policy Discussions

- **Proposal for a National Blood Law:** Ongoing debate and representation in Parliament about passing a unified, comprehensive law to standardise operations, mandate NAT, clarify licensing, and codify penalties for violations ^[7].

Future Prospects and Recommendations

Building Resilient and Equitable Blood Systems

With the integration of digital platforms, greater regulatory clarity, and targeted public health campaigns, India can move closer to universal, safe, and timely access to blood. The following actions are crucial:

- **Accelerate the Shift to 100% Voluntary, Non-Remunerated Donation:** Sustained public outreach, myth-busting, and specific campaigns for women and marginalised groups.
- **Close District-Level Gaps:** Invest in cold chain, storage, and transport in blood deserts and underserved regions; consider mobile and satellite blood banks.
- **Universalise NAT and PRT:** Make the most advanced safety screening mandatory, especially in high-use centres and for multi-transfused patients.
- **Update and Pass National Blood Law:** A comprehensive legislative framework would clarify standards, licensing, HR, penalties, and innovation mandates.
- **Expand Training and Accreditation:** Additional training centres, online dashboards, and incentives for NABH/EQAS participation for all centres.
- **Enhance Ethical and Inclusivity Standards:** Move toward behaviour-based, not identity-based, donor screening. Prioritise confidentiality, notification, and anti-stigma protocols ^[31].
- **Bolster Research and Data Use:** Use predictive analytics, machine learning, and robust national surveillance to drive quality improvements and anticipate future needs.

Conclusion

India's journey in blood bank development reflects a complex interplay of public health needs, scientific progress, regulatory innovation, and enduring social and logistical barriers. From humble, war-driven beginnings to the present-day digital networks linking thousands of blood centres, the sector has made impressive progress in safety, accessibility, and efficiency. Yet, formidable challenges remain, marked by regional inequalities, pervasive supply gaps, gender and social inequities, and the need for modernisation of both infrastructure and legislation. The next era for Indian blood banks lies in completing the transition to voluntary, coordinated, and technologically robust systems, underpinned by national quality standards and a legally coherent framework—a future in which every critical care scenario is met with swift, safe, and ethically sourced blood, regardless of geography or social background.

ACKNOWLEDGMENTS:

Nil

CONFLICTS OF INTEREST:

Nil

DATA AVAILABILITY:

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

References:

1. Admin. Pioneers of the 70 years of Voluntary Blood Donation in India [Internet]. Medgate Today. 2024b. Available from: <https://medgatetoday.com/pioneers-of-the-70-years-of-voluntary-blood-donation-in-india/>
2. Mammen JJ, Asirvatham ES, Sarman CJ, Ranjan V, Charles B. A review of legal, regulatory, and policy aspects of blood transfusion services in India. Asian Journal of Transfusion Science [Internet]. 2021b Jul 1;15(2):204–11. Available from: https://doi.org/10.4103/ajts.ajts_65_20
3. Blood Transfusion Services | National AIDS Control Organization | MOHFW | GOI. Available from: <https://www.naco.gov.in/blood-transfusion-services>
4. Blood Transfusion Services | National AIDS Control Organization | MOHFW | GOI. Available from: <https://www.naco.gov.in/blood-transfusion-services>
5. Watchdoq. Blood Bank Discovery Service: a game changer for emergency healthcare in India 2025 [Internet]. Watchdoq: Trusted Healthcare Blog. 2025b. Available from: <https://watchdoq.com/blog/post/blood-bank-discovery-service:-a-game-changer-for-emergency-healthcare-in-india-2025>
6. National Standards for Blood Centres - MoHFW. <https://www.mohfw.gov.in/sites/default/files/National%20Standards%20for%20Blood%20Centres.pdf>
7. Sinha TA. Safeguarding Every Drop: Modi Government's milestones in blood safety and the road ahead. ETGovernment.com [Internet]. 2025b Jun 14; Available from: <https://government.economictimes.indiatimes.com/blog/modi-governments-impact-on-blood-safety-innovations-and-future-directions/121829681>
8. Blood Bank Development The evolution of blood bank technology: Advancements and innovations - FasterCapital. FasterCapital. Available from: <https://fastercapital.com/content/Blood-Bank-Development-The-Evolution-of-Blood-Bank-Technology--Advancements-and-Innovations.html>
9. About eRaktKosh. <https://eraktkosh.mohfw.gov.in/BLDAHIMS/bloodbank/about.cnt>
10. vajiramandravi. India to Integrate Rare Blood Donor Registry with e-Rakt Kosh for Faster, Safer Transfusions. User's Blog [Internet]. 2025c Jun 24; Available from: <https://vajiramandravi.com/current-affairs/india-to-integrate-rare-blood-donor-registry-with-e-rakt-kosh-for-faster-safer-transfusions/>
11. Shamsheer Daula SM, Siva Lakshmi K, Jaya Lakshmi N, Geethanjali B. IoT based Smart Blood Bank Management System [Internet]. Vol. 11, International Journal of Innovative Research in Technology. 2025 p. 4266–7. Available from: https://ijirt.org/publishedpaper/IJIRT175533_PAPER.pdf
12. Blood transfusion services. Available from: <https://dghs.mohfw.gov.in/bts.php>
13. Swasth Nari, Sashakt Parivar Abhiyaan. Available from: <https://campaign.mohfw.gov.in/>
14. Digital transformation in blood banking: The Story of E-Raktkosh. Vol. 6, International Journal for Multidisciplinary Research (IJFMR). 2024 Mar p. 1–3. Available from: <https://www.ijfmr.com/papers/2024/2/14122.pdf>
15. National Institute of Biologicals. <https://nib.gov.in/haemovigilance.aspx>

16. Ministry Of Health And Family Welfare. The Gazette of India : Extraordinary [Internet]. The Gazette of India. 2020 Feb. Available from: <https://thehealthmaster.com/wp-content/uploads/2020/03/GSR-166-E-11-03-20-Blood-Bank-Blood-Centre.pdf>
17. Blood bank and diagnostic lab licensing process in India. GenZCFO. Available from: <https://genzcfo.com/growthx/blood-bank-and-diagnostic-lab-licensing-process-in-india>
18. National Blood Transfusion Council. Blood Centre licensing and operation Guidelines [Internet]. National Blood Transfusion Council. p. 1–4. Available from: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadBloodBank/Blood%20Centre%20Division_FAQs.pdf
19. Govt notifies new rules for blood banks for effective compliance. Available from: <https://drugscontrol.org/news-detail.php?newsid=25994>
20. Aaseeni. NABH Accreditation for Blood Bank 2025 - Oasis Hospital Solutions [Internet]. Oasis Hospital Solutions. 2025. Available from: <https://oasishospitalsolutions.com/nabh-accreditation-for-blood-bank/>
21. National Accreditation Board for Hospitals & Healthcare Providers (NABH). Available from: <https://portal.nabh.co/bloodbank.aspx>
22. Ministry of Health and Family Welfare. The Gazette of India : Extraordinary [Internet]. The Gazette of India. 1999 Apr. Available from: [https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/drug_rules/DR_G.S.R.%20245\(E\)%20dt_05.04.1999_Amendment%20to%20Rule%20122_Requirements%20of%20blood%20bank.pdf](https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/drug_rules/DR_G.S.R.%20245(E)%20dt_05.04.1999_Amendment%20to%20Rule%20122_Requirements%20of%20blood%20bank.pdf)
23. Gopchade Am, Government Of India, Ministry Of Health & Family Welfare, Department Of Health And Family Welfare, Patel A. Unstarred Question No.275 [Internet]. Rajya Sabha. 2025 Feb. Available from: https://sansad.in/getFile/annex/267/AU275_7S6puM.pdf?source=pqars
24. ‘India Needs Blood Every Two Seconds’: Health Ministry ... - News18. <https://www.news18.com/india/india-needs-blood-every-two-seconds-health-ministry-launches-blood-group-testing-drive-to-encourage-donation-9069798.html>
25. Arora I. Comparative study of Voluntary and Replacement blood donors from Blood Bank, Chamba (H.P). Journal of Medical Science and Clinical Research [Internet]. 2018 Aug 2;6(8). Available from: <https://doi.org/10.18535/jmscr/v6i8.14>
26. Kundu S, Valencia AM, Virk SK, Kumar N, Gadgil A, Mammen JJ, et al. Defining blood deserts and access to blood products for 660 million people: a geospatial analysis of eight states in Northern India. BMJ Global Health [Internet]. 2024 Oct 1;9(10):e015637. Available from: <https://gh.bmj.com/content/9/10/e015637>
27. A Handbook for the Improvisation of a blood bank in low ... - NITI Aayog. https://www.niti.gov.in/sites/default/files/2023-03/Improvisation-of-a-blood-bank-in-low-cost-resource-setting_NITI-approved.pdf
28. Princy PM II, Shobhana N, I Sastra Deemed University. Optimizing blood inventory Management: best practices for hospitals [Internet]. Vol. 15, International Journal of Current Science. 2025 Feb p. 510–1. Available from: <https://www.rjpn.org/ijcspub/papers/IJCSP25A1059.pdf>



29. Guidelines for Voluntary Blood Donation.
<https://dghs.mohfw.gov.in/uploads/assets/LObdj4B2n7cnlXdHGOqgsP47FOkbuWeyLU3Vt6u0.pdf>
30. Nabi M. Blood rules and human rights: Why India still bars LGBTQ+ from donating [Internet]. Feminism in India. 2025. Available from: <https://feminisminindia.com/2025/09/01/blood-rules-and-human-rights-why-india-still-bars-lgbtq-from-donating/>
31. Ethical and legal considerations in blood donor counselling | Sankalp India Foundation. Available from: <https://www.sankalpindia.net/news/ethical-and-legal-considerations-blood-donor-counselling>
32. Qamar US. Why choose community stem cell banking over others! [Internet]. Lifecell International Pvt Ltd. 2025. Available from: <https://www.lifecell.in/blog/stem-cells/private-stem-cell-banking-vs-community-stem-cell-banking>
33. Comparing Public vs. Private Cord Blood Banking: Which is More Affordable? | Anja Health. Available from: <https://www.anjahealth.com/blog/cord-blood-banking-for-every-family-costs-6ce7c>
34. Jyoti A. India faces critical blood shortage: WHO urges action on World Blood Donor Day [Internet]. Outlook India. 2025. Available from: <https://www.outlookindia.com/healthcare-spotlight/india-faces-critical-blood-shortage-who-urges-action-on-world-blood-donor-day>