A Report on the

"Assessment of Blood Banks in Meghalaya, India"

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National Blood Transfusion Council (NBTC),
Ministry of Health and Family Welfare, Government of India
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Abbreviations

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

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Executive Summary

Blood Banks in Meghalaya

According to Central Drugs Standard Control Organization (CDSCO), there were 7 blood banks in Meghalaya in 2015. The assessment exercise identified 6 functional blood banks across the state. Of the 6 blood banks,all were supported by National AIDS Control Organization, Ministry of Health and Family Welfare, Government of India.

Out of the 11 districts in the state, only 3 districts had all the 6 blood banks. East Khasi Hills (4) had the highest number of blood banks followed by East Garo Hills (1), West Jaintia Hills (1).All the 6 blood banks were Naco supported.

Considering the number of blood banks per one million population, all the three districts , East Khasi Hills (4.8), West Jaintia Hills (3.7) and West Garo Hills(2.1) recorded more than the State average of 2.0 blood banks per 1,000, 000 (one million) population.

For the assessment 6 blood banks, all NACO that submitted the assessment forms in complete were included in the analysis.

Description of blood banks

- Around 33% (2) of the blood banks in the state had component separation facility.
- The not-for-profit sector owned 33.3% of the blood banks in the state and 66.7% of blood banks were owned by public sector.
- The two blood banks with blood component separation facility belonged to public sector.
- The majority of the blood banks (5; 83.3%) were attached to hospitals, and one was standalone blood bank.
- The majority of the blood banks (5; 83%) had a valid and current license, and the remaining one had applied for renewal.

Annual Collection and Voluntary Blood Donation

- During January 2015 to December 2015, the annual blood collection from all the blood banks that reported was 13,536 of which 38.3% units were through voluntary blood donations and the remaining were from replacement donations.
- The average annual collection of blood units of all the blood banks in the state was 2,256 units.
- The blood banks with component separation units recorded a higher average collection of 5,400 units compared to blood banks without blood component separation units which was 807 units.

Transfusion Transmitted Infections

- HIV reactivity was found to be 0.16%, Hepatitis-C was 0.47%, Hepatitis-B 0.78%, Syphilis 0.73% and Malaria 0.04%. However, there is a huge variation between districts.

Component Separation

- Around 73% of blood units collected by blood banks with component separation facilities, were used for component separation in state and all the blood banks were NACO supported.

Quality Management Systems

- All the blood banks (100%) reported that they adhered to the NBTC guidelines.
- Availability of document control system was reported by only 16.7% of the blood banks in the state.
- All the blood banks reported to have standard operating procedures (SOPs) for technical processes.
- Practice of internal quality control (IQC) for Immunohematology was reported by 100% of the blood banks and IQC for TTIs was reported by 66.7% of all the blood banks.
- All the 6 blood banks reported carrying out quality control for kits, reagents and blood bags.
- No blood bank enrolled in EQAS for immunohematology and for TTIs. No blood banks out of the total 6 blood banks that participated in the assessment were accredited by National Accreditation Board for Hospitals & Healthcare Providers (NABH).
- Designated and trained Quality Managers and Trained Technical managers were available only in 16.7% of the blood banks respectively.
- Majority 83.3% of the blood banks reported that they had a regular equipment maintenance programme and equipment calibration as per requirement.

The current status of blood banks based on the assessment

- The mean assessment score of blood banks in the state was 65.0 (SD: 4.05).
- At the state level, the majority of blood banks (5; 83%) scored between 35 to 70, and only one blood bank scored more than 70.
- Among the districts, East Khasi Hills (66.8) scored the highest and West Jaintia Hills (60.0) scored the least.

- The mean score of blood banks without component facilities (65.25; SD: 4.79) was found to be slightly higher than the mean score of those with component facilities (64.50; SD: 3.54).
- The mean assessment score of NGO/Trust/Charitable owned blood banks (69.00; SD: 2.83) was found to be slightly higher than the public owned blood banks (63.00; SD: 2.94).
- The mean assessment score of blood banks that collected less than 3000 blood units (64.50; SD: 3.54) was found to be higher than those which collected between 3001 to 5000 (64.50; SD: 3.54).
- No blood bank was enrolled in EQAS for IH and TTI in the state of Meghalaya.
- None of the blood banks were accredited by National Accreditation Board of Hospitals and Health care Providers (NABH).

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 across the state.

Assessment of Blood Banks in Meghalaya

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 state during the reporting period-January to December 2015. In order to create a comprehensive and accurate list of functional blood banks in the state, 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, components	Methods, Performances
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 to 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=2) and, 2. Blood banks without component separation facility (n=4). 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 (Red); 36 to 70 (Yellow) and above 70 (Green).

4. Key Findings

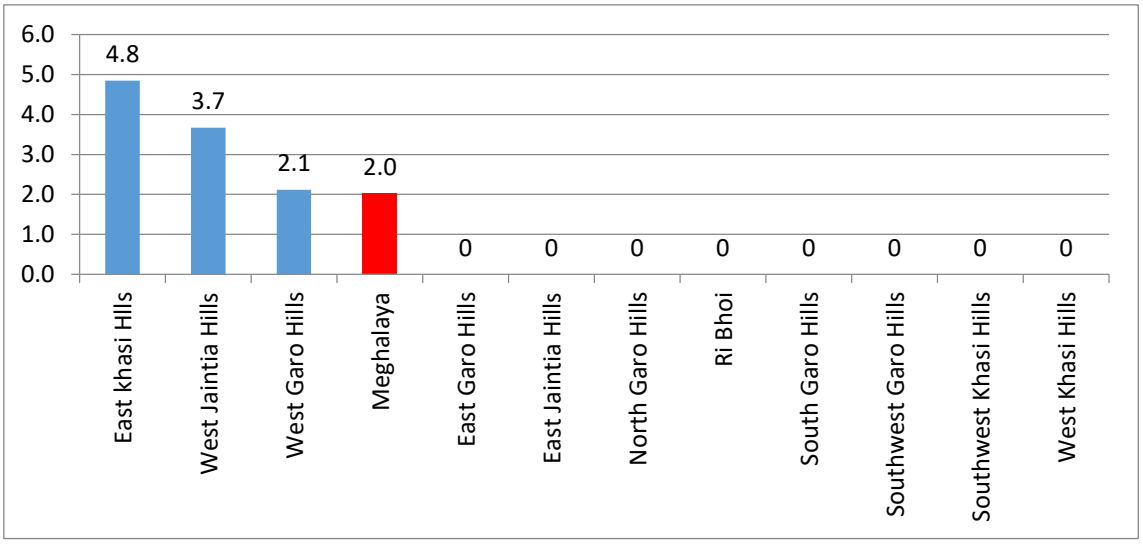
According to CDSCO, there were 7 blood banks in the state of Meghalaya in 2015 (CDSCO, 2015). However, the assessment exercise identified 6 functional blood banks across the state. Of the total functional blood banks, all the 6 blood banks were NACO supported which have submitted the assessment forms in complete and were included in the analysis.

Table -3 District Wise Description of Blood Banks

District	NACO Supported	Non-NACO	Total
East Garo Hills	-	-	-
East Jaintia Hills	-	-	-
East Khasi Hills	4	-	4
North Garo Hills	-	-	-
Ri Bhoi	-	-	-
South Garo Hills	-	-	-
Southwest Garo Hills	-	-	-
Southwest Khasi Hills	-	-	-
West Garo Hills	1	-	1
West Jaintia Hills	1	-	1
West Khasi Hills	-	-	-
Meghalaya	**6**	**-**	**6**

Table - 3 indicates the district wise details of all the blood banks in the state, including the description of NACO supported and Non-NACO blood banks. Out of the 11 districts in the state, only 3 districts had all the 6 blood banks. East Khasi Hills (4) had the highest number of blood banks followed by East Garo Hills (1) and West Jaintia Hills (1).All the 6 blood banks were NACO supported.

Fig 1 Availability of BBs per 1,000,000 (1 million) Population



Considering the number of blood banks per one million population, all the three districts , East Khasi Hills (4.8), West Jaintia Hills (3.7) and West Garo Hills (2.1) recorded more than the State average of 2.0 blood banks per 1,000,000 (one million) population.

4.1 Basic details of blood banks (n=6)

As indicated earlier, 6 blood banks,all NACO supported that submitted the assessment forms were included in the analysis.

4.1.1 Category of Blood Banks: Out of 6 NACO supported blood banks 33.3% (2) of the blood banks had component separation facility and the remaining were without component separation facility.

Table-4 Basic details of blood banks

Specifics	Description	Total
Type of BB	With components	2 (33.3%)
	Without components	4 (66.7%)
Ownership	NGO/Trust/Charitable	2 (33.3%)
	Private	-
	Public	4 (66.7%)
Licence	Valid	5 (83.3%)
	Under Renewal	1 (16.7%)
Attachment	Attached to Hospital	5 (83.3%)
	Attached to lab	-
	Stand alone	1 (16.7%)

At the District level, East Khasi Hills district had both the BCSUs.

4.1.2 *Ownership:* As depicted in Table:-4, around 33 percent (2) are owned by not-for-profit sector and public sector owned (4, 66.7%) blood banks. The two blood banks with blood component separation facility belonged to public sector.

Table-5 District wise list of blood banks by Ownership

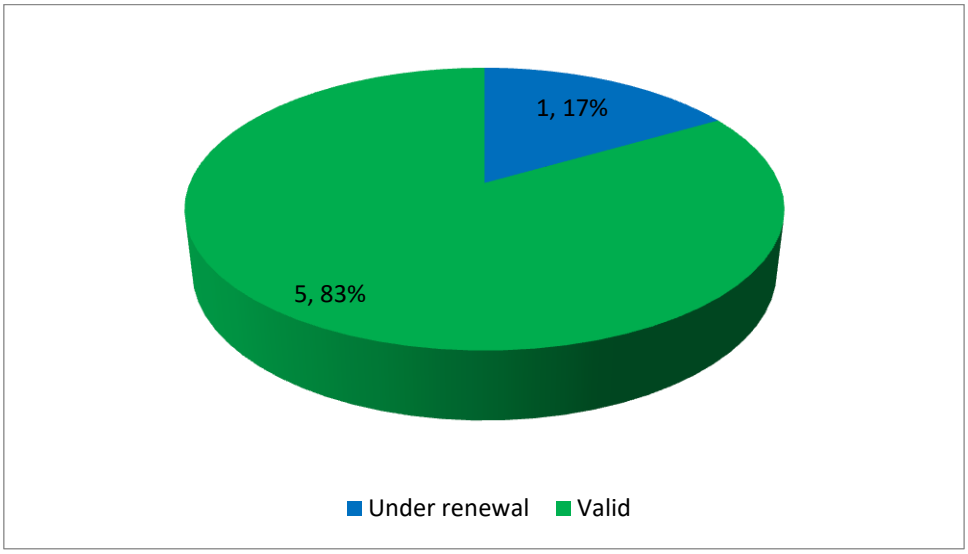
District	Public	%	Not-for-profit	%	Private	%	Total
East khasi Hills	2	50.0%	2	50.0%	-	-	4
West Garo Hills	1	100.0%	-	-	-	-	1
West Jaintia Hills	1	100.0%	-	-	-	-	1
Meghalaya	4	66.7%	2	33.3%	-		6

4.1.3 ***Organizational Attachment:*** The majority of the blood banks (5; 83.3%) were attached to hospital and only one was standalone blood bank.

4.1.4 ***License details of blood banks:*** The license status was categorized as "valid" which means that the blood bank has current and active license; and "deemed renewal" which means that the blood bank had applied for renewal which is pending.

The majority of the blood banks (5; 83%) had a valid and current license, and the remaining one had applied for renewal. Similarly, both the not-for-profit blood banks, and 75% (3) of the public blood banks had a valid and active license.

Fig-2 License Status (n=6)



The one blood bank which have reported as "deemed renewal" had their last inspection by licencing authority done between the last 1 to 2 years.

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 the state with a population of 29,66,889, currently needs around 29,669 units of blood. As per this criteria, Meghalaya is producing less than what is required.

4.2.1 ***Annual Collection of Blood:*** During January 2015 to December 2015, the annual blood collection from all the blood banks that reported was 13,536 of which 38.3% units were through voluntary blood donations and the remaining were from replacement donations.

Fig- 3 Annual Collections and Voluntary Donation

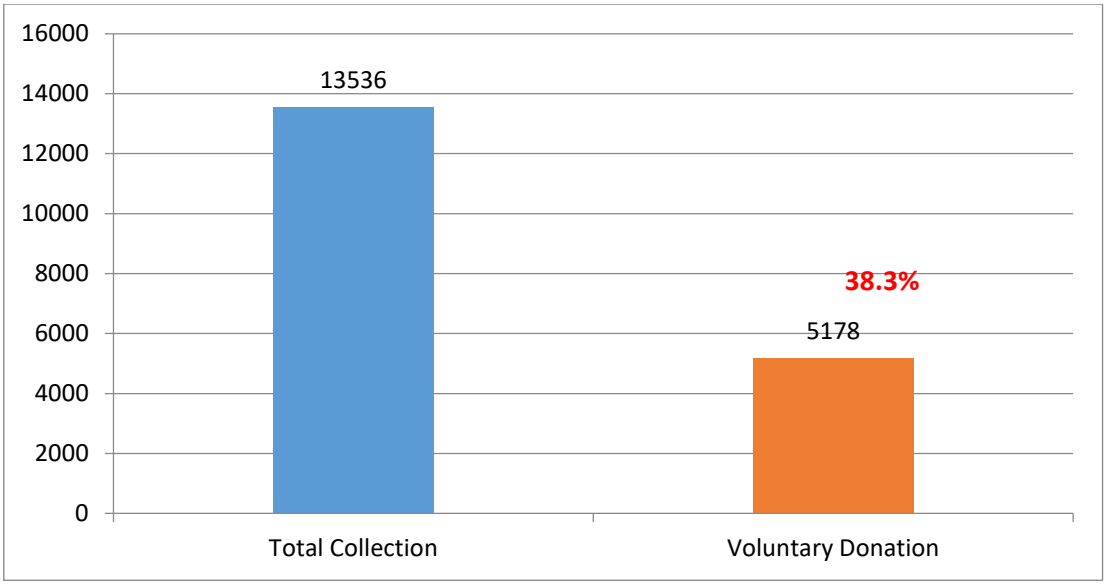
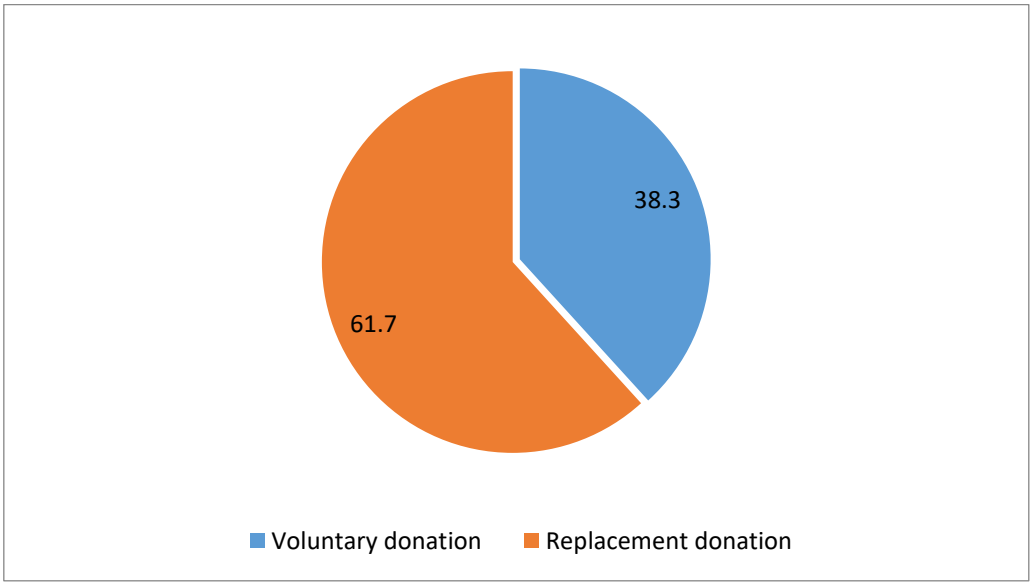


Fig-4 Type of Blood Donation (Voluntary vs Replacement Donation %)



The average annual collection of blood units of all the blood banks in the state was 2,256 units.

Table- 6 Average Annual collection

District	All BBs
East Khasi Hills	2586.5
West Garo Hills	2852
West Jaintia Hills	338
Meghalaya	**2256**

Similarly, the blood banks with component separation units recorded a higher average collection of 5,400 units compared to blood banks without blood component separation units which was 807 units. However, the variation in the collection was found to be very high across and within districts.

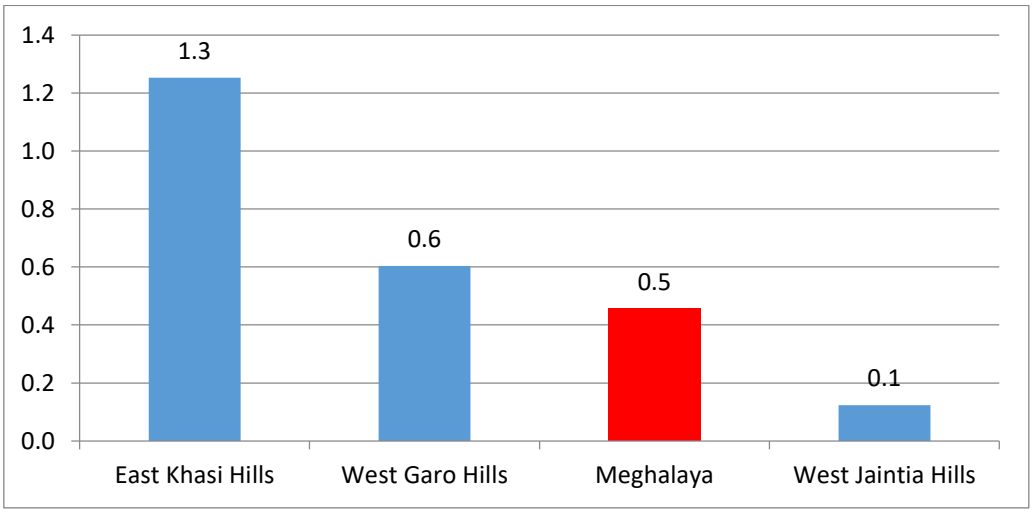
Blood banks with component separation facility collected around 86% of blood units (415,748) and the remaining 14% (67,791) were collected by blood banks without the component facility. Similarly, blood banks owned by public sector collected 85.1% (11,516) of the total collection and the remaining by the not-for-profit sector 14.9% (2,020).

Table-7 indicates the district-wise details of the total annual collection, voluntary and replacement donation in the state of Meghalaya. Blood banks reported a varying proportion of VNRBD ranging from 4.8 to 48.1%.

Table-7 Annual blood collection and percentage of VBD

District	Voluntary Donation	Replacement Donation	Annual Collection	VBD %
East Khasi Hills	4975	5371	10346	48.1
West Garo Hills	137	2715	2852	4.8
West Jaintia Hills	66	272	338	19.5
Meghalaya	**5.178**	**8,358**	**13,536**	**38.3**

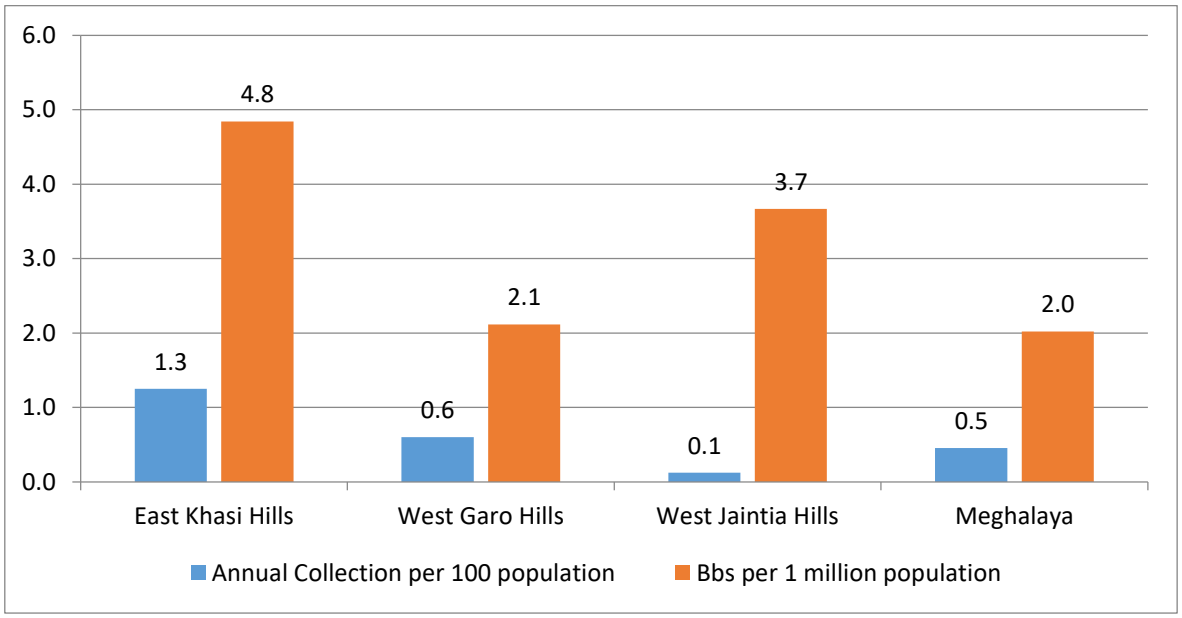
Fig- 5 Annual Collection per 100 population- District wise



The annual collection of blood units per 100 individuals was found to be around 0.5% in the state, which is not meeting the WHO suggested requirement that 1% of the population can meet a nation's (populations) most basic requirements for blood. However, there is a huge disparity in the collection of blood between districts.West Jaintia Hills (0.1%) district collected less than state average of 0.5 units per 100 populations. Two districts in the state recorded more than the state average of 0.5 units per 100 population that are, East Khasi Hills (1.3) and West Garo Hills (0.6). (Refer Fig-5)

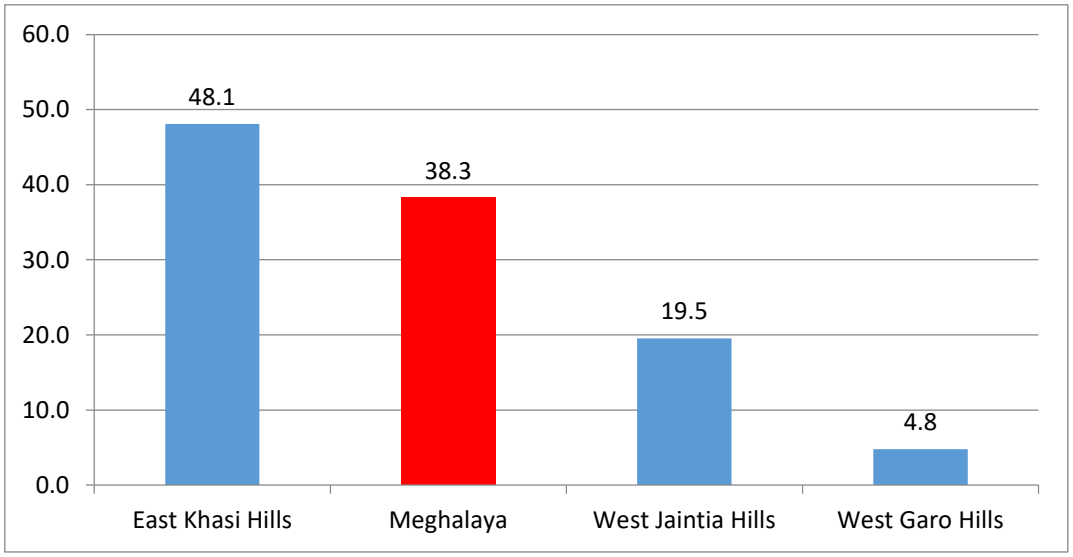
Figure 6 illustrates the district wise comparative information of annual collection per 100 population and number of blood banks per one million population. This indicates that the state had around 2 blood banks per million population that collected around 0.5 units per 100 population at the ratio of 2 BB: 0.5 blood unit. The ratio was wide in West Jaintia Hills district. This district collects relatively less blood with more number of blood banks proportionate to population.

Fig- 6 Annual Collection per 100 population Vs BBs per 1 million- District wise



4.2.2 ***Voluntary blood donation:*** As depicted in Figure-7, one district East Khasi Hills recorded more than the state average of 38.3%.West Garo Hills district recorded the lowest percentage of VBD in the state (4.8%).

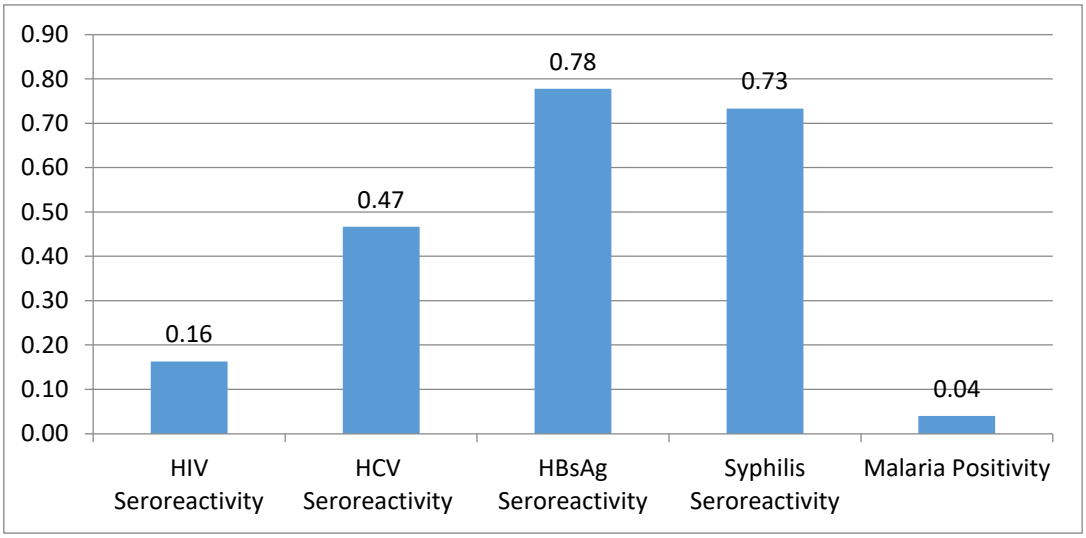
Fig-7 Percentage of Voluntary Blood Donation by District (Overall)



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.

Fig-8 Transfusions Transmitted Infection (%)-Jan-Dec 2015



The seroreactivity of TTI among blood donors in the year 2015 is depicted in Fig-8.HIV reactivity was found to be 0.16%, Hepatitis-C was 0.47%, Hepatitis-B 0.78%, Syphilis 0.73% and Malaria 0.04%. However, there is a huge variation between districts.

HIV, HCV, and Syphilis reactivity/positivity rates were recorded higher in the state of Meghalaya than the national average.

Table- 8 Transfusion Transmitted Infections (%)

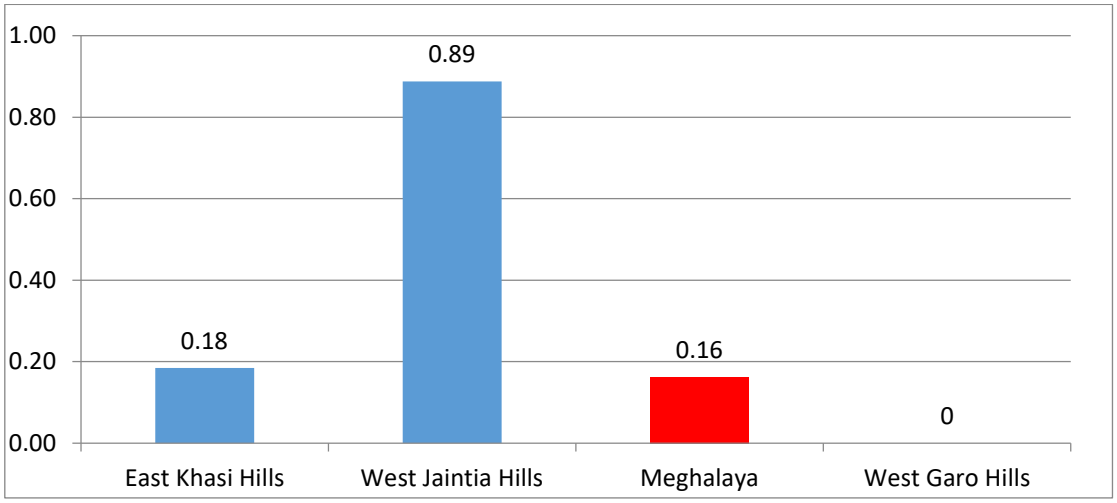
Category of BB	Transfusion Transmitted Infections %				
	HIV	HCV	HBV	Syphilis	Malaria
NACO Supported	0.16	0.47	0.78	0.73	0.04
Non-NACO	-	-	-	-	-
Overall	**0.16**	**0.47**	**0.78**	**0.73**	**0.04**

4.3.1 Transfusion Transmitted Infections by Category of blood banks: HIV, HCV, HBV and Syphilis reactivity rates were found to be higher in blood banks with component facility as compared to blood banks without component separation facility.

Table- 9 Transfusion Transmitted Infections by category of blood banks

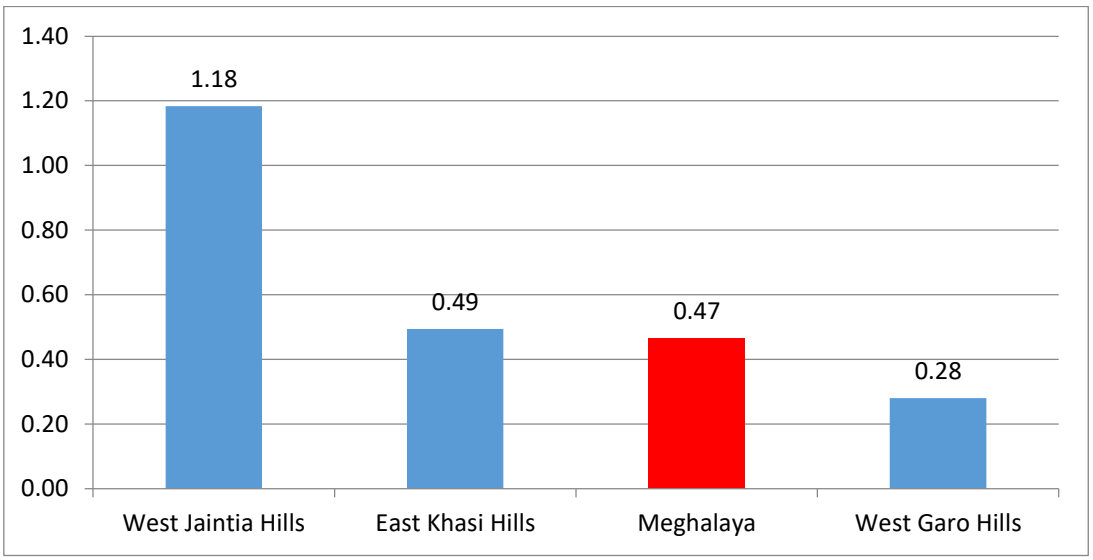
Category of BB	Transfusion Transmitted Infections %				
	HIV	HCV	HBV	Syphilis	Malaria
BBs with component facility	0.20	0.61	0.85	1.09	0
BBs without component facility	0.10	0.23	0.66	0.15	0.08
Overall	**0.16**	**0.47**	**0.78**	**0.73**	**0.04**

Fig-9 HIV Seroreactivity- By District (%)



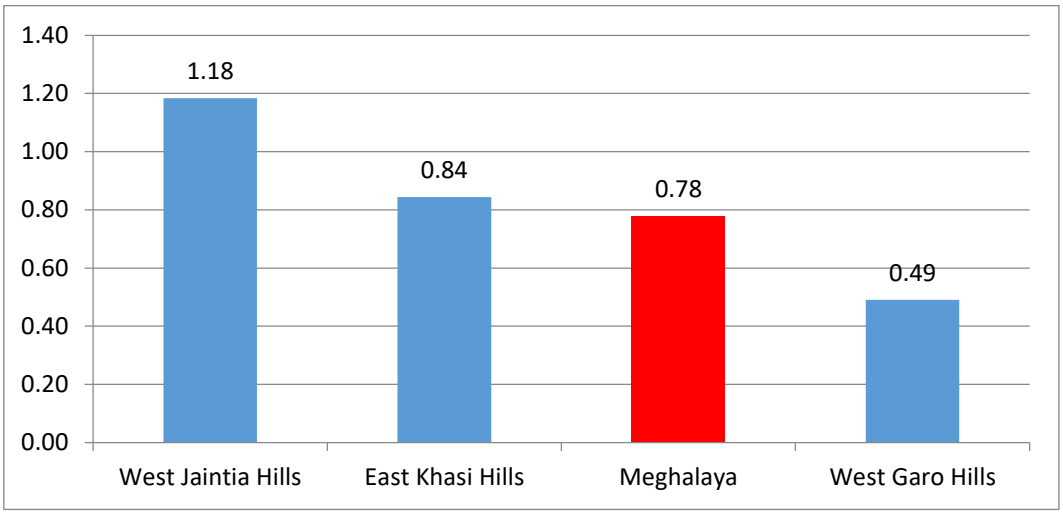
The two districts East Khasi Hills (0.18%) and West Jaintia Hills (0.89%) indicated higher HIV reactivity than the state HIV reactivity level of 0.16%. However, West Garo Hills did not report HIV seroreactivity among donors. In general, HIV reactivity in the state recorded a higher reactivity as compared to other states in the country.

Fig-10 HCV Seroreactivity- By District (%)



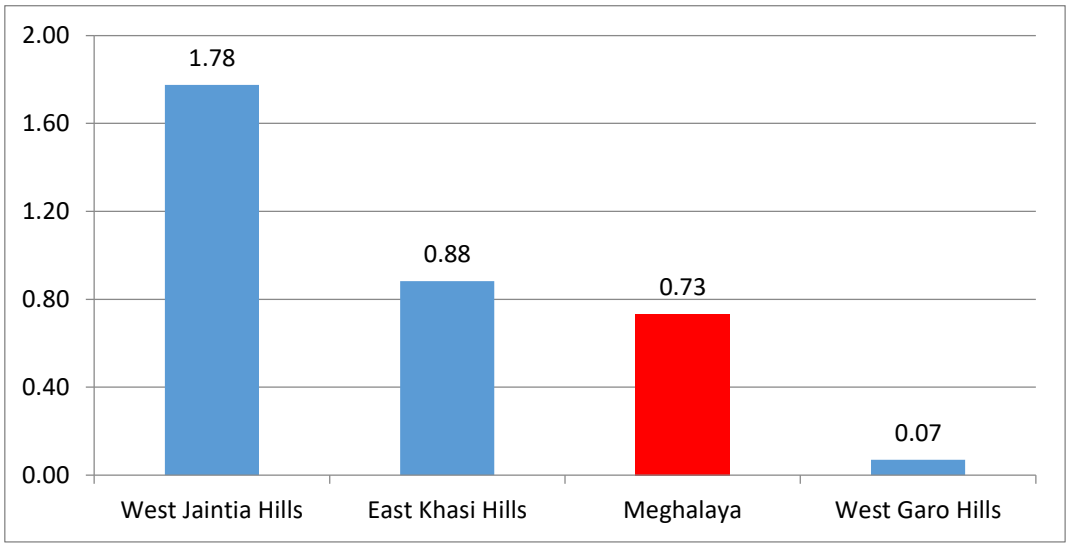
When considering Hepatitis C infection, districts like West Jaintia Hills (1.18%), East Khasi Hills (0.49) indicated a higher reactivity level as compared to the state average of 0.47%.

Fig- 11 HBV Seroreactivity- By District (%)



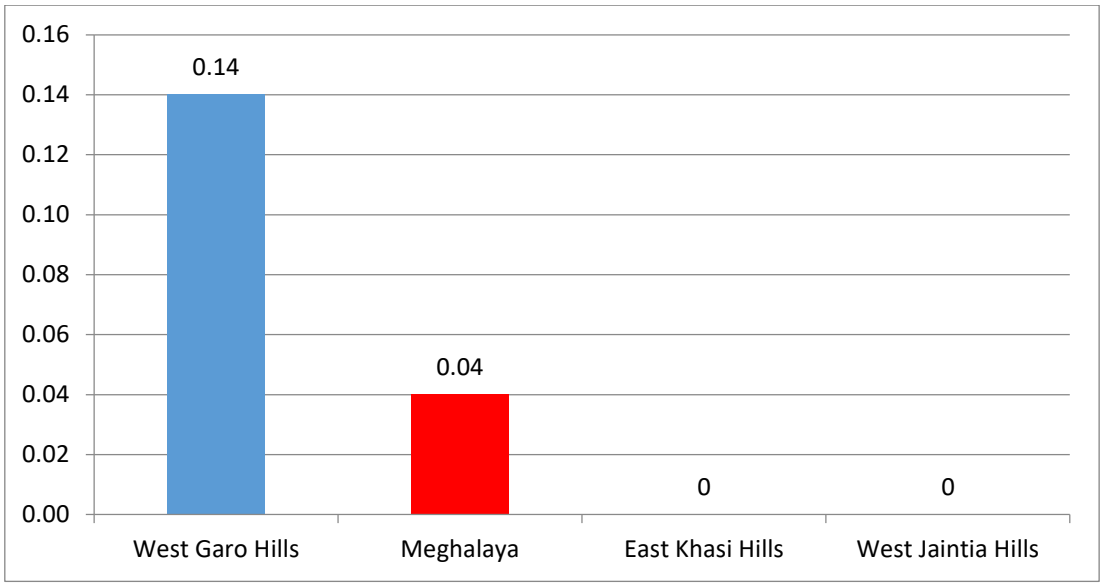
Hepatitis B seroreactivity was found to be higher than the state average of 0.78% in districts like West Jaintia Hills (1.18%) and East Khasi Hills (0.84%).One district west Garo Hills (0.49%) recorded less than the state average.

Fig-12 Syphilis Seroreactivity- By District (%)



Syphilis seroreactivity was found to be higher than the state average of 0.73% in districts like West Jaintia Hills (1.78%) and East Khasi Hills (0.88%).West Garo Hills reported 0.07% syphlis seroreactivity which is less than the state average.

Fig- 13 Malaria Reactivity- By District (%)



The only district that indicated a higher reactivity of Malaria than the state reactivity of 0.04% was West Garo Hills (0.14%) whereas the other two districts reported no malaria positivit

4.4 Component Separation

As depicted in Figure-16, around 73% of blood units collected by blood banks with component separation facilities were used for component separation in state and all the blood banks were NACO supported.

Fig- 14 Total Blood Collection and Component Separation

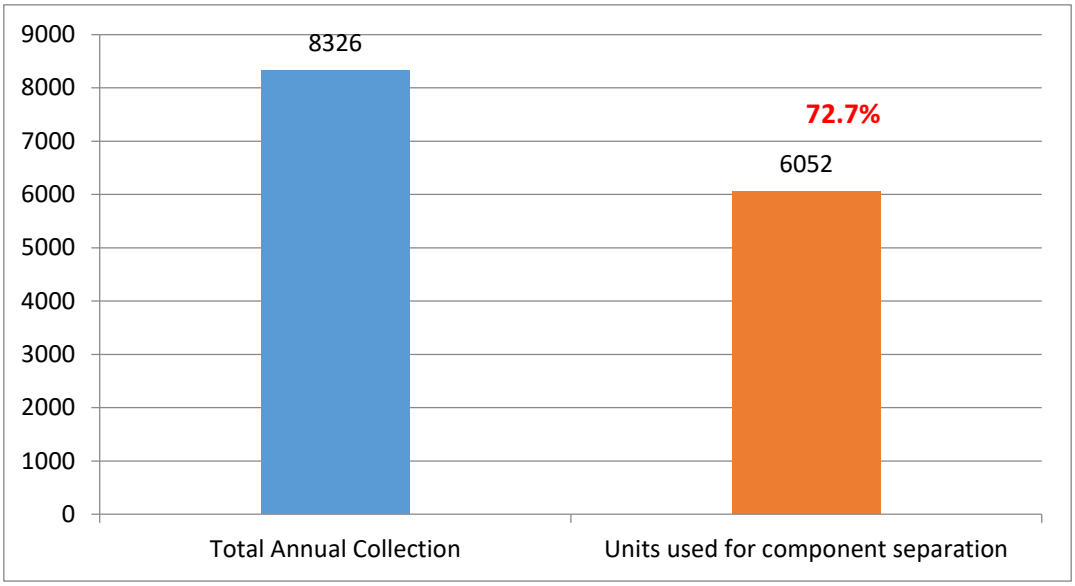


Table- 10 Total Annual Collections by BCSUS and Percentage of Component Separation

District	TOTAL Annual Collection	TOTAL Collection by BCSUs	Percentage of component separation
East Khasi Hills	10346	8326	72.7
West Garo Hills	2852	-	-
West Jaintia Hills	338	-	-
Meghalaya	**13536**	**8326**	**72.7**

The percentage of component separation out of the total collection was around 73% in the district East Khasi Hills.

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 -11. All the blood banks (100%) reported that they adhered to the NBTC guidelines. Availability of document control system was reported by only 16.7% of the blood banks in the state.In terms of Standard Operating Procedures (SOPs) for technical processes, more than 100% reported that they had SOPs.

Table- 11 Availability of Quality Parameters in Blood Banks

Quality Parameters	All Blood Banks (n=6)
Compliance with NBTC guidelines	6
	100%
Availability of Documental Control System (DCS)	1
	16.7%
SOPs for Technical Processes	6
	100%
IQC for IH	6
	100%
IQC for TTI	4
	66.7%
QC for kits, reagents and blood bags	6
	100%
EQAS for IH	-
	-

EQAS for TTI	-
	-
NABH accreditation for blood banks	-
	-
Availability of designated and trained Quality Manager	1
	16.7%
Availability of designated and trained Technical Manager	1
	16.7%
Programme for regular Equipment maintenance	5
	83.3%
Equipment calibration as per regulatory requirement	5
	83.3%

At the state level, Internal Quality Control (IQC) for Immunohematology was reported by around 100% of the blood banks and IQC for TTIs was reported by 66.7% of the blood banks. All the 6 blood banks reported carrying out quality control for kits, reagents and blood bags. No blood bank enrolled in EQAS for immunohematology and for TTIs. No blood banks out of the total 6 blood banks that participated in the assessment were accredited by National Accreditation Board for Hospitals & Healthcare Providers (NABH).

Designated and trained Quality Managers and Technical managers were available only in 16.7% blood banks. Majority 83.3% of the blood banks reported that they had a regular equipment maintenance programme and equipment calibration as per requirement.

4.6. Reporting and Documentation

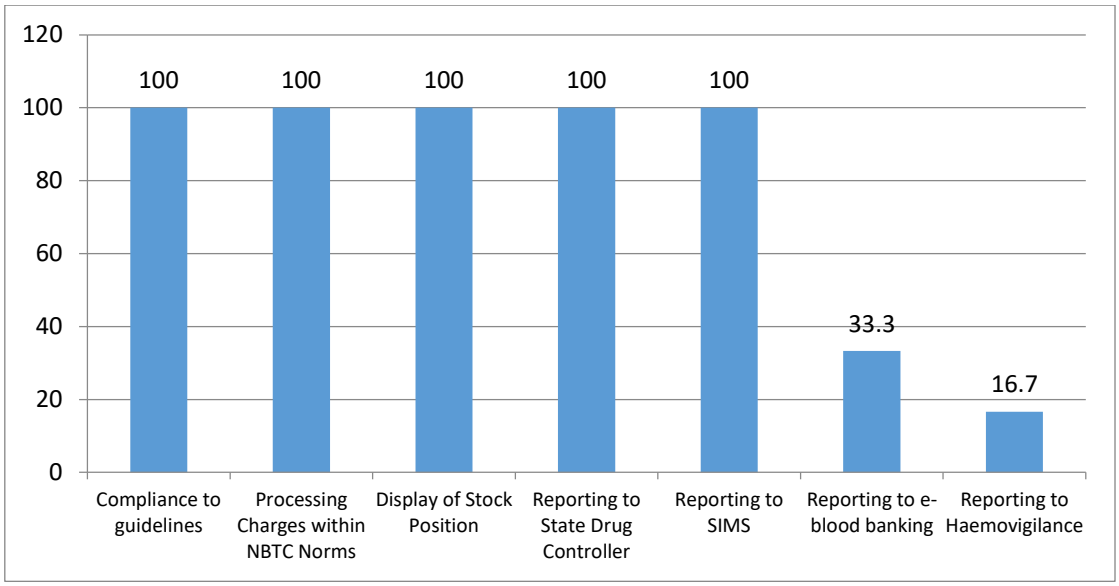
4.6.1. Compliance to NBTC guidelines

All the blood banks (100%) reported to be compliant with NBTC guidelines and were recovering processing charges within NBTC/SBTC norms. Also all the blood banks reported that they were displaying stock position in their Blood bank Premises.

4.6.2. Reporting requirements

In terms of reporting requirement, all the blood banks submitted regular reports to state drug controller and regularly reported in national strategic information management systems (SIMS). However, only 33.3% regularly reported in E-blood banking either national or state e-blood banking. Only 16.7% of blood banks were members of National Haemovigilance Program.

Fig- 15 Reporting and Documentation

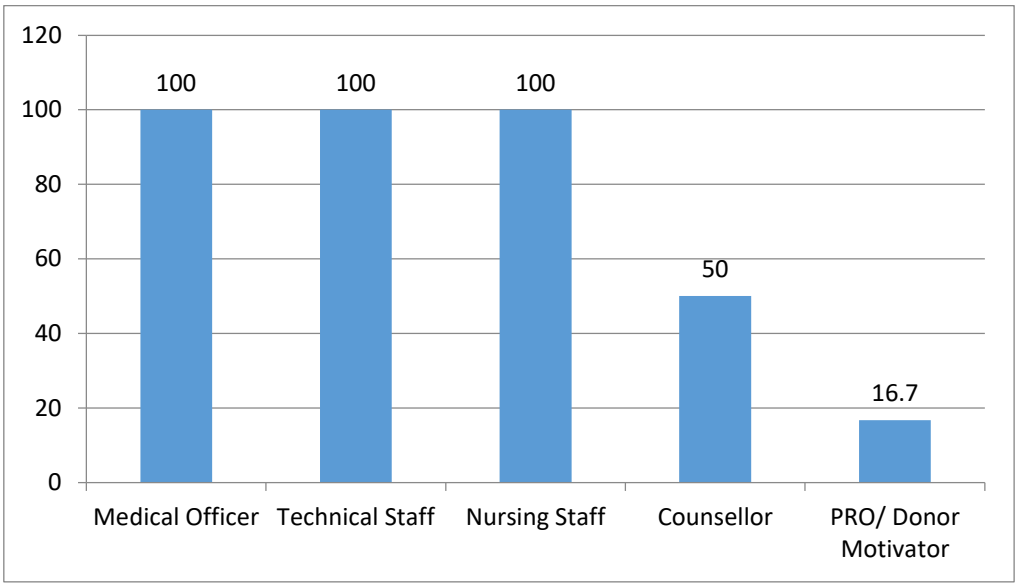


4.7. Human Resources

4.7.1. Availability of staff

The mean number of employees in the blood bank was 11.8 (SD 8.0). It ranges from two employees to 62 employees. All the 6 blood banks reported to have medical officers, technical staff and nursing staff. However, only 50% had counsellors and 16.7% reported to have PRO/Donor motivators.

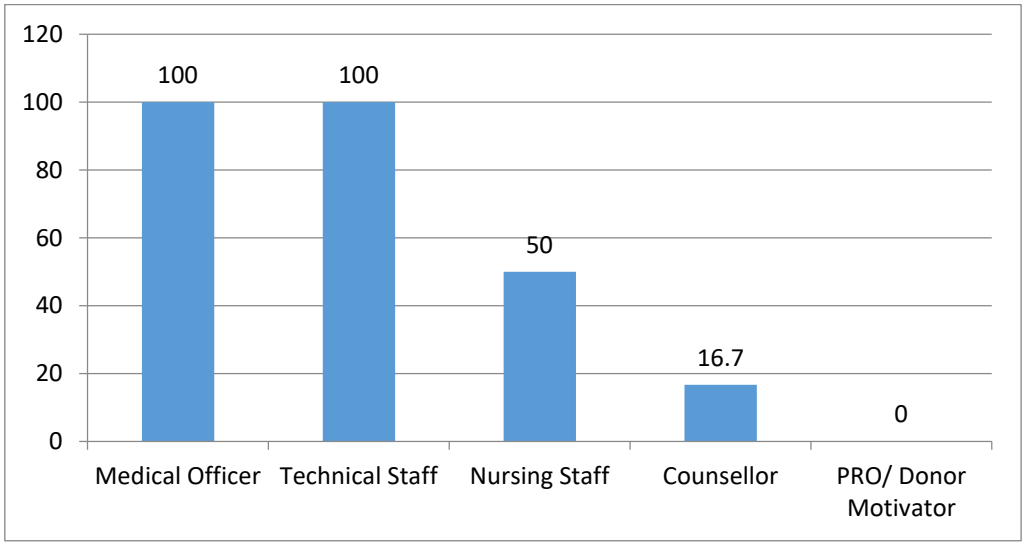
Fig-16 Percentage of BB Manpower (At least one)



4.8. Training of Blood Bank Personnel

According to the assessment, all the 6 blood banks reported that they had at least one medical officer and technical officer trained by NACO/NBTC. 50% reported having trained nursing staff, 16.7% had trained counsellors and no blood bank reported having trained PRO/donor motivators.

Fig -17 Percentage of BBs having at least one trained



4.9. Equipment and Supplies

4.9.1. Regular supply kits/supplies

All the 6 blood banks (100%) reported that they had regular supply of blood bags, regular supply of TTI kits and reported to have regular supply of blood grouping reagents.

4.9.2. Equipment Availability (working condition)

Table 12 indicates the percentage of blood banks that have different equipment in working condition.

Table-12 BBs having Equipment in working condition

BBs having at least one equipment in working Condition		
Sl No	**Equipment**	**% BB**
1	Donor Couches	100
2	Instrument for Hb Estimation	83.3
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	83.3
8	General lab centrifuge for samples	33.3
9	Bench top centrifuge for serological testing (Immunohaematology)	100
10	Blood transportation box (No. in inventory)	66.7
11	Emergency drugs box / Crash card	83.3
12	Autoclave machine	100
13	Water bath	100
14	Blood bank refrigerator (storage of tested blood) with temperature recorder	100
15	Automated pipettes	83.3
16	Refrigerated centrifuge	33.3
17	Blood container weighting device	100
18	Serology rotator	83.3

4.10. The current status of blood banks 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.

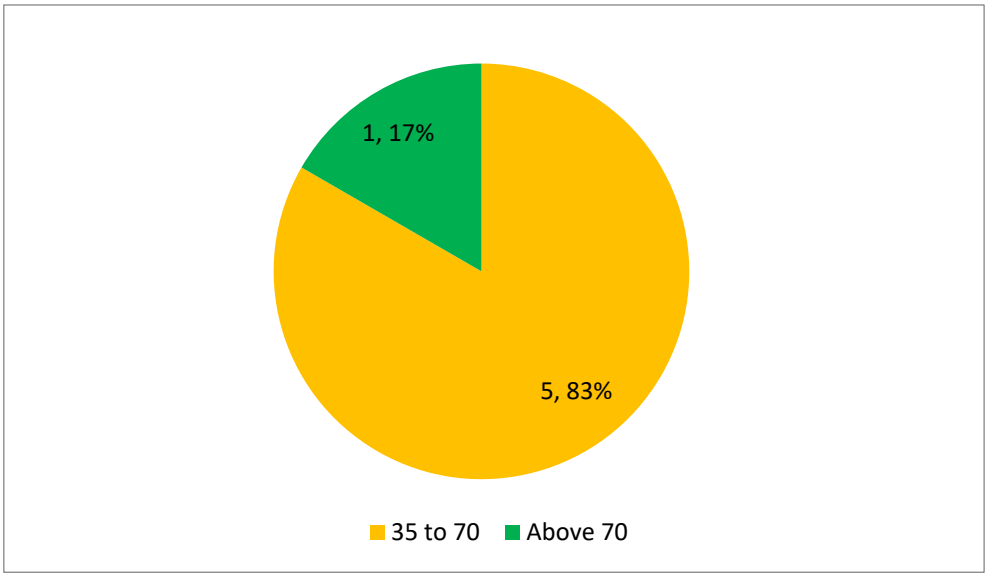
The mean assessment score of blood banks in the state was 65.0 (SD: 4.05).

Table- 13 Mean Assessment score

Type of BB	N	Mean	SD
NACO supported	6	65.0	4.05
Non-NACO	-	-	-
Total	**6**	**65.0**	**4.05**

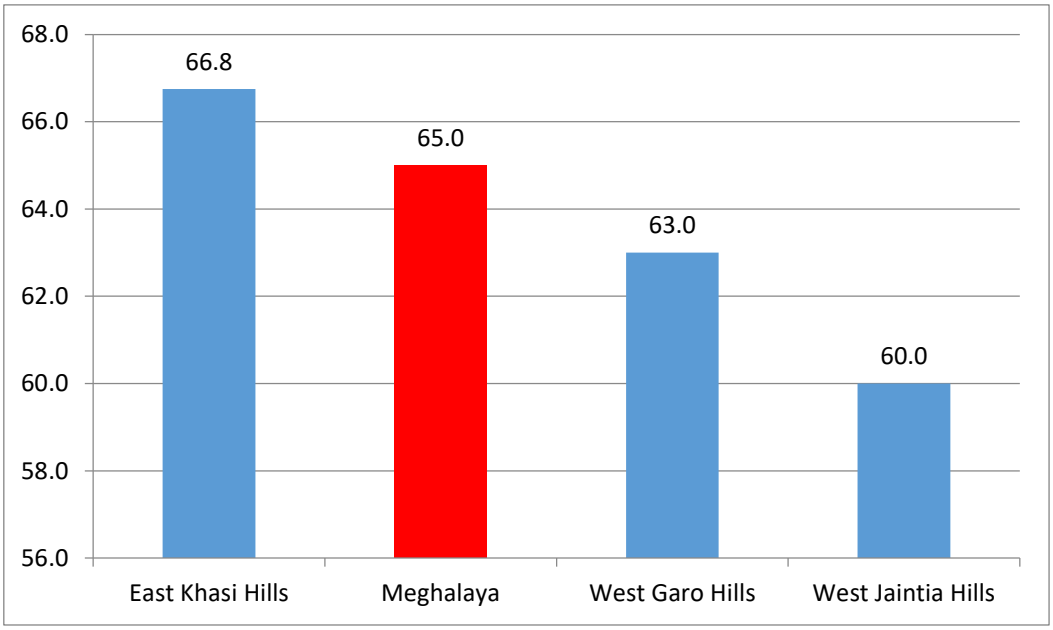
At the state level, the majority of blood banks (5; 83%) scored between 35 to 70, and only one blood bank scored more than 70.

Fig -18 Categorisation of Blood banks (n=6)



Among the districts, East Khasi Hills (66.8) scored the highest and West Jaintia Hills (60.0) scored the least. Only East Khasi district scored above the state average. More than half of the blood banks (66.7%) were located in these districts.

Fig-19 Mean Assessment Score – By Districts (All BBs)



Only one blood bank in East Khasi Hills district scored more than 70. Of the 5 blood banks that scored between 35 to 70 score, 3 (72%) were in East Khasi Hills and one each in West Garo and West Jaintia Hills.

4.10.1 Assessment score by Category of blood banks: The mean score of blood banks without component facilities (65.25; SD: 4.79) was found to be slightly higher than the mean score of those with component facilities (64.50; SD: 3.54).

Table -14 Mean assessment score by category of blood banks

Type of Blood Bank	TOTAL		
	N	Mean	SD
BCSUs	2	64.50	3.54
Without BCSU	4	65.25	4.79

4.10.2 Assessment score by Ownership: The mean assessment score of NGO/Trust/Charitable owned blood banks (69.00; SD: 2.83) was found to be slightly higher than the public owned blood banks (63.00; SD: 2.94). (Refer Table 15).

Table-15 Mean assessment score by Ownership

Ownership	TOTAL		
	N	Mean	SD
NGO/Trust/ charitable	2	69.00	2.83
Private	0		
Public	4	63.00	2.94

4.10.3 Assessment score of Private Sector Blood Banks: Irrespective of the NACO support status, 78.5% (128) blood banks were owned by private sector, of which, 70 (54.6%) were owned by not-for-profit sector such as, NGO, Trust, and charitable organizations. The mean score of private sector owned blood banks including not-for-profit sector was 64.97 (SD: 8.94) and the mean score of public owned blood banks was 65.17 (SD 6.79). Among the private sector, not-for-profit sector (65.00; SD: 9.64) scored slightly higher than the other private blood banks (64.93; SD: 8.10).

Nevertheless, it is also important to note that the average annual collection was higher in public owned blood banks(6,554 units) compared to private blood banks (2,052 Units). Similarly, the percentage of voluntary blood donation was higher in public owned blood banks (93.4%) compared to the private blood banks (74.6%). Of the total private blood banks, 46% (59) had component separation facility whereas 54.2% (19) of public blood banks had component separation facility.

4.10.4 Assessment score by Annual Collection: The mean assessment score of blood banks that collected less than 3000 blood units (64.50; SD: 3.54) was found to be higher than those which collected between 3001 to 5000 (64.50; SD: 3.54).

Table 16 Mean assessment score by annual collection

Annual Collection	TOTAL	
	Mean	SD
Up to 3000	65.25	4.79
3001 to 5000	64.50	3.54

4.10.5 Assessment score by Voluntary Blood Donation: The mean assessment score of blood banks that have been categorized by percentage of voluntary blood donation does not indicate any pattern.

4.10.6 Assessment score by participation in External Quality Assessment Scheme (EQAS) for Immunohematology and Transfusion Transmitted Infections (TTI): No blood bank was enrolled in EQAS for IH and TTI in the state of Meghalaya.

4.10.7 Assessment score by Accreditation status: None of the blood banks were accredited by National Accreditation Board of Hospitals and Health care Providers (NABH).

The list of blood banks under different categories of score is given in Table- 17

Table- 17 Distribution of Blood banks by Districts and mean assessment score categories

Score Category				
District	**Upto 35**	**35 to70**	**Above 70**	**TOTAL**
East Khasi Hills	-	3	1	4
West Garo Hills	-	1	0	1
West Jaintia Hills	-	1	0	1
Meghalaya	-	**5**	**1**	**6**

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 in Meghalaya 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 state.

The 6 NACO supported blood banks which were included in the review are 100% of the total blood banks (6) existing in the state. The annual collection of these blood banks was 13,536 units which is approximately 45.6% of the total blood requirement based on WHO's estimation that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2010). However, there is a huge variation between districts that ranges from 0.1 units to 1.3 units per 100 population. 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 relatively lower collection of blood in the few districts could be due to the fact that there is lower demand for blood because of the gaps in availability, accessibility, and affordability of health care services.

Though there has been an increase in the percentage of voluntary blood donation over the years (around 82.6% in 2015), there is still a huge variation between districts that ranges from 4.8% to 48.1%. A targeted program to increase the non-remunerated voluntary blood donors will go a long way towards ensuring a safer option for our patients.

It is also evident that the distribution of blood banks is skewed with 66.7% of the all the blood banks in the state relegated to only onedistrict. Three districts of the 4 districts have less than the state average of 2 blood banks per million population. The potential impact of this distribution of blood banks and collection of blood on other health indices may be further studied.

One blood bank had their licensing status in pendency may be an indication of an opportunity to strengthen the regulatory system by modern technological modalities to ensure a standardized, timely and transparent licensing process. It is also essential to review and update the regulatory framework to keep up with recent scientific developments and modernize the transfusion practice in the state.

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. The inequity in the distribution of component separation facilities across districts and region is very evident. 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 is still the remit of the state, 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. This review indicated a mean score of 65 with significant variations across the category of blood banks, ownership, voluntary blood donation, participation in proficiency testing (EQAS) and accreditation status. It is important to understand that there is a huge variation between districts on several parameters included in the assessment. This suggests the need for targeted and customized approach to address the gaps and challenges faced by the blood banks in the state. This assessment suggests that blood banks owned by trusts/charities in the private sector seemed to have performed slightly better in the quality parameters. This may be partly due to access to resources, both financial and technical, to enhance capacity and modern technology to overcome potential barriers to quality.

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 across the state.

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7. Annexures

7.1 Individual Blood Banks Summary

District	Name	Type	Ownership	Annual Collection	Score (Out of 100)
East Khasi Hills	Blood Bank, M/S, North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences	BCSU	Public	4817	67
	Regional Blood Bank	BCSU	Public	3509	62
	M/S Nazareth Hospital	Non BCSU	NGO/Trust/ Charitable - NACO supported	1092	71
	Dr H Gordan Roberts Hospital Blood Bank	Non BCSU	NGO/Trust/ Charitable - NACO supported	928	67
West Garo Hills	M/S. Civil Hospital Blood Bank Tura	Non BCSU	Public	2852	63
West Jaintia Hills	Towai Civil Hospital Blood Bank	Non BCSU	Public	338	60

7.2 NACO/NBTC – Questionnaire for Blood Banks

NACO/NBTC - Questionnaire for Blood Banks								
Data Filled by								
Mobile Phone *Number* ***(Person filled the data)***								
Section A – GENERAL								
A 1	**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							
7	State							
8	Pin code							
9	Blood Bank Phone number (Land line including area code)							
10	Blood bank Email ID							
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 Licence, the current medical officer?	Yes						
		No						
14	Designation *(Please enter designation of the 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						
16	Specify branch/Broad speciality							

17	Email ID: *(Official/Personal Email where the medical officer can be directly contacted). This is apart from the 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 blood Bank	
		Blood Component Separation Units	
		Major Blood Bank	
		District level blood bank	
		Others	
22	Who is the blood bank owned by?	Public (Central/State/Local government)	
		Public (Other than ministry of health e.g. PSU, Army etc.)	
		NGO/Trust/Charitable – NACO Supported	
		NGO/Trust/Charitable	
		Private - Others	
23	Is the Blood Bank attached to any of the following?	Hospital	
		Lab	
		Stand alone	
24	If attached to Private Hospital, specify level of hospital	Medical College Hospital	
		Tertiary care hospital (other than medical college)	
		Secondary care hospital	
25	If attached to public/govt. hospital, specify the level of the hospital	Sub-District hospital	
		District level hospital	
		Medical College hospital	
		Tertiary care hospital (other than Medical College)	
26	If the blood bank is attached to a hospital, please specify the number of inpatient beds available		
27	Are you permitted to conduct Blood donation camp?	Yes	
		No	
28	How many Blood storage centres are linked to your blood bank?		
29	BB working hours *(Specify hours per day)*		

A 2	**License Information**	
1.	**BB License Number** *(Enter your license number. This should be exactly as is displayed in your license issued by the Drugs Controller Office and will be used for verification*	

	purposes. This is a mandatory field and should be entered regardless of the status of license - under-renewal etc. (**You will have to submit a self-attested photocopy of the currently displayed license along with this form**.)		
2	Status of Current License	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	
A 3	**Basic Statistics (Date of reporting from Jan-2015- 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 statistics		**Number tested**	**Number positive**
	HIV(Anti-HIV I & II)		
	HCV (Anti-HCV)		
	HBV (HBs Ag)		
	Syphilis (RPR/TPHA/ELISA)		
	Positive for Malaria (Any method)		
A 4.	**Reporting Summary**		
1	Are you in compliance with NBTC guidelines?	Yes	
		No	
2	Are you recovering processing charges for blood/components within NBTC/SBTC norms?	Yes	
		No	
3	Are you displaying stock position in the blood bank premises?	Yes	
		No	
4	Are you submitting statistics to the State Drugs controller?	Regular	
		Occasional	
		No	
5	Are you reporting in SIMS (strategic Information Management System- NACO)?	Regular	
		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 the future?	Yes	
		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)	
		Other(Specify	
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 future?	Yes	
		No	

SECTION B			
B1	**Blood Donor(Reporting from Jan 2015- Dec 2015)**		
Definition of VBD = Close relatives should NOT be counted as VBD			
1	Are you recruiting voluntary blood donors?	Yes	
		No	
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 conducted in the reporting period? *(Provide numbers of VBD camps conducted during the period January - December 2015.)*		
8	Does the blood bank have dedicated staff for the promotion of Voluntary blood donors? *(If your blood bank has dedicated staff for camps, answer yes.)*	Yes	
		No	
8 a.	if Yes to 8, select as applicable *(More than one may be selected)*	Donor Motivator	
		Public relations 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 *(Donor database is essential to contact donors to remind them or to call during an emergency?)*	Yes	
		No	
12	If yes to Q 11, is it in electronic format or paper based?	Electronic	
		Paper	
		Both	
13	What percentage of the voluntary blood donors are repeat blood donors? (%)		
14	Does your blood bank have a mobile blood collection facility? *(Answer yes if your Blood bank has a mobile facility (bus or van with donor couches)*	Yes	
		No	
15	Source of funds for the mobile blood collection *(Indicate the source of funding for the purchase of the mobile blood donor van.)*	State	
		Central	
		Donor	
		Others	
16	Specify, other source of funds		
17	Is there a record for donor adverse reactions?	Yes	
		No	
18	Is there a referral system for HIV sero-reactive blood donors?	Yes	
		No	
19	If yes to Q 18, please specify what is the process adopted.		

Section C
Technical – Immunohematology

C1.	Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed?	**Blood Group (Tick as applicable)**		**Rh Type** (Tick as applicable**)**
		Forward	Reverse	
C1.1.	Slide			
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?	Monoclonal reagent	
		Polyclonal reagent	
		Both	
2	Do you perform irregular antibodies screening on blood donations and patient sample?	Yes	
		No	
3	Do you perform direct antiglobulin test (DAT/DCT)? *(If you are performing Direct Antiglobulin test (DAT) - earlier called as Direct Coombs Test (DCT), answer yes.)*	Yes	
		No	
4	If yes to previous question, please specify method	Tube	
		Column agglutination	
		Solid phase	
5	Do you perform indirect antiglobulin test (IAT/ICT)?	Yes	
		No	
6	If yes, to previous question please specify method	Tube	
		Column agglutination	
		Solid phase	
7	Number of group and type tests performed in reporting period (Jan - Dec 2015*) (Specify the number of group and type tests performed - Total of all patient and donor tests in the reporting period - January to December 2015.)*		
8	Number of compatibility testing performed in reporting period. *(Specify number of compatibility tests performed in the reporting period January to December 2015)*		
9	Total Number of DAT/DCT tests performed in the reporting period *(Specify number of DAT/DCT tests performed in the reporting period (January to December 2015)*		
10	Total Number of IAT/ICT tests performed in the reporting period *(Specify number of DAT/DCT tests performed in the reporting period (January to December 2015)*		
11	Total Number of antibody screening performed in reporting period *(If you answered YES to Q2, Specify number of antibody screening tests performed in the reporting period (January to December 2015).*		
12	Do you have automation for Immunohematology testing? *(If you have implemented any kind of automation, please indicate so.)*	Yes	
		No	
13	Do you perform Internal QC for all immunohematology tests (blood group/DAT/IAT etc.)? *(Please answer yes if you are performing internal quality control (IQC) for the immunohematology tests listed above. They include daily QC on reagents and cells.)*	Yes	
		No	
14	Do you participate in an external quality assessment program or scheme (EQAS) for Immunohematology tests usually performed in your laboratory?	Yes	
		No	
15	If yes to 14, Specify name of program/provider		
16	If yes to 14, EQAS Membership ID number/ PIN#.		
17	If yes 14, specify Highest level of EQAS program participant in	Inter-lab	
		National	

		International	
18	If you are not participating in EQAS for immunohematology, will you be willing to do so in the future?	Yes	
		No	
19	If Yes to above question, will your blood bank be able to allocate financial resources (about Rs.2500 per year)?	Yes	
		No	
20	If your answer to Q 19 is NO, when do you think you will be ready for EQAS participation? (immunohematology)	Next 6 months	
		Later than 6 month	
21	Are you a member of National Haemovigilance Program of India (HVPI)?	Yes	
		No	
22	If yes, provide HVPI ID Number		
23	If not, would you be willing to participate in HVPI in the near future?	Yes	
		No	
24	Are you reporting all adverse events to the National Haemovigilance Program of India?	Yes	
		No	
25	Number of adverse reactions recorded in the reporting period		
26	Does your hospital have regular transfusion committee meetings?	Yes	
		No	
27	What is the frequency of Transfusion committee meetings?	Annual	
		Half-yearly	
		Quarterly	
		Occasional	

Section D
Technical - Screening For Transfusion Transmissible Infections (TTI)

Does the blood bank screen the following TTIs?

	Type of Test	Platform (please tick appropriate)		Method (please tick appropriate)
1	**HIV I & II**	Rapid		
		ELISA		Manual ☐ Automated ☐
		CHEMI		Manual ☐ Automated ☐
		NAT		Manual ☐ Automated ☐
1.1	Specify % of donors tested by Rapid Test?			
2	**Hepatitis B**	Rapid		
		ELISA		Manual ☐ Automated ☐
		EM		Manual ☐ Automated ☐
		NAT		Manual ☐ Automated ☐
2.1	Specify % of donors tested by Rapid Test?			

3	**Hepatitis C**	Rapid		
		ELISA		Manual ☐ Automated ☐
		CHEM		Manual ☐ Automated ☐
		NAT		Manual ☐ Automated ☐
3.1	Specify % of donors tested by Rapid Test?			
4	**Syphilis**	RPR		Manual ☐ Automated ☐
		TPHA		Manual ☐ Automated ☐
		ELISA		Manual ☐ Automated ☐
5	**Malaria**	Rapid		
		Fluorescent		Manual ☐ Automated ☐
		Slide microscopy		
		ELISA		Manual ☐ Automated ☐

6	Does the blood bank have an algorithm for units that test POSITIVE in initial screening? *(If you have a method of verifying a sample that has tested positive on the screening test please answer yes.)*	Yes	
		No	
7	If yes to Q6 , Repeat testing with same test/ technique	Yes	
		No	
8	If Yes to Q6, Repeat testing with different test/technique	Yes	
		No	
9	If yes to Q6, Recalling donor for repeat sample	Yes	
		No	
10	Do you perform independent internal QC (Third party controls) with TTI testing?	Yes	
		No	
11	Do you participate in an external quality assessment program or scheme (EQAS) for TTI *(Viral Markers, Malaria, and Syphilis) testing?*	Yes	
		No	
12	If yes, Specify program/provider		
13	Membership ID number (PIN)		
14	Level of EQAS	Inter-lab	
		National	
		International	
15	If you are not participating in EQAS for TTI screening, will	Yes	

	you be willing to participate in future?	No	
16	If Yes to Q15, will your blood bank be able to provide financial support (about Rs. 2500 per year)	Yes	
		No	
17	If your answer to Q 15 is NO, when do you think you will be ready for EQAS (TTI screening) participation?	Next 6 months	
		Later than 6 months	

Section E
Technical - Component Preparation (Applicable only to BCSU)

1	Does your blood bank prepare components?	Yes	
		No	

If your answer to Q1 is NO, SKIP TO SECTION F

If Yes, List the components and number prepared and issued in the period Jan to December 2015

2	Number of donated blood that was used for component preparation during the period Jan- December 2015.	

		Number prepared	No. issued (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?	Yes	
		No	
	If yes to above question, Specify the following details		

		Number prepared	No. issued (utilized)
10	Platelet concentrate IP		
11	Fresh frozen plasma (FFP)		
12	Granulocytes concentrates		
13	Other (specify)		

14	Do you perform QC for the components prepared? *(If you perform quality control for all components, answer yes.)*	Yes	
		No	
15	If yes to above, Are the Factor assays on Fresh Frozen plasma/Cryoprecipitate performed at your Blood Bank?	Yes	
		No	
16	If yes for above question, do you participate in external quality assessment scheme (EQAS)?	Yes	
		No	
17	If yes, to above question, Specify agency		

SECTION F
Quality Management Systems

F 1	Are you aware of quality management systems for Blood bank	Yes	
		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 registers as D&C act?		Yes	
			No	
4	Do you have Standard Operating Procedures (SOPs) for all technical processes?		Yes	
			No	
5	Do you have written responsibilities for all levels of staff?		Yes	
			No	

How many staff are currently employed in each of the following categories and how many of them have been trained during the reporting period Jan 2015 - Dec 2015? (Questions 6 - 15)

	Staff Details	Total number of staff	Number on contract	NACO/NBTC Supported in-service training	Other National Training
6	Professor				
7	Associate Professor				
8	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				

Total number of staff			
17	In your opinion, does the BB have adequate staff to function optimally (24x7)? This may be decided based on the volume and duration of work hours.	Yes	
		No	
18	Do you monitor Quality indicators or Key Performance indicators?	Yes	
		No	
19	If yes to above question, please specify names of indicators		
20	Do you have a designated and trained Quality manager?	Yes	
		No	
21	Do you have a designated and trained Technical Manager?	Yes	
		No	
22	If you do not have either a trained Quality manager or Technical Manager please state reasons?		

23	Please specify if you have a plan for recruitment in the future?

F2. EQUIPMENT AND SUPPLIES				
1	Does the blood bank have adequate equipment to meet regulatory requirements? *(If your blood bank has adequate equipment in working condition to meet expected workload, please answer yes.)*		Yes	
			No	
2	How is equipment purchase funded?	Local bodies		
		Central or upper (state) level agencies		
		Donors		
		Others (specify)		
3	Does the blood bank have a program for regular equipment maintenance?		Yes	
			No	
4	Are all the equipment calibrated regularly as per regulatory requirement?		Yes	
			No	
5	How are consumables purchased?	Local bodies		
		Central or state level agencies		
		Donors		
		Others (specify)		
6	Do you evaluate kits at your facility prior to procurement*? (Are kits evaluated locally (at your blood bank) prior to purchase (e.g. Titre and avidity for blood group Anti Sera?))*		Yes	
			No	
7	Is quality control for kits, reagents and blood bags carried out at your blood bank? *(Is quality control for kits performed locally (at your blood bank) Prior to use (e.g. Titre and avidity for blood group Anti Sera?))*		Yes	
			No	
8	Did you have a regular supply of the following items? (Jan to Dec 2015)			
8.1	Blood Bags		Yes	
			No	
8.2	TTI Screening Kits		Yes	
			No	
8.3	Blood grouping / IH reagents		Yes	
			No	
9	Number of staff vaccinated for Hepatitis B?			

EQUIPMENT LIST (Below is a summary equipment list (a subset of D&C list). Please specify the number in inventory and number in working condition? If you are using shared resources of hospital, you can mention that as well

		Number in inventory	**Number in working condition**
10	Donor beds/couches		
11	Any instrument for Hb Estimation *(other than CuS04 method)*		

12	Blood collection monitor (Blood agitator)		
13	Quarantine Blood bank refrigerator to store untested units with temperature recorder		
14	Container for safe disposal of sharps		
15	Oxygen supply equipment		
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		

7.3 Scoring sheet

Individual Scoring Sheet - Blood Component Separation Units			
GENERAL	**GENERAL SUMMARY**	**WEIGHTAGE**	**TOTAL**
Licence	Under renewal	1	
	Valid	3	
Subtotal			**3**
Annual collection	Below 1000	0	
	1000 to 2000	0.5	
	2000 to 5000	1	
	5000 to 10000	1.5	
	Above 10,000	2	
Subtotal			**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	
Hep B	Rapid	1	
	Elisa	2	
	Advanced	3	
Hep C	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**

Individual Scoring Sheet - Without Blood Component Separation 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	
Hep B	Rapid	1	

	ELISA	3	
Hep C	Rapid	1	
	ELISA	3	
Syphilis	RPR	1	
Malaria	Slide/Rapid	1	
Subtotal			**20**
COMP	*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 carried out at blood bank with regular supply	2	
	Quarantine Blood bank refrigerator to store untested units with temperature recorder	3	
	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**