



**Management of Blood Transfusion Services in India:
An Illustrative Study of Maharashtra and Gujarat States**

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Management of Blood Transfusion Services in India: An Illustrative Study of Maharashtra and Gujarat States

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Abstract

Blood is a vital healthcare resource routinely used in a broad range of hospital procedures. It is also a potential vector for harmful, and sometimes fatal, infectious diseases such as HIV, HBV, and HCV. Morbidity and mortality resulting from the transfusion of infected blood have far-reaching consequences. The economic cost of a failure to control the transmission of infection is visible in countries with a high prevalence of HIV. Shortfalls in blood supply have a particular impact on women with pregnancy complications, trauma victims and children with severe life-threatening anaemia. Ensuring a safe, source and ethical supply of blood and blood products and rational clinical use of blood are important public health responsibilities of every national government.

Blood transfusion services in India rely on very fragmented mix of competing independent and hospital based blood banks of different levels of sophistication, serving different types of hospitals and patients. Voluntary and non-remunerated blood is in short supply. The SACS ensure only the availability of safe blood in blood banks. Clinical use of blood is not monitored, and the use of blood components is very low.

Managing blood transfusion services involves donor management, blood collection, testing, processing, storing, issue of safe blood and blood products when clinically needed, and staff training. Maharashtra Government, by setting up its State Blood Transfusion Council as an independent unit under the Department of Health, has set up an excellent example to address the above managerial issues in meeting the transfusion requirements than any fragmented system. We strongly recommend the Maharashtra model to all other states and union territories in India.

Key words: Management, Blood, Blood components, Transfusion

Management of Blood Transfusion Services in India: An Illustrative Study of Maharashtra and Gujarat States

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“Despite all technological marvels that humanity is experiencing, a reliable and safe blood supply is still out of the reach for untold millions of people around the world”.

Director General, WHO, World Health Day 2000.

1. Objectives of the Study

The objectives of our study are to understand the existing systems of blood transfusion services in India and to identify the managerial issues in implementing the Supreme Court's directives. Towards this, we have reviewed the existing literature and also analyzed the activities of the Maharashtra State Blood Transfusion Council set up as an independent unit under the State Ministry of Health, and the activities of Gujarat State Blood Transfusion Council set up under the Gujarat State AIDS Control Society.

2. Need for Safe Blood

Whole blood is a living tissue that circulates through the heart, arteries, veins and capillaries carrying nourishment, electrolytes, hormones, vitamins, antibodies, heat and oxygen to the body's tissues. It is a vital healthcare resource routinely used in a broad range of hospital procedures.

Blood is also a potential vector for harmful, and sometimes fatal, infectious diseases such as HIV, HBV, and HCV. Every year, millions of people are exposed to avoidable, life-threatening risks through the transfusion of unsafe blood. Between 5% and 10% of HIV infections worldwide are transmitted through the transfusion of infected blood and blood products. As per WHO Global data Base 2002, data from 178 countries indicates that out of 83 million units of blood collected annually, 13 million units are not screened for HIV or other transfusion-transmissible infections.

Developing countries account for 80 % of the population, but contribute only 40 % of the global blood supply. More than 60 % of the blood supply in developing countries is collected from family/replacement donors and paid blood donors, who are at a significantly higher risk for transfusion-transmissible infections than voluntary donors.

The human costs of unsafe blood are incalculable. Morbidity and mortality resulting from the transfusion of infected blood have far-reaching consequences, not only for the recipients themselves, but also their families, their communities and the wider society. Since a person can transmit the infection during the asymptomatic phase, it can contribute to an ever-widening pool of infection in the wider population.

The economic costs of a failure to control the transmission of infection have already been demonstrated in countries with a high incidence and prevalence of HIV and

AIDS. Increased requirements for medical care, higher levels of dependency and loss of productive labour all place heavy burdens on overstretched health and social services and on the national economy.

Shortfalls in blood supply have a particular impact on women with pregnancy complications, trauma victims and children with severe life-threatening anaemia. Globally, up to 150 000 pregnancy-related deaths could be avoided each year through access to safe blood. In India alone, about 25000 women die every year due to post partum haemorrhages. According to the Sample Registration Survey of India, haemorrhage alone accounts for nearly 38 percent of all maternal deaths, which is the highest cause of maternal death. Also, almost half the women in the reproductive age group are moderate to severe anaemic, according to NFHS surveys (1998-99).

The provision of safe and adequate blood supply at national level is the responsibility of the government/national health authority of each country. Blood Transfusion Services (BTS) should be established in accordance with the agreed national blood policy and plan and within a legislative framework. It should be responsible for establishing and maintaining a national quality system, including the development of guidelines and standards, staff training, a data/information management system and a system for monitoring and evaluation of all blood transfusion activities.

3. Estimating the Requirement for Safe Blood

There are several ways to estimate the requirements of blood for a given population.

WHO bases its estimates on the number of “acute beds” in a given district; this requires an understanding of what constitutes an acute bed and then converting the total number of beds into equivalent number of acute beds. This conversion depends on the type of medical services available and the location of the health facility. For example, 100 beds in an urban medical college hospital and 100 beds in a rural district hospital do not get converted into the same number of acute beds.

As a thumb rule, if one percent of the population in a district can donate blood once a year that would suffice the needs of that district.

The above estimates are based on the assumption that human body needs whole blood.

Actually, human body requires blood components most of the time than whole blood¹. Whole blood consists of several components; Red Blood Cells, Platelets and Plasma, and the plasma itself contain a variety of proteins.

¹ WHO recommends that the ratio of the use of blood components to whole blood should be 90:10, since only a limited category of clinical interventions requires whole blood (NACO, GOI, 2003).

- Red Blood Cells- probably the most recognizable component of whole blood, red blood cells contain hemoglobin, a complex iron-containing protein that carries oxygen throughout the body and gives blood its red colour.
- White Blood cells-responsible for protecting the body from invasion by foreign substances such as bacteria, fungi and viruses
- Platelets – very small cellular components of blood that help the clotting process by sticking to the lining of blood vessels.
- Plasma-the liquid portion of blood – a protein-salt solution in which red and white blood cells and platelets are suspended.

All of these components have different uses and patients will need different components depending on their own blood type and on their condition. For instance, an anaemic person will only require RBC, while a haemophiliac needs clotting factors from plasma.

Use of blood components instead of whole blood, known as “Blood Component Therapy”, allows several patients to benefit from one unit of donated whole blood. Note that one unit of whole blood can give 4 blood components and thereby meet the requirements of four patients. However, most developing countries depend on whole blood than blood components. In India, 80 % of blood used is whole blood [NACO, GOI 2003].

Many developing countries have invested in blood component separation facilities², but these investments (capital expenditure, human resources, materials, equipment, and other infrastructure needs) remain underutilized. Promoting blood component therapy would not only bring down the requirement of whole blood by as much as 60 to 70 % (since one unit of whole blood can give four blood components which could meet the requirements of four patients), it would also ensure optimum utilization of all resources invested in the blood component separation facility.

4. Evolution of National Blood Policy in India

1975: In 1975, Resolution WHA 28.72 of the Twenty Eighth World Health Assembly urged Member States to promote the development of a national blood service based

² The process of blood component separation consists of two steps: In the first step, the whole blood is separated into RBC and Platelets Rich Plasma (PR Plasma) in a centrifuge. The second step involves loading the centrifuge with PR Plasma and separating the Platelets from Plasma (and we get Fresh Frozen Plasma). The process of separating whole blood into blood components takes about 1 hour. The blood components need special arrangements for storage, such as agitators, cold rooms etc and have different shelf lives. For example, RBC can last 35 days, while Platelets can last for only 5 days.

on voluntary non-remunerated blood donation. Voluntary non-remunerated blood collection ensures a safe, source and ethical supply of blood and blood products.

1987: Blood Safety Program in India began to take shape with the establishment of the National AIDS Control Organization (NACO) in 1987. NACO was set up in the Directorate of Health Services, Ministry of Health and Family Welfare, Government of India, with three major components: (i) surveillance, (ii) health education and information, and (iii) screening of blood and blood products.

1992: In 1992, the Drug Controller General, India (DCG-I) was vested with the power of Central License Approving Authority to approve license of notified drugs viz. blood and blood products. The Drug and Cosmetic Rules 1945, framed under the Drugs and Cosmetic Act 1940 were amended in 1993. The licensing of blood banks was brought under the dual authority of the state and central government. The state licensing authority issues the license, while DCG-I is the central license approving authority. Prior to approval, the blood banks are inspected jointly by the filed officers of the state and central government, and if satisfied, the state licensing authority issues the license and forwards the same to DGC-I for approval.

1992: 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.

1996: In 1996, the Supreme Court of India passed an order in *Common Cause v/s Union of India and others* directing the government to improve blood transfusion services. As a result, the National and State Blood Transfusion Councils (NBTC and SBTC) were created to develop policies and programs for blood transfusion services.

1992-99 (NACP I): NACO launched a scheme to modernize blood banks by providing government assistance to states to upgrade and provide minimum facilities to blood banks in the public sector, as well as those run by charitable organizations. The assistance facilitated purchase of equipment, consumables, test kits, blood bags, reagents and so on. Under this scheme, NACO modernized 815 blood banks (282 major blood banks³ and 533 district level blood banks) and also set up 40 blood component separation facilities to promote the rational use of blood. Nearly 90 % of the blood banks modernized through this scheme are in the government sector.

1994: NACO constituted a Technical Resource Group (TRG) on Blood Safety. TRG deliberates the best practices in the clinical use of blood and issues National Guidelines on the rational use of blood and blood products.

1999-2004 (NACP II): The Blood Safety Program initiated in NACP I was considerably strengthened in NACP II with modernizing more blood banks, establishing Model Blood Banks and setting up Blood Storage Centres in rural areas where it may be infeasible to establish full fledged blood banks.

³ Major blood banks are expected to collect between 5000 to 10,000 units and district blood banks between 3000-5000 units of blood per year.

2002: The Government of India adopted the National Blood Policy in 2002 which aims at ensuring easy accessibility and adequate supply of safe and quality blood and blood components collected from Voluntary and non-remunerated blood donors.

5. Objectives of India's National Blood Policy

Below we state the objectives of our National Blood Policy. Please see Annexure 5.1 for a detailed understanding of the National Blood Policy of India.

Objective 1: To reiterate firmly the Government commitment to provide safe and adequate quantity of blood, blood components and blood products.

Objective 2: To make available adequate resources to develop and re-organize the blood transfusion service in the country

Objective 3: To make latest technology available for operating the blood transfusion services and ensure its functioning in an updated manner

Objective 4: To launch extensive awareness program for blood banking services including donor motivation, so as to ensure adequate availability of safe blood

Objective 5: To encourage appropriate clinical use of blood and blood components

Objective 6: To strengthen the manpower through human resource development

Objective 7: To encourage Research and Development in the field of Transfusion Medicine and related technology

Objective 8: To take adequate legislative and educational steps to eliminate profiteering in blood banks

6. Computerized Management Information System (CMIS)

An information system is defined as sets of interrelated components that collect, process, store and distribute information to support decision making and control in an organization.

The information system used by NACO is called Computerized Management Information System (CMIS). Developed by ORG MRAG Research Pvt. Ltd, CMIS helps in concurrent monitoring and evaluation of the ongoing program on blood safety (see Exhibit 6.1).

Each blood bank sends its data on blood collections every month to the respective SACS or MACS (see Exhibit 6.2). Each SACS/MACS feeds the data on blood collection from all its blood banks into the CMIS and sends the blood safety statistics to NACO every month. The existing set of indicators on blood safety in CMIS is the following.

Core Indicators:	Collected blood units tested for HIV Proportion of Voluntary Blood Donors
Additional Indicators:	Setting up of component separation facilities in States Proportion of previous voluntary blood donors who have come back for repeat blood donation

7. Blood Transfusion Services in India

While the Indian Health sector has made some noteworthy achievements over the last 50 years, it has not responded satisfactorily to meet the national goals on blood transfusion services.

In India, public bodies concerned with the organization and administration of blood services include Central, State, and autonomous government institutes, municipal corporations, cantonment boards, railway services, employee state insurance authorities and the armed forces. Most of these hospital based blood banks often operate with minimal infrastructure and inadequate/irregular supply of blood. As a result, there is a fragmented mix of competing independent and hospital based blood banks of different levels of sophistication, serving different types of hospitals and patients. In addition, there are a large number of trusts, independent commercial and private blood banks with the Indian Red Cross Society holding a primary position. The piecemeal evolution of blood banking is linked to the burgeoning population and the expanding and poorly regulated private healthcare market.

The Blood Safety Program in India under the State AIDS Control Society (SACS) only ensures availability of safe blood in blood banks in their respective states. No SACS takes the responsibility to supply safe blood to public and private health facilities as and when needed. There are many licensed private blood banks in each state which do not report their blood collection statistics to their respective SACS, even though it is a legal requirement for all licensed blood banks. As a result, there is no supervision of blood supply from the blood banks to hospitals and nursing homes. Blood banks, on receipt of requests for blood (or blood components) from hospitals and nursing homes supply blood (or blood components), but do not maintain proper records of their supplies. Also, there is no monitoring of the clinical use of blood and blood products by the hospitals and nursing homes.

Our transfusion services infrastructure is highly decentralized and lacks many critical resources; overall shortage of blood, especially from volunteer donors; limited and erratic testing facilities; an extremely limited blood component production/availability and use; and a shortage of health care professionals in the field of transfusion services [Sardana, VN, 1996].

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 another centre in the same city. The hospital based decentralized blood banking system has led to a skewed distribution of resources and makes difficult any implementation of a stringent quality control program.

The only data available at the national level on blood banking services are the number of licensed blood banks in the public and private (including those under the management of trusts) sector, blood collection and availability of safe blood (Table 7.1). A significant portion of blood banking activity is done by voluntary agencies and private sector blood banks. It can be seen from Table 7.2 that the total blood collection in India has gone up over the last few years and recorded a collection of 4 million units in the year 2004. However, 4 million units of blood meet only 40 percent of our needs, as against a requirement of 10 million units (@ 1% of 1 billion population). Even the total number of blood bags sold in the country in 2004 is only around 6 million. We summarize our observations on blood banking services in India in Tables 7.3 and 7.4.

To summarize, blood transfusion services in India rely on very fragmented systems. The licensing of blood banks is under the dual authority of the state and central governments; the state licensing authority issues the license, while the Drug Controller General, India (DCG-I) is the central license approving authority. A large number of public, private, independent and trust managed blood banks operate in India. Voluntary and non-remunerated blood is in short supply. The SACS under NACO are responsible for ensuring availability of safe blood in blood banks in their respective states. There is minimal supervision or quality control for supply of blood and blood products from the blood banks to hospitals and nursing homes. Clinical use of blood is not monitored. As a result, many transfusions are clinically unnecessary, providing little or no benefit to the patients who receive them and wasting a scarce resource that may result in a shortage of blood and blood products for patients in real need.

Ensuring a safe, source and ethical supply of blood and blood products and the appropriate and rational clinical use of blood are important public health responsibilities of every national government. There is enough evidence in the literature to show that a well organized, nationally coordinated blood transfusion service is safer and more cost effective than hospital based or other fragmented systems. This will allow blood and blood products to be equitable, safe, accessible, and adequate to meet the transfusion requirements of the patient population (WHO)

8. Blood Transfusion Services in Maharashtra

Maharashtra, situated on the Western coast, is the second largest state in India both in population (96.75 million) and in size (3.08 lakh sq. km.). About 56 % of the state population lives in rural areas. Literacy rate in the state is 77.3 percent with the sex ratio of 922 females per 1000 males. Maternal Mortality Rate is 149 per 100,000 live births. Infant Mortality Rate is 36 per thousand live births, and Total Fertility Rate is 2.5 (SRS, 2006). Health Infrastructure in the state includes 10500 Sub Centres, 1800 PHCs, 440 rural hospitals, 26 district hospitals, 6 women hospitals and 32 medical colleges.

Following the Apex Court Intervention of 4th January 1996, the state government of Maharashtra established its Blood Transfusion Council (BTC) on 2nd July 1996 as a separate entity with the objective to coordinate the fragmented blood supply system in

the state while providing adequate and safe blood and its components at the reasonable rate. It was also registered under Society Act, 1860 on 22nd Jan 1997 and Trust Act, 1950 on 17th April 1998.

The Government of India provided financial assistance of Rs 8.6 million while the Government of Maharashtra provided 2000 sq ft of office space, and financial assistance for Information Communication Technology infrastructure. Various program committees such as Voluntary Blood Donation Committee, Thalassaemia committee etc were established to facilitate the program implementation. SBTC also maintains good coordination with the Blood safety units in the Maharashtra State/District AIDS Control Societies, and many international donor partners for various types of assistance.

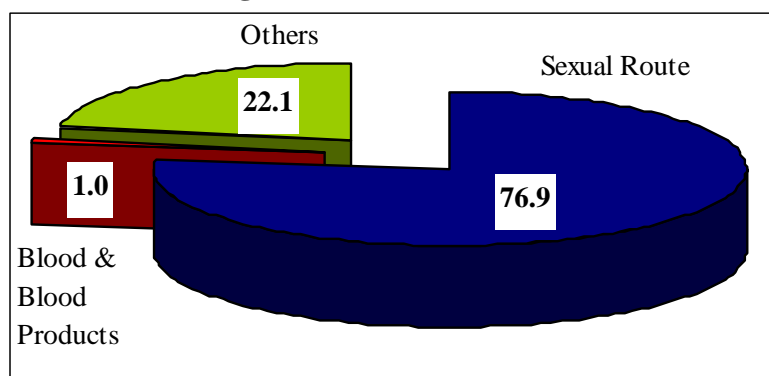
The Governing body of the State Council to whom the management of its affairs is entrusted is constituted in the following manner:

1	Secretary, Ministry of Health & Family Welfare	President
2	Director of Health Services	Member
3	State Drugs Controller	Member
4	Representative of Ministry of Finance	Member
5	Representative of State Red Cross Society	Member
6	Representative of Private Blood Banks	Member
7&8	Maximum two experts in Blood, Transfusion Medicine & Health Institution of the State	Member
9	Representative of Non-Government Organisation (active in the field)	Member
10	Representative of Nodal Blood Centres	Member
11	Director, State Council	Member, Secretary

Source: <http://www.mahasbtc.com>

In Maharashtra reported transmission of AIDS is 77 %, through sexual route, while transmission through blood/blood product is only around one percent, as can be seen from Figure 8.1 below.

Figure 8.1
Transmission Categories in AIDS Cases (2005), Maharashtra



Source: NACO, 2005

Since establishing SBTC, the performance of blood banking services in the state has improved significantly. The evidence of this is as follows.

Blood Collection: Total blood collection has gone up from 465,030 units in 1998 to more than 874,000 units by 2005; voluntary blood donation from 47 % in 1998 to 75 % by 2005. The number of blood donation camps has tripled from 3200 in 1998 to more than 10,000 in 2005. Details can be found in Tables 8.1.

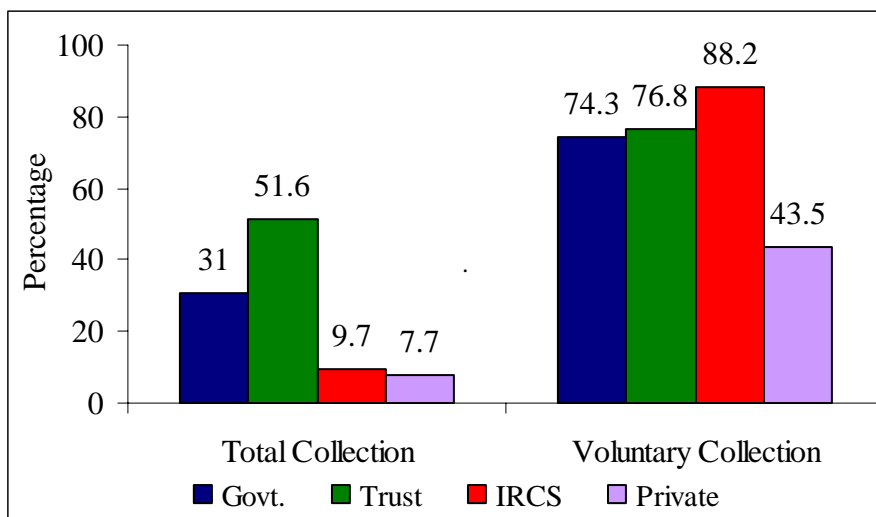
Voluntary Blood Collection: Increase in voluntary blood donation is mainly from the blood banks in the non-government sector: Blood banks under trusts, IRCS, and private sector, as can be seen from Table 8.2.

Sero-positivity: Sero-positivity for HIV has gone down from 1.82 in 1998 % to 0.66 % by 2005. Similar improvements can be seen across HBV, HCV, and VDRL. Details can be found in Table 8.3.

The detailed performance of SBTC for the year 2005 can be seen from Figure 8.2 as well as Table 8.4 and Table 8.5.

Figure 8.2 displays the performance of various sectors in total blood collection and blood collection by voluntary means. It can be seen that the majority of blood collection is done by the blood banks managed by trusts (52%) followed by government blood banks (31%), IRCS (10%) and private blood banks (8%). IRCS blood banks account for maximum collection from voluntary donors (88 %), followed by trust managed blood banks (77%), government blood banks (74%) and private blood banks (44 %).

Figure 8.2
Sector Wise Total and Voluntary Blood Collection (2005), Maharashtra



Source: Maharashtra State Blood Transfusion Council, 2005

Table 8.4 demonstrates the number of blood banks in each category by each district and proportion of population donating blood. The state has a total of 273 registered blood banks (excluding 25 blood banks which are not operational now), consisting of

74 government blood banks, 134 blood banks managed by Trusts, 10 IRCS blood banks and 55 private blood banks. District wise variation in number of blood banks can be seen in the Table 8.4. About 0.9 percent of the population in Maharashtra donates blood. In the district of Akola, Aurangabad, Kalhapur, Mumbai, Nagpur, Pune, Sangli and Solapur, more than one percent of the population donates blood.

Table 8.5 reveals the district wise information on total blood collection, blood collection by voluntary means, prevalence of HIV, HBV, HCV, VDRL, Malaria, number of blood donation camps organized and percent of voluntary collection through camps. It is worthwhile to mention that four districts, namely, Mumbai, Pune, Thane, and Nagpur account for almost 50 % of the total blood collection in the state. The blood collection through voluntary means is very high in all districts except the district of Yavatmal and Mumbai Circle. Nearly 69 percent of the voluntary blood collection is through camps. Voluntary collection through camps is the highest in the district of Solapur, Sindhudurga, Lature, Aurangabad, Nandurbar and Pune.

Camps: Each health facility (PHC, Rural Hospital, District Hospital etc) is given an annual target for blood donation camps. Uniform guidelines for blood donation camps are circulated in the state. SBTC organizes special camps for creating motivation and removing misconceptions about blood donation. A record was established on June 1, 2003, while collecting 10,923 units in a single mega blood donation camp with the help of 57 blood banks (100 doctors, 300 technicians, 1000 volunteers). Similarly, camps in Nasik (2003) generated 6,490 units within 10 hrs, with the support of 35 blood banks. On May 30, 2004, 14,883 units of blood were collected during a single day at 8 different locations. On June 3, 2005, a blood donation camp organised to remove the misconceptions and apprehensions among doctors resulted in blood collection from 1,021 doctors. On June 4, 2005, a drive organized by the state reserve police force under SBTC resulted in a collection of 1,385 units.

Modernization of Blood Banks: Under the Blood Bank Modernization scheme of NACO, the state has 31 Major blood banks and 41 District level blood banks. A Metropolitan blood bank is being established at J.J. Hospital, Mumbai with an estimated annual voluntary collection of 50,000 units at a cost of Rs. 50 million.

Blood Components: The state has 96 blood component separation facilities: 69 trust managed blood banks, 10 government blood banks, 4 IRCS and 13 private blood banks. However, 40 percent of the total blood units collected are separated into components.

Free Blood to Special Categories: SBTC provides free blood to all registered Thallasaemia, Haemophilia, and Sickle cell patients. Identity cards are issued to identify repeated voluntary blood donors as well as those patients suffering from Thallasaemia, Haemophilia, and Sickle who need blood regularly from the Council Committees have been established at District level to ensure registration of every individual in a district and for free supply of blood (Exhibit 8.1). Approximately, 40,000 units of blood are given to Thalassaemia patients and 3,000 units to other patients every year, free of charge.

All voluntary blood donors are also entitled for one unit of blood free of charge services for use by self or friends and relatives, with the help of uniform voluntary blood donor card.

Donor Management: State Blood Transfusion Council of Maharashtra disseminates information on voluntary blood donation and creates awareness of blood safety through various mediums like print, competitions, rallies etc.

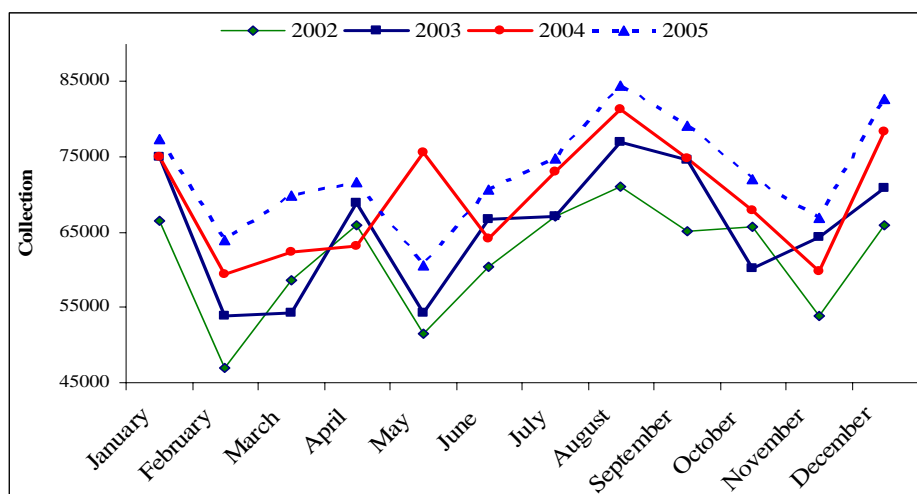
SBTC involves the entire health infrastructure, starting from PHC, RH, to District Hospitals in blood donation campaigns. Action Plans are prepared for various activities, such as mass media campaigns, blood grouping camps, video films, cassettes, articles, messages, slogans, posters, fact sheets, and rangoli competitions. Registration of prospective blood donors is carried out at different public places in Mumbai. Blood donation awareness rallies, distribution of educational materials, appreciation and felicitation of centurion donors etc are part of IEC activities adopted by SBTC for promoting voluntary blood donation (Exhibit 8.1). Camp organizers, who collect more than 1000 units of blood, are also facilitated. Efforts such as birthday blood donation campaigns are on to retain voluntary repeated blood donors.

Training programs: SBTC conducts regular training programs on various issues so as to strengthen the capacities of professionals engaged in blood banking services, viz. training on

- Modular Training (NACO) for all Blood Bank personnel.
- Training on Hepatitis-C, Elisa Reader maintenance & repair, Bio-safety measures for all zonal BTC Blood Transfusion Officers and Technicians
- Component preparation for Blood Transfusion Officers and Technicians
- Blood Group Serology for Blood Transfusion Officers and Technician at ICMR
- Genetic Blood Disorder detection for Blood Transfusion Officers and Technicians
- Training for Drug Inspectors
- Quality Management training - Blood Transfusion Officers
- Transfusion and Transplantation Science
- Key Blood Transfusion Officers from medical colleges trained as key trainers to undertake training for technicians of FRU.

Management Information System: SBTC maintains a reasonably good MIS system. Reports are compiled at the state level by the 5th of every month and feedback given to the regional health officers by the 15th of every month. At the starting of every year, monthly analysis of blood collection of previous year is done to formulate strategies to compensate for the deficit in blood collection in a particular month (Figure 8.3).

Figure 8.3
Monthly Trend in Blood Collection (2002-2005), Maharashtra



Source: Maharashtra State Blood Transfusion Council

Future Activities: Future activities proposed by SBTC include the following:

- A metropolitan blood bank at Kandivali and Kharghar in Bombay.
- A Model District Blood Bank at Akola with component separation facility, genetic blood disorder detection technology, and centralised testing and distribution system. Five FRUs will be linked to this model district blood center.
- Online blood bank management system at every district
- Training Institute at Mumbai, and starting a PG course in Transfusion Medicine.
- Establishment of Fractionation Center
- SBTC also plans to computerize all blood banks, promote the use of components, establish a training institute and to start a PG course in Transfusion Medicine.

9. Blood Transfusion Services in Gujarat

Gujarat State situated on the Western coast of India has a population of 50.56 million spread over 1.96 lakh sq. km. In the state 30.69 million population (63 percent) stays in the rural areas. Literacy rate in the state is 69.9 percent with the sex ratio of 921 females per 1000 male. Maternal Mortality Rate is 173 per 100,000 live births. Infant Mortality Rate is 53 per 1000 live births, and Total Fertility Rate 2.4. Health Infrastructure in the state includes 7250 Sub Centres, 1070 PHCs, 250 community health centres, 53 district and civil hospitals, as well as 11 medical colleges.

In 1996, following the directives of the Apex Court, Gujarat government established its SBTC, and appointed the Additional Director of GSACS to head the SBTC. As a result, Gujarat SBTC is not a separate independent unit, unlike the Maharashtra SBTC.

Gujarat SBTC Governing Board has the following composition:

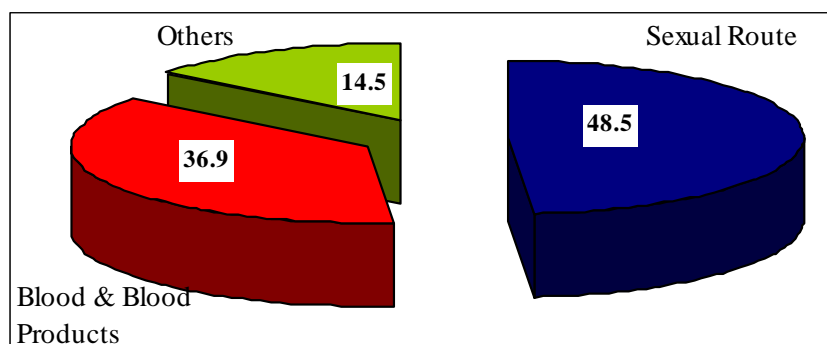
President Secretary of Health and Family Welfare

Members Commissioner, Health, Medical Service Medical Education
 Secretary, Expenditure Finance Department,
 Commissioner, Food and Drugs Control Administration
 Director, Gujarat State Blood Transfusion Council and
 Representatives from
 Civil Hospital,
 State Medical Collages,
 Indian Association of Blood Banks-Gujarat,
 Indian Red Cross Society,
 Medical and Health Institution
 NGOs active in the field of Voluntary Blood Donation

During the NACP I period (1992-99) Gujarat was facing a serious problem regarding the transmission rate of HIV through blood and blood products. Out of the total AIDS cases in Gujarat since 1986, approximately 12 percent was transmitted through blood and blood products. Gujarat AIDS cell (subsequently Gujarat AIDS Control Society GSACS) took up the Blood Safety program with utmost priority and successfully brought down the HIV transmission rates (through blood) rapidly over the next decade.

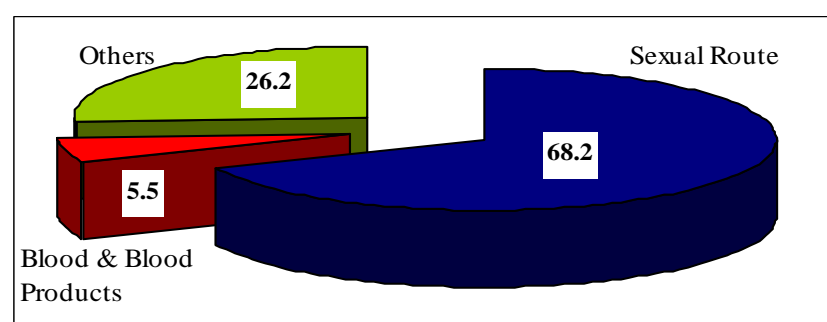
Transmission of AIDS through sexual route was 49 percent during 1998, which increased to 68 percent in 2005. However, transmission through blood/blood product reduced from 37 percent in 1998 to 5.5 percent by 2005, as can be seen from Figure 9.1a and Figure 9.1b.

Figure 9.1a
Transmission Categories in AIDS Cases (1998), Gujarat



Source: Gujarat State AIDS Control Society

Figure 9.1b
Transmission Categories in AIDS Cases (2005), Gujarat



Source: Gujarat State AIDS Control Society

The performance of blood banking services in the state has improved significantly during 1998 and 2005.

Blood Collection: Total Blood collection has gone up from 253,000 in 1998 to 513,000 units by 2005. Voluntary blood donation has risen from 33 % to 64 % during the same period. Almost 98 % of the total blood collection is safe blood. GSACS maintains data on Blood Donation Camps since 2002. During 2002, 9,184 camps were organized in the state of Gujarat. Out of these, more than 6,000 camps were organized by Prathama Blood Centre. A decline in blood donation camps can be observed during the year 2005 (Table 9.1).

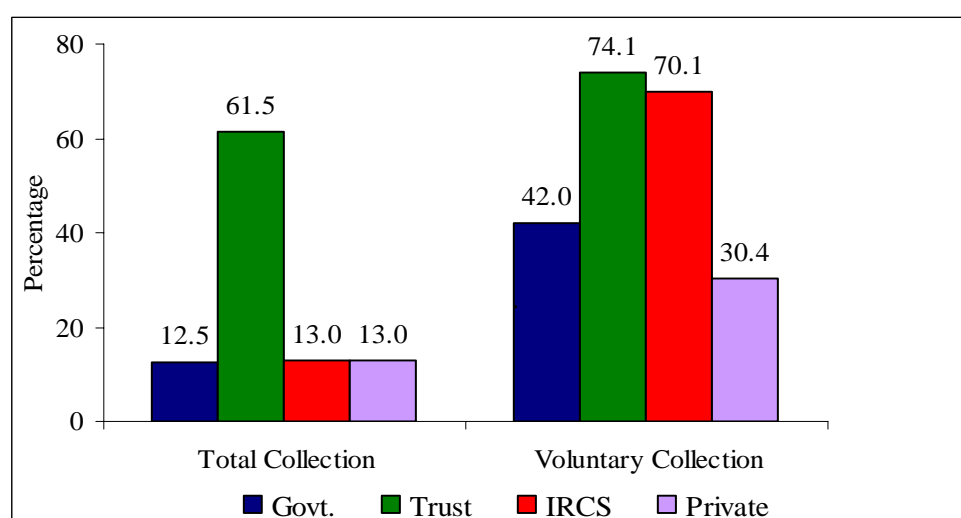
Voluntary Blood Collection: Increase in voluntary blood donation is mainly from the blood banks in government sector, and blood banks under IRCS and trust (See Table 9.2).

Sero-positivity: Seropositivity for HIV has come down marginally from 0.36 % in 1998 to 0.32 % by 2005. It is surprising that HIV seropositivity in voluntary blood is not very different from that in replacement blood. A reduction of 22% and 50% has been observed in Hepatitis B and Hepatitis C respectively during 1998 and 2005. However, VDRL infection has increased from 0.05 to 0.25 during 1998 and 2005. Details can be found in Table 9.3.

The detailed performance of SBTC for the year 2005 can be seen from Figure 9.2 as well as Table 9.4 and Table 9.5.

Figure 9.2 shows the performance of the various sectors in total blood collection and voluntary blood collection. Blood banks managed by the trusts contribute as high as 62 % of the total blood collection in the state, followed by government, IRCS and private blood banks, each contributing around 13 %. Voluntary blood donation is as high as 74 % in the trust managed blood banks, followed by IRCS blood banks (70 %), government blood banks (42 %) and private blood banks (30 %).

Figure 9.2
Sector Wise Total and Voluntary Blood Collection (2005), Gujarat



Source: Gujarat State AIDS Control Society, 2005

Table 9.4 exhibits the number of blood banks in each category by each district and proportion of population donating blood. The state has a total of 164 registered blood banks consisting 29 in the government sector, 49 under the management of various Trusts, 11 under IRCS, and the remaining 75 blood banks in the private sector. Only 110 blood banks are regularly reporting to GSACS regarding their blood collection statistics. District wise variation in number of blood bank can be seen in the Table 7.4. Around 1% percent of population donates blood in the state of Gujarat. In the district Bhavnagar, Porbandar, Rajkot, Surat, Vadodara and Valsad, more than 1% of population donates blood, whereas in Ahmedabad District more than 2 percent of population donating blood.

Table 9.5 represents the district wise information on total blood collection, blood collection by voluntary mean, the prevalence of HIV in voluntary and replacement blood collection, prevalence of HBV, HCV, VDRL and Malaria in total collection and number of camps organized. It is important to mention that 50 % of the total blood collection in the state comes from three districts: Ahmedabad, Surat and Rajkot. Voluntary blood collection is the lowest in Surendranagar district and the highest in Valsad district. In the total collection, highly infected blood has been found in the district of Valsad and Navsari.

Modernization of Blood Banks: Under the NACO Blood Bank Modernization scheme, Gujarat has so far upgraded 15 blood banks as Major Blood Banks and another 42 as District level blood banks. In addition, there are 6 Zonal Blood testing centres in Gujarat.

Blood Components: Many government hospitals still rely on whole blood. As a result of health education and advocacy programmes, 23 Blood banks are providing blood components in the state. Six centres are funded by GSACS, of which four are functioning and two are in the process of getting licenses. The percentage of blood units subjected to component separation has gone up from 5.54 % in 1998 to 38 % by 2005. It can be seen from Table 9.6. that the blood banks managed by trust segregate the highest proportion of blood into components (46 percent) followed by IRCS (24 percent).

In Gujarat, Surat Raktdaan Kendra and Prathma Blood Bank ensure 100 percent conversion of collected blood unit into blood components. Red Cross Society started its blood component separation unit 3 years back. Only 10 percent of the collected blood is being converted into blood components, where as this proportion in VS hospital and Cancer Hospital is approximately 30 percent and 50 percent respectively.

Donor Management: Behavioural Surveillance Survey (2001) indicates that 86 percent of the population in Gujarat is exposed to the promotional campaign for voluntary donation, which is highest in the country. Promotion of voluntary blood donation and awareness creation through various mediums like print, competitions, rallies etc. is done by individual blood banks (Exhibit 9.1).

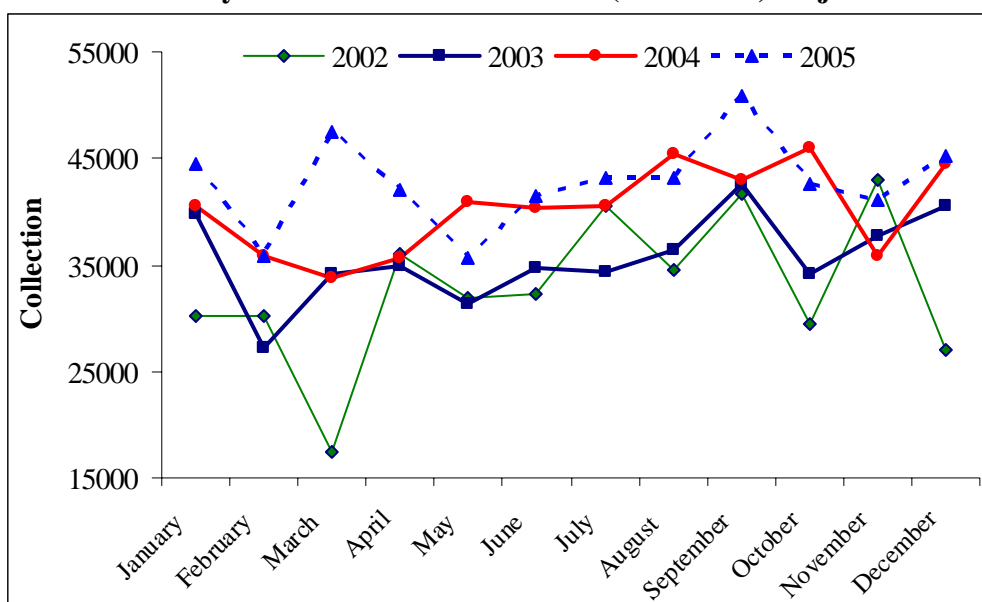
A few blood banks in Gujarat facilitate Centurion Blood Donors, Handicapped Blood Donors and Female Blood Donors. In 2003, GSACS facilitated centurion Female Blood donors. GSACS is appealing to the blood banks for providing iron supplements

to the women who visit blood banks. Donor base is being created while creating awareness through School Adolescent Education Programs, targeted to all students in 9th and 11th classes. Children, whose parents are blood donors, are provided with the badges, stating 'my parents are regular Blood Donors'.

Training program: Training programs for Blood Bank Personnel are offered regularly for updating their skills and knowledge. Once in three months trainings programs are conducted in different regions of the state. The training programmes usually address topics on safe blood, rational use of the blood, and clinical procedures.

Management Information System: GSACS maintains a regular database for all the licensed blood banks. It prepares a monthly statement on blood collected, tested, and availability of safe blood (Figure 9.3).

Figure 9.3
Monthly Trend in Blood Collection (2002-2005) Gujarat



Source: Gujarat State AIDS Control Society

Recent Initiatives: Last year, Gujarat University has started a PG course in Blood Transfusion. Gujarat SBTC has just initiated a free blood policy to Thallasaemia, Haemophilia, and Sickle cell patients.

10. Management of Blood Banks

Blood Bank activities include:

- Donor recruitment and retention,
- Blood Collection
- Blood Testing
- Blood Processing
- Storage of Blood and Blood components
- Issue of Blood and Blood components, for use when clinically needed.
- Training of Staff

Some of the major issues facing the management of blood banks in India are described below.

Inadequate Government Commitment

Government support for blood transfusion services is still not adequate. Some blood transfusion services continue to rely on Philanthropic funding for basic operations, such as procuring test kits or carrying out donor recruitment activities. These essential activities often have to be stopped when such philanthropic funding ends.

Lack of Blood Donors

Lack of voluntary non-remunerated blood donors is still the main constraint for blood safety. Family replacement donors still provide the bulk of blood for the Blood banks. Donors are still clandestinely paid in some states.

Poor Organization of Blood Supply System

Blood transfusions rely on very fragmented blood supply systems. Such systems mean that control is exercised by different layers of government, which makes it very difficult to assure the quality of blood and blood products. More resources as well as stronger political will and leadership are needed if systems are to be reformed.

India has a large number of independent and hospital based blood banks of different levels of sophistication, serving different types of hospitals and patients. Central, state and autonomous government institutes, municipal corporations, cantonment boards, railway services, ESI authorities, armed forces etc are among the public bodies concerned with the organization and administration of blood services. In addition, there is a spectrum of trusts, independent commercial and private blood banks, with IRCS holding a primary position.

Low Status of Blood Banks

Hospital based blood banks usually have a low status within laboratories and are usually run by a laboratory technologist, who is often inappropriately trained and inadequately supervised (WHO, 2004).

Inadequate Coverage of Blood Screening

India has policies to screen donated blood for HIV and HBV and HCV. However, coverage of all blood units in the country and the sustainability of screening depend on the availability of testing reagents and budget for the same. Because some blood services have not achieved full coverage, in rural areas or in emergencies blood transfusion sometimes has to take place with blood that not been tested at all.

Lack of quality Control

Quality control is considered to be less an essential component but a luxury that adds costs to under-resourced blood banks. A lack of quality assurance measures (including manuals of standard operating procedures, appropriate training and competency certification programs, and continuous assessment systems) often hinders the implementation of good laboratory and manufacturing practices.

Inappropriate use of Blood

The inappropriate use of blood is widespread. This includes the transfusion of blood or blood products when it is not strictly needed or when safer alternative therapies are available. In addition, whereas in most developed countries 75% -100% of the blood collected is transfused as components, in developing countries most of the blood is transfused without being separated in components.

Blood Component Therapy

It is necessary to promote blood component therapy. Some of the advantages are

One unit of whole blood gives four components. As the human body requires blood components most of the time, we should provide only the required component to the body, and not the whole blood. The unused components from one unit of blood can possibly save three other lives.

Investments in blood component separation should be utilized fully. If government cannot address this concern satisfactorily, it may be worthwhile to explore public private partnerships.

CMIS Indicators:

The existing set of indicators in CMIS are very few as mentioned in chapter 6.

It is necessary to develop additional indicators to plan and monitor

- Donor recruitment and retention (repeat volunteer blood donors)

- Blood collection (camps, walk-ins, volunteer, replacement)

- Testing (ensure safe blood, window period for HIV+)

- Processing

- Storage (whole blood Vs components)

- Issue to health centers

- Usage in health centers (beneficiaries, transfusion within a time period)

So as to ensure an adequate supply of safe blood and blood components, for use when clinically needed.

Blood Transfusion Services should be established in accordance with the agreed national blood policy and plan and within a legislative framework. It should be responsible for establishing and maintaining a national quality system, including the development of guidelines and standards, staff training, a data/information management system and a system for monitoring and evaluation of all blood transfusion activities.

11. Conclusion

Ensuring a safe, source and ethical supply of blood and blood products and the appropriate and rational clinical use of blood are important public health responsibilities of every national government.

While the Indian Health sector has made some noteworthy achievements over the last 50 years, it has not responded satisfactorily to meet the national goals on blood transfusion services. As a result, there is a fragmented mix of competing independent and hospital based blood banks of different levels of sophistication, serving different types of hospitals and patients. There are a large number of trusts, independent commercial and private blood banks with the Indian Red Cross Society holding a primary position. The piecemeal evolution of blood banking is linked to the lack of policy and priority for Blood banking by the government.

Many states, with the exception of Maharashtra and a few North Eastern States, have set up their State Blood Transfusion Councils under their State AIDS Control Society. The Blood Safety Program under the State AIDS Control Society (SACS) only ensures safety of blood in blood banks in their respective states. No SACS takes the responsibility to supply safe blood to public and private health facilities as and when needed.

Mahaarashtra Government, by setting up its State Blood Transfusion Council as an independent unit under the Department of Health, has set up an excellent example to show that a well organized and coordinated blood transfusion service is safer, more cost effective and more dependable in meeting the transfusion requirements of the patient population than any fragmented system. We strongly recommend the Maharashtra model to all other states and union territories in India.

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Table 7.1
Number of Licensed Blood Banks* (2004), India and States

States	Government	Trust#	Private	Total
India	826	257	980	2063
Andaman & Nicobar	2	--	--	2
Andhra Pradesh	66	25	113	204
Arunachal Pradesh	2	1	--	3
Assam	35	3	20	58
Bihar	42	4	32	78
Chandigarh	3	1	--	4
Chhatisgarh	12	1	16	29
Dadra & Nagar Haveli	--	1	--	1
Daman & Diu	1	--	--	1
Delhi	18	3	24	45
Goa	5	--	--	8
Gujarat	30	70	67	167
Haryana	17	5	28	50
Himachal Pradesh	14	1	--	15
Jammu & Kashmir	14	--	--	15
Jharkhand	4	--	5	9
Karnataka	39	16	91	146
Kerala	34	5	95	134
Madhya Pradesh	42	17	45	104
Maharashtra	82	29	153	264
Manipur	3	--	--	3
Meghalaya	3	--	--	5
Mizoram	3	--	--	5
Nagaland	3	--	--	3
Orissa	4	46	12	62
Pondicherry	5	--	--	11
Punjab	41	5	30	76
Rajasthan	44	5	18	67
Sikkim	3	--	--	3
Tamil Nadu	98	10	113	221
Tripura	3	--	--	6
Uttar Pradesh	69	4	68	141
Uttaranchal	14	--	4	18
West Bengal	71	5	29	105

Source: Drug Controller General, Dte, New Delhi. From Health Information of India, 2004

* Blood Bank Licensed as approved by CENTRAL LICENSE APPROVAL AUTHORITY (CLAA)

Voluntary Includes Red Cross, Lions Club, Rotary Club, etc.

Table 7.2
Blood Collection Status (2002-2004), India and States

SACS/MACS	2002			2003			2004		
	Total Coll. Units	Voluntary Coll.		Total Coll. Units	Voluntary Coll.		Total Coll. Units	Voluntary Coll.	
		Units	%		Units	%		Units	%
India	3197541	1462366	45.7	4001758	2001119	50.0	4050128	2079963	51.36
Ahd MACS	93276	55049	59.0	108353	63944	59.0	100378	58565	58.3
A & N Islands	3543	2387	67.4	3778	2756	73.0	1750	1256	71.8
Andhra Pradesh	268814	109702	40.8	295793	138393	46.8	348934	166822	47.8
Arunachal Pradesh	638	608	95.3	1424	1370	96.2	1524	1491	97.8
Assam	27156	8090	29.8	46761	19981	42.7	59364	25640	43.2
Bihar	20004	6592	33.0	46796	14056	30.0	43650	8296	19.0
Chandigarh	47543	22720	47.8	47790	26560	55.6	49146	30909	62.9
Chennai MACS	266	162	60.9	90522	65190	72.0	76299	57875	75.9
Chattisgarh	0	0		27008	7266	26.9	20799	5794	27.86
Daman & Diu	156	107	68.6	223	155	69.5	379	281	74.14
Delhi	312742	63641	20.4	245873	60422	24.6	199662	46887	23.48
Goa	9223	3321	36.0	16734	6032	36.1	10797	5860	54.27
Gujarat	380947	201696	53.0	411209	239840	58.3	440396	266789	60.58
Haryana	74494	19347	26.0	93204	25984	27.9	107348	28924	26.94
Himachal Pradesh	10601	6075	57.3	15508	8521	55.0	15657	9697	61.93
Jammu & Kashmir	14949	1927	12.9	5253	1276	24.3	23226	3898	16.78
Jharkhand	0	0		4565	356	7.8	48227	15917	33.00
Karnataka	287793	131800	45.8	335039	165285	49.3	347595	182376	52.47
Kerala	149913	59105	39.4	147915	56957	38.5	117830	42847	36.36
Lakshadweep	14	14	100.0	10	10	100.0			0.00
Madhya Pradesh	51360	12083	23.5	74281	22554	30.4	153274	50712	33.09
Maharashtra	240477	190048	79.0	306400	250373	81.7	154646	130356	84.29
Manipur	16847	1349	8.0	43086	3919	9.1	12072	1337	11.08
Meghalaya	2424	119	4.9	3164	102	3.2	3810	362	9.50
Mizoram	10748	3994	37.2	12275	5956	48.5	13272	7774	58.57
Mumb.MACS	134350	61127	45.5	195517	100674	51.5	198786	106033	53.34
Nagaland	1981	921	46.5	1633	934	57.2	1535	867	56.48
Orrisa	111280	20807	18.7	85543	25160	29.4	131467	44496	33.85
Pondicherry	15011	5166	34.4	17561	6654	37.9	6811	2934	43.08
Punjab	94516	13225	14.0	133946	19886	14.9	118750	20767	17.49
Rajasthan	7474	492	6.6	119622	20131	16.8	93877	13989	14.90
Sikkim	1172	74	6.3	1416	188	13.3	1670	238	14.25
Tamil Nadu	176625	101153	57.3	272101	166443	61.2	369200	264314	71.59
Tripura	4540	1715	37.8	15423	7515	48.7	8227	4627	56.24
Uttar Pradesh	239582	57242	23.9	296845	77076	26.0	273894	72510	26.47
Uttranchal	9375	1304	13.9	15941	2419	15.2	20171	2900	14.38
West Bengal	377707	299204	79.2	463246	386781	83.5	475705	395623	83.17

Source: Report generated from CMIS on 2004 for NACO, MOH&FW

Table 7.3
Blood Units Tested and Percent Positive for all Diseases (2004), India and States

States	Total Tested	HIV +		HB+		HCV +		VDRL +	
		N	%	N	%	N	%	N	%
India	4050128	13810	0.34	48497	1.20	19584	0.48	11121	0.27
Ahd MACS	100378	433	0.43	1059	1.06	487	0.49	445	0.44
A & N Islands	1750	0	0.00	25	1.43	0	0.00	1	0.06
Andhra Pradesh	348934	2064	0.59	5303	1.52	1824	0.52	957	0.27
Arunachal Pradesh	1524	10	0.66	22	1.44	12	0.79	12	0.79
Assam	59364	78	0.13	246	0.41	77	0.13	84	0.14
Bihar	43650	66	0.15	586	1.34	48	0.11	86	0.20
Chandigarh	49146	96	0.20	536	1.09	512	1.04	170	0.35
Chennai MACS	76299	122	0.16	1202	1.58	366	0.48	51	0.07
Chhatisgarh	20799	48	0.23	189	0.91	24	0.12	37	0.18
Daman & Diu	379	0	0.00	6	1.58	1	0.26	0	0.00
Delhi	199662	781	0.39	2895	1.45	1160	0.58	902	0.45
Goa	10797	108	1.00	107	0.99	92	0.85	14	0.13
Gujarat	440396	1465	0.33	4706	1.07	1876	0.43	1172	0.27
Haryana	107348	317	0.30	1522	1.42	1036	0.97	337	0.31
Himachal Pradesh	15657	30	0.19	113	0.72	13	0.08	1	0.01
Jammu & Kashmir	23226	60	0.26	225	0.97	120	0.52	5	0.02
Jharkhand	48227	64	0.13	487	1.01	58	0.12	112	0.23
Karnataka	347595	1719	0.49	4190	1.21	1153	0.33	705	0.20
Kerala	117830	185	0.16	864	0.73	437	0.37	118	0.10
Lakshadweep	0	0	0.00	0	0.00	0	0.00	0	0.00
Madhya Pradesh	153274	234	0.15	2211	1.44	292	0.19	375	0.24
Maharashtra	154646	1181	0.76	2489	1.61	871	0.56	515	0.33
Manipur	12072	80	0.66	61	0.51	212	1.76	41	0.34
Meghalaya	3810	4	0.10	49	1.29	8	0.21	52	1.36
Mizoram	13272	87	0.66	314	2.37	264	1.99	51	0.38
Mumbai MACS	198786	1558	0.78	3511	1.77	2122	1.07	935	0.47
Nagaland	1535	9	0.59	12	0.78	7	0.46	20	1.30
Orissa	131467	175	0.13	613	0.47	218	0.17	101	0.08
Pondicherry	6811	21	0.31	158	2.32	21	0.31	32	0.47
Punjab	118750	218	0.18	959	0.81	1714	1.44	321	0.27
Rajasthan	93877	228	0.24	1878	2.00	426	0.45	532	0.57
Sikkim	1670	1	0.06	13	0.78	3	0.18	8	0.48
Tamil Nadu	369200	727	0.20	4050	1.10	1392	0.38	392	0.11
Tripura	8227	7	0.09	200	2.43	19	0.23	104	1.26
Uttar Pradesh	273894	396	0.14	2321	0.85	1218	0.44	451	0.16
Uttaranchal	20171	13	0.06	157	0.78	59	0.29	49	0.24
West Bengal	475705	1225	0.26	5218	1.10	1442	0.30	1933	0.41

Source: Report generated from CMIS on 2004 for NACO, MOH&FW

Table 7.4
Details of All Components of Blood Bank (2005), India and States

States	Donors			% Vol	% Repl	No. of donors counseled	Voluntary blood donation camps	Repeat Vol. donors	HIV +	% HIV +
	Vol.	Repl	Total							
India	1596173	1290710	2886883	55.29	44.71	1278954	36855	69618	9923	0.34
Ahmedabad MACS	61909	34044	95953	64.52	35.48	79574	687	6255	362	0.38
Andaman & Nicobar	0	0	0	0.00	0.00	0	21	0	0	0.00
Andhra Pradesh	154450	159165	313615	49.25	50.75	109752	2730	1960	1636	0.52
Arunachal Pradesh	683	0	683	100.0	0.00	0	0	0	2	0.29
Assam	18430	23806	42236	43.64	56.36	27480	34	3	84	0.20
Bihar	1298	10008	11306	11.48	88.52	5516	250	27	28	0.25
Chandigarh	36223	14096	50319	71.99	28.01	20324	514	8906	97	0.19
Chennai MACS	92203	9966	102169	90.25	9.75	39895	1265	1901	139	0.14
Chhatisgarh	5163	11389	16552	31.19	68.81	6015	40	0	36	0.22
Dadra & Nagar Haveli	738	0	738	100.0	0.00	267	6	0	6	0.81
Daman & Diu	0	0	0	0.00	0.00	0	7	0	0	0.00
Delhi	28552	85361	113913	25.06	74.94	25912	219	0	388	0.34
Goa	4231	4045	8276	51.12	48.88	4887	97	36	71	0.86
Gujarat	254930	133927	388857	65.56	34.44	186443	7567	37370	1350	0.35
Haryana	25466	65884	91350	27.88	72.12	54831	847	0	191	0.21
Himachal Pradesh	7288	4476	11764	61.95	38.05	9705	88	0	24	0.20
Jammu & Kashmir	173	2214	2387	7.25	92.75	222	3	0	1	0.04
Jharkhand	8652	25295	33947	25.49	74.51	7621	2913	1487	47	0.14
Karnataka	75536	69987	145523	51.91	48.09	61849	527	0	547	0.38
Kerala	30954	45943	76897	40.25	59.75	3593	517	13	91	0.12
Lakshadweep	0	0	0	0.00	0.00	0	0	0	0	0.00
Madhya Pradesh	43893	66659	110552	39.70	60.30	37750	283	446	198	0.18
Maharashtra	126144	23173	149317	84.48	15.52	62132	1985	3534	1008	0.68
Manipur	818	9503	10321	7.93	92.07	0	17	0	72	0.70
Meghalaya	99	1473	1572	6.30	93.70	880	1	6	2	0.13
Mizoram	1578	2049	3627	43.51	56.49	1499	31	772	19	0.52
Mumbai MACS	77132	69857	146989	52.47	47.53	32383	845	3933	1095	0.74
Nagaland	69	124	193	35.75	64.25	15	1	5	0	0.00
Orissa	61575	51592	113167	54.41	45.59	31077	637	214	117	0.10
Pondicherry	3519	5109	8628	40.79	59.21	3610	35	36	27	0.31
Punjab	10978	65574	76552	14.34	85.66	46359	176	29	149	0.19
Rajasthan	2167	9184	11351	19.09	80.91	3981	61	1	35	0.31
Sikkim	81	389	470	17.23	82.77	470	2	20	2	0.43
Tamil Nadu	111262	41858	153120	72.66	27.34	57327	1136	1605	238	0.16
Tripura	5647	2561	8208	68.80	31.20	3807	136	0	8	0.10
Uttar Pradesh	59130	178135	237265	24.92	75.08	91489	7614	565	338	0.14
Uttaranchal	2969	18612	21581	13.76	86.24	9688	45	27	31	0.14
West Bengal	282233	45252	327485	86.18	13.82	252601	5518	467	1484	0.45

Source: Report generated from CMIS on 2005 for NACO, MOH&FW

Note: The table values need to be validated as there are several discrepancies.

Table 8.1
Trends in Blood Banking (1998-2005), Maharashtra

Year	1998	1999	2000	2001	2002	2003	2004	2005
No of licensed Blood Banks	--	225	235	249	264	272	283	298
Total Blood Units	465030	585040	666508	698768	744871	787197	834865	874034
% Voluntary	47.8	49.3	54.0	65.0	67.1	71.5	73.6	74.9
Total Safe Blood (Units)	456566	560293	640181	673333	720290	762322	807732	846764
Percent*	98.18	95.77	96.05	96.36	96.70	96.84	96.75	96.88
Number of Camps	--	---	6140	7395	7793	8963	9443	10461

Source: Maharashtra State Blood Transfusion Council

* The infected units were discarded and properly disposed by the blood banks

---Did not maintained in reports

Table 8.2
Trends in Sector Wise Voluntary Blood Collection (2001-2005), Maharashtra

Sector	Voluntary Collection %				
	2001	2002	2003	2004	2005
Govt.	72.2	71.3	74.3	72.7	74.3
Trust	62.5	66.3	72.9	75.9	76.8
IRCS	84.7	83.0	84.8	87.2	88.2
Private	39.7	49.1	51.2	49.8	43.5
Total Collection	454199	499808	562846	614461	654651
%	65.0	67.1	71.5	73.6	74.9

Source: Maharashtra State Blood Transfusion Council

Table 8.3
Trends in HIV, HB, HCV and VDRL Prevalence in Total Collected Blood (1998-2005), Maharashtra

Year	1998	1999	2000	2001	2002	2003	2004	2005
Total Blood Units	465030	585040	666508	698768	744871	787197	834865	874034
HIV+	1.82	1.36	1.19	1.14	0.95	0.78	0.74	0.66
HBs AG+	--	2.26	2.11	2.05	2.00	1.91	1.69	1.73
HCV +	--	--	--	--	--	--	0.54	0.48
VDRL +	--	0.61	0.65	0.45	0.35	0.47	0.28	0.25

Source: Maharashtra State Blood Transfusion Council

---Did not maintained in reports

Table 8.4
Type of Blood Banks (2005), Maharashtra

Districts	Population	Female Population (15-49)	Proportion of Popn. Donating Blood	Blood Banks					
				Corp.	Govt.	IRCS	Trust	Private	Total
Ahmednagar	4040642	976240	0.63	0	1	0	10	0	12
Akola	1630239	399737	1.19	0	3	0	3	6	12
Amravati	2607160	646219	0.89	0	1	0	1	3	5
Aurangabad	2897013	670978	1.28	1	1	0	5	1	7
Bhandara	1136146	295332	0.28	0	1	0	0	0	1
Beed	2161250	473806	0.32	0	2	0	0	0	2
Buldhana	2232480	527660	0.34	0	3	0	1	3	7
Chandrapur	2071101	535079	0.63	0	1	0	4	0	5
Dhule	1707947	411221	0.91	0	1	0	5	0	6
Gadchiroli	970294	244725	0.30	0	2	0	0	0	2
Gondia	1200707	313764	0.50	0	1	0	0	0	1
Jalgaon	3682690	896390	0.52	0	2	2	3	1	8
Jalna	1612980	359555	0.26	0	1	0	2	0	3
Kolhapur	3523162	923147	1.01	1	1	0	6	1	9
Latur	2080285	467349	0.78	0	1	1	2	0	4
Mumbai	11978450	3100517	1.94	10	10	1	25	17	63
Nagpur	4067637	1068638	1.65	0	4	0	9	3	16
Nanded	2876259	644032	0.41	0	1	1	0	1	3
Nandurbar	1311709	315035	0.27	0	0	0	2	0	2
Nasik	4993796	1219812	0.71	1	2	0	5	1	9
Osmanabad	1486586	329556	0.17	0	1	0	1	0	2
Parbhani	1527715	340327	0.35	0	1	0	0	2	3
Pune	7232555	1890629	1.43	1	4	1	18	0	24
Raigad	2207929	577416	0.18	0	1	0	3	2	6
Ratnagiri	1696777	455587	0.51	0	1	0	1	1	3
Sangli	2583524	652376	1.31	0	1	1	5	0	7
Satara	2808994	717331	0.58	0	2	0	7	0	9
Sindhudurga	868825	229354	0.37	0	2	0	0	0	2
Solapur	3849543	926000	1.41	0	1	3	4	0	8
Thane	8131849	2122236	0.47	1	4	0	10	8	23
Wardha	1236736	314078	0.68	0	1	0	2	0	3
Yavatmal	2458271	598122	0.43	0	1	0	0	5	6
Maharashtra	96878627	24099325	0.90	15	59	10	134	55	273

Source: Maharashtra State Blood Transfusion Council, 2005

Table 8.5
District Wise Collection of Blood Units and Tested (2005), Maharashtra

Sr. No	Districts	Total							Safe Blood		Number of Camps	% of voluntary collection through camp
		Vol %	Units	% HIV+	% HBs AG+	% HCV+	% VDRL+	% Malaria	Units	%		
1	Akola	83.6	19407	0.41	1.33	0.08	0.19	0	19017	98.0	213	32.1
2	Amravati	89.3	23322	0.52	1.26	0.67	0.02	0	22746	97.5	303	66.3
3	Buldhana	79.4	7699	0.31	1.31	0.21	0.19	0	7543	98.0	100	19.5
4	Yavatmal	44.7	10577	1.07	1.58	0.08	0.41	0.02	10243	96.8	65	69.7
	Akola Circle	78.5	61005	0.55	1.35	0.32	0.16	0	59553	97.6	681	49.1
5	Aurangabad	87.9	37112	1.21	2.31	0.14	0.05	0.02	35728	96.3	931	88.8
6	Jalna	95.6	4249	0.49	1.77	0.35	0.35	0	4123	97.0	151	67.1
7	Parbhani	74.9	5315	0.49	1.78	0.63	0.57	0	5131	96.5	71	72.2
	Aurangabad Circle	87.1	46676	1.07	2.21	0.21	0.14	0.02	44972	96.4	1153	85.0
8	Kolhapur	86.7	35601	0.88	1.85	0.22	0.05	0	34533	97.0	472	64.9
9	Sangli	90.5	33839	0.84	1.52	0.42	0.25	0	32814	97.0	333	43.6
10	Sindhudurga	96.2	3236	0.38	0.91	0.37	0.00	0.00	3182	98.3	93	89.3
	Kolhapur Circle	88.9	72676	0.84	1.65	0.32	0.14	0	70532	97.1	898	56.0
11	Beed	80.0	6965	0.86	1.69	0.7	0.01	0	6738	96.7	198	75.4
12	Latur	73.7	16269	0.61	2.71	0.47	0.12	0	15633	96.1	291	89.6
13	Nanded	77.5	11689	0.59	2.97	0.27	0.02	0	11239	96.2	202	62.6
14	Osmanabad	75.8	2548	0.63	1.61	0.35	0.08	0	2480	97.3	46	52.4
	Latur Circle	76.2	37471	0.65	2.53	0.44	0.07	0	36088	96.3	737	75.8
15	Mumbai Circle	51.8	231815	0.66	1.76	0.75	0.41	0.01	223493	96.4	1180	78.1

Contd...

Table 8.5 (contd.)
District Wise Collection of Blood Units and Tested (2005), Maharashtra

Sr. No	Districts	Total							Safe Blood		Number of Camps	% of voluntary collection through camp
		Vol %	Units	% HIV+	% HBs AG+	% HCV+	% VDRL+	% Malaria	Units	%		
16	Bhandara	78.5	3229	0.58	0.47	0.14	0.03	0	3190	98.8	43	38.6
17	Chandrapur	65.9	13107	0.6	0.68	0.08	0.12	0.03	12909	98.5	187	47.5
18	Gadchiroli	87.0	2885	0.9	1.46	0.45	0.1	0	2801	97.1	90	61.6
19	Gondia	72.1	6034	0.04	0	0	0.05	0	6029	99.9	61	72.5
20	Nagpur	67.6	67018	0.72	1.31	0.2	0.18	0.01	65396	97.6	716	63.8
21	Wardha	87.1	8403	1.13	2.15	0.86	0.43	0	8019	95.4	130	34.9
	Nagpur Circle	70.2	100676	0.7	1.2	0.24	0.18	0.01	98330	97.7	1227	58.4
22	Ahmednagar	81.6	25534	0.49	1.79	0.42	0.17	0	24801	97.1	395	56.7
23	Dhule	66.1	15539	0.49	1.66	0.28	0.21	0.01	15127	97.4	206	67.4
24	Jalgaom	81.7	19224	0.57	1.89	0.38	0.19	0.01	18640	97.0	273	63.8
25	Nandurbar	99.4	3595	0.53	1.31	0.31	0.31	0.03	3505	97.5	76	87.3
26	Nasik	92.2	35488	0.37	1.47	0.16	0.1	0	34743	97.9	785	77.6
	Nasik Circle	83.6	99380	0.46	1.66	0.29	16	0.01	81074	81.6	1735	68.9
27	Pune	88.4	103185	0.51	1.53	0.44	0.17	0	100451	97.4	1209	73.3
28	Satara	93.3	16250	0.46	2.03	0.22	0.13	0	15789	97.2	284	65.5
29	Solapur	93.1	54420	0.87	2.54	0.89	0.55	0	51781	95.2	861	92.4
	Pune Circle	90.3	173855	0.62	1.9	0.56	0.29	0	167996	96.6	2354	78.7
30	Riagad	82.8	8704	0.47	1.17	0.21	0.1	0	8534	98.1	106	53.1
31	Ratnagiri	96.4	3932	0.28	0.84	0.03	0.03	0	3886	98.8	105	70.0
32	Thane	74.5	37844	0.58	1.9	0.6	0.28	0.01	36569	96.6	285	32.0
	Thane Circle	77.7	50480	0.54	1.69	0.49	0.23	0.01	48986	97.0	496	39.6
	MAHARASHTRA	74.6	874034	0.66	1.73	0.48	0.25	0.01	846677	96.9	10461	68.6

Source: Maharashtra State Blood Transfusion Council, 2005

Table 9.1
Trends in Blood Banking (1998-2005), Gujarat

Year	1998	1999	2000	2001	2002	2003	2004	2005
No of licensed Blood Banks	127	134	147	160	160	162	164	164
Total Blood Units	253203	228873	275020	376264	394575	427563	482481	513203
% Voluntary	33.69	39.77	39.65	44.2	52.63	58.01	60.74	63.86
Total Safe Blood (Units)	247493	223920	269501	367398	386525	418071	471397	503606
Percent*	97.70	97.80	98.00	97.60	98.00	97.80	97.70	98.13
Number of Camps	---	---	---	---	9184 [#]	2908	5592	4248

Source: Gujarat State AIDS Control Society

* The infected units were discarded and properly disposed by the blood banks

More than 6000 camps were conducted by Prathma Blood Banks

Table 9.2
Trends in Sector Wise Voluntary Blood Collection (2001-2005), Gujarat

Sector	Voluntary Collection %				
	2001	2002	2003	2004	2005
Govt.	14.5	13.7	7.7	37.0	42.0
Trust			70.8	69.8	74.1
IRCS	81.0	81.9	15.5	64.0	70.1
Private	4.5	4.4	6.0	29.4	30.4
Total Collection	166309	207665	248029	293059	327731
%	44.2	52.63	58.01	60.74	63.86

Source: Gujarat State AIDS Control Society

Table 9.3
Trends in HIV, HB, HCV and VDRL Prevalence in Total Collected Blood (1998-2005), Gujarat

Year	1998	1999	2000	2001	2002	2003	2004	2005	
Total Blood Units	253203	228873	275020	376264	394575	427563	482481	513203	
HIV +	Vol.	0.36	0.39	0.45	0.42	0.34	0.33	0.36	0.34
	Repl.	0.37	0.45	0.43	0.47	0.44	0.38	0.33	0.31
	Total	0.36	0.42	0.44	0.45	0.39	0.35	0.35	0.32
HBs AG+	1.38	1.31	1.07	1.24	1.11	1.15	1.09	1.07	
HCV +	0.46	0.42	0.44	0.45	0.39	0.35	0.43	0.23	
VDRL +	0.05	0.01	0.06	0.22	0.15	0.37	0.43	0.25	

Source: Gujarat State AIDS Control Society, 2005

* The infected units were discarded and properly disposed by the blood banks

More than 6000 camps were conducted by Prathma Blood Banks

Table 9.4
Type of Blood Banks (2005), Gujarat

Districts	Population	Female Population (15-49)	Proportion of Popn. Donating Blood	Blood Banks				
				Govt.	IRCS	Trust	Private	Total
Ahmadabad	5816519	1563267	2.33	4	1	8	16	29
Amreli	1393918	354605	0.36	2	1	0	0	3
Anand	1856872	487676	0.74	0	2	3	1	6
Banas Kantha	2504244	592070	0.31	1	0	2	5	8
Bharuch	1370656	352681	0.69	0	1	1	2	4
Bhavnagar	2469630	604482	1.04	1	0	3	4	8
Dohad	1636433	385817	0.03	1	0	1	3	5
The Dangs	186729	44723	0.03	1	0	0	0	1
Gandhinagar	1334455	358367	0.71	1	1	2	2	6
Jamnagar	1904278	492922	0.77	2	0	1	4	7
Junagadh	2448173	631604	0.46	1	0	2	4	7
Kheda	1583225	394645	0.73	1	2	0	3	6
Kachchh	2024216	526294	0.75	1	0	2	3	6
Mahesana	1837892	483377	0.91	1	0	3	3	7
Narmada	514404	128675	0.00	0	0	0	0	0
Navsari	1229463	334023	0.89	1	1	1	0	3
Panch Mahals	2025277	490544	0.26	1	1	0	1	3
Patan	1182709	297565	0.88	1	0	2	1	4
Porbandar	536835	139659	1.14	1	0	1	1	3
Rajkot	3169881	839843	1.71	2	0	5	4	11
Sabar Kantha	2082531	535390	0.49	1	1	0	3	5
Surat	4995174	1287367	1.53	1	0	7	1	9
Surendranagar	1515148	372233	0.22	1	0	0	5	6
Vadodara	3641802	964990	1.05	2	0	2	5	9
Valsad	1410553	366363	1.54	1	0	5	0	6
Gujarat	50671017	13029182	1.01	29	11	51	71	162

Source: Gujarat State AIDS Control Society, 2005

Table 9.5
District Wise Collection of Blood Units and Tested (2005), Gujarat

Sr. No.	District	Vol %	Voluntary		Replacement		Total						Safe Blood		Number of Camps
			Units	% HIV+	Units	% HIV+	Units	% HIV+	% HBs AG+	% HCV+	% VDRL+	% Malaria	Units	%	
1	Ahmedabad	61.0	82623	0.35	52868	0.27	135491	0.32	1.01	0.27	0.27	0.00	132953	98.1	891
2	Amreli	62.8	3195	0.59	1889	0.00	5084	0.37	0.63	0.08	0.00	0.00	5029	98.9	196
3	Anand	54.7	7505	0.27	6214	0.16	13719	0.22	0.47	0.23	0.27	0.00	13555	98.8	118
4	Banaskhatha	64.2	5045	0.20	2818	0.25	7863	0.22	0.59	0.08	0.04	0.03	7789	99.1	439
5	Bharuch	45.8	4315	0.23	5116	0.29	9431	0.27	1.16	0.07	0.04	0.00	9286	98.5	22
6	Bhavnagar	50.8	13089	0.17	12676	0.50	25765	0.33	1.47	0.27	0.35	0.01	25139	97.6	170
7	Dahod	58.0	293	0.00	212	0.00	505	0.00	0.00	0.00	0.00	0.00	505	100.0	11
8	Dang	10.0	5	0.00	45	0.00	50	0.00	0.00	0.00	0.00	0.00	50	100.0	0
9	Gandhinagar	35.1	3318	0.12	6139	0.11	9457	0.12	0.81	0.05	0.57	0.05	9305	98.4	47
10	Jamnagar	38.8	5671	0.16	8950	0.36	14621	0.28	1.07	0.19	0.64	0.00	14302	97.8	82
11	Unagadh	77.7	8654	0.25	2486	0.12	11140	0.22	0.48	0.06	0.04	0.00	11049	99.2	77
12	Kheda	43.3	5015	0.16	6579	0.26	11594	0.22	0.48	0.09	0.74	0.00	11416	98.5	67
13	Kutch	23.5	3574	0.08	11620	0.16	15194	0.14	0.47	0.03	0.07	0.00	15086	99.3	48
14	Mehsana	59.8	9990	0.15	6719	0.30	16709	0.21	0.57	0.40	0.34	0.00	16454	98.5	94
15	Narmada	---	0	---	0	---	0	---	---	---	---	---	0	---	---
16	Navsari	81.2	8910	0.48	2061	0.53	10971	0.49	2.34	0.75	0.36	0.00	10538	96.1	104
17	Panchmahal	55.0	2859	0.10	2336	0.30	5195	0.19	0.40	0.13	0.27	0.00	5143	99.0	40
18	Patan	40.7	4231	0.14	6172	0.26	10403	0.21	0.75	0.10	0.15	0.00	10277	98.8	46
19	Porbandar	44.9	2742	0.29	3364	0.18	6106	0.23	0.44	0.05	0.00	0.00	6062	99.3	2
20	Rajkot	91.1	49332	0.31	4801	0.60	54133	0.34	1.11	0.22	0.18	0.01	53126	98.1	494
21	Sabarkhatha	49.9	5094	0.22	5119	0.33	10213	0.27	1.06	0.37	0.19	0.00	10020	98.1	52
22	Surat	78.8	60173	0.27	16219	0.27	76392	0.27	1.21	0.16	0.13	0.04	75005	98.2	753
23	Surendranagar	15.2	510	0.39	2845	0.21	3355	0.24	0.77	0.09	0.48	0.03	3301	98.4	19
24	Vadodara	55.9	21320	0.20	16835	0.48	38155	0.32	1.02	0.19	0.26	0.00	37473	98.2	183
25	Valsad	93.8	20310	1.18	1347	0.97	21657	1.16	2.47	0.56	0.28	0.00	20688	95.5	293
GUJARAT		63.9	327773	0.34	185430	0.31	513203	0.32	1.07	0.23	0.25	0.01	503551	98.1	4248

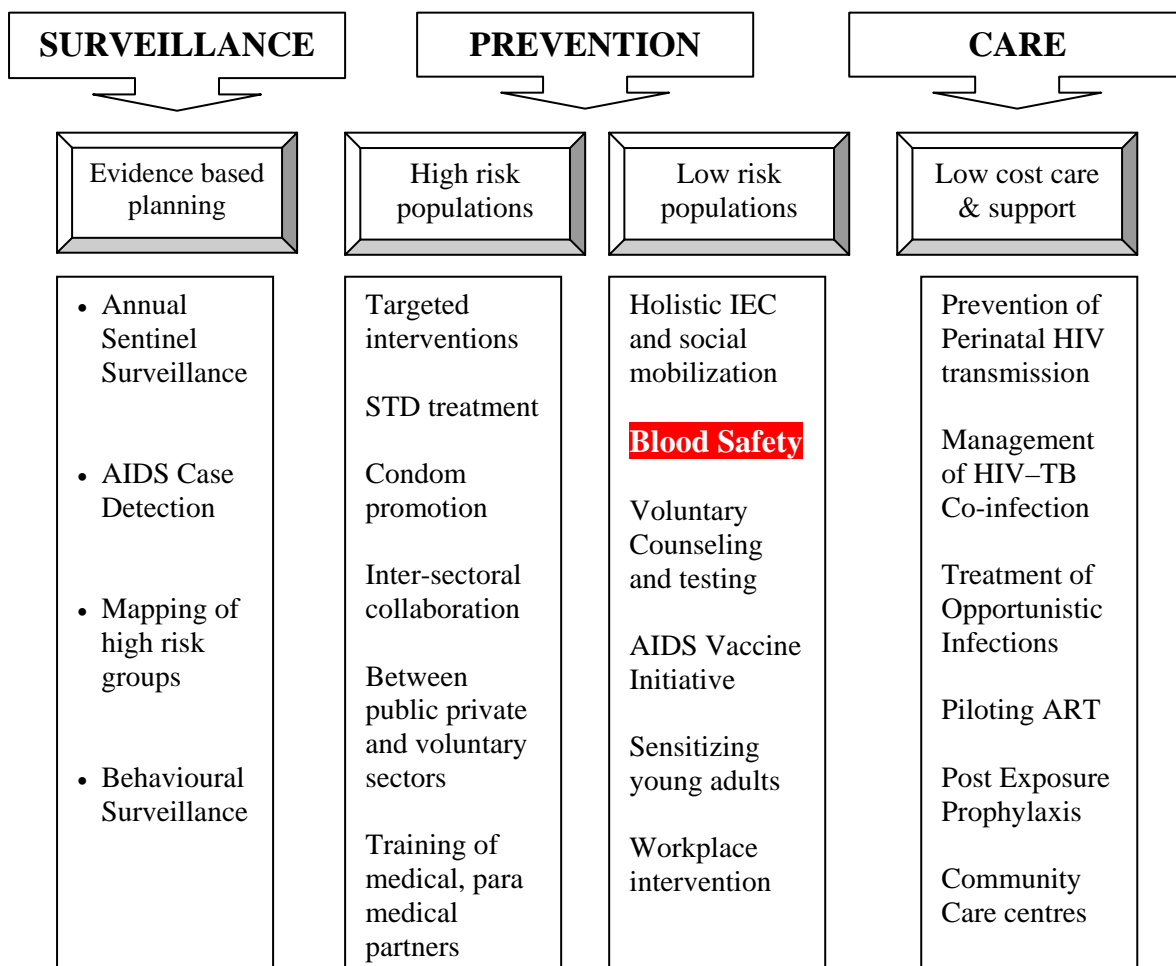
Source: Gujarat State AIDS Control Society, 2005

Table 9.6
Details of Blood Component Separation (2005), Gujarat

Type of Blood Bank	Number of blood banks	Total blood collection (units)	Total units used for components	% total collection used for components
Government	29	64228	5159	8.0
IRCS	11	66806	15922	23.8
Trusts	75	315654	144242	45.7
Private	46	66515	6116	9.2

Source: Gujarat State AIDS Control Society, 2005

Exhibit 6.1
Components of the Second National AIDS Control Programme (1999-2006)



Source: National AIDS Control Society, Annual Report 2002-2004

Exhibit 6.2

Unique ID No. of Blood Bank: _____ Monthly CMIS Formats for Blood Banks

Monthly Input Formats for Blood Banks

1. Name of Blood Bank:	_____
2. Address of Blood Bank:	_____
City: _____; District: _____	
3. Reporting Period:	_____ Month _____ Year
4. Name of Officer In-charge:	_____
NOTE: Please notify any changes in telephone nos., fax nos., e-mail IDs, name of Medical Officer Incharge	

(i) Status of Availability of Equipment and Consumables

<i>(Col. 1)</i> Availability & Functionality of:	<i>(Col. 2)</i> Whether Functional and Available in Adequate Quantity <i>(encircle response)</i>	<i>(Col. 3)</i> If, No List the ones not available in adequate quantity/ not functional
Critical Equipment	1. Yes 2. No	_____ _____ _____
Critical Consumables	1. Yes 2. No	_____ _____ _____

Unique ID No. of Blood Bank: _____

Monthly CMIS Formats for Blood Banks

(ii) Stock Position of Testing Kits and Blood Bags

(Col. 1) Items*	(Col. 2) Balance at the Beginning of the Month (in nos.)	(Col. 3) Nos. Received During the Month	(Col. 4) Nos. Used During the Month	(Col. 5) Nos. Damaged/Wasted During the Month	(Col. 6) Balance at End of the Month (in nos.)
1. HIV ELISA Kits					
2. HIV Rapid Test Kits					
3. Hepatitis B ELISA Test Kits					
4. Hepatitis B Rapid Test Kits					
5. Hepatitis C ELISA Test Kits					
6. Rapid Hepatitis C Test Kits					
7. VDRL Test Kits					
8. Blood bags					
9. Others (specify)					

*Note.: Mention the stock position for each of the items in terms of Nos. of tests that each kit can undertake, that is multiply number of tests that each kit can undertake with the numbers of kits available. For example; for HIV ELISA kits, if a kit can undertake 96 tests and 10 such kits are available as opening balance in the beginning of the month then specify $96 \times 10 = 960$ as the balance in the beginning of the month. Follow this pattern for all the items in this table.

(iii) Status of Testing of Blood Units

(Col. 1) Tests Conducted	(Col. 2) Voluntary Collection Units		(Col. 3) Replacement Collection Units		(Col. 4) Total	
	(Col. 2.a) Tested	(Col. 2.b) Positive	(Col. 3.a) Tested	(Col. 3.b) Positive	(Col. 4.a) Tested	(Col. 4.b) Positive
1. HIV						
2. Hepatitis-B						
3. Hepatitis-C						
4. VDRL						
5. Malaria						

Unique ID No. of Blood Bank: _____ Monthly CMIS Formats for Blood Banks

(iv) Details of Blood Units Collected and Voluntary Donation Camps Organized

(Col.1) Type of Donors	(Col. 2) No. of Donors During the Month			(Col. 3) Details
	(Col. 2.a) Male Donors	(Col. 2.b) Female Donors	(Col. 2. c) Total Donors	
1. Voluntary Donors				
2. Replacement Donors				
Total Donors				
Total no of donors come back for repeat Blood Donation				
1. Are donor counseling services provided at blood bank ?				1. Yes 2. No (encircle response)
3. No. of donors counseled				
2. No. of blood units supplied during the month by the blood bank				_____ nos.
4. No. of voluntary blood donation camps organized during month.				_____ nos.
5. No. of donors from whom blood was collected in camps				

(v) Details of Blood Components Supplied

Are Blood Component Separation Facilities available in your Blood Bank? (encircle response)

1. Yes

2. No

If 'Yes' please provide details of Blood Components supplied

(Col.1) Blood Components	(Col. 2) Nos. Supplied
1. Packed Cells	
2. Plasma	
3. Platelet Rich Plasma (P.R.P)	
4. Fresh Frozen Plasma (F.F.P)	
Total Component Units Supplied (1+2+3+ 4)	

Source: Gujarat State AIDS Control Society

**Exhibit 8.1
IEC Materials, Maharashtra**

Token of appreciation to voluntary donors and blood donation card



Thalassemia Identity Card



Thank you Greetings



Poster



Translation: *There is no factory or laboratory to manufactured Blood.
Animal Blood can not be given to human being.
Blood is generated only in your and my body.*

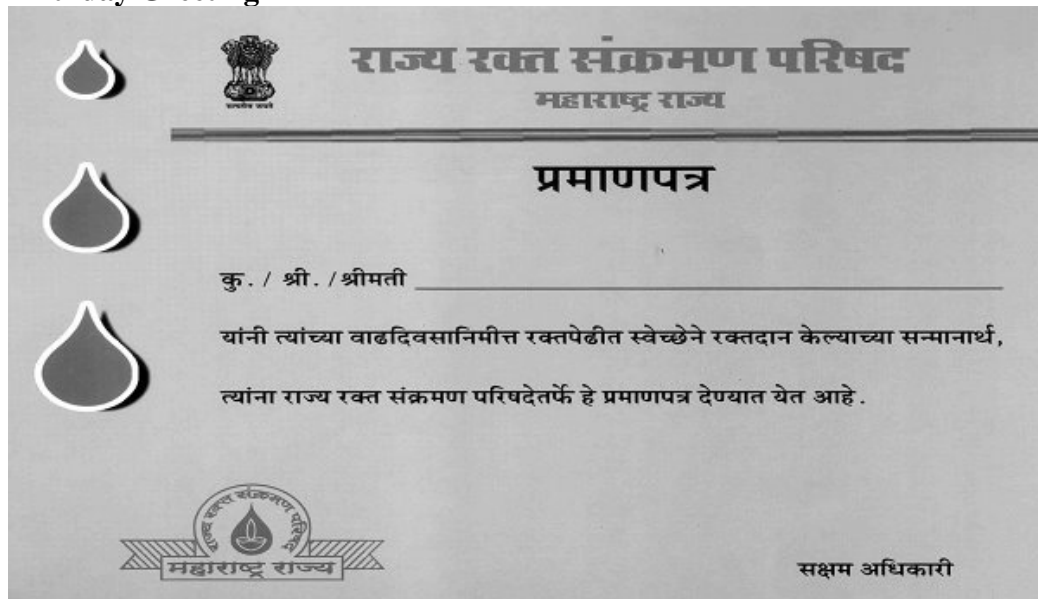
Calendar



Translation: *Talash Is Rang ki, Taaki Koi Chitthi Kisi ko na Rulae. (Availability of Safe Blood can save the Precious Life)
Donate Blood, Fill Happiness in Life*

Donate Blood and Save Life.

Birthday Greeting



Translation : Km. / Shri./Smt. _____ has voluntarily donated blood on the occasion of her/his Birthday, the State Blood Transfusion Council is honouring with the certificate.

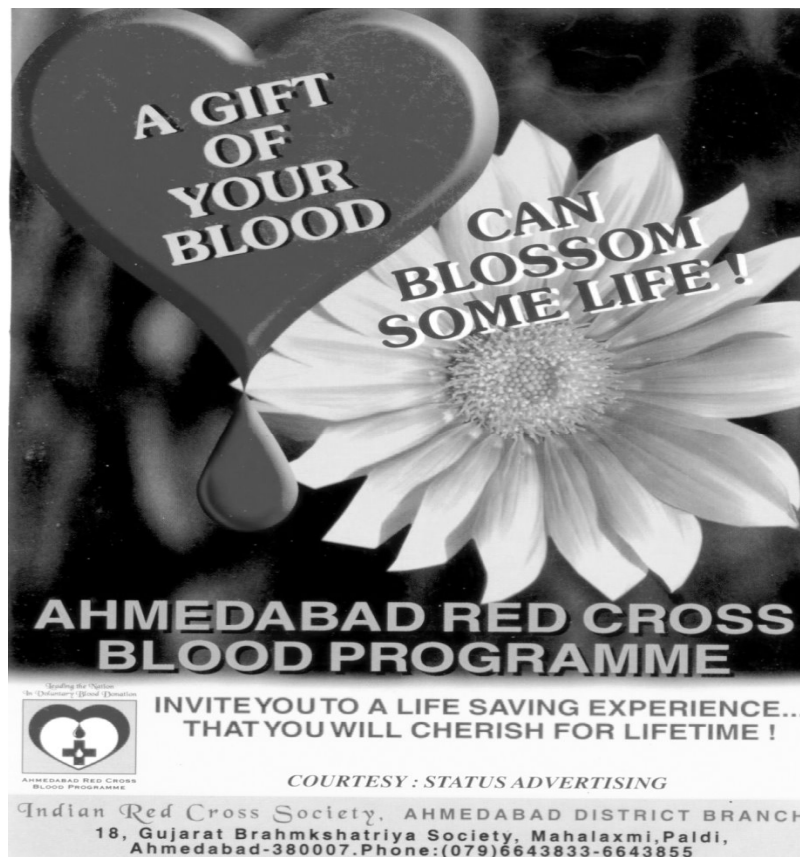
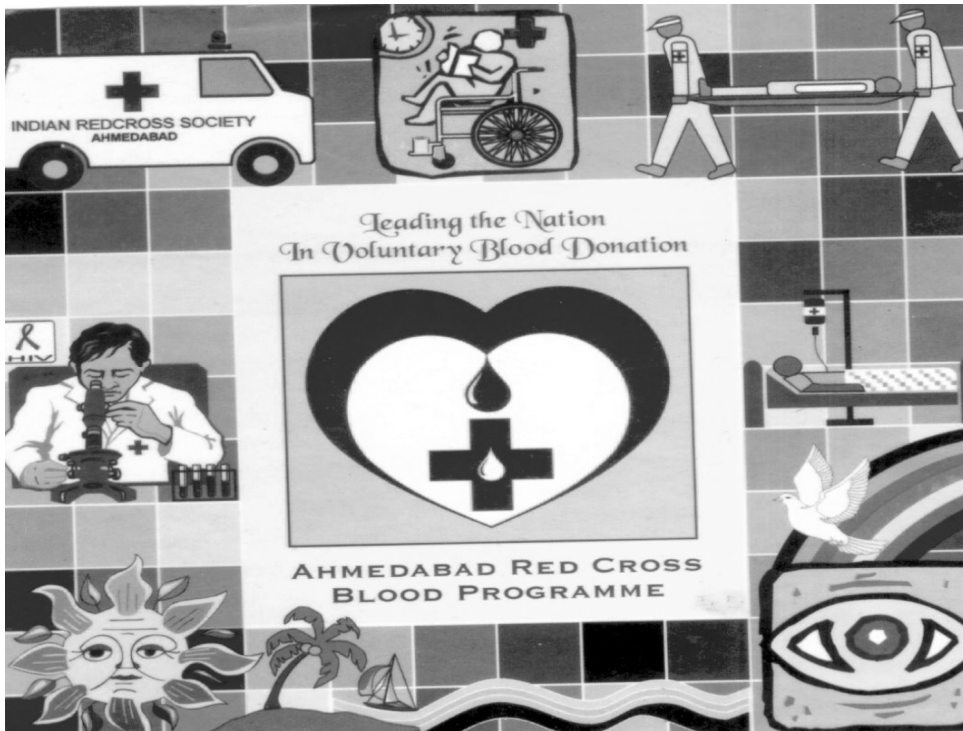
Mass Media Campaign- Newspaper



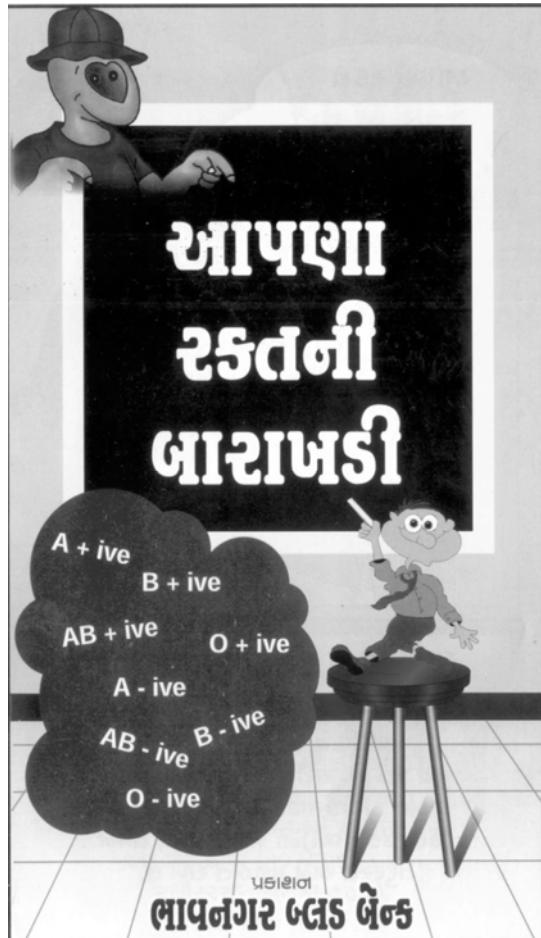
Source: Maharashtra State Blood Transfusion Council

Exhibit 9.1 IEC Materials, Gujarat

Stickers



Booklets



*"Our Life has become
A lot Easy & Happy
Because you gifted precious Blood!"*

A Message of Gratitude from
The Mother of aThalassemia Child

Your regular Blood Donation is the only hope of life
for over 490 Thalassemia Children...
Receiving around 20 Blood Transfusions in a year
under our care and attention!

**AHMEDABAD RED CROSS
BLOOD PROGRAMME**

Indian Red Cross Society, AHMEDABAD DISTRICT BRANCH
18, Gujarat Brahmshatriya Society, Mahalaxmi, Paldi, Ahmedabad-380007.
Phone : (079) 2664 3833, 2664 3855 Email : redcrossahd@sify.com

Source: Indian Red Cross Society, Ahmedabad

An Action Plan for Blood Safety

National AIDS Control Organisation
Ministry of Health & Family Welfare
Government of India
www.naco.nic.in



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Designed by: Anil Ahuja

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
DHS	Director of Health Services
ELISA	Enzyme Linked Immunosorbant Assay
EQAS	External Quality Assurance Scheme
HIV	Human Immunodeficiency Virus
FFP	Fresh Frozen Plasma
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 Transmitted Infections
UT	Union Territory
VCTC	Voluntary Counselling and Testing Centre
WHO	World Health Organisation
ZBTC	Zonal Blood Testing Centre



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Foreword

Improved blood safety has been a major achievement of the organized health care services in India. Amendments to the Drugs and Cosmetics Act, 1940, and the Rules, 1945 makes mandatory the universal screening of blood units for five transmissible infections: hepatitis B, hepatitis C, HIV, syphilis and malaria. Blood banks may be set up only after obtaining a license from the competent authority, and this license must be renewed at regular intervals.

922 blood banks have been modernized in the public and voluntary sectors across the country. Equipment has been upgraded in government blood banking facilities, technical assistance facilitated, and diagnostic kits financed for HIV, HBV and HCV. Blood banks and blood storage centers are reaching most districts in India.

In 2002, Government of India adopted the National Blood Policy which aims at ensuring easy accessibility and adequate supply of safe and quality blood and blood components collected from voluntary and non-remunerated blood donors. Nation-wide implementation of the strategies adopted called for a meticulous Action Plan. The Action Plan on Blood Safety brings about a paradigm shift in the management of organized blood transfusion services, providing for

- the accreditation of blood banks
- the revelation of status in respect of all transfusion transmitted infections (not permissible so far)
- a multi agency response, through partnerships between government, the Indian Red Cross Society, NGOs, the private sector, and others.
- the rational use of blood and blood products among clinicians, and
- external quality control mechanisms for public sector blood banks,

The Action Plan on Blood Safety is the combined effort of our rather energetic and enthusiastic National Blood Transfusion Council, and the thoughtful comments received from our State Blood Transfusion Councils. All members and invitees participated diligently. I wish to place on record our gratitude to all members, invitees and participants, to the Regional and Country offices of WHO and to the Blood Safety team at NACO.

Meenakshi Datta Ghosh
Additional Secretary, & Project Director,
National AIDS Control Organisation
Ministry of Health & Family Welfare , INDIA



National Blood Transfusion Council

INDIA

A. EX-OFFICIO MEMBERS

- | | | |
|----|---|------------------|
| 1. | Dr. Meenakshi Datta Ghosh
Additional Secretary & Project Director,
National AIDS Control Organisation | President |
| 2 | Shri Rakesh Behari
Joint Secretary & Financial Advisor,
Ministry of Health & Family Welfare | Member |
| 3 | Dr. Ira Ray
Addl. DGHS | Member |
| 4 | Shri Ashwini Kumar
Drugs Controller General (India) | Member |
| 5 | Colonel P. S. Dhot
Commanding Officer, AFTC | Member |
| 6 | Dr. P. Salil
Joint Director, NACO | Member Secretary |

B. Non-Official Members

- | | | |
|---|-------------------------|--------|
| 1 | Dr. Vimla Ramalingam | Member |
| 2 | Shri Apurba Ghosh | Member |
| 3 | Dr. F. U. Ahmed | Member |
| 4 | Dr. Z. S. Bharucha | Member |
| 5 | Dr. R. N. Makroo | Member |
| 6 | Dr. Latha Jagannathan | Member |
| 7 | Dr. K. M. Radhakrishnan | Member |
| 8 | Dr. U. P. Sinha | Member |

C. Permanent Invitees

- | | |
|---|--|
| 1 | Joint Director/Deputy Director (Incharge of Blood Safety)
Nagaland State AIDS Control Society |
| 2 | Joint Director/Deputy Director (Incharge of Blood Safety)
Manipur State AIDS Control Society |

D. Invitees

- | | |
|---|----------------------|
| 1 | Dr. Sudarshan Kumari |
| 2 | Dr. Arvind Lal |
| 3 | Dr. Shobha Broor |
| 4 | Dr. Usha K. Baweja |
| 5 | Dr. Veena Doda |
| 6 | Dr. Ambika Nanu |
| 7 | Dr. Rama Bhasin |
| 8 | Lt. Col. Velu Nair |



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, this 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 3 per cent 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 transmitted 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

Introduction

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 donors or even to strengthen licensing requirements. In response to a lawsuit brought by an NGO, the Supreme Court of India, passed a judgement¹ 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 blood banks 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 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 Ferguson² 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 1993³. 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



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

2. Appointed by GOI

3. 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.

and central government, and, if satisfied, the state licensing authority signs the licences in triplicate and forwards the same to the DCGI 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 amended⁴ 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, 1999⁵ and 2001⁶. In December 2001, a notification⁷ 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.

4. Added by Finance Act, 1996, w.e.f. 1.4.1997

5. 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

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

7. GSR No.631 dated 20.12.2001



National Blood Policy: April 2002

Government 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 used is whole blood, and only 20 per cent blood 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. This 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, and 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 I

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 Thalasseemics (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 will 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 SBTCs will assess the requirement for blood within their respective states, with respect to sites where blood is 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 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, 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 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	NBTC 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
4. Monitoring system for action plan	1.09.03	3 months	Director NBTC/ SBTC	Secretary Health, of the State	NBTC SBTC DHS



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 for appropriate pricing of blood and blood components provided by the blood banks. In order to arrive at appropriate pricing 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.

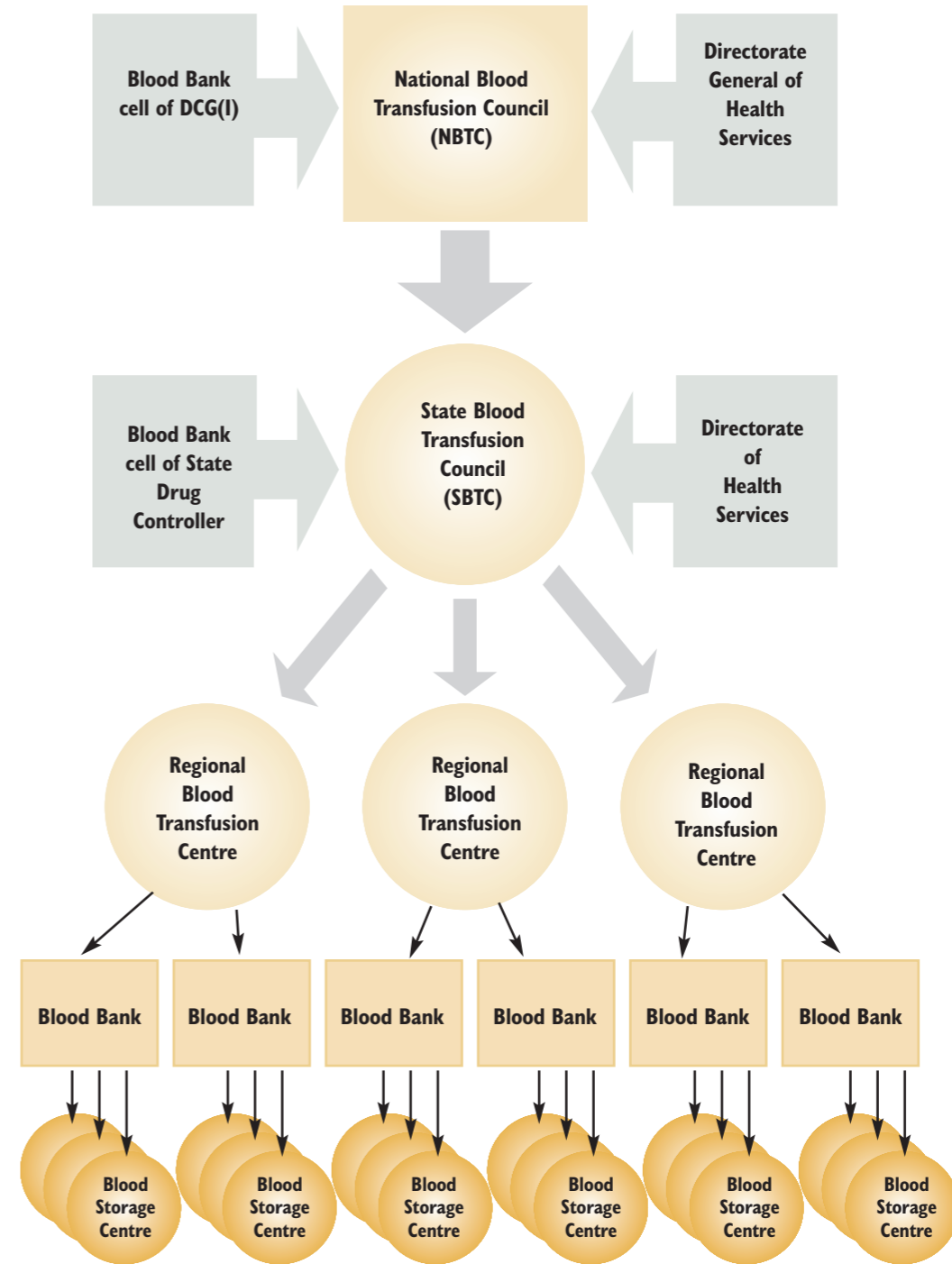
2.3 Formal requests for specific assistance from multi- and bi-lateral donor agencies will be processed by NACO and transmitted to donors.



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

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

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 of the standards 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 centers 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 certifies that a health care facility (example, a blood bank) 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 account-



Objective 3

ability 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 at the national level. The partnership between diverse stakeholders will provide a platform for consensus building through a 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 This 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 needs 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.



Objective 3

Activity	Date of commencement	Date of completion	Responsible Officer	Responsible supervisor	Budgetary source
1. Standards prepared by TRG to be printed	1-9-03	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 to NRL for EQAS	1-9-03	16 weeks	APD(T), NACO	PD, NACO	NBTC SBTC DHS
4. Formation of Working group for developing accreditation programme	1-9-03	8 weeks	JD (BS)	PD, NACO	NBTC
5. Accreditation process to be initiated	1-9-03	24 weeks	JD(BS)	PD, NACO	NBTC



Objective 4

To launch extensive awareness program for blood banking services including donor motivation, so as 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** The total requirement of blood will be sourced 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 Bank Society, Chandigarh has been implementing a blood insurance scheme which guarantees 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.



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 the 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 form (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 the 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.



An Action Plan For Blood Safety

Objective 4

Activity	Date of commencement	Date of completion	Responsible Officer	Responsible supervisor	Budgetary source
1. Development of IEC campaign	1-9-03	6 months	JD (IEC)	PD, NACO	NBTC SBTC
2. Development of Logo by an advertising agency	1-9-03	12 weeks	JD (BS)/TRG	PD, NACO	NBTC
3. Approving Logo for the BTS	1-9-03	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	1-9-03	6 months	Incharge, Blood Bank & VCTC	PD, NACO/ Chairperson SBTC	NBTC SBTC

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 drug regulatory officials during the course of inspections. SBTC should ensure annual auditing and put mechanisms in place to ensure optimal utilisation of blood components.

5.7 NBTC will develop a program of national haemo-vigilance, with the help of the technical resource group and a 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	31-12-03	JD (BS)/ WHO SEARO	PD, NACO	NBTC
2. Training programme	1-09-03	Continuous	Director SBTC	PD, NACO	NBTC SBTC DHS
3. Hemovigilance system	1-09-03	1 year	MS hospital/ transfusion committee/ DCG (I)	PD, NACO	NBTC SBTC DHS

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 Colleges 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 post-graduate 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 timely 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
I. Identification & infrastructure strengthening of training centres	1-09-03	6 months	JD (BS)/ Finance Controller, NACO / TRG	PD, NACO	NBTC SBTC DHS

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 needs 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

Objective 7

An Action Plan For Blood Safety

facilitate research in transfusion medicine and technology relating to developing a modernised blood banking system. Annual plans for funding of any project specific research proposal could also 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

To take adequate legislative and educational 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 .

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

8.2 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 fulfilling 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.

8.3 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.

8.4 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.

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

8.6 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.

8.7 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.

8.8 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.

8.9 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 authority in a time bound manner.

Activity	Date of commencement	Date of completion	Responsible Officer	Responsible supervisor	Budgetary source
I. 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 organising and coordinating 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

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.



- (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 services 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

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 for 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

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

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



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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.



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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

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:

Telephone: Mobile No. :

Would you like us to call you on your mobile : Yes No

Fax No. Email:

Have you donated previously: Yes No

If yes, how many occasions : When last:

Your blood group: Time of last meal:

Did you have any discomfort during / after donation? Yes No



(✓) the appropriate answer:

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?

- Heart Disease Lung Disease Kidney Disease
- Cancer / Malignant Disease Epilepsy
- Diabetes Tuberculosis
- Abnormal bleeding tendency Hepatitis B / C
- Allergic Disease Jaundice (last 1 yr)
- Sexually Trans. diseases Malaria (6 months)
- Typhoid (last 1 yr) Fainting spells

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

- Antibiotics Aspirin Alcohol
- Steroids Vaccinations
- Dog Bite / Rabies vaccine (1 yr)

8. Is there any history of surgery or blood transfusion in the past 6 months ?

- Major Minor Blood Transfusion

9. For women donors,

- Are you pregnant Yes No
- Have you had an abortion in the last 3 months Yes No
- Do you have a child less than one year old? Yes No





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

Yes No

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 risks 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

