A Report on the "Assessment of Blood Banks in Dadra and Nagar Haveli, India"

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Abbreviations

- Blood Bank BB**BCSU** - Blood Component Separation Units **BTS** - Blood Transfusion Service - Central Drug Standard Control Organisation **CDSCO** - Chemiluminescence **CHEMI** DAT - Direct Antiglobulin Test **DCT** - Direct Coombs Test **DNH** - Dadra and Nagar Haveli **ELISA** - Enzyme Linked Immuno Sorbent Assay **EOAS** - External Quality Assessment Scheme **FFP** - Fresh Frozen Plasma HIV - Human Immunodeficiency Virus **HBV** - Hepatitis B virus - Hepatitis C virus **HCV** - Haemovigilance Program of India **HVPI** - Indirect Antiglobulin Test **IAT** - Indirect Coombs Test **ICT** - Immunohematology ΙH **IQC** - Internal Quality Control **IQR** - Interquartile Range - Ministry of Health and Family Welfare **MoHFW NACO** - National AIDS Control Organisation **NAT** - Nucleic Acid Testing - National Blood Transfusion Council **NBTC** NGO - Non Governmental Organisation **NHP** - National Health Portal **PSU** - Public Sector Undertaking OC - Quality Control - Quality Manager OM - Quality Management Systems **QMS** - Rapid Plasma Reagin **RPR** - State AIDS Control Societies **SACS** - State Blood Transfusion Council **SBTC** SD - Standard Deviation - Strategic Information Management System **SIMS** - Standard Operating Procedures **SOPs** - Transfusion Transmitted Infection TTI TM- Technical Manager **TPHA** - Treponema Pallidum Hemagglutination Assay - Union Territory UT - Voluntary, Non-Remunerated Blood Donation **VNRBD** - Voluntary Blood Donor/Donation **VBD** - World Health Organization **WHO**

Table of Contents

1.	. F	Bac!	kgro	ound	1
2.	. (Obje	ectiv	/es	4
3.	. N	Met	hodo	ology	4
4.	. I	Key	Fin	dings	7
	4.1		Bas	ic details of blood banks (n=1)	8
	4.2	2	Anı	nual Blood Collection and Voluntary Blood Donation	8
	4	1.2.	1	Annual Collection of Blood:	8
	4.3		Tra	nsfusion Transmitted Infections(TTIs)	10
	4.4		Cor	nponent Separation	11
	4.5		Qua	ality Management Systems	11
	4.6		Rep	porting and Documentation	12
		4.6	.1.	Compliance to NBTC guidelines and Reporting Requirements	12
	4.7	•	Hur	man Resources	13
	4	1.7.	1.	Availability of staff	13
	4.8		Equ	ripment and Supplies	13
	4	1.8.	1.	Regular supply of kits/supplies and Equipment Availability	13
	4.9		The	current status of the blood bank based on the assessment	14
5.	. (Con	clus	ion	15
6.	. F	Refe	eren	ce	16
7.	. <i>A</i>	Ann	exu	res	17
	7.1		NA	CO/NBTC – Questionnaire for Blood Banks	17
	7.2		Sco	ring sheet	29

Tables and Figures

Tables

Table 1- Details of technical areas included in the assessment	5
Table 2- Scoring details and weight	6
Table 3 - Basic details of blood banks	8
Table 4 - Availability of Quality Parameters in the Blood Bank	12
Table 5 - Equipment in working condition	13
Figures	
Figure 1- Availability of BBs per 1,000,000 (1 million) Population	7
Figure 2 - Voluntary Blood Donation %	9
Figure 3 - Annual Collection per 100 population	9
Figure 4 - Annual Collection per 100 population Vs BBs per 1 million	10
Figure 5 - TTI (%) DNH vs. India	10

Assessment of Blood Banks in Dadra and Nagar Haveli

1. Background

Blood Transfusion Service (BTS) is an essential part of modern health care system without which medical care is impossible (Pal, Kar, Zaman, & Pal, 2011). Adequate measures to ensure blood safety play a major role in preventing the transmission of HIV, Hepatitis and other bloodborne pathogens in health care settings. The blood and its products must not only be safe but must be clinically effective, and of appropriate and consistent quality (WHO, 2012). Ensuring the safety and availability of blood and blood products is an essential public health responsibility which is primarily the responsibility of the government or the appropriate national health authority of each country (Ramani, Mavalankar, & Govil, 2007). Therefore, it is important to establish a sustainable national blood system that should be supported by a national blood policy, strategic plan, and appropriate legal instruments (WHO, 2011). The Twenty-eighth World Health Assembly resolution number WHA 28.72 of 1975 urged member countries to promote the development of national blood services based on voluntary non-remunerated blood donation (VNRBD); 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).

However, provision of safe and quality blood for a country like India involves a highly complex operation involving various stakeholders, and the magnitude and complexity of issues raise several challenges (GOI, 2003). This requires a holistic and comprehensive approach to planning, designing and operationalizing the BTS. It is important to ensure coordination between blood transfusion services, health services and hospitals, educational institutes, religious, social and industrial organizations, mass media, and other stakeholders including the general public. The system should ensure adequate resources and inputs into the legislative, regulatory, technical, social, and cultural aspects of making this life-saving product accessible and safe.

The need for blood is paramount and universal. However, millions of patients requiring transfusion do not have timely access to safe blood, and there is a major imbalance between developing and industrialized countries in access to safe blood (WHO, 2009). There is a huge inequity in the availability of blood within countries, with the 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. In order to ensure universal access to safe and quality blood, achieve 100% voluntary blood donation and quality-assured testing of donated blood, strengthening the blood transfusion services with evidence-based, innovative and result-oriented strategies are essential. It is also imperative to optimize blood usage, develop quality systems in the transfusion chain, strengthen the workforce, adopt new developments, and build effective partnerships (WHO, 2008).

The National AIDS Control Organization(NACO), under the Ministry of Health and Family Welfare, and the National Blood Transfusion Council (NBTC), which is the apex policy making body, are the prime bodies responsible for the functioning of blood transfusion services and blood safety in India at the national level. At the state level, the respective state AIDS Control societies(SACS) and State Blood Transfusion Councils (SBTCs) are responsible for the smooth functioning of blood transfusion services. As blood and blood products are considered as drugs, the Central Drug Standard Control Organisation (CDSCO) and State Drug Control Organisations play a vital role in key aspects such as, approval of licenses, and enforcement of standard transfusion practices to ensure safe, quality and efficacious blood and blood components in clinical practices.

Several directions, guidelines, and legal measures during the last two decades facilitated the significant improvement of blood transfusion services in the country. The Supreme Court verdict in 1996 directed the government to improve the blood transfusion services that resulted in establishing the National and State Blood Transfusion Councils. The Drugs and Cosmetics Rules, 1945, framed under the Drugs and Cosmetics Act, 1940 were amended in 1993, as a result of which the licensing of blood banks was brought under the dual authority of the state and central government (MoHFW, 2013). The state licensing authority issues the license, while the Drug Controller General (India) is the central license approving authority. In 2002, the WHO Guidelines on the Clinical Use of Blood was adopted by NACO. In the same year, the Government of India framed and adopted the National Blood Policy (NBP) (NACO, 2007a).

In 2007, the National AIDS Control Organization developed standards for blood banks and blood transfusion services. This clearly spelled out the need for mandatory licensing and compliance to all regulatory norms; compliance to policies/ guidelines of NBTC; donor selection/ recruitment/ retention/ counseling based on voluntary non-remunerated regular repeat blood donors; appropriate blood collection procedures; mandatory testing of all donated Blood units for HIV, HBV, HCV, Syphilis and Malaria; transportation of blood and blood components ensuring cold chain maintenance; manpower requirements; maintenance of quality assurance system; regular maintenance and calibration of equipment; biosafety; waste disposal mechanisms; documentation, record keeping and regular reporting under the national programme(NACO, 2007b).

Since the inception of the National AIDS Control programme in 1992, the blood safety programme in India under the National AIDS Control Organization has been making significant strides towards ensuring access to safe, and quality blood and blood products to all those who are in need of a transfusion. The goals and objectives of the programme are to ensure provision of safe and quality blood even to the most remote areas of the country. NACO has been taking continuous steps to strengthen the blood banks across the country by providing equipment, consumables, manpower and capacity building. The efforts to modernizing blood-banks, establishing model blood banks, and setting up blood storage centres in rural areas have improved the quality of blood transfusion services in the country.

The current phase of the NACP IV (2012 -2017) focuses on blood safety that aims to support 1,300 blood banks, and achieve 90,00,000 blood units from NACO supported Blood Banks and 95% Voluntary Blood Donation in 2016-17. The key strategies under NACP IV are strengthening management structures of blood transfusion services, streamlining the coordination and management of blood banks and blood transfusion services, and developing new initiatives such as the establishment of Metro Blood Banks and Plasma Fractionation Centre (NACO, 2014).

Due to the continuous efforts in India, the availability of safe blood increased from 44 lakh units in 2007 to 100 lakh units by 2014-15; during this time HIV seroreactivity also declined from 1.2% to 0.2%, and Voluntary Blood Donation increased substantially (NACO, 2016). NACO has been providing technical and operational support to improve the efficiency and effectiveness of these blood banks, thereby, increasing the availability and accessibility of safe and quality blood and blood products to those who are in need. Though there has been a substantial improvement in BTS in India over a period of time, there are still gaps in ensuring access to quality blood and blood products that needs to be addressed at the district, state and regional levels through an evidence-based approach.

In order to have evidence-based programmes, and policies, accurate and updated information at the district, state and national level is an essential prerequisite. Lack of updated information is one of the key barriers affecting the planning and implementation of blood transfusion services across the country. Though current programmes emphasize Quality Management Systems (QMS) including EQAS and accreditation in blood banks, not much information is available related to this area. In particular, information on the existing practices of blood banks, their potential, and willingness to get involved in the programmes on QMS are critical factors that will facilitate developing appropriate strategies and programmes related to QMS at the National level.

Therefore, facility-wise updated information on structural and programmatic components, the gaps, and challenges are required which will not only facilitate in developing better programmes and policies in BTS, but also serve as a baseline for specific programmes that are being, and will be implemented at the district, state, regional, and national levels. Considering the above factors, a nationwide assessment of all the Blood Banks was conducted.

2. Objectives

The overall purpose of this assessment was to understand the current situation of blood banks, in terms of facilities, services, practices, performance, gaps, and challenges.

The specific objectives were:

- To review the existing situation in blood banks in terms of collection of blood, voluntary blood donation, quality management systems, and other programme areas.
- To categorize and grade the blood banks using a scoring system, for implementation of phased quality improvement systems.
- To provide evidence for the formulation of evidence-based policies and programs for blood transfusion services in India.
- To develop an updated database with basic essential details of blood banks in the country.

3. Methodology

This assessment was a cross-sectional survey that captured the current situation of all the blood banks that are owned by the government, private, non-profit and not-for-profit organizations in the UT during the reporting period – January to December 2015. In order to create a comprehensive and accurate list of functional blood banks in the UT, data (list of blood banks) from multiple sources were obtained which included NACO, NBTC, CDSCO, State Drugs Control Organizations, SACS, and SBTCs. These were further reviewed for duplication, errors in name and other necessary details, and triangulated to arrive at a comprehensive list of district wise functional blood banks.

Following this, an assessment tool was designed as a web-based survey tool in REDCap Software - Version 6.11.2 which was developed by an informatics core at Vanderbilt University with support from National Center for Research Resources (NCRR) and National Institute of Health (NIH) grants. An exclusive online survey link for each blood bank, generated from REDCap, was sent to all the blood banks. This online link was linked to the email ID of the blood bank and Unique IDs created for each blood bank. Since many blood banks did not have adequate internet facility, a paper format was also developed which was sent to all the blood banks by post with a pre-stamped and self-addressed envelope. The data from the completed paper forms were then entered into REDCap.

Tool: A self-assessment questionnaire that included all the below-mentioned components was developed in consultation with programme officials and experts from the areas of public health, epidemiology, bio-statistics, and transfusion medicine.

The review focused on the following components:

Table 1 - Details of technical areas included in the assessment

S No	Component	Description	
1	General	Basic details, Ownership, Category,	
		License, etc.	
2	Collection and VBD	Annual Collection, VNRBD and donor	
		management	
3	Technical – IH, TTIs,	Methods, Performances	
	components		
4	Quality Management System	Check for compliance to guidelines and	
		standards	
5	HR, Training, and Equipment	Availability and Participation	

Data Management and Analysis: The database for this study was developed and maintained by Clinical Data Management Centre (CDMC), Department of Biostatistics, Christian Medical College, and Vellore, India. In-built validation checks were incorporated in the system to confirm that all study related parameters are captured completely and accurately.

Data were analyzed using SPSS Version 21 for Windows. The data were screened for outliers and extreme values using histograms, frequency distribution and Box plots. To summarize the whole data, frequency distributions and bar/pie charts were done for qualitative (categorical) variables such as ownership, type of blood banks etc., and descriptive statistics like mean, standard deviation (SD), median, minimum, and maximum were done for quantitative variables such as annual collection, voluntary blood donation, etc.

Categorisation of blood banks and scoring: In order to study variables that impact quality, the blood banks have been categorized into two groups based on the availability of component separation facility. The first category comprises of blood banks with component separation facility that includes Model Blood Banks and Blood Component Separation Units (BCSU) in NACO supported blood banks. Model blood banks collect more than 10,000 units and BCSUs collect between 5,000 to 10,000 units of blood annually. The second category includes blood banks without component separation facility that covers major blood banks and District Level blood banks (DLBB) in NACO supported blood banks. Major blood banks collect between 3,000 and 5,000 units and district level blood banks collect up to 3,000 units annually.

Each component of the tool was given a weight based on the programmatic and quality priorities. The maximum achievable sum of all weighted scores under each component totaled 100 marks.

Table 2 - Scoring details and weight

Details	With Components	Without Components
Licence	3	3
Annual Collection, VBD, Repeat donation and		
Counselling	11	16
Technical - IH, TTI and Component separation	43	38
Quality Management Systems	35	35
Reporting	8	8
TOTAL	100	100

The scoring pattern was different based on the category of blood banks that are: 1. Blood banks with component separation facility (n=1) and 2. Blood banks without component separation facility (n=0). Scores were allocated to each indicator under specific components based on the expected level of performance by these two categories of blood banks.

The blood banks were categorized based on the scores obtained by each blood bank that are, less than and equal to 35; 36 to 70 and above 70.

4. Key Findings

According to CDSCO, there was one blood bank in the Union Territory (UT) of Dadra and Nagar Haveli (DNH) in 2015 (CDSCO, 2015). The assessment exercise also identified one functional blood bank across the UT. This blood bank was NACO supported and had submitted the assessment form in complete so as to be included in the analysis.

DNH covers an area of 487 km² and consists of two talukas – 1. Dadra, and 2. Nagar Haveli. The blood bank was located in Silvassa which is the headquarters of the Nagar Haveli taluka, comprising Silvassa town and 68 other villages. This NACO supported blood bank is the only blood bank in the UT and is owned by the not-for-profit sector which comprises NGOs/Trusts/Charitable Associations. The blood bank is run by the Indian Red Cross Society (IRCS) and is a stand-alone blood bank with a Blood Component Separation Unit. This blood bank had reported as having a valid and current license.

For a UT like DNH with a total population of 343,709 (according to Census, 2011), the availability of blood banks per million population is 2.9 which is more than the national average of 2.2. Hence, the IRCS, Silvassa is found successfully catering to a relatively small population as compared to the entire country.

3.5 3.5 2.9 2.2 1.5 1 0.5 0

DNH

India

Figure 1- Availability of BBs per 1,000,000 (1 million) Population

4.1 Basic details of blood banks (n=1)

As indicated earlier, the IRCS, Silvassa blood bank is the only blood bank in the UT of DNH which is NACO supported.

Table 3 - Basic details of blood banks

	Specifics	Description
	Type of BB	With components
IRCS Blood Bank,	Ownership	NGO/Trust/Charitable
Silvassa	Licence	Valid
	Attachment	Stand alone

4.2 Annual Blood Collection and Voluntary Blood Donation

According to WHO, it is estimated that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2016b), which means that DNH with a population of 3,43,709, currently needs around 3,437 units of blood. As per this criteria, DNH is producing more than what is required.

4.2.1 *Annual Collection of Blood:* During January 2015 to December 2015, the annual blood collection from the blood bank was 7,497 units of which 100% were through voluntary blood donations. DNH was the only place in India where the percentage of voluntary blood donation was 100%. Overall, India's average VBD% was 71.9%. The blood bank reported to have had 49% repeat donors.

Figure 2 - Voluntary Blood Donation %

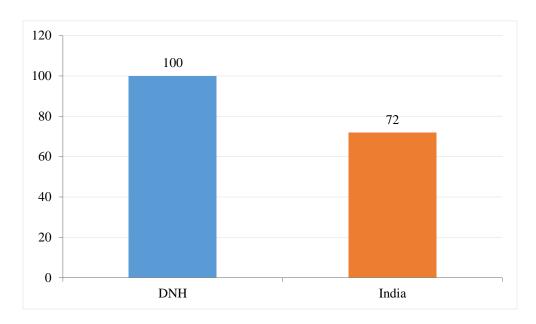
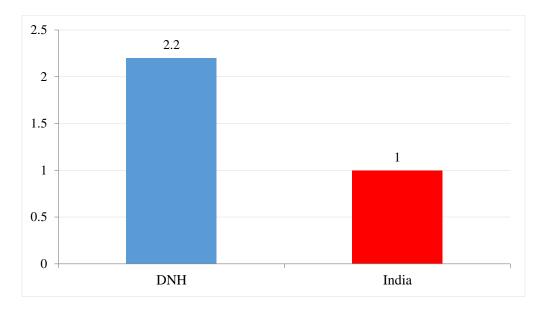


Figure 3 - Annual Collection per 100 population



The annual collection of blood units per 100 individuals was found to be around 2.2% in the UT, which is significantly more than the WHO suggested requirement that 1% of the population can meet a nation's most basic requirements for blood.

Figure 5 illustrates the comparative information of annual collection per 100 population and number of blood banks per one million populations between DNH and India. This indicates that the UT had around 2.9 blood banks per million population that collected around 2.2 units per 100 population at the ratio of 2.9 BB: 2.2 blood unit which is well above the national average.

3.5

2.9

2.5

2.2

2.1

1

0.5

DNH India

Annual Collection per 100 population

BBs per 1 million population

Figure 4 - Annual Collection per 100 population Vs BBs per 1 million

4.3 Transfusion Transmitted Infections(TTIs)

Transfusion-Transmitted Infections (TTIs) are major problems associated with blood transfusion (Chandra, Rizvi, & Agarwal, 2014; Gupta, Singh, Singh, & Chugh, 2011). Screening for TTIs such as HIV 1, HIV 2, Hepatitis B, Hepatitis C, Malaria, and Syphilis is mandatory in India. Due to the concerted and active efforts, the seroreactivity percentage of TTIs has come down significantly over the years.

The seroreactivity of TTI among blood donors in the year 2015 is depicted in Fig-5. HIV reactivity was found to be 0.08%, Hepatitis-C was 0.03%, Hepatitis-B 1.79% and Syphilis 0.28%. There were no donors tested positive for Malaria during the reporting period.

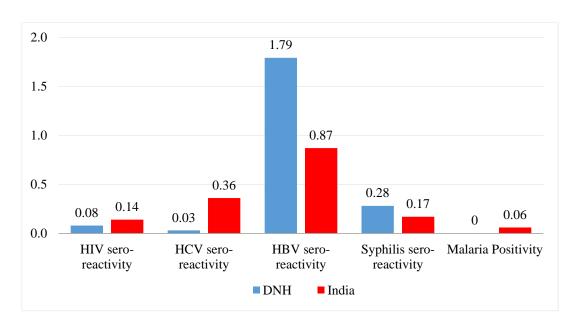


Figure 5 - TTI (%) DNH vs. India

Hepatitis B seroreactivity was found to be higher than the national average of 0.87% in DNH, which was 1.79%. The UT has recorded the second highest Hepatitis B reactivity among its donors after the UT of Puducherry. The Syphilis reactivity(0.28%) is also higher than the national average.

4.4 Component Separation

Around 59% of the blood collected by the IRCS blood bank was used for component separation in the UT. The total collection by this facility was 7,497 units of which 4,436 units were used for component separation.

4.5 Quality Management Systems

Quality is defined as the totality of characteristics of an entity that bears on its ability to satisfy the stated and implied needs (Schlickman, 1998). It is a spectrum of activities and processes that shape the characteristics of a product or service. Quality systems are defined as the organizational structure, resources, processes, and procedures needed to implement quality management (ISO-8402, 1994) and Quality Management System is the sum total of all business policies, processes and procedures required for the execution of production, development or service of an organization.

Blood transfusion is a multi-step process with the risk of error in each process from selecting donors, collecting and processing donations, testing of donor and patient samples, issue of compatible blood, to transfusing the patient (WHO, 2016a). An effectively planned and implemented quality system that includes internal quality assessment, external quality assessment, and education and training of staff can significantly reduce the risk associated with blood transfusion.

The assessment captured several parameters that influence the quality of service provision. Some of the key parameters are mentioned in Table -10. The IRCS Blood Bank has reported that they adhered to the NBTC guidelines and had Standard Operating Procedures (SOPs) for technical processes. Internal Quality Control (IQC) for Immunohematology and TTI was reported 100% by the blood bank. They have also reported as carrying out quality control for kits, reagents and blood bags, and had a regular equipment maintenance programme as well as calibrated the equipment as per requirement.

Table 4 - Availability of Quality Parameters in the Blood Bank

Quality Parameters	Availability
Compliance with NBTC guidelines	100%
Availability of Documental Control System (DCS)	-
SOPs for Technical Processes	100%
IQC for IH	100%
IQC for TTI	100%
QC for kits, reagents and blood bags	-
EQAS for IH	-
EQAS for TTI	-
NABH accreditation for blood banks	-
Availability of designated and trained Quality Manager	-
Availability of designated and trained Technical Manager	-
Programme for regular Equipment maintenance	100%
Equipment calibration as per regulatory requirement	100%

On the other hand, the blood bank did not have a document control system, was not found enrolled in EQAS by recognized providers for Immunohematology and TTIs and was not accredited by National Accreditation Board for Hospitals & Healthcare Providers (NABH). Designated and trained Quality Managers and Technical Managers were not available as well.

4.6. Reporting and Documentation

4.6.1. Compliance to NBTC guidelines and Reporting Requirements

The blood bank reported that they were recovering processing charges within NBTC/SBTC norms but did not display stock position in their Blood Bank premises.

In terms of reporting requirements, the blood bank submitted regular reports to state drug controller and in the national strategic information management systems (SIMS). But they did not regularly reported in e-blood banking either national or state e-blood banking nor were members of the National Haemovigilance Program.

4.7. Human Resources

4.7.1. Availability of staff

The total number of employees in the blood bank was 10. The blood bank had one medical officer, seven technical staff and two nursing staff. However, the blood bank had no counsellors and PRO/Donor motivators. As reported by the blood bank, there were no personnel trained by NACO/NBTC.

4.8. Equipment and Supplies

4.8.1. Regular supply of kits/supplies and Equipment Availability

The IRCS blood bank reported that they had a regular supply of blood bags and TTI kits. Table 5 indicates the percentage of blood banks that have different equipment in working condition.

Table 5 - Equipment in working condition

	Equipment in working Condition					
S No	Equipment	% BB				
1	Donor Couches	100				
2	Instrument for Hb Estimation	-				
3	Blood collection monitor	100				
4	Quarantine Blood Bank Refrigerator to store untested blood	100				
5	Container for safe disposal of sharps	100				
6	Oxygen supply equipment	100				
7	Computers with accessories and software	100				
8	General lab centrifuge for samples	100				
9	Bench top centrifuge for serological testing	100				
	(Immunohaematology)	100				
10	Blood transportation box (No. in inventory)	100				
11	Emergency drugs box / Crash cart	100				
12	Autoclave machine	100				
13	Water bath	100				
14	Blood bank refrigerator (storage of tested blood) with	100				
14	temperature recorder	100				
15	Automated pipettes	100				
16	Refrigerated centrifuge	100				
17	Blood container weighting device	100				
18	Serology rotator	_				

4.9. The current status of the blood bank based on the assessment

As mentioned in the methodology section, the blood banks were assessed and categorized based on the scores obtained. Though the assessment captured all aspects of blood transfusion services in blood banks, adequate importance and weightage were given to technical aspects and adherence to quality management systems.

The assessment score of the blood bank in the UT was 62.50 which is higher than the national average of 62 as well as the national average score of NACO supported blood banks which was 61.2. However, in terms of organizational attachment and the type of blood bank it has scored below the national average of 64.18 and 64.69, respectively.

5. Conclusion

Considering the importance of blood transfusion services in the provision of medical care, ensuring quality systems and standards in blood banks are vital, as the blood and its products must not only be safe but also clinically effective and of appropriate and consistent quality. From the programmatic perspective, adequate, accurate and updated information at the district, state and national level is essential for planning and implementation of quality management systems in blood transfusion services across the country. Generation of accurate and essential data from blood banks at regular intervals is imperative to effectively monitor the progress, gaps and challenges in the service provision which would not only facilitate appropriate corrective measures but also facilitate the development of evidence-based policies and programmes.

This state-wide assessment captured most of the required information related to the structure, services, facilities, availability of human resources, equipment, quality management system and practices in blood banks across the state. All blood banks function subject to obtaining and maintaining a license for operations from the FDA which means compliance to basic quality standards mentioned in the Drugs and Cosmetic Act 1940 and Rules 1945 there upon. However, this assessment brings out specific gaps and possible opportunities to improve quality standards in Transfusion Services at the UT.

The NACO supported blood bank which was included in the review is the only blood bank existing in the UT. The annual collection of this blood bank was 7,497 units which is approximately 2.2% of the total blood requirement based on WHOs estimation that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2010). Clinical demand for blood and blood products can happen only when there is a health care facility with adequate infrastructure in proximity to a blood bank.

The provision of a blood component separation unit in the blood bank and the volume of collection apparently have a positive influence on the quality. However, it is important to note that in the absence of reliable laboratory support, it will not be possible to ensure rational use of blood and its components. It is difficult to sustain cost-effective component production when the volume of operations is low without compromising the quality of the blood provided to the patients who access this service. Given that the provision of safe and high-quality blood in areas where access is a challenge, it is essential to explore new cost effective innovative methods in partnership with non-governmental agencies.

For the first time, a quality score system has been created and applied to the blood banks across the nation. This review indicated a score of 62.50 for the blood bank. It is evident from the assessment that blood banks that focussed on quality improvement systems performed better than others. Considering the deleterious effect of poor quality practices on patient care, it is imperative that specific programmes and strategies to improve quality systems in blood transfusion services are developed and implemented.

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7. Annexures

7.1 NACO/NBTC – Questionnaire for Blood Banks

	NACO/NBTC - Questionnaire for Blood Banks						
Data	a Filled by						
Mok	oile Phone <i>Number</i>						
(Per	son filled the data)						
	Section A – GENERAL						
A1	Basic Information						
1	Name of the Blood Bank						
	(as mentioned in the licence)						
2	Address 1						
	(Institution name)						
3	Address 2 (Door number & Street name – if						
	applicable)						
4	Address 3 (Important land mark - if						
_	applicable)						
5	City/Town						
6	District						
b	District						
7	State						
8	Pin code						
9	Blood Bank Phone number						
	(Land line including area code)						
10	Blood bank Email ID						
						1	
11	Do you have internet facility?					Yes	
						No	
12	Name of the Blood Bank In-charge						
	(This should be the name of the current Medical Officer in charge)						
13	Is the name of the Medical officer mentioned	in the Lic	ence th	A CULTAN	nt l	Yes	
13	medical officer?	III the Lic	ence, tri	e currer		No	
14	Designation (Please enter designation of the					110	
	Medical Officer in the blood bank (e.g. Civil						
	surgeon, or academic like Asst. Prof etc.)						
15	Highest Qualification (Tick only one)				MBBS	;	
					MD)	
					MS		
					Diploma		
10	Charify branch / Droad and sight.				וווטוקום	'	
16	Specify branch/Broad speciality						
17	Email ID: (Official/Personal Email where the 17	,					

	medical officer can be directly contacted).		
	This is apart from the blood bank email ID	blood bank email ID	
	provided above.		
18	Fax number		
19	Telephone number 1 – Medical Officer (Mobile)		
20	Telephone number 2 – Medical Officer		
	(Landline including STD code)		
21	Type of blood bank as per NACO category	Model b	lood Bank
	,, , , , , , , , , , , , , , , , , , , ,	Blood Component Separa	tion Units
			lood Bank
		District level b	
			Others
22	Who is the blood bank owned by?	Public (Central/S	tate/Local
	,	gov	vernment)
		Public (Other than ministry	of health
		e.g. PSU,	Army etc.)
		NGO/Trust/Charitab	le – NACO
		!	Supported
		NGO/Trust/	Charitable
		Privat	e - Others
23	Is the Blood Bank attached to any of the		Hospital
	following?		Lab
		St	and alone
24	If attached to Private Hospital, specify level	Medical Colleg	
	of hospital	Tertiary car	
		(other than medic	
		Secondary car	
25	If attached to public/govt. hospital, specify	Sub-Distri	
	the level of the hospital	District lev	•
		Medical Colleg	
		Tertiary car	•
26		(other than Medic	
26	If the blood bank is attached to a hospital, pl beds available		
27	Are you permitted to conduct Blood donation	ı camp?	Yes
		Г	No
28	How many Blood storage centres are linked		
	to your blood bank?		
20	DD working bours (Chasify bours nor day)		
29	BB working hours (Specify hours per day)		
A2	License Information		
1.	BB License Number		
	(Enter your license number. This should be ex	-	
	is displayed in your license issued by the		
	Controller Office and will be used for ver		
	purposes. This is a mandatory field and sh		
	entered regardless of the status of license	- under-	

	renewal etc. (You will have to submit a self-			
	photocopy of the currently displayed licens with this form.)	se along		
2	Status of Current License	l .	Valid	
			Under renewal	
3	Date of issue of current licence			
	DD/MM/YYYY			
4	Last Inspection by licensing authority		< 1 year	
			1-2 years	
			2-3 years	
			3-4 years	
			>4 years	
А3	Basic Statistics (Date of reporting from Jan-2	015- Dec-2015)		
1	Number of voluntary donations			
2	Number of replacement donations			
3	Number of autologous deposits			
4	Total Annual collection for reporting period			
	(Jan - Dec 2015) Total Annual collections			
	(sum of A3.1+A3.2+A3.3)			
5. Transfusion Transmissible Infections - Annual Number tested Number positi				
stati				
	HIV(Anti-HIV I & II)			
	HCV (Anti-HCV)			
	HBV (HBs Ag)			
	Syphilis (RPR/TPHA/ELISA)			
	Positive for Malaria (Any method)			
A4.	Reporting Summary			
1	Are you in compliance with NBTC guidelines?		Yes	
			No	
2	Are you recovering processing charges for blo	od/components	Yes	
L	within NBTC/SBTC norms?		No	
3	Are you displaying stock position in the blood	bank premises?	Yes	
			No	
4	Are you submitting statistics to the State Drug	gs controller?	Regular	
			Occasional	
			No	
5	Are you reporting in SIMS (strategic Informati	ion Management	Regular	
	System- NACO)?		Occasional	
			No	
6	If yes to Q5, please provide your SIMS ID			

7	If you are not reporting to SIMS, would you be willing to report in	Yes	
	the future?	No	
8	Are you reporting in the E-blood banking?	Regular	
		Occasional	
		No	
9	If Regular/ Occasional to 8, specify (more than one can be selected)	State	
		National	
		(NHP)	
10	Please provide E Blood banking user ID (State)		
11	Please provide E Blood banking user ID (National)		
12	If not part of e-blood banking, would you be willing to participate in	Yes	
	future?	No	

	SECTION B						
B1	Blood Donor(Reporting from Jan 2015- Dec 2015)						
Defin	Definition of VBD = Close relatives should NOT be counted as VBD						
1	Are you recruiting voluntary blood donors?	Yes					
2	Is donor selection performed as per regulatory norms?		Yes				
			No				
3	Do you maintain records of donor deferral?		Yes				
			No				
4	Is pre-donation counselling being performed for	blood donors?	Regular				
			Occasional				
			No				
5	Is post donation counselling being performed for blood donors?		Regular				
			Occasional				
		No					
6	Are you conducting Blood donor drives/Blood collection camps?		Regular				
			Occasional				
			No				
7	If you conduct camps, how many have been cond	ducted in the					
	reporting period? (Provide numbers of VBD camp	s conducted					
	during the period January - December 2015.)						
8	Does the blood bank have dedicated staff for the	promotion of	Yes				
	Voluntary blood donors? (If your blood bank has	dedicated staff for	No				
	camps, answer yes.)						
8 a.	if Yes to 8, select as applicable (More than one	Don	nor Motivator				
	may be selected) Public relation		officer (PRO)				
	Social Worker						
9	Is there a specific budget for donor program?		Yes				
			No				
10	If Yes, Specify budget source		Central				

						State	
			Others (Specify)				
11	Is there a donor database in the blood bank	k (Don	or databa	se is	Yes		
	essential to contact donors to remind them or to call during an emergency?)			an an	No		
12	f yes to Q 11, is it in electronic format or paper Electronic						
	based?		Paper				
	Both						
13	What percentage of the voluntary blood do	nors	are repeat	blood do	nors? (%)	
14	Does your blood bank have a mobile blood			•		Yes	
	(Answer yes if your Blood bank has a mobility with donor couches)	le fac	ility (bus c	or van		No	
15	Source of funds for the mobile blood colle	ection	(Indicate	the		State	
	source of funding for the purchase of the	mobile	e blood do	onor	(Central	
	van.)					Donor	
						Others	
16	Specify, other source of funds						
17	Is there a record for donor adverse reaction	ns?	•			Yes	
						No	
18	Is there a referral system for HIV sero-react	ive bl	ood donor	rs?		Yes	
						No	
19	If yes to Q 18, please specify what is the process adopted.						
		ion C					
	Technical – Imr			•			
C1.	Which of the following tests are performed	d		d Group			h Type
	for determination of ABO and Rh (D)) <u> </u>		Reverse	≥)	•	Fick as
C1.1.	groups and what techniques are followed Slide	: F	orward	Reverse		aht	olicable)
C1.2	Tube						
C1.3	Micro plate						
C1.4	Column agglutination Gel/Microparticle)						
C1.5	Solid phase						
C1.6	Other Specify						
1	How do you perform RhD typing?			Monoc	lonal r	eagent	
						J .	
				Polycl	onal r	eagent	
				Polycl	onal r	eagent Both	

	T		T	
2	Do you perform irregular antibodies screening	Yes		
_	and patient sample?		No Yes	
3		Do you perform direct antiglobulin test (DAT/DCT)?		
	(If you are performing Direct Antiglobulin test as Direct Coombs Test (DCT), answer yes.)	(DAT) - earlier callea	No	
4	If yes to previous question, please specify	Tube		
4	method	Column agglutination	on .	
	metriod	Solid phase)II	
5	Do you perform indirect antiglobulin test (IAT	·	Yes	
,	bo you perform maneet antigloballin test (IAT)	/ IC1 / :	No	
6	If yes, to previous question please specify	Tube	INO	
0	method	Column agglutination	nn e	
	metriod	Solid phase) i	
7	Number of group and type tests performed	1		
′	(Jan - Dec 2015) (Specify the number of grou			
	performed - Total of all patient and donor te			
	period - January to December 2015.)	sts in the reporting		
8	Number of compatibility testing performed in	reporting period		
	(Specify number of compatibility tests perform	. • .		
	period January to December 2015)	ned in the reporting		
9	Total Number of DAT/DCT tests performed in	the reporting period		
	(Specify number of DAT/DCT tests performed			
	period (January to December 2015)			
10	Total Number of IAT/ICT tests performed in the	ne reporting period		
	(Specify number of DAT/DCT tests performed			
	period (January to December 2015)			
11	Total Number of antibody screening performe	ed in reporting period		
	(If you answered YES to Q2, Specify number of	antibody screening		
	tests performed in the reporting period (Janua	ary to December		
	2015).			
12	Do you have automation for Immunohematol		Yes	
	(If you have implemented any kind of automa	tion, please indicate	No	
	so.)		140	
13	Do you perform Internal QC for all immunohe	matology tests	Yes	
	(blood group/DAT/IAT etc.)?			
	(Please answer yes if you are performing inter		No	
	(IQC) for the immunohematology tests listed of	above. They include		
	daily QC on reagents and cells.)			
14	Do you participate in an external quality asses		Yes	
	scheme (EQAS) for Immunohematology tests	usually performed in	No	
15	your laboratory?			
15	If yes to 14, Specify name of program/provide	31		
16	If yes to 14, EQAS Membership ID number/ PI	N#		
10	in yes to 14, 100 to Membership to number/ 11			
17	If yes 14, specify Highest level of EQAS progra	am	Inter-lab	
	participant in		National	
			International	
L	<u>I</u>			

18	If you are not participating in EQAS for immunohematology, will			Yes	
	you be willing to do so in the future?			No	
19	If Yes to above question, will your blood bank be able to allocate			Yes	
	financial resources (about Rs.2500 per year)?			No	
20	If your answer to Q 19 is NO, when do you think you will be ready for EQAS participation? (immunohematology)			months	
	ready for Ed to participat	(mmanone.maco.og/)	Later t	han 6 month	
				1	
21	•	ional Haemovigilance Program of	India	Yes	
22	(HVPI)? If yes, provide HVPI ID No	umhor		No	
22	il yes, provide river ib in	unibei			
23	-	ng to participate in HVPI in the nea	ır	Yes	
	future?			No	
24	_	erse events to the National		Yes	
	Haemovigilance Program	of India?		No	
25	Number of adverse reacti	ions recorded in the reporting			
26	<u> </u>	regular transfusion committee me	etings?	Yes	
		G	Ü	No	
27	What is the frequency of	Transfusion committee meetings?	Annua	l	
			Half-ye	early	
			Quarte	erly	
			Occasi	onal	
		Section D			
		ening For Transfusion Transmissi	ble Infec	tions (TTI)	
Does	the blood bank screen the				
	Type of Test	Platform		Method	
		(please tick appropriate)	(þ	lease tick app	ropriate)
1	HIV I & II	Rapid			
		ELISA	Man		=
		CHENAL	Mar	omated	
		CHEMI	_		=
		NAT	Mar	omated	_
		NAT		omated	_
1.1	Specify % of donors test	ed by Rapid Test?	race		
2	Hepatitis B	Rapid			
		ELISA	Mar	iual	
			Auto	omated	
		EM	Mar	ıual	
			Auto	omated	
		NAT	Mar	nual	
			Auto	omated	
2.1	Specify % of donors test	red by Rapid Test?			
3	Hamatitia C	Rapid			
	Hepatitis C	i napiu			
	Hepatitis C	ELISA	Mar	nual	
	Hepatitis C			nual	

		CHEM		Manual	
				Automated	
		NAT		Manual	
				Automated	
3.1	Specify % of donors tes	ted by Rapid Test?			
4	Syphilis	RPR		Manual	
				Automated	
		TPHA		Manual	
				Automated	
		ELISA		Manual	ļ
				Automated	İ
5	Malaria	Rapid			
		Fluorescent		Manual	j 1
				Automated	<u> </u>
		Slide microscopy			
		ELISA		Manual	
	December bleed beat be			Automated	l
6	POSITIVE in initial scree	_		Yes	
		of verifying a sample that has i ng test please answer yes.)	tested	No	
7	If yes to Q6 , Repeat tes	sting with same test/ techniqu	ie	Yes	
				No	
8	If Yes to Q6, Repeat tes	ting with different test/techn	ique	Yes	
				No	
9	If yes to Q6, Recalling (donor for repeat sample		Yes	
				No	
10	Do you perform indepe	endent internal QC (Third party	/	Yes	-
	-			No	
11	, , ,	n external quality assessment QAS) for TTI (<i>Viral Markers, M</i> o	alaria,	Yes	
	and Syphilis) testing?			No	
12	If yes, Specify program	/provider			
13	Membership ID numbe	r (PIN)			
14	Level of EQAS			Inter-lab	
				National	
			1	International	
15	If you are not participate you be willing to participate.	ting in EQAS for TTI screening,	will	Yes	
	you be willing to particl	pate in ruture:		No	
16	If Yes to Q15, will your	blood bank be able to provid	e	Yes	

	financial support (about Rs. 2500 per year)	No					
17	If your answer to Q 15 is NO, when do you think you will be ready for EQAS (TTI screening)			months			
	participation?		Later the months				
	Section E	A	l! = = l. ! ·				
1	Technical - Component Preparation (App	licable o	nly to BC			
1	Does your blood bank prepare components?				Ye Ne		
If your	answer to Q1 is NO, SKIP TO SECTION F				IN	U	
_	List the components and number prepared and is:	SUE	l in the n	eriod Ian	to D	ecemb	er 2015
2	Number of donated blood that was used for com			erioù jari	10 0	ecemb	2013
2	preparation during the period Jan- December 20	•	Cit				
	preparation during the period san Describer 20		ımber pr	epared	No	. issued	d (utilized)
3	Packed red cells IP (With or without Additive)						(
4	Platelet concentrate IP						
5	Fresh frozen plasma (FFP)						
6	Cryoprecipitated antihaemophilic factor IP						
7	Human plasma IP						
8	Other (specify)						
9	Do you perform apheresis for components?				Ye	es	
					No	0	
	If yes to above question, Specify the following de	tails	;				
		Nu	mber pre	epared		o. issue tilized)	d
10	Platelet concentrate IP						
11	Fresh frozen plasma (FFP)						
12	Granulocytes concentrates						
13	Other (specify)						
14	Do you perform QC for the components prepare	d? (I)	f you per	form	Ye	es	
	quality control for all components, answer yes.)				N	0	
15	If yes to above, Are the Factor assays on Fresh Fr				Ye	es	
	plasma/Cryoprecipitate performed at your Blood				No		
16	If yes for above question, do you participate in ex	xterr	nal qualit	:y	Ye	es	
	assessment scheme (EQAS)?				No	0	
17	If yes, to above question, Specify agency						

	SECTION F						
	Quality Management Systems						
F 1	F 1 Are you aware of quality management systems for Blood bank						
			No				
1	Is the blood bank accredited?	,	Yes				
			No				
2	If yes, provide Name of Accrediting Body						
3 Do you have a document control system - other than mandatory		tory	Yes				

	registers as D&C act?				No Yes	
ļ	Do you have Standard Operating Procedures (SOPs) for all technical					
	processes?				No	
5	Do you have written responsibili	ties for all level	s of staff?		Yes	
					No	
	many staff are currently employed in been trained during the reporting po					any of them
	Staff Details	Total number of staff	Number on contract	NACO/NE Support in-servion trainin	ed ce	Other National Training
6	Professor					
7	Associate Professor					
3	Assistant Professor					
9	Senior Resident/Tutor					
10	Medical Officer (include					
	senior/Junior)					
11	Technical Staff					
12	Nursing staff					
13	Counsellor					
14	PRO/Donor motivator					
15	Administrative staff					
16	Support staff					
	If other staff, please specify	-				
10tai	In your opinion, does the BB have (24x7)? This may be decided base hours.	•			Yes No	
18	Do you monitor Quality indicator	rs or Key Perfor	mance indicato	ors?	Yes No	
19	If yes to above question, please s names of indicators	specify			-	1
20	Do you have a designated and tra	ained Quality m	nanager?		Yes	
21	Do you have a designated and tr	ninad Tachnical	Managora		No Yes	
4	Do you have a designated and tra	ameu recillical	ivialiagel!		No	
22	If you do not have either a traine manager or Technical Manager p state reasons?	•			NO	
23	Please specify if you have a plan	for recruitment	in the future?			
F2. E0	QUIPMENT AND SUPPLIES					
1	Does the blood bank have adequate	e equipment to	meet regulate	rv	Yes	

15	Oxygen supply equipment			
14	Container for safe disposal of sharps			
13	Quarantine Blood bank refrigerator to store untested un with temperature recorder	its		
12	Blood collection monitor (Blood agitator)			
11	Any instrument for Hb Estimation (other than CuS04 metho	od)		
10	Donor beds/couches			
		Number in inventory	Number in working condition	
	PMENT LIST (Below is a summary equipment list (a subset of E tory and number in working condition? If you are using shared r II	· · · · · · · · · · · · · · · · · · ·	•	
9	Number of staff vaccinated for Hepatitis B?			
	2.554 8.5		No	
8.3	Blood gro	uping / IH reagents	Yes	
5.2		oc. cerming Kitts	No	
8.2		TTI Screening Kits	Yes	
8.1		Blood Bags	Yes No	
8	Did you have a regular supply of the following items? (Ja	,	Vos	
	bank) Prior to use (e.g. Titre and avidity for blood group		INO	
7	Is quality control for kits, reagents and blood bags carried blood bank? (Is quality control for kits performed locally	y (at your blood	Yes No	
	evaluated locally (at your blood bank) prior to purchase avidity for blood group Anti Sera?))		No	
6	Do you evaluate kits at your facility prior to procuremer	· · · · · · · · · · · · · · · · · · ·	Yes	
		Others (specify)		
		Donors		
		agencies		
J	The are consumates parenasea.	Central or state leve	el	
5	How are consumables purchased?	Local bodies	110	
4	Are all the equipment calibrated regularly as per regulat	lory requirement?	No	
4	Are all the equipment calibrated regularly as nor regulati	tony requirement?	No Yes	
3	Does the blood bank have a program for regular equipm	nent maintenance?	Yes	
		Others (specify)		
		Donors		
		level agencies		
		Central or upper (st	ate)	
2		How is equipment purchase funded? Local bodies		
	requirements? (If your blood bank has adequate equipment in working condition to meet expected workload, please answer yes.)			

16	Computer with accessories and software	
17	General lab centrifuge for samples	
18	Bench top centrifuge for serological testing	
19	Blood transportation box	
20	Emergency drugs box/Crash card	
21	Autoclave machine (shared resource should be specified)	
22	Water bath	
23	Blood bank refrigerator (storage of tested blood) with temperature recorder	
24	Automated pipettes	
25	Refrigerated centrifuge (BCSU)	
26	Blood container weighting device	
27	Serology rotator	

7.2 Scoring sheet

ı	ndividual Scoring Sheet - Blood Component Separa	ntion Units	
GENERAL	GENERAL SUMMARY	WEIGHTAGE	TOTAL
Licence	Under renewal	1	
	Valid	3	
Subtotal			3
Annual	Below 1000	0	
collection	1000 1 2000	0.5	
	1000 to 2000	0.5	
	2000 to 5000	1	
	5000 to 10000	1.5	
	Above 10,000	2	
Subtotal	221 19222 (4)	_	2
VNRBD	BB by VNRBD (%)	0	
	<25%	0	
	25-49%	1	
	50 - 74%	3	
	75-90%	4	
	Above 90	5	
Repeat DON	Repeat donation >25%	2	
Counselling	Pre and post donation counselling - Regular	2	
Subtotal			9
TECH-IH	BB performing only slide grouping (forward typing)	0	
	BB using tube method for forward typing	2	
	BB performing reverse grouping (Serum group)	2	
	BB performing tube method for compatibility testing	3	
	BB performing IQC for IH	3	
	BB Participating in EQAS for IH	3	
	Direct antiglobulin test (DAT/DCT)- Direct Coombs Test (DCT)	2	
	Indirect antiglobulin test (IAT/ICT)	2	
	Automation for Immunohematology testing	1	
Subtotal			18
TECH - TTI	BB performing IQC for TTI	3	
	BB Participating in EQAS for TTI	3	
	BB with follow up program for HIV Sero-positive donors	3	
HIV Testing	Rapid	1	
	Elisa	2	
	Advanced	3	
Нер В	Rapid	1	
-	Elisa	2	
	Advanced	3	

Нер С	Rapid	1	
	Elisa	2	
	Advanced	3	
Syphilis	RPR	1	
Malaria	Slide/Rapid	1	
Subtotal			20
COMP			
	Component separation < 25	0	
	Component separation < 25-50%	1	
	Component separation 51 to 80%	2	
	Component separation > 80%	3	
	BB that performs component QC	2	
Subtotal			5
QMS	BB MO with relevant PG Qualification	3	
	Staff Nurse with NACO/NBTC Training	3	
	Technician with NACO/NBTC training	3	
	BB with designated and trained QM	2	
	BB with designated and trained TM	2	
	BB with Document control system	4	
	BB with calibration of equipment	4	
	BB with AMC for equipment	4	
	Quality control for kits, reagents and blood bags carried out at blood bank with regular bags supply	2	
	Quarantine Blood bank refrigerator to store untested units with temperature recorder	3	
	Blood bank accredited	5	
Subtotal			35
GEN	BB reporting regularly on SIMS under National AIDS Control Programme	3	
	BB Participating in Haemovigilance Program of India	1	
	E blood banking participation NBTC/NHP	1	
	E blood banking participation – State level	1	
	More than 50% of the staff are vaccinated for Hep B	1	
	Compliance with NBTC norms	1	
Subtotal			8
SCORES	TOTAL		100

Indivi	dual Scoring Sheet - Without Blood Component Se	paration Units	
GENERAL	GENERAL SUMMARY	WEIGHTAGE	TOTAL
Licence	Under renewal	2	
	Valid	3	
Subtotal			3
Annual collection			
	500 - 1000	1	
	1001 to 2000	2	
	2001 to 3000	3	
	3001 - 5000	4	
	>5000	5	
Subtotal			5
VNRBD	BB by VNRBD (%)		
	25-49%	1	
	50 - 74%	3	
	75-90%	4	
	Above 90	5	
Repeat DON	Repeat donation >25%	2	
	pre donation counselling - regular	2	
Counselling	post donation counselling - regular	2	
Subtotal			11
TECH-IH	BB performing slide ONLY for forward grouping	1	
	BB performing TUBE for forward grouping	2	
	BB performing reverse grouping (Serum group)	2	
	Compatibility testing with tube	3	
	BB performing IQC for IH	3	
	BB Participating in EQAS for IH	3	
	Direct antiglobulin test (DAT/DCT)- Direct Coombs Test (DCT)	2	
	Indirect antiglobulin test (IAT/ICT)	2	
	Automation for Immunohematology testing	1	
Subtotal			18
TECH - TTI	BB performing IQC for TTI	3	
	BB Participating in EQAS for TTI	3	
	BB with follow up program for HIV Sero-positive donors	3	
HIV Testing	Rapid	1	
	ELISA	3	
Нер В	Rapid	1	

	ELISA	3	
Нер С	Rapid	1	
	ELISA	3	
Syphilis	RPR	1	
Malaria	Slide/Rapid	1	
Subtotal			20
СОМР	Not applicable		
QMS	BB MO with relevant PG Qualification	3	
	Staff Nurse with NACO/NBTC Training	3	
	Lab technician with NACO/NBTC training	3	
	BB with designated TM/QM	2	
	BB with SOPs	2	
	BB with Document control system	2	
	BB with more than 75% equipment functional	2	
	BB with calibration of equipment	4	
	BB with AMC for equipment	4	
	Quality control for kits, reagents and blood bags	2	
	carried out at blood bank with regular supply		
	Quarantine Blood bank refrigerator to store	3	
	untested units with temperature recorder		
	Blood bank accredited by NABH	5	
Subtotal			35
GEN	BB reporting regularly on SIMS under National AIDS Control Programme	3	
	BB Participating in Haemovigilance Program of India	1	
	E blood banking participation NBTC/NHP	1	
	E blood banking participation – State level	1	
	Compliance with NBTC norms	1	
	More than 50% of the staff are vaccinated for Hep B	1	
Subtotal			8
SCORES	TOTAL		100