

## Legal and ethical issues in safe blood transfusion

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### ABSTRACT

Legal issues play a vital role in providing a framework for the Indian blood transfusion service (BTS), while ethical issues pave the way for quality. Despite licensing of all blood banks, failure to revamp the Drugs and Cosmetic Act (D and C Act) is impeding quality. Newer techniques like chemiluminescence or nucleic acid testing (NAT) find no mention in the D and C Act. Specialised products like pooled platelet concentrates or modified whole blood, therapeutic procedures like erythropheresis, plasma exchange, stem cell collection and processing technologies like leukoreduction and irradiation are not a part of the D and C Act. A highly fragmented BTS comprising of over 2500 blood banks, coupled with a slow and tedious process of dual licensing (state and centre) is a hindrance to smooth functioning of blood banks. Small size of blood banks compromises blood safety. New blood banks are opened in India by hospitals to meet requirements of insurance providers or by medical colleges as this a Medical Council of India (MCI) requirement. Hospital based blood banks opt for replacement donation as they are barred by law from holding camps. Demand for fresh blood, lack of components, and lack of guidelines for safe transfusion leads to continued abuse of blood. Differential pricing of blood components is difficult to explain scientifically or ethically. Accreditation of blood banks along with establishment of regional testing centres could pave the way to blood safety. National Aids Control Organisation (NACO) and National Blood Transfusion Council (NBTC) deserve a more proactive role in the licensing process. The Food and Drug Administration (FDA) needs to clarify that procedures or tests meant for enhancement of blood safety are not illegal.

**Key words:** Blood transfusion services, Drugs and Cosmetic Act (D and C Act), ethical, legal, National Aids Control Organisation, transfusion

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### INTRODUCTION

Legal issues play a vital role in shaping the structure of blood transfusion services (BTS) in the country and ethical issues play a more significant role in determining the quality of transfusion services. Thanks to the Supreme Court directive in 1993, making licensing of blood banks in the country mandatory, all blood banks are licensed today. Licensing became mandatory consequent to the landmark judgement in the petition – “Common Cause vs. Union of India in January, 1992.<sup>[1]</sup> The honourable court also directed that the National Blood Transfusion Council (NBTC) along with State Blood Transfusion Councils (SBTC) be set up for monitoring the activity of blood banks in India.<sup>[2]</sup>

Blood has been treated as a ‘drug’ under the Drugs and Cosmetic Act (D and C Act), 1940 and Drugs

and Cosmetics Rules, 1945.<sup>[3]</sup> With the classification of blood as a drug, the drugs controller became the regulatory authority. Licensing is only the first step towards quality. The Indian BTS is highly fragmented with over 2500 blood banks and poses unique challenges.

### ELEMENTS OF BLOOD SAFETY

#### Safe donor

Safe blood comes from an ‘altruistic’ voluntary donor who donates blood without any expectations. A ‘repeat voluntary donor’<sup>[4]</sup> is one who donates blood at least once a year and is considered safer than occasional voluntary donors, as the blood bank is aware of his previous test results also. Friends and relatives of patients called ‘replacement donors’ constitute a significant chunk of blood donors in our country but

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are not really safe donors<sup>[5]</sup> as they are forced by family or friends to donate blood. Professional/paid donors may sometimes be passed off as replacement donors too. Some papers have shown that one time voluntary donors are no better than replacement donors<sup>[6]</sup>

### Safe blood

Blood banks have traditionally employed enzyme linked immunosorbent assay (ELISA) techniques for donor screening. Tests with greater sensitivity or those which take lesser time duration like chemiluminescence (CLIA)/enzyme-linked fluorescence assay (ELFA) are increasingly being used by blood banks.<sup>[7]</sup> Of late, expensive technologies like nucleic acid testing (NAT) have added to blood safety.<sup>[8-10]</sup> In addition to transfusion transmitted infections (TTI) testing, red cell antibodies screening being adopted by many blood banks and the newer gel/bead techniques have also added to blood safety. Blood processing techniques like leukoreduction,<sup>[11]</sup> Irradiation<sup>[12]</sup> and pathogen inactivation<sup>[13,14]</sup> are expected to play an increasingly important role in enhancing blood safety in future.<sup>[15]</sup>

### Safe transfusion

While there are some guidelines for safe donor selection and safe blood processing, there are no transfusion triggers or national guidelines for safe transfusion. The (D and C Act) does not speak about patient informed consent, patient identification, and administration of blood or haemovigilance [Figure 1].

## FRAMEWORK OF INDIAN BLOOD TRANSFUSION SERVICES

### National blood policy

The National Blood Policy<sup>[16]</sup> (NBP) was published by the Government of India in 2002. The NBP reiterates government commitment to safe blood and blood components and has well documented strategies, for making available adequate resources, technology and training for improving transfusion services. It also outlines methods for donor motivation and appropriate clinical use of blood by clinicians. It has also taken steps for R and D in transfusion medicine. Further, it is also entrusted with the job of ensuring legislation and education to eliminate profiteering in blood banks



**Figure 1:** Elements of blood safety.

**Source:** Editor-Dr. Shivaram. Transfusion Medicine for Clinicians, Prism Publications, 2011

### Role of National Aids Control Organization

Many improvements seen in our country over the last decade and a half has been the result of licensing which laid down minimum requirements in terms of space, staff and equipment and also National Aids Control Organization (NACO) support for blood safety.<sup>[17]</sup> While the drugs controller is the regulatory authority, NACO/NBTC has been the main technical body to frame guidelines for the practice of transfusion medicine. The NBP is an offshoot of the National Aids Control Program.<sup>[18]</sup> NACO together with NBTC has played a pivotal role in improving blood safety by infrastructure development, setting up component separation units, promoting voluntary blood donation, training staff and has also laid down standards for blood banks in India [Figure 2].<sup>[19]</sup>

### Licensing of blood banks by drugs controller

The procedure for licensing of blood banks is written in the D and C Act 1940 and Drugs and Cosmetics Rules, 1945. Basic licensing standards for blood banks have remained unchanged over the past decades.<sup>[20]</sup> The D and C act has only seen minor changes such as rising the age of donation from 60 to 65 years and recognition of transfusion medicine as a specialty. Perhaps the only major amendment has been the guidelines for setting up blood storage centres.

### Who can operate a blood bank

Any individual or institution can apply for opening of a blood bank. Following an application to the drugs controller, a joint inspection is conducted by drug control authorities from state and centre which make a recommendation to the Central Licensing Approving Authority (CLAA), which is the ultimate authority for grant of license. This drug controller inspection is preceded by an inspection by the SBTC, the advisory body, which gives its consent to the drugs controller.

### Space requirements

Minimum standards for space, equipment and staff have to be met with by all blood banks, and these are inspected at the time of grant/renewal of the license. An area of 100 sqm for whole blood and an additional 50 sqm for blood components and 10 sqm for aphaeresis is needed for operating a blood bank in India.

### Staff requirements

The medical officer may be a person with MD in Transfusion Medicine or Pathology, Diploma in Pathology with 6 months experience or MBBS qualified with 1-year experience in blood banking.

Technicians with BSc (MLT) or DMLT and staff nurses are additional requirements [Table 1].

### PITFALLS IN LICENSING PROCESS

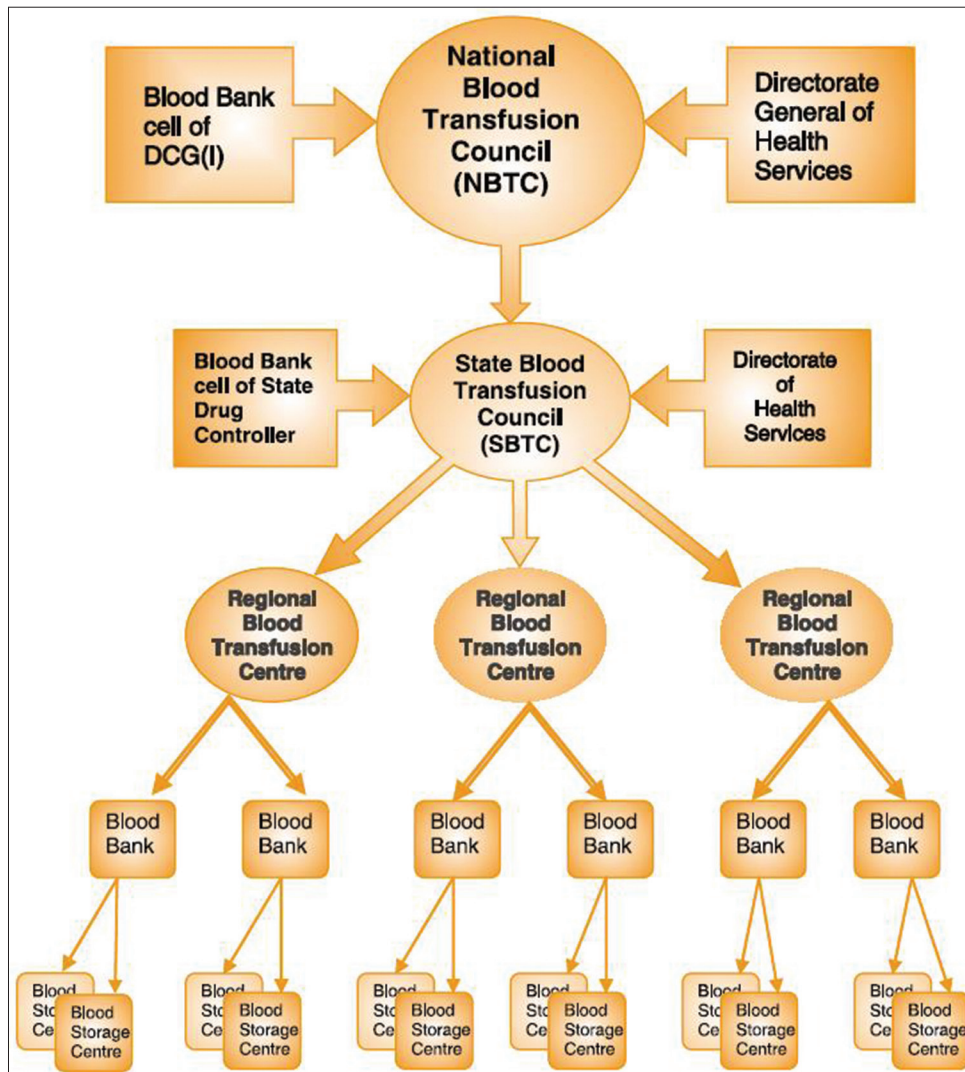
#### Who should regulate

Whether a blood bank should come under the purview of the regulatory authority overseeing Food and Drug

Administration is a matter of debate.<sup>[21]</sup> The drugs controller is already burdened with so many drugs, devices and clinical trial licensing that monitoring 2500 + blood banks in the country is a herculean task. Transfusion medicine is emerging as a super-specialty today including blood banking, aphaeresis, cell biology, molecular biology and therapeutic procedures. Drugs controllers being basically pharmacologists have no training in transfusion medicine but are expected to look into quality control (QC) of blood components, TTI testing, immuno-haematology. NACO/NBTC is a technical body well equipped to regulate and monitor blood banks but plays an advisory role only. Thus, while the legal aspects pertaining to infrastructure, equipments, spacing and staff are monitored by the drugs controller effectively, the medical and quality aspects of transfusion medicine are neglected. Involving carefully chosen experts in transfusion

**Table 1 Steps in blood bank licensing process**

- Application with fees by individual/institution called the licensee in form 27-C
  - Scrutiny of application by state DC and SBTC
  - Inspection of blood bank by SBTC and grant of no objection certificate for grant of license
  - Inspection of blood bank premises by joint (centre and state) inspection team
  - Recommendation to CLAA for licensing
  - Grant of license in form 28-C
- 
- SBTC – State Blood Transfusion Council; DC – Drug Controller; CLAA – Central Licensing Approving Authority



**Figure 2:** Organogram of Indian Blood Transfusion Service.  
**Source:** Action Plan for Blood safety Manual-NACO/NBTC<sup>[16]</sup>

medicine with the Drug controllers complimenting them will make regulation more meaningful.

### The dual licensing system

The dual licensing system for grant or renewal of the license has made the licensing process very tedious and slow with no time limits. Like in some departments, non-administrative considerations too play an important role in getting a license in some places. The excessive regulations (License Raj) related to system and minimum requirements for blood banks should be removed and updated more rationally; delays in updating the D and C Act or in setting up a mechanism to audit the blood banks is impeding blood safety considerations in India.

### The Drugs and Cosmetic Act

This needs urgent revision due to advances in transfusion science. Clarity on what blood banks can or cannot do is essential. For instance, leukoreduced and irradiated blood components, without which many cancer patients and thalassaemic children would not be alive, find no place in the D and C Act. The act does not specify whether a separate license is needed for leukoreduction and irradiation. However, there are national standards for QC of leukoreduction and irradiation laid down by NACO. One suggestion by authors, pending revamping of the D and C Act, is to clarify by way of a circular that any additional procedure done to improve blood safety-like leukoreduction, irradiation or NAT testing requires no licensing.

### Apheresis licensing

Blood banks are required to seek special permission showing equipment, space and staff available for Apheresis. The D and C Act mentions only plateletpheresis, plasmapheresis and leukapheresis on donors whereas it is the products, that is, single donor (apheresis) platelets (SDP), plasma and leukocytes (granulocytes/mono-nuclear cells) that need licensing and not procedures. Many other specialised products like modified whole blood (whole blood minus platelets or cryoprecipitate) must also be included. While it is legal to give six random donor platelets one after the other, the same cannot be pooled in a closed system, filtered and given together as pooled platelet concentrate. Pooled platelet concentrates<sup>[22-25]</sup> are used in Europe as an effective substitute to the more expensive SDP.

### Therapeutic procedures

Today many blood bankers are competent enough to do specialized procedures like therapeutic

plateletpheresis, plasmapheresis, leukapheresis peripheral blood stem cell [PBSC] collection and red cell exchange. Blood bankers are the most competent staff to perform these procedures in conjunction with the clinicians. Clarity is needed in the D and C Act on therapeutic procedures. Surely, use of PBSC for traditional applications like leukaemia, lymphomas, aplastic anaemia, myelomas, haemoglobinopathies needs no permission. If that were to be the case then appendectomy, hysterectomy, cataract surgery would also need licensing. Accreditation, a peer review process could be an effective alternative wherever licensing is deficient but national guidelines are available.

## PROBLEMS FACED BY THE INDIAN BLOOD TRANSFUSION SERVICE

### Fragmented blood transfusion service

Blood banks are opened in India for various reasons. Some hospitals open blood banks as they are denied permission to open storage centres. Only Regional Blood Transfusion centre (RBTC) are permitted to open storage centres and very few blood banks are RBTCs. Some hospitals open blood banks because insurance providers allow them to charge higher for their services with a blood bank. Medical colleges open blood banks to meet Medical Council of India requirement.<sup>[26]</sup> The government opens blood banks in various districts due to pressure from elected representatives. When blood banks are opened, not because there is a real need and when there are not enough competent people to run them, or enough workload to sustain the operations, then quality is compromised. More blood storage centres and not more blood banks is the solution.

### Size of blood banks and screening methodologies

Studies<sup>[27]</sup> have shown that compared with medium and large labs, small labs have higher rates of false negativity for human immunodeficiency virus and hepatitis B surface antigen. Blood banks with small workloads (5-10 donors/day) compromise safety by using rapid tests, which are associated with a delay of over 1 week in antibody detection.<sup>[28]</sup> QC measures to guarantee safety in TTI testing like Levy Jennings chart for ELISA, is almost non-existent, except in few blood banks.

### Absence of standards for safe transfusion

National Aids Control Organisation/NBTC standards address only safe donor and safe blood issues and do not cover safe transfusion, the third element of blood safety. Transfusion triggers are at best limited



to individual institutions. Further, there are no audits by a competent technical body to ensure compliance with standards.

#### **Curbs on conducting blood donation camps**

Only licensed RBTCs, government blood banks, Indian Red Cross Society or licensed blood bank run by voluntary or charitable organisations are permitted to hold blood donation camps as per the D and C Act.<sup>[29]</sup> Withholding permission for camps affect many good blood banks and could be a factor impeding voluntary blood donation. This law needs a relook, if we want to achieve 100% voluntary blood donation.

#### **Failure to incorporate new technologies and employ centralised testing**

Newer testing technologies like NAT/CLIA/ELFA do not find any mention in the D and C Act, and some regulatory authorities are also ignorant about these new techniques. While closing down small blood banks in a fragmented BTS is easier said than done, centralization of TTI testing is not difficult to achieve by legislation. WHO also recommends centralized/regionalised testing as one of the policies to be adopted to improve blood safety.<sup>[30]</sup> Centralised testing centres for ELISA/NAT manned by experts in transfusion medicine, coupled with an effective courier system may be set up as a first step towards consolidation of the Indian BTS.

#### **Over reliance on testing technologies**

TTI testing alone cannot guarantee safe blood. The world has moved on from testing technologies to processing technologies but processing technologies find no mention in the D and C Act. While NACO/NBTC laid down guidelines for leukoreduction and irradiation as early as in 2007, there is ignorance regarding this among many blood bankers and drug inspectors alike.

#### **Deficiencies in documentation and monitoring of bedside transfusions**

##### **Blood request form**

As per the D and C Act “the blood and/or its components shall be distributed on the prescription of a Registered Medical Practitioner.” However, owing to practical difficulties, this rule is seldom followed. The D and C Act must be revamped to replace manual signatures with electronic signatures of doctors.

#### **Indication for transfusion**

This is another D and C Act requirement which is seldom followed, possibly because there are no standard guidelines.

#### **Informed consent for transfusion**

This requirement again is an offshoot of a legal directive by the National Consumer Redressal Forum. In the case of *M. Chinnaiyan vs Sri Gokulam Hospital and Anr*, which declared “consent of the patient is required for transfusion of blood.... Surgery carries risks, but blood transfusion carries additional risks.<sup>[31]</sup>”

Informed consent must be a written document explaining the risks, benefits and alternatives to transfusion<sup>[32,33]</sup> taken after a dialogue between the treating physician and the transfusion recipient. For minors and unconscious patients the next of kin should sign an informed consent. Authors also feel that it is safer to have a neutral witness in the case of high-risk transfusions, like autoimmune haemolytic anaemia.

#### **Positive patient identification**

A documented method/protocol for positive (correct) patient identification is essential. Absence of this may lead to wrong transfusions and may be construed as negligence on the part of the doctors. Use of wrist bands is one-way of achieving this. Clerical errors account for the majority of preventable adverse transfusion reactions.<sup>[34]</sup>

#### **Monitoring transfusion**

Transfusion should be prescribed and administered under medical direction. National (NACO) guidelines recommend continuous supervision during transfusion.

Most international guidelines<sup>[35]</sup> recommend monitoring the vital signs before the start of transfusion (time 0), 15 min after transfusion, completion of transfusion and 1 h post-transfusion for delayed reactions. A transfusion card developed on the lines of the drug card to document patient demographic data and vital signs along with details of the unit administered will help in correct and complete documentation.

#### **Failure to amalgamate good manufacturing practices with good clinical practices**

The clinical establishment (registration and regulation act 2010) if implemented will go a long way in blending of good manufacturing practices with good clinical practices guidelines and can bring blood bankers closer to clinicians and help in delivery of safer transfusion practices. This is, unfortunately, implemented to a small extent in some states only.

## **CHANGING FACE OF TRANSFUSION MEDICINE IN INDIA**

Thankfully things are changing in India. Non-governmental organisations can be credited for

improving voluntary blood donation with support from NACO. Private hospitals are trying to improve the quality by focusing on emerging technologies. The industry must be credited for pushing improved testing in the form of NAT, antibody screening, antigen typing, better blood bags, leukoreduction and bacterial detection systems. The transfusion medicine associations like Indian Society of Transfusion Medicine and Asian association of Transfusion Medicine also deserve credit for the reforms that we see with respect to blood usage. Whole blood is a thing of the past and now in many good institutions technologies like leukoreduction, irradiation is a routine practice. We have a National Accreditation Board for Hospitals and Healthcare Providers (NABH) accreditation programme exclusively for blood banks, run by Quality Council of India (QCI). We also have a National Haemovigilance Program of India<sup>[36]</sup> to monitor recipient adverse transfusion reactions, but these being voluntary programs, participation is limited.

## ETHICAL ISSUES IN SAFE BLOOD TRANSFUSION

Hospital based blood banks are compelled to practice replacement donations as they are denied permission to hold camps. Scientifically, directed donations are to be discouraged, but practically they are sought after by recipients and physicians, posing an ethical challenge to blood bankers. All blood bankers would like to use blood judiciously as blood components, however demand for whole blood leads to the contrary. The transfusion trigger for red cells was set at 10 g/dl at the turn of the 20<sup>th</sup> century as it left little room for anaesthetic errors.<sup>[37]</sup> This has changed considerably over the years. However, some anaesthetists refuse to administer anaesthesia unless the haemoglobin is up to their expectation leading to unnecessary transfusions. A blood bank doing life-saving procedures like erythropheresis, plasma exchange, not mentioned in the D and C Act is scientifically and ethically correct, but may be legally incorrect. NBTC prescribes differential rates for different blood components, based on economic considerations, rather than ethical considerations. If the money is for processing only, then all components should be priced uniformly. Blood bankers are expected by community to provide the highest quality blood, free or at a low price, which maybe ethically right but economically unviable. Ethical practices need to be implemented by management and staff of blood banks. Conflict of interest involving management and staff of blood

banks need to be avoided to ensure ethical practices especially with reference to manufacturers/suppliers of kits and reagents. Hierarchy of reporting should be clearly delineated with checks and balances to avoid bias and ensure that science and ethics play a more important part than commerce in the practice of transfusion medicine.

Absence of transfusion triggers poses an ethical challenge to blood bankers, as the treating physician who goes by his instinct is always right. The community perceives blood bankers as businessman selling blood to earn a livelihood. In reality blood bankers are one of the poorly paid professionals compared to other clinical specialties. If blood bankers need minimum qualification to run a blood bank, so do drug inspectors. Drug inspectors must be trained for at least a year in the basics of blood banking, apheresis and molecular biology before inspecting blood banks. Inspection team should be drawn from a list of experts with blood banking experience lead by a technical expert and should include the drugs controller.

## SUMMARY

The D and C Act needs to be reviewed every 2 years, to keep in tune with the changing times and needs to be modified to state that in the event of any component or procedure not included in the D and C Act, the same may be performed by the blood bank as per standards laid down by NACO/NABH. NBTC should engage in the licensing process more actively. Dual licensing system by state and centre should be abolished, and the licensing procedure simplified to grant/renew licenses within a maximum of 3 months. SBTCs must run one large state-of-the-art blood bank in every state to get an idea of the costing of blood, which can be employed to fix processing fees for other blood banks. Accredited regional testing centres by private players or through public-private partnership should be encouraged to ensure quality in testing and bring down cost. Suitable amendments to the act are necessary to facilitate this. Emphasis of inspection, audits should be to enhance the quality by adherence to standards and protocols and must facilitate smooth functioning of blood banks. Licensing should not become a hindrance to the adoption of safe transfusion practices.

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