Blood Market in Delhi

Sneha Bhaskar

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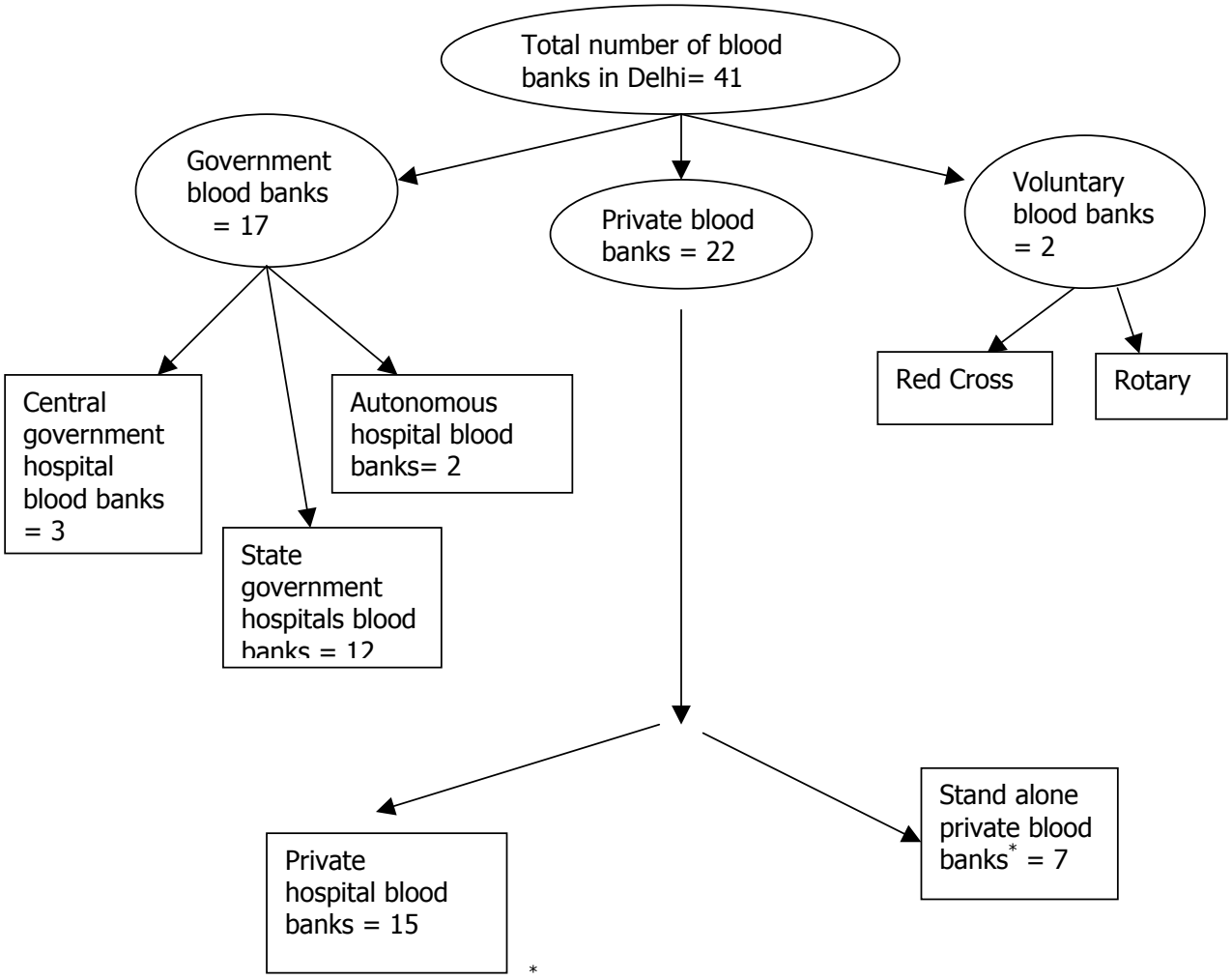
Centre for Civil Society
K-36 Hauz Khas Enclave, New Delhi 110016
Tel: 2653 7456/ 2652 1882 Fax: 2651 2347
Email: ccs@ccsindia.org Web: www.ccsindia.org

"*Ek blood donor ka 1500 lagega, aur jitne aadmi chahiye mil jayenge*." This is the deal offered by a "*chola bhatura*' *wala* sitting in front of a hospital. Surprised? confused? Welcome to the "Blood market" in Delhi.

Number of blood banks in Delhi

Delhi, with a population of over 16 million people, requires 3.5 lakh units of blood every 0year. Blood collection is done by blood banks all over the country. A blood bank means a place or organisation or unit or institution or other arrangements made by such organisation, unit or institution for collection, apheresis[1], storage, processing and distribution of blood drawn from donors and/or for preparation, storage and distribution of blood components. The distribution of blood banks in Delhi is as follows:



[1] Apheresis is a special blood donation where only one component of blood is collected from a voluntary donor.
[*] Stand alone blood banks are those, which are not associated with any hospital - government or private.

Thus, there are three kinds of blood banks–government, private and voluntary organisations. The first step in opening a blood bank is to obtain a license for which one has to satisfy certain infrastructure requirements, as given in Appendix I.

Grant of license for a blood bank

The next step after having the requisite infrastructure in place is to apply for a license. The prescribed form for grant of license is included in the Drugs and Cosmetics Act, 1940. To obtain a license, the applicant has to comply with certain conditions laid down by the Act of 1940 which can be summarised as follows: -

1. The licensee should be able to provide and maintain the required infrastructure for the proper operation of a blood bank.
2. The licensee should maintain the records of all the tests performed on blood and blood components. The licensee should also preserve reference samples of all the blood collected in adequate quantity for supply to the inspector for checking and for conducting the prescribed tests. There are other conditions regarding the grant of license as given in Appendix II.

The application form for grant of license (as given in appendix IV) requires information about the premises for blood bank, the names and qualifications of the medical and technical staff, the time by which all the required infrastructure namely premises, equipments will be ready. The application for grant of license is submitted on the prescribed form along with a **license fee of Rs 600.** Before grant of license an inspection is done on the " would be" blood bank. The applicant has to pay an **inspection fee of Rs 1000** for this inspection**.** Also after a blood bank is functional, a periodic check is done twice or thrice a year to confirm whether the blood bank is complying with the conditions laid down by the Drugs and Cosmetics act. So the licensee along with the grant of license form has to pay an additional amount of **Rs 500 for every inspection thereof or for the purpose of the renewal of license.**

The licensee has to submit two copies of the application form for grant of license: one to the central license approving authority and one to the state drugs controller. An application form then goes through various stages of checking and cross checking by numerous authorities. The hierarchy of officials scrutinising the license application is as follows:

Application to the licensing authority on the prescribed form along with the licensing fees.

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Licensing authority, if satisfied, sends a report along with the application and license to the **Central License Approving Authority**.

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Inspectors, along with an expert in the blood banking field, inspect the area, equipments and qualification of technical staff.

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If every requirement is satisfied the license is granted by the **Central Licensing Approving Authority**.

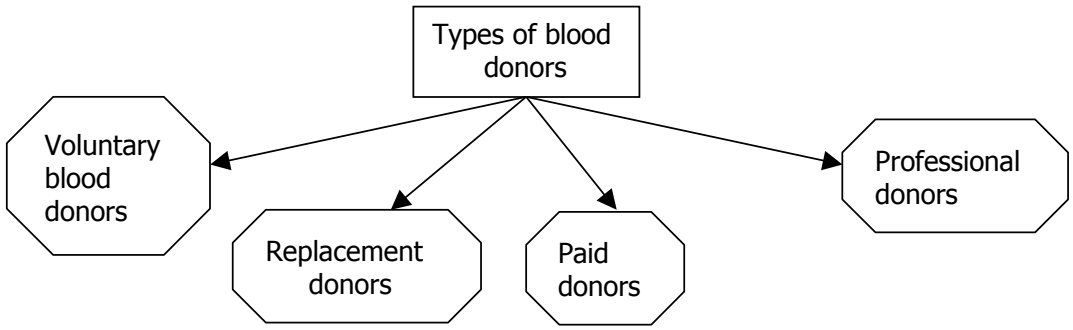
A blood bank license is valid for five years from the date it has been granted. If the applicant applies for renewal of license after the expiry date, but within six months of the expiry date, the fee payable for the renewal of license shall be Rs 6000 and inspection fee of Rs 1500 plus an additional fee at the rate of Rs 1000 per month.

The check performed on the licensed blood banks twice or thrice a year by drug inspectors appointed by the Drug Control Authority of the state is supposed to be a surprise check.

Functioning of a blood bank

After the licensing of a blood bank, we look at how a blood bank functions. The sources of blood supply for a blood bank are the blood donors. Before a person can donate blood, he or she has to fill a form that consists of various questions about the donor's previous medical history. The haemoglobin count is also checked. The minimum haemoglobin count for a person to be able to donate blood is 12.5 gms/dl and he or she should have a body weight of more than 45 kgs. The person should be aged between 18 – 60 years and should not have donated blood in the past three months. If a person satisfies all these conditions, only then he is allowed to donate blood. A person with body weight below 60 kgs of weight can donate 350ml of blood and a person above 60 kgs of body weight can donate 450 ml of blood. The various categories of blood donors are as follows: -

Types of blood banks



Voluntary blood donors are those people who donate blood willingly without any incentive. Replacement donor means a donor who is a family friend or a relative of the patient/ recipient. Replacement donation works in the following manner –if a patient needs blood, his or her relatives or friends have to donate blood. In return, the blood group needed by the patient is supposed to be provided by the hospital.

Paid donors are the people who donate blood for their friend's family or relatives and receive material gifts in return which may or may not be monetary. These categories of donors do not pose any threat to the society, as the patients and their families know them.

Professional donors on the other hand are the people who sell their blood for money. These are the people who belong to the lower strata of society The professional donors' category mainly comprises of semi–nourished people, rickshaw pullers, drug addicts, sex workers etc. This is a high-risk group for AIDS, Hepatitis B, Syphilis and other sexually transmitted diseases. Because of the threat this category of donors pose a threat to the well being of the society. The Supreme Court of India passed a directive in 1998, banning collection of blood from professional donors.

Another Supreme Court order passed in 1996 (appendix III) sought to put an end to commercial blood banks as the commercial blood banks[@] were collecting most of their blood from professional donors. These blood banks were called commercial blood banks because they bought and sold blood, thus treating blood like a commodity instead of a life-saving component. These blood banks paid Rs 200 – Rs 300 to a professional donor and sold the blood at almost double the price at which they collected blood.

The Supreme Court ordered that new commercial blood banks should not be allowed to come up. This was brought into effect by denying them license. After the Supreme Court directive of 1998, no new commercial blood banks have been allowed to come up in Delhi and the number of such blood banks has remained at a constant seven since then. Since these blood banks have stopped accepting blood from professional donors, hence the system of paying for blood has ended. Hence, the commercial blood banks have been renamed as stand alone blood banks. These are called stand alone blood banks as they are not attached to any hospital, government or private, and are separate entities as blood banks. There are seven stand alone blood banks in Delhi.

Testing of blood

The next step after collection of blood is testing the blood for various infections and diseases. The Supreme Court order of 1996 laid stress on the proper testing of blood and hence provided funds to state governments to modernise the blood banks in terms of equipments and testing kits. The blood tests made mandatory by the Government of India are:

1. HIV-AIDS
2. Hepatitis B
3. Hepatitis C
4. Syphilis
5. Malaria

Tested as well as untested blood is stored in special refrigerators manufactured specially for the purpose of storing blood. These refrigerators maintain a uniform temperature of 2^{o} – 6^{o}c required for storing blood. On testing, blood which is found to be infected with any of the above said infections is discarded. The total disposal rate of blood for most of the blood banks is 5-7 per cent. But in voluntary blood banks where most of the blood comes from voluntary donors, the disposal rate is lower than other blood banks and is about 1 –2 per cent. Blood in many blood banks is burnt in incinerator plants. Those blood banks which do not have an incinerator plant first autoclave the blood and then give it to some agency which is responsible for disposal of biomedical waste.

Cost of blood

Money spent on testing of blood and storage is charged as processing fee when blood is bought from the blood banks. The government of India has prescribed rates of blood and blood products. The price list is as follows:

Item	**Price**
Whole Blood	Rs 500/unit
Fresh Frozen Plasma	Rs 400/unit
Packed Cell	Rs 300/unit
Platelet Concentrate	Rs 400/unit

[@] Commercial blood banks are now referred to as stand alone blood banks.

However, most blood banks use these as rough guideline values and charges can vary, depending on the demand. Even where blood is collected for free[#], banks have to spend for processing, storage and testing. In almost all cases, private blood banks charge more than government blood banks.

Blood is stored in plastic bags, each of which is labelled. The labels on every bag containing blood or blood component contain particulars like name of the product inside the bag, name and address of the blood bank, license number, serial number, date on which blood is collected and the expiry date, blood group and details of the tests done on the blood. From the serial number it is possible to trace the blood back to the donor whose record is maintained. The blood donor record consists of the serial number, date of donation, name, address, other particulars of age, height, weight, haemoglobin count, blood group, signature of donor etc. This is the basic framework of the working of a blood bank.

Hierarchy in blood banking

The blood banking system consists of certain organisations. The hierarchy of these organisations is as follows:

National blood transfusion council → **State blood transfusion council** → **Regional blood transfusion**

National Blood Transfusion Council (NBTC) is the policy formulating apex body in relation to all the matters pertaining to operation of blood centres. National AIDS Control Organisation (NACO) allocates a budget to NBTC for strengthening Blood Transfusion services. NBTC has to ensure involvement of other ministries and other health programmes for various activities related to blood transfusion services. NBTC is supposed to develop the guidelines to define NGO run blood centres so as to avoid profiteering in blood banking.

State Blood Transfusion Councils (SBTC) are responsible for implementation of the blood programme at the state level, as per the recommendations of the National Blood Transfusion Council. SBTCs are supposed to organise blood transfusion service through the network of RBTC's, Indian Red Cross Society ad NGO run blood centres ad monitor their functioning**.**

The Regional Blood Transfusion Centres (RBTCs) are autonomous in their day to day functioning and are guided by the recommendations of the SBTC.. The RBTCs act as a referral centre for the region assigned to them. This means that the RBTCs are assigned an area in which other blood banks and hospitals, which are linked to the RBTCs, will be assisted for any requirement and shall be audited by the RBTCs. They also help the SBTC in collecting the data from the respective region it is in.

In Delhi, there are eight RBTCs divided into zones. They are as follows: -

East zone

1. Guru Teg Bahadur hospital

West zone

1. Deen Dayal Upadhyaya hospital

[#] Blood banks under the Central government's control do not charge any money for their unit of blood.

Central zone
1. Red Cross
2. Lok Nayak Jay Prakash hospital

North zone
1. Hindu Rao hospital

South zone
1. All India Institute of Medical Sciences
2. Rotary Blood Bank
3. Armed Forces Transfusion Centre

One of the main aims of the Supreme Court order of 1996 was to revamp the blood transfusion services and establishment of organisations for monitoring the functioning of blood banks in an efficient manner and this led to the formation of NBTC, SBTC and RBTC.

Loopholes in the system

Blood bank inspection

At the outset, the blood banking system seems to be running more or less efficiently but on taking a closer look, we realise that not all is well. The "supposed" surprise checks which are performed on the licensed blood banks twice or sometimes thrice a year by drug inspectors appointed by the drug control authority of the state are random and can happen anytime without the prior knowledge of the blood bank authorities.

However, in reality, these checks are hardly a surprise. An established doctor working with a government hospital blood bank for the past 15 years, on the condition of anonymity, said that they come to know before hand about these "surprise checks". Most blood bank officials know the drug inspectors and share friendly relations with them. The drug inspectors inform their "friends" a couple of days before the checks, giving a chance to the blood banks to set their records straight. Also the blood banks are supposed to keep blood samples for random checking by the drug inspectors. A drug control department official said that they do not have the infrastructure to pick up random blood samples and check whether all the mandatory screening tests are being conducted or not.

In case, during the course of inspection in a government hospital, some equipment is found to be faulty, instead of reporting that, the drug inspectors give them a time, say 3 months, to get the equipment back to a functioning condition.

The scenario in private hospitals is even worse. Due to a constant threat of their license being cancelled, the private hospitals try to keep the drug inspectors happy by simply adopting the easier method of bribing the inspectors. However, the stand alone blood banks claim that the Drug Control Department in Delhi is one of the best and the drug inspectors are very strict about the surprise inspections and always keep the stand alone blood banks on their toes.

As expected, the blood bank authorities deny this and they try to come up with an explanation of their own. Government blood banks say that the purpose of private organisations is to make money and hence bribing is just a small price to pay for renewal of license. The private blood banks justify themselves by saying that government blood banks have an advantage over them because they feel that the government would not do anything against their own blood banks whereas a private blood bank has to microscopically adhere

to all the standards set by the drug control authority, else the government will cancel its license. They feel that it is this constant fear of license cancellation that makes a private blood bank far better than a government blood bank in terms of quality standards.

The government bodies get grants from the government and hence they do not need alternative sources of earning money whereas a private organisation has to fend for itself. The private blood banks say that we have to repay the loans we have taken from the banks for buying expensive medical equipments, so that money has to be recovered from somewhere.

Disparity in cost of blood

This brings us to the question of how much do the government and private blood banks actually charge from their patients. The three hospitals under the central government do not charge any money for the blood they provide. Most banks attached to government hospitals charge Rs 250 from their own patients. For an outsider or if there is demand for blood from a private nursing home, the charge goes up to Rs 500.

In the private blood banks, the charges keep varying but they are definitely higher than the charges of their government counterparts. Several of these private hospitals claim to be carrying out tests in addition to the one made mandatory by the government, to screen the blood against potential infections.

Indraprastha Apollo hospital charges Rs 1370 for one unit of whole blood. One of the doctors in the Apollo blood bank explained that the reason for the high cost of their blood is that the bags used to store blood are imported and each bag costs about Rs 500. (These bags are used to segregate red cells from white blood cells. The white blood cells are drained away as these are known to cause reactions during transformation.)

The Apollo blood bank also carries out a special test for Hepatitis B core antibody test (IGG and IGM). Hence, the plastic bags along with extra tests on blood lead to increased blood prices.

There is conflict between government and private even on this point. The government blood banks feel it is pointless to use such expensive plastic bags when cheaper plastic bags of reasonably good quality are available and which are being used by government blood banks. The government blood banks reason that when both the type of blood banks provide the same quality of blood to the end user then why use imported blood bags?

The government also feels that the extra tests done on blood are unnecessary and is only a part of the money making strategy adopted by the private blood banks. Apollo justifies the extra test by saying that because of one extra test they do, the disposal rate of infected blood goes from one or two per cent to eleven per cent.

Among the voluntary blood banks, Red Cross charges Rs 500 per unit. A Red Cross official said that the service charge had to be introduced because the earlier costs were not enough to cover expenses, as a result the blood bank used to incur heavy losses, and the bank was becoming non-viable day by day. Even in voluntary organisations like Rotary blood bank when a person went to get three units of O negative blood, the technician asked her for Rs 1800 per unit of blood instead of the regular Rs 900 because she wanted a rare blood group. Is this really the trait of a voluntary organisation?

Delhi health minister A K Walia concludes that the blood banks have varying overhead costs that have to be recovered from the service charges and this is one of the major reasons why a uniform pricing policy cannot be implemented.

Discrepancy in testing of blood

There is discrepancy even in the testing of blood. The Ministry of Health, India, has made certain tests mandatory for all blood banks. On paper, it is shown that all the tests are done but in reality, tests for malaria are usually not performed. The reason for this is that malaria is very difficult to detect. The malarial parasite is released into the blood stream only when the patient gets a bout of fever and shivering. So when such a patient who is a carrier of malarial parasite comes as a blood donor, he or she may not be suffering from fever and hence there are no malarial parasites in his or her blood stream. If the donor is suffering from fever, he or she is not allowed to donate blood. In addition, the procedure for testing of malaria is a cumbersome one. A doctor with a government blood bank says, " We get thirty blood donors everyday. In order to test for malaria we will have to perform extra tests and if we test thirty blood samples everyday for malaria, our technicians and laboratory people will be very overworked. Moreover, malaria is an endemic disease in India and majorities of the population are carriers of this parasite. Therefore, even if we test for malaria we will have to discard major portions of the blood collected because of malaria. However, it is not really a problem if we skip this test. If after three days of blood transfusion a patients shows symptoms of malaria, we give him four tablets of Chloroquinine and that takes care of the malaria." So tough detection combined with easy cure leads to no testing being done.

Existence of professional donors

In January 1998, the Supreme Court of India gave a directive, banning collection of blood from professional donors. Nevertheless, the Supreme Court ban did not appreciably change things. Professional donors existed before the directive and they exist even now. The government claims that right now there are zero per cent professional blood donors in Delhi. However, the picture is not as perfect as it seems. As a part of my research, I decided to verify the government's view about professional donors. And I did not have to make much effort.

CASE STUDY

Along with a friend, I posed as people (strangers in Delhi) who were in desperate need of five units of O negative blood group for our mother. We went to one of the busiest hospital areas in Delhi, a place in front of Safdurjung hospital and All India Institute of Medical Sciences (both of them established government hospitals). With a distressed look on our face, we went to a cigarette stall and asked him if he knew someone who sells blood. He directed us to another cold drink stall who further directed us to a "chola bhatura" stall. Again, when we repeated that we urgently needed blood and were looking for professional donors, a well-built middle-aged man came towards us. He took us behind his stall and told us that he could provide us five professional donors. He charged us Rs 1500 per donor. On bargaining, he came down to Rs 1400 per donor. He asked both of us to come back the next morning at 9:30 am. He said that he will keep five donors ready and there will be a sixth person who will accompany us and supervise the entire proceedings of blood donation. He also said that if we needed he could provide us with more professional donors. While this deal was being struck up, police constables were roaming about near us, but they were least bothered. It took us precisely one minute to locate a professional blood donor. It was surprising to see that an illegal deal was finalised in front of police and this almost led us to believe that the margins between legal and illegal had blurred to an extent of being invisible. In such a scenario, what value does a Supreme Court ban have and who will check this illegality in the system?

Shortage of blood

This also brings us to the question that if there is enough blood in Delhi then why do people have to opt for professional donors instead of just getting blood from a blood bank? The figures of demand and supply of blood in Delhi is also a debatable issue. While the demand is 3.5 lakh units per year, the supply is 2.9 lakh units per year. The Drug Control Department is quick to add that this is a marginal shortage and can be covered by increasing the number of voluntary donors. The Drug Controller also added that till date he has no knowledge of anybody dying due to need for blood. The Drug Controller feels that even though there is shortage of blood the situation is still in control. But some blood bank officials say that the demand rate is much higher, probably around 6 –7 lakhs while the supply is approximately 3 lakhs.

Blood shortage is much severe in summers. This is because during summers the colleges and educational institutions are closed. That makes the donation camps few and far between. Also, during summers, because of the heat, there is an almost universal lethargy among donors and the recurrent summer infections leave quiet a few donors clinically unable to donate blood.

It is not hard to imagine that if the condition is so deplorable in Delhi then what would it be like in the rural areas located at the border of Delhi. Infact in the peripheral areas of Delhi, the nursing homes and hospitals that are far from blood banks do not take the trouble of getting blood from blood banks. They simply ask the patient's family to get donors whose blood group matches that of the patient. When they get the required donors, the blood is directly transfused from the donor to the patient without any tests being conducted. But the patient's family is charged for the blood. So at the end, the nursing home or the hospital does not spend anything on the testing and storage of blood but they charge the patient for it.

The problems do not end here. There was a plan to connect all the blood banks in Delhi through the internet. It was planned that all the blood banks would go online with their blood stock status. The move was aimed at pooling together all the resources of all the blood banks so that if blood of a particular group is not available at a given blood bank, arrangements can be made for procuring it from another blood bank where it is available. But till date only three hospitals namely, Deen Dayal Upadhyaya hospital, Guru Teg Bahadur hospital and Lok Nayak hospital have gone online. There is no valid reason for the blood banks not going online. This lack of transparency is attributed to the fact that most private hospitals do not want to disclose the matters of their blood banks, how much blood they collect and how much of it is actually used. What is the reason for such secrecy when ultimately blood is meant for common people like us – why hide things from us, which are meant to save our lives?

Organising blood donation camps

A major grouse of the private hospitals and stand alone blood banks is that they are not allowed to organise blood donation camps. They think it is very contradictory that the government on one hand talks about increasing voluntary donation and on the other hand confines blood donation camps to RBTCs, Red Cross and Rotary only. Whenever a private hospital or stand alone blood bank wants to organise a blood donation camp they have to do so in co-ordiantion with the RBTCs of their area. In such camps, sixty percent of the blood collected goes to the RBTC and forty percent goes to the private blood bank. If the RBTC of their respective area are not free to hold a camp, then either the private blood bank has to go to a RBTC of another zone or has to temporarily postpone the idea of holding a camp. This is an inconvenience for all the private blood banks but an appeal to the

government is of no help. The government feels that if private blood banks are allowed to organise camps, it would lead to profiteering. The private blood banks would get voluntary blood, which they would sell at higher price to their patients and thus make profit. But aren't the private blood banks already selling blood at higher rates with prices ranging from Rs 700 – Rs 1800?

Achievements

It is not as if the government is not trying. Even though professional donors still exist, they have reduced in number. Earlier stand alone blood banks like Sunil blood bank, Central polyclinic blood bank used to collect 8000 - 10000 units of blood yearly which included lots of professional donors. But after the Supreme Court ban in 1998, their blood collection went down to 3000 – 4000 units per year, which is almost half their collection earlier.

Probable solutions

But in spite of all that the government has done, it still has a long way to go before it can establish a good blood banking system.

One of the ways, which many blood banking officials feel should be adopted to make the blood banking system efficient, is to centralise the whole system. The idea is that instead of having 41 blood banks with different standards of testing and different pricing structure, Delhi should have three to four main centres in which all the blood collected in Delhi would be tested and from there distributed to satellite centres all over Delhi. These satellite centres would be responsible only for storage of blood and not testing. This would lead to uniform testing quality for all the blood collected and would also reduce the amount of money spent on storage, buying and maintaining equipments for 41 blood banks and consequently reduce the cost of blood thus making it more user friendly.

However, the most important step they have to take is to increase voluntary donation in the country. Right now we have a dismal 18 – 20 per cent of voluntary donation in Delhi. Until and unless this percentage is increased it will be very difficult to cover the gap between demand and supply. Creating awareness among people and informing them about the benefits of blood donation can achieve this. Also, the government should try to encourage the already existing voluntary donors by giving them gifts in kind, giving them momentos and honouring them so that they get motivated to donate blood again and again. Also there should be an effort to convert the replacement donors into voluntary donors. This policy along with an honest effort on behalf of all the blood banking officials is the need of the hour and it is the only way by which we can put an end to the "chola bhaturawala" with whom we started this research paper and many more like him.

Appendix I

Infrastructure Requirements for Blood Banks				
Space Requirement				
		Up to 5000 Blood Units (Yearly)	**Up to 10,000 Blood Units (Yearly)**	**Up to 20,000 Blood Units (Yearly)**
1.	Reception Room	20 Sq. Mtr	25 Sq. Mtr	40 Sq. Mtr
2.	Bleeding Room	40 Sq. Mtr	55 Sq. Mtr	100 Sq. Mtr
3.	Refreshment Room	15 Sq. Mtr	23 Sq. Mtr	30 Sq. Mtr
4.	Kitchen/Pantry	5 Sq. Mtr	5 Sq. Mtr	10 Sq. Mtr
5.	Aphaeresis Area	-	-	40 Sq. Mtr
Laboratory Area				
1.	Laboratory for routine work, antenatal work	25 Sq. Mtr	40 Sq. Mtr	50 Sq. Mtr
2.	Laboratory for special RBC serology quality control	-	25 Sq. Mtr	50 Sq. Mtr
3.	Laboratory for specialized work Platelets HLA serology	-	-	50 Sq. Mtr
4.	Issue counter and contingency counter	15 Sq. Mtr	18 Sq. Mtr	20 Sq. Mtr
5.	Hepatitis, AIDS, VDRL etc	20 Sq. Mtr	20 Sq. Mtr	30 Sq. Mtr
6.	Wash Basin, Distillation plant etc	20 Sq. Mtr	20 Sq. Mtr	30 Sq. Mtr
7.	Component basis	-	25 Sq. Mtr	40 Sq. Mtr
8.	Component - Advanced and Freeze Diving etc	- -	- -	50 Sq. Mtr 50 Sq. Mtr
9.	Room for arrival	-	20 Sq. Mtr	30 Sq. Mtr
General Area				
1.	Doctor's office	15 Sq. Mtr	15*2 Sq. Mtr	15*4 Sq. Mtr
2	Donor Recruitment, social worker and associated clerical staff	25 Sq. Mtr	30 Sq. Mtr	50 Sq. Mtr
3.	Blood Bank officer	15 Sq. Mtr	15 Sq. Mtr	25 Sq. Mtr
4.	Stores	20 Sq. Mtr	25 Sq. Mtr	35 Sq. Mtr
5.	Technical common room	15 Sq. Mtr	20 Sq. Mtr	25 Sq. Mtr
6.	Toilets	5*2 Sq. Mtr	5*2 Sq. Mtr	5*2 Sq. Mtr

Staff Working 24 hours for 7 days		**Requirement**		
		Up to 5000 Donors unit Processed per year	**Up to 10,000 Donors unit processed per year with round the clock service**	**Up to 20,000 Donors unit processed per year with round the clock service**
Bleeding Room				
1.	Jr. Doctor	2	4	4
2.	Nurse	2	3	4
3.	Social worker	1	1	2
4.	Attendant	1	1	2
Aphaeresis Room				
1.	Nurse	-	-	2
2.	Attendant	-	-	1
Laboratory				
1.	Technician Supervisor	-	1	4
2.	Tech. Assistant	2	4	8
3.	Technician	5 (+3 for shift works)	11	13
4.	Laboratory Asst	1	2	4
5	Laboratory	2 (+1 for shift works)	4	5
Donor organizer				
1.	Associated clerical staff	-	1	2
Service staff clerical staff				
1.	Clerk typist - Part time	1	1	1
2.	Store keeper - Part time	1	1	1
3.	Cleaner Sweeper - Part time	1	1	2
Medical Doctor				
1.	Consultant professor	1 Pathologist	1 Assistant	1 Professor
2.	Asst Professor.	-	-	1
3.	Lecturer	-	-	3

Appendix II

Conditions of licence

A licence in Form 28-C, Form 28-E, Form 26-G or Form 26-I shall be subject to the special conditions set out in Schedule F, Part XII-B and Part XII-C, as the case may be, which relate to the substance in respect of which the licence is granted or renewed and to the following general conditions, namely:

(i) (a) The licensee shall provide and maintain adequate staff, plant and premises for the proper operation of a Blood Bank for processing whole human blood, its components and/or manufacture of blood products.

(b) The licensee shall maintain staff, premises and equipments as specified in Rule 122-G. The licensee shall maintain necessary records and registers as specified in Schedule F, Parts XII-B and XII-C.

(c) The licensee shall test in his own laboratory whole human blood, its components and blood products and [maintain records and] registers in respect of such tests as specified in Schedule F, Part XII-B and Part XII-C. The records and registers shall be maintained for a period of five years from the date of manufacture.

(d) The licensee shall maintain/preserve reference [sample and] supply to the Inspector the reference sample of the whole human blood collected by him in adequate quantity to conduct all the prescribed tests. The licensee shall supply to the Inspector the reference sample for the purpose of testing.

(ii) The licensee shall allow an inspector appointed under the Act to enter, with or [without] prior notice, any premises where the activities of the Blood Bank are being carried out, for the processing of Whole Human Blood and/or Blood Products, to inspect the premises and plant and the process of manufacture and the means employed for standardizing and testing the substance.

(iii) The licensee shall allow an Inspector appointed under the Act to inspect all registers and records maintained under these rules and to take samples of the manufactured product and shall supply to Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed.

(iv) The licensee shall from time to time report to the Licensing Authority any changes in the expert staff responsible for the operation of a Blood Bank/processing of whole human blood for components and/or manufacture of blood products and any material alterations in the premises or plant used for that purpose which have been made since the date of last inspection made on behalf of the Licensing Authority before the grant of the licence.

(v) The licensee shall on request furnish to the Licensing Authority, or Central Licence Approving Authority or to such Authority as the Licensing Authority, or the Central Licence Approving Authority may direct, from any batch unit of drugs as the Licensing Authority or the Central Licence Approving may from time to time specify, sample of such quantity as may be considered adequate by such Authority for any examination and, if so required, also furnish full protocols of the test which have been applied.

(vi) If the Licensing Authority or the Central Licence Approving Authority so directs, the licensee shall not sell or offer for sale any batch/unit in respect of which a sample is, or protocols are furnished under the last preceding sub-paragraph until a certificate authorizing the sales of batch/unit has been issued to him by or on behalf of the Licensing Authority or the Central Licence Approving Authority.

(vii) The licensee shall on being informed by the Licensing Authority or the Controlling Authority that any part of any batch/unit of the substance has been found by the Licensing Authority or the Central Licence Approving Authority not to conform with the standards of strength, quality or purity specified in these Rules and on being directed so to do so, withdraw, from sales and so far as may in the particular circumstances of the case be practicable recall all issues already made from that batch/unit.

(viii) No drug manufactured under the licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture. Further no batch/unit manufactured under this licence shall be supplied/distributed to any person without prescription of Registered Medical Practitioner.

(ix) The licensee shall comply with the provisions of the Act and of these Rules and with such further requirements, if any, as may be specified in any Rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the Rules, these would come in force four months after publication in the Official Gazette.

(x) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and defects noticed.

(xi) The licensee shall destroy the stocks of batch/unit which does not comply with standard tests in such a way that it would not spread any disease/infection by way of proper disinfection method.

(xii) All bio-medical waste shall be treated, disposed off or destroyed as per the provisions of The Bio-Medical Wastes (Management and Handling) Rules 1996.

(xiii) The licensee shall neither collect blood from any professional donor or paid donor nor shall he prepare blood components and/or manufacture blood products from the blood drawn from such a donor.

Appendix III

IMMEDIATE

No 505/92/SC/PILC

All communications should be addressed to the Registrar, Supreme Court, by designation NOT by name
Telegraphic address :— "SUPREMECO"

SUPREME COURT
INDIA

Dated New Delhi, the 11th January, 1996 19

FROM Raj Gopal,
Asst.Registrar(PIL.CELL)

TO 1. The Union of India
through Secretary to the
Govt. of India,
Ministry of Health and
Family Welfare,
(Department of Health),
Nirman Bhawan,
Maulana Azad Road,
New Delhi (Respondent No.1)

2. Drug Controller,
Ministry of Health and
Family Welfare,
Nirman Bhawan,
Maulana Azad Road,
New Delhi (Respondent No.2)

3. Shri H.D.Shourie,
(Director of Common Cause),
A-31, West End,
New Delhi

4. The Director General of Health Services,
Ministry of Health and Family Welfare,
Nirman Bhawan,
Maulana Azad Road,
New Delhi

5. The Additional Secretary,
Ministry of Health and Family Welfare,
Govt. of India, holding charge of
Director,
National Aids Control Organisation,
Nirman Bhawan,
New Delhi

15 JAN 1996

IN THE MATTER OF:

WRIT PETITION NO.91 OF 92
(Under Article 32 of the Const. of India)

Common Cause a Registered Society ... Petitioner

Versus

Union of India and others ... Respondents

Sir,

I am directed to forward herewith for your information and necessary action a certified copy of the Judgment of the Supreme Court dated 4.1.96 passed in the Writ Petition above mentioned. They are required to submit a report by July 15. 1996 as directed by this Hon'ble Court.

Yours faithfully,

ASSISTANT REGISTRAR

IN THE SUPREME COURT OF INDIA

CIVIL EXTRAORDINARY JURISDICTION

48801

WRIT PETITION (CIVIL) NO. 91 OF 1992

Common Cause ..Petitioner

versus

Union of India & Ors. ..Respondents

J U D G M E N T

S.C. AGRAWAL, J :

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

is available with the blood banks for use is healthy and free from infection.

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

For the purpose of regulating its collection, storage and supply, blood is treated as a 'drug' under the Drugs and Cosmetics Act, 1940 (hereinafter referred to as 'the Act'). In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as 'the Rules') made under the Act, provisions regarding equipment and supplies required for a blood bank were contained in Part XII-B, which was inserted vide Notification dated June 24, 1967. In the said part, requirements regarding Equipment, Blood collection supplies, Canter equipment and Emergency equipment for the Blood Donor Room

were prescribed. Similarly provisions were made for the Laboratory, General suppliers, Technical staff, Accommodation for Blood Bank, Lable for whole blood and Colour scheme for Label etc.

In 1990, M/s.A.F.Ferguson & Co., a Management Consultancy Firm, was entrusted by the Government of India, Ministry of Health with the study of blood banking system in the country. The scope of the said study was to :

i) assess the status of Government, Private, Commercial and Voluntary blood banks;

ii) recommended policy and procedural changes; and

iii) prepare a scheme for modernisation;

The report submitted by the said consultancy firm to the Government in July, 1990, high-lights the deficiencies with regard to the facilities of testing blood, licensing of blood banks and professional donors and storage of blood. In the said report it was stated :

i) Out of the total number of 1018 blood banks as many as 616 are reported to be unlicensed. There are only 201 licensed commercial blood banks; the supply of blood by licensed commercial blood banks is only about 1/4th of the blood used in the hospitals of the country.

ii) No medical check up is done on the blood sellers; their health status is not examined. The blood trade flourishes with poor people like unemployed, rickshaw pullers, drug addicts selling their blood. Such blood-sellers suffer from various infections and their haemoglobin is lower than

the prescribed level: It has been reported that there are many persons who donate blood 5-6 times in a month; poverty makes them to do so at first but later it is reported to become like an addiction, the blood seller enjoying the dizziness due to reduced supply.

iii) It is a mandatory requirement to conduct tests on blood which is to be administered to a patient or to be issued to hospitals for transfusion. The blood so issued has to be free from AIDS, viral hepatitis, malaria, veneral diseases etc. It is reported that mandatory tests which are required to be done are rarely conducted. Most of the AIDS surveillance centres are not functioning efficiently and upto 85 per cent of blood collected in the country is not screened for AIDS. Under an action plan to screen blood for AIDS 37 blood testing centres were to be set up in 29 cities, but only 11 testing centres were functioning by July, 1990, and training of technicians for these centres was lagging.

iv) The blood banks presently thrive on bleeding 4000 to 5000 regular professional donors in 18-20 cities. The professional blood donors, which include many women, are reported to be victims of ill health, low haemoglobin levels and many infections, and are bled at frequent intervals by the commercial blood banks.

v) Storage facilities in the blood banks are far from satisfactory. The blood banks have necessarily to possess facilities like refrigerators exclusively for storage of blood with a specified range of temperature for ensuring safety of blood. In the existing blood banks many items of equipment remain unattended for years, electricity failures are frequent, generators are a rarity. This applies not only to commercial blood banks but even to some of the government hospitals. Many items of the basic equipment needed for blood banks are not available and a good part of them do not have even adequate storage facilities.

vi) Many of the blood banks are located in unhygenic environment and they collect and store blood in very dirty conditions.

vii) In some places strong middle men operate for the blood banks by arranging for donors. The middle men dictate the charges to be paid and take a heavy commission; the selection of donors disregards the leval of health etc.

viii) A large part of the professional donors are alcoholics or drug abusers, have indiscriminate sexual habits and are a high risk group for Hepatitis 8 and AIDS and are unfit to donate blood.

ix) Trained personnel are generally not available in the blood banks. Most of the blood banks lack trained post-graduates at the helm; they have no donor oganisers to bring voluntary donors: and many of them are manned by technical staff who do not have requisite qualification of a diploma in Medical Laboratory Technology. At present there is not even a course to provide post-graduate specialisation in the field of blood donation and transfusion as in developed countries. The Drug Control departments, which are expected to ensure the appropriate functioning of the blood banks, do not themselves have specified trained personnel.

x) In the storage of blood the basic and essential requirements of clean environment, shelf life of blood etc. are ignored. Nexus is reported to be existing between the attending doctor of the patient and the commercial blood bank, with the former directing the patients to the latter, and the latter giving a percentage of the sale to the former.

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

In the counter affidavit filed by Dr.Lalgudi Vaidyanathan Kannan, Deputy Drugs Controller, on behalf of the Union of India it is stated that after the receipt of the report of M/s.Ferguson & Co., the Drugs Controller, India, by his letter dated August 23, 1990 asked all the State Drug Controllers (who are the licensing and enforcing authorities under the Act) to ensure that inspections are carried out of all commercial blood banks and unlicensed Government blood banks keeping in view the standards prescribed in the Act and Rules and a phased programme of inspection covering first the commercial/private blood banks and thereafter the Government blood banks was suggested. It was also suggested that the private/commercial blood banks should not be allowed to operate unless they fulfil all the requirements prescribed in the Rules and each unit of blood is tested for blood transmissible diseases (Hepatitis, HIV, Syphilis etc.) and that unlicensed blood banks are to be licensed only after ascertaining that they conform to the standards laid down under the Rules. It was also suggested to the State Governments that the licences of blood banks who do not comply with the provisions of the Rules should be cancelled and the State Drug Controllers were asked to send the status reports of blood banks in their respective States. As per the information forwarded by 23 State Governments/Union Territories about 341 blood banks are unlicensed and most of them are run by Red Cross Societies and Charitable institutions. In the said counter affidavit mention is also made of the steps tha

have been taken in the matter of testing of blood for AIDS, storage facilities in blood banks, for upgradation and modernisation of Government managed blood banks, and training of drugs inspectors and blood bank technical personnel.

During the pendency of this writ petition, action has also been taken to revise the Rules governing the licencing and operation of the blood banks and by the Drugs and Cosmetics (First Amendment) Rules, 1982 published in the Gazette of India vide Notification dated January 22, 1993, Part X-B has been inserted in the Rules and Part XII-B has been substituted. In part X-B (Rules 122-F to 122-f) provisions have been made prescribing the requirements for collection, storage, processing and distribution of whole human blood, human blood components by blood banks and manufacture of blood products and for grant and for renewal of licence for the operation of a blood bank/processing of human blood for components/manufacture blood products. Under the said provisions licence can only be granted/renewed with the approval of the Central Licence Approving Authority viz. the Drugs Controller of India. Part XII-B contains provisions relating to space, equipment and supplies required for a Blood Bank.

During the course of the hearing of this petition, the petitioner submitted a draft scheme and a scheme was also submitted by the Union of India. In the affidavit filed by Dr.Shiv Lal, Addl.Director, National Aids Control Organisation, along with the scheme, it was stated that the Central

Council of Health, in which the State Health Ministers are members, is the highest Forum for Policy frame work and that the said Council has given guidelines in respect of Blood Bank and Transfusion Service and its recommendations are as under :

"Blood being a vital input in the present day medicare services the acute shortage of which is hampering the effectiveness of our services the joint Conference recommends that urgent steps should be taken by the States/Union Territories Governments and the Central Government -

1. To build up adequate blood banking services at State/District level including provision of trained/qualified man power. Necessary action should be initiated in right earnest for achieving the objective in view.

2. To educate and motivate people about blood donation on a voluntary basis.

3. To provide adequate encouragement to voluntary donors.

4. To enforce quality control of blood in all its facets of collection, distribution and storage."

In the said affidavit it was also stated that although the World Health Organisation has prescribed that nearly 40 lakhs units of blood is required for the country, the collection is only 19.5 lakhs units at present and, therefore, it is not possible to ban professional donors at this stage unless the donations of blood by way of voluntary donation are increased. In the said affidavit it was further stated that most of the Government Blood Banks are lacking in man power,

training and laboratory facilities to test blood for blood transmissible diseases and to augment this, the Central Government has provided funds to various State Government during 1990-91 and 1991-92 to modernise the Government Blood Banks. According to the said affidavit, the main objective for the modernisation of the Blood Banks have been provided into long term objectives and medium term objectives as under :

"I. Long term objectives:

(a) Make available high quality blood and blood components in adequate quantity to all users.

(b) Ensure wide usage of blood components.

(c) Expand voluntary and replacement donor base, so as to phase out professional blood donors.

II. Medium term objectives:

(a) To provide minimum possible facilities for blood collection, storage and testing in all Government Blood Banks.

(b) To make available the trained man-power in all Government Blood banks.

(c) To ensure the awareness of clinicians and Blood Banks staff on the advantages of blood components.

(d) To ensure the effective geographical coverage keeping in mind the different volumes of blood requirement in different cities.

(e) To increase public awareness about the risks in using blood from commercial Blood Banks and professional donors and the harmlessness of blood donation."

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

1. Additional Secretary, Ministry of Health holding the charge of Director, National Aids Control Organisation as Chairman.

2. Drugs Controller of India.

3. Mr.H.D.Shourie.

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

tions by the Committee constituted by the Court, the Indian Red Cross Society constituted a committee of experts to examine the matter and to prepare a draft blue print. The said committee of experts in its report dated April 15, 1995 has indicated the following fields in which measures are required to be taken :

"1. Building a powerful voluntary blood donation movement to augment supplies of safe quality blood and blood components.

2. Exercising economy by processing whole blood for blood components.

3. Introducing screening procedure to minimize the danger of transmissible diseases like AIDS, Hepatitis etc.

4. Standardize technological procedures for rigid enforcement of quality control, and good manufacturing practices.

5. Providing technical services for raising the standard of Blood centre operations and assistance for administrative, motivational and technical problems encountered."

It has proposed an action plan in three parts : Immediate Plan, Short Term Plan and Long Term Plan, which are as follows :

"Immediate Plan

1. To establish an administrative unit at the national headquarters under the charge of a project director.

2. To identify and strengthen a minimum of 2 Red Cross blood centres for each state for augmenting the existing blood programme. Necessary inputs towards staff, equipment and consumables for the

development should be made available at once. Basic requirements to procure accreditation from DC(I) should be ensured.

3. Donor recruitment and intensification of donor motivation drive may be taken up on priority basis. Involvement of media may be ensured through Information and Broadcasting Ministry.

4. A crash programme for short term training of medical officers, technicians and medical social workers nurses of concerned centres may be undertaken. This distance learning programme prepared by the WHO may be helpful in updating the knowledge of technologists at the centres being strengthened.

5. In addition to the blood centre, strengthening programme, steps may be taken for planning and initiating action for the establishment of Regional blood centres at the following 16 metropolitan cities with 2 million population having many large medical superspeciality institutions

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

Each centre will be expected to collect 150 to 200,000 units annually. These will be screened processed and distributed as blood components to local hospital based centres against service charges. As the regional centres will supplement the blood supplies through the existing system it would help in weeding out the blood supply from paid blood sellers. Therefore it is of paramount importance that top priority is given for the establishment of these centres.

Short Term Plan:

1. Coordination of the blood programme of large medical colleges having more than 1000 beds and or collecting over 10,000 units.

2. Establishment of post graduate training centers at places where facilities for fulfilling the norms of the Medical Council of India exist. In the initial stages Faculty support can be ob-

tained from departments of pathology. At the following cities post graduate training can be started:

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

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

3. Coordination of all other voluntary organisations working for the promotion of the blood programme by the Red Cross Society would further help in achieving the target of donor recruitment with greater vigour and better evaluation.

4. A national workshop at the Red Cross headquarters may be organised for officers of all centres being strengthened and the representatives of regional centres to provide necessary guidance for uniform and standardised policies and practices.

Long Term Plan:

1. To upgrade all other blood centres.

2. Establishment and upgradation of blood centres in areas where it does not exist.

3. Planning of more regional centres.

4. Establishing fractionation centres.

5. Establishment of therapeutic centres for blood related disorders.

6. Programmes for indegenisation of equipped software and reagents.

7. Establishment of tissue typing facilities for Bone Marrow and organ transplant."

After considering the said report of the Committee of experts set up by the Indian Red Cross Society, the Committee constituted by the Court submitted its final report which was filed

along with the affidavit of Shri Ashwini Kumar, Deputy Drugs Controller of India in the Directorate General of Health Services dated October 26, 1995. The Committee has made the following recommendations and has suggested steps for revamping the system of blood banks in the country in the form of plans for implementation on immediate basis and for long term implementation.

FOR IMMEDIATE IMPLEMENTATION:

(i) A National Council on Blood Transfusion should be established. It should consist of Director General of Health Services, Drug Controller of India, representative of Ministry of Finance, high-level representatives of Indian Red Cross Society and selected five major medical and health institutions of the country, and three eminent citizens, presided over by the Additional Secretary of the Ministry of Health who is incharge of operations of the programme of National Aids Control Organisation. The Council should be provided the basic secretariat under charge of a Director by the Ministry of Health and be located in suitable premises at Delhi for effective functioning.

It would be desirable to register the Council as a Society under the Societies Registration Act for enabling it to have its own identity and funds and also for enabling it to raise funds from various sources including contributions from trade, industry and individuals. The basic requirements of its functioning should be provided by the Ministry of Health. The Council will be policy formulating body in relation to all matters pertaining to operation of blood banks.

(ii) The Ministry of Health, with the assistance of National Council, will ensure the establishment of State level Councils, at suitable centres, preferably headquartered at the premises of some outstanding medical institutions or hospitals. The State Councils should have on them representatives of important medical institutions of the State, selected representatives of blood banks of repute, a representative of Red Cross, and should include the State Director of Health Services as well as State Drug Controller operating under a designated

Director and presided over preferably by the State Government Secretary incharge of health. A representative of the State Ministry of Finance should also preferably be on the Council. The size of State Council should preferably be restricted to the maximum of about 11 members. The Director of Health Services should provide the Committee the basic essentials of secretariat and funds for its functioning. The State Councils, as in the case of National Council, should be registered as Society under the Societies Registration Act for maintaining their identity and for purposes of collection of funds in the shape of contributions from individuals and corporate bodies. The State Councils should endeavour to operate on the basis of policies formulated by the National Council, effectively implementing the policies and programmes formulated by them.

(iii) Programmes and activities of the National Council and State Councils should cover the entire range of services related to operation and requirements of blood banks including the launching of effective motivation campaigns through utilisation of all media for stimulating voluntary blood donations, launching programmes of blood donation in educational institutions, among the labour, industry and trade, establishments and organisations of various services including civic bodies, training of personnel in relation to all operations of blood collection, storage and utilisation transport, quality control and archiving system, cross-matching of blood between donors and recipients, separation and storage of components of blood, and all the basic essentials of the operations of blood banking.

LONG TERM OBJECTIVES:

i) The programme formulation at the national level and State levels should take into account the requirements of laying down targets for achievement including the establishment of appropriately designed and equipped blood banks, ensuring that all blood banks are licensed, making satisfactory arrangements for collection and storage of collected blood, fractionalisation of blood into the components. Special emphasis will need to be laid in the programme on the attainment of prescribed targets of organising camps for voluntary collection of blood through motivational campaigns and utilisation of the media. The State Councils shall submit their programmes and targets to the National Council and thereafter continue to submit quarterly reports to the Central Council

about the fulfilment of the targets relating to the programmes.

ii) The National Council and State Councils should launch effective programmes and organise campaigns for collecting funds for implementation of their programmes, suplementing the funds allotted to them respectively by the Government of India and the State Governments. For the purpose of facilitating the collection of funds for blood banking purposes the Government of India in the Ministry of Finance should, at the earliest, be approached by the Ministry of Health to secure special dispensation u/s 35 of the Income Tax Act, making it possible to grant exemption of 100 per-cent basis to the donations given to registered and authorised National Council and State Councils. The fulfiiment of this objective should be specifically reported by the Ministry of Health to the Hon'ble Supreme Court. The National Council and State Councils should also utilise opportunities which may be available for securing financial sanction and other support to their blood banking programmes from International sources and other donor agencies.

iii) The Ministry of Health should follow up the recommendations made by the Expert Committee set up by the Indian Red Cross Society to start M.D.Course in blood transfusion technology, and to also undertake the preparation of comprehensive programme for training of personnel operating in relation to various aspects of functioning of blood banks, storage of blood, fractionalisation of blood, and transfusion of blood.

iv) The system of licensing of blood banks will be strengthened to ensure that all quality banks operating in the country are equipped with licenses within a period of not more than one year. Where any blood banks remain ill-equipped for being licensed, and remain unlicensed after the expiry of the period of one year, their operations should be rendered impossible through suitable action under appropriate legislation. It shall be a policy objective of the Ministry of Health, as well as the National Council and the State Councils established on the basis of these recommendations that the prevalent system of professional donors is discouraged through utilisation of all appropriate media, through withdrawal of licenses where any such blood bank has been licensed, and by launching prosecutions under the appropriate provisions of law. The objective of total elimination of professional donors should be achieved in a period

of not more than two years through utilisation of all requisite measures. For attainment of objectives & programmes of the local organisations, the State Govt. will be approached for providing the requisite Inspectorate for continuing inspection of blood banks."

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

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

We have heard Shri H.D.Shourie, the petitioner in person, Shri A.S.Nambiar, the learned Senior Counsel for the Union of India, Shri P.P.Rao, learned Senior Counsel for the Indian Association of Blood Banks, Dr.V.Gauri Shankar, learned Senior Counsel for the Indian Red Cross Society and the learned counsel appearing for the States. Keeping in view the report of the Committee that has been constituted by this Court and the report of the Committee of Experts set up by the Indian Red Cross Society and the programme that is being implemented by the National Aids Control Organisation as well as the submissions of the learned counsel, we are of the view that suitable action should be taken by the Union Government as well as the Governments of the States and the Union Terri-

tories Administration in accordance with the plan for Immediate implementation as well as the plan for Long Term implementation suggested by the Committee constituted by this Court.

It is no doubt true that after the report of M/s.A.F.Ferguson & Co. the Union Government has taken certain steps towards improving the state of affairs regarding the blood banks in the country and the National Aids Control Organisation is also working in this field. But a lot more is required to done as would be evident from the reports of the Committee constituted by this Court and the Committee of Experts appointed by the Indian Red Cross Society. The Committee constituted by this Court has made concrete suggestions in this regard. We are in agreement with the recommendations of the said committee that the entire range of schemes related to operation and requirements of blood banks including the launching of effective motivation campaigns for stimulating voluntary blood donations, launching programmes of blood donations, training of personnel in relation to all operations of blood banking should be entrusted to an autonomous representative body at the national level which may be called the National Council on Blood Transfusion, as suggested by the Committee. The National Council would exercise the functions entrusted to it in coordination with similar bodies established at State level which may be called State Councils. In order that they may have their own individuality and funds and are able to raise funds from various sources

including of contributions from trade, industry and individuals the National Council and the State Councils should be constituted as societies registered under the Societies Registration Act. The National Council and the State Councils should undertake the measures suggested by the Committee constituted by the Court as well as the Committee of experts appointed by the Indian Red Cross Society and while doing so they should coordinate their activities with those of the National Aids Control Organisation and other agencies in this field. Keeping in view the potentialities of the harm in the prevailing state of affairs and the need for speedy action in this regard, we consider it appropriate to give the following directions :

1. The Union Government shall take steps to establish forthwith a National Council of Blood Transfusion as a society registered under the Societies Registration Act. It would be a representative body having in it representation from the Directorate General of Health Services of the Government of India, the Drug Controller of India, Ministry of Finance in the Government of India, Indian Red Cross Society, private blood banks including the Indian Association of the Blood Banks, major medical and health institutions of the country and non-Government organisations active in the field of securing voluntary blood donations. In order to ensure coordination with the activities of the National Aids Control Organisation, the Additional Secretary in the Ministry of

Health, who is incharge of the operations of the programme of National Aids Control Organisation for strengthening the blood banking system could be the President of the National Council.

2. The National Council shall have a secretariat at Delhi under the charge of a Director.

3. The basic requirements of the funds for the functioning of the National Council shall be provided by the Government of India but the National Council shall be empowered to raise funds from various other sources including contributions from trade, industry and individuals.

4. In consultation with the National Council, the State Governments/Union Territory Administration shall establish a State Council in each State/Union Territory which shall be registered as a society under the Socities Registration Act. The State Council should be a representative body having in it representation from Directorate of Health Services in the State, State Drug Controller, Department of Finance of the State Government/Union Territory Administration, important medical institutions in the State/Union Territory, Indian Red Cross Society, private blood banks, Non-Governmental Organisations active in the field of securing voluntary blood donations. The Secretary to the Govern-

ment incharge of the Department of Health could be the President of the State Council.

5. The State Council should have its headquarters at the premises of the premier medical institution or hospital in the State/Union Territory and should function under the charge of a Director.

6. The funds for the State Council shall be provided by the Union of India as well as the State Government/Union Territory Administration . The State Council shall shall also be empowered to collect funds in shape of contributions from trade, industry and individuals.

7. The programmes and activities of the National Council and the State Councils shall cover the entire range of services related to operation and requirements of blood banks including the launching of effective motivation campaigns through utilisation of all media for stimulating voluntary blood donations, launching programmes of blood donation in educational institutions, among the labour, industry and trade, establishments and organisations of various services including civic bodies, training of personnel in relation to all operations of blood collection, storage and utilisation, sepration of blood groups, proper labelling, proper storage and transport, quality control and archiving system, cross-matching of blood between donors and recipi-

ents, separation and storage of components of blood, and all the basic essentials of the operations of blood banking.

8. The National Council shall undertake training programmes for training of technical personnel in various fields connected with the operation of blood banks.

9. The National Council shall establish an institution for conducting research in collection, processing, storage, distribution and transfusion of whole human blood and human blood components, manufacture of blood products and other allied fields.

10. The National Council shall take steps for starting special post-graduate courses in blood collection, processing, storage and transfusion and allied fields in various medical colleges and institutions in the country.

11. In order to facilitate the collection of funds for the National Council and the State Councils, the Government of India (Ministry of Health and Ministry of Finance) should find out ways and means to secure grant of 100% exemption from income tax to the donor in respect of donations made to the National Council and the State Councils.

12. The Union Government and the Governments of the

States and Union Territories should ensure that within a period of not more than one year all blood banks operating in the country are duly licensed and if a blood bank is found ill equipped for being licensed, and remains unlicensed after the expiry of the period of one year, its operations should be rendered impossible through suitable legal action.

13. The Union Government and the Governments of the States and Union Territories shall take steps to discourage the prevalent system of professional donors so that the system of professional donors is completely eliminated within a period of not more than two years.

14. The existing machinery for the enforcement of the provisions of the Act and the Rules should be strengthened and suitable action be taken in that regard on the basis of the Scheme submitted by the Drugs Controller (I) to the Union Government for upgradation of the Drugs Control Organisation in the Centre and the States (Annexure - II to the affidavit of Shri R.Narayanaswami, Assistant Drug Controller, dated September 16, 1994).

15. Necessary steps be taken to ensure that Drugs Inspectors duly trained in blood banking operations are posted in adequate numbers so as to ensure periodical checking of the operations of the blood banks throughout the country.

16. The Union Government should consider the advisability of enacting a separate legislation for regulating the collection, processing, storage, distribution and transportation of blood and the operation of the blood banks in the country.

17. The Director General of Health Services in the Government of India, Ministry of Health shall submit a report by July 15, 1996 about the action taken in pursuance of these directions.

18. It will be open to the Director General of Health Services, Government of India as well as the National Council to seek clarification/modification of these directions or further directions in this matter.

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

.....J.
[S.C. AGRAWAL]

.....J.
[G.B. PATTANAIK]

New Delhi,
January 04, 1996.

Appendix IV

Form 26-G
(See Rule 122-F)

CERTIFICATE OF RENEWAL OF LICENCE TO OPERATE A BLOOD BANK FOR PROCESSING OF WHOLE HUMAN BLOOD AND/OR* FOR PREPARATION FOR SALE OR DISTRIBUTION OF ITS COMPONENTS

1 1 Certified that licence number _____granted on _____ to M/s _____ for the operation of a Blood Bank for processing of whole blood and / or for preparation of its components at the premises situated at _____ is hereby renewed with effect from _____ to _____.

2 2 Name (s) of Items :
1.
2.
3.

3. 3. Name(s) of competent Technical Staff :
1.
2.
3.
4.
5.
6.

Dated _____ Signature _____

Name and Designation _____
Licensing Authority

_____
Central Licence Approving Authority

* delete, whichever is not applicable.";

(b) after Form 26-H, the following Form shall be inserted, namely :-

Form 26-I
(See rule 122-I)

CERTIFICATE OF RENEWAL OF LICENCE FOR MANUFACTURE OF BLOOD PRODUCTS

Certified that licence number _____granted on _____ to M/s _____ for manufacture of blood products at the premises situated at _____ is hereby renewed with effect from _____ to _____.

2. 2. Name(s) of item(s) :
1.
2.
3.

3. 3. Names of competent Technical Staff :

(a) responsible for manufacturing	(b) responsible for testing
1.	1.
2.	1. 2.
3.	2. 3.
4.	3. 4.
	4.

Signature _____

Name and Designation _____

Licensing Authority

_____

Central Licence Approving Authority".;

(c) for Form 27-C, the following form shall be substituted, namely:-

Form 27-C
(See rule 122-F)

APPLICATION FOR GRANT / RENEWAL * OF LICENCE FOR THE OPERATION OF A BLOOD BANK FOR PROCESSING OF WHOLE BLOOD AND/OR* PREPARATION OF BLOOD COMPONENTS

1. I/We _____of M/s_____hereby apply for the grant of licence / renewal of licence number _____dated _____ to operate a Blood Bank, for processing of whole blood and/or* for preparation of its components on the premises situated at _____.

2. Name(s) of the item(s):
   1.
   2.
   3.

3. The name(s), qualification and experience of competent Technical Staff are as under :

   (a) (a) Name(s) of Medical Officer.

   (b) (b) Name(s) of Technical Supervisor.

   (c) (c) Name(s) of Registered Nurse.

   (d) (d) Name(s) of Blood Bank Technician.

4. The premises and plant are ready for inspection/ will be ready for inspection on _____.

5. A licence fee of rupees _____ and an inspection fee of rupees _____ has been credited to the Government under the Head of Account _____ (receipt enclosed).

Signature _____

Dated _____ Name and Designation _____

* delete, whichever is not applicable.

Note 1. The application shall be accompanied by a plan of the premises, list of machinery and equipment for collection, processing, storage and testing of whole blood and its components, memorandum of association/ constitution of the firm, copies of certificate relating to educational qualifications and experience of the competent technical staff and documents relating to ownership or tenancy of the premises.

2. A copy of the application together with the relevant enclosures shall also be sent to the Central Licence Approving Authority and to the concerned Zonal/Sub- Zonal Officers of the Central Drugs Standard Control Organization.";

(d) after Form 27-D, the following Form shall be inserted, namely :-

Form 27-E
(See rule 122-F)

APPLICATION FOR GRANT/RENEWAL*OF LICENCE TO MANUFACTURE BLOOD PRODUCTS FOR SALE OR DISTRIBUTION

1. I/We _____of M/s_____hereby apply for the grant of licence/renewal of licence number _____ dated _____ to manufacture blood products on the premises situated at _____

2. Name(s) of item(s) :
   1.
   2.
   3.
   4.

3. The name(s), qualification and experience of competent Technical Staff as under :
   (a) responsible for manufacturing (b) responsible for testing

4. The premises and plant are ready for inspection / will be ready for inspection on_____

5. A licence fee of rupees _____and an inspection fee of rupees _____ has been credited to the Government under the Head of Account _____ (receipt enclosed),

Dated _____ signature _____

Name & Designation _____

* delete, whichever is not applicable.

NOTE 1. The application shall be accompanied by a plan of the premises, list of machinery and equipment for manufacture of blood products, memorandum of association/constitution of the firm, copies of certificate relating to educational qualifications and experience of the competent technical staff and documents relating to ownership or tenancy of the said premises.

2. A copy of the application together with the relevant enclosures shall also be sent to the Central Licence Approving Authority and to the concerned Zonal / Sub Zonal Officers of the Central Drugs Standard Control Organisation.";

(e) for Form 28-C, the following Form shall be substituted, namely :-

Form 28-C
(See rule 122-G)

LICENCE TO OPERATE A BLOOD BANK FOR COLLECTION, STORAGE AND PROCESSING OF WHOLE HUMAN BLOOD AND/OR* ITS COMPONENTS FOR SALE OR DISTRIBUTION

1. Number of licence _____ date of issue _____at the premises situated at _____

2. M/s _____ is hereby licensed to collect, store, process and distribute whole blood and / or its components.

3. Name(s) of the item(s) :
   1.
   2.
   3.

4. Name(s) of competent Technical Staff :
   1.
   2.
   3.
   4.
   5.
   6.

5. The licence authorizes licensee to manufacture, store, sell or distribute the blood products, subject to the conditions applicable to this licence.
6. The licence shall be in force from _____ to _____
7. 7. The licence shall be subject to the conditions stated below and to such other
conditions as may be specified from time to time in the Rules made under the Drugs and Cosmetics Act, 1940.

Dated _____

Signature _____

Name and Designation _____
Licensing Authority

_____
Central Licence Approving Authority

*delete, whichever is not applicable

CONDITIONS OF LICENCE

1. The licensee shall neither collect blood from any professional donor nor paid donor nor shall he prepare blood components from the blood collected from such a donor.
2. The licence and any certificate of renewal in force shall be displayed on the approved premises and the original shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
3. Any change in the technical staff shall be forthwith reported to the Licensing Authority and / or Central Licence Approving Authority.
4. The licensee shall inform the Licensing Authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm

operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh licence has been taken from the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.";

(f) after Form 28-D, the following Form shall be inserted, namely :-

Form 28-E
(See rule 122-G)

LICENCE TO MANUFACTURE AND STORE BLOOD PRODUCTS FOR SALE OR DISTRIBUTION

1. Number of licence _____ date of issue _____at the premises situated at _____
2. M/s _____is hereby licensed to manufacture, store, sell or distribute the following blood products :-
3. Name(s) of the item(s) :
   1.
   2.
   3.
   4.
   5.
4. Name(s) of competent Technical Staff :

(a)responsible for manufacturing	(b) responsible for testing
1.	1.
2.	2.
3	3.

5. The licence authorizes licensee to manufacture, store, sell or distribute the blood products, subject to the conditions applicable to this licence.
6. The licence shall be in force from _____ to _____
7. The licence shall be subject to the conditions stated below and to such other conditions as may be specified from time to time in the Rules made under the Drugs and Cosmetics Act, 1940.

Dated _____

Signature _____

Name and Designation _____
Licensing Authority

_____
Central Licence Approving Authority

*delete, whichever is not applicable

CONDITIONS OF LICENCE

1. The licensee shall not manufacture blood products from any professional donor or paid donor.
2. This licence and any certificate of renewal in force shall be displayed on the approved premises and the original shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
3. Any change in the technical staff shall be forthwith reported to the Licensing Authority and / or Central Licence Approving Authority.
4. The licensee shall inform the Licensing Authority and/ or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm, operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh licence has been taken from the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.