



सत्यमेव जयते

Ministry of Health & Family Welfare
Government of India

COMPENDIUM NATIONAL BLOOD POLICY AND GUIDELINES 2016



National Blood Transfusion Council
Ministry of Health & Family Welfare
Government of India



NBTC

राष्ट्रीय रक्त संचरण परिषद्
National Blood Transfusion Council

First Edition 2016

The compendium 2016 is a collection of National Blood Policy and important guidelines issued by National Blood Transfusion Council from time to time. They prevail over all earlier guidelines. The policy decision making is a continuous process and efforts will be made to update the compendium as and when required.

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National Blood Transfusion Council

INDIA

(Governing Board- As per GOI ORDER No S.12016/05/2012-NACO-NBTC, Dated 28th January 2015)

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Message

Blood Transfusion Services (BTS) is an integral component of modern health care system without which efficient medical care is impossible. Provisioning adequate, safe and quality blood supply is the responsibility of the Government.

There are total 2760 licensed blood banks in the country spread across 676 districts. The annual requirement calculated based on the norm of 1% of population is 12 million units, of which annual blood collection is 10.8 million. The voluntary contribution to the total collection is reported to be 78 %, but there is a rampant reliance on replacement blood donation which requires to be phased out. The gap between demand and supply also needs bridging. Thus a wide spread campaign for voluntary blood donation is need of the hour.

Out of the 676 districts in the country, 72 districts do not have even one blood bank. States must step up their efforts to establish blood banks at such districts on priority with the assistance from ongoing centrally sponsored health programs and making adequate provision for the same in the State budget.

Evidence exists that a well-organized, nationally coordinated blood transfusion service is a prerequisite for a safer and more cost-effective blood supply than a hospital based system or other fragmented system. This allows blood and blood products to be equitable, safe, accessible and adequate to meet the transfusion requirement of patients.

Efforts are being made by National Blood Transfusion Council to develop centrally coordinated transfusion services through strengthened and effective functioning of State Blood Transfusion Councils. National Transfusion services core coordination committee has proposed amendments to Drugs & Cosmetic Act 1940 and Rules 1945 there upon, which are under process.

This compendium of policy and guidelines issued by NBTC will help the State authorities to plan and organize blood transfusion services in conformity with the National Blood Policy.

28 January 2016

Director, National Blood Transfusion Council

DOCUMENT-1



National Blood Policy

National AIDS Control Organisation
Ministry of Health and Family Welfare
Government of India
New Delhi



National Blood Policy

NBTC

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National Blood Transfusion Council



National AIDS Control Organisation
Ministry of Health and Family Welfare
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Introduction

A well organised Blood Transfusion Service (BTS) is a vital component of any health care delivery system. An integrated strategy for Blood Safety is required for elimination of transfusion transmitted infections and for provision of safe and adequate blood transfusion services to the people. The main component of an integrated strategy include collection of blood only from voluntary, non-remunerated blood donors, screening for all transfusion transmitted infections and reduction of unnecessary transfusion.

The Blood Transfusion Service in the country is highly decentralised and lacks many vital resources like manpower, adequate infrastructure and financial base. The main issue, which plagues blood banking system in the country, is fragmented management. The standards vary from state to state, cities to cities and centre to centre in the same city. In spite of hospital based system, many large hospitals and nursing homes do not have their own blood banks and this has led to proliferation of stand-alone private blood banks.

The blood component production/availability and utilisation is extremely limited. There is shortage of trained health-care professionals in the field of transfusion medicine.

For quality, safety and efficacy of blood and blood products, well-equipped blood centres with adequate infrastructure and trained manpower is an essential requirement.

For effective clinical use of blood, it is necessary to train clinical staff. To attain maximum safety the requirements of good manufacturing practices and implementation of quality system moving towards total quality management, have posed a challenge to the organisation and management of blood transfusion service.

Thus, a need for modification and change in the blood transfusion service has necessitated formulation of a National Blood Policy and development of a National Blood Programme which will also ensure implementation of the directives of Supreme Court of India - 1996.

Mission Statement

THE policy aims to ensure easily accessible and adequate supply of safe and quality blood and blood components collected/procured from a voluntary non-remunerated regular blood donor in well equipped premises, which is free from transfusion transmitted infections, and is stored and transported under optimum conditions. Transfusion under supervision of trained personnel for all who need it irrespective of their economic or social status through comprehensive, efficient and the total quality management approach will be ensured under the policy.

OBJECTIVES OF THE POLICY:

To achieve the above aim, the following objectives are drawn:

1. To reiterate firmly the Govt. commitment to provide safe and adequate quantity of blood, blood components and blood products.
2. To make available adequate resources to develop and re-organise the blood transfusion services in the entire country.
3. To make latest technology available for operating the blood transfusion services and ensure its functioning in an updated manner.
4. To launch extensive awareness programmes for donor information, education, motivation, recruitment and retention in order to ensure adequate availability of safe blood.
5. To encourage appropriate clinical use of blood and blood products.
6. To strengthen the manpower through human resource development.
7. To encourage Research & Development in the field of transfusion medicine and related technology.
8. To take adequate regulatory and legislative steps for monitoring and evaluation of blood transfusion services and to take steps to eliminate profiteering in blood banks.

OBJECTIVE – 1

To reiterate firmly the Govt. commitment to provide safe and adequate quantity of blood, blood components and blood products.

STRATEGY:

- 1.1** A national blood transfusion Programme shall be developed to ensure establishment of non-profit integrated National and State Blood Transfusion Services in the country.
 - 1.1.1** National Blood Transfusion Council (NBTC) shall be the policy formulating apex body in relation to all matters pertaining to the operation of blood centres. National AIDS Control Organisation (NACO) shall allocate a budget to NBTC for strengthening Blood Transfusion Service.
 - 1.1.2** State/UT Blood Transfusion Councils shall be responsible for implementation of the Blood Programme at State/UT level, as per the recommendations of the National Blood Transfusion Council.
 - 1.1.3** Mechanisms for better co-ordination between NBTC and SBTCs shall be developed by the NBTC.
 - 1.1.4** Mechanisms shall be developed to monitor and periodically evaluate the implementation of the National Blood Programme in the country.
 - 1.1.5** The enforcement of the blood and blood products standards shall be the responsibility of Drugs Controller General (India) as per Drugs and Cosmetics Act/Rules, with assistance from identified experts.
 - 1.1.6** NBTC shall ensure involvement of other Ministries and other health programmes for various activities related to Blood transfusion services.
- 1.2.** Trading in blood i.e. Sale & purchase of blood shall be prohibited.
 - 1.2.1** The practice of replacement donors shall be gradually phased out in a time bound programme to achieve 100% voluntary non-remunerated blood donation programme.
 - 1.2.1.1** State/UT Blood Transfusion Councils shall develop an action plan to ensure phasing out of replacement donors.
- 1.3** The following chain of Transfusion Services shall be promoted for making available of safe blood to the people.
 - 1.3.1** State Blood Transfusion Councils shall organise the blood transfusion service through the network of Regional Blood Centres and Satellite Centres and other Government, Indian Red Cross Society & NGO run blood centres and monitor their functioning. All Regional Centres shall be assigned an area around in which the other blood banks and hospitals which are linked to the regional centre will be assisted for any requirement and shall be audited by the Regional Centre. It will also help the State Blood Transfusion Council in collecting the data from this region.

OBJECTIVE – 1

- 1.3.2** The Regional Centres shall be autonomous for their day to day functioning and shall be guided by recommendations of the State/UT Blood Transfusion Councils. The Regional Centre shall act as a referral centre for the region assigned to it.
- 1.3.3** NBTC shall develop the guidelines to define NGO run blood centres so as to avoid profiteering in blood banking.
- 1.4** Due to the special requirement of Armed Forces in remote border areas, necessary amendments shall be made in the Drugs & Cosmetics Act/Rules to provide special licenses to small garrison units. These units shall also be responsible for the civilian blood needs of the region.

OBJECTIVE – 2

To make available adequate resources to develop and re-organise the blood transfusion services in the entire country.

STRATEGY:

- 2.1** National & State/UT Blood Transfusion Councils shall be supported/strengthened financially by pooling resources from various existing programmes and if possible by raising funds from international/bilateral agencies.
- 2.2** Efforts shall be directed to make the blood transfusion service viable through non-profit recovery system.
 - 2.2.1** National Blood Transfusion Council shall provide guidelines for ensuring non-profit cost recovery as well as subsidised system.
 - 2.2.2** Efforts shall be made to raise funds for the blood transfusion service for making it self-sufficient.
 - 2.2.3** The mechanism shall be introduced in government sector to route the amounts received through cost recovery of blood/blood components to the blood banks for improving their services.

OBJECTIVE – 3

To make latest technology available for operating the blood transfusion services and ensure its functioning in an updated manner.

STRATEGY:

- 3.1** Minimum standards for testing, processing and storage shall be set and ensured.
 - 3.1.1.** Standards, Drugs & Cosmetics Act/Rules and Indian Pharmacopoeia shall be updated as and when necessary.
 - 3.1.2.** All mandatory tests as laid down under provisions of Drugs & Cosmetics Act/Rules shall be enforced.
 - 3.1.3.** Inspectorate of Drugs Controller of India and State FDA shall be strengthened to ensure effective monitoring.
 - 3.1.4.** A vigilance cell shall be created under Central/State Licensing Authorities.
- 3.2** A Quality System Scheme shall be introduced in all blood centres.
 - 3.2.1** Quality Assurance Manager shall be designated at each Regional Blood Centre/any blood centre collecting more than 15,000 units per year to ensure quality control of Blood & its components in the region assigned. He shall be exclusively responsible for quality assurance only.
 - 3.2.2** Every blood centre shall introduce an internal audit system to be followed by corrective actions to reduce variations in Standard Operating Procedures (SOPs) as a part of continuous improvement programme.
 - 3.2.3** Regular workshops on the subject of quality assurance shall be conducted to update the personnel working in blood centres.
 - 3.2.4** Regular proficiency testing of personnel shall be introduced in all the blood centres.
- 3.3** An External Quality Assessment Scheme (EQAS) through the referral laboratories approved by the National Blood Transfusion Council shall be introduced to assist participating centres in achieving higher standards and uniformity.
 - 3.3.1** Reference centres shall be identified in each State/UT for implementation of EQAS. All blood centres shall be linked to these reference centres for EQAS.
 - 3.3.2** NBTC shall identify a centre of national repute for quality control of indigenous as well as imported consumables, reagents and plasma products.
- 3.4** Efforts shall be made towards indigenisation of kits, equipment and consumables used in blood banks.
- 3.5** Use of automation shall be encouraged to manage higher workload with increased efficiency.
- 3.6** A mechanism for transfer of technology shall be developed to ensure the availability of state-of-the-art technology from outside India.

OBJECTIVE – 3

- 3.7** Each blood centre shall develop its own Standard Operating Procedures on various aspects of Blood Banking.
- 3.7.1** Generic Standard Operating Procedures shall be developed by the National Blood Transfusion Council as guidelines for the blood centres.
- 3.8** All blood centres shall adhere to bio-safety guidelines as provided in the Ministry of Health & Family Welfare manual 'Hospital-acquired Infections : Guidelines for Control' and disposal of bio-hazardous waste as per the provisions of the existing Biomedical Wastes (Management & Handling) Rules - 1996 under the Environmental Protection Act - 1986.



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National Blood Transfusion Council

OBJECTIVE – 4

To launch extensive awareness programmes for donor information, education, motivation, recruitment and retention in order to ensure adequate availability of safe blood.

STRATEGY:

- 4.1** Efforts shall be directed towards recruitment and retention of voluntary, non-remunerated blood donors through education and awareness programmes.
 - 4.1.1** There shall not be any coercion in enrolling replacement blood donors.
 - 4.1.2** The replacement donors shall be encouraged to become regular voluntary blood donors.
 - 4.1.3** Activities of NGOs shall be encouraged to increase awareness about blood donation amongst masses.
 - 4.1.4** All blood banks shall have donor recruitment officer/ donor organiser.
 - 4.1.5** Each blood centre shall create and update a blood donor's directory which shall be kept confidential.
 - 4.1.6** In order to increase the donor base specific IEC campaigns shall be launched to involve youth in blood donation activities.
- 4.2** Enrolment of safe donors shall be ensured.
 - 4.2.1** Rigid adherence to donor screening guidelines shall be enforced.
 - 4.2.2** At blood donation camps, appropriate attention shall be paid on donor enrolment and screening in accordance with national standards instead of number of units collected.
 - 4.2.3** A Counsellor in each bloodcentre shall be appointed for pre and post donation counselling.
 - 4.2.4** Result seeking donors shall be referred to a Blood Testing Centre (BTC) for post donation information and counselling.
- 4.3** State/UT Blood Transfusion Councils shall recognise the services of regular voluntary non-remunerated blood donors and donor organisers appropriately.
- 4.4** National/State/UT Blood Transfusion Councils shall develop and launch an IEC campaign using all channels of communication including mass-media for promotion of voluntary blood donation and generation of awareness regarding dangers of blood from paid donors and procurement of blood from unauthorised blood banks/laboratories.
- 4.5** National / State / UT blood transfusion councils shall involve other departments / sectors for promoting voluntary blood donations.

OBJECTIVE – 5

To encourage appropriate clinical use of blood and blood products.

STRATEGY:

- 5.1** Blood shall be used only when necessary. Blood and blood products shall be transfused only to treat conditions leading to significant morbidity and mortality that cannot be prevented or treated effectively by other means.
- 5.2** National Guidelines on '**Clinical use of Blood**' shall be made available and updated as required from time to time.
- 5.3** Effective and efficient clinical use of blood shall be promoted in accordance with guidelines.
 - 5.3.1** State/UT Governments shall ensure that the Hospital Transfusion Committees are established in all hospitals to guide, monitor and audit clinical use of blood.
 - 5.3.2** Wherever appropriate, use of plasma expanders shall be promoted to minimise the use of blood.
 - 5.3.3** Alternative strategies to minimise the need for transfusion shall be promoted.
- 5.4** Education and training in effective clinical use of blood shall be organised.
 - 5.4.1** Medical Council of India shall be requested to take following initiatives:
 - 5.4.1.1** To introduce Transfusion Medicine as a subject at undergraduate and all post graduate medical courses.
 - 5.4.1.2** To introduce posting for at least 15 days in the department of transfusion medicine during internship.
 - 5.4.1.3** To include Transfusion Medicine as one of the subjects in calculating credit hours for the renewal of medical registration by Medical Council of India, if it is introduced.
 - 5.4.2** CME and workshops shall be organised by State Blood Transfusion Councils in collaboration with professional bodies at regular intervals for all clinicians working in private as well public sector in their States.
- 5.5** Blood and its components shall be prescribed only by a medical practitioner registered as per the provisions of Medical Council Act - 1956.
- 5.6** Availability of blood components shall be ensured through the network of regional centres, satellite centres and other blood centres by creating adequate number of blood component separation units.
- 5.7** Appropriate steps shall be taken to increase the availability of plasma fractions as per the need of the country through expanding the capacity of existing centre and establishing new centres in the country.
- 5.8** Adequate facilities for transporting blood and blood products including proper cold-chain maintenance shall be made available to ensure appropriate management of blood supply.
- 5.9** Guidelines for management of blood supply during natural and man made disasters shall be made available.

OBJECTIVE – 6

To strengthen the manpower through Human Resource Development.

STRATEGY:

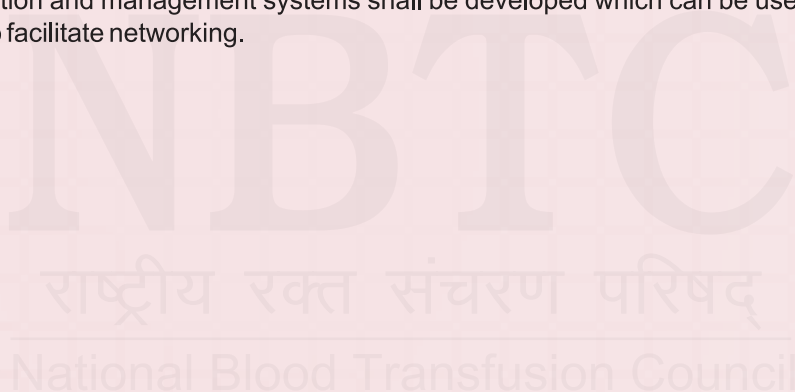
- 6.1** Transfusion Medicine shall be treated as a speciality.
 - 6.1.1** A separate Department of Transfusion Medicine shall be established in Medical Colleges.
 - 6.1.2** Medical Colleges/Universities in all States shall be encouraged to start PG degree (MD in Transfusion Medicine) and diploma courses in Transfusion Medicine.
 - 6.1.3** PG courses for technical training in transfusion medicine (PhD / MSc) shall also be encouraged.
- 6.2** In all the existing courses for nurses, technicians and pharmacists, Transfusion Medicine shall be incorporated as one of the subjects.
- 6.3** In-service training programmes shall be organised for all categories of personnel working in blood centres as well as drug inspectors and other officers from regulatory agencies.
- 6.4** Appropriate modules for training of Donor Organisers/Donor Recruitment Officers shall be developed to facilitate regular and uniform training programmes to be conducted in all States.
 - 6.4.1** Persons appointed as Donor Organisers/Donor Recruitment Officers shall undergo training for Donor Motivation and Recruitment organised by State Blood Transfusion Councils.
- 6.5** Short orientation training cum advocacy programmes on donor motivation and recruitment shall be organised for Community Based Organisations (CBOs) and NGOs who wish to participate in Voluntary Blood Donor Recruitment Programme.
- 6.6** Inter-country and intra-country exchange for training and experience of personnel associated with blood centres shall be encouraged to improve quality of Blood Transfusion Service.
- 6.7** States/UTs shall create a separate cadre and opportunities for promotions for suitably trained medical and para medical personnel working in blood transfusion services.

OBJECTIVE – 7

To encourage Research & Development in the field of Transfusion Medicine and related technology.

STRATEGY:

- 7.1** A corpus of funds shall be made available to NBTC/SBTCs to facilitate research in transfusion medicine and technology related to blood banking.
- 7.2** A technical resource core group at national level shall be created to co-ordinate research and development in the country. This group shall be responsible for recommending implementation of new technologies and procedures in coordination with DC(I).
- 7.3** Multi-centric research initiatives on issues related to Blood Transfusion shall be encouraged.
- 7.4** To take appropriate decisions and/or introduction of policy initiatives on the basis of factual information, operational research on various aspects such as various aspects of Transfusion Transmissible Diseases, Knowledge, Attitude and Practices (KAP) among donors, clinical use of blood, need assessment etc shall be promoted.
- 7.5** Computer based information and management systems shall be developed which can be used by all the centres regularly to facilitate networking.



OBJECTIVE – 8

To take adequate regulatory and legislative steps for monitoring and evaluation of blood transfusion services and to take steps to eliminate profiteering in blood banks.

STRATEGY:

- 8.1** For grant/renewal of blood bank licenses including plan of a blood bank, a committee, comprising of members from State/ UT Blood Transfusion Councils including Transfusion Medicine expert, Central & State/UT FDAs shall be constituted which will scrutinise all applications as per the guidelines provided by Drugs Controller General (India).
- 8.2** Fresh licenses to stand-alone blood banks in private sector shall not be granted. Renewal of such blood banks shall be subjected to thorough scrutiny and shall not be renewed in case of non-compliance of any condition of license.
- 8.3** All State/UT Blood Transfusion Councils shall develop a State Action Plan for the State/UT Blood Transfusion Service where in Regional Blood Transfusion Centres shall be identified. These centres shall be from Government, Indian Red Cross Society or other NGO run blood banks of repute. Approved regional blood centres/government blood centres/Indian red cross blood centres shall be permitted to supply blood and blood products to satellite centres which are approved by the committee as described in para 8.1. The Regional Centre shall be responsible for transportation, storage, cross-matching and distribution of blood and blood products through satellite centres.
- 8.4** A separate blood bank cell shall be created under a senior officer not below the rank of DDC(I) in the office of the DC(I) at the headquarter. State/UT Drugs Control Department shall create such similar cells with the trained officers including inspectors for proper inspection and enforcement.
- 8.5** As a deterrent to paid blood donors who operate in the disguise of replacement donors, institutions who prescribe blood for transfusion shall be made responsible for procurement of blood for their patients through their affiliation with licensed blood centres.
- 8.6** States/UTs shall enact rules for registration of nursing homes wherein provisions for affiliation with a licensed blood bank for procurement of blood for their patients shall be incorporated.
- 8.7** The existing provisions of drugs & Cosmetics Rules will be periodically reviewed to introduce stringent penalties for unauthorised/irregular practices in blood banking system.

DOCUMENT-2



**National Policy For
Access To
Plasma Derived Medicinal Products
From Human Plasma For
Clinical / Therapeutic Use:**

**Addendum To
National Blood Policy 2003**



**National Policy for
Access to
Plasma Derived Medicinal Products
from Human Plasma for
Clinical / Therapeutic Use:
Addendum to
National Blood Policy 2003**

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National Blood Transfusion Council



**Department of AIDS Control
Ministry of Health & Family Welfare,
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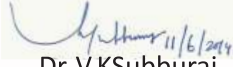


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सवास्थ्य एवं परिवार कल्याण मंत्रालय
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Department of AIDS Control provides guidelines for the blood collection, preparation of blood components and manufacturing of plasma-derived medicinal products (PDMPs) in order to optimize the use of human blood. These guidelines are aligned with National Blood Policy and scaling up of facilities for blood component separation is being established. Thus, increasing volumes of human plasma is being recovered in the blood banks, which has been tested and found safe for clinical use, stored under appropriate conditions.

Plasma has limited utility in its raw form for various coagulopathies, plasma exchange, etc., but is one such important blood component is the raw material for the manufacture of many more life saving proteins of immense clinical significance. At present, all the recovered plasma is not being used clinically or for Plasma fractionation. The policy aims at enabling the mobilization of this excess plasma stocks from blood banks to the plasma fractionation units in order to obtain higher value products than can be made available for wider and easily accessible clinical use. As these products are not available in adequate quantities, to meet the clinical requirements, huge gap of demand and supply of life saving PDMPs, exist in our country.

The policy on unutilized plasma aims at making available, easily accessible and adequate supply of high quality of human plasma derived proteins for clinical/therapeutic use. Thus a step forward to decrease the gap of demand-supply of PDMPs and bring about self sufficiency in safe blood and blood products, based on voluntary non remunerated blood donors, in due course of time.


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अपनी एच आई वी अवस्था जाने, निकटतम सरकारी अस्पताल में मुफ्त सलाह व जांच पायें
Know your HIV status, go to the nearest Government hospital for free Voluntary Conselling and testing

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Introduction

The Plasma Policy aims at making available, easily accessible and adequate supply of high quality of human plasma derived proteins for clinical/ therapeutic use. The plasma is prepared as part of safe and quality blood and blood components collected/procured from a voluntary non-remunerated regular blood donor in well-equipped premises, which is free from transfusion transmitted infections, and is stored and transported under optimum conditions.

Plasma has limited utility in its raw form for various coagulopathies, plasma exchange, etc, but is one such important blood component is the raw material for the manufacture of many more lifesaving proteins of immense clinical significance. Such proteins are known as Plasma Derived Medical Products (PDMPs). Examples of PDMPs include Albumin, coagulant proteins such as FVIII, immunoglobulin's such as IVIG and hyperimmunes products from specialized source plasma HBlg, Tetanus Ig etc.

Plasma forms the raw material for the manufacture of Plasma Derived Proteins (PDMPs). Currently plasma derived proteins are manufactured within the country in limited quantity by existing Plasma Fractionation Centres. These centres fractionate the unused plasma recovered from whole blood at various licensed blood component separation units of the country but since the plasma availability in the country is limited, a significant quantity of PDMPs, plasma or its intermediates are obtained through import from other countries.

At present, all the recovered plasma is not being used clinically or for plasma fractionation. The policy aims at enabling the mobilization of this excess plasma stocks at the blood banks for fractionation to make some more high value products, which hitherto are not often available in adequate quantities to meet the increasing clinical requirements.

The process of collecting standard plasma and transporting them under optimum conditions for fractionation, identifying critical parameters for safety, ensuring compliance with regulatory requirements, training for the appropriate usage of these products will be covered under this policy. The policy reiterates the endeavor of the government to facilitate supply of affordable products to the needy, regardless of their economic status. The policy will result in a comprehensive way to optimize usage of plasma for the manufacture of high quality blood components, and make our country self-reliant and standardize their availability and utilization through comprehensive, efficient and a total quality management approach.

Objectives of the Policy

To achieve the aim of facilitating national access to Plasma Derived Medical Products (PDMPs) for clinical/therapeutic use, the following objectives are drawn:

1. To reiterate that Government will facilitate availability and utilization of safe and adequate quantity of plasma derived products for clinical/ therapeutic use.
2. To make available adequate resources to develop and organize the plasma/ PDMPs mobilization throughout the country.
3. To take adequate Regulatory and Legislative steps for monitoring of the activities related to plasma derived products.
4. To encourage Research & Development in the field of blood components, plasma fractionation and plasma derived products.
5. To strengthen Quality Systems in Blood Transfusion Services for plasma collection, transportation, processing, production and distribution of PDMPs.

OBJECTIVE 1

To reiterate that Government will facilitate availability of safe and adequate quantity of plasma derived products for clinical/ therapeutic use.

STRATEGY:

- 1.1 To augment set up & functioning of Blood Component Separation Units (BCSU), including plasma pheresis, with the help of national and state blood transfusion services in the country in order to optimize recovery and utilization of surplus plasma as raw material for plasma fractionation and manufacturing of PDMPs.
- 1.2 To establish guidelines for plasmapheresis, to collect source plasma for fractionation.
- 1.3 To establish a mechanism in place for appropriate transfer of plasma from BCSU to warehouses / Plasma Fractionation Centers (PFC).
- 1.4 To standardize screening of plasma for infections prior to further processing for fractionation.
- 1.5 To put in place mechanisms to improve co-ordination and interaction between various BCSU and plasma warehouses/PFCs in order to achieve desired end product quality.
- 1.6 To advocate for effective and judicious clinical use of human plasma and PDMPs to minimize unwarranted use of whole blood/ plasma/PDMPs.
- 1.7 To formulate national guidelines on 'Clinical use of plasma derived products' and update as required from time to time.
- 1.8 To review plasma (raw material for fractionation) / PDMPs (finished products for clinical use) utilization by various facilities acting as an end user individuals / organizations.
- 1.9 To promote interdepartmental activities with all concerned including other Ministries, stakeholders and health programs that would help optimize production & utilization of PDMPs.
- 1.10 To facilitate access and availability of PDMPs to cater to special requirement including remote locations will be done with closed coordination with DGAFMS.
- 1.11 To establish evidence based latest technology and time to time upgradation to bring about self-sufficiency for PDMPs.
- 1.12 To participate in public private partnership/ collaborations to improve production and improve availability of PDMPs.
- 1.13 To evolve mechanisms for periodical review and evaluate the implementation of the policy across the country.

OBJECTIVE 2

To make available adequate resources to develop and organize the plasma mobilization throughout the country.

STRATEGY:

- 2.1 To support/ strengthen the existing network of Blood Transfusion Services (BTS) so as to consolidate and improve blood and plasma donor base, blood componentization and recovery of safe and good quality of plasma.
 - 2.1.1 To allocate resources and funds in existing public health programs as well as advocate for resource allocation by corporate sectors, bilateral/international agencies for plasma mobilization.
 - 2.1.2 To additionally strengthen source plasma collection through licensed plasma collection centers across country existing BCSU/ Apheresis/ Blood banks with capacity of conducting plasmapheresis.
- 2.2 To ensure engagement of trained manpower at all levels to facilitate plasma mobilization.
- 2.3 To ensure proper infrastructure, equipment and transportation facilities to have high quality of plasma.
- 2.4 To direct efforts towards recruitment and retention of voluntary, non-remunerated blood donors, through education and awareness programs also incorporating IEC strategies, NGO involvement, special donor registries for hyperimmune products etc. as an integral part of voluntary blood donation programs.
- 2.5 To standardize pricing, with the help of existing policies/ resources, to ensure not for profit but techno-financial viable and self-sustaining mechanisms of various types plasma, used as raw material, and PDMPs.

OBJECTIVE 3

To take adequate Regulatory and Legislative steps for monitoring of activities related to plasma derived products.

STRATEGY:

- 3.1 Formulate regulations to ensure 80% componentization of whole blood and mandatory channelization of excess unutilized plasma for fractionation.
- 3.2 Legislative steps to legalize the collection of source plasma for fractionation and licensing mechanism for establishment of plasma collection centers to collect source plasma.
- 3.3 To facilitate the regulatory approval of updated methodology with the purpose of increasing plasma recovery from donated blood.

OBJECTIVE 3

- 3.4 To review the regulatory framework with respect to availability/ manufacturing and distribution of acceptable quality of PDMPs for clinical use.
- 3.5 To review and update Standards, Drugs & Cosmetics Act/Rules and Indian Pharmacopoeia, with respect to national blood policy, from time to time.
- 3.6 To periodically review the existing provisions of prevailing regulatory frameworks as well as introduce stringent penalties for unauthorized/irregular practices in plasma processing and delivery of PDMPs.

OBJECTIVE 4

To encourage Research & Development in the field of blood components, plasma fractionation and plasma derived products.

STRATEGY:

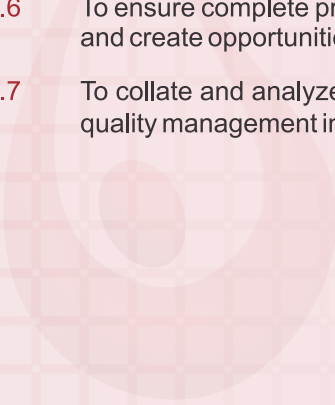
- 4.1 To organize capacity building/exposure visit & hands on training of personnel dealing with plasma fractionation, related to all process and quality aspects.
- 4.2 To facilitate research in blood components, plasma fractionation and PDMPs in association with recognized national and international bodies including ICMR, DST and DCG.
- 4.3 To make available financial support for the conduct of R&D in processing of plasma & PDMPs through various channels.
- 4.4 To collaborate with industry and academia to launch blood products faster and promote Inter- country and intra-country exchange for training and experience of personnel associated with plasma fractionation.
- 4.5 To direct efforts towards development of indigenous kits / processes and technology, to make them cost competitive.
- 4.6 To facilitate evidence based practices in research involving utilization of human plasma/ blood, from units unused/ discarded from blood banks due to any reason and evolve a regulatory framework there of.

OBJECTIVE 5

To strengthen Quality Systems in Blood Transfusion Services for plasma collection, transportation, processing, production and distribution of PDMPs.

STRATEGY:

- 5.1 To set national quality standards covering all aspects in manpower, equipment, processes, procedures, products and quality systems.
- 5.2 To articulate a continuous all round improvement program in plasma fractionation as part of quality systems as an endeavor to work towards gold standards.
- 5.3 To mandate that Plasma Fractionating Centres allocate resources for improving the quality of plasma as a raw material to linked BCSU in form of manpower, equipment, logistics etc.
- 5.4 To encourage training programs to ensure proficiency, accreditation and other changing quality parameters from time to time.
- 5.5 To encourage higher standards and uniformity, External Quality Assurance Scheme (EQAS) shall be introduced through the referral laboratories approved by the National Blood Transfusion Council.
- 5.6 To ensure complete process control with sound documentation system, to inculcate data sharing and create opportunities to promote learning and growth.
- 5.7 To collate and analyze the data and share with all stakeholders, regularly as a part of the larger quality management initiative in the area of plasma fractionation.


राष्ट्रीय रक्त संचरण परिषद्
National Blood Transfusion Council

DOCUMENT-3 :

ROLE AND FUNCTIONS OF NATIONAL BLOOD TRANSFUSION COUNCIL (NBTC)

Role and functions of National Blood Transfusion Council (NBTC)

The National Blood Transfusion Council (NBTC) is a society registered under the societies registration act. It is a representative body having representation from the Directorate General of Health Services, Drug Controller General of India Govt. of India, representatives from Ministry of Finance, Govt. of India, Indian Red Cross Society, major medical institutions in the country, representatives from private blood banks & N.G.O. run blood banks under the presidentship of the Additional secretary & project director NACO. The NBTC is the policy formulating apex body for all matters pertaining to the organisation, operation, standards and training of a sustainable and safe blood transfusion service for the country. The responsibilities of NBTC encompass:

Administrative:

- Developing a mechanism for better coordination between NBTC and SBTC and compliance by SBTC of decisions taken by NBTC.
- Identifying and/or assisting in establishing institutions for research and development in the field of transfusion services.
- Taking appropriate steps to increase the availability of plasma fractions as per the need of the country through expanding the capacity of existing centre and facilitating in establishing new centres.
- Developing policies for levying service charge for blood and blood products.
- Developing a management information system for networking of transfusion services in the country.
- Providing technical, financial and managerial assistance to SBTC as needed to implement the national blood programme.
- Appeals and applications for money and funds in furtherance of the objectives of the NBTC and to accept for the aforesaid purpose gifts, donations, contributions, grants, financial assistances and subscriptions of cash and securities of any property whether movable or immovable from individuals or organisations.
- Creation of administrative, technical and ministerial and other posts under the society and to make appointments thereto in accordance with the rules and regulations of the societies.
- Printing, publishing and exhibiting any papers, posters, pamphlets, periodicals and books for furtherance of the objects of the NBTC.
- Providing guidelines for ensuring non-profit cost recovery as well as subsidised system for blood & blood components.

- Doing all such lawful things as are conducive or incidental to attainment to the objects of the National Council.
- Attending to matters related to property and financial issues as related to the NBTC.
- Preparing guidelines for management of blood supply during disasters.
- Involving other ministries and other health programmes for all activities related to BTS.

National and International Linkages

- Exchange of information and expertise with other institutions, associations, societies and international organisations engaged and interested in the subjects similar to those of the NBTC.
- Encourage inter and intra country exchange programmes for training and experience of personnel associated with blood banks to improve their quality.

Quality Assurance

- Developing a comprehensive quality management system for the BTS including EQAS/ accreditation, appropriate infrastructure and personnel.
- Defining and documenting specifications and standards for equipment and consumables for blood centres identifying referral laboratories and establishing linkages to BTS.
- Identifying a centre of national repute of quality control of indigenous as well as imported consumables, reagents and plasma products.

Training & Research

- Training of Technicians, drug inspectors, donor motivators and medical officers in relation to all operations of blood centres.
- Initiating steps for starting special PG courses in transfusion medicine in various medical colleges and institutions in the country.
- Advocate with Medical Council of India to Incorporate transfusion medicine as one of the subjects in the existing courses for para medical personnel viz. Nurses, Technicians and Pharmacists.
- Advocate with Medical Council of India to introduce transfusion medicine as a subject in undergraduate and postgraduate courses and include transfusion medicine as one of the subjects in calculating credit hours for renewal of medical registration, if introduced.
- Introducing multi centric research initiatives on issues related to BTS.
- Creating a technical resource core group to coordinate research and development in the country.
- Developing guidelines to define NGO run blood centres so as avoid profiteering in blood banking.

DOCUMENT- 4

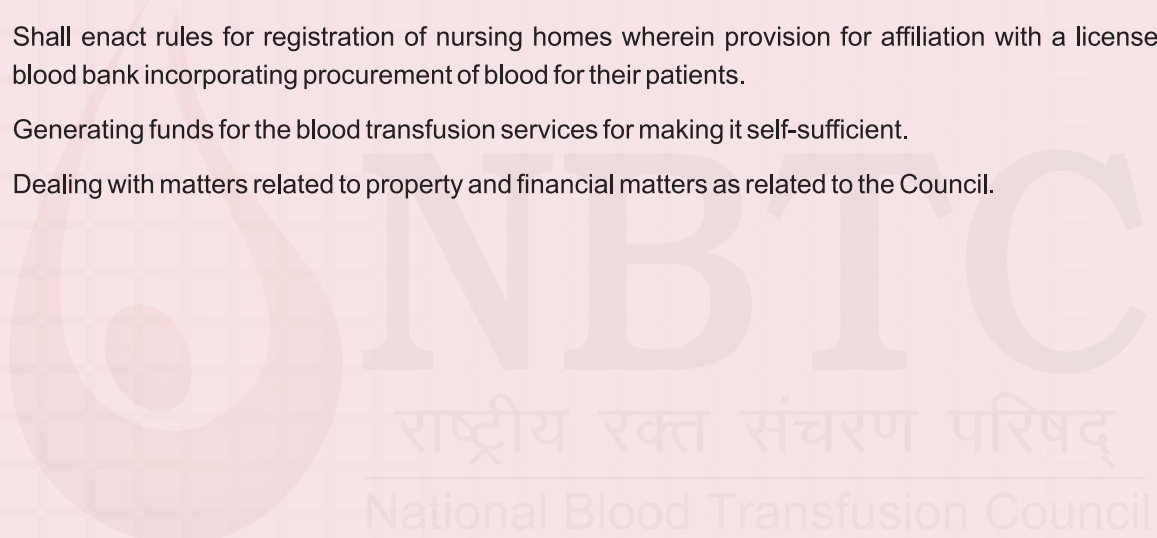
ROLE AND FUNCTIONS OF STATE BLOOD TRANSFUSION COUNCILS (SBTCs)

Role and Functions of State Blood Transfusion Councils (SBTCs)

The State Blood Transfusion Council is a society registered under the Societies registration Act. The SBTC should be a representative body having in it representation from the Directorate of Health Services in the state, State Drug Controller, Department of Finance of the State/UT, Indian Red Cross Society, private blood banks, NGO active in the field of securing voluntary blood donations. The Secretary to the Government incharge of Department of Health would be the president of the SBTC. The SBTC will be responsible for overall implementation, within individual state/UT, all policy decisions for the BTS taken by the NBTC, within the parameters of the NBP and as detailed in the Action Plan for blood safety. This encompass:

- Organising the BTS in their state /UT into a network of RBTC, BB and BSCs with participation from government, private, IRCS and other NGO run blood centres with SBTC monitoring their functioning.
- Formally linking blood banks in the State/UT to the nearest VCTC.
- Identifying RBTC across the state /UT that conform to the parameters of RBTC as defined in the action plan.
- Developing a structured donor recruitment and retention programme for the state including IEC campaigns for youth, to generate voluntary non-remunerated blood donors and phase out replacement donors.
- Implementing a mechanism to recognise the services of regular voluntary donors and donor organisers. Developing a comprehensive quality management system for the BTS in the state including EQAS/ accreditation.
- Providing adequate facilities for transporting blood and blood products including cold chain maintenance and ensuring appropriate management of blood supply.
- Equipping RBTC/ BB's with blood component separation units in sufficient numbers to make blood components available through the network of regional and satellite blood centres.

- Advocate creating department of Transfusion Medicine in medical colleges within state and in starting MD Transfusion Medicine and Diploma courses in Transfusion Medicine.
- Organise in-service training programme for all category of personnel working in the BTS including drug inspectors and other officers from regulatory agencies.
- Create a separate cadre for the blood transfusion services in the state to retain suitably trained medical and paramedical personnel in the field and improve their career prospects and opportunities for promotion.
- Make a corpus of funds available to facilitate research in transfusion medicine and technology related to blood banking.
- Ensuring adherence to bio safety guidelines and disposal of bio hazardous waste as per the provisions of the existing guidelines/rules.
- Shall enact rules for registration of nursing homes wherein provision for affiliation with a licensed blood bank incorporating procurement of blood for their patients.
- Generating funds for the blood transfusion services for making it self-sufficient.
- Dealing with matters related to property and financial matters as related to the Council.



DOCUMENT- 5

GUIDELINES ON UNIFORM PROCESSING CHARGES FOR BLOOD AND BLOOD COMPONENTS

No.S.12016/01/2012-NACO(NBTC)
Government of India
Ministry of Health and Family Welfare
Department of AIDS Control

9th Floor, Chandralok Building,
36 Janpath, New Delhi – 110001.
Dated: 12th February 2014

To,
The Director/Member Secretaries of
all State Blood Transfusion Councils

Subject: Guidelines for Recovery of Processing Charges for Blood and Blood Components-reg.

Sir/Madam,

The National Blood Transfusion Council in its 24th Governing Body Meeting held on 20.1.2014 has approved Processing Charges for Blood and Blood Components. A copy of the Guidelines approved by National Blood Transfusion Council on the subject is enclosed.

As per the guidelines, processing charges may be subsidized by the State Governments/State Blood Transfusion Councils for the blood banks in the government sector / DAC supported blood banks. The SBTCs may constitute an expert sub-committee to assess the additional testing/service being included in the processing charges required to enhance blood safety. Due diligence is expected to consider that additional charges are the maximum donated units as per testing/processing of Blood Components based on operative protocols/SOPs of the blood banks.

In continuation to this, it is mandatory for all blood banks (DAC supported and non DAC supported) to provide blood/blood component free of cost to the following patients, who requires repeated blood transfusion as a life saving measure:

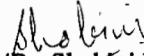
1. Thalassemia patients
2. Hemophilia patients
3. Sickle Cell anemia patients
4. Any other blood dyscrasia requiring repeated blood transfusions

State Government/SBTCs may additionally decide to provide blood/blood components free of cost to any other category of patients according to the State Government norms.

Processing charges for Blood and Blood products for below poverty line (BPL) patients accessing blood from non DAC supported blood banks shall be in compliance with the charges decided by respective State Governments/SBTC.

The order will be come into force with immediate effect.

Yours sincerely,


(Dr. Shobini Rajan)
Director, National Blood Transfusion Council

Copy to

1. The Project Directors of all SACS.
2. Website of DAC.

Encl: Guidelines of 6 pages on Processing Charges for Blood & Blood Components

Guidelines for recovery of Processing Charges for Blood and Blood Components

As per the decision taken in the 23rd Governing Body Meeting of National Blood Transfusion Council held on 2.12.2011, an Expert Group was constituted for Revision of Processing Charges for Blood and Blood Components. The Expert Group revised the Processing Charges and also considered the recommendations of 16 Member Committee constituted by Maharashtra SBTC. The report of Expert Group Committee has been approved by Governing Body of NBTC in its 24th Meeting held on 20.1.2014.

Revised guidelines for processing charges for blood and blood components for blood banks are as follows: -

1. The basic principle of non-profitability should be followed in blood banking, and continue to levy no charge for blood as such, as it is to be collected from voluntary non remunerated blood donors who are not to be paid for donating blood.
2. The nomenclature of "**Service Charges**" should be changed to the nomenclature "**Processing Charges**" which are defined as the charges for processing of blood and blood components for safe blood transfusion to patients. The processing charges are not inclusive of establishment cost i.e. cost of building, equipment etc.
3. Differential cost recovery should be followed for Public and non Public sector blood banks, as processing charges would differ in private sector in view of different rates of kits and consumable offered to private blood banks by the vendors.
4. For Government blood banks, the processing charges are recommended as detailed below.

1.	Whole Blood.	-	Rs. 1050/- per unit
2.	Packed Red Cells	-	Rs. 1050/- per unit
3.	Fresh frozen Plasma	-	Rs. 300/- per unit
4.	Platelet concentrate	-	Rs. 300/- per unit
5.	Cryoprecipitate	-	Rs. 200/- per unit

5. For non- government blood banks, the processing charges are worked out as detailed below.

1.	Whole Blood	-	Rs. 1450/- per unit
2.	Packed Red Cells	-	Rs. 1450/- per unit
3.	Fresh frozen Plasma	-	Rs. 400/- per unit
4.	Platelet concentrate	-	Rs. 400/- per unit
5.	Cryoprecipitate	-	Rs. 250/- per unit

6. Charges for any specialized requirements/tests/ procedures done by the blood bank must be disclosed to the recipient / receiver of blood.

The committee has worked out the maximum charges for the specialized tests per whole blood unit, which can be divided amongst components, as under. The charges for Chemiluminescence and antibody screening were included and charges for NAT were revised keeping in view the cost of specific reagents and additional consumables required for conducting the tests.

Tests	Charges
NAT	Rs. 1200
Chemiluminescence	Rs. 500
IV Generation ELISA(HIV)	Rs. 50
IV Generation ELISA(HBs Ag)	Rs. 50
IV Generation ELISA(HCV)	Rs. 150
Anti Hbc	Rs. 250
Antibody screening (donor)	Rs. 300

The cost of specialized tests which are component specific would be added to the basic charges for that particular component.

Tests/ procedures	Charges	Applicable to
Leuco filtration Red cells	Rs. 1000	Whole blood/ Red cells
Leuco filtration Platelets	Rs. 1500	Platelets
Grouping and cross matching by automation	Rs. 280	Whole blood/ Red cells
Grouping and cross matching by semi automation	Rs. 120	Whole blood/ Red cells
Phenotyping for extended serology	Rs. 500	Whole blood/Red cells
Irradiation	Rs. 1000	Whole blood/Red cells/ Platelets/Granulocytes
Bacterial detection	Rs. 1000	Platelets

The processing charges of blood are exclusive of cost for patient antibody screening and antibody identification, charges for which may be fixed by the blood bank/ hospital.

7. Additional processing charges for blood components using Quadruple bags by bully coat method are recommended as follows

Red Cells	Rs. 150
Platelets	Rs. 150
Plasma	Rs. 100

8. The cost of platelet apheresis should not exceed Rs. 11000/- per unit in non-government blood banks.
9. The committee is of the considered view that the charges for services being provided by blood banks may have variations due to differences in market availability of skilled manpower, items, and other ancillary requirements, which may vary from state to state, and sector to sector. However, it is necessary that the costs of providing blood are recouped by the blood banks. Accordingly, an average of these factors has been considered while arriving at the overall processing charges for blood and blood components. The guidelines so issued are indicative in nature and the concerned department of the state may take its own decisions.
10. The processing charges may be subsidized by the State Governments/ State Blood Transfusion Councils for the blood banks in the government sector and DAC supported blood banks. The State Blood Transfusion Councils may constitute an expert sub-committee to assess the additional testing/ service being included in the processing charges.
11. It would continue to remain mandatory for all blood banks (DAC supported and non-DAC supported) to provide blood/ blood components free of cost to the following, who require repeated blood transfusions as a life saving measure
1. Thalassaemia patients
 2. Haemophilia patient
 3. Sickle cell anaemia patients
 4. Any other blood dyscrasia requiring repeated blood transfusions
- State Governments/ State Blood Transfusion Council may additionally decide to provide blood/ blood components free of cost to any other category of patients according to the State Government norms.
- 12 Processing charges for Blood and Blood components for below poverty. line patients accessing blood from non DAC supported blood banks shall be in compliance with the charges decided by respective State Governments/ State Blood Transfusion Councils.
13. The processing charges for the blood/ blood components should be displayed prominently in the blood bank premises for the benefit of recipients.
14. The guidelines would be revised every three years.

**Details of Recovery of Processing Charges for Blood & Blood
Component**

Costing for Whole Blood			
S.No.	Determinants of cost	Whole Blood Government	Whole Blood Non Government
1	Consumables / material (Including stationery & IEC)		
	Blood Bags	50	60
	Kits for Transfusion Transmitted infection testing	200	250
	Donor Haemoglobin	30	50
	Blood grouping	70	70
	Cross Matching	70	70
	Chemicals	10	30
	Stationery	20	50
	Glassware and plastic ware	70	70
2	Salary (human resource)	300	500
3	Equipments Maintenance and depreciation	50	80
4	Power (electrical supply including generator backup)	70	90
5	Biomedical waste management	10	10
6	Donor Refreshment	25	25
7	Quality Assurance	25	25
		1000	1380
8	Wastage (@ approximately 5%for whole blood, 7% for components)	50	70
	Total Effective cost	1050	1450

**Details of Recovery of Processing Charges for Blood & Blood
Component**

Costing for Blood Components			
S.No.	Determinants of cost	Components Government	Whole Blood Non Government
1	Consumables / material (Including stationery & IEC)		
	Blood Bags	200	200
	Kits for Transfusion Transmitted infection testing	200	250
	Donor Haemoglobin	30	50
	Blood grouping	70	70
	Cross Matching	70	70
	Chemicals	10	30
	Stationery	35	60
	Glassware and plastic ware	100	100
2	Salary (human resource)	400	600
3	Equipments Maintenance and depreciation	140	250
4	Power (electrical supply including generator backup)	140	200
5	Biomedical waste management	20	20
6	Donor Refreshment	25	25
7	Quality Assurance	100	100
		1540	2105
8	Wastage (@ approximately 5%for whole blood, 7% for components)	110	145
	Total Effective cost	1650	2250

DOCUMENT- 6

LETTER ABOUT CHANGE IN THE DEFINITION OF VOLUNTARY BLOOD DONATION

No.S.12016/01/2014-NACO (NBTC)
Government of India
Ministry of Health & Family Welfare
(Department of AIDS Control)

9th Floor, Chandralok Building,
36, Janpath, New Delhi.
Dated 24 June 2014

To,

Director/Member Secretaries
All State Blood Transfusion Council

Subject: Order reg Blood Donation Camps


Sir,

The Technical Resource Group for Blood Transfusion Services under the Department of AIDS Control has reviewed and revised the definition of Voluntary Blood Donor and the norms on organization of Mega Blood Donation Camps. The same is detailed below:-

1. Definition of VBD has been modified and updated in accordance to WHO definition as follows:
"A voluntary non-remunerated 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 for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation."
2. Blood Donation in blood donation camps should be based on the need and utilization capacity of blood banks.
3. Maximum number of blood units which can be collected in a single blood donation camp is 500 unit.
4. Any blood donation camp expected to collect more than this limit should have a written approval of respective SBTC/SACS.
5. Any blood donation camp expected to involve blood banks from more than one state should have the written approval of NBTC/DAC.
6. Calendar of camps should be prepared by SBTC/SACS and shared with DAC quarterly.

Copy of order dated 11.03.2014 regarding Pattern of assistance for conducting Voluntary Blood Donation camps in outdoor location and in Blood Mobiles is also enclosed for reference and necessary action. This is in supercession to all previous orders regarding Blood Donation Camps.

Yours faithfully,


(Dr Shobini Rajan)
Asst Director General
(Blood Transfusion Services) &
Director (National Blood Transfusion Council)

Copy to:

1. Project Directors,
State AIDS Control Societies
2. Drug Controller General (India)
3. Director General of Health Services

No.S.12016/13/2013-NACO(NBTC)
Government of India
Ministry of Health and Family Welfare
Department of AIDS Control

9th Floor, Chandralok Building,
36 Janpath, New Delhi – 110001.

Dated: 11th March 2014

To,

The Project Director of
all State AIDS Control Society

Subject: Pattern of assistance for conduction of Voluntary Blood Donation camps in outdoor location and in Blood Mobiles-reg.

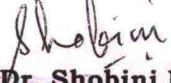
Sir/Madam,

The National Blood Transfusion Council in its 24th Governing Body Meeting held on 20.1.2014 has approved the pattern of assistance for conduction of Voluntary Blood Donation camps in outdoor location and in Blood Mobiles.

The revised pattern of assistance is enclosed herewith for further needful action.

The order will be come into force with immediate effect.

Yours sincerely,


(Dr. Shobini Rajan)

Director, National Blood Transfusion Council

Copy to

1. The Director/Member Secretary of all SBTC.
2. Website of DAC.

Pattern of Assistance for conduction of Voluntary Blood Donation Camp

The revised pattern of assistance for location is as under :-

	Unit Cost	Total per camp of 75 donations
Certificate and badge/ pins/momento	Rs. 15 per donor	1125
Transportation		Rs. 1000
IEC Material (Banners/ Leaflets)		Rs. 375
Total		Rs. 2500
Donor Refreshment	Rs. 25 per donor	Rs. 1875

DA for staff attending the camps may be borne as per the state norms through state funds for the government hospitals and for the charitable blood banks from the blood banks.

Pattern of assistance for Blood Mobiles is as under: -

1. Blood Donation Mobile is a property of respective State AIDS Control Society (SACS) or the State Blood Transfusion Council (SBTC) and shall be registered in the name of Project Director/ Director of the respective SACS/ SBTC.
2. Blood Donation Mobile Van shall be preferably designated to meet the demands of many districts and Blood Banks as decided by respective SACS / SBTC. Blood Donation Mobile Van shall be used exclusively for the purpose of organization of Voluntary Blood Donation Camps only.
3. SACS /SBTC may ask DAC supported blood banks to provide their monthly calendar regarding blood donation camps.
4. Maintenance of Blood Donation Mobile Van (including equipment's, log books) including the recruitment of staff (Driver 8r, Helper) shall be the responsibility of respective SACS/ SBTC/ Blood Bank.
5. Blood Donation Mobile Van must be optimally used for not less than 25 days and possibly 1 camps per day collecting around 30-40 units per camp.
6. Vehicle may be moved in the peripheral area of 250 km of model blood bank. Vehicle should be used by all the blood banks coming in that territory.

Budget for the camps conducted in blood mobile would be similar to that for outdoor camps excluding transportation. Additional funds for fuel over and above the support from DAC needs to be borne by the state.

Also proper camp schedule should be framed by the Blood Banks in advance.

DOCUMENT- 7

GUIDELINES FOR ISSUANCE OF "NOC" FOR NEW BLOOD BANK, RENEWAL OF LICENSE, CRITERIA'S FOR DESIGNATION BLOOD BANK AS RBTC



सत्यमेव जयते

एन. एस. कंग, भा.प्र.से
अपर सचिव

NAVREET SINGH KANG, IAS
Additional Secretary



भारत सरकार

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

राष्ट्रीय एड्स नियंत्रण संगठन

Government of India

Ministry of Health & Family Welfare

National AIDS Control Organisation

D. O. No. S-12016/1/2014-NBTC

Dated : 21st September, 2015

My Dear Secretary,

You would be aware that the Government of India had adopted the National Blood Policy in April 2002, which sought a comprehensive, efficient and a total quality management approach within a nation-wide system, to ensure access to adequate and safe blood supply. The National Blood Transfusion Council (NBTC) has also been set up to oversee and coordinate the functioning of blood transfusion services through the State/UT Blood Transfusion Councils, who are responsible for overall implementation of an organized blood transfusion service through a network of Regional Blood Transfusion Centres and other blood banks.

2. In the past, clarifications has been sought by various States regarding the procedure to be adopted for allowing establishment of new blood banks, renewal thereof, and grant of status of Regional Blood Transfusion Centres etc. The matter was accordingly considered by the NBTC in its meeting on 05.08.2015 and the norms for the above have been approved. These norms are detailed in the enclosure and include

- Norms for setting up of blood banks;
- Norms for grant of no objection certificate for licensing of new blood banks and renewal of license of existing blood banks;
- Norms for grant of status of Regional Blood Transfusion Centre; and
- Norms for grant of permission for conducting voluntary blood donation camps.

3. These have been approved so as to bring clarity and uniformity in the practice and procedure across different States. It may be ensured that the State Blood Transfusion Council in your State adopts and implements the same.

4. Action taken in this regard may be intimated to undersigned within a month of receipt of this communication.

With regards,

Yours sincerely,

(N. S. KANG)

To

Principal Secretary (Health) (By name)
All States as per list

6th Floor, Chandralok Building, 36 Janpath, New Delhi -110001, Telefax : 011-23325331/ 23351700

E-mail : nacoasdg@gmail.com

ok issued
21/sep/15

NORMS FOR STATE BLOOD TRANSFUSION COUNCIL AS APPROVED BY GOVERNING BODY OF NATIONAL BLOOD TRANSFUSION COUNCIL

A. Norms for set up of New Blood Banks

Every district should have at least one blood bank, but clustering of blood banks in urban/ semi-urban areas should be avoided. New blood banks need to be set up based on geographic location and population demand only.

B. Norms for grant of 'No objection certificate' (NOC) by the SBTC

B1. For New Blood Bank License:

1. A registered voluntary or charitable organizations, which is registered in the, territory of Union of India or Union Territory, as the case may be under any such law which is at the time of enforcement of this rule in force.
2. The aforesaid organization must be atleast two years old and should not be a family society or trust.
3. The objectives mentioned in the Memorandum of Association must include the activities related to health care delivery system or blood transfusion services.
4. The activities undertaken by the organization must showcase social accountability and be reflected in the annual Audited Statement of accounts of the last two year (i.e. before the submission of application).
5. The organization should submit undertaking to ensure annual blood collection - more than 2000 units per year with nearing 100% contribution from Voluntary blood donor, preferably collected from outdoor blood donation camps.
6. The organization should submit undertaking to appoint Medical Social Worker (MSW) and Counselor with the blood bank for arranging Voluntary Blood Donation (VBD) camps and Pre and Post Test counseling respectively.
7. The organization should submit undertaking to establish blood component separation facility of its own or a storage facility for components within a period of two years from receiving license to operate blood bank.
8. The organization should submit undertaking to abide with the guidelines of - SBTC/NBTC issued from time to time, including the guidelines for processing charges for blood and blood components.

Note:

- c. The Organization should submit undertaking on the letter head expressing willingness to abide with aforesaid conditions.
- d. The SBTC should process the application within thirty days from the date of its receipt in the office; failing which NOC shall be deemed granted to the organization.

B2 For Renewal Blood Bank License:

1. The compliance to point no. 1-4 of norms at B1 (No objection certificate (NOC) for New Blood Bank License) shall be ensured.
2. The organization should submit photocopy of license and application months before the expiry of validity period of license.
3. The organization should submit Annual blood collection report wherein the total blood collection (Jan-Dec) is shown with voluntary contribution to total collection along with number of blood donation camps conducted. (The annual blood collection should be more than 2000 units per year with nearing 100% contribution from Voluntary blood donor, preferably collected from outdoor blood donation camps. The condition may be relaxed for rural, tribal, hilly region, desert, island and Armed Forces)
4. The organization should submit the proof and details of appointment of Medical Social Worker (MSW) and Counselor with the blood bank for arranging Voluntary Blood Donation (VBD) camps and Pre and Post Test counseling respectively along with the training certificates.
5. The organization should submit Annual report indicating blood component separation facility has been established either of its own or a storage facility, wherein the components were sourced from RBTC approved by SBTC.
6. The organization should submit details of processing charges collected by the blood bank after 12th February 2014. The SBTC should verify, if charges collected are subsidized or at par with guidelines issued by NBTC.

Note :

- c) The Organization should submit undertaking on the letter head expressing willingness to abide with aforesaid conditions.
- d) The SBTC should process the application within thirty days from the date of its receipt in the office; failing which NOC shall be deemed granted to the organization.

C. Norms for grant of 'Regional Blood Transfusion Center' (RBTC) status to blood banks.

RBTC is a blood bank approved by the SBTC taking into consideration the regional needs of blood & blood components and the ability of RBTC in terms of premises, personnel and equipment to cater to the same. A center will be designated as RBTC only after SBTC formally networks it with blood bank/ blood storage centers in the region and establishes two way linkages for exchanges of blood and blood components.

1. The blood bank should be licensed and provide round the clock service
2. The blood bank should have minimum collection of 2000 per annum with voluntary contribution nearing to 90%. (The criteria for minimum collection may be relaxed in rural, tribal, hilly region, desert, island and Armed Forces).
3. The Blood bank should have component separation facility. Alternatively, Blood bank should provide undertaking to establish component separation facility within two years' time frame.
4. The blood bank should have adequate facilities to store and transport blood and blood components at required temperature and ambient conditions.

5. The blood bank should have minimum TTI screening by ELISA facility for atleast 80% collected unit and should be practicing tube method for blood grouping and cross matching. (The criteria for minimum testing may be relaxed in -rural, tribal, hilly region, desert, island and Armed Forces).
6. The blood bank should be capable of imparting periodic training to staff attached with Blood Storage Center for blood grouping, cross matching, storage, identifying haemolysis and record keeping.
7. All equipment in the blood bank should be under AMC/CMC and calibrated at the time of applying for RBTC Status and subsequent renewal every year as mandated under Drugs and Cosmetic Act.
8. All records books should be available with the Blood Bank as stipulated in the Drugs and Cosmetics Act 1940 and Rules 1945 there upon.
9. The blood bank should have computer and trained staff to maintain database of donor, blood and products and inventory of demand and supplies made on daily basis.
10. The blood bank must update its stock status of blood availability blood group wise online with NBTC website.

Note:

The RBTC status accorded will be initially for a period of two years only. However, it would be renewed based on the performance and fulfillment of all aforesaid conditions for a further period of five years and at five years interval thereafter.

D. Norms for grant of permission to conduct voluntary blood donation camps:

Drugs and Cosmetics Act, 1940 and rules 1945 thereupon under Schedule F- Part XII B has permitted following types of licensed Blood Banks to collect blood by conducting voluntary blood donations camps.

1. Government Blood Bank.
2. Indian Red Cross Society Blood Bank.
3. Regional Blood Transfusion Centers designated by SBTC.
4. Blood Banks managed by registered voluntary or charitable trust organizations recognized by BTC.

However, to ensure 100% blood collection from voluntary non remunerated blood donors in the country, it was decided to permit hospital based private blood banks also to conduct blood donation camps. The DCGI was requested to examine the same and introduce a suitable amendant to the act.

DOCUMENT- 8

GUIDELINES ON BULK TRANSFER OF BLOOD.



एन. एस. कंग, भा.प्र.से
अपर सचिव
NAVREET SINGH KANG, IAS
Additional Secretary



भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
राष्ट्रीय एड्स नियंत्रण संगठन
Government of India
Ministry of Health & Family Welfare
National AIDS Control Organisation
D.O. No. S-12015/04/2015-NBTC
Dated 28 October 2015

Dear,

I am writing this to highlight an important initiative that can lead to increase in the efficiency of Blood Transfusion Service in the country, namely permitting bulk transfer of blood between licensed blood banks.

2. You would be aware that there have been reports about surplus blood being wasted in some blood banks, whereas scarcity of blood is reported in other parts of the country at the same time. To obviate this, a policy regarding promoting transfer of blood from one blood bank to another blood bank has been under consideration for some time. The subject was initially considered by a group of experts, and has been approved by the National Blood Transfusion Council in its meeting of 05.08.2015. The Health Ministry has also granted its approval to the new initiative.

3. Bulk transfer of blood and blood components amongst licensed blood banks in the country would henceforth be allowed under the following conditions.

- I. Transfers shall be allowed between licensed blood banks in any sector (Public, NGO, and Private).
- II. Transfer of blood and components in bulk shall be permitted across State borders to also ensure the availability at the point of need.
- III. All transfers shall be done at the recommended temperature and as per prescribed storage conditions for whole blood and components. The supplier blood bank shall be responsible for compliance thereof.
- IV. The recipient blood bank should have the capacity to hold the units requested for, at appropriate temperature till the time of utilization.
- V. Broad based donor consent should be incorporated in the standard donor form to ensure that the donor agrees to his blood unit being utilized beyond the blood bank where it is donated.
- VI. The supplier blood bank can levy the prescribed processing charges on the patient/recipient/recipient blood bank as per NBTC norms. However, the recipient blood bank can levy only processing charging for compatibility testing (cross-matching), in addition to charges levied by the supplier blood bank, from the patient/recipient for such transferred units.

6th Floor, Chandralok Building, 36 Janpath, New Delhi -110001, Telefax : 011-23325331/ 23351700

E-mail : nacoasdg@gmail.com

अपनी एचआईवी अवस्था जानें, निकटतम सरकारी अस्पताल में मुफ्त सलाह व जाँच पाएँ
Know Your HIV status, go to the nearest Government Hospital for free Voluntary Counselling and Testing

- VIII. Records of traceability shall be retained throughout the process.
- IX. Supplier blood bank would be responsible for all the complications except for those related to compatibility testing, which will be the responsibility of the recipient blood bank. Recipient blood bank shall report and evaluate all the adverse transfusion reactions, including those happening due to blood that has been transferred from supplier blood bank.
- X. Documents accompanying transfer shall include TTI testing report and record of transport in appropriate temperature.
- XI. All recipient blood banks are considered deemed approved to act as functional storage centers for blood and blood components, even though the upper limit of 2000 units utilization per annum is not applicable.
- XII. All blood banks and storage units be instructed to issue blood to all patients needing transfusion and not restricting blood issue to captive requirements of institution to which they are attached.
- XIII. Blood banks would be informing regarding bulk transfers to SBTC and in case of inter-state bulk transfers to NBTC.
4. The formats for request and issue of bulk transfer of blood are enclosed, and may be followed in the interest of maintaining uniformity of record.
5. I would seek your personal attention towards successful implementation of this policy.
- With regards,

Yours sincerely,


(N.S Kang)

Encl: A/A.

To

All Principal Secretary (H)

Copy to:

1. All Director, Health Services
2. All Project Director State AIDS Control Societies


(R S Gupta)
DDG(BTS)

A- Request Form for Inter Blood Bank Transfer of Blood/Components

Date:.....

Time:.....

To.

The Blood Bank I/C,

Name & Address of Blood Bank (Supplier)

.....

.....

.....

Dear Sir/Madam,

Please issue the following tested Blood Units/ Components as detailed below for use in Blood Bank at requisite temperature.

S.No	Blood Group	Whole blood/Components	No. of units required
1			
2			
3			
4			
5			

Name of I/C Blood Bank (Recipient)
Blood Bank Name & Contact Details

.....
With Signature & Seal

Receipt

1. Name of Supplier Blood Bank:- _____

2. Address _____

3. Phone Number:

4. License No. _____ Valid upto: _____

5. RBTC: YES/NO _____

Received request dated.....as detailed above.

Signature of C Blood Bank (Supplier) with seal

Date

Time

Note : Fill two copies of this form. One signed copy of each to be retained in supplier blood bank and recipient blood bank.

B- Issue form for Inter Blood Bank Transfer of Blood/Components

Date:.....
Time:.....

To.

The Blood Bank I/C,

Name & Address of Blood Bank (Recipient)

.....
.....
.....

Dear Sir/Madam,

The following units of Blood / Components are issued for use in your Blood Bank as per request dated It is certified that all units detailed below are tested and found non-reactive for TTI (Syphills, Malaria, HIV, HBV, HCV) and are being transported in requisite temperature.

S.No	Blood Unit No.	Blood Group	WB/ Comp	Date of Collection	Date of Expiry	Status of Testing				Date of Testing	Segment No.
						Syphills	Malaria	HIV	HBV		

National Blood Transfusion Council

Name of I/C Blood Bank (Recipient)
Blood Bank Name & Contact Details

.....
With Signature & Seal

Receipt

1. Name of Supplier Blood Bank:- _____
2. Address _____
3. Phone Number: _____
4. License No. _____ Valid upto: _____
5. RBTC: Yes/No _____

Received Blood and Blood Components as detailed above.

Signature of C Blood Bank (Supplier) with seal

Date

Time

Note : Fill two copies of this form. One signed copy of each to be retained in supplier blood bank and recipient blood bank.

DOCUMENT- 9

GUIDELINES ON EXCHANGE OF SURPLUS PLASMA WITH INDIGENOUS FRACTIONATORS.



सत्यमेव जयते

एन. एस. कंग, भा.प्र.से
अपर सचिव

NAVREET SINGH KANG, IAS
Additional Secretary



भारत सरकार

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

राष्ट्रीय एड्स नियंत्रण संगठन

Government of India

Ministry of Health & Family Welfare

National AIDS Control Organisation

D.O.No.S-12016/01/2012-NACO (NBTC)

Dated 28th Oct.2015

Dear

I am writing this to highlight an important initiative that can lead to increase availability of indigenous plasma products, namely by permitting blood banks with component separation facility to exchange their surplus plasma with indigenous fractionators in the country.

2. You would be aware that there have been reports about surplus plasma being wasted in some blood banks. To obviate this, and to increase the availability of indigenous plasma products, a policy regarding permitting blood banks to provide surplus plasma to indigenous fractionators, to increase availability of these products has been under consideration for some time. The subject was initially considered by a group of experts, and has been approved by the National Blood Transfusion Council in its meeting of 05.08.2015. The Health Ministry has also granted its approval to the new initiative.

3. The permission to allow blood banks to provide surplus plasma to indigenous fractionators in the country would henceforth be under the following conditions.

- I. The fractionators must undertake to fulfill needs of Indian market first and none of products recovered from the Indian plasma should be exported before fulfilling domestic demand.
- II. Uniform exchange value of Rs. 1600/- (Rs. sixteen hundred only) per liter of Plasma was agreed upon.
- III. All blood banks must ensure taking of the informed consent of the blood donor for allowing the use of his blood for fractionation, and derivation of essential plasma derived medicines there from.
- IV. The modalities for use of exchange value would be finalized by the respective State Blood Transfusion Councils and would be primarily directed towards ensuring availability of plasma derived products to patients requiring them. These would include :

6th Floor, Chandralok Building, 36 Janpath, New Delhi -110001, Telefax : 011-23325331/ 23351700

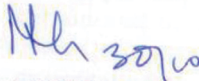
E-mail : nacoasdg@gmail.com

अपनी एचआईवी अवस्था जानें, निकटतम सरकारी अस्पताल में मुफ्त सलाह व जाँच पाएँ
Know Your HIV status, go to the nearest Government Hospital for free Voluntary Counselling and Testing

- a) Buy back of plasma derived products of equivalent value for clinical use by needy patients accessing care at the institution where the blood bank exchanging the plasma is located.
 - b) Receipts of equipment or consumables for strengthening of blood banks capacity and improving component recovery, storage and utilization.
 - c) Any other modality approved by NBTC.
- V. Blood Component Separation Units would directly enter into an agreement with the fractionators, as per mutually agreed terms and conditions approved by respective SBTC before sending plasma for fractionation.
- VI. Feedback would be provided by fractionators to NBTC/ respective SBTC in order to provide evidence of the quality of the plasma being fractionated, so as to enable corrective and preventive action.
- VII. NBTC would review the fractionators periodically so as to prevent any misuse of this strategy.
4. I would seek your personal attention towards successful implementation of this policy.

With regards,

Yours sincerely,


(N.S.Kang)

To,

All Principal Secretary (Health & FW)
& President State Blood Transfusion Council,

Copy for information to :

1. PPS to Secretary Health & Family Welfare, Ministry of Health & Family Welfare, Govt. of India, New Delhi.
2. PPS to Directorate General of Health Services, Govt. of India.
3. Drugs Controller General of India, CDSCO, New Delhi.

DOCUMENT- 10

LETTER TO BBS FOR MANDATORY DATA ENTRY OF BLOOD STOCK ON NHP PORTAL



President



सत्यमेव जयते

राष्ट्रीय रक्त संचरण परिषद
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
भारत सरकार

National Blood Transfusion Council
Ministry of Health and Family Welfare
Government of India

D. No.: S-12015/1/2013-NACO (BS)
Dated: 22nd December, 2015

Dear Doctor,

In pursuit of the Govt.'s e governance initiatives the National Blood Transfusion Council (NBTC) is partnering with the National Health Portal to develop a web presence for Blood Transfusion Services through making available information pertaining to licensed blood banks on line.

NACO/NBTC launched a mobile blood locator app on World Blood Donor Day 14th June, 2015 in partnership with Centre for Health Informatics, Ministry of Health and Family Welfare. The mobile app for the nearest blood bank is currently available on android platform and will be extended to other platforms in due course. The website for NBTC in India for Blood transfusion Services (BTS) is conceptualized to be a dynamic site, providing up-to-date consolidated Blood Bank stock positions and locations.

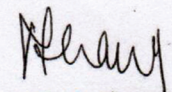
All licensed Blood Banks have been enrolled on the National Health Portal. The individual facilities are required to provide authentic information pertaining to blood/component stock status and the same has to be updated regularly as this information would be in public domain and has to be fruitful to the end user. Kindly ensure required information is completed/verified/ corrected and up to date.

All licensed Blood Banks in the government/charitable/private sector must comply to the above mentioned directive and make the blood/component stock display available on the NBTC-NHP platform.

Also, along with this online update similar information needs to be on display in the Blood Bank premises for general public viewing along with date & time of stock updation.

The above may be complied with strictly.

The Medical Officer In-Charge,
All Licensed Blood Bank.


(N. S. Kang)

DOCUMENT- 11

SUPREME COURT JUDGMENT COPY.

48800

I N THE SUPREME COURT OF INDIA

CIVIL EXTRAORDINARY JURISDICTION

WRIT PETITION (CIVIL) NO. 91 OF 1992

Common
cause

Petitioner

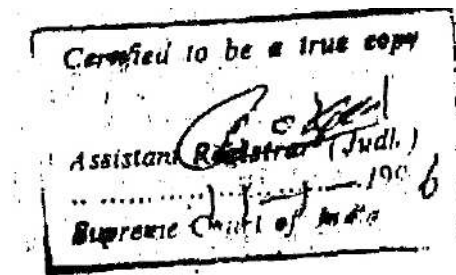
versus

Union of India & Ors.

. . Respondents.

Supreme court Judgment copy.

J U D G M E N T



S.C. AGRAWAL. J

:

Blood is an essential component of the body which provides sustenance to life. There can be no greater service to the humanity than to offer one's blood to save the life of other fellow human beings. At the same time, blood instead of saving a life can also lead to the death of the person to whom life blood is given if the blood is contaminated. As a result of developments in medical science it is possible to preserve and store blood after it has been collected so that it can be available in the case of need. There are blood banks which undertake the task of collecting, testing and storing the whole blood and its components and make the same available when needed. In view of the dangers inherent in the supply of contaminated blood, it must be ensured that the blood that is available with the blood banks for use is healthy and free from Infection

In this petition filed by way of Public Interest Litigation under Article 32 of the Constitution, the petitioner has highlighted the serious deficiencies and shortcomings in the matter of collection, storage and supply of blood through the various blood centres operating in the country and has prayed that an appropriate writ order or direction be issued directing the Union of India and the States and the Union territories, who have all been impleaded as respondents in this petition, to ensure that proper positive and concrete steps in a time bound programme are immediately initiated for obviating the malpractices, malfunctioning and inadequacies of the blood banks all over the country and to place before this court a specific programme of action aimed at overcoming the deficiencies in the operation of blood banks.

For the purpose of regulating its collection, storage and supply, blood is treated as a 'drug' under the Drugs and Cosmetics Act, 1940 (hereinafter referred to as 'the Act'). In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as 'the Rules') made under the Act, provisions regarding equipment and supplies required for a blood bank were contained in Part XII - B, which was inserted Vide Notification dated June 24, 1967. In the said part, requirements regarding Equipment Blood collection supplies, Canter equipment and Emergency equipment for the Blood Donor Room were prescribed. Similarly, provisions were made for the Laboratory, General suppliers, Technical staff, Accommodation for Blood Bank, Label for whole blood and Colour scheme for Label etc, In 1990, M/s. A. F. Ferguson & Co., a Management Consultancy Firm, was entrusted by the Government of India, Ministry of Health with the study of blood banking system in the country. The scope of the said study was to

- i) Assess the status of Government, Private, Commercial and Voluntary blood banks;
- ii) Recommended policy and procedural changes; and
- iii) Prepare a scheme for modernisation;

The report submitted by the said consultancy firm to the Government in July 1990 highlights the deficiencies regard to the facilities of testing blood, licensing of blood banks and professional donors and storage of blood.

In said report it was stated:

- i) Out of the total number of 1018 blood banks, as many as 616 are reported to be unlicensed. There are only 201 licensed commercial blood banks; the supply of blood by licensed commercial blood banks is only about 1/4th of the blood used in the hospitals of the country.
- ii) No medical check up is done on the blood sellers; their health status is not examined. The blood trade flourishes with poor people like unemployed, rickshaw pullers, drug addicts selling their blood. Such blood sellers suffer from various infections and their haemoglobin is lower than the prescribed level. It has been reported that there are many persons who donate blood 5-6 times in a month; poverty makes them do so at first but later it is reported to become like an addiction; the blood seller enjoying the dizziness due to reduced supply.
- iii) It is a mandatory to the requirement to conduct tests on or blood which is to be administered to a patient to be issued to hospitals for transfusion. The blood so issued has to be free from AIDS, viral hepatitis, malaria, venereal diseases etc. It is reported that mandatory tests which are required to be done are rarely conducted. A host of the AIDS surveillance centres are not functioning efficiently and up to 85 percent blood collected in the country is not screened for AIDS. Under an action plan to screen blood for AIDS, 37 blood testing centres were to be set up in 29 cities, but only 11 testing centres were functioning by July 1990, and training of technicians for these centres was lagging.
- iv) The blood banks presently thrive on in bleeding 4000 to 5000 regular professional donors in 18-20 cities. The professional blood donors, which include many women, are reported to be victims of ill health, low haemoglobin levels and many infections, and are bled at frequent intervals by the commercial blood banks.
- v) Storage facilities in the blood banks are far from satisfactory. The blood banks have necessarily to possess facilities-like refrigerators exclusively for storage of blood with a specified range of temperature for ensuring the safety of blood. In the existing blood banks many items and equipments remain unattended for years, electricity failures are frequent, and generators are a rarity. This applies not only to commercial blood banks but even to some of the government hospitals. Many items of the basic equipment needed for blood banks are not available and a good part of them do not have even adequate storage facilities.

- vi) Many of the blood banks are located in an unhygienic environment and they collect and store blood in very dirty conditions.
- vii) In some places strong middlemen operate for the blood banks by arranging for donors. The middlemen dictate the charges to be paid and take a heavy commission for the selection of donors' disregarding the level of health etc.
- viii) A large part of the professional donors are alcoholics or drug abusers, have indiscriminate sexual habits and are a high-risk group for Hepatitis B and AIDS and are unfit to donate blood.
- ix) Trained personnel are generally not available in the blood banks. A host of the blood banks lack trained post-graduates at the helm; they have no donor organisers to bring voluntary donors and many of them are manned by technical staff who do not have the requisite qualification of, a diploma in Medical Laboratory Technology. At present, there is not even a course to provide post-graduate specialisation in the field of blood donation and transfusion as in developed countries. The Drug Control departments, which are expected to ensure the appropriate functioning of the blood banks, do not themselves have specified trained personnel.
- x) In the storage of blood the basic and essential requirements of the clean environment, the shelf life of blood etc are ignored. Nexus is reported to exist between the attending doctor of the patient and the commercial blood bank, with the former directing the patients to the latter, and the latter giving a percentage of the sale to the former.

According to the report of M/s. A.F. Ferguson & Co. out of the total number of 1018 blood banks in the country, 203 are commercial blood banks and the rest are controlled by the Central Government, State Governments, Private Hospitals and voluntary organisations. The volume of the blood collected by the commercial Blood banks is 4.7 lakhs units out of the total 19.5 lakhs units by all blood banks and that commercial blood banks are collecting blood mostly from professional donors while the other blood banks under the control of the State Governments, Central Governments, Private organisations and voluntary organisations are collecting blood mostly from the relatives of the patients or from the voluntary donors.

In the counter affidavit filed by Dr Lalgudi Vaidyanathan Kannan, Deputy Drugs Controller on behalf of the Union of India, it is stated that after the receipt of the report of M/s. Ferguson & Co., the Drugs Controller, India, by his letter dated August 23, 1990 asked all the State Drug Controllers (who are the licensing and enforcing authorities under the Act) to ensure that inspections are carried out of all commercial blood banks and unlicensed Government blood banks keeping in view the standards prescribed in the Act and Rules and a phased programme of inspection, covering first the commercial/private blood banks and thereafter the Government blood banks was suggested. It was also suggested that the private/commercial blood banks should not be allowed to operate unless they fulfil all the requirements prescribed in the Rules and each unit of blood is tested for blood transmissible diseases' (Hepatitis, HIV, Syphilis etc.) and that unlicensed blood banks are to be licensed only after ascertaining that they conform to the standards laid down under the Rules. It was also suggested to the State Governments that the licences of blood banks who do not comply with the provisions of the Rules should be cancelled and the State Drug Controllers were asked to send the status reports of blood banks in their respective States.

As per the information forwarded by 23 State Governments/Union Territories, about 341 blood banks are unlicensed and most of them are run by Red Cross Societies and Charitable institutions. In the said counter affidavit mention is also made of the steps that have been taken in the matter of testing of blood for AIDS, storage facilities in blood banks, for up gradation and modernisation of Government managed blood banks, and training of drugs inspectors and blood bank technical personnel.

During the pendency of this writ petition, action has also been taken to revise the Rules governing the licencing and operation of the blood banks and by the Drugs and Cosmetics (First Amendment) Rules, 1982 published in the Gazette of India vide: Notification dated January 22, 1993, Part X-β has been inserted in the Rules and Part XII-B has been substituted. In part X-B (Rules 122-F to 122-f) provisions have been made prescribing the requirements for collection, storage, processing and distribution of whole human blood, human blood components by blood banks and manufacture of blood products for grant and for renewal of licence for the operation of a blood bank/processing of human blood for components/manufacture blood products. Under the said provisions licence can only be granted/renewed with the approval of the Central Licence Approving Authority viz, the Drugs Controller of India Part XII-B contains the provision relating to space, equipment and supplies required for a Blood Bank. During the course of the hearing of this petition, the petitioner submitted a draft scheme and a scheme was also submitted by the Union of India. In the affidavit filed by Dr Shiv Lai, Addl. Director, National Aids Control Organisation, along with the scheme, it was stated that the Central Council of Health, in which the State Health Ministers are members, is the highest Forum for Policy framework and that the said Council has given guidelines in respect of Blood Bank and Transfusion Service and its recommendations are as under :

“Blood being a vital input in the present day Medicare services; the acute shortage of which is hampering the effectiveness of our services, the joint Conference recommends that urgent steps should be taken by the States/Union Territories”

Governments and the Central Government -.

- 1 To build up adequate blood banking services at State/District level including the provision of Trained/qualified manpower, necessary action should be initiated in right earnest for achieving the objective in view.
2. To educate and motivate people about blood donation on a voluntary basis.
3. To provide adequate encouragement to voluntary donors.
4. To enforce quality control of blood in all its facets of collection, distribution and storage.

“In the said affidavit it was also stated that although the World Health Organisation has prescribed that nearly 10 lakhs units of blood are required for the country, the collection is only 19.5 lakhs units at present and, therefore, it is not possible to ban professional donors at this stage unless the donations of blood by way of voluntary donation are increased. In the said affidavit it was further stated that most of the Government Blood Banks are lacking in manpower. Training and laboratory facilities to test blood for blood transmissible diseases and to augment this, the central Government have provided funds to various State Governments during 1990-91 and 1991-92 to modernise the Government Blood Banks. According to the said affidavit, the main objectives for the modernisation of the Blood Banks have been provided into long-term objectives and medium-term objectives as under:

I. Long term objectives:

- (a) Make available high-quality blood and blood components in adequate quantity to all users.
- (b) Ensure wide usage of blood components.
- (c) Expand voluntary and replacement donor base, so as to phase out professional blood donors.

II. Medium-term objectives:

- (a) To provide minimum possible in facilities for blood collection, storage and testing all Government Blood Banks.
- (b) To make available the trained manpower in all Government Blood banks.
- (c) To Banks ensure the awareness of clinicians and Blood staff on the advantages of blood components.
- (d) To ensure the effective geographical coverage keeping in mind the different volumes of blood requirement in different cities.
- (e) To increase public awareness about the risks in using blood from commercial Blood Banks and Professional donors and the harmlessness of blood donation.

On a perusal of the Draft scheme that was submitted by the 'petitioner and the Draft scheme submitted by the Union of India, it was felt that it would facilitate matters if the question of necessary steps which may be required for further strengthening the existing framework about licensing of blood banks and obtaining blood donations is examined by a Committee which would place its suggestions before the Court for consideration. By order dated 11th February 1994, a Committee of the following persons was constituted to examine the matter and submit its report:

1. Additional Secretary, Ministry of Health holding the charge of Director, National Aids Control Organisation as Chairman.
2. Drugs Controller of India.
3. Mr. H. D. Shourie

The said Committee felt that since Indian Red Cross Society is presently involved to a considerable extent in blood banking operations and it has branches spread all over the country and it has capacity to further, strengthen, itself for looking after the various aspects of functioning of blood banks, it may be recognised as a nodal agency in the field of blood banking and blood transfusion technology in the country.

The Committee suggested that detailed discussions to finalise assessment in this regard may be held with the Indian Red Cross Society. Having regard to the said suggestions by the Committee constituted by the Court, the Indian Red Cross Society constituted a committee of experts to examine the matter and to prepare a draft blueprint. The said committee of experts in its report dated April 15, 1995, has indicated the following, fields in which measures are required to be taken:

1. Building a powerful voluntary blood donation movement to augment supplies of safe quality blood and blood Components.
2. Exercising economy by processing whole blood for blood components.
3. Introducing the screening procedure to minimize the danger of transmissible diseases like AIDS, Hepatitis etc.
4. Standardize technological procedures for the rigid enforcement of quality control and good manufacturing practices.
5. Providing technical services for raising the standard of Blood centre operations and assistance for administrative motivational and technical problems encountered, " It has proposed an action plan in three parts: Immediate Plan, Short Term Plan and Long Term Plan 1, which are as follows:

Immediate Plan

1. To establish an administrative unit at the national headquarters under the charge of, a project director.
2. To identify and strengthen a minimum of 2 Red Cross blood centres for each state for augmenting the existing blood programme. Necessary inputs towards staff, equipment and consumables for the development should be made available at once, basic requirements to procure accreditation from DC (1) should be ensured.
3. Donor recruitment and intensification of donor motivation drive may be taken up on priority. Basis Involvement of media may be ensured through information and Broadcasting Ministry.
4. A crash programme for short-term training of medical officers, technicians and medical social workers nurses of concerned centres may be undertaken. The WHO distance learning programme prepared may be helpful in updating the knowledge of technologists at the centres being strengthened.

5. In addition to the blood centre strengthening programme, steps must be taken for planning and Initiating an action for the establishment of Regional blood centres at the following 16 metropolitan cities with 2 million populations having many large medical super speciality institutions

- | | |
|-------------|----------------|
| 1. Delhi | 9. Bhopal |
| 2. Lucknow | 10. Ahmedabad |
| 3. Patna | 11. Bombay |
| 4. Calcutta | 12. Hyderabad |
| 5. Gauhati | 13. Bangalore |
| 6. Cuttack | 14. Trivandrum |
| 7. Nagpur | 15. Madras |
| 8. Jaipur | 16. Chandigarh |

Each centre will be expected to collect 150 to 200,000 units annually. These will be screened, processed and distributed as the blood components to local hospital-based centres against service charges.

As the regional centres will supplement the blood supplies through the existing system it would help in weeding out the blood supply from paid blood sellers. Therefore, it is of paramount importance that top priority is given for the establishment of these centres.

Short Term Plan:

1. Coordination of the blood programme of large medical colleges having more than 1000 beds, and or collecting over 10,000 units.
2. Establishment of post-graduate training centres at the places where facilities for fulfilling the norms the Medical Council India exist. In the Initial stages, faculty support can be obtained from departments of pathology. At the following cities, post-graduate training can be started

- | | |
|---------------|---------------|
| 1. Chandigarh | 6. Bombay |
| 2. Delhi | 7. Hyderabad |
| 3. Lucknow | 8. Bangalore |
| 4. Calcutta | 9. Trivandrum |
| 5. Jaipur | 10. Madras |

Training of paramedical workers can also be undertaken at these centres.

1. Coordination of all other, voluntary organisations working for the promotion of the blood programme by the Red Cross Society would further help in achieving the target of donor recruitment with greater vigour and better evaluation.
2. A national workshop at the Red Cross headquarters may be organised for officers of all centres being strengthened and the representatives of regional centres to provide necessary guidance for uniform and standardised policies and practices.

Long Term Plan:

1. To upgrade all other blood centres.
2. Establishment and up gradation of blood centres in areas where it does not exist.
3. Planning of more regional centres.
4. Establishing fractionation centres.
5. Establishment of therapeutic centres for blood-related disorders.
6. Programmes for indigenization of equipped software and reagents.
7. Establishment of tissue typing facilities for Bone Marrow an organ transplant.

After considering the said report of the Committee of experts, set up by the Indian Red Cross Society, the Committee constituted by the Court submitted us final report which was filed along with the affidavit of Shri Ashwini Kumar, Deputy Drugs Controller of India in the Directorate General of Health Services dated October 26, 1995. The Committee has made the following recommendations and has suggested steps for revamping the system of blood banks in the country in the form of plans for implementation on immediate basis and for long-term implementation.

FOR IMMEDIATE IMPLEMENTATION:

- (i) A National Council on Blood Transfusion should be established. It should consist of Director General of Health Services, Drug Controller of India, representative of Ministry of Finance, high level representatives of Indian Red Cross Society and selected five major medical and health institutions of the country, and three eminent citizens, presided over by the Additional Secretary of the Ministry of Health, who is in charge of operations of the programme of the National Aids Control Organisation. The Council should be provided with the basic secretariat under the charge of a Director by the Ministry of Health and be located at the suitable premises in Delhi for effective functioning, as it would be desirable to register the Council, a Society under the Societies Registration Act for enabling it to have its own identity, and funds and also for enabling to raise funds from various sources including contributions from trade, industry and individuals. The basic requirements of its functioning should be provided by the Ministry of Health. The Council will be policy formulating body related to all matters pertaining to operation of blood banks.
- (ii) The Ministry of Health with the assistance of National Council, will ensure the establishment of State-level Councils, at suitable centres, preferably headquartered at the premises of some outstanding medical institutions or hospitals. The State Councils should have on them representatives of important medical institutions of the State, selected representatives of blood banks of repute, a representative of Red Cross, and should include the State Director of Health Services as well as State Drug Controller operating under a designated Director and presided over preferably by the State Government Secretary in charge of health. A representative of the State Ministry of Finance should also preferably be on the Council. The size of State Council should preferably be restricted to the maximum about 11 members. Director of Health Services should provide the Committee with the basic essentials of the secretariat and funds for its functioning. The State Councils, as the case of National council, should be registered as the Society under the Societies Registration Act for maintaining their identity and for the purposes of collection of funds in the shape of contributions from individuals and corporate bodies. The State Councils should endeavour to operate the basic of policies formulated by the National Council, effectively implementing the policies and programmes formulated by them.
- (iii) Programmes and activities to cover the National Council and State Councils should have the entire range of services related to operation and requirements of blood banks including the launching of effective all motivation for campaigns through utilisation of media stimulating voluntary blood donations, launching programmes of blood donation in educational institutions, among the labour Industry and trade, establishments and organisations of various services including civic bodies, training of personnel in relation to overall operations of blood collection, storage and utilisation transport, quality control and archiving system, cross-matching of blood between donors and recipients, separation and storage of components of blood, and all the basic essentials of the operations of blood banking.

LONG TERM OBJECTIVE

- i) The programme formulation at the National level and State levels should take account the requirements of laying down targets for achievement including the establishment of appropriately designed and equipped blood banks ensuring that all blood banks are Licenced, making satisfactory arrangements for collection and storage of collected blood, fractionalization of blood into the components, special emphasis will need to be laid in the programme on the attainment of prescribed targets of organising camps for voluntary collection of blood through motivational campaigns and utilisation of media. The State-Councils shall submit their programme and targets to the National Council and thereafter continue to submit quarterly reports to the Central Council about the fulfillment of the targets relating to the programmes.
- ii) The National Council and State Councils should launch effective programmes and organise campaigns for collecting funds, implementation of their programmes and supplementing the funds allotted to them respectively by the Government of India and the State Governments. For the purpose of facilitating the collection of funds for blood banking purposes, Government of India and the Ministry of Finance should, at the earliest, be approached by the Ministry of Health to secure special dispensation u/s 35 of the income Tax Act, making it possible grant exemption of 100 percent basis to the donations given to registered and authorised National Council and State Councils. The fulfillment of this objective should be specifically reported by the Ministry Health, the Noble Supreme Court. The National Council and State Councils should utilise opportunities which may available for securing financial sanction and other support to their blood banking programmes from International sources and other donor agencies.
- iii) The Ministry of Health should follow up the recommendations made by the Expert Committee set up by the Indian Red Cross Society to start M.D. Course in blood transfusion technology, and also to undertake the preparation of comprehensive programme for training of personnel operating in relation to various of aspects of functioning of blood banks; storage blood, fractionalisation of blood, and transfusion of blood.
- iv) The system of licencing of blood banks will be strengthened to ensure that all quality banks operating in the country are equipped with licences within a period of not more than one year. Where any blood bank remains ill-equipped for being licenced and remain unlicensed after the expiry of the period of one year, their operations should be rendered impossible through suitable legal action. It shall be the policy objective of the Ministry of Health as well the National Council and the State Councils established on the basis of these recommendations that the prevalent system of professional donors are discouraged through utilisation of appropriate provisions made through withdrawal of licences where any such blood bank has been licensed, and by launching Prosecutions under the appropriate provisions of law. The objective of total elimination of professional donors should be achieved in a period of not more than two years through utilisation of all requisite measures. For the attainment of objectives & programmes, the local organisations, the State Govt. will be approached for providing the requisite Inspectorate for continuing inspection of blood banks.

The Committee has 'taken note of the programme for preventing infection and strengthening of Blood Banking system in the country that is being implemented by the National Aids Control Organisation, which is annexed as Annexure - 1 to the report of the Committee.

The Indian Association of Blood Banks has been impleaded as a party in these proceeding and an affidavit of Dr. V.B.Lal, President of the said association, has been filed.

We have heard Shri H.D. Shourie, the petitioner in person, Shri A .S .Nambiar, the learned Senior Counsel for the Union of India, Shri .P.P.R. a.o., learned Senior Counsel for the Indian Association of Blood Banks, Dr.V. Gauri Shankar, learned Senior Counsel for the Indian Red Cross Society and the learned counsel appearing for the States.

Keeping in view the report of the Committee that has been constituted by this Court and the report of the Committee of Experts set up by the Indian Red Cross Society and the programme that is being implemented by the National Aids Control Organisation as well as the submissions of the learned counsel, we are of the view that suitable action should be taken by the Union Government as well as the Governments of the States and the Union Territories Administration in accordance with the plan for Immediate implementation as well as the plan for Long Term implementation suggested by the Committee constituted by this Court.

It is no doubt (true) that after the report of M/s. A. F. Ferguson & Co. the Union Government has taken certain steps towards improving the state of affairs regarding the blood banks in the country and the National Aids Control Organisation is also working in this field. But a lot more is required to be done as it would be evident from the reports of the Committee constituted by this Court and the Committee of Experts appointed by the Indian Red Cross Society.

The Committee constituted by this Court has made concrete suggestions in this regard.

We are in agreement with the recommendations of the said committee that the entire range of schemes related to the operation and requirements of blood banks including the launching of effective motivation campaigns for stimulating voluntary blood donations, launching programmes of blood donations, training of personnel in relation to overall operations of blood banking should be entrusted to an autonomous representative body at the national level which may be called the National Council on Blood Transfusion, as suggested by the Committee. The National Council would exercise the functions entrusted to it in coordination with similar bodies established at State level which may be called State Councils. In order that they may have their own individuality and funds and are able to raise funds from various sources including contributions from the trade, industry and individuals, the National Council and the State Councils should be constituted as societies registered under the Societies Registration Act. The National Council and the State Councils should undertake the measures suggested by the Committee constituted by the Court as well as the Committee of Experts appointed by the Indian Red Cross Society and while doing so, they should coordinate their activities with those of the National Aids Control Organisation and other agencies in this field. Keeping in view the potentialities of the harm in the prevailing state of affairs and the need for speedy action in this regard, we consider it appropriate to give the following directions.

- 1 The Union Government shall take steps to establish forth with a National Council of Blood Transfusion as a society registered under the Societies Registration Act. It would be a representative body having in it representation from the Directorate General of Health Services of the Government of India, the Drug Controller of India, Ministry of Finance in the Government of India, Indian Red Cross Society, private blood banks including the Indian Association of the Blood Banks major medical and health institutions of the country and, non-Government organisations active in the field of securing voluntary blood donations. In order to ensure coordination with the activities of the National Aids Control Organisation, the Additional Secretary in the Ministry of Health who is in charge of the operations of the programme of National Aids Control Organisation for strengthening the blood banking system, would be the president of the National Council.
- 2 The National Council shall have a secretariat at Delhi under the charge of a Director.
- 3 The basic requirements of the funds for the functioning of the National Council shall be provided by the Government of India but the National Council shall be empowered to raise funds from various other sources including contributions from the trade, industry and individuals.
- 4 In consultation with the National Council, the State Governments/Union Territory Administration shall establish a State Council in each State/Union Territory which shall be registered as a society under the Societies Registration Act. The State Council should be a representative body having in it, the representation from Directorate of Health Services in the State, State Drug Controller, Department of Finance of the State Government/Union Territory Administration, important medical institutions in the State/Union Territory, Indian Red Cross Society, private blood banks, Non-Governmental Organisations active in the field of securing voluntary blood donations. The Secretary to the Government in charge of the Department of Health could be the President of the State Council.
- 5 The State Council should have its headquarters at the premises of the premier medical Institution or hospital in the State/Union Territory and should function under the charge of a Director.

- 6 The funds for the State Council shall be provided by the Union of India as well as the State Government/Union Territory Administration. The State Council shall also be empowered to collect funds in the shape of contribution from trade, industry and individuals.
- 7 The programmes and activities of the National Council and the State Councils shall cover the entire range of service related to operation and requirements of blood banks including the launching of effective motivation campaigns through utilisation of all media for stimulating voluntary blood donations, launching programmes of blood donation in educational institutions among the labour, industry and trade, establishments and organisations of various services including civic bodies, training of personnel in relation to all operations of blood collection, storage and utilisation, separation of blood groups, proper labelling, proper storage and transport, quality control and archiving system, cross-matching of blood between donors and recipients, separation and storage of components of blood, and all the basic essentials of the operations of blood banking.
- 8 The National Council shall undertake training programmes for training of technical personnel in various fields connected with the operation of blood banks.
- 9 The National Council shall establish an institution for conducting research in collection, processing, storage, distribution and transfusion of whole human blood and human blood components, manufacture of blood products and other allied fields.
- 10 The National Council shall take steps for starting special post-graduate courses in blood collection, processing, storage and transfusion and allied fields in various medical colleges and Institutions in the country.
- 11 In order to facilitate the collection of funds for the National Council and the State Councils, the Government of India (Ministry of Health and Ministry of Finance) should find out ways and means to secure grant of 100% exemption from income tax to the donor in respect of donations made to the National Council and the State Councils.
- 12 The Union Government and the Governments of the States and Union Territories should ensure that within a period of not more than one year that all blood banks operating in the country are duly licensed and if a blood bank is found ill-equipped for being licensed, and remains unlicensed after the expiry of the period of one year, its operations should be rendered impossible through suitable legal action.
- 13 The Union Government and the Governments of the States and Union Territories shall take steps to discourage the prevalent system of professional donors so that the system of professional donors is completely eliminated within a period of not more than, two years.
- 14 The existing machinery for the enforcement of the provisions of the Act and the Rules should be strengthened and suitable action be taken in that regard on the basis of the Scheme submitted by the Drugs Controller (I) to the Union Government for up-gradation of the Drugs Control Organisation in the centre and the States (Annexure -II to the affidavit of Shri R. Narayanaswami, Assistant Drug Controller, dated September 16, 1994).

- 15 Necessary steps are taken to ensure that Drugs Inspectors duly trained in blood banking operations are posted in adequate numbers so as to ensure periodical checking of the operations of the blood bank throughout the country.
- 16 The Union Government should consider the advisability of enacting a separate legislation for regulating the collection, processing, storage, distribution and transportation of blood and the operation of the blood banks in the country.
- 17 The Director General of Health Services in the Government of India, Ministry of Health shall submit a report by July 15, 1996, about the action taken in pursuance of these directions.
- 18 It will be open to the Director General of Health Services, Government of India as well as the National council to seek clarification / modification of these directions or, further directions in this matter.

The writ petition is disposed of with these, directions. No order as to costs.

New Delhi,
January 04, 1996

[S.C.AGRAWAL]

[G.B. PATTANAİK]

NBTC
राष्ट्रीय रक्त संचरण परिषद्
National Blood Transfusion Council

