BLOOD SAFETY

Blood Transfusion Services constitute a crucial part of healthcare delivery system. Adequate and safe supply of blood and blood components is essential, to enable a wide range of critical care procedures to be carried out in hospitals. Unfortunately, blood transfusion themselves can be a cause of illness like transmission of dreaded viruses like HIV, etc. While the vast majority of HIV infections in India are attributed to the sexual route of transmission, we are mindful that the transfusion of unsafe blood and blood products account for 2.07 percent of the HIV infections in the country in 2004-2005. When viewed against the fact that in 1999 unsafe blood and blood products accounted for over 9 percent of AIDS cases, this drop to 2.07 percent is certainly encouraging. Ensuring the widespread availability of safe and quality blood is a critical component of the National AIDS Prevention and Control Programme.

<u>Infrastructure development</u>

During Phase-I (1992-1999) of this programme, 815 public sector blood banks and those run by charitable organizations were modernized, 40 Blood Component Separation Units was established and a countrywide network of HIV testing facilities was set up.

The National and State Blood Transfusion Councils were registered as societies in 1996, and supported by the National AIDS Control Organisation (NACO). At state levels, these councils maintain oversight over the voluntary blood donation and the appropriate clinical use of blood, training and manpower development, and supervision of the programme.

During Phase II (1999-2006) of this National AIDS Prevention and Control Programme, the NACO has supported the installation of 42 additional Blood Component Separation Units in different parts of the country. NACO is continuing to support modernization of all major blood banks at state and district levels. **255** major blood banks, **883** district level blood banks were modernized, **82** Blood Component facilities and **10** State of Art blood banks were established in identified under-served areas.

In addition to constantly enhancing awareness about the need to access safe blood and blood products, NACO supports the procurement of equipment, test kits and reagents as well as the running expenditure for government blood banks, and those run by charitable organizations that were modernized during the first phase of the National AIDS Control Programme (NACP). In the second phase of the NACP, NACO is committed to expanding and building upon the blood safety activities carried out during the first phase as well as introducing new programmes like Accreditation of blood banks, External Quality Assessment

Scheme (EQAS) for HIV testing, organizing workshops on "Appropriate clinical use of blood" for clinicians and "Quality Management Programme in Blood Transfusion Services" and "Promotion of Voluntary Non-Remunerated Blood Donation"

Articulation of Policy and Programme during NACP II

April, 2002_:

A National Blood policy formulated by NACO was adopted by Government of India.

July 2003 :

A meticulous Action Plan on Blood Safety was finalized and adopted by government.

Through the Action Plan on Blood Safety we sought to operationalise the National Blood Policy. We have:

- Mandated the revelation of HIV status to the result-seeking donor, in Blood banks.
- Commenced the process of accreditation of blood banks to ensure uniform implementation of standard operating procedures, also not attempted previously in the government sector. Our Quality Management Programme in collaboration with the WHO had enhanced standards of blood transfusion services across the country.
- Raised the overall collection of blood through voluntary blood donation. We continue to aggressively motivate all segments of our healthy population, particularly the youth, to participate in voluntary blood donation programme. Blood collection from Voluntary (non-remunerated) blood donors are definitely on the rise, particularly in States such as West Bengal, Maharashtra, Tamilnadu, Gujarat, Chandigarh and Himachal Pradesh. The State AIDS Control Societies has undertaken several activities to promote public awareness of the need for voluntary blood donation and safe blood. The proportion of Voluntary Blood Donation has increased from 20% at start of NACP II to the present figure of more than 50%.

Blood Storage Centres

The Drugs and Cosmetic Rules 1945 have been amended to permit the establishment of blood storage centres at sub district levels, at First Referral Units (FRUs). These blood storage centres will take care of emergencies, particularly in the rural areas where it is not feasible to establish full-fledged blood banks. They will also help fulfill an urgent need for trauma care services,

including facilities for emergency blood transfusions for accident victims along the highways, and for emergency obstetric care. The blood storage centres will be affiliated to larger blood banks.

Establishing State-of-the-art Model Blood Banks

Ten State-of-the-art model blood banks set up in eight under-served States and will be initially managed by NACO prior to being handed over to the respective state governments. These blood banks are expected to function as demonstration projects for the region in which they are being set-up. Under NACO's supervision, in the initial period, the staff will be fully trained to establish high quality systems of service delivery. These centres will also be networked with the existing blood banks in the area to ensure optimal availability of safe blood.

External Quality Assessment Scheme (EQAS)

In 1999 NACO initiated the External Quality Assessment Scheme (EQAS) for HIV testing for the Blood Banks and laboratories, which were involved with carrying out HIV testing. The objective of this scheme was to bring qualitative improvement in these Blood banks and laboratories for HIV testing.

In the first phase of the programme (1999-2000) National Institute of Biological (NIB), NOIDA has been identified as an Apex Laboratory and 12 National referral laboratories (NRL) were established all over the country. They evaluated 10-panel sample and prepared a format for reporting the results. In the next phase 64 State Reference Laboratories (SRL) were established and the Medical Microbiologists in charge of HIV testing and technicians were imparted training in their respective regions to assess the quality of their respective laboratories. These SRLs has been strengthened to train their respective VCTCs and blood banks with support from NRLs and SACS. In the third phase of EQAS, training programme for respective VCTCs and Blood Bank in-charges and technicians started. The number of SRLs has been increased from existing 64 to 99.

All the Blood Banks in public sector and voluntary sector are to be covered under the training programme of EQAS by 12 NRLs and 99 SRLs. The training programme has already commenced in the Phase III of EQAS. Training has been implemented to Blood Bank Medical Officers and Technicians of **1200** Blood Banks. The report submitted by these trainees to their respective NRLs is highly satisfactory.

Quality Management Programme

In order to improve observance of standard operating procedures in blood banks, NACO conducts the Quality Management Training Programmes. Workshops to

train blood bank personnel and sensitize state programme officers have been conducted with the help of WHO to ensure application of systems for high quality service delivery. An accreditation scheme for the blood transfusion services in the country is on the anvil.

Accreditation of Blood Banks

The Action Plan on Blood Safety brings about a paradigm shift in the management of organized Blood Transfusion services, with special emphasis on improving quality of care. Promoting the concept of accreditation of Blood Banks and identifying resources to commence the accreditation is a primary objective of the Action Plan. To operationalize this activity, NACO been pursuing through the National Blood Transfusion Council (NBTC), the task of accreditation of blood banks. The preliminary work on Accreditation of Blood Banks has already being initiated with 4 blood banks in the country (PGIMER, Chandigarh, SGPGIMS, Lucknow, Tata Memorial Hospital, Mumbai and MGR University, Chennai) identified for accreditation in the Phase-I. The final inspection of all these Blood banks is completed by two accreditation agencies i.e ICRA and CRISIL.

Promoting appropriate use of blood

Now a days more stress is given to approach the clinicians for practicing appropriate use of blood. This will help in reducing unnecessary transfusion, selecting the right blood component in the right dose for the patient and reducing donor exposure. A well-planned transfusion can definitely reduce the risk of transfusion and thereby reducing morbidity and mortality associated with it. Appropriate use of blood and blood products will help to improve upon the shortage of blood in blood bank due to avoidance of unnecessary transfusion.

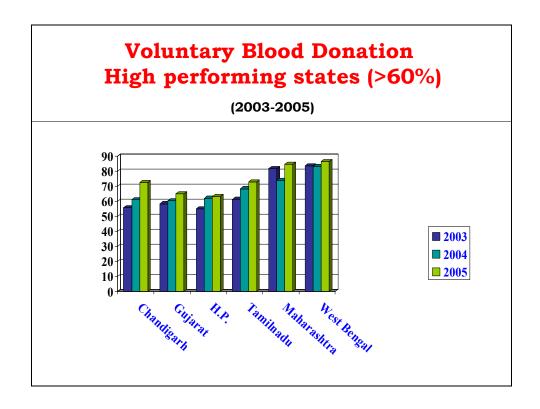
Three Regional workshops on "Appropriate clinical use of blood" has been organised involving all states. One clinician, one blood bank physician and one programme officer of every State AIDS Control Society participated in this workshop. During these workshops, an Action Plan was formulated to involve the three resource persons from each state to organise similar workshops in their states with participation of more clinicians. These will help in propagating the appropriate usage of blood among clinicians.

To prevent wastage of plasma in the country, NACO has taken the initiative to revive and refurbish the National Plasma Fractionation Centre (NPFC) located at K.E.M. Hospital campus, Mumbai. Once this centre is made operational, number of patients in the country will be benefited by the availability of low cost and high quality plasma products. This will also help in promoting rational use of blood. The process of refurbishment has already been started and NPFC and is expected to become fully operational by June –2006.

Voluntary Blood Donation

Blood collected from voluntary (non-remunerated) blood donors all over the country demonstrated a definite rise in the year 2005, but it has yet to reach 50% in many of the states. The proportion of blood units collected through voluntary blood donations in the country for the year 2004 was 52.2%, 53.4 % in 2005 and 56.4% in year 2006. Some of the states like West Bengal (86.3%), Maharashtra (84.6%), Tamilnadu (72.7%), Chandigarh (72.3%), Gujarat(65%) and Himachal Pradesh (63.3%) has done reasonably good in voluntary blood collections during the year 2004. In few of these states, State AIDS Control Societies has undertaken several activities to promote public awareness of the need for blood donation along with their respective NGOs. Workshops on Motivation of Voluntary Blood donations are being organised to promote this programme. October 1 is being celebrated as National Blood donation day all over the country.

Other states are lagging behind, which needs active participation of Voluntary organizations. NGOs working for promotion of Voluntary Blood Donation are almost non-existent in many states. 2nd World Blood Donors day was celebrated in several parts of country with a two days national workshop on Voluntary Non-remunerated Blood Donation (VNRD) conducted by WB SAPCS at Darjeeling. Awareness programmes on VNRD are carried out regularly by every SACS jointly with NCC, NSS and other NGOs involving the youth.



Action Plan for Blood Safety under NACP – III (2007-2012)

Vision:

 Provision of safe and quality blood to every patient in need of transfusion in the country through a well coordinated national blood transfusion service.

Goal:

- Regular voluntary non-remunerated blood donors should form the main source of blood through phased increase in donor recruitment and retention.
- Promote appropriate use of blood, blood components and blood products.
- Aim to reduce the transfusion associated HIV transmission to < 0.5%.
- Develop long-term policy for capacity building to achieve efficient and selfsufficient blood transfusion services.

Priority Issues:

- To develop a nationally coordinated Blood Transfusion Services as per the Action Plan.
- To increase the voluntary blood donation to 80%, out of this, 50% should be from regular repeat donors.
- Appropriate use of Blood, Blood Components and Blood products.
- Capacity Building in the Blood Transfusion Services.
- Emphasis on quality assurance Programmes.

Strategies:

Strategy – 1: Establish proper institutional mechanism for planning and implementation of blood safety.

Action Plan:

- Critically evaluate the constitution and functioning of the State Blood Transfusion Councils (SBTC) for fulfillment of their role in Blood Transfusion Safety.
- All SBTC should prepare an action plan on blood safety, review it on an annual basis and report to the National Blood Transfusion Council.
- Blood Bank Cell should be established in the office of DCG(I) and State Drug Control Authority.

- Identify Regional Blood Transfusion Centres in every state as per approval from NBTC.
- Establish Blood Storage Centres (BSC) in all health care settings providing emergency medical care requiring blood transfusion. BSC should have appropriate linkage with the RBTC/BB, to look after the transfusion needs in a defined area. (Health Care settings include Community Health Centres in Rural Areas and medical establishment in urban areas).
- Guidelines on setting up of BSC should be made widely known.
- Set up Blood Storage Centres in each of the Community Health Centres 3222 in number as per the guidelines evolved.
- A uniform quality assurance programme for BTS must be developed.
- Accreditation of Blood Banks has been initiated in NACP II, needs to be up scaled in NACP – III.

Strategy – 2: Encourage Rational Blood use for transfusion.

Action Plan:

- Component separation facility should be set up at all tertiary care institutions and at least 50% of the collection should be separated into components.
- Promotion of use of blood components through sensitisation of clinicians on regular basis.
- Promotion of Autologous Blood Donation.
- Constitution of hospital transfusion committee. Guidelines will be given by NBTC regarding constitutions and functioning of HTC.
- Build up plasma fractionation facility in the country. The plasma fraction and blood products preparation should be regulated by NBTC and DCG(I).
- Establishment of independent departments of Transfusion Medicine should be made mandatory in all tertiary care institutions.
- MCI & DNB to be approached to include appropriate transfusion practices in the syllabus of MD/MS clinical subjects.

Strategy – 3: Steadily increase in the proportion of the voluntary blood donation up to 80% of the blood units collected.

Action Plan:

- An appropriate uniform communication strategy should be developed to strengthen the VBD movement in the country. This strategy should be worked out by the NBTC.
- An appropriate information system for registration and recall of VBD needs to be worked out.

- Specific projects to be invited from community based NGOs for strengthening the VBD movement, funding to be provided by the NBTC.
- Blood mobiles to be given to tertiary care institutions functioning as RBTC/State of the art model Blood Bank to collect blood from VNRBD and to distribute tested blood to BSC.

Strategy – 4: Enhance and institutionalise Quality Assurance in Blood Banks and also increase the counselling to those voluntary blood donors whose samples test reactive.

Action Plan:

- Provide one QA officer in each of the BBs supported by NACO –
 Major BB and Tertiary Care Institutions. The specific role and
 responsibility of the QA officer should be defined to ensure
 improvement in the standards and quality of services and provide
 technical advisory support to district blood bank, blood storage
 centre.
- In the State Health Services doctors and technologists posted in blood bank should undergo regular induction training as per the curriculum and training duration to be specified by NBTC.
- Regular reorientation at least once in two years to apprise them of recent advances and practices in BTS.
- Attach medical social workers one to district level BB and two to tertiary care institutions.
- Provide computer operator cum record keeper for tertiary care institutions to maintain voluntary donor data.
- Regular mechanism to be developed for refurbishment of the existing equipment as well as maintenance.
- Minimum contingency grant to be worked out in relation to worked and necessary assistance provided.
- Need based research to look into issues of donor and recipient safety.
- Review of testing protocols for detection of malaria.

Monitoring and Evaluation:

- Need based research to look into issues of donor and recipient safety.
- Development of protocol for M & E functions in blood banks.

Indicators:

Percentage of VBD

- o 80% voluntary.
- o 50% them regular VBD.
- Percentage of blood being processed into components from 20% to 50%

Physical Targets:

- Setting up of District level Blood banks / Blood storage centres in 39 districts with no Blood transfusion facility.
- 3222 CHC to have BSC.
- State of the art Blood Bank in 22 States.
- Ultra Modern Blood Banks in Four Metros.
- BCSU to be set up in each tertiary care hospital.
- Blood mobiles in all BCSU 162
- Two more Plasma Fractionation Facility. One in the Northern and one in the Eastern region.
