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A review of legal, regulatory, and policy aspects of blood transfusion services in India: Issues, challenges, and opportunities

Joy John Mammen, Edwin Sam Asirvatham[1], Charishma Jones Sarman[1], Varsha Ranjan[1], Bimal Charles[1]

Abstract:

BACKGROUND: Blood transfusion services (BTS) in India have progressed significantly during the last three decades. However, there is still inequity in the availability and access to blood due to various demand and supply-side issues. Appropriate laws, regulations, policies, and guidelines are critical to ensure universal access to blood.

AIMS AND OBJECTIVES: This article aims to review the evolution and current status of legal, regulatory, and policy framework and analyses the issues, challenges, and opportunities for improvement of BTS in India.

METHODS: This article is based on an extensive review of currently available literature and government documents.

RESULTS: The review highlights the gaps and challenges in terms of licensing, safety and quality, voluntary blood donations, the organization of BTS, access to services, and regulatory bodies. The findings emphasize the need for a coordinated response by either the National Blood Transfusion Council or a newly established autonomous "National Blood Authority" consisting of technical, administrative, and legal experts which must be exclusively responsible for regulating the BTS. As adherence to quality management systems in blood banks is not a mandatory requirement, it recommends a legal measure to ensure mandatory quality assurance in blood banks and storage centers. Towards ensuring efficiency and universal access to blood, this article recommends evidence-based criteria for establishing new blood banks to avoid skewed distribution of blood banks, component separation facilities, and blood storage centers.

CONCLUSION: The review emphasizes the need for periodic reviews and updates of the legal, regulatory and policy framework, considering the rapid developments and technical advancements with increasingly complex systems and processes in transfusion medicine.

Keywords:

Availability and access to blood transfusion, blood safety and quality, blood transfusion services in India, legal, regulatory and policy aspects

Department of Transfusion Medicine, Christian Medical College, Vellore, Tamil Nadu, [1]Christian Medical Association of India, New Delhi, India

Address for correspondence:
Dr. Edwin Sam Asirvatham, Christian Medical Association of India, Block A3, Janakpuri, New Delhi - 110 058, India.
E-mail: aedwinsam@yahoo.com

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Introduction

Blood transfusion services (BTS) ensures the availability and quality of blood, establishes donor management and storage provisions, tests for transfusion transmissible infection (TTI) and practices appropriate usage of blood.[1-4] Ever since the first blood bank in India was established in 1942 in Kolkata to meet the war needs, BTS has been evolving through the amalgamation of laboratory technology and knowledge. In 2019, India has a network of 3108 blood banks owned by public, private, and not-for-profit sector, with around 50% having blood component separation units (BCSUs). The blood banks range from small facilities that collect less than 500 units to large ones collecting more than 50,000 units per annum. In 2018–2019, they collected around 12.4 million units of blood, of which around 50% were separated into the components.[5,6] In addition, there are around 1849 blood storage centers (BSC), responsible for improving the access to blood in the remote areas, especially during the time of emergency.[7-9]

Despite the significant progress during the last three decades, there is still inequity in the availability and access to blood due to poor distribution of blood banks, lack of infrastructure, sub-optimal voluntary blood donation, poor supply chain management system, shortage of functional equipment, shortage of competent and trained staff, poor regulatory mechanisms, and lack of coordination within and between institutions.[9,10] The establishment of blood banks in a given geographic area is neither based on specific criteria nor demand analysis. BTS in India provides business incentives to start blood banks mostly in urban areas, leading to inequitable distribution and compromising the purpose of establishing blood banks.[11] They are operated with less competent workforce and workload, often hindering the efficiency and quality of BTS.[12]

Appropriate laws, regulations, policies, and guidelines are critical to ensure a well-coordinated BTS which would facilitate universal access to quality transfusion services.[9,13] They play a central role in determining the structure of BTS as well.[14] Considering the importance, this article aims to review the evolution and current status of legal, regulatory, and policy framework and analyzes the issues, challenges, and opportunities for improvement of BTS in India.

Methodology

This article is based on an extensive review of literature that included a review of the constitution, laws, court judgments, reports, policies, guidelines, government gazette notifications, and journal articles related to BTS in India. We conducted literature search primarily in the National Library of Medicine (PubMed) and Google scholar. In addition, we used general search engines to access non-peer reviewed publications and documents. We limited the search to English and selected the documents by reviewing their titles and abstracts with additional references identified from the reference lists of selected articles.

Results

The review highlights the evolution and current status in terms of licensing, safety and quality, voluntary blood donations, organization of BTS, access to services, and regulatory bodies.

The Legal and Regulatory Framework of Blood Transfusion Services

Law is a body of rules of action or conduct prescribed by controlling authority and having binding legal force, which must be obeyed and followed by citizens' subject to sanctions or legal consequence.[15] Regulation is rule-based, mostly to convey higher level decisions to lower operating levels[16] which are usually developed and enforced by all levels of government.[17]

The laws and regulations concerning BTS are covered under section 3 (b) of the Drugs and Cosmetics (D and C) Act, 1940, as blood and blood components are categorized as a "drug" due to their internal administration. The act was formulated to regulate the import, manufacturing, and distribution of drugs.[18,19] Based on the D and C act, drug and cosmetic rules were framed in 1945. The act and the rules thereof, serve as the legal framework for regulating the blood banks, which determine the quality of services as well.[20,21] Since then, the act has been expanded, and the rules have been amended multiple times to address the emerging concerns.

Licensing

Part-X B of the D and C rules, 1945 specifies the requirements for licensing, collection, storage, processing, and distribution of blood and components in blood banks. Schedule F Part-XII B defines the rules pertaining to the functioning of blood banks and preparation of blood components. As a result of the concerns expressed by the Supreme Court of India and the Parliament, the act was amended in January 1993 that made dual licensing of blood banks mandatory. The Drug Controller General of India (DCGI) under the Central Drugs Standard Control Organization (CDSCO) was vested with the power as central license approving authority along with state licensing authority, to approve the license of notified drugs that include blood and blood products as per rules 68A, part X B and part-XII B of schedule-F.[18,22,23]

Blood safety and quality

The legal framework concerning blood safety is

outlined in the D and C act and the rules thereof, which demand mandatory testing for TTI, including HIV which is based on a notification issued in 1989. Later in 1999, screening for Hepatitis-B was included, and subsequently, in 2001, Hepatitis-C screening was made mandatory as per the 2nd Amendment of D and C rules, 1945.[22,24,25] In 1999, blood bank legislation was extensively revised to include good manufacturing practices, standard operating procedure, and validation of equipment.[26] Before this initiative, as early as 1987 at the state level, the Goa Public Health (Amendment) Act 1987, section 53 (1) sub-section (vi) mandated testing of blood donors for HIV/AIDS or any communicable disease if suspected by the health officer.[27,28]

The Indian Penal Code chapter-XIV, section 269 and 270 specifies that any negligent and malignant act that is likely to spread the infection of disease dangerous to life including infections transmitted through blood transfusion will be entitled to punishment with imprisonment.[29] In 1995, the Supreme Court upheld the National Consumer Commission's judgment of April 1992 that enabled both the blood donor and recipient to take cover and claim damages for receiving deficient services under the Consumer Protection Act 1986.[30,31] In 2012, following a public interest litigation (PIL) to make polymerase chain reaction (PCR) test as mandatory, the Gujarat high court directed the government to constitute a body of experts to examine the feasibility of having PCR to ensure safety.[32] Later, though, the court recognized the superiority of PCR compared to enzyme-linked immunosorbent assay, it refused to give an order making PCR or nucleic acid amplification test mandatory for HIV screening during blood transfusion.[33] In 2018, National Blood Transfusion Council (NBTC) suggested that Nucleic acid testing could not replace mandated serological testing due to its high cost and lack of technical expertise in most blood centers; however, it could be an additional layer of safety.[34]

Voluntary blood donation

In 1992, a PIL-Common Cause versus Union of India prompted India to focus on voluntary blood donation (VBD) as a priority to ensure safe blood, since the risk of blood-borne infections were reported to be lower among voluntary unpaid donors.[1,35] The third Amendment of D and C Act, in 2001 provides legal provision for VBD in outdoor camps. According to the amendment, camps can be conducted only by a licensed blood bank owned by government, Indian Red Cross Society, or a nongovernmental organization designated as a regional blood transfusion center (RBTC) by the State Blood Transfusion Council (SBTC).[19] Later in 2017, it was further amended to offer legal provisions for all licensed blood banks to conduct outdoor camps.[36]

In 1996, in response to the PIL by the Common Cause versus Union of India regarding safety of blood, the Supreme Court of India banned professional donation. Based on this judgment, the DCGI issued a notification that banned the collection of blood from paid donors from January 1998 to ensure a safe supply of blood.[37,38]

Organization of blood transfusion services

In 1996, the Supreme Court directed the government to enact legislation to regulate the collection, processing, storage, distribution, and operation of blood banks. In addition, the apex court directed the government to constitute a NBTC and SBTC which were established subsequently within the National AIDS Control Organization (NACO) and State AIDS Control Societies (SACS), respectively.

Toward generating resources for BTS, the Supreme Court in 1996, directed the government to amend the section 80G of Income Tax Act, 1961, to make all donations to the NBTCs and SBTCs eligible for tax deductions from an assessee.[39] In 2013, the Gujarat high court emphasized the duty of the state government and directed them to appoint a sufficient number of inspectors to ensure that rules for running of blood banks are strictly complied with as per the law. It ordered the blood banks to display a rate card as per the NBTC rates. In addition, it directed the committee to ensure nonprofiteering and to evolve a policy to clarify profiteering and the consequences thereof.

Availability and access to services

Toward ensuring access to blood in remote areas, and to vulnerable population such as women in labor, the amendment of the D and C Act in 2001 exempted BSCs run by first referral units (FRU), community health center, primary health center or any hospital from obtaining a license with the approval of state drug autority.[8,40] The initiative was intended to provide blood to the health facilities whose requirement is less than 2000 units per annum.[41]

On April 2017, the D and C Act, 1940, was amended to allow the transfer of blood and components, under the prescribed storage conditions, from one blood bank to another to enhance the availability where there is a scarcity. Most importantly, the Constitution of India made provisions and rights to safeguard its citizen's health through safe and quality blood transfusion. The *Fundamental Right to freedom-Right to life and personal liberty (Article-21)* of the Constitution establishes health as an essential component to make an individual's life meaning, purposeful, and compatible with personal dignity.[42]

Unbanked Direct Blood Transfusion was reported as a regular practice in many parts of the country which ensured access to blood to some extent, especially in the rural areas. It was legal until the government amended the rule in the D and C Act in 1999, with the exception for armed forces through field ambulances, mobile medical units, and other field medical units including blood supply units in border-sensitive areas.[19,43,44]

Regulatory Bodies and their Functions Related to Blood Transfusion Services

The CDSCO, headed by the DCGI is the regulatory body at the central level, discharging functions under the D and C Act. The apex body functions under the DGHS are responsible for approval of license of blood banks, new drugs, blood components and products, clinical trials, formulating standards for drugs, monitoring the quality of imported drugs, and overseeing drugs consultative committee and Drugs Technical Advisory Board meetings.[20,45,46] At the state level, the state drug controller or the Food and Drug Administration (FDA) is responsible for regulation and licensing. After a joint inspection by state and central authorities, the state drug controller or state FDA's issues or renews the license, with approval from CDSCO which is valid for 5 years.[23,47-49]

Policies and Guidelines Related to Blood Transfusion Services

A well-coordinated BTS guided by a national blood policy is critical to maintain quality and safety in the provision and administration of blood and blood products.[50] Two national institutions are responsible for the organization of BTS and formulation of related policies that are the NACO and NBTC.

The advent of HIV epidemic brought blood services in India under greater scrutiny in the '80s, as the transfusion-transmitted HIV infection in the mid-1980s raised concerns on blood safety.[51] As a result, the blood safety program in India was initiated in 1992 with the establishment of the NACO, initially focusing on surveillance; health education and information; and screening of blood and blood products.[52] Currently, the NACO and respective SACS are responsible for ensuring access to safe blood through appropriate programs and strategies in the country.

The NBTC, registered as a society in 1996 play an advisory role in policy formulation on safe blood-transfusion services and is supported by the NACO.[10] The NBTC is responsible for establishing an institutional mechanism for planning and implementation of blood safety programs, development of guidelines for constitution of a hospital transfusion committee and operationalization of plasma fractionation facility and promotion of quality management systems (QMS) in blood banks.[37] The SBTCs, the autonomous body under the state health services, are responsible for the formulation of policies, regulation, and enforcement of operational requirements of BTS in the state. The training of workforce and quality control are also the functions of the Councils.[53,54] In general, SBTCs operate under the respective SACS except in Maharashtra and Nagaland.[10]

The first national blood policy in India was framed in 2002 which highlighted the government's commitment to ensure equitable access to safe blood, adequate resources, technology, and capacity building of health-care personnel.[14,37] Mandatory licensing, 100% voluntary, nonremunerated blood donation, banning of professional donors, prohibition of trading, transfusion under the supervision of trained personnel, the means of funding, appropriate legislation, and total quality management were some of the key aspects emphasized in the policy.[55] An action plan was also developed to operationalize the priorities and objectives set out in the national blood policy.[39] However, the national blood policy has never been reviewed and updated after the initial formulation.

The standards for blood banks were developed in 2002 to ensure the quality of services in blood banks.[46] The guidelines for establishing BSCs were developed in 2007 to facilitate blood storage or transfusion facilities at the FRU which was considered as a major constraint in the provision of emergency obstetric care services.[8] In the same year, guidelines for VBD were developed.[56]

In January 2014, the NBTC approved the recovery of processing charges for blood and blood components and subsequently developed a guideline document for uniform charges, with an option to revise it once in 3 years. As per the guidelines, the charges may be subsidized by the respective state governments or SBTCs in the public sector. The guidelines highlighted the basic principle of nonprofitability through voluntary nonremunerated blood donation. It also emphasized the mandatory provision of free blood for conditions such as thalassemia, hemophilia, sickle cell anemia, and other blood dyscrasia requiring repeated transfusio.

On March 2014, the NBTC notified the pattern of financial assistance for conducting camps in outdoor locations and mobile blood donation vehicles with the objective of streamlining VBD in NACO supported blood banks. It also redefined VBD in accordance with the WHO definition. According to this, a voluntary nonremunerated blood donor gives blood, plasma or cellular components of his or her own free will and

receives no payment either in the form of cash or in kind which could be considered a substitute of money.[57]

The national plasma policy, an addendum to the national blood policy was introduced in June 2014 to ensure adequate supply and access to high-quality human plasma-derived proteins for the clinical and therapeutic use. The policy aims to mobilize the excess plasma at blood banks for fractionation to meet the increasing demand for plasma products. It highlights the process of collection and transportation under optimum conditions, identification of critical parameters for safety, regulatory requirements, and training for appropriate use of products.[58] Importantly, the policy has not incentivized plasma donation for fractionation, unlike certain other countries.

On September 2015, the NBTC revised the norms for setting up of blood banks, granting no objection certificate for license, renewal of license, granting RBTC status and permission to conduct VBD camps, to ensure uniform practices and procedures across the country.[59] In October 2015, a policy decision was taken to allow bulk transfer of blood and blood components between licensed blood banks with few conditions. It aims to address both the wastage due to surplus and scarcity of blood in different geographical regions. It was later included as amendments in the D and C Act.[36,60] On June 2017, the guidelines for donor selection and referral were revised to ensure donations from lower risk donors and refer every probable TTI reactive donor for the accurate diagnosis and management.[61]

Issues, Challenges, and Opportunities

The episodic reviews of laws, regulations, policies, guidelines, and standards related to BTS in India, have led to a number of amendments, development of standards, guidelines, and policy changes. Although these efforts have improved the availability and access to safe blood, there are still issues and challenges that hinder the efficiency and effectiveness of services.

Drugs and cosmetic act

The D and C Act has been amended several times; however, it was not based on a comprehensive review and analysis of the current context, technical advancements, and existing requirements. Specific areas such as human resource, space requirements, license process, including the inspection team, patient management, including informed consent, patient identification, donor criteria, and hemovigilance aspects of the D and C Act require comprehensive analysis and appropriate response.[62] Considering the current context, it is essential to incorporate criteria for BSCs; blood components; advanced testing technologies and equipment; and centralized testing centres with a robust supply-chain management system, to maximize the operational efficiency.

It is apparent that the licensing process of blood banks is slow and tedious.[14] According to NACO, a significant number of blood banks are in under-renewal status for more than 4 years due to noncompliance and delay in inspections.[5] This necessitates the need for rational revision of the processes in the act and rules to acquire or renew a license.

Historically, the amendments of the act have been reactive and mostly directed by the courts or initiated after being raised in different fora. As new practices and procedures in BTS emerge continuously due to rapid technological advancements, it is essential to have periodic review, and amendments of the act and rules thereof, in consultation with all the relevant stakeholders. Moreover, a separate blood law is a necessity, as laws pertaining to blood banks and BTS form a small part of the D and C Act in India.

The regulatory mechanisms

The BTS in India has a multiplicity of authority, with CDSCO, and State Drug Controller/FDA having regulatory role and NACO, NBTC, SACS, and SBTC, having advisory and program implementation roles.[10] It leads to the lack of coordination, poor monitoring, and regulation of blood banks. Besides, the present regulatory functions are neither uniform nor consistently applied across the country. For instance, the licensing processes, adherence to QMS, donor management system, human resources, and practices vary between and within states.[5]

Regarding licensing, it is essential to define a fixed time limit for completing the process to get a new and renewal of license. Uniform standards and guidelines are required to ensure adherence to a standardized protocol with transparent information system which would specify the details of nonconformance, response by blood banks, and action taken by the drug controller with timeline. It is also essential to have an appellate authority and mechanism to appeal against any decision that is not acceptable to the blood banks.

Neither NACO nor NBTC has any regulatory control over blood banks as their roles are technical and advisory.[20,37,63] On the other hand, CDSCO and state drug controller/FDA have been entrusted to regulate the entire pharmaceutical sector that includes drugs, devices, and clinical trial licensing.[14] Considering the rapid advancement in Transfusion medicine with complex systems and processes, it is important to have either NBTC or a newly established autonomous "National Blood Authority" consisting of technical, administrative,

and legal experts which must be exclusively responsible for regulations of BTS. Moreover, it is imperative to review the existing regulatory mechanisms to reorient the structure and responsibilities to avoid the multiplicity.

Quality assurance in blood banks

There have been a number of policy initiatives, standards, guidelines, and programs that aimed at improving the quality of BTS. However, a significant number of blood banks indicated deficit in the quality of services with wide variations between geographic regions, ownership, and type of blood banks.[5] Licensing which is mandatory under the D and C Act presumes a certain level of quality; however, the process of licensing is not uniform to ensure optimum quality across the country. In 2016, the license of 34% of blood banks was under renewal of which 17% had their inspection between 1 and 2 years, 6.2% between 2 and 3 years, 2.3% between 3 and 4 years, and 4.7% had their inspection before 4 years.[5] It clearly indicates that possession of a license does not necessarily reflect the quality of services.

Although accreditation is a reflection of quality of services, it is not mandatory in India.[64] However, obtaining and maintaining accreditation is not simple, due to its stringent processes and financial requirements. Similarly, the practice of Internal Quality Control and participation in an External Quality Assessment Program (EQAP) are not mandatory. As a result, only a small proportion of blood banks are enrolled in a formal EQAP and implementing QMS. The D and C Act and the rules thereof, have not given adequate importance to QMS that ensure patient safety and quality. This calls for appropriate legislative and policy changes to make QMS a mandatory requirement in blood banks. Similarly, a legal framework needs to be developed to ensure mandatory quality assurance in BSCs.

Ensuring efficiency and universal access to blood

The annual collection of blood in India may be adequate to meet the demand if there is optimum component separation, an efficient supply-chain mechanism, and an effective patient blood management program. However, India may be facing a situation of non-availability of blood in places where it is most required. There is a substantial variation in the availability of blood banks between and within states. For instance, Bihar had only 0.7 blood banks, whereas Kerala and Telangana had around five blood banks per million populations. Similarly, there is a significant variation in the collection between states that range from 0.2 units to 8.5 units per 100 population.[5] The situation suggests the importance of establishing new blood banks based on a comprehensive need analysis considering the population size, geographic location, health-care system, clinical demand for blood, and the epidemiological situation. It also stresses the need for suitable amendments of laws or policies that specify the criteria for the establishment of new blood banks.

The distribution of BCSUs must also be based on certain criteria which would reduce the proliferation of BCSUs. The licensing of BCSUs should mandate the blood banks to process a minimum level of component separation to ensure efficiency. There could be a mechanism to review the blood banks that collect consistently low volume and not meeting the clinical demand in its potential catchment area. Besides, it is necessary to set strict guidelines for conducting camps, especially mega camps to ensure optimum utilization and reduce wastage.

The BSCs transact a low volume of blood due to inadequate supply from mother blood banks and mother blood banks demanding replacement of blood.[41] The blood policy and the act do not have any mention about them, although there is a guideline for setting up a BSC. A review and revision of rules, policies, and guidelines will facilitate the establishment of additional BSCs, as required, to ensure access to blood in the rural and remote areas. Toward ensuring equitable access, NBTC guidelines made it mandatory to provide blood free of cost for conditions that require repeated blood transfusion. However, a provision is required to provide ambulatory BTS (day-care) to these patients.

Conclusion

Appropriate legislation, regulations, policies, and guidelines are critical to ensure right blood, for the right patient at the right time and at the right place. They provide strategic direction for the overall functioning of BTS. However, they need to be contextual, feasible, and should lead to better patient services. In India, various central and state level agencies and a framework comprising D and C Act and rules, amendments, court judgements, policies, guidelines, standards, and government notifications, together provide overall strategic direction for BTS. However, universal access to blood, equitable distribution of services, efficiency in operations, quality and safety, adaptation of innovation and technology, and ethical practices are prevailing challenges but providing an opportunity for improvement.

Considering the rapid developments and technical advancements with increasingly complex systems and processes in Transfusion Medicine, it is essential to have periodic reviews and updates of the legal, regulatory and policy framework. Most importantly, the country needs to have a clearly defined structure, systems and, strategies to enforce the laws, policies, standards and guidelines with the appropriate monitoring mechanism which will ensure quality, efficiency and universal access to blood and blood products.

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