



# An Action Plan For Blood Safety



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





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# Glossary

AFTS	Armed Forces Transfusion Service
AIDS	Acquired Immunodeficiency Syndrome
AMC	Annual Maintenance Contract
BB	Blood Bank
BTS	Blood Transfusion Service
CMIS	Computerised management Information System
DCG (I)	Drug Controller General (India)
DGHS	Directorate General of Health Services
DHS	Director of Health Services
ELISA	Enzyme Linked Immunosorbant Assay
EQAS	External Quality Assurance Scheme
FFP	Fresh Frozen Plasma
HIV	Human Immunodeficiency Virus
ICMR	Indian Council of Medical Research
MOHFW	Ministry of Health and Family Welfare
NACO	National AIDS Control Organisation
NARI	National AIDS Research Institute
NBTC	National Blood Transfusion Council
NIB	National Institute of Biologicals
NGO	Non Government Organisation
PD NACO	Project director NACO
QA	Quality Assurance
RBTC	Regional Blood Transfusion Centre
SACS	State AIDS Control Society
SBTC	State Blood Transfusion Council
SC	Storage Centre
SEARO	South East Asia Regional Office
TRG	Technical Resource Group
TTI	Transfusion Transmissible Infections
UT	Union Territory
VCTC	Voluntary Counselling and Testing Centre
WHO	World Health Organisation
ZBTC	Zonal Blood Testing Centre



# Introduction



Human blood is an essential element of human life, and there are no substitutes. Blood transfusion services occupy a vital space in any National Health Service delivery system. Blood is also a scarce resource. The availability of safe and adequate blood saves lives. If not properly screened, however, blood becomes a conduit for transmitting life threatening viral, bacterial and protozoal infections, e.g. hepatitis B, hepatitis C, HIV/AIDS, syphilis and malaria.

Following upon the National Blood Policy, 2002, the Action Plan on blood safety is driven by the need to continually improve and upgrade the availability and safety of blood and blood products, and to facilitate a self sustaining national blood transfusion programme.

Till the mid-nineties, up to 8 per cent of new HIV infections in India, were attributed to the transmission of unsafe blood. Currently, and largely on account of overall improvement in the quality of blood and blood products, less than 2 percent of new HIV infections are traceable to the transmission of unsafe blood.

Typically, two categories of persons need blood transfusion: those with emergent requirements e.g., victims of road accident, civilian and military disaster; and those with repeated, frequent and regular requirement e.g., patients with thalassemia, haemophilia, renal dialysis, severe anaemia and cancer. Patients who must undergo repeated transfusions are at greater risk of acquiring transfusion transmissible infections (TTIs). The only way to protect recipients of blood is to put in place structures, processes and procedures that will ensure access to safe and sufficient blood supply. This is now a vital medical need.

## Background

Human blood is categorised as a "drug" under Section 3 (b) of the Drugs and Cosmetics Act, 1940. This Act and the Rules thereof provide the legal framework for regulating the functioning of blood banks, which in turn directly impacts and determine blood transfusion service delivery in the country. Since initial formulation, the ambit of the Drugs and Cosmetics Act, 1940 has been expanded, and the Rules have accordingly been frequently amended to incorporate ongoing and current concerns.

The National AIDS Control Project, 1992-99 funded by the World Bank, Government of India, and co-financed by the World Health Organisation, had 30 per cent of its project cost focussing on blood safety. This has contributed significantly to improving the quality of blood / blood products and service delivery in India. The project financed HIV test kits, facilitated technical assistance on blood safety, and upgraded equipment in government blood banking facilities. It also sponsored information, education and communication (IEC) campaigns at both national and state levels to generate awareness about the potential danger of unsafe blood from unlicensed blood banks and professional donors, and promoted a movement for voluntary blood donation.

There remained, however, several systemic problems. While the National AIDS Control Organisation (NACO) was responsible for ensuring the safety of blood supply, it had limited ability to enforce a ban on professional donation or even to strengthen licensing





requirements. In response to a lawsuit brought by an NGO, the Supreme Court of India, passed a judgement<sup>1</sup> that generated some key changes in the regulatory environment. In a nutshell, (i) responsibility for ensuring blood safety was shifted to the national drug control authority; (ii) a ban was to be imposed on 'professional' blood donations by 1997; and (iii) all blood banks were to be licensed in the next two years or face closure. The spread of the HIV epidemic in India reinforced the urgency of regulating and promoting blood safety across the country. During 1989, Ministry of Health & Family Welfare made the testing of HIV 1 & 2 antibodies of whole human blood as mandatory prior to further utilising the blood in transfusion. Three laboratories viz. National Institute of Communicable Diseases Delhi, National Institute of Virology, Pune, and CMC Vellore were notified to test HIV antibodies in human blood and human blood products. Since trained technicians were not immediately available in blood banks to carry out the test for HIV 1 & 2 antibodies, the Ministry of Health & Family welfare notified Zonal Blood Testing Centres, to act as testing labs for the blood banks to comply with this new requirement. A report by M/s Ferguson<sup>2</sup> brought out several deficiencies in respect of non-uniformity in the licensing of blood banks. Accordingly, during 1992-93, the Drugs Controller General, India was vested with the power of Central Licence Approving Authority (CLAA) to approve the licence of notified drugs viz. blood and blood products, IV fluids, vaccines and sera. The Drugs and Cosmetics Rules, 1945, framed under the Drugs and Cosmetics Act, 1940 were amended in 1993<sup>3</sup>. The licensing of blood banks was brought under the dual authority of the state and central government. The state licensing authority issues the licence, while the Drug Controller General (India) is the central licence approving authority. Licences are issued only after the approval of the DCG(I). Prior to approval, the blood banks are inspected jointly by the field officers of the state and central government, and, if satisfied, the state licensing authority signs the licences in triplicate and forwards the same to the DCG for approval. After scrutiny, the DCGI either approves or rejects the licence, and returns the papers to the State Licensing Authority for further necessary action.

In compliance with the mandate of the Supreme Court, Section 80G of the Income Tax Act, 1961 was amended<sup>4</sup> so as to make all donations to the National Blood Transfusion Council (NBTC) and to the State Blood Transfusion Councils (SBTCs) eligible for tax deductions from the taxable income of an Assessee. The Drugs and Cosmetics Rules, 1945 were further amended in the years 1996, 1999<sup>5</sup> and 2001<sup>6</sup>. In December 2001, a notification<sup>7</sup> was issued to regulate and streamline the blood storage centres, which will help community health centres, small hospitals / nursing homes whose requirement is less than 2000 units of blood per annum.

<sup>1</sup> AIR 1996 Supreme Court 929 in Common Cause versus Union of India and others.

<sup>2</sup> Appointed by GOI

<sup>3</sup> Chapter X-B was added, which indicates requirements to be fulfilled by blood banks for the *collection, storage, processing and distribution* of whole human blood and human blood components, and for the *manufacture of blood products*.

<sup>4</sup> Added by Finance Act, 1996, w.e.f. 1.4.1997

<sup>5</sup> Part XII-B was added to Schedule F indicating requirements to be fulfilled for the functioning / operation of a blood bank and /or for the preparation of blood components.

<sup>6</sup> Part XII-C was added to Schedule F of the Rules, prescribing in detail the requirements before blood products can be manufactured.

<sup>7</sup> GSR No.631 dated 20.12.2001



# National Blood Policy: April 2002



**G**overnment adopted the National Blood Policy (NBP) in April 2002. The NBP sought a "comprehensive, efficient and a total quality management approach" within a nation-wide system, to ensure easy access to adequate and safe blood supply. The National Blood Transfusion Council (NBTC) would oversee and coordinate the functioning of blood transfusion services. The State/UT Blood Transfusion Councils would be responsible for overall implementation of an organised blood transfusion service (BTS) through the network of regional blood transfusion centres and satellite centres, besides other government, Indian Red Cross and NGO run blood centres. The establishment of the Drugs Controller General of India (DCGI) would ensure quality control and also monitor the functioning of the blood banks. The National Blood Policy (NBP) envisages technical training in transfusion medicine, and encourages the use of current technology for blood transfusion services, and even provides for a corpus of funds to be directed towards research and development in the field of transfusion medicine and related technology.

## Motivating the Action Plan

The ground reality however, is that the blood transfusion services are plagued by fragmented management, a situation not conducive to blood safety. While our collection of blood demonstrates no absolute shortages, there are occasional and seasonal shortages. WHO recommends that the ratio of the use of blood components and whole blood should be 90:10 since only a limited category of clinical interventions require whole blood. In India, 80 per cent of blood is used as whole blood, only and 20 per cent units are utilised as components. Blood banks and blood transfusion centres operate in total isolation; their standards vary from state to state, city to city and from one centre to the other centre within the same city. Most of the blood banks are hospital based and often operate with minimal infrastructure and inadequate / irregular supply of blood. The hospital based decentralised blood banking system has led to a skewed distribution of resources, and makes difficult any implementation of a stringent quality control programme.

The purpose of this Action Plan for Blood Safety is to operationalise the priorities and objectives set out in the national blood policy and to address the infirmities in existing





systems in terms of quality, structures, linkages and procedures that govern the blood transfusion services in the country.

- ✿ A primary objective is to have a well-knit and regionally coordinated blood banking system, with structured blood transfusion services and an inbuilt mandatory Quality Assurance Programme, to be achieved through a series of linked interventions.
- ✿ Blood should be meticulously screened for infectious agents, prior to transfusion. To fully operationalise and achieve this objective, we articulate systems for continually imparting appropriate education and training to the concerned staff as well as to the community.
- ✿ Blood for transfusion should be obtained only from low risk, voluntary donors. Procedures are specified to promote donor retention.
- ✿ Within the national blood transfusion programme, we articulate an effective quality management mechanism so that a commitment to quality enhancement permeates every single regional blood transfusion centre, blood bank and blood storage centre. Individually and collectively each of these entities and structures must become synonymous with safe blood & blood products.
- ✿ And finally, in order to ensure the optimal availability of blood for life saving situations, we promote the appropriate clinical use of blood. As a rule of thumb, blood and blood products must be prescribed only when the benefits of transfusion outweigh the risks.

All of this can be achieved if we link vertically and horizontally all blood banks and blood testing centres with a mandate for quality assurance. The Action Plan for Blood Safety aims to put in place a network of accredited regional blood centres (RBTCs), blood banks (BBs), inclusive of blood storage centres (BSCs) which will make available closer to the people, appropriately screened, safe blood procured through voluntary donation.

Formulation of the Action Plan for Blood Safety has been a dynamic process. Each Section of the Action Plan recapitulates an objective cited in the National Blood Policy (NBP), 2002, all objectives of the NBP are addressed. Each objective cited is followed by a listing of diverse and wide ranging operational strategies whose implementation calls for a multi-agency response from government, the private sector, the Red Cross Society of India, the Indian Council of Medical Research, Medical Council of India, NGOs / CBOs and others.



## Objective 1

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To reiterate firmly Government's commitment to provide safe and adequate quantity of blood, blood components and blood products.



# Objective 1

To reiterate firmly Government's commitment to provide safe and adequate quantity of blood, blood components and blood products.

## Establishing a national blood transfusion programme

1.1 The national blood transfusion council (NBTC) will develop a distinct identity with wide-ranging membership and representatives from among experienced clinicians, blood transfusion specialists, pathologists and motivators from the public, private and corporate sectors, and other NGOs of repute, the Red Cross Society of India, Federation of Indian Thalassemics (FIT) and Haemophilia Federation of India (HFI). Membership at the state level state blood transfusion councils should also reflect similar wide-ranging participation, and include representatives from the state level Red Cross, the FIT, and the HFI. Experts may be invited and co-opted on to the NBTC. A full time Director will be the Member Secretary of the NBTC.

1.2 Director Health Services (DHS) /Director of Medical Services (DMS) in each state and UT will be an active member of the State Blood transfusion Council (SBTC). The resources and infrastructure available to the state DHS/DMS shall be utilised for the routine functioning of the SBTCs. The Director will be assisted by one Deputy / Asst. Director, with administrative support.

1.3 Staff should be put in position in the national and state blood transfusion councils (SBTCs) at the earliest. The roles and responsibilities of the NBTC, the SBTC and the RBTC (regional blood transfusion centre) are articulated in Annexure II, III and IV.

1.4 The staff in the NBTC and SBTC will be fully trained in respect of their specific role, duties and responsibilities.

1.5 The Director Health services/Director Medical Services in coordination with the SBTC in each state/UT shall develop a sub-plan, which articulates a coordinated management structure and specifies the network and the horizontal and vertical linkages





between the regional blood transfusion centres, the blood banks, and blood storage centres. The blood transfusion services within the state and region may be organised in a hub and spoke approach, through a network of RBTC, BBs and BSCs. The RBTC will serve as the hub. The DHS / SBTC will identify the appropriate RBTC (that which is run in conformity with the definition of RBTC in Annexure 1) and will document the specific plan for linkages involving the blood banks run by the Red Cross Society of India, by the corporate sector, and by all government and non-government (NGO) stakeholders across the state.

1.6 The state blood transfusion council (SBTC) is responsible for implementing the national blood policy and the action plan for blood safety in their respective state / UT. The implementation will be funded by the state government and the NBTC.

1.7 The NBTC will coordinate response at the central level, provide appropriate direction and facilitate the SBTC to provide integrated and coordinated management within the state.

1.8 Heads of SBTCs will forward regular monthly reports to Director NBTC in respect of their physical and financial achievement, as well as emerging problems or barriers to implementation. All information from individual blood banks, the SACS, and the SBTCs may be forwarded in NACO' CMIS format. To improve coordination and facilitate dialogue, President NBTC shall invite all heads of SBTCs twice every year to review their implementation of the programme.

### Provision of blood and blood products

1.9 The Director of Health Services /Director Medical Services in each state / union territory will undertake, jointly with the SBTC, a mapping of the blood banks, blood storage centres, and blood transfusion centres within his jurisdiction. Mapping should be completed within three months of adoption of this Action Plan. One output of this exercise will be a comprehensive inventory of the regional level, state level, district and sub-district level blood banks, blood transfusion centres and blood storage centres in medical and non-medical settings, urban and rural areas, and in the public, private, NGO and corporate sectors, inclusive of those run by the Red Cross Society of India.

1.10 NBTC will formulate, finalise and disseminate specific guidelines in respect of provisioning of blood by public, private, NGO and corporate sector blood banks.

1.11 The NBTC / SBTC will encourage public-private-civil society partnerships in an effort to build upon, and coordinate the comparative advantages, strengths and capacities of diverse stakeholders example, IRCS blood banks, voluntary and charitable sector blood banks, private sector blood banks and government blood banks, in order to ensure that meticulously screened blood becomes more visible, available and accessible.

1.12 NBTC should initiate dialogue with the armed forces in respect of making special provision of blood and blood products to garrison units of armed forces in remote border areas, and then coordinate the course of action agreed upon.



1.13 The NBTC shall develop short, medium and long-term proposals to improve the availability of and access to plasma protein therapy required in diverse diseases for all age groups. The single plasma fractionation facility in India, i.e. the National Plasma Fractionation Centre, Mumbai caters to a very small segment. There is heavy reliance on importing these increasingly expensive products, with serious availability problems. NBTC may examine the feasibility of public-private partnerships in this area, example contract fractionation. The NBTC must develop proposals to:

- ensure the availability of safe and consistent supply of raw material (plasma);
- articulate a regulatory framework for the collection, storage, processing and purchasing of plasma from blood bankers.

### Increasing access to screened voluntary blood

1.14 The SBTC will assess the requirement for blood within their respective states where blood is most most regularly required and used, example, surgery and obstetrics units, trauma care centres, cancer management centres, cardio-thoracic centres and paediatric centres, inclusive of rural settings. These requirements will be mapped using geographical information systems.

1.15 SBTC will articulate and design linkages between existing blood transfusion centres / blood banks and hospitals / nursing homes / hospices / community care centres in the Government / NGO / private sector. This will ensure that the onus of procuring screened blood will depend on the smooth referrals between these sites, and not solely upon the relatives of patients.

1.16 Where the supply of blood is seen as adequate to service the peripheral demand centres, the existing systems of logistics will be reviewed, and revitalised. Strategies will be clearly articulated for strengthening the supply chain: SBTC to RBTCs to blood banks. Inventories in the peripheral blood storage centres and the central blood bank will be linked to users and blood donation registries, through a web based system.

1.17 In some pockets, the need may arise for setting up additional blood storage centres, and even rationalising and relocating present ones or augmenting existing capacity through improved voluntary blood donation and other means, as necessary and feasible

1.18 Storage licence for blood components will be granted to all blood banks, as feasible. This will greatly facilitate and improve availability of blood components.

1.19 Special transfusion requirements for haemophilia, thalassemia and other bone marrow failure syndromes will be provided at peripheral levels, through blood storage centres, particularly in endemic areas.

### Monitoring and evaluation systems

1.20 NBTC will implement through the SBTC and /or monitoring committees of stakeholders, compliance with guidelines in order to monitor the quality of regional





blood banks, the Indian Red Cross and NGO run blood banks, and all others run in the public sector, private hospitals and institutions.

1.21 Blood bank cells and licensing committees within the central and establishment of the Drugs Controller General of India (DCGI) should be fully functional at all levels.

1.22 Licensed blood banks will provide standardised service delivery with well-trained staff and technicians.

1.23 A State Level Blood Safety Management Information System should be instituted early.

1.24 The NBTC will facilitate the development of a minimum standard for electronic information exchange between blood banks, so that all blood banks intending to computerize their operations are able to exchange information with each other; and so that their systems are compatible with the unified Voluntary Blood Donor Database. Several such standards are already in existence in other countries and can be adapted and modified for use in India.

1.25 The Regional Blood Transfusion Centres should also develop a special crisis cell which shall be responsible for coordinating information and requirement across blood banks in times of emergencies or shortages of blood in any hospital or institution.

Activity	Date of commencement	Date of completion	Responsible Officer	Responsible supervisor	Budgetary source
1. Establishment of an office and full time Director and support staff for NBTC	1.09.03	1 year	Member Secretary, NBTC	AS & PD, NACO	NACO/ NBTC
2. Establishment of an office and full time Director and support staff for SBTC	1.09.03	1 year	PD, SACS	Secretary, Health of the State / UT	SBTC/ DHS
3. Functioning of NBTC and SBTC	1.09.03	1 year	Chairperson NBTC and PD, SACS	Health Secretary of the State/ UT	NBT C <sub>1</sub> SBTC DHS
4. Development of a sub-plan by SBTC for a co-ordinated management structure	1.09.03	6 months	PD, SACS Dir, SBTC	DHS, DMS	SBTC
5. Monitoring system for action plan	1.09.03	3 months	Director NBTC/ SBTC	Secretary Health, of the State / UT	NBT CSBT DHS



## Objective 2

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To make available adequate resources to develop and re-organize the blood transfusion service in the entire country



# Objective 2

To make available adequate resources to develop and re-organize the blood transfusion service in the entire country

2.1 The activities outlined in this Action Plan requires additional resources. These would be met from internal and external sources. Internal resources mobilisation calls fo appopriate pricing of blood and blood components provided by the blood banks. In order to arrive at appropriate picing the NBTC will commission an exercise to arrive at financial and economic costs. Once, average and incremental costs are worked out the NBTC will have to decide on the modalities of price fixation. In this process the questions of basis of costing, extent and manner of subsidy and differential treatment of public and private sector will need to be decided upon.

## Resource Provision

2.2 Diverse sources for additionality in funds will be identified:

- ✿ NACO-NBTC-SBTC (domestic budgetary sources)
- ✿ State Health Ministries
- ✿ International and bilateral donor organisations.
- ✿ Philanthropic sponsors.
- ✿ User fees.

2.3 Formal requests for specific assistance from multi- and bi-lateral donor agencies will be processed by NACO and transmitted to donors.

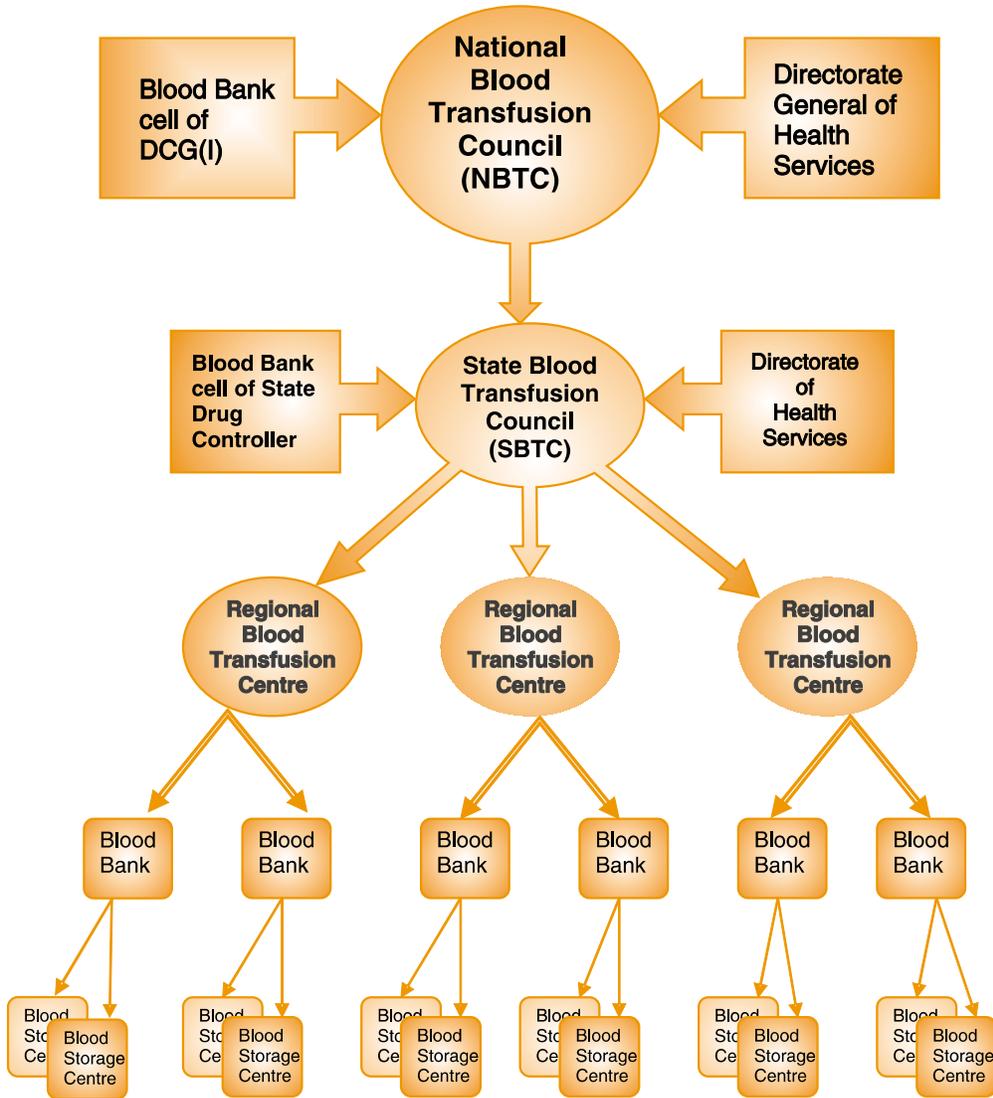




Activity	Date of commencement	Date of completion	Responsible Officer	Responsible supervisor	Budgetary source
1. Costing	Preliminary costing already done by TRG	6 months	Chairperson NBTC/ SBTC	AS & PD, NACO	-
2. Economic feasibility study by any agency	1.09.03	6 months	JD (BS) / PD NACO to appoint an agency	AS & PD, NACO	NBTC SBTC
3. Funds made available	1.09.03	31.3.04	JD (BS)	AS & PD, NACO	NACO SBTC



ORGANOGRAM FOR BLOOD TRANSFUSION SERVICES





## Objective 3

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To make latest technology available for operating the blood transfusion services and ensure its functioning in an updated manner and to set up a blood product monitoring and evaluation system that ensures quality blood and blood product supply



# Objective 3

To make latest technology available for operating the blood transfusion services and ensure its functioning in an updated manner & to set up a blood product monitoring and evaluation system that ensures quality blood and blood product supply.

## Administrative Actions

3.1 The NBTC will revisit the WHO minimum standards adopted for the blood transfusion services, make such modifications as may be necessary, and will notify the standards adopted. The NBTC will ensure wide circulation to all stakeholders, and participants in the public, NGO, and corporate sectors.

3.2 Standard Operating Procedures (SOPs) for laboratories will be developed by the NBTC and disseminated to all state governments & UT administrations, regional, state, district and sub district level blood transfusion centres, blood banks, and blood storage centers. A Standard Operating Procedures (SOPs) manual will be developed and disseminated to all blood centers nationwide.

3.3 A QA manager will be identified and made functional in respect of all BBs collecting over 10,000 units of blood per annum. He will formulate procedures / test-checks / flow charts to ensure uniformity in the observance of standard operating procedures in the RBTC, the BBs and BSCs. The QA manager shall also oversee monitoring of viral markers. National Blood Transfusion Council will identify (through a formal selection process) external reference centres that will transparently monitor and externally evaluate the quality of blood services.

## Monitoring and Quality Control

3.4 The Drugs and Cosmetics Act 1945 will be appropriately amended to reflect all revisions in respect of the minimum standards prescribed, and other updates.

3.5 The NBTC will ensure notification of specifications and standards in respect of





kits and reagents being certified by the apex laboratory and by any other referral laboratory identified by NBTC. Stringent processes for pre-test and post marketing surveillance will be notified. External Quality Assurance will be included.

3.6 A list of approved equipment, certified test kits, reagents and other consumables will be issued by NACO to all licensed blood banks and will also be placed on the NACO website, and will be duly updated every year. Attempts should be made to strictly adhere to international standards in respect of all equipment, test kits, reagents, consumables, and any other items used, or to upgrade existing specifications, wherever feasible.

3.7 The RBTCs and the SBTCs have a specific role and responsibility in respect of procurement of equipment. All procurement must be based on a facility-specific needs assessment, to be pursued by the concerned SBTC in consultation with the RBTC.

3.8 Specifications and standards will be developed and notified by the NBTC in respect of all equipment to be procured. Annual maintenance contracts and appropriate warranty will be included in the bidding documents.'

3.9 Appropriate strengthening of the Inspectorate of the Drugs Controller General of India inclusive of state level counter parts needs to be undertaken.

### Introducing accreditation of blood banks

3.10 Within any health care delivery system, accreditation results in a continuous commitment to quality enhancement. It ensures that high quality is consistently achieved and maintained.

3.11 Accreditation is a formal process by which a recognised body assesses and recognises that a health care facility (example, blood banks) is complying with applicable, pre-determined and published standards. Standards for accreditation are:

- Optimal and achievable
- Designed to encourage continuous improvement efforts within accredited organisations

3.12 NBTC shall set up a Working Group with the Indian Council of Medical Research (ICMR), to develop and finalise the legal framework and business model for an accreditation programme made applicable to the blood transfusion services of India. NBTC could consider contracting out some pilot projects for accreditation. The Working Group could include representatives from the professional societies of blood transfusion, as also legal experts in this field.

3.13 Accreditation systems are to be designed and operationalised at two levels, the national level and at the level of the accreditation organisation. The national level (in this case, the NBTC) will coordinate the development and implementation of standards, guidelines and protocols, training modules as well as the accountability and audit of accreditation bodies, in consultation with relevant stakeholders. The methods of assessment will be continually refined for incorporation into the accreditation process.



**3.14** The accreditation organisation will have the primary responsibility of implementing the accreditation as designed by the national level. The partnership between diverse stakeholders will provide a platform for consensus building transparent process. Any standards defined by the accreditation body will be assessed by peer review.

**3.15** NBTC will finalise the schedule and frequency of accreditation.

**3.16** The Action Plan contemplates specific incentives for those who wish to be accredited. Blood banks and structures that are accredited will gain from being included in contracts for service provisioning through public-private collaboration, for carrying out training of government and non-government practitioners, and for research grants. In this manner, government will encourage and place a premium on quality assurance. The NBTC will identify one or more professional bodies, inclusive of medical associations, or groups of stakeholders for implementing the accreditation. Thus the Action Plan addresses both compliance with existing standards, and encouraging higher standards

**3.17** Any business model developed for this purpose need to incorporate issues such as participation of government blood banks, NGO blood banks, not for profit blood banks, and any others in the accreditation programme. Organisations of blood donors' and blood users, should be accorded the status of monitors in civil society.

**3.18** NBTC will undertake to develop procedures for adopting standards, setting prices, developing advertising campaigns and creating a curriculum for training assessors.

**3.19** The benefits of an accreditation programme are significant enough to merit government support. Since government in India performs the role (so far) more of a service provider rather than a purchaser of services (in health care, in particular), the cost of accreditation should be borne fully or partially by the central government. The NBTC may also negotiate with international and bilateral organisations for financial support.

**3.20** SBTC with the assistance of RBTCs will carry out internal and external audit of all BB's in the region each year.





Activity	Date of commencement	Date of completion	Responsible Officer	Responsible supervisor	Budgetary source
1. Standards prepared by TRG to be printed	1-09-03	8 weeks	JD (BS)	PD, NACO	NACO
2. Identification of NRL for EQAS.	Already identified	-	JD (BS)/ TRG	PD, NACO	NBTC SBTC DHS
3. Support of NRL for EQAS.	1-09-03	16 weeks	APD(T), NACO	PD, NACO	NBTC SBTC DHS
4. Formation of Working group for developing accreditation programme	1-09-03	8 weeks	JD (BS)	PD, NACO	NBTC
5. Accreditation process to be initiated	1-09-03	24 weeks	JD(BS)	PD, NACO	NBTC



## Objective 4

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



# Objective 4

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

## IEC Campaign Implementation

- 4.1 Each SBTC will undertake a communication needs assessment and develop an IEC strategy within its jurisdiction.
- 4.2 NBTC will finalise (with technical assistance as appropriate from partners and bilateral agencies), an IEC strategy and a plan for the national campaign.
- 4.3 The national campaign and some key specific IEC campaigns will be launched early.
- 4.4 Counselling services will be set up and implemented for pre- and post-blood donation in all states.
- 4.5 Sourcing the total requirement of blood through voluntary blood donation
- 4.6 The critical set of strategies for ensuring safe and adequate blood supply is to pursue the motivation, recruitment, selection and retention of voluntary non-remunerated blood donors.
- 4.7 The aim is to phase out replacement donors, and to focus our attention on augmenting blood collection through voluntary blood donations for over 95 per cent of blood requirement. This can be achieved by following the four steps to improving voluntary blood donation: (1) regular IEC in respect of voluntary blood donation, (2) providing appropriate facilities for citizens to donate blood at their convenience, (3) prompt and sympathetic response when an individual is in need of blood, (4) maintaining up to date donor records in order to promote donor retention and encouraging the





role of voluntary workers and members of NGOs and community based organisations (CBOs) in motivating and encouraging voluntary blood donors. Massive information, education and communication campaigns through newspapers and electronic media will encourage the movement for voluntary blood donation. These steps will also help reduce transfusion transmitted infections. The Director, SBTC will have overall responsibility for implementing an effective voluntary donor programme within individual states. The SBTC shall be duly assisted by the respective RBTCs in this endeavour.

**4.8** NBTC and SBTCs will develop innovative, multi-media IEC campaigns, and will adapt these to diverse settings, as feasible, to include interpersonal counselling, folk dances, theatre and hand bills. NBTC will encourage Doordarshan and All India radio to spread the message of voluntary blood donation.

**4.9** State governments must encourage young people to form voluntary blood donation clubs at college / institutional / community levels. Holding blood donation camps in schools for parents and faculty would prove of immense educational value in teaching young children about the safety and harmlessness of donating blood. Linkages should be developed at state and district levels with ongoing programmes targeting the young, for example, volunteers of National Service Scheme (NSS), Nehru Yuvak Kendras (NYK) and National Cadet Corps (NCC) who would willingly participate in any action for voluntary blood donation movement. Similarly, educational institutions and faith groups must be similarly motivated to proactively participate in the cause of voluntary blood donation.

**4.10** State governments must pilot innovative approaches that provide recognition for blood donation. In Maharashtra, the Nehru Yuvak Kendra Scheme (NYKS) has launched a scheme wherein blood donors are given a green card, which gives them priority in respect of treatment in public hospitals. Another intervention which could be attempted on a pilot basis is to provide free transport to carry a donor from his home to the blood bank and back. For nearly two decades the Blood Banks Society, Chandigarh has been implementing blood insurance scheme which guarantees the provision of blood to the immediate relatives of a voluntary blood donor for a period of 12 months from the date of donation. Similar schemes could be encouraged on a pilot basis.

**4.11** The contribution of blood donors & donor organisers will be recognised through a series of bi-annual awards to medical colleges/ organizations/ and individuals at the national level by the NBTC, and at the state level by the SBTC.

**4.12** NACO will facilitate mobility, by supporting the provisioning of vehicles to RBTC/ district level blood banks. This is perceived as vital for the dissemination of material pertaining to information, education, communication and behaviour change, and for promoting a movement for voluntary blood donation.



## An Action Plan For Blood Safety

### Increasing supply of screened voluntary blood

4.13 Educating the public, and in particular the donor about the importance of blood donation, and the enormous risk to the recipient from contaminated blood is key to ensuring a regimen for a safe blood supply. Leaflets explaining, the transfusion transmissible infections, their risks and the modes of prevention will be prepared by the NBTC to be used in all blood banks in the country.

The donor questionnaire is a crucial aid to building a lasting relationship between the donor and the blood bank, as well as to elicit details regarding his/her exposure to risk of HIV infection. Most persons are cagey about sharing information in respect of a single exposure or about high-risk behaviour overall. A uniform model donor questionnaire with direct questions to the donor about behaviour that may have resulted in exposure, has become necessary. This in turn rests on strict and complete confidentiality, which calls for maturity and professionalism among the blood bank staff and the donor. In some countries, example Australia, specific legislation is enacted creating offences where donors of blood etc. make a false or misleading declaration. In India, the Indian Penal Code has provisions to penalise persons who negligently and malignantly transmit a disease dangerous to life. False depositions by donors in the donor questionnaire in essence, could lead to transmission of life threatening diseases. The safety and credibility of the blood programme hinges largely on regulations concerning donors, testing, informed consent and confidentiality.

The questionnaire to be filled in by a potential donor must specifically ask for the consent of the donor to reveal the result of the tests.

4.14 Every Blood Bank will have facility for pre-test counselling so that any potential blood donor will make an informed choice, and will voluntarily fill in the donor questionnaire. The donor questionnaire (Annexure-VII) has been standardized to include a listing of the mandatory screening tests carried out in the blood bank, and also a consent form.

4.15 In order to ensure that informed consent of donors is taken, it is important that donors state that they have understood the questions and answered it honestly before signing on the donor questionnaire form. Informed consent of the donor should be taken in the language and in the manner he / she understands.

### Revealing the Transfusion Transmitted Infection status of the individual

4.16 Every unit of blood donated / collected is tested for at least five major infections: Hepatitis B, Hepatitis C, Syphilis, Malaria and HIV. Prior to every test the informed consent of the donor is taken by detailing in the donor questionnaire, a listing of the tests proposed to be conducted in respect of the blood he/she donates. Specific consent of the donor should be taken in respect of disclosing the result of the tests.





4.17 Prior to accepting the donation of blood, steps will be taken by blood banks to ensure that complete information and adequate counselling has been provided to the donor. For this purpose, the SBTC must prescribe linkages between all blood banks and the VCTCs within their jurisdiction. Any blood bank not having these linkages in place will inform the SBTC and the DHS within the state. The NBTC will monitor this aspect every month.

4.18 The blood donor will be offered the option of knowing his TTI status, by the blood bank when the blood donor questionnaire and consent from (Annexure VII) is filled. In the event that the blood sample of a donor (who wishes to know his TTI status) is found to be reactive to Hepatitis 'B' or Hepatitis 'C' or HIV, apart from destroying the blood unit in accordance with the existing procedure, the donor shall be requested to visit the blood bank personally by simply informing him / her that some of the immediate results are not conclusive, and need to be confirmed.

4.19 When the donor contacts the blood bank, the following steps must be observed:

- (i) if the blood sample of the blood donor has been found to be reactive to Hepatitis 'B' or Hepatitis 'C', a fresh sample of blood is taken in the blood bank, and the donor is counselled. This fresh sample of blood is once again tested for hepatitis. If the second test once again confirms the reactivity to hepatitis 'B' or hepatitis 'C', then the donor is referred to a physician.
- (ii) if the blood sample of the blood donor has been found to be reactive to syphilis or malaria, then the donor is referred to a physician.
- (iii) if the blood sample of the blood donor has been found to be sero-positive to HIV, then the blood bank will direct the donor to the linked voluntary counselling and testing centre (VCTC). The VCTC will counsel the donor, and also take a fresh sample of blood. The VCTC will conduct the confirmatory tests for HIV. If the donor is positive, then the VCTC will convey the result to the concerned blood bank, to ensure that the donor does not donate blood again. For this purpose, the blood bank and the VCTC shall maintain permanent records as may be prescribed and respect standards of confidentiality vis a vis status of the donor.
- (iv) The VCTC will provide comprehensive counselling to the donor, inclusive of information on care, support and treatment. The VCTC will communicate and convey the HIV status to the infected person. This is a major departure from existing practice wherein the HIV status of the person was never revealed. Implementation will start after completion of orientation training of BB's as well as VCTC staff.



Activity	Date of commencement	Date of completion	Responsible Officer	Responsible supervisor	Budgetary source
1. Development of IEC Campaign	1-09-03	6 Months	JD (IEC)	PD, NACO	NBTC SBTC
2. Development of Logo by an advertising agency	1-09-03	12 weeks	JD (BS)/ TRG	PD, NACO	NBTC
3. Approving Logo for the BTS	-	8 weeks	JD(BS)	PD NACO	NBTC
4. Donor questionnaire	Already developed To be reviewed	4 weeks	JD(BS)TRG	PD, NACO	NBTC
5. Revealing TTD status to donor	1-09-03	6 months	Incharge, Blood Bank & VCTC	PD, NACO/ Chairperson SBTC	NBTC SBTC





## Objective 5

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To encourage appropriate clinical use of blood and  
blood products



# Objective 5

To encourage appropriate clinical use of blood and blood products

## Effective Clinical Blood Supply

5.1 The NBTC will adopt and disseminate the WHO Guidelines on the Clinical Use of Blood. This document will be circulated to all hospitals, blood banks, corporate hospitals, Red Cross Society of India, Indian Medical Associations, Association of Nursing Homes, medical colleges and teaching institutions, and to all stakeholders.

5.2 NBTC will pursue with the Medical Council of India, the Continuing Medical Education (CME) of clinicians, to be organised in consultation with transfusion specialists on appropriate use of blood and its components. Clinicians must familiarise themselves with the systems for collection, screening and processing of blood, and understand any limitations that it may impose on the safety or availability of blood. The appropriate use of blood and blood products optimises the clinical benefits of blood transfusion while minimising adverse effects.

5.3 In consultation with the Medical Council of India (MCI), transfusion medicine will be introduced as a subject or a module in undergraduate and postgraduate medical courses.

5.4 Use of blood components (red cell, fresh frozen plasma (FFP), plasma, platelet concentrate & cryoprecipitate) enables a single blood donation to go a longer way by pre-empting transfusion of components a patient may not require and addresses the needs of more than one patient. Guidelines in respect of blood components will be compiled and disseminated.

5.5 Usually, blood banks collecting  $\geq 10,000$  units of blood per year will seek to set up





blood component separation units. Exceptions may be made for the north east and for outlying union territories like the Andaman & Nicobar Islands. Once the RBTC, the BB and the BSC are networked in a chain of backward and forward linkages, components prepared in the RBTC can be distributed to BBs / BSCs. This will further extend the outreach and availability of blood components.

5.6 An audit in respect of blood collection and blood component preparation by blood banks shall be carried out by the durg regulatory officials during the course of inspections. SBTC should ensure annual auditing and put mechanisms in place to ensure optional utilisation of blood components.

5.7 NBTC will develop a program of national haemo-vigilance, with the help of the technical resource group and monitoring committee. This should be implemented by all SBTCs.

Activity	Date of commencement	Date of completion	Responsible Officer	Responsible supervisor	Budgetary source
1. Distribution of WHO books	started	24 weeks	JD (BS)/ WHO SEARO	PD, NACO	NBTC
2. Training programme	0-09-03	continuous	Director SBTC	PD, NACO	NBTC SBTC DHS
3. Hemovigilance system	0-09-03	1 year	MS hospital/ transfusion committee/ DCG (I)	PD, NACO	NBTC SBTC DHS



## Objective 6

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To strengthen the manpower through human resource development



# Objective 6

To strengthen the manpower through human resource development

## Human Resource Development

6.1 In consultation with the Medical Council of India (MCI) medical colleges may consider setting up separate departments of transfusion medicine. NBTC will pursue with MCI, with State Governments and with the central government, that government medical college should be encouraged to create Departments of Transfusion Medicine equipped to provide postgraduate degrees [MD] and diploma courses in transfusion medicine. Similarly, transfusion medicine should be included for purposes of calculating credit hours prior to renewal of medical registration. Additionally, during internship, doctors must be posted in blood banks, for at least 15 days, to gain some hands-on experience and exposure.

6.2 NBTC will facilitate the development of training modules on blood safety for medical and nursing students in consultation with MCI.

6.3 Personnel working in blood banks will be given opportunities to acquire postgraduate qualifications in transfusion medicine. The National Board of Examinations will be requested to start Diplomate of National Board (DNB) courses and the MCI for MD in transfusion medicine courses in additional institutions. In the interim period a diploma or a certificate course could be started by the institutions awarding post graduate degrees in transfusion medicine to address the immediate requirement of trained manpower. The States/UTs may consider creating a separate cadre for doctors in transfusion medicine with clear opportunities for promotions.





6.4 All staff of blood centers will undergo at least one round of training within three months of adoption of the Action Plan.

6.5 Quarterly state level training programmes (Continuing Medical Education) on the subject of Good Clinical Practices and Appropriate Use of Blood will be instituted for clinicians and nurses. Post-graduates of other disciplines should be taught about transfusion medicine in their curriculum.

6.6 NBTC will pursue with MCI the issue of incorporating transfusion medicine as a subject in all existing courses for nurses, technicians, and pharmacists. Efforts will be made to start registration of trained blood bank technicians.

6.7 NBTC will develop guidelines for all SBTCs to organise in-service modular training for different categories of personnel working in the RBTC, BB, BSC such as medical officers, nurses, donor motivators and donor organisers and technical staff on a regular basis. The training modules for conducting these activities will be updated on a continuous basis.

6.8 Transfusion Medicine should be treated as a speciality distinct from pathology, microbiology or haematology. This will be pursued with the Medical Council of India.

6.9 All the Drug Inspectors who inspect blood banks for purposes of licensing should also be sensitised, oriented and trained in respect of basic norms of blood banking.

Activity	Date of commencement	Date of completion	Responsible Officer	Responsible supervisor	Budgetary source
1. Identification & infrastructure strengthening of training centres	1-09-03	6 months	JD (BS)/ Finance Controller, NACO / TRG	PD, NACO	NBTC SBTC DHS



## Objective 7

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



# Objective 7

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

## R&D Requirements

7.1 The Technical Resource Group on Blood Safety appointed by the NBTC will meet at least once a quarter to deliberate and develop a research and development programme, in lieu of the piecemeal research going on currently. A short term and medium-term (3-year), priority research plan will be developed with inputs from public, private sector and multi-/bilateral agencies.

7.2 Operational research on various aspects of transfusion transmitted diseases, knowledge, attitude and practices among donors, rational use of blood and blood components, rapid need assessment techniques and use of information technology in blood transfusion services will be promoted and encouraged.

7.3 Transfusion medicine related research proposals will also be considered for funding by NACO, in consultation with ICMR.

7.4 Feasibility studies, appraisals and peer review will be encouraged in respect of proposals to set up manufacturing units of blood products. Mandatory prior permissions from the office of the DCG(I) and formal advice from the ICMR will be a pre-requisite prior to actually venturing into manufacturing.

7.5 Operation research projects designed and initiated by institutions in the area of sound voluntary blood donation and rational use of blood products, including medical waste disposal will be given priority.





- 7.6 A corpus of funds will be made available to blood transfusion councils to facilitate research in transfusion medicine & technology relating to developing a modernised blood banking system. Annual plans for funding of any project specific research proposal could also be considered.

Activity	Date of commencement	Date of completion	Responsible Officer	Responsible supervisor	Budgetary source
1. Development of a short and medium term research plan	1-09-03	6 weeks	NBTC	PD, NACO	NBTC SBTC
2. Monitoring committee for R&D	1-09-03	4 weeks	JD (BS), NBTC	PD, NACO	NBTC



## Objective 8

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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 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.

## Suggested Legislative Priorities

8.1 Revised Guidelines for licensing of blood banks, blood transfusion centres and blood storage centres will be developed and notified in consultation between the Drug Controller General of India, the NBTC, the SBTC and other stakeholders. A cell with a nodal officer may be created in each drugs control department to ensure full attention to state blood transfusion services.

8.2 Licenses shall be issued to those blood banks run by Indian Red Cross Society, Government Hospitals, Private Hospitals, Charitable trusts and voluntary organisations.

8.3 The procedure of licensing shall be made more transparent, rapid, simple and efficient. Pending applications shall be processed at an early date and licenses shall be issued to those blood banks who are complying the requirements as prescribed under the provisions of Drugs and Cosmetics Act & Rules there under. The list of licensed blood banks shall be posted on the NACO website, and will be updated every three months.

8.4 All revisions that have become necessary in the Drugs and Cosmetics Rules, following the adoption of the Action Plan for Blood Safety (2003), pertaining to diverse aspects of blood banking and blood transfusion services shall be carried out speedily.

8.5 The NBTC will oversee the task of revisiting and reformulating, as necessary, norms for space, staff and equipment, based on workload for RBTCs / BBs / BSCs, as part of the overall exercise on providing quality assurance and maintaining quality management.





8.6 NBTC will document in consultation with legal experts the legislative and educational steps to eliminate profiteering in blood banks.

8.7 Though the buying and selling of blood has been banned by the Supreme Court of India, no legislative provision provides for any punitive action to be taken in case an individual or organisation indulges in profiteering in blood. At present the only action the authorities can take is to cancel the license of the blood bank. NBTC will recommend, following detailed consultation with legal experts and other stake-holders, necessary amendments in the Drug and Cosmetics Act and Rules, or the Indian Penal Code in order to make profiteering in blood a cognisable offence. This will become a deterrent to anyone indulging in such activities.

8.8 At present an individual professional donor posing to be a replacement donor goes scot-free even when detected. NBTC will consider appropriate amendments in the law for appropriate punishment to professional donors at the individual level.

8.9 NBTC should deliberate the ethical aspects in situation where any person who knows that his blood is unsafe for transfusion and continues to donate blood, as to whether this action should be made punishable under criminal jurisprudence. NBTC may consult legal experts and stake holders about developing appropriate statutes in this respect.

8.10 A complete list of licensed blood banks in the country is available now. The SBTC is assigned the responsibility of monitoring blood banks and storage centres. The SBTC will forward regular updates in respect of the blood banks within their jurisdiction to (i) the respective Drugs Controllers of their state for necessary action, if any and (ii) to the National Blood Transfusion Council (NBTC). The grant and renewal of licenses to the blood banks will be done by the office of DCG (I) and State Licensing Authorities in a time bound manner.

Activity	Date of commencement	Date of completion	Responsible Officer	Responsible supervisor	Budgetary source
1. Revision of Drug Rules to reflect changes in action plan	1-09-03	12 months	JD (BS) / DCG (I)	PD, NACO/ DGHS	NBTC DGHS

### Conclusion

Government is fully committed to modernising the blood transfusion services within the country, so as to make these widely available accessible and affordable.

Since we have the will, we have articulated a roadmap for achieving these objectives.



# Annexure I

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Evolution of blood safety programme in India



# Annexure I

## Evolution of blood safety programme in India 1987-92:

### Implemented by the Directorate General of Health Services

In 1987, the National AIDS Control Programme began to take shape in the Directorate of Health Services, Ministry of Health and Family Welfare, Government of India, with three major components: (i) surveillance; (ii) health education & information; and (iii) screening of blood and blood products. During 1989-90, a programme on "Prevention of infection and modernisation of blood banking services" commenced, with emphasis on:

#### 1. Modernisation of Blood Banks:

138 blood banks generating over 2000 units of blood per annum received financial assistance for purchase of equipment to up-scale and modernise.

Screening of blood for HIV was made mandatory (1988), under the Drug & Cosmetic Rules, 1945, amended from time to time.

#### 2. HIV testing facilities:

HIV testing facilities were identified in 154 Zonal Blood Testing Centres (ZBTC) with functional linkages to blood banks that did not have the facilities to screen blood for HIV. These ZBTC were to function in a hub and spoke approach, with the ZBTC receiving units of blood from all the linked blood banks, for screening / testing in respect of the HIV virus. They were equipped with the Enzyme Linked Immunosorbant Assay (ELISA) readers and HIV testing kits. Public, private and voluntary sector blood banks sent blood samples to the ZBTC for HIV testing. The test results were returned to the respective blood banks, often on the same day with clear instructions that only sero negative blood units may be utilised for blood transfusion. The HIV testing kits would detect both HIV I & HIV II strains. Any unit found sero-reactive in respect of HIV antibodies was to be discarded with the appropriate measures for bio-safety.





This strategy put in place systems for the testing of blood units instead of blood donors to ensure recipient safety.

### 3 Training:

Every year, and on a regular basis, laboratory technicians working in ZBTC were provided "hands- on" training in respect of the protocols to be followed for testing of blood.

#### 1992-1999

#### Implemented by the National AIDS Control Organisation (NACO)

The Drug Controller General of India, in accordance with the Drugs and Cosmetics Act, licenses Blood Banks in India. Standards in respect of blood banks differ from state to state, and policing of violations was initially limited, though on the increase. In 1992 a writ petition was filed in the Supreme Court of India, against the Union of India and others to address the deficiencies and shortcomings in the collection, storage and supply of blood in the country. In 1996, Supreme Court of India passed an order in Common Cause v/s Union of India and others directing government to improve the blood transfusion service. Resultantly, the National and State Blood transfusion Councils (NBTC / SBTC) were created to develop policies and programmes for bringing about improvements in blood centres.

#### 1. Guidelines for testing for HIV

By 1992, the spread of HIV / AIDS in India had begun to raise issues well beyond the purely medical aspects. These related to privacy, confidentiality and ethics. National Guidelines were formulated, in line with the WHO guidelines, in respect of testing for HIV.

The view prevailed that testing for HIV would have the following objectives:

- (i) Surveillance: in order to evaluate trends in the spread and prevalence of disease within a given segment of population. In turn this would facilitate an appropriate intervention. This objective was best achieved by an unlinked anonymous ELISA test for HIV, on two different antigen preparations. A unit of blood testing positive by one ELISA is tested with a second ELISA having a different test protocol/ antigen systems.
- (ii) Protection from transfusion transmitted infections: in order to minimise the risk of transfusion transmitted infections, blood being utilised for transfusion would mandatorily be screened and tested for Hepatitis B and C, Syphilis, Malaria and HIV. For HIV a single ELISA test was perceived as sufficient to ensure protection in the event of transfusion, In the event that a unit of blood tested sero-positive for HIV, then the sample was to be discarded and destroyed and not to be deployed in transfusion.



## An Action Plan For Blood Safety

- (iii) Provisioning for adequate numbers of testing facilities for pre-test and post-test counselling to prepare persons to access voluntary testing for HIV (on account of asymptomatic / symptomatic HIV related infections).



### 2. Modernisation of blood banks:

The National AIDS Control Organisation launched a scheme providing central government assistance to states to upgrade and provide minimum facilities to blood banks in the public sector, as well as those run by charitable organisations. This assistance facilitated the purchase of equipment, consumables, test kits, chemicals, glassware, blood bags and reagents. NACO has supported the modernising of 815 blood banks (282 major blood banks, and 533 district level blood banks). 40 blood component separation facilities were set up between 1992-97, to promote the rational use of blood.

#### 1999-2004

#### Implemented by the National AIDS Control Organisation (NACO)

The blood safety programme begins to build upon and consolidate the initiatives of Phase I (1992-99). NACO has already strengthened / modernised 815 blood banks, and 40 component separation units. During Phase II, NACO plans to set up an additional 20 major blood banks, 40 blood component separation units, and to augment and strengthen blood banks at district levels. Voluntary blood collection has improved.

#### Highlights

##### 1. Establishing model blood banks:

In under-served states, in terms of quality transfusion services in the government sector, National AIDS Control Organisation supports the establishment of model blood banks. States selected for setting up model blood banks are Assam, Bihar, Chhatisgarh, Jharkhand, Madhya Pradesh, Rajasthan, Uttaranchal and Uttar Pradesh. Sites for setting up these blood banks have been identified and the procurement process for equipment has been initiated. It is envisaged that for the states of Bihar and Jharkhand, NACO would assist them in operating the project for the initial three years, after which it will be handed over to the state government. During this period, the staff will be fully trained in respect of standardised protocols and management of transfusion services. For other states, NACO would provide logistic and technical support for upgrading services of the existing blood banks. In order to enhance supply of blood and blood products, these blood banks would be linked to existing blood banks in the vicinity. These blood banks will function as demonstration projects in the states or regions where they are set up. They are also expected to function as nodal blood banks, which look after training and quality control requirements of transfusion services in the region.





## 2. HCV testing facilities:

Testing of blood for Hepatitis C Virus (HCV) antibodies was made mandatory with effect from June 1, 2001. Training was provided by the National Institute of Biologicals, Government of India, at different regional blood banks. Mandatory testing for hepatitis C, hepatitis B, HIV, syphilis and malaria is being implemented, in respect of all donated blood units.

## 3. Upgrading Training:

With a view to improving standards of service delivery in blood banks, NACO facilitates frequent workshops (with WHO assistance), for training of blood banking personnel and sensitisation of programme officers from states.

## 4. Blood Storage Centres:

In order to enhance access to safe blood, particularly in rural areas where it may be infeasible to establish full-fledged blood banks, government has facilitated the setting up of blood storage centres. These will be affiliated to larger blood banks, and will store screened blood for transfusion. The blood storage centres will be invaluable in the event of emergency obstetric care (EOC), and other emergent requirements as in road / rail accidents.

## 5. Technical Resource Group (TRG):

NACO constituted a TRG on Blood Safety in 1994. This TRG has been deliberating the best practices in the clinical use of blood. National guidelines on the rational use of blood were circulated during 1995. More recently, in 2002, the WHO Guidelines on the Clinical Use of Blood have been adopted by NACO, and are being widely circulated to all stakeholders, in order to disseminate the protocol, and inter alia, to encourage and promote the rational use of blood.

## 6. Role of the Non-Government, Armed forces and the Private Sector

6.1 A significant portion of the blood banking activity in India is carried out in the non-government sector for instance, through the Indian Red Cross (IRCS), other NGOs, as well as private, for-profit hospitals, and so on. The IRCS is already well known in the field of donor recruitment and has several well-known blood centres in the country. It has recently embarked on an ambitious project to develop its blood service on the principles of voluntary blood donation, screening blood, quality management and good transfusion practice. Initially, linkages were provided to these blood banks with a view to ensuring that (a) all units of blood used for purposes of transfusion, without exception, is appropriately screened and tested and further (b) to bring on board all stakeholders in a movement for blood safety. When the ELISA equipment and HIV testing kits became readily available in the market, the blood banks outside of the public sector started investing in testing, autonomous of government. The private and the non-government sectors have made a remarkable contribution to the blood banking



industry in India. It is a recognised fact that the private health care industry will play a major role in the overall health care sector and therefore the private / non government blood banks should be deemed eligible for facilities extended to government blood banks (the not for profit facilities in particular). This will provide due encouragement and incentive to improve performance and service delivery.

- 6.2 In order to improve the blood transfusion services and to have "good manufacturing practices (GMP)", it is imperative that this activity of blood banking be adequately modernised. All blood banks should be equipped with the state-of-the-art equipment and reagents. Similarly, any evaluation of the demand for blood and blood products cannot overlook the requirements of the non-government sectors.
- 6.3 Armed Forces Transfusion Services (AFTS): The AFTS with 52 hospital blood banks is a well organised network providing life saving blood and blood components to Armed forces personnel and their dependants. The AFTS also provides support for civilian emergencies, natural disasters and to populations in remote and inaccessible areas.





# Annexure II

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Definitions



# Annexure II

## DEFINITIONS

### 1. Regional Blood Transfusion Centre (RBTC)

RBTC is a blood bank approved by the SBTC taking into consideration the regional needs of blood & components and the ability of RBTC in terms of premises, personnel and equipment. A centre will be designated as RBTC only after SBTC formally networks it with BBs and BSCs in the region and establishes two way linkages for donors, QA, production and exchange of blood & components, problem solving and training. An RBTC with networked blood banks & storage centres (BB & SC) will be considered a unit to serve a population of 20-30 lakhs in metro cities. Exceptions: Semi-urban and rural population, armed forces, mountainous areas, desert areas, islands.

#### RBTC must conform as under:

1. Should be licensed and provide round the clock service.
2. Must oversee standards of BB & SC linked to it.
3. RBTC must function as a regional nodal centre for quality assurance and voluntary donor functions.
4. Infrastructure be adequate to support good manufacturing practice (GMP), counselling and training.
5. Minimum annual collection for RBTC should be  $\geq$  10,000 units, in eight metropolitan cities and 5000 units in other cities.
6. There should be an organised programme for promoting 100% voluntary blood donation in collaboration with SBTC.
7. At least 50% of the blood collected at RBTC should be separated into components.
8. There should be facility to store at least 1000 RBCs, 500 FFP/cryoprecipitate and sufficient platelet concentrates including quarantine storage.





9. Must produce & provide blood components for BB & SC linked to it and take responsibility for providing blood & components to the geographic area defined by the State Blood Transfusion Council (SBTC).
10. Facilities for transportation of blood products and for conducting outdoor drives as specified by licensing requirements should be available.
11. The centre should be capable of handling referred technical and clinical problems from the region it oversees.
12. Must have ability to upgrade the existing facility in terms of technology and infrastructure with the growing demands of the region.
13. Should not be attached to a stand-alone pathology laboratory.
14. RBTC should be able to function as a nodal centre for training all levels of staff.
15. RBTC should be able to maintain a database for the SBTC.
16. Any government / IRCS / Private hospital blood bank is eligible to apply for RBTC status if it fulfils above criteria.
17. SBTC can take a decision to qualify a blood centre as RBTC based on the states' population, geography and requirement of blood keeping within the parameters defined.

## 2. Voluntary Blood Donor

A voluntary blood donor is a person who gives blood, plasma or other blood components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered as a substitute for money. This includes time off work, other than reasonably needed for donation and travel. Small token refreshments and reimbursements of travel costs are compatible with voluntary non remunerated blood donations.

*(Definition of International Federation of Red Cross and Red Crescent Societies, 1991)*

## 3. Stand Alone Blood Bank

Blood bank whose facilities and staff are not under the administrative control of any hospital and hospital does not assume legal responsibility for the blood bank.



# Annexure III

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Role and functions of National Blood Tansfusion  
Council (NBTC)



# Annexure III

## 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

- (a) Training of Technicians, drug inspectors, donor motivators and medical officers in relation to all operations of blood centres.
- (b) Initiating steps for starting special PG courses in transfusion medicine in various medical colleges and institutions in the country.



- (c) 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.
- (d) 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.
- (e) Introducing multi centric research initiatives on issues related to BTS.
- (f) Creating a technical resource core group to coordinate research and development in the country.
- (g) Developing guidelines to define NGO run blood centres so as to avoid profiteering in blood banking.





# Annexure IV

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Role and Function of State Blood Transfusion Council (SBTCs)



# Annexure IV

## 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.



# Annexure V

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Role of National AIDS Control Organisation

# Annexure VI

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Role of State AIDS Control Societies



# Annexure V



## Role of National AIDS Control Organisation

1. Operate Blood Safety programme as an integral component of NACP through technical, financial and administrative support.
2. Establish National Blood Transfusion Council.
3. Support funding of NBTC and facilitate its functioning as the apex policy making and implementation body.
4. Provide funds for NBTC and SBTC.
5. Provide support to TRG for best practices in the BTS.
6. Provide funds for training program in the area of blood transfusion to different functionaries.





# Annexure VI

## Role of state AIDS Control Societies:

1. Operate Blood Safety programme as an integral component of NACP through technical, financial and administrative support.
2. To establish SBTC.
3. Support funding of SBTC and facilitate its functioning as per the role assigned to it by NBTC for implementation of the action plan in the state.
4. Ensure that the policies laid down by NBTC are followed.



# Annexure VII

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Blood Donor Questionnaire & Consent Form



# Annexure VII

## Blood Donor Questionnaire & Consent Form

Name and address of the Blood Bank

License No. :

Blood Unit No. :

### CONFIDENTIAL

Tick wherever applicable

*Pl. answers the following questions correctly. This will help to protect you and the patient who receives your blood.*

Name :	Male	Female
Date of Birth:	Age	Father's Name :
Occupation	Organization:	
Address for communication:		
<hr/>		
Telephone:	Mobile No. :	
Would you like us to call you on your mobile:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Fax No.	E mail:	
Have you donated previously:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, on how many occasions:	When last:	
Your blood group:	Time of last meal:	
Did you have any discomfort during/after donation?	<input type="checkbox"/> Yes	<input type="checkbox"/> No





[√] Tick wherever applicable

1. Do you feel well today?: Yes No
2. Did you have something to eat in the last 4 hours?: Yes No
3. Did you sleep well last night?: Yes No
4. Have you any reason to believe that you may be infected: Yes No  
by either Hepatitis, Malaria, HIV/AIDS, and/or venereal disease?:
5. In the last 6 months have you had any history of the following:
  - Unexplained weight loss
  - Repeated Diarrhoea
  - Swollen glands
  - Continuous low-grade fever
6. In the last 6 months have you had any:-
  - Tattooing
  - Ear Piercing
  - Dental Extraction
7. Do you suffer from or have suffered from any of the following diseases?
 

<input type="checkbox"/> Heart Disease	<input type="checkbox"/> Lung disease	<input type="checkbox"/> Kidney Disease
<input type="checkbox"/> Cancer/Malignant Disease		<input type="checkbox"/> Epilepsy
<input type="checkbox"/> Diabetes	<input type="checkbox"/> Tuberculosis	
<input type="checkbox"/> Abnormal bleeding tendency		<input type="checkbox"/> Hepatitis B/C
<input type="checkbox"/> Allergic Disease	<input type="checkbox"/> Jaundice	
<input type="checkbox"/> Sexually Trans. Diseases	<input type="checkbox"/> Malaria	
<input type="checkbox"/> Typhoid (last 1 yr.)	<input type="checkbox"/> Fainting spells	

Are you taking or have taken any of these in the past 72 hours?

- |  |                                       |                                  |
|--|---------------------------------------|----------------------------------|
| <input type="checkbox"/> Antibiotics                     | <input type="checkbox"/> Aspirin      | <input type="checkbox"/> Alcohol |
| <input type="checkbox"/> Steroids                        | <input type="checkbox"/> Vaccinations |                                  |
| <input type="checkbox"/> Dog Bite/Rabies vaccine (1 yr.) |                                       |                                  |
8. Is there any history of surgery or blood transfusion in the past 6 months?
 

<input type="checkbox"/> Major	<input type="checkbox"/> Minor	<input type="checkbox"/> Blood Transfusion
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  9. For women donors,
 

Are you pregnant	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Have you had an abortion in the last 3 months	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Do you have a child less than one year old?	<input type="checkbox"/> Yes	<input type="checkbox"/> No



## An Action Plan For Blood Safety

10. Would you like to be informed about any abnormal test result at the address furnished by you?

- Yes                       No



11. Have you read and understood all the information presented and answered all the questions truthfully, as any incorrect statement or concealment may affect your health or may harm the recipient.

- Yes                       No

I understand that

(a) blood donation is a totally voluntary act and no inducement or remuneration has been offered

(b) donation of blood/components is a medical procedure and that by donating voluntarily, I accept the risk associated with this procedure.

(c) my blood will be tested for Hepatitis B, Hepatitis C, Malarial parasite, HIV/AIDs and venereal diseases in addition to any other screening tests required to ensure blood safety

I prohibit any information provided by me or about my donation to be disclosed to any individual or government agency without my prior permission.

Date : \_\_\_\_\_ Time : \_\_\_\_\_ Donor's signature: \_\_\_\_\_

General Physical Examination:

Weight \_\_\_\_\_ Pulse \_\_\_\_\_ Hb \_\_\_\_\_

BP \_\_\_\_\_ Temperature \_\_\_\_\_

Accept                       Defer                       Reason \_\_\_\_\_

Signature of Medical Officer : \_\_\_\_\_

Blood safety begins with a Healthy Donor







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

