Report of Working Group on Blood Safety: 18th July 2011.

1. Introduction:

The availability of blood and blood products is an essential element of health care delivery system in the country. Currently, Blood Safety is one of the components of National AIDS Control Programme with the objective of ensuring access to safe and quality blood through a well coordinated Blood Programme.

The key strategies during NACP-III are (1) to increase regular voluntary non-remunerated blood donation (2) to establish Blood Storage Centres in the First Referral Units (3) to promote rational use of blood in healthcare facilities and (4) capacity building to achieve efficient and self sufficient blood transfusion services.

2. Current Status

During the course of NACP III, the status of various activities under Blood safety are as follows:

- The total blood collection increased from 4.4 million units in 2007 to 7.9 million units in 2011, against an estimated requirement of 10 million units per year.
- Voluntary blood donation increased from 52% to 79.5% and HIV sero-reactivity declined from 1.2% to 0.2%.
- 73 blood component separation facilities were added to 82 existing ones, to ensure appropriate clinical use of blood.

- 18 district level blood banks and 685 blood storage centres were established to increase accessibility of blood in some uncovered districts and sub-district level facilities.
- Blood mobile and blood transport vans were provided to augment voluntary blood collection and transportation of blood from Blood Banks to Blood Storage Centres.
- Capacity building through in-service training to various categories of staff was imparted.

Thus, significant quantum of activities was carried out as per Project Implementation Plan of NACP III.

However, there still remains a gap in availability and accessibility of blood at peripheral level. There are still some districts in the country with no government supported blood centre. The voluntary blood donation is still less than expectation of NACP III. Lack of human resources with issues of capacity building and lack of adequate quality management systems in majority of blood banks are the other key areas requiring attention. Although blood banking is under the overarching umbrella of NACP III, health being a state subject, there are still issues of regulation, ownership and coordination between Centre, State and regulatory authorities for proper implementation of the programme.

3. **Key strategies for NACP IV:**

   The strategy for blood programme during NACP-IV will remain largely unchanged, however the implementation of activities will be suitably addressed as per the identified gaps and requirement of the programme.

Strategy I: Augmentation of Voluntary Blood Donation

During NACP-IV, the aim is to achieve 90% of the annual requirement of blood exclusively through voluntary non remunerated donation.

Key activities

- Educating the society for recruitment and retention of low-risk blood donors.
- Training of voluntary organizations in donor recruitment and retention.
- One dedicated donor motivator cum counselor to be provided up to district level blood bank.
- Augment partnerships with government departments and nongovernmental organizations such as national Red Cross, voluntary blood donor organizations, national service organizations. For targeting rural areas, co-ordinate with NYKS to promote VBD.
- Pledge 25 VBD Clubs in colleges and universities, involving youth organizations and establish linkages.
- Establishment and maintenance of a database/register of donor records; Rare group directories need to be maintained in the blood banks.
- Targeted IEC for Voluntary blood donation at The National and State level.
- Nodal committees at the district level to augment VBD programme in the districts.
- Indicator: %age of blood collected through VBD

Strategy II: Access to safe and quality blood

1. Upgradation of facilities

Access to safe blood is mandated by law and is the primary responsibility of the government. Currently blood safety programme under NACP is supporting 1127 blood banks including 155 Component separation centres, and 685 Blood Storage Centres in public/voluntary/charitable sector.

However accessibility is limited by imbalance between demand and supply and lack of linkages within the existing transfusion network consisting of government, non-government charitable and private blood banks compounded with inappropriate clinical use. Within the limitations of Drugs and Cosmetics Act, there is no provision for stock transfer of blood within the transfusion network. The nomenclature, roles and responsibilities of blood banks within the transfusion network across the country needs to be reviewed. There is shortage of trained human resources also at all levels of the blood transfusion service.

Key activities:

1. To determine the annual requirement of blood for the country, a district wise need assessment of blood based on the bed strength and the level of healthcare will have to be carried out. This will help in planning the VBD programme for the country.

2. To develop the horizontal and vertical linkages of blood banks and storage centres within the states. This needs to be coordinated by SACS/SBTCs. The nomenclature and responsibilities of each category of blood bank needs to be defined.

3. Formulation of appropriate guidelines within the provisions of Drugs and Cosmetics Act to facilitate easy transfer of blood within the transfusion network.

Facilities

a. Based on the performance assessment and agreement of the state who can support the physical infrastructure and equipment, the

programme should support the running cost of these facilities. The no. of such facilities is estimated to be 219 blood banks.

b. 21(+new districts) Blood banks, 2537 blood storage centres at district and sub district levels will be established where such facilities are non-existent. Computerization up to district level blood bank will be required for implementation of networking with one data entry operator in each blood bank and a nodal officer at the state level. Blood transport mechanism to be strengthened by providing 402 (250+152) blood transportation vans which are tailor made to serve the purpose of both transportation and VBD camps.

Blood Screening

Blood transfusion service is facing critical issue of standardization and adequate quality assurance of testing protocols and kits/reagents in use.

Key activities

It is imperative that only those kits/reagents which are evaluated and meet the standards should be provided by the programme. Further, staff needs to be trained on validation protocols for ensuring reliable test results.

A scheme needs to be drafted under the programme to designate certain blood banks as Referral centres (1 apex, 4 regional & state level) for carrying out various functions such as a) evaluation of the equipment and reagents b) carrying out proficiency testing (EQAS) for TTI and immunohematology tests c) performing confirmatory tests and counseling for all transfusion transmissible infections and d) piloting newer technologies.

There is a need to introduce a phase wise automation in 200 large volume blood banks collecting more than 10,000 units per year (155+35+10)

Although there is a mandatory requirement for the screening of identified TTIs, the support for screening is only limited to HIV and Hepatitis B&C which should be extended to Malaria and syphilis.

For carrying out multi-centric studies for instituting newer and innovative technologies, funding and support needs to be provided. Research on emerging and re-emerging transfusion transmissible infections such as dengue, chikangunia, leptospirosis, leishmaniasis etc would be important to know whether these need to be included in the routine blood screening procedure.

2. Quality Management systems

Lack of adequate quality management systems, non compliance of the existing regulation and standards, shortage of trained human resource and inadequate monitoring are some of the key areas requiring attention during NACP-IV.

Hence there is a need to implement quality management systems, encourage and support accreditation of blood banks. Developing quality policy, procedures and reporting formats to ensure uniformity in documentation and traceability.

Capacity building and provision of a handbook, e- learning/distance learning programme for training of all staff at district/sub-district in the blood banks for implementing process control. Provision of a quality manager in all large volume blood centres is essential. A phase wise programme for accreditation of blood banks starting from model blood banks up to district level, needs to be implemented.

Introduction of complaint redressal system is required for performance improvement.

The blood banks need to be aware of all statutory requirements and strictly follow them by introduction of a monitoring and vigilance system.

Strategy III: Appropriate Use of blood and blood products

Appropriate use of blood is essential for safety, efficiency and clinical benefits. Blood component preparation and usage needs to be increased. 80% of the blood collected in existing BCSUs should be converted into components.

There is lack of awareness amongst the clinicians on appropriate use of blood. For sensitization of clinicians, national guidelines should be prepared on clinical use of blood and circulated.

Capacity building is necessary at the undergraduate and postgraduate level besides in-service training. At the UG and PG level the issue should be taken up with MCI to incorporate the subject in their curriculum. Standardized modules should be used for in-service training at regular intervals.

It would be vitally important to consider the newer developments like cord blood bank, stem cell registry and bone marrow transplant by properly incorporating them within the programme.

Hospital transfusion committees should be functional and perform clinical audit on blood usage and report to state nodal agency.

Haemo-vigilance to be piloted in select centres and then scaled up in a phased manner.

Strategy IV: Adequate Implementation Structure at all levels

The blood transfusion service requires an independent implementation structure for an effective and centrally coordinated ‘National Blood Programme’.

In view of this, the existing tiers of infrastructure need to be strengthened as per the requirements of the programme.

Key activities

1. The existing policy and monitoring level structures need to be amalgamated in the proposed structure. **The role of the regulatory authority both at central and state level to be clearly defined and linkages established.**

2. The services pertaining to Transfusion dependent disorders (example Thalassemia, Haemophilia etc.) must be integrated into the blood programme for provision of specific needs through the upcoming metro (CoE) blood banks and PFC.

The proposed structure is as follows

The requirement of dedicated human resources for various functions such as Programme Management, Administration, SCM, Finance, HRD and VBD are essential for implementation of the blood transfusion service network.

There should be specific provision in terms of one senior level official with transfusion medicine background heading the programme along with adequate support staff addressing all the thematic areas as mentioned above to the carry out the these functions.

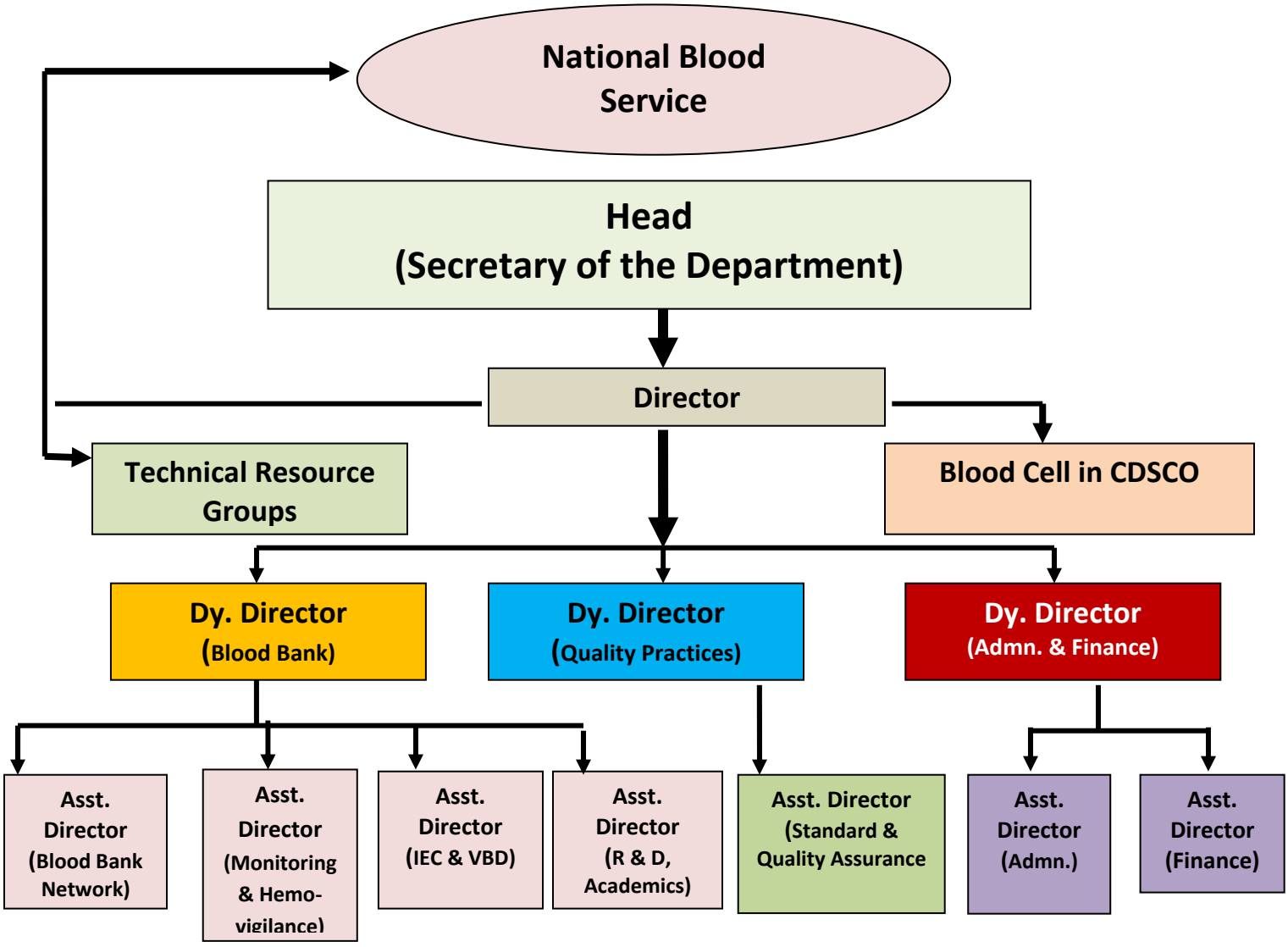
At the state level there is a need to provide a parallel structure addressing key elements of blood transfusion service network.

At the blood centre, facility level, apart from the manpower provided by the state, there is a strong need for an additional provision of a social worker at each centre up to the district level. Data entry operators need to be provided at the facilities collecting more than 10,000 units.

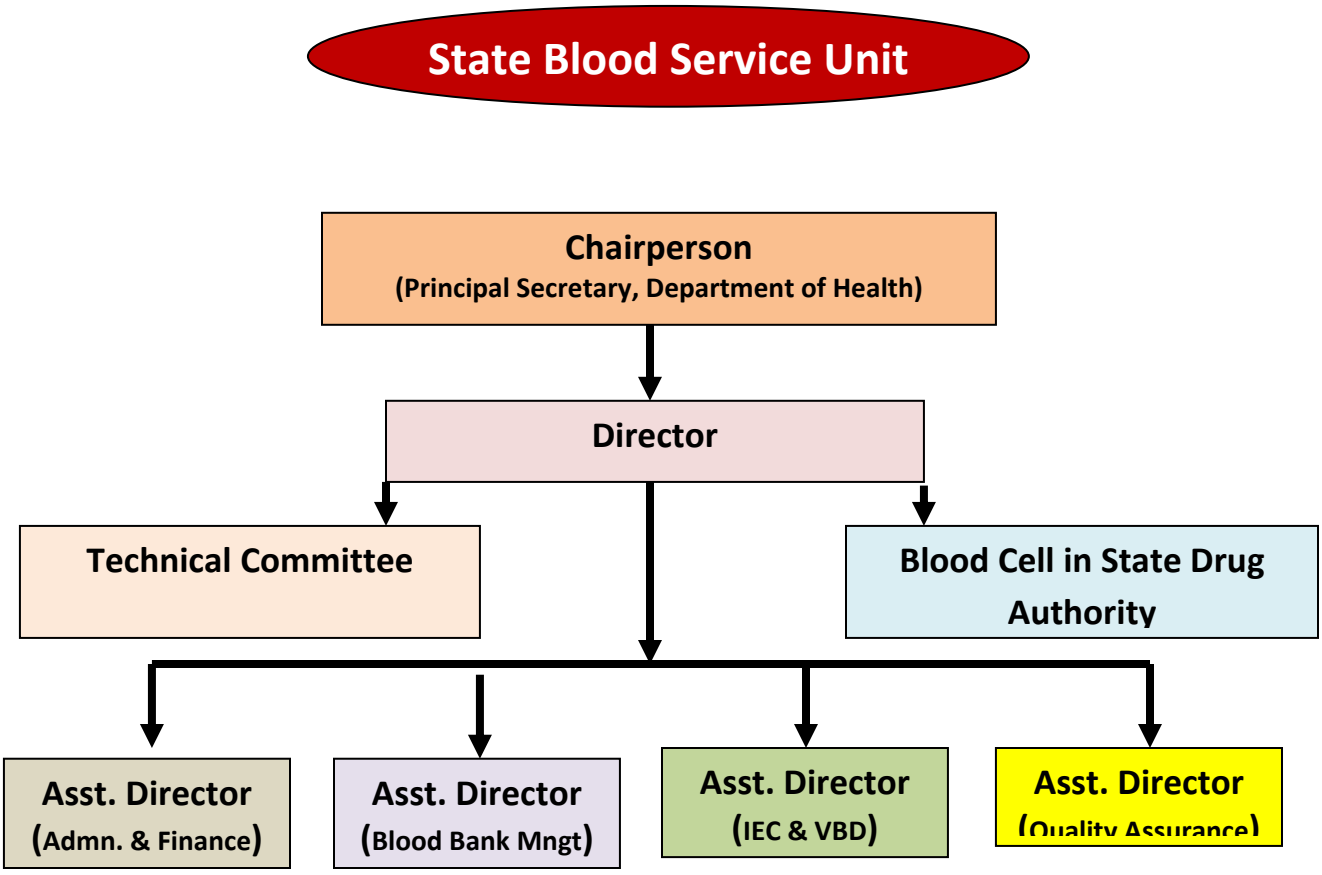
It is important that there should be full ownership of the entire gamut of blood banking activities by the state. The support from the national level for any activity which is state subject (health, blood banking) should be

perceived only as a value addition to the activities primarily meant to be actively implemented by the state. Such a level of ownership and accountability should be specifically developed and sustained.

At National level:



At State level:



Strategy V: Efficient Supply Chain Management (SCM)

There is a need for capacity building for procurement and SCM. This calls for addressing the issues of forecasting, lack of reporting, contingency plan and management of supply chain at the State for uninterrupted supply of equipment, consumables and disposables.

Key activities

1. If the goods are to be procured centrally, the programme should ensure regular and timely supply to the facility through an efficient mechanism.
2. In the event of an exigency, the SACS will be delegated for short term procurement.

3. Efficient system for inventory management at various levels.

Strategy VI: Convergence With NRHM/other departments and ministries

- Access to safe blood at the FRU level will ensure improvement in health indicators in general and maternal health in particular.
- Further establishment of blood storage centre in First Referral Units by NRHM. NRHM/ Health system to provide infrastructure, equipment and human resources. NACP shall ensure the capacity building and provision of consumables.
- Ensuring availability of Blood in the FRUs through mother blood banks and management of efficient Supply Chain/transportation .
- Linkage of VBD program with Anemia Control Program through Department of Health/ WCD for Prevention of Anemia to ensure that significant number of voluntary donors who are deferred due to anemia will be able to donate blood.
- Sensitization and capacity building of State/district officials for issues related to blood.
- A joint coordination committee at State Level of SACS, NRHM and other health officials to be constituted for supervision and monitoring of various facilities under the programme.

Physical Targets: already in built in individual strategic plans.

Monitoring indicators:

1. % age of collection against the estimated demand
2. % age of blood collected through voluntary blood donation
3. % age of blood separated into components
4. %age reduction in sero prevalence of TTIs
5. %age reduction in discard rate of blood collected

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