



TAMIL NADU State Blood Policy & Implementation Framework

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Abbreviations

BB – Blood Banks

BSC – Blood Storage Centres

BMO – Block Medical Officer

BTS – Blood Transfusion Services

CAMC - Comprehensive Annual Maintenance Contracts

DBTO – District Blood Transfusion Officer

ELISA - Enzyme-Linked Immunosorbent Assay

GIS - Geographic Information System

IQC - Internal Quality Control

IH - Immunohematology

ICTC - Integrated Counselling and Testing Centres

JSSK - Janani Shishu Suraksha Karyakaram

PICME - Pregnancy Infant Cohort Monitoring & Evaluation Software

PIP – Programme Implementation Plan

QMS – Quality Management System

SBTC – State Blood Transfusion Council

SHDRC - State Health Data Resource Center

SIMS – Strategic Information Management Systems

TTI - Transfusion- Transmissible Infections

VNBRD - Voluntary non-remunerated blood donation

Executive Summary

Providing safe and adequate blood should be an integral part of every state's health care policy and infrastructureⁱ. The provision of universal access to safe blood for those who are in need is the responsibility of the State. The **Tamil Nadu State Blood Policy and Implementation Framework**, which is first of its kind in India, is one of the many steps taken by the Government of Tamil Nadu to improve the access and quality of blood transfusion services provided by blood banks and blood storage centers across the state. It aims to address the key challenges in the health system and envisages that universal access to safe and good quality blood and blood products will be made possible in the required quantity and in a time-bound manner to ensure optimal health outcomes in the state irrespective of geographical disparities.

The policy advocates six main pillars or components that are critical for the effective and efficient functioning of blood transfusion services in the state. They are Organization and Management of Blood Transfusion Services, Universal access to blood and products, Voluntary Non Remunerated Blood Donation, Quality Management Systems, Patient Blood Management and appropriate Regulation, Policies and Guidelines.

Ensuring universal access to adequate supply of safe blood that fulfills standard quality requirements and promotes need-based, rational and safe clinical practice of transfusion, without any discrimination, including the adoption of haemovigilance processes for patients and donors to achieve a coordinated blood transfusion service in order to fulfill state and national level health care goals is the objective of this document.

The National assessment of blood banks provides evidence that the provision of blood and the efforts to ensure blood safety in the state of Tamil Nadu are better as compared to the country scenario. But, we are also aware of the fact that the demand for blood is high in our State, because of number of reasons which

include well developed tertiary care system that provides advanced medical services, rising demand with respect to maternal health and an evolving cutting edge Trauma Care System.

Tamil Nadu contributes to the highest number (14.9% of total) of road traffic accidents (RTA) (7th leading causes of DALYs in Tamil Nadu – 3.3%)ⁱⁱ in India. It also stands second highest in the number of people killed during the RTA which is 11.4% as of 2016 data. Another huge challenge of maternal deaths in Tamil Nadu, the maternal mortality ratio stands at 79 per 100,000 live birthsⁱⁱⁱ, most of which is caused by anemia (5th leading cause of DALYs in Tamil Nadu – 3.6%)ⁱⁱ and postpartum hemorrhage (PPH) which needs timely blood transfusion. The state is also continually engaged in tackling vector borne diseases such as dengue where many high risk patients require urgent platelet transfusion to avoid death. Also, there are several ongoing challenges that exist in terms of donor recruitment, testing, blood component production and patient side operations of the blood bank.

“Universally equitable, affordable access to safe and quality blood and blood products will be made possible in a time-bound manner to ensure optimal health outcomes and further improvement in health indicators in the State”

There is a huge emphasis given to Voluntary Non Remunerated Blood Donation (VNRBD) as this is the first crucial step in providing reliable and safe blood services. In 2016-17, 3,12,339 units of blood were collected through 3726 camps. But our current annual requirement is more than 16 lakhs units. This means that the blood donation has to be improved by five times to meet the demand. This is one of the reasons why we will be actively engaged with the private sector hospitals in order to distribute the blood units (including rare groups) across all providers to ensure good availability of blood and blood products.

Human resources form the core of a well – functioning blood transfusion services system and the policy has mentioned specific objectives linked to capacity building and training of these professionals at periodic intervals. Measures have to be put in place to ensure optimal usage of whole blood and the healthcare professionals need to be trained in using the right product for the right health condition. Therefore, the policy emphasizes the need for continual training to reinforce the rational use of blood and blood products to reduce wastage and adhere to good clinical transfusion practices including patient blood management.

Throughout the different stages of implementation, the policy strongly advocates for the adoption of evidence based programs as essential to ensure safe and efficient delivery of blood and blood products. Every step in the process of providing these services is monitored and evaluated at various levels to improve equitable and efficient provision of blood services. This calls for a robust data management system integrated with GIS systems which will provide a timely picture about demand and supply across the state.

We believe that the Tamil Nadu State Blood Policy and Implementation Framework would serve as a ready reckoner and guide for key policy decisions for all stakeholders including the health care professionals and practitioners, which would be critical in improving our services to serve the needy, ailing patients by ensuring provision of good quality blood and blood products at the right time.

Tamil Nadu State Blood Policy and Implementation Framework

1. Introduction

1.1 Blood transfusion services play an essential, underpinning role in health systems without which medical care is impossible. The government is primarily responsible for ensuring universal access to blood and blood products that are safe, clinically effective and of appropriate and consistent quality, available at reasonable cost, adequate to meet the needs of patients, transfused only when necessary, and provided as part of a sustainable blood programme within the existing health care system. The World Health Assembly urged member countries to promote the development of national blood services based on voluntary non-remunerated donation of blood; to enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products (WHO, 1975).

1.2 Globally, more than half a million women die each year during pregnancy, childbirth or in the postpartum period and 99% of them are from the developing world. According to available estimates, 35% of all maternal deaths are due to post-partum hemorrhage and the incidence of PPH is reported as 2% - 4% after vaginal delivery and 6% after cesarean section; with uterine atony being the cause in about 50% cases in India {AbouZahr, 1998 #1}. The Sample Registration system 2001-2003, and Estimates of maternal mortality ratio in India done by ICMR in 2003 indicated PPH as a leading cause of maternal mortality in India. Reports indicate that 70% of the PPH related deaths are due to lack of immediate availability of blood. In addition, the increasing number major surgeries (234 million), 63 million trauma-induced surgeries, 31 million cancer-related procedures and 10 million pregnancy-related complications require blood transfusions. Apart from these, there are disorders like sickle cell anemia, thalassemia, and hemophilia that require repeated blood transfusions.

1.3 Though there has been a significant improvement over the years, there are still gaps and challenges in providing access to safe and quality and blood products in the country. India has a large number of licensed blood banks (2,626), but, they are neither distributed according to the need, population size, terrain, usage nor as per the projected requirement. Still, a significant number of patients requiring transfusion do not have timely access to safe blood and there is an imbalance between states and districts in access to safe blood. Besides, there is a huge inequity in the availability of blood with urban areas having more

access to the majority of blood available. Even if sufficient blood is available, many are exposed to avoidable, life-threatening risks through the transfusion of unsafe blood. The country faces scenario, where there are blood banks with good infrastructure but lack trained personnel; there are blood banks with trained personnel but lack equipment, provision of supplies and facilities to maintain the good cold chain. In addition, a lack of systematic surveillance mechanism, lack of a robust monitoring and evaluation system supported by continuous generation of evidence through research, insufficient inter-sectoral coordination and a lack of application of legal and regulatory system and few other factors hindering the provision of HIV-free, safe and quality blood and products in the country. Hence, it is essential to optimize collection of blood, utilization, develop quality systems in the transfusion chain, strengthen the workforce, adopt new technology and developments and build effective partnerships.

2. Review of Blood Transfusion Services in Tamil Nadu: Gaps and Challenges

2.1 Organization of Blood Transfusion services: Blood transfusion services in the state are centralized and have fragmented structures and operations. Three government bodies, which are the state AIDS Control Society, State Blood Transfusion Council and State Drug Controller control and operate blood transfusion services. The key issue here is that, although these institutions have defined roles and responsibilities, there is an overlap of functions and lack of coordination between them. The lack of coordination between the state level bodies and the national authorities is also a concern. This has led to inefficiency in oversight and management BTS in the state. Although the BTS activities are to be planned and coordinated at the district level considering the local contextual issues, there is no government body to coordinate the activities at the district level.

2.2 Access to Blood Transfusion Services: Access to Blood Transfusion services depends on the availability of blood banks or blood storage centres, location, coordination between blood banks and blood storage centres, adequate collection, human resources, interrupted supplies, and facilities for transporting blood and its components including proper cold-chain maintenance. The demand side factors include, knowledge and awareness without myths and misconception, health-seeking behavior, affordability, and proximity to services. Above all, the demand for blood depends on the capacity of the health system that actually initiates blood transfusion.

2.3 Availability Blood Banks in the state: Tamil Nadu which is one of the most developed states in the country has 265 blood banks (NACO - NBTC, 2016). The public and not-for-profit sector own 38% each and the private sector owns 24% of blood banks. The majority of the blood banks (76%) are attached to hospitals, 22% are standalone and 2% are attached to laboratories. The state has a higher ratio of 3.7 blood banks per one million population as compared to the country scenario of 2.2 blood banks per million population. However, they are inequitably distributed with Chennai district having the maximum (14%) followed by Coimbatore and Kanchipuram having 8%, and Salem 6%. More than half of the blood banks are located in 8 districts of the state. According to the State Licensing Authority, Tamil Nadu has 519 blood storage centres, as on October 2017, in the Government sector of which 89% are functional. The state has 519 BSCs out of which 387 (out of 387, only 284 are functional) are in government and 132 in private. The average consumption of blood units per CHC/upgraded PHC is 5 per month (annually 60 units) and average blood storage is 15 units per month (annually 202 units) in taluk hospitals.

2.4 Annual Blood Collection: Tamil Nadu recorded an annual collection 844,908 units which is exceeding the basic requirement of blood according to WHO's one percent criteria in the state. Though the state seems to be self-sufficient in terms of blood requirement, there is a huge disparity in the collection of blood between districts. Ariyalur and Tiruvannamalai collected only 0.1 units of blood per 100 population followed by Nagapattinam (0.2), Viluppuram (0.2), Pudukottai (0.3), Nilgiris (0.3), Ramanathapuram (0.4), Cuddalore (0.4), Dharmapuri (0.5) and Krishnagiri (0.5). The low collection in proportion to population is likely to affect the service delivery in the state.

Moreover, around 46% of the blood banks in the state collected less than 2,000 units per annum, 12% of blood banks in Tamil Nadu are collecting <500 units per annum and 24% collecting <1000 units. Though investments in terms of infrastructure, human resources, equipment and testing modalities are same, output varies from more than 30,000 units of collection to less than 100 units per annum which indicate sub-optimal utilization of existing resources. Considering the higher socioeconomic conditions with the fairly good health care system and access to health care, the blood requirement in Tamil Nadu may be much higher.

2.5 Voluntary Blood Donation (VBD): Around 93% of the annual collection is reported to be through Voluntary donation, and the majority of the districts had reported a higher proportion of voluntary blood donation, with huge variations between districts. However, the percentage of repeat voluntary non-remunerated blood donation (VNRBD) which is considered as the safest is relatively less (around 30%). The key factors affecting VBD are,

lack of awareness, motivation, systematic and organized donor management, lack of initiatives etc.

2.6 Component separation: According to WHO, the ratio of use of blood components and whole blood should be 90:10 since only a limited category of clinical interventions require whole blood. In Tamil Nadu. Only 43% of blood banks have BCSUs and only 49% of all blood units collected were used for component separation. The percentage of component separation in districts ranges from 100% to less than 10%. Majority of blood banks collect and stock whole blood as clinicians are generally ignorant of the practice of component therapy. In addition, lack of trained manpower, space, equipment and supplies, automation for component separation and modern procedures are the key factors affecting the blood component separation. Licensing requirements do not have mandates to suggest the blood banks to process the collected blood into components or for institutions to introduce blood-use audits. Further, considering the significant investments made in BCSUs, poor utilization due to the low volume of collection indicates inefficiency which is very critical.

2.7 Transfusion Transmissible Infections: In Tamil Nadu, the pre-transfusion screening data among donors showed that Hepatitis-B seroreactivity was 0.68% (0.87% - India average) as compared to HIV (0.05% vs India at 0.14%), Hepatitis C (0.11% vs India at 0.34%), and Syphilis (0.07% vs India at 0.17%) (NACO Assessment, State reports, 2016) with huge variation between districts. The higher seropositivity suggests the need for even more improved and efficient donor screening and recruitment strategies, especially in outdoor camps.

2.8 Quality in Blood Transfusion: Quality in Blood Transfusion Services cover the entire transfusion process which includes donor recruitment from voluntary unpaid blood donors from low-risk populations to quality-assured testing for transfusion-transmissible infections, blood grouping and compatibility testing and to the follow-up of the recipients of transfusion.

In Tamil Nadu, there are several challenges that exist in terms of donor recruitment, testing, blood component production and patient side operations of the blood bank. The specific gaps and challenges include, lack of standardized donor counselling and registration process, pre-donation counselling and awareness program, different methods ranging from copper sulphate to colorimetry, POCT devices and cell counters for donor haemoglobin screening, collection related issues (lack of automated recording and GMP audit trails), potential phlebotomy site contamination of blood bags, and lack of cold chain and transportation facilities with systematic tracking documentation.

In terms of Immunohematology testing, most blood banks perform slide method which does not allow optimum antigen-antibody reaction. In terms of Transfusion- Transmissible Infections (TTI) Testing, most blood banks still use rapid tests without follow-up testing. ELISA platform is reported to be unavailable in many blood banks in the state.

Lack of automation in high volume blood banks, standardized protocols, systematic long-term planning for equipment management, reported shortage of quality consumable such as testing kits, and adequately trained human resources are few other reasons that make the access to safe and quality blood, a difficult commodity. In Tamil Nadu, the practice of Internal Quality Control (IQC) for Immunohematology (IH) was reported by 76% of blood banks and IQC for TTIs was reported by 58% of all the blood banks. Only 17% and 8% of the blood banks in the state have enrolled themselves in External Quality Control Systems (EQAS) by recognized providers for immunohematology and TTIs respectively and only four blood banks were accredited by National Accreditation Board for Hospitals & Healthcare Providers (NABH).

2.9 Human resource: Availability of trained human resources is one of the key factors that affect the functioning blood transfusion system. Trained staff are inadequate in proportion to the volume of collection, processing, component separation, and utilization. Less than half of the blood banks in the state had donor motivator or counselor. It is essential to understand that there are no capacity specific staffing criteria and no systematic long-term education and training for all cadres in blood banks in the state. Hence it is important to conduct periodic training programs to improve and assess their skills. As for qualification for BBMO, we have set the qualification criteria as MD Transfusion Medicine/MD Pathology/MD. Immuno Haematology Blood Transfusion (IHBT) and Diploma in Clinical Pathology (DCP). In case of nonavailability of these graduates, MBBS with training in blood bank procedures for 6 months will be qualified for BBMO selection. Blood banks will be provided license only if the specialist, medical officer/lab technician (CMLT and DMLT with one year experience)/ or staff nurse have undergone the mandated training specified for them. Measures should be taken to retain the cadre of medical officers under blood banks in the state.

2.10 Reporting and Data Management: The state is performing well in terms of reporting, 86% submitting regular reports to state drug controller, 92% submitting reports to NACO. However, the use of data for programme planning and management needs improvement. The low level of reporting in E-blood banking and National Haemovigilance Program is a concern. However, redundant data reporting

requirements, lack of dashboards to monitor quality indicators and the absence of feedback on submitted data are significant drawbacks. Training needs to be provided to all clinicians for them to actively report adverse events arising following blood transfusion to the Hemovigilance programme of India (HvPI) portal.

2.11 Technology Updation: There has been a slow adoption of technological advancements in blood banks in the state. Very low proportion of blood banks has analytical automation in spite of the large volume of collection. Lack of computerization also has led to difficulties in data management and day to day operations in blood banks.

2.12 Knowledge and awareness among the public: In spite of the significant improvement, there is still gaps in terms of correct knowledge and awareness among the population on the need for blood and products, voluntary blood donation, patient rights and informed consent. Myths and misconceptions about blood transfusion still prevail. There is no official channel for dissemination of reliable information to the public related to the availability of services, bloodstock availability etc.

2.13 Cost of Services: Though services provided by public health facilities are free of cost, blood banks are permitted to recover processing charges especially when blood bags are given to the private sector in times of emergency. The NBTC guidance for recovery of cost is not being enforced uniformly across the state in both public and the private sector. The inadequacies in voluntary blood donation result in potential commercialization leading to out of pocket expenditure for patients.

2.14 Efficiency in Service Provision: In general, the overall efficiency of services has improved over a period time in terms collection, component separation and reduction in wastage. However, there are significant number of blood banks that report low collection in blood banks, low percentage of component preparation, lack of technology adoption, lack of effective supply chain management system, over-collection through mega blood donation camps, absence of wastage monitoring systems lead to inefficiency in blood transfusion services. These variations should be monitored and avoided by the DBTO of each district.

2.15 Regulatory and Policy measures: National Blood Policy adopted in 2002 gives overall direction for the effective functioning of Blood Transfusion Services (BTS) in the country. However, it is essential to have state-specific policies, regulations and guidelines developed as per the need, and context in the state.

3. Statement of Purpose

The state blood policy reiterates the commitment of the state to ensure universal access to adequate supply of safe blood that fulfills standard quality requirements, sourced from repeat non-remunerated voluntary blood donors that have been collected, processed, stored and transported efficiently under optimum conditions by competent personnel in licensed blood banks or storage centres. The policy further promotes need-based, rational and safe clinical practice of transfusion, without any discrimination, including the adoption of haemovigilance processes for patients and donors. To this end, the state is committed to the development of empowered human resources and the use of necessary innovation to achieve a coordinated blood transfusion service in order to fulfill state and national level health care goals.

4. Specific Objectives

The overall aims of this policy and implementation framework document are to provide direction to the state to develop and implement appropriate strategies and programmes leading to universal access to blood and blood products.

The specific objectives are,

- To strengthen organizational/management structures and operations for a well-coordinated service delivery
- To ensure timely universal access to blood and components
- To promote repeat non-remunerated voluntary blood donation
- To implement quality management systems in all the blood banks in a phased manner for provision of safe and quality assured blood/components in adequate quantities
- To increase awareness about blood and components and ensure their rational use in clinical practice
- To ensure appropriate and evidence-driven regulation, policies and guidelines related to blood transfusion services in the state.

The expected outcomes from this policy framework and further implementation are,

- Improved collection through voluntary non-remunerated blood donation
- Universal access to safe blood and blood products in the state

- Increased awareness and rational use of blood and blood products
- Quality assured, safe and uniform blood transfusion services across the state
- Reduced transfusion-transmitted infections
- Improved multistakeholder engagement and public-private partnerships
- Improved health care service delivery and health outcome

5. Guiding Principles

The policy and implementation framework was developed considering the following guiding principles integrated into all the components,

1. Universal access
2. Inclusive and participatory (vis a vis non-discriminatory)
3. Equity
4. Efficiency
5. Quality and Safety
6. Innovation and technology
7. Patient centred
8. Ethical practices

6. Policies and implementation framework

The policy and implementation framework has been divided into six components that are critical for the effective and efficient functioning of blood transfusion services in the state.

1. Organization/Management of Blood Transfusion services
2. Universal Access to Blood and Products
3. Voluntary non-remunerated blood donation (VNRBD)
4. Quality Management Systems
5. Patient Blood Management
6. Appropriate Regulation, Policies and Guidelines

6.1 Organization/Management of Blood Transfusion services:

6.1.1 Considering the need for better coordination and based on Supreme Court's direction, the policy proposes to have the **State Blood Transfusion Council (SBTC) as the coordinating body** to plan and implement activities related to BTS in the state.

The SBTC will be primarily responsible for coordination and functioning of Blood transfusion Services. The Chief Secretary of the state will be the chairperson of SBTC. There is a need for regular coordination meetings (once every two months) to plan and review the activities in the state under the supervision and guidance of the Chief Secretary. SBTC will function as the highest unit with regulatory, administrative, legislative and financial authority concerning BTS services in the state. The SBTC will be responsible for developing the roles and responsibilities, monitor and evaluate the progress of the programme periodically. The members of the SBTC will be Executive Secretary - Principal Secretary, Mission Director (NHM), Project Director (TANSACS) representatives from State AIDS Control Society, all three Directorates, State Drug Control Authority, experts from the specialty of Transfusion Medicine, NHM coordinator, District Blood Transfusion Officers (DBTO) (HOD of Blood Bank/ Senior most Blood Bank Medical officers/ HOD of Pathology), Blood Bank Medical Officers from both public and private sector.

6.1.2 The Policy proposes to have a **District level planning and coordination body (District Blood Authority)** headed by the District Collector and closely supervised by the JD (Medical Services). The members of this body will be Deans, DBTO, DDHS, District Drug Inspector, district coordinator from 108, representatives from CEmONC and representatives from all private blood banks. The DD (Public Health) may be the Nodal officer with representatives from other relevant departments. The key roles and responsibilities of this body will be to review demand and supply of blood, assess the gaps and challenges and develop an 'Annual Blood Donation camp Schedule' for the district in order to maintain adequate stock availability including rare blood groups for emergency cases as well. The responsibility of blood transfusion services at the district level is to ensure adequate supply to all those in need and thereby absolve the patient and his/her relatives of "finding blood". The District Blood Authority will review the annual blood donation camp schedule and disseminate it to the community. The District Blood Authority is required to meet once in a month to review the district level BTA activities. The district activities will be reviewed semi-annually by the SBTC.

6.1.3 The policy emphasizes the need for **coordination/collaboration** between public, private and not-for-profit blood banks in the district for maximum utilization available blood units and facilities. The policy proposes to develop a guideline document for better coordination between blood banks, blood storage centres and healthcare facilities. The district blood transfusion officer will be responsible for the coordination this activity and ensure that 20% of the blood collected by private

blood banks is submitted to the District HQ hospital or Medical College hospitals which are 'giant consumers'

6.1.4 The DBTO should ensure that the 20% of blood collected includes the rare variety blood groups such as O-negative which are difficult to procure for emergency cases.

6.1.5 SBTC will be the single channel for dissemination of policy related communication to all concerned stakeholders at the district and state level.

6.1.6 In order to ensure evidence-based planning, regular review and analysis of available data (eg SIMS) are recommended for programmatic correction and future planning including creating state-level benchmarks and feedback to individual blood banks. The SIMS data should be regularly validated by SHDRC.

6.1.7 The policy proposes a coordinated effort to ensure adequate financial resources to achieve the stated goals. Continuous revenue generation for sustainable funding needs to be ensured that can be from government allocation - both state and central governments, CSR funding from corporates and donors. The Government funding should prioritize activities such as research, IEC, modernization and innovation of BTS in the state.

6.1.8 Considering the high percentage of blood banks with "under renewal" license status, it is suggested to have specifications that define timely inspection and resolution of non-conformances during licensing using a standard checklist. The SBTCs and District level coordination body may provide necessary technical and financial support to address the non-conformance. If required, risk based surveillance can be conducted at frequent intervals (2 yrs) to renew the license.

6.1.9 The policy recommends the implementation of process automation and unified information systems at all levels of the blood bank functioning to avoid manual procedures and improve workflow efficiencies.

6.1.10 The policy suggests collaborations for new research and development initiatives in the domain of BTS – both scientific and operational - in coordination with the medical colleges and centres of excellence in the state. A Technical resource group can be created to coordinate this effort. A corpus of funds to support such activities may be also considered.

6.2 Universal access to blood and related services

Universal access to safe blood and products depends on availability of blood banks, adequacy of blood collection, the percentage of voluntary blood donation, and affordability of services. BTS should be able to be commensurate to the demand posed by the health system.

6.2.1 The policy seeks to ensure adequate number of blood banks and blood storage centres with adequate inventory of blood and components to ensure universal access. Considering the huge number of blood banks available in the state, the policy proposes to ensure at least a **Blood Storage Centre (BSC)** within a predefined travel time (suggested 45 minutes) in proximity to even the lowest level of health care facility where maternal health care delivery and trauma care is currently available and blood transfusion services are required. The DBTO is required to closely monitor the activities of all the listed BSCs and ensure that the BSC is fully functional. Additionally, DBTO (under a mandate from SBTC) is required to monitor that the Blood Collection Transportation Vehicle (BCTV) or van is within 45 minutes reach of the health facility where the BSC is established. The BSC need to be distributed in proportion to the population and available health care facilities (i.e clinical demand).

6.2.1.1 A GIS mapping will be done by the State Health Data Resource Centre (SHDRC) team to visualize real-time availability of blood and blood products. This will also display the nearest blood bank or blood storage centres for public and private healthcare facilities. This will inform the policymakers about current geographic access-related issues and help ensure that no further crowding of blood banks occur in a small geographic location.

6.2.1.2 All healthcare facilities need to be linked to a blood bank or a storage facility.

6.2.1.3 It is essential to track supply, demand, utilization and wastage and decide on benchmarks for the blood banks in the state. Analysis and review of results may be carried out on a quarterly basis at the district and state level by the DBTO and SBTC/SACS.

6.2.2 In order to ensure efficiency of collection of blood in each district, the blood banks that collect less than 2000 units of blood and blood storage centres that utilise less than the actual clinical demand may be assessed to understand factors hindering the collection and take appropriate steps to address the issues. Those blood banks that do not have the scope for improvement may be converted as blood storage centres considering geographical factors and logistics involved.

6.2.3 The policy suggests that the SBTC sets clear and stringent **guidelines, standards and regulation for conducting camps** especially, mega camps for both public and private sectors. The submission of an action-plan has to be made mandatory before conducting camps vis-à-vis distribution of collected units as per need and consumption, transportation and storage. This is critical as bulk collection may lead to wastage due to the short lifespan and consumption pattern in healthcare facilities.

6.2.4 The policy emphasizes the need to **transfer blood** from one blood bank to another to overcome the inequality in the availability of blood. The BSC which are unable to utilise the blood and blood component units within the mentioned shelf life period, need to transport it to the Mother Blood Bank and get a refreshed stock. State-specific guidelines need to be immediately developed and operationalized to enable inter-blood bank transfer of blood, irrespective of state/district borders. Adequate facilities for transporting blood and its components including proper cold-chain maintenance shall be made available to ensure appropriate management of blood supply.

6.2.5 In order to achieve self-sufficiency for components in line with 90% component separation criteria as recommended by WHO, provision of adequate human resources, training, and infrastructure is suggested.

6.2.5.1 The policy seeks to optimize the distribution of BCSUs based on geographic issues, clinical demand and administrative considerations. The SBTC will be responsible for reviewing the information and making decisions. These selected BCSUs must be strengthened to provide efficient blood component services to the area under coverage. Adequate human resources, equipment and consumables must be provided – based on the productivity. SBTC will include a grievance redressal team to actively seek and address issues related to biomedical equipment maintenance in all the BSC and Blood banks.

6.2.5.2 The policy seeks to achieve optimum blood collection and component production with minimal wastage and maximum utilization of all products through transparent inventory management, bulk transfer and product derivation from the surplus.

6.2.5.3 According to NACO, consent has to be provided by donor regarding excess plasma usage.

6.2.5.4 Considering the lack of awareness among clinicians on the use of components and its rational use, the policy suggests sensitization and capacity building of all clinicians. DBTO is required to convene a CME meeting once every two months to discuss about the rational use of blood and blood products, provide feedback and disseminate the standard protocols on the rational use of blood and blood products.

6.2.5.5 It should be made mandatory for the Blood banks to report to NIB which falls under the Haemovigilance Programme of India.

6.2.5.6 The blood banks which provide 24x7 obstetric, trauma and other emergency services, must have a dedicated lab technician for night time (after hospital hours).

6.2.5.7 Automation for component separation and modern procedures such as pooling of components are suggested for blood banks which collect more than 20000 units of blood per year and have a blood component separation unit

6.2.5.8 The key challenge of wastage due to expiry and other factors especially for the components with low lifetime need to be monitored and efficient inventory management system needs to be implemented in all blood banks in the state. In addition, education of providers, enhanced transport containers, robust temperature monitoring systems, and alteration of RBC storage protocols, continued follow-up, including monthly meetings with clinical staff, blood wastage audits, and retraining of blood bank staff are suggested.

6.2.6 The policy proposes to have uniform pricing of blood and its components to be fixed in public and private sector.

6.2.7 The policy will ensure that no patient will be denied access to blood for economic reasons. Hence, the policy proposes to provide blood and components for maternal health and child health needs free of cost in public sector. In this regard, linkage with the mother's unique authentication PICME number is mandatory for

reimbursement of the cost incurred. The cost may be borne by JSSK Free Blood Services fund through PIP.

6.2.8 The policy stresses the need for innovative low-cost cold chain management and monitoring systems and appropriately equipped vehicles/vans to be made available to transport blood on demand, between blood banks, storage units and healthcare facilities.

6.2.9 The policy emphasizes the need for generation of knowledge through behavior change communication (BCC), IEC to increase the awareness about VNRBD, Transfusion Transmissible Infections (TTI) awareness among donor and recipient population and visibility about state-run programmes for blood transfusion.

6.2.10 The policy seeks to ensure registration of 100% blood banks both private and blood banks, in the online blood management system (e-blood banking). All necessary information such as camp details, stock availability etc. may be made available to relevant stakeholders.

6.3 Voluntary non-remunerated blood donation (VNRBD)

The policy envisages to achieve 100% voluntary non-remunerated blood donation (VNRBD) including at least 50% of repeat donors to ensure a safe, secure and sufficient supply of blood and blood products. The policy seeks to encourage innovative and cost-effective innovative measures to achieve this.

In India, it is essential to clearly define VNRBD as per international standard as there are misperceptions about this. *“Voluntary non-remunerated blood donation (VNRBD) means that a person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary non-remunerated donation”*

6.3.1 Reluctance and unwillingness towards blood donation are mainly due to inadequate and incorrect knowledge for its necessity and misconceptions and hence the policy suggests to have appropriate IEC and other promotional activities that primarily clear the myths and misconceptions. There should be targeted messages

and campaigns focusing on different groups including young adult population with the aims of increasing donation rate among the younger generation, increase the number of repeat donors and to secure wider community support for blood donation. Organizations dealing with youth such as YRC, Scouts, NSS and NCC must be co-opted to assist in this campaign. Eligible family or replacement donors should be motivated to become repeat voluntary blood donors.

6.3.2 The policy emphasizes the need to track blood donors using the Unique Identification system –linked to biometric information for authentication to ensure prevention of frequent donations by professional donors.

6.3.3 The policy suggests having dedicated manpower for VNRBD recruitment, motivation and retention in blood banks where the requirement for blood is high (> 5000 donations per annum). Especially counselors to conduct pre and post donation counseling sessions in order to encourage and retain the donors and refer the deferred donors to the ICTC centres, STD clinics and specialty liver clinics to manage and where needed treat the detected infections. Since we lose many deferred donors, it is important to ensure the biometric details of the donor is taken before the screening of donated blood (at the time of donor registration).

6.3.4 The policy emphasizes the need for having institutional, District and State level donor registry.

6.3.5 Adequate publicity must be given about the availability the dedicated 104 phone number in the state that people can use to get assistance for issues regarding blood donation. Social media platforms must be effectively utilized to increase awareness among the general public.

6.3.6 The policy emphasizes the need for a voluntary blood donor recognition program – such as a letter of appreciation, greeting cards, SMS reminder etc and creation of Voluntary donor network to encourage and retain blood donors. Donors can be provided with cards to identify them as such and reflect their number of donations. Organise international and national days to motivate and appreciate donors.

6.3.7 The policy recommends dedicated blood collection facilities that can be developed in public sector in order to facilitate ease and convenience of donation for regular donors. This will require regulatory permissions. All the blood collected here

must be transported with cold chain to the designated component preparation facility.

6.3.8 The policy seeks to promote multi stakeholder involvement to promote VBD program – other government departments, NGOs and Red Cross to increase awareness and develop recruitment strategies. SBTC will be accountable for this activity. The policy recognizes the potential of mobile blood donor facilities to improve VBD program. This also includes the strengthening of BCTV network and placing them on priority in high donor/ demand areas in the district. A well-planned program must be designed around this including awareness, donor –outreach, GIS mapping and social media platforms to encourage systematic blood donation.

6.3.9 Realizing that women form only a small proportion of voluntary donors there must be a concerted effort to increase awareness of dietary and health practices that will lead to better gender representation.

6.3.10 Disaster Management Systems: For all natural and man-made disasters, we should have contingency plans to supply blood and blood components. This requires assessment, efficient communication systems, planning and dedicated teams at four regional centres across the state.

6.4 Quality Management Systems

6.4.1 The policy proposes a systematic implementation of quality systems in blood banks. The baseline assessment of blood banks of Tamil Nadu (NACO 2016-17) provides a platform for initial planning and interventions. The SBTC may be authorized to prioritize the areas that need intervention to start with.

6.4.1.1 Blood banks that have received a high score in the assessment will undergo Quality Management Training in a phased manner.

6.4.1.2 The remaining blood banks must implement corrective action to strengthen their baseline status to achieve a score of >75 when they can also be phased into QMT activities.

6.4.1.3 Blood banks that have undergone QMT must be supported for implementation of QMS activities through the provision of budgetary or technical assistance as needed.

6.4.1.4 All blood banks must participate in proficiency testing programs for all testing procedures.

- 6.4.1.5 All blood bank staff must have access to continuing education program.
- 6.4.1.6 Transfusion committee must be set up in all healthcare facilities and report to District Transfusion Authority. The HTC team should meet every quarter to reiterate on the usage pattern of blood and its components and to impart clinical awareness among clinicians regarding the rational use of blood and its components
- 6.4.1.7 All blood banks must enroll in the national haemovigilance program of India (HVPI).
- 6.4.1.8 All blood Banks must take adequate and required steps to implement automation related to blood bank processes and maintain an optimal human resource based on their annual blood unit collection to ensure the desired quality of blood banking practices.
- 6.4.1.9 All blood banks must prepare an individualized inventory control management plan and bulk transfer policy based on their annual blood unit collections to maximise the usage of this precious resource (blood) and to prevent its wastage.
- 6.4.1.10 All blood banks attached to academic institutions who have adequate facility, human resources and competency must take requisite steps to start M.D. programme in Transfusion Medicine/Immunohematology and Blood Transfusion to maintain a pool of well-qualified clinicians and to expand this field for maintaining quality service of blood banking in the State of Tamil Nadu.
- 6.4.1.11 Graduates from Diploma in Clinical Pathology (DCP), MD Pathology, MD Transfusion medicine need to be given priority and be designated as Blood Bank/ Blood Storage Medical Officers.** see also clause 6.4.5.1
- 6.4.1.12 The SBTC shall liaise with the Directorate of Medical Education (DME) to provide immediate placement opportunities in government blood banks for graduates who have completed the Certified Medical Lab Technician (CMLT) courses successfully in recognized centres such as CMC, Vellore and the Tamil Nadu Dr. MGR Medical University or any university that is recognised by the State and Central government
- 6.4.1.13 The Health Department, Government of Tamil Nadu along with its associated funding and monitoring agencies should support and ensure timely supply and maintenance of necessary and mandatory equipment and necessary accessories along with required financial support.
- 6.4.1.14 A technical cadre of blood bank staff – clinical, nursing and technical must be developed to ensure continuity of quality management systems and to maximize benefits of capacity building efforts. Adequate medical

personnel must be positioned to ensure that competent person (medical officer) is in charge of the blood bank.

6.4.2 Standardized quality assured donor-friendly operations will be implemented and supported.

6.4.2.1 There is a separate section dealing with Voluntary Non-remunerated Blood Donor where details will be provided. The mention here is for emphasis.

6.4.3 There is a commitment to ensure the provision of resources to ensure that all blood banks meet desired quality of testing in terms of platforms, reagents and proficiency, both in IH and TTI domains.

6.4.3.1 All blood banks must be supported to enhance immunohematology testing and infectious disease testing based on the level of services offered.

6.4.3.2 For centrally procured consumables there must be comprehensive guidelines for acquisition, quality assurance and continuity of supply.

6.4.3.3 Adoption of technology that leads to enhanced quality and effective delivery of services in a cost-effective manner will be given priority.

6.4.3.4 The audit committee is required to monitor and evaluate the compliance to cold chain conditions practiced during transportation of reagents, blood and blood products in the institution, BCTV and vehicles.

Measures will be put in place to ensure efficient lifecycle management of equipment through standardized procedures.

6.4.4 A Senior Lab Technician trained in the field of blood transfusion services should be made the quality manager at the institution level.

6.4.5 The policy seeks to commit to ensuring adequate qualified proportional human resources to ensure around the clock access to blood and components for patient care.

6.4.5.1 A cadre of blood bank staff – clinical, nursing and technical must be developed to ensure continuity of quality management systems and to maximize benefits of capacity building efforts.

6.4.5.2 Adequate medical personnel must be positioned to ensure that competent person (medical officer) is in charge of the blood bank.

6.4.5.3 Personnel must be made available proportional to the volume of blood donors, component preparation (if applicable) complexity of operations and time of service availability at the facility.

6.4.5.4 Resources for the continuing in-service refresher training and education must be made available to all blood bank staff. It must be mandatory for all staff to undergo at least one training program every two years and demonstrate competency.

6.4.6 The policy seeks to achieve optimum blood collection and component production with minimal wastage and maximum utilization of all products through transparent inventory management, bulk transfer and product derivation from the surplus.

6.4.7 The policy emphasized the need for compliance with current state and national regulation for biomedical waste management activities.

6.4.8 List of Common Bio-medical Waste Treatment Facilities (CBWTFP) for each district must be compiled and disseminated and linkage of blood banks to the local company must be ensured.

6.4.9 All blood banks should be autoclaved before disposal by deep burial.

6.5 Patient Blood Management

Safe and rational use of blood is essential to reduce unnecessary and unsafe transfusions and to improve patient outcomes and safety, thus minimizing the risk of adverse events including errors, transfusion reactions and transmission of infections.

6.5.1 The policy seeks to actively promote awareness about existing blood components and rational blood use among clinicians. Considering the poor awareness level on “rational use of blood and blood products”, it is suggested to develop an action plan to sensitize the clinicians of Medical Colleges at the first phase followed by District hospitals where components are predominantly used. Continuing Medical Education Programmes (CME) on rational use blood may also be considered.

6.5.2 It is essential to create a group of clinicians as resource persons to provide training and continued inputs.

6.5.3 It is suggested to develop Informational material about blood components, including contents, shelf life, indication and dosage, relevant lab tests needed to assess the patient, protocols to be followed, clinical use guidelines and impact of wastage of blood/components.

6.5.4 It is proposed to make Blood Safety and rational use of blood/components an agenda for various professional medical bodies. SBTC should ensure that all latest and advanced technological methods for screening the blood for TTI, for example, Nucleic Acid Test (NAT) is made mandatory in all the blood banks in a phased manner.

- Promote joint awareness programs with State level arms of National societies of Medical, Surgical, Obstetric and Paediatric specialties.
- Ensure access to haematology laboratories to ensure reliable testing to provide evidence needed for rational blood transfusion.

6.5.5 Clear protocols which specify the rational use of blood and blood products mentioning which component needs to be used for which ailments, to reduce unnecessary transfusions and minimize the risks associated with transfusion, and to encourage the use of alternatives to perform transfusion, wherever possible.

6.5.6 The policy suggests the need for transfusion committees in all Medical College and District hospitals which will be responsible for monitoring and prevention of adverse effects of transfused blood products. In addition, it is suggested to promote hemovigilance programs for the blood banks to ensure patient safety by tracking and reducing the occurrence of adverse events associated with blood donations.

6.5.7 The policy emphasizes the need for implementing an evidence-based transfusion protocol in all the Medical College and District hospitals with continued reinforcement on the rationale for transfusion.

6.5.8 State level unique ID: to register both donors and recipients. This ID will be linked to the biometrics of the person which will help us communicate with the donors and recipients at regular intervals.

6.5 Regulation, Policies and Guidelines

Appropriate policies, regulations and guidelines are very critical to ensure right blood, for the right patient at right time and the right place. Policies, regulation and guidelines provide strategic direction for the overall functioning of blood transfusion services. But, they need to be appropriate, contextual, and feasible and should lead to better patient service delivery and outcome.

6.5.1 The policy emphasizes the need for blood banks holding a valid license. It is proposed to have a transparent information system which would indicate all the details of non-conformance, response by blood banks with actual timeline (days). It is essential to fix a time limit for renewal and issue of new license. Undue delay beyond a certain time needs to be addressed by SBTC. Regular review by SBTC in coordination with drug controller is critical to ensure that that licensing for all blood banks are current.

6.5.2 The policy suggests that BCSU in the states must be restricted to identified zones or regions based on geographical issues, collection, and requirement. Unnecessary proliferation must be avoided to prevent fragmentation of resources.

6.5.3 It is suggested that the Drugs and Cosmetics Act 1940 and Rules 1945, be reviewed considering the current context, technical advancements and other developments happening in blood transfusion services.

6.5.4 The policy seeks to ensure adequate and qualified human resources to ensure around the clock access to blood and components for patient care. It is suggested to develop guidelines for human resources in blood banks based on specific criteria. Personnel must be made available proportional to the volume of blood donors, component preparation (if applicable), the complexity of operations and time of service availability at the facility.

6.5.5 The policy suggests the need for having guidelines for training plan and schedule which includes ongoing in-service refresher training and education to all blood bank staff. It must be mandatory for all staff to undergo at least one training program every two years and demonstrate competency.

2. Conclusions

The provision of universal access to safe blood for those who are in need is the responsibility of the state. The National assessment of blood banks provides evidence that the provision of blood and the efforts to ensure blood safety in the state of Tamil Nadu are better as compared to the country scenario. The demand for blood may be due to the increased access to health care services which also indicates the strength of the healthcare system in the state. The concerted efforts of the state and national initiatives including various health insurance schemes and increased awareness about healthcare due to high literacy are contributory factors for the increased access to healthcare to the population.

This policy framework has been designed to address all the building blocks of health systems suggested by WHO such as, health service delivery, health workforce, health information systems, access to essential medicines, health systems financing and leadership and governance. Universal access, Inclusiveness, Equity, Efficiency, Quality and Safety, Innovation and technology, Patient centeredness, and Ethical practices were the principles adopted in the development of the policy and implementation framework.

Specific gaps have been identified through a comprehensive literature review and secondary data analysis which are classified under 6 major sections. Besides proposing interventions in all the six domains, high impact issues that are to be addressed in the short term have been prioritized. Commonly recurring themes such as equipment availability and systematic training have been comprehensively addressed. The need for analytic and process quality is identified as an area of importance and participation in proficiency testing is mandated. Implementation of appropriate automation justified by volume of work and quality parameters has been mooted. The provision and retention of trained and competent human resources at all levels were emphasized. There is a renewed commitment to focus on voluntary blood donor-related activities since that is the starting point of reliable and safe blood transfusion services.

One of the significant policy recommendations is the constitution of a district level authority to coordinate blood donor-related activities at the district level. This will ensure a locally coordinated contextually sensitive response to ensure adequacy and access to blood while ensuring decreased wastage. Ongoing monitoring and evaluation is highlighted as a requirement for the successful implementation of proposed policy initiatives and activities. The role of the SBTC is now even more crucial for robust data review and evaluation systems that will provide feedback to blood banks which will help in continuous improvement. The use of modern technology such as GIS systems linked to demand and supply data will assist the authorities to address access related issues in a scientific manner.

The need for evidence-based programs is an essential factor highlighted in this policy framework and the SBTC has been empowered to propose and partner with suitable organizations to conduct data analysis and research that will provide evidence for better policies, programs, and regulations. There is an effort to ensure financial fairness and address inequity in access to blood transfusion services among the vulnerable populations.

Realizing that provision of financial support is critical, a coordinated effort has been suggested to ensure mobilization of adequate resources.

The policy and implementation framework for blood transfusion services in Tamil Nadu which is first of its kind at the state level envisage that universal access to safe and quality blood and blood products will be made possible in a time-bound manner which will ensure elimination of deaths due to lack of blood and ensure optimal health outcome in the state.

3. References

To be completed after comments

4. Annexures

To be completed after comments

Summary of actions resulting from policy shift for achieving analytic and component quality in the lab - Phase 1 (Phase 2 in Shaded rows)			
Parameter	Current	Proposed shift	Gaps
Donor screening – haemoglobin	Copper sulphate	1. Quality Controlled copper sulphate in blood banks	The copper sulphate method is dependent on specific gravity. With temperature fluctuation in the screening area, the method will not provide reliable results. This is accentuated in out-door camps.
		2. Explore low-cost reliable haemoglobin analysis devices for the blood bank and field testing	
IH - Blood Grouping	Slide and Tube	Tube only	Tests are reliable and reproducible More sensitive Slide test does not allow optimum antigen-antibody reaction. There is no scope for enhancing of this reaction with additives when done on slides; can be done on tubes – LISS, Albumin and Coombs phase
Automation for blood group testing	Column agglutination (CAT)	When volume is more than 250 samples per day (patient and donor)	Reliable Reproducible Audit trail Data management
Reagent selection	Centralized	1. Centralized Standard screening of candidate reagents by the designated lab.	Need documented procedure for selection of IH reagents. No clarity on how the

		2. Reporting of quality by all blood banks – lot level – on supplied reagents	quality of supplied reagents is checked and procedure if the supplied reagent is not of desired quality.
IH - Antibody screening	Performed with random pooled O cells (not phenotyped)	1. Tube test Pooled O cells- at sub-district level BB.	Detection of unusual antibodies that will prevent immune reactions
		3 cell panel at District BB and above	
TTI screening	Rapid	1. To be performed on <10% of collected blood	1. All samples screened by rapid must be subjected to ELISA 2. Rapid tests have lower sensitivity and specificity in day-to-day operations. While the overheads and infrastructure required is less, the sensitivity and specificity is to be reviewed critically.
	Platforms available: ELISA - Manual	Manual – where volume is <2000 per annum	Hub and spoke operation will help to reduce the number of testing facilities – improve QA and cost Initially district level. Need administrative and regulatory authority's permission for testing of concept.
	Automation ELISA/Chemiluminescence	Semi-Automated ELISA when for 2000 to 15000 collections and fully automated systems when collection exceeds that.	Regional testing
	3 rd Generation	Latest generation of ELISA where available	Increased Sensitivity leading to early detection of TTI positive samples and use of referral linkages.
IH - Compatibility testing	Slide	To be stopped Only tube test to be done	Not reliable – several antigen-antibody reactions will not occur without optimum conditions. This can potentially lead to

			transfusion reactions and incompatible unit transfusions
	Automation Column agglutination (CAT)	When volume is more than 250 cross-matches per day	Reliable Reproducible Audit trail Data management
Components	Production Within 6 hrs QC of components 82/104 BB reported; Currently 19.5% of these BB are NOT doing QC Need to increase to 100% Need to ensure that all QC parameters are covered	<ol style="list-style-type: none"> 5. 100% Component production to start within 6 hours 6. Mandatory to perform QC of components 7. Document review and action taken in case of failures 8. Storage - & transport : Cold chain maintenance 9. Linkage with referral centre for lab 	Reasons for not reaching 100% to be explored - *Production Adequate space, equipment and trained personnel. * Currently ##% of blood banks perform component QC in TN. This has to increase to 100%. Component QC need to be reviewed rigorously

IMPLEMENTATION FRAMEWORK

	IMPLEMENTATION FRAMEWORK FOR STATE BLOOD POLICY			
	Components	Responsible person/team	Directorate	Timeline
A	Organization/Management of Blood Transfusion services			
	i, Establishment of State Blood Transfusion Council (SBTC) headed by Chief Secretary	Project Director, TANSACS	TANSACS, NHM	
	ii, Establishment of District level Planning and Coordination body	Project Director - TANSACS, District collector	TANSACS	
	iii, Coordination between public and private blood banks	Project Director - TANSACS, State Drug Controller	TANSACS	
	iv, NEW Research and Development initiative	State Drug Controller, Director of Medical Education, Deans/Dept of Transfusion Medicine of Govt/private medical college hospitals	DME	
	v, Evidence based planning and monitoring, Data validation	MD NHM, PD TNSACS	SHDRC-NHM, M & E wing -TANSACS	
	vi, Finances	State Grants, MD NHM, PD - TANSACS,PD TNHSP (CMCHIS)	TANSACS, NHM	

	vii, Formation of audit committee at District Level	SBTC, DBTO	SBTC,DBTO	
B	Universal Access to Blood and Blood Products			
	i, Mapping of blood banks/blood storage centers	DPH, State Drug Controller for Private blood banks, DME/DMS for Government BBs and BSC	DPH	
	ii, Strengthening of Blood Component Separator Units	PD - TANSACS	PD - TANSACS,DME, DMS	
	iii, Strengthening of Blood Storage Centres	PD - TANSACS, DBTO	PD - TANSACS,DME, DMS, DPH	
	iv. Active surveillance of equipments used in BBs and BSCs, BCSU for issues related to biomedical equipment maintenance	DMS, DME ,MD TNMSC	PD - TANSACS,DME, DMS, DPH	
	v, Monitoring the BCTV functions	DBTO, CMO, BMO, Medical Superintendent of concerned Public health facilities	PD - TANSACS,DME, DMS, DPH	
	vi, Demand based supply and reducing wastage	DBTO, PD -TANSACS	SBTC, DBTO	
	vii. E-Blood Banking (SIMS/Erakt kosh)	PD TANSACS, MD NHM	M & E wing of TNSACS & SHDRC	
	viii. Utilizing 'data logger' to ensure cold chain maintenance	SBTC, DBTO		

	viii, Mapping of HR: Doctors, nurses, lab technicians, supervisors, counsellors, MPW, DEO etc at institutional, district, state level	DBTO, PD -TANSACS	PD - TANSACS,DME, DMS, DPH	
	ix. Audit of storage centres for cold chain maintenance	SBTC		
	x. Establishment of a centralized lab at district level	Drug controller, SBTC		
	XI. Establishment of centralized blood bank at district level after conducting assessment of gaps and geographical requirements	Drug controller, SBTC, DBTO		
C	Voluntary Non Remunerated Blood Donation (VNRBD)			
	i. Conduction of blood donation camps & follow up on distribution of blood bags based on need (Public & private)	DBTO, PD -TANSACS	PD - TANSACS,DME, DMS, DPH	

	ii, Ensuring that 20% of blood collected through private camps are handed over to the Government blood banks	DBTO, Drug controller, SBTC	State drug controller, SBTC	
	iii, IEC-BCC activities for donors	JD IEC TANSACS, DPMU coordinators	PD - TANSACS,DME, DMS, DPH	
	iv, Institutional, District & State level blood donor registry	DBTO, PD -TANSACS	PD - TANSACS,DME, DMS, DPH	
	v, Creation of units to collect blood in places frequented by public (apart from Blood bank)	MD NHM & PD TANSACS	TANSACS, NHM	
	vi, Collaborate with 1or 2 key stakeholders from Private blood banks, NGOs for to increase number of vountary blood donations	PD TANSACS	SBTC	
	vii, Submission of annual voluntary blood donation camp plan at the district level	DBTO, SBTC	SBTC, DMS, DMS, DPH	
	viii, Ensuring donor welfare by referring donors found positive for potentially hazardous infections & diseases during counselling, to the concerned department specialist in hospitals & follow up	PD TANSACS	SBTC, DME, DMS, DPH	
D	Quality Management Systems			
	I, Ensure entry and maintenance of valid real-time data online for SBTC access 24x7	SBTC	DME, DPH, DMS	

	ii, Equipment maintenance and regular check up CAMC, AMC updates linked with toll-free biomedical equipment maintenance number	MD TNMSC, PD- TANSACS	TNMSC	
	iii, Ensuring disposal of blood and blood products in compliance with Biomedical waste management rules, 2016	DMS, DPH, DME	DMS, DPH, DME	
	iv, Providing quality management training to all staff employed in Blood Component centre, blood Bank, storage centre (both public & private sector)	SBTC	TANSACS, Drug Controller	
	V, Enrollment of all Blood Banks & storage centers in national haemovigilance program of India (HvPI), External Quality Assessment & perform mandatory Internal Quality control in each facility	SBTC, State Drug controller/DME/DMS/DPH/NHM	TANSACS, State Drug controller, NHM	
E	Patient Blood Management			
	i. Periodical continuous medical education programs, sensitization workshops on Blood banking principles	DME, SBTC(public & private)	DME, TANSACS	
	ii. Creation and dissemination of evidence-based transfusion protocols, information material on rational use of blood & blood components through books and webinars	SBTC, DME/DMS/ Private Stakeholders, eg., CMC, Vellore	TANSACS	

	III. Transfusion committees at MCH & DHQ	DBTO, DME,DMS & SBTC	TANSACS,DME,DMS	
	iv, Ensuring safe blood availability by providing latest & approved technology, suitably assessed by experts in all blood banks	SBTC	TANSACS	
	v. Train clinicians in reporting signals under haemovigilance program of India run by NIB	DME		
F	Appropriate Regulation, Policies and Guidelines			
	i.Ensure rational deployment of adequate and trained human resources to ensure around the clock access to blood and components based on the demand faced by Hospitals	SBTC& Drug Controller, DME	TANSACS	
	ii, Fast tracking graduates who have completed MD Transfusion Medicine, MD Pathology, Diploma Clinical Pathology through MRB to be placed in BTS services	Chairman-MRB ,DME, DMS	DME, DMS	
	iii, Improve HR in BTS by allowing more graduates to do CMLT course in CMC Vellore and Dr MGR University	PD - TANSACS, DME	DME, TANSACS	

	iv, Conduct periodic in-service refresher training and education for all blood bank staff in private & public sector; Review and revise key topics as suggested by SBTC	SBTC& Drug Controller	TANSACS	
	v, Ensure that all blood banks& blood storage centres hold a valid dual license approved by SBTC & validated by Drug Controller	SBTC& Drug Controller	Drug controller, TANSACS	
	vi, Plasma for fractionation IP - Rollout donor consent forms	State Drug Controller, SBTC, PD- TANSACS, DBTO	DME, DPH, DMS	

ⁱ World Health Organization (WHO), Blood safety and availability, Fact sheet, Reviewed June 2017

ⁱⁱ Global Burden of Diseases study in Tamil Nadu shows that mental health disorders contributing to many Years of life lost (YLLs) in 2016, India: Health of the Nation's States, The India State level Disease Burden initiative, 2017

ⁱⁱⁱ Sample Registration System (SRS), Vital Statistics, Government of India 2013

BLOOD TRANSFUSION SERVICES - Budget

Name of State

1.5	Blood Safety					
S.No.	Sub-Component	Cost Head	Unit cost in Lakh	Items/ Activities	No of Blood Banks	Allocation (Rs. In Lakhs)
1	Model Blood Banks	Consumables	4.76	Glasswares, plastic wares, instruments, chemicals and emergency medicines	1	4.76
		Salary	35.52	Salary of 3 Mos, 3 SNs, 3 LT, 1 Counsellor, 1 Lab Attendant, 1 Data Entry Operator, Security, Housekeeping, through outsourcing	1	35.52
2	MBB with BCSU	Consumables	4.00	Glasswares, plastic wares, instruments, chemicals and emergency medicines	37	148
		Salary	19.08	Salary of 2 Mos, 2 SNs, 2 LT & 1 Counsellor	37	705.96

3	DLBB	Consumables	0.75	Glasswares, plastic wares, instruments, chemicals and emergency medicines	51	38.25
		Salary	10.32	Salary of 1 MO, 1 SN, 1 LT & 1 Counsellor	51	526.32
4	Blood Storage Centers	Consumables	0.3	Glasswares, plastic wares, instruments, chemicals and emergency medicines	391	117.3
		Salary	2.4	Salary of 1 Staff Nurse	391	938.4
5	Blood Transportation Vans	Salary	2.04	Salary of 1 Driver & 1 support staff	32	65.28
6		Salary	1.56	Salary of 1 LT	32	49.92
7	Maintenance of BT Vans in form of POL for logistics	Recurring	1.5	PoL & Contingency	32	48
8	Blood Mobile	Salary	2.88	Salary for 1 Driver, 2 support staff,	8	23.04
9		Recurring	4	Expenditure for Diesel and Contingency	8	32

10	Training	Recurring	0.48	Training of one BB-MO, two LT, one Nurses per DAC supported Blood Bank, One Blood Bank Counselor, Clinicians on rational use of blood, Donor Motivators	89	42.72
11	Supportive Supervision	Recurring	0.1	TA/DA for visit to the DAC supported blood banks, Monitoring visits to VBD camps, Core Committee supervisory visits	89	8.9
12	Procurement					0
13	Equipments for new BCSU	Non-recurring	18	List of Equipments as per DAC guidelines	51	918
14	Grants for AMC and Calibration	Recurring	1	AMC/ CMC and calibration of essential blood bank equipments supplied by DAC	89	89
15	Grant for SBTC					0
16	Voluntary Blood Donation Camps	Recurring	0.025	Hiring of Vehicle, Printing of banner, POL	8000	200

17	Observance of Blood Donation Days	Recurring	5	Advertisement, state level and district level activities for 12th January, 14th June and 1st October	3	15
18	Development of IEC material	Recurring	1.1	Design, development, translation and replication of IEC material for promotion of Voluntary blood donation including thank you cards, certificates of appreciation, pins, badges, hoardings	89	97.9
19	Donor Refreshment	Recurring	0.0005	Provision of post donation refreshment to all blood donors	500000	250
20	Blood Bags	Recurring		Single, Double, Triple and Quadruples Blood Bags	500000	687.4
21	Blood Testing Kits	Recurring		HIV, HBV, HCV , RPR, Malaria	500000	1750
22	Fully Automated Machine for TTI (HIV, HBV, HCV, Malaria and Syphilis) Screening (1 Time)	Recurring	70	Fully Automated machine equipment with one year consumables.	2	140

23	Semi-Automated Machine for TTI (HIV, HBV, HCV, Malaria and Syphilis) Screening(1 Time)	Recurring	57	Semi-Automated machine equipment with one year consumables.	8	456
24	Fully Automated Machine for Immunohematology (Blood Grouping, Typing, Cross Matching, ICT, DCT, Antibody screening)(1 Time)	Recurring	40	Fully Automated machine equipment with one year consumables.	2	80
25	Semi-Automated Machine or Immunohematology (Blood Grouping, Typing, Cross Matching, ICT, DCT, Antibody screening) (1 Time)	Recurring	25	Semi-Automated machine equipment with one year consumables.	8	200
26	EQAS	Recurring	4000		89	3.56

27	Thermo label to monitor temperature during transportation	Recurring				
28	GIS Mapping and real time tracking of blood and blood products	Nonrecurring				
29	Webinar classes for physicians to emphasise rational use of blood and blood products	Recurring				3
TOTAL						7674.23

Draft for