

# NACP IV Working Group on Blood safety

## 1<sup>st</sup> round of consultation

### **I. Current status of blood safety:**

- 1 Total blood collection increased from 4.4 million units in 2007 to 7.9 million units in 2011.
- 2 Incidence of Voluntary non remunerated blood donation increased from 52% in 2007 to 79.5% in 2011.
- 3 Incidence of HIV seroreactivity reduced from 1.2% in 2007 to 0.2% in 2011.
- 4 73 blood component separation facilities established in addition to existing 82 BCSU totaling to 155 to ensure appropriate clinical use of blood.
- 5 Established 18 district level blood banks to ensure access to blood in unserved areas.
- 6 Established 685 blood storage centres to ensure availability of blood below district level, at the first referral units.
- 7 Provided 250 BTVs for district level mother blood banks, for maintaining cold chain during transport of blood.
- 8 35 Blood mobile vans provided one per state to augment voluntary blood collection.
- 9 Capacity building by Implementation of Training programs for blood bank medical officers, technicians, nurses, Counsellors all over the country through 17 regional training centres.

### **II. Issues and concerns:**

- 1 Lack of centrally coordinated programme for blood transfusion services.  
Decentralised and fragmented blood transfusion services managed by three different bodies viz Deptt of Health, Deptt of AIDS control and DCGI. With no coordination between NACO/SACS/NBTC/SBTC etc.
- 2 Inadequate availability and accessibility of safe blood.
- 3 Lack of Administrative control on vital areas like Organisation, Manpower development, Regulatory affairs. Unlawful practices by private blood banks and Education/Teaching/ Research/ Training
- 4 Lack of Experts in Transfusion Medicine for Technical component
- 5 In effective appropriate clinical use of blood
- 6 Lack of human resource at National & state level
- 7 Inadequate systems of procurement

**The above issues and concerns for blood safety in NACP IV need to be addressed in the strategic plan, as under:**

**1 Voluntary Blood Donation**

- I. lack of support to VB donor organizations at all levels
- II. Lack of dedicated staff on VBD in blood banks
- III. Lack of state specific IEC material in VBD
- IV. Issue of mega blood donation camps
- V. Lack of focus of VBD in adolescence
- VI. Lack of quality in donor recruitment and retention

**2 Introduction of strategies to increase blood collection to improve supply for the increasing demand by the following**

- Revision of the pattern of support to be provided to these organizations
- Provision of one dedicated social worker for VBD activities in each blood bank at least up to district level
- Ensure availability of state specific IEC material in vernacular language
- Restriction as per capacity and utilization with not more than 1000 units per camp per venue except in case of a disaster with intimation to the regulatory authority
- Inclusion of VBD in school education program
- Ensuring donor care and management

**3. Inadequate availability and accessibility of safe blood**

- i) lack of transfusion networking of blood banks in states / regions and Lack of data for need assessment, demand and utilization
- ii) Confusion in Nomenclature adopted for blood banks as metro blood banks, Model blood banks, RBTC, BCSU, Major BB, DLBB, BSC.
- iii)\_Limited RoE of private sector
- iv) Limitations of Drugs and Cosmetics Act

**a) Access of Safe, Quality blood to General public can be ensured by**

- Geographical mapping for need assessment
  - Mapping for existing facilities and linking of facilities
  - Develop one nodal agency in coordination with related depts. (DME, DHS, state drug control dept.) - communication of network plan to all agencies
  - Define responsibilities and develop linkages for availability and blood security
  - Simplify nomenclature of blood banks- Metro BB to be designated as Centres of excellence, Major blood banks to be renamed as per their capacity .
  - All Govt. Blood banks not under NACO support at present to be brought under NACO support
  - An effort to be made to ensure that all other blood banks in the charitable sector to be a part of the transfusion network
  - Encourage involvement of private sector through professional bodies (IMA, federations of various specialty organizations) to ensure they work on a not for profit basis
  - Amendment required in Drugs and Cosmetics Act
- **Resources required for Access of Safe, Quality blood to General public:**
    - Manpower – Designating a nodal officer at every centre
    - Computerization - Common software with transparency for networking and blood safety
    - Provision of Blood mobiles
    - Need based support of Blood Transport vans to blood banks

#### **4. Quality in Blood transfusion services**

- I. Lack of Quality Management Systems
- II. Inadequacy and lack of uniformity in following the existing guidelines
- III. Lack of proficiency in testing for TTI and immuno-haematology.
- IV. No Targets for accreditation for Blood banks
- V. Automation in blood banks collecting more than 10,000 units
- VI. Capacity building for component separation

#### **The possible solutions for the above issues to ensure blood safety are**

- Capacity Building for strengthening the QMS

- Developing systems for proficiency testing for identifying mechanisms of delivery at least up to a level of BCSU.
- Provide a Handbook for implementation of quality management manual for capacity building for accreditation
- Provide infrastructure and equipment support and a data entry system for operations including bar coding
- Enhance components separation and apheresis in the existing BCSUs by providing the requisite equipment and infrastructure
- Standardization and quality assurance of testing protocol/kits for Screening of Transfusion Transmitted Infections is to ensure all kits used in the BB must have undergone a pre dispatch testing as per standardized quality procedure.
- Develop referral centers for piloting use of newer technologies for innovation using newer available technology
- Develop/strengthen complaint / redressal mechanism for quality of TTI kits

## 5 Procurement issues

Lack of in house capacity at the NACO Level, thereby dependence on the external procurement agencies for

**1 Consumables** - Reporting ,Forecasting @state level, Lack of contingency plan@ SACS,Stock position reporting

**2 Non consumables** - Site assessment, Uniform technical specifications

### Develop In house capacity to be built for procurement

1. Rate contract
2. Supervision by SACS (verification of stock through random visits)
3. State level technical supervisory core group to be set up
4. Monitoring
  - Lab technicians to be held responsible
  - Regular meetings of the technical core group and share experiences
  - Maintenance meeting with the suppliers on a regular basis. Penalty
  - Guidelines for condemnation and disposal of expired items

## **6 Appropriate Use of Blood - capacity building for Clinicians by**

- Provision of Standardized modules and IEC material
- Training of clinicians

**7 Lack of independent authority for blood transfusion services . Decentralised and fragmented blood transfusion services rest on three different bodies viz Deptt of Health, Deptt of AIDS control and DCGI. With No coordination between NACO/SACS/NBTC/BTCthem**

## **9. Implementation Structure**

### **NACO -**

- I. Lack of human resources
- II. Lack of systems and mechanisms
- III. Inadequate Program management
- IV. Lack of Coordination with SACS and peripheral units

**Need of the hour is for a Separate program with distinct identity (beyond NACP) with Different divisions for programme management, admin procurement, Finance and IEC**

### **The human resource required at Central Level is**

- 1 DDG and 2 ADG level officer with experience in blood banking
- Team of 8 Programme officers for VBD, Quality, TTI, Transfusion service network, Training, clinical use of blood and haemo- vigilance research and SCM
- Technical officer for each of the above and 3 for M&E function along with support staff

### **Action to be taken –**

- 1 NBTC and SBTC to be amalgamated into the proposed structure
2. Issues related to transfusion dependent diseases to be integrated into this structure
3. Newer developments in the field of transfusion medicine e.g. cord blood bank, stem cell registry and bone marrow transplant to be integrated with this program

### **At State level : SACS**

- JD, DD with VBD and a quality manager and M&E officer with support staff in large states.
- Medium and small states JD, VBD and a QM and M&E officer

### **Blood centre facility level**

- Social worker at each center at least up to the district level
- Data entry operator at the facility collecting more than 10,000 units over and above the existing staff

### **Action to be taken**

1. SBTC to be amalgamated into the proposed structure
2. Issues related to transfusion dependent diseases to be integrated into this structure

### **10. Integration with NRHM**

- Ownership of BSCs with Operationalization and monitoring of BSCs.
- Orientation of all staff on use of blood
- Establishing coordination and linkages with SACS and NRHM
- To Ensure the supply chain of blood.

### **11 Integration with other Ministries and other Departments within the Min. of Health**

Lack of coordination at National and State level - DCGI, Department of Education, National Disaster Management Authority/ NHAI, Min. of Rural development, Min of Tribal Affairs, Min. of Youth and Sports, Min. of Info and broadcasting, Other programs in Min. of Health ( RCH, malaria, Anemia etc)

**Way forward is constitution of coordination committees at National and state level and Identification of a nodal person in the respective department/ministry at the central and state level.**

### **12. Others issues as Lack of plasma fractionation facilities in the Govt. sector can be addressed by Developing plasma fractionation facilities**