A Report on the
"Assessment of Blood Banks in Mizoram, India"

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National Blood Transfusion Council (NBTC),
Ministry of Health and Family Welfare, Government of India
in collaboration with
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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 Mizoram

According to Central Drugs Standard Control Organization (CDSCO), there were 10 blood banks in Mizoram in 2015. The assessment exercise identified all the 10 blood banks which are supported by National AIDS Control Organization, Ministry of Health and Family Welfare, Government of India, as functional across the state, and which had submitted the assessment forms in complete and were included in the analysis.

Out of the eight districts, Aizawl and Lunglei districts had the highest number of blood banks with 2 blood banks, followed by Champhai, Kolasib, Lawngtalai, Mamit, Saiha and Serchhip having one blood bank each. The state did not have any Non- NACO blood banks.

Considering the number of blood banks per one million population, 5 districts recorded more than the State average of 9.1 blood banks per 1,000,000 (one million) population. Saiha (17.7) recorded the highest followed by Serchhip (15.4), Lunglei (12.4), Kolasib (11.9) and Mamit (11.6). Three districts which are Lawngtalai (8.5), Champhai (8.0) and Aizawl (5.0) had recorded less than the state average.

Description of blood banks

- Out of 10 NACO supported blood banks 20% (2 of the blood banks had component separation facility situated in Aizawl district.
- Out of the 10 blood banks 70% of blood banks are owned by public sector and 30% was owned by not-for-profit sector such as NGOs, charitable trusts, societies, foundations etc.
- All the districts except Serchhip had one public owned blood bank, whereas districts such as Aizawl, Lunglei and Serchhip had one not-for-profit blood bank each. There were no blood banks in Mizoram owned by the private sector.
- All the blood banks in the state were attached the hospital.
- In the state of Mizoram, 40% (4) of the blood banks had valid license which were equally distributed in the not-for- profit sector and the public sector. Of the remaining 60% of blood banks which had applied for renewal, 50% were owned by the public sector and 10% were owned by the not-for-profit sector.

Annual Collection and Voluntary Blood Donation

- During January 2015 to December 2015, the annual blood collection from all the blood banks that reported was 24,658 units of which 75.2% units were through voluntary blood donations and the remaining 25% were from replacement donations.
- The average annual collection of blood units of all the blood banks in the state was 2,466 units. The average annual collection of Aizawl (8,161units) was found to be highest and Mamit district (405 units) had the lowest average annual collection.

- the blood banks with component separation units recorded a higher average collection of 8,161 units compared to blood banks without blood component separation units which was 1,042 units.

Transfusion Transmitted Infections

- The seroreactivity of TTI among blood donors in the year 2015 is depicted in Fig-10. HIV seroreactivity was found to be 0.30%; Hepatitis-C was 1.24%, and Hepatitis-B 0.94%. There were no seroreactivity cases for Syphilis and positivity cases for Malaria in Mizoram.

Component Separation

- Around 80% of blood units collected by blood banks with component separation facilities, were used for component separation in state.

Quality Management Systems

- The majority of blood banks (90%) reported that they adhered to the NBTC guidelines.
- Availability of document control system was reported by 50% of the blood banks in the state.
- In terms of Standard Operating Procedures (SOPs) for technical processes, all the blood banks reported that they had SOPs.
- At the state level, Internal Quality Control (IQC) for Immunohematology was reported by 80% of the blood banks and IQC for TTIs was reported by 50% of the blood banks.
- All the blood banks reported carrying out quality control for kits, reagents and blood bags.
- There were no blood banks which were enrolled in EQAS for Immunohematology or TTI.
- The state of Mizoram had no blood banks 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 30% of the blood banks.
- Around 80% of the blood banks reported that they had a regular equipment maintenance programme and all the blood banks reported that they calibrate the equipment as per requirement.

Reporting and Documentation

- All the blood banks reported that they were recovering processing charges within NBTC/SBTC norms and 80% of blood banks reported that they were displaying stock position in their Blood bank Premises.
- In terms of reporting requirement, 80% of the blood banks submitted regular reports to state drug controller and are regularly reporting in national strategic information management systems (SIMS).

Human Resources

- All the blood banks reported to have at least one medical officer and technical staff. 90% of the blood banks had nursing staff and 40% of the blood banks reported to have one counsellor. However, only 10% of the blood banks reported to have PRO/Donor motivators.
- According to the assessment, 60% of the blood banks reported that they had at least one technical staff trained by NACO/NBTC; 40% of the blood banks reported they had atleast one trained medical officer and nursing staff. The state reported that didn't have any trained counsellors or PRO/donor motivators in the blood banks.
- All of the blood banks reported that they had regular supply of blood bags and regular supply of blood grouping reagents, and 80% of the blood banks reported that they had regular supply of TTI kits.

The current status of blood banks based on the assessment

- The mean assessment score of blood banks in the state was 57.40 (SD: 6.47).
- All the blood banks in Mizoram had scored between 35 to 70.
- There were 4 districts which scored above the state average of 57.4 with Champhai district (67) scoring the highest followed by Kolasib (62), Mamit (60) and Aizawl (59). Out of the remaining 4 districts which had scored lower than the state average, Serchhip and Saiha (51) had scored the lowest.
- The mean score of blood banks with component facilities (59; SD: 4.24) was found to be higher than the mean score of those without component facilities (57; SD: 7.09). Further analysis shows that among the BCSU's, the public sector blood bank had a higher mean score of 62 than not-for-profit blood bank (56).
- The mean assessment score of public owned blood banks (57.86; SD: 7.20) was found to be slightly higher than the NGO/Trust/Charitable (56.33; SD: 5.51).
- Majority of the blood banks had an annual collection upto 3000 units of blood. There was one blood bank which had an annual collection between 3001-5000 units and one blood bank which collected above 5000 units of blood. The mean assessment score of blood banks that collected above 5000 blood units (62) was found to be higher than those which collected between 3001 to 5000 (56) and upto 3000 units of blood (57:00; SD: 7.09).
- There were no blood banks which were enrolled in EQAS for Immunohematology or TTI.

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 Mizoram

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 seroreactivityalso 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=8). 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 10 blood banks in the state of Mizoram in 2015 (CDSCO, 2015). The assessment exercise identified all the 10 blood banks which are NACO supported as functional across the state, and which had submitted the assessment forms in complete and were included in the analysis.

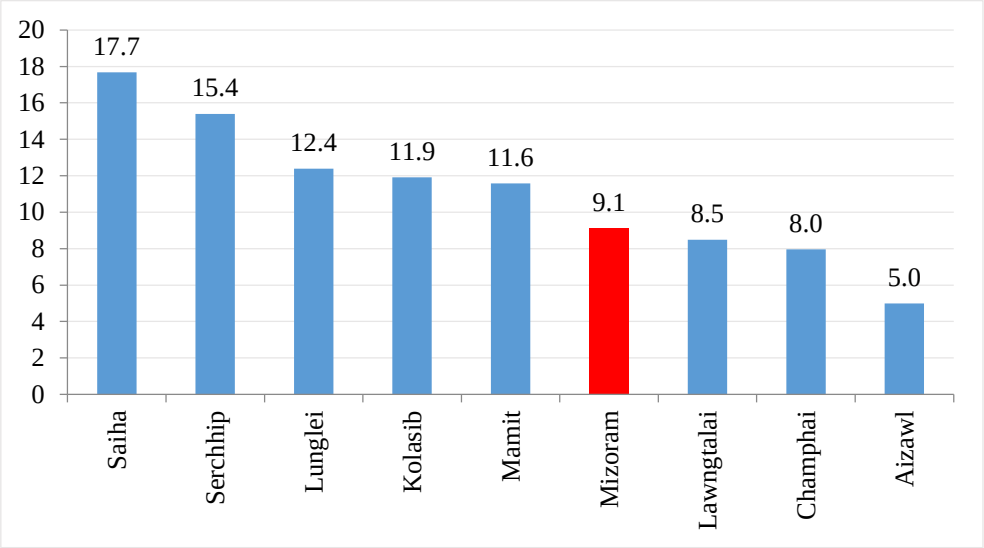
Table 3- District Wise Descriptions of Blood Banks

District	No of BBs
Aizawl	2
Champhai	1
Kolasib	1
Lawngtalai	1
Lunglei	2
Mamit	1
Saiha	1
Serchhip	1
Mizoram	**10**

Table - 3 indicates the district wise details of all the NACO supported blood banks in the state. Aizawl and Lunglei districts had the highest number of blood banks with 2 blood banks, followed by Champhai, Kolasib, Lawngtalai, Mamit, Saiha and Serchhip having one blood bank each. The state doesn't have any Non- NACO blood banks.

Considering the number of blood banks per one million population, 5 districts recorded more than the State average of 9.1 blood banks per 1,000,000 (one million) population. Saiha (17.7) recorded the highest followed by Serchhip (15.4), Lunglei (12.4), Kolasib (11.9) and Mamit (11.6). Three districts which are Lawngtalai (8.5), Champhai (8.0) and Aizawl (5.0) had recorded less than the state average.

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



4.1 Basic details of blood banks (n=10)

As indicated earlier, 10 blood banks which are NACO supported and had submitted the assessment forms in complete, were included in the analysis.

4.1.1 Category of Blood Banks: Out of 10 NACO supported blood banks 20% (2 of the blood banks had component separation facility situated in Aizawl district.

Table 4- Basic details of blood banks

Specifics	Description	BBs
Type of BB	With components	2 (20%)
	Without components	8 (80%)
Ownership	NGO/Trust/Charitable	3 (30%)
	Private	0
	Public	7 (70%)
Licence	Valid	4 (40%)
	Under Renewal	6 (60%)
Attachment	Attached to Hospital	10 (100%)
	Attached to lab	0
	Stand alone	0

4.1.2 ***Ownership:*** As depicted in Table - 4, Out of the 10 blood banks 70% of blood banks are owned by public sector and 30% was owned by not-for-profit sector such as NGOs, charitable trusts, societies, foundations etc.

As depicted in Table-5, all the districts except Serchhip had one public owned blood bank, whereas districts such as Aizawl, Lunglei and Serchhip had one not-for-profit blood bank each. There were no blood banks in Mizoram owned by the private sector.

Table 5-District wise list of blood banks by Ownership

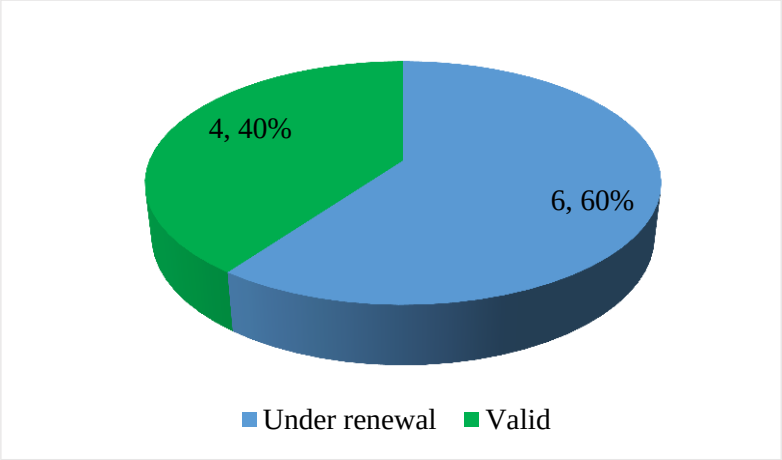
District	Public	%	Not-for-profit	%	Total
Aizawl	1	50	1	50	2
Champhai	1	100	-	-	1
Kolasib	1	100	-	-	1
Lawngtalai	1	100	-	-	1
Lunglei	1	50	1	50	2
Mamit	1	100	-	-	1
Saiha	1	100	-	-	1
Serchhip	-	-	1	100	1
Mizoram	**7**	**70**	**3**	**30**	**10**

4.1.3 ***Organizational Attachment:*** All the blood banks in the state were attached the hospital.

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.

In the state of Mizoram, 40% (4) of the blood banks had valid license which were equally distributed in the not-for- profit sector and the public sector. Of the remaining 60% of blood banks which had applied for renewal, 50% were owned by the public sector and 10% were owned by the not-for-profit sector.

Figure 2- License Status (n=10)



The majority of the blood banks (n=10) which have reported as “deemed renewal” had their last inspection by licencing authority during the last one year (5; 83.3%); and one blood bank had their inspection more than 4 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 10,97,206 currently needs around 10,972 units of blood. As per this criteris, Mizoram, whose total collection is 24,658 units, is producing more than the required amount of WHO's criteria of total requirement of blood.

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 24,658 units of which 75.2% units were through voluntary blood donations and the remaining 25% were from replacement donations.

Figure 3-Annual Collections and Voluntary Donation

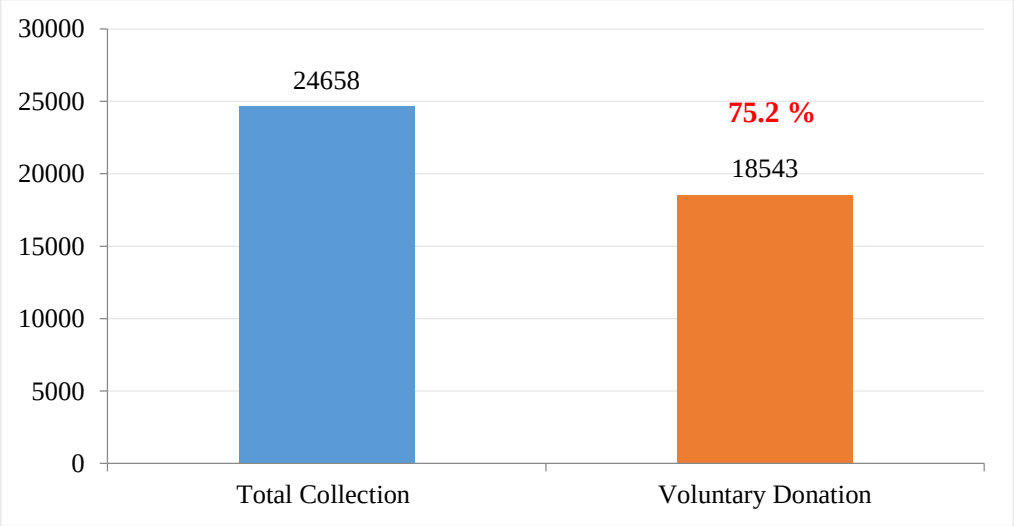
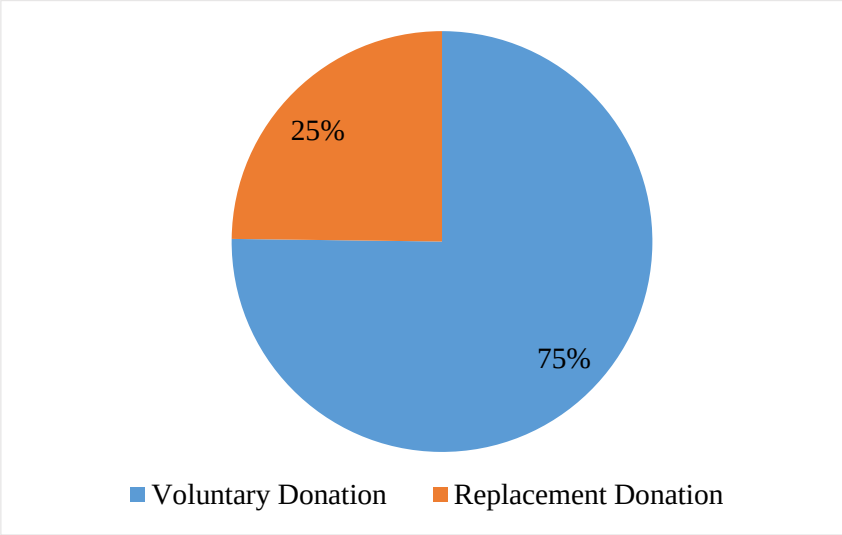


Figure 4- Type of Blood Donation (Voluntary vs Replacement Donation %)



The average annual collection of blood units of all the blood banks in the state was 2,466 units. The average annual collection of Aizawl (8,161 units) was found to be highest and Mamit district (405 units) had the lowest average annual collection.

Table 6- Average Annual collection

District	NACO supported
Aizawl	8161
Champhai	1118
Kolasib	753
Lawngtalai	459
Lunglei	1925
Mamit	405
Saiha	994
Serchhip	759
Mizoram	**2466**

Similarly, the blood banks with component separation units recorded a higher average collection of 8,161 units compared to blood banks without blood component separation units which was 1,042 units.

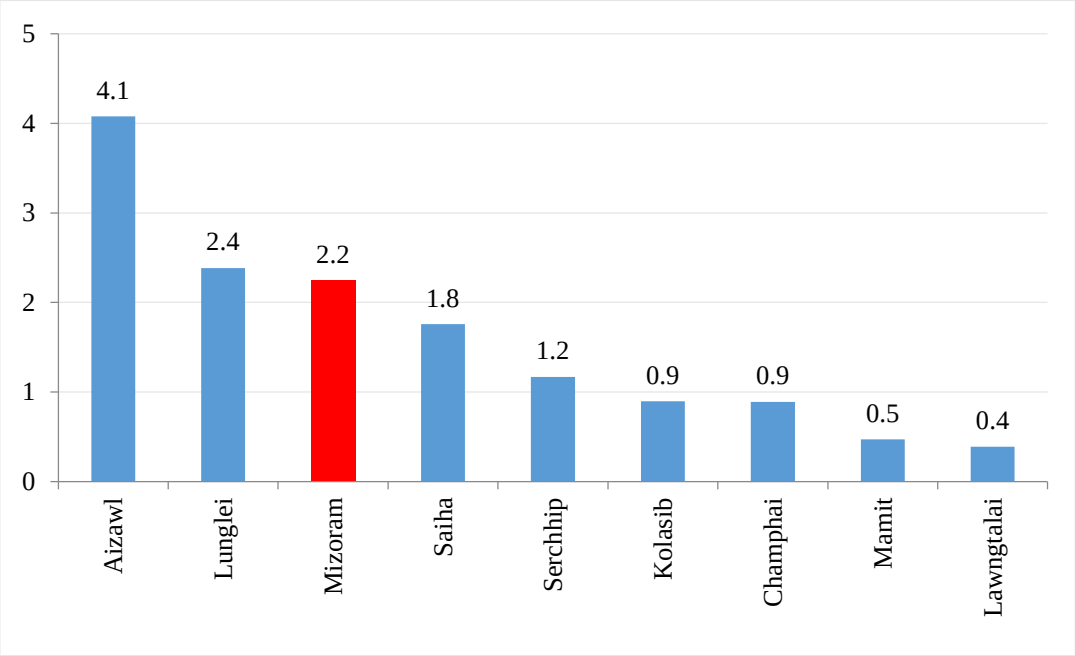
Blood banks with component separation facility collected 66.2% of blood units (16,321) and the remaining 33.8% (8,337) were collected by blood banks without the component facility. Similarly, blood banks owned by public sector collected 76.7% (18,911units) of the total collection and the remaining which is 23.3% (5,747 units) of the blood was collected by the not-for-profit sector blood banks.

Table-7 indicates the district-wise details of the total annual collection, voluntary and replacement donation in the state of Mizoram. Blood banks reported a varying proportion of VNRBD ranging from 63.1% to 95.8%.

Table 7- Annual blood collection and percentage of VBD

Districts	Total Voluntary Donation	Replacement Donation	Annual Collection	VBD%
Aizawl	12440	3881	16321	76.2
Champhai	705	413	1118	63.1
Kolasib	700	53	753	93.0
Lawngtalai	355	104	459	77.3
Lunglei	2632	1217	3849	68.4
Mamit	388	17	405	95.8
Saiha	745	249	994	74.9
Serchhip	578	181	759	76.2
Mizoram	**18543**	**6115**	**24658**	**75.2**

Figure 5- Annual Collection per 100 population- District wise



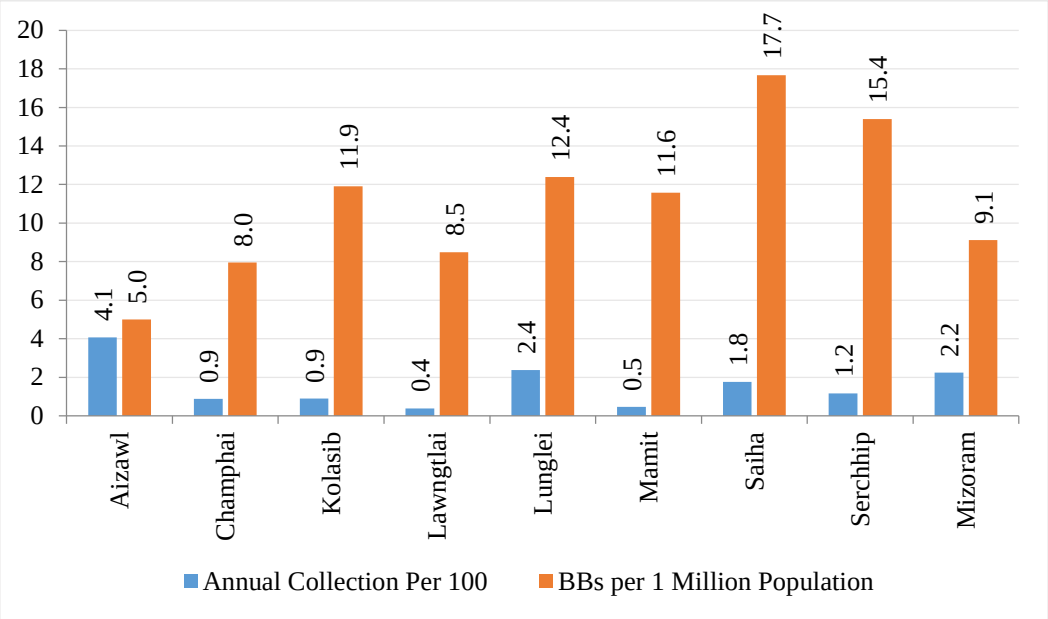
The annual collection of blood units per 100 individuals was found to be 2.2 in the state, which is above the WHO suggested requirement that 1% of the population can meet a nation's (populations) most basic requirements for blood. However, there is a huge disparity in the collection of blood between districts.

Districts such as Aizawl (4.1) and Lunglei (2.4) had collected more than the state average of 2.2 units per 100 population. The remaining 6 districts fall below the state average with Mamit (0.5) and Lawngtalai (0.4) having the least recorded. (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 populations. This indicates that Mizoram had 9.1 blood banks per million population that collected 2.2 units per 100 population at the ratio of 9.1 BB: 2.2 blood unit.

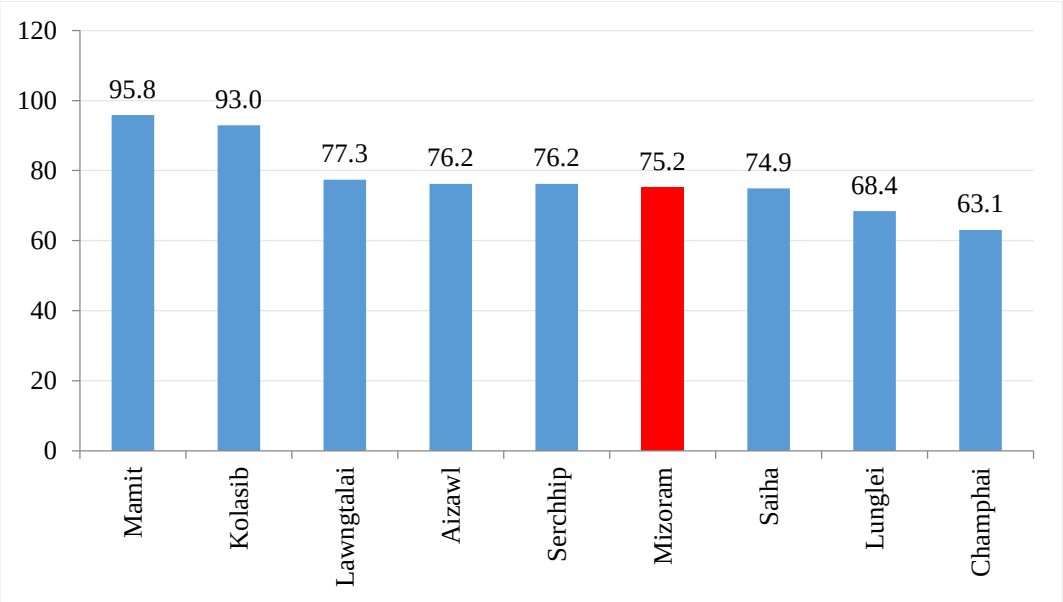
The ratio was wide in districts such as Lunglei, Mamit, Saiha, Serchhip and Kolasib, where the collection of blood was relatively less while having more number of blood banks proportionate to population.

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



4.2.2 ***Voluntary blood donation:*** As depicted in Figure-7, there were five districts, Mamit (95.8), Kolasib (93.0), Lawngtalai (77.3%), Aizawl (76.2%) and Serchhip (76.2%) which have recorded more than the state average of 75.2%. Champhai district (63.1%) had reported the least percentage of voluntary blood donations.

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

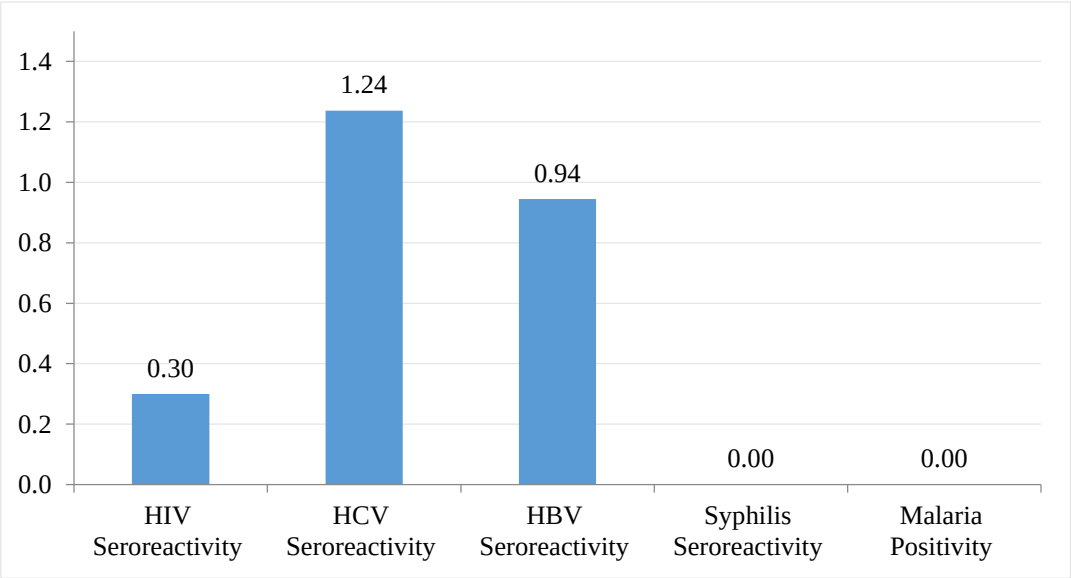


There were no Non-NACO blood banks in Mizoram.

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.

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



The seroreactivity of TTI among blood donors in the year 2015 is depicted in Fig-10. HIV seroreactivity was found to be 0.30%; Hepatitis-C was 1.24%, and Hepatitis-B 0.94%. There were no seroreactivity cases for Syphilis and positivity cases for Malaria in Mizoram.

Table 8-Transfusion Transmitted Infections (%)

Category of BB	Transfusion Transmitted Infections %				
	HIV	HCV	HBV	Syphilis	Malaria
NACO Supported	0.30	1.24	0.94	-	-
Non-NACO	-	-	-	-	-
Overall	0.30	1.24	0.94	0.00	0.00

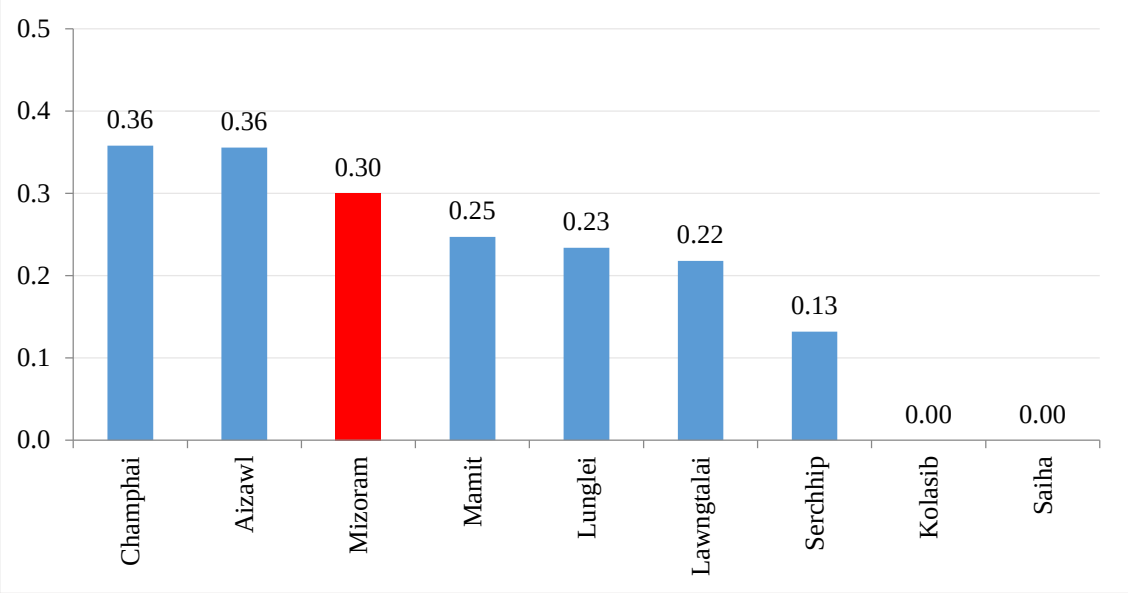
4.3.1 Transfusion Transmitted Infections by Category of blood banks: HIV and HCV, seroreactivity rates were found to be higher in blood banks with component facility as

compared to blood banks without component separation facility, and HBV seroreactivity was found to be higher in Blood banks without component separation facility.

Table 9- Transfusion Transmitted Infections by category of blood banks

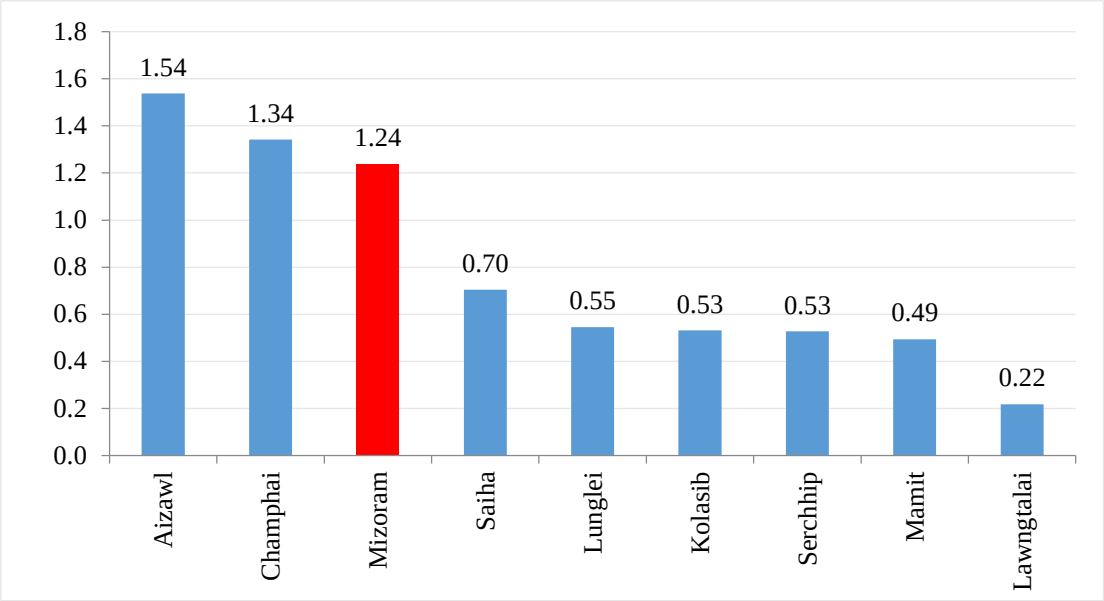
Category of BB	Transfusion Transmitted Infections %				
	HIV	HCV	HBV	Syphilis	Malaria
BBs with component facility	0.36	1.54	0.87	-	-
BBs without component facility	0.19	0.65	1.09	-	-
Overall	**0.30**	**1.24**	**0.94**	**0.0**	**0.0**

Figure 9- HIV Seroreactivity- By District (%)



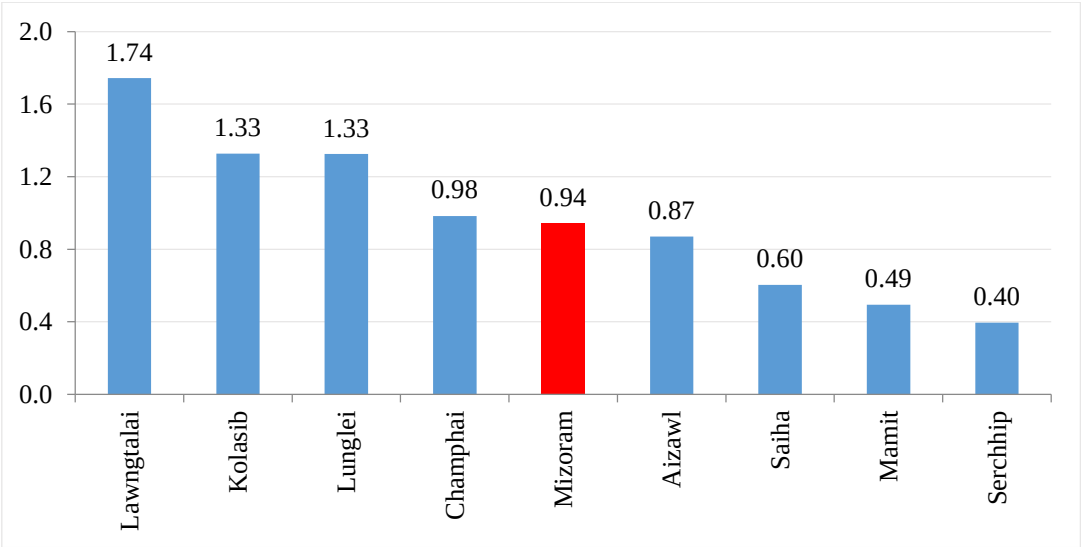
The majority of districts indicated lower HIV seroreactivity than the state HIV seroreactivity level of 0.30%. Champhai and Aizawl district recorded the highest seroreactivity at 0.36. The remaining districts which are Mamit (0.25%), Lunglei (0.23%), Lawngtalai (0.22%), and Serchhip (0.13%) had recorded seroreactivity level lower than the state average of 0.30%. Kolasib and Saiha district did not report to have any HIV seroreactivity.

Figure 10- HCV Seroreactivity- By District (%)



When considering Hepatitis C infection, districts like Aizawl (1.54%) and Champhai (1.34%) recorded a higher seroreactivity compared to the state average of 1.24%. Lawngtalai district (0.22%) recorded the lowest HCV seroreactivity level.

Figure 11-HBV Seroreactivity- By District (%)



Hepatitis B seroreactivity was found to be higher than the state average of 0.94% in four districts like Lawngtalai (1.74%), Kolasib (1.33%), Lunglei (1.33%) and Champhai (0.98%). Serchhip (0.40%) reported to have the lowest HBV seroreactivity.

4.4 Component Separation

As depicted in Figure -16, 79.9% of blood units collected by blood banks with component separation facilities, were used for component separation in state.

Figure 12-Total Blood Collection and Component Separation

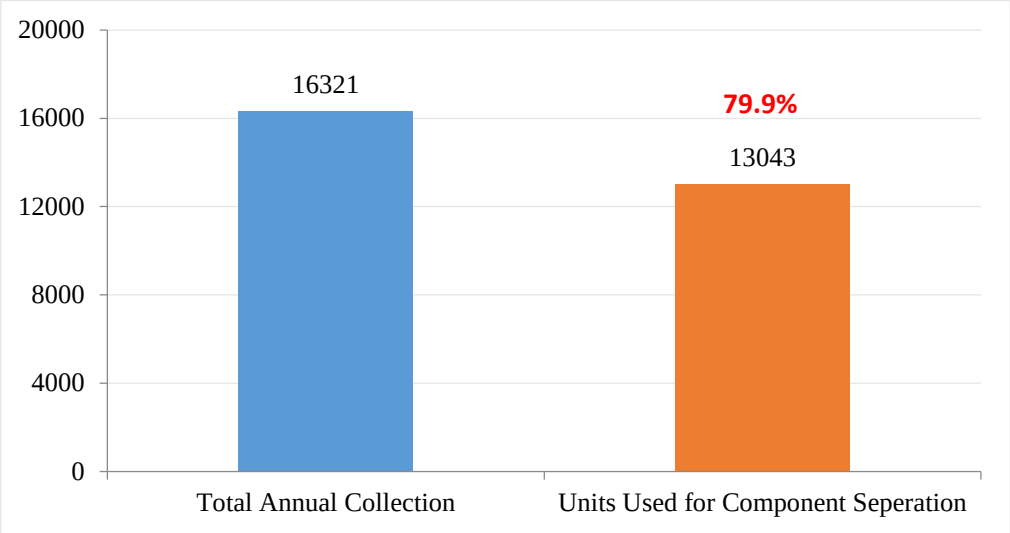


Table 10- Total Annual Collections by BCSUS and Percentage of Component Separation

Districts	Total Annual Collection	Total Annual Collection by BCSUs	Percentage of Component Separation
Aizawl	16321	16321	79.9
Champhai	1118	-	-
Kolasib	753	-	-
Lawngtalai	459	-	-
Lunglei	3849	-	-
Mamit	405	-	-
Saiha	994	-	-
Serchhip	759	-	-
Mizoram	**24658**	**16321**	**79.9**

Only Aizawl district had two blood banks with Blood Component Separation facilities where around 80% of the annual blood collected by BCSU's was used for component separation. Out of these two blood banks one was owned by the public sector and the other was owned by the not-for-profit sector.

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. The majority of blood banks (90%) reported that they adhered to the NBTC guidelines. Availability of document control system was reported by 50% of the blood banks in the state. In terms of Standard Operating Procedures (SOPs) for technical processes, all the blood banks reported that they had SOPs.

Table 11- Availability of Quality Parameters in Blood Banks

Quality Parameters	BBs (n=10)
Compliance with NBTC guidelines	9
	90%
Availability of Documental Control System (DCS)	5
	50%
SOPs for Technical Processes	10
	100 %
IQC for IH	8
	80 %
IQC for TTI	5
	50 %
QC for kits, reagents and blood bags	10
	100%
EQAS for IH	-
	-
EQAS for TTI	-
	-
NABH accreditation for blood banks	-

	-
Availability of designated and trained Quality Manager	3
	30%
Availability of designated and trained Technical Manager	3
	30%
Programme for regular Equipment maintenance	8
	80 %
Equipment calibration as per regulatory requirement	10
	100%

At the state level, Internal Quality Control (IQC) for Immunohematology was reported by 80 of the blood banks and IQC for TTIs was reported by 50% of the blood banks.

All the blood banks reported carrying out quality control for kits, reagents and blood bags. There were no blood banks which were enrolled in EQAS for Immunohematology or TTI. The state of Mizoram had no blood banks 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 30% of the blood banks. Around 80% of the blood banks reported that they had a regular equipment maintenance programme and all the blood banks reported that they calibrate the equipment as per requirement.

4.6. Reporting and Documentation

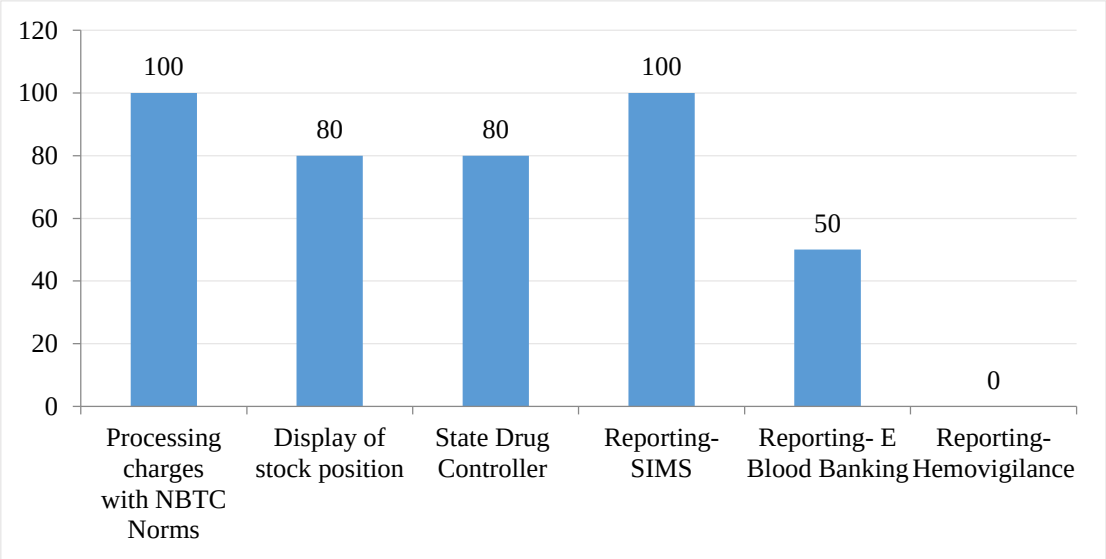
4.6.1. Compliance to NBTC guidelines

In terms of Recovering processing charges, all the blood banks reported that they were recovering processing charges within NBTC/SBTC norms and 80% of blood banks reported that they were displaying stock position in their Blood bank Premises.

4.6.2. Reporting requirements

In terms of reporting requirement, 80% of the blood banks submitted regular reports to state drug controller and are regularly reporting in national strategic information management systems (SIMS). However, only 50% regularly reported in E-blood banking either national or state e-blood banking. There are no blood banks which report to be members of National Haemovigilance Program.

Figure 13-Reporting and Documentation

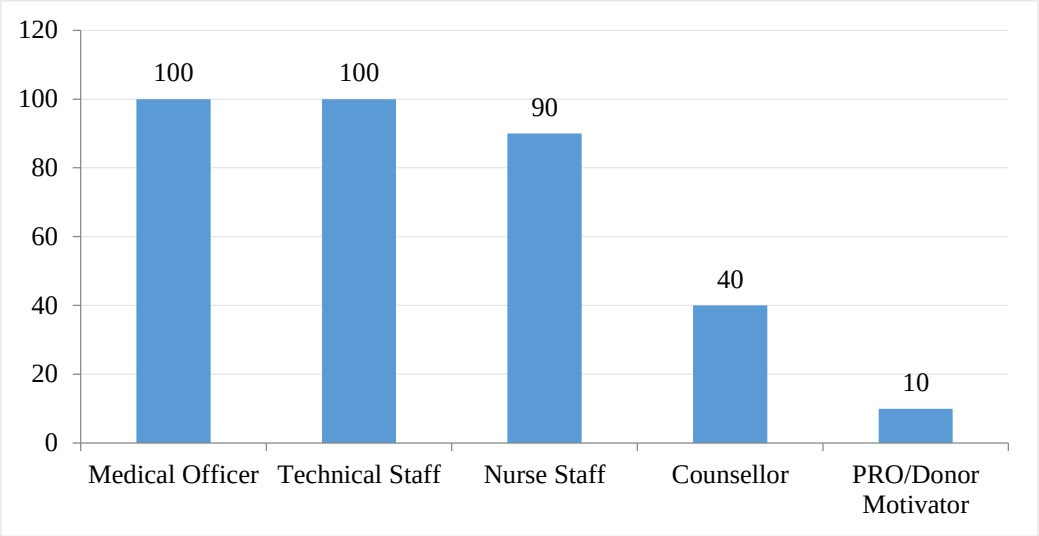


4.7. Human Resources

4.7.1. Availability of staff

The mean number of employees in the blood bank was 7.1 (SD 6.5). It ranges from four employees to 25 employees. All the blood banks reported to have at least one medical officer and technical staff. 90% of the blood banks had nursing staff and 40% of the blood banks reported to have one counsellor. However, only 10% of the blood banks reported to have PRO/Donor motivators.

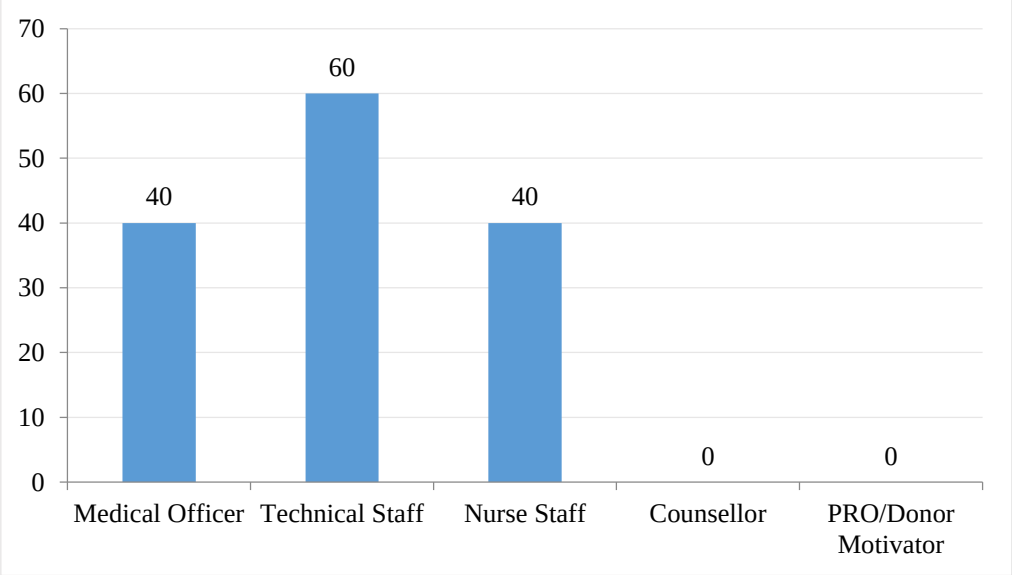
Figure 14-Percentage of BB Manpower (At least one)



4.8. Training of Blood Bank Personnel

According to the assessment, 60% of the blood banks reported that they had at least one technical staff trained by NACO/NBTC; 40% of the blood banks reported they had atleast one trained medical officer and nursing staff. The state reported that didn't have any trained counsellors or PRO/donor motivators in the blood banks.

Figure 15- Percentage of BBs having at least one trained

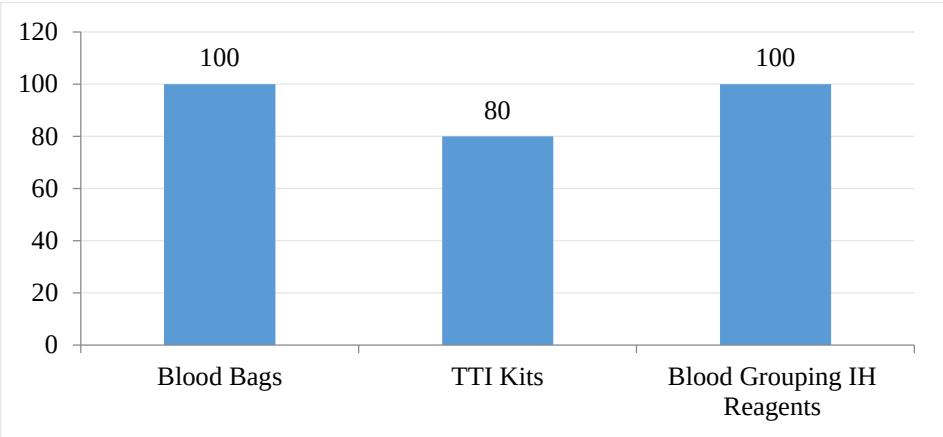


4.9. Equipment and Supplies

4.9.1. Regular supply kits/supplies

All of the blood banks reported that they had regular supply of blood bags and regular supply of blood grouping reagents, and 80% of the blood banks reported that they had regular supply of TTI kits.

Figure 16- Regular Supply of Kits



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	90
3	Blood collection monitor	100
4	Quarantine Blood Bank Refrigerator to store untested blood	20
5	container for safe disposal of sharps	60
6	Oxygen supply equipment	90
7	computers with accessories and software	80
8	General lab centrifuge for samples	80
9	Bench top centrifuge for serological testing (Immunohaematology)	90
10	Blood transportation box (No. in inventory)	60
11	Emergency drugs box / Crash card	100
12	Autoclave machine	90
13	Water bath	80
14	Blood bank refrigerator (storage of tested blood) with temperature recorder	40
15	Automated pipettes	80
16	Refrigerated centrifuge	30
17	Blood container weighting device	90
18	Serology rotator	60

4.10. The current status of blood banks based on the assessment

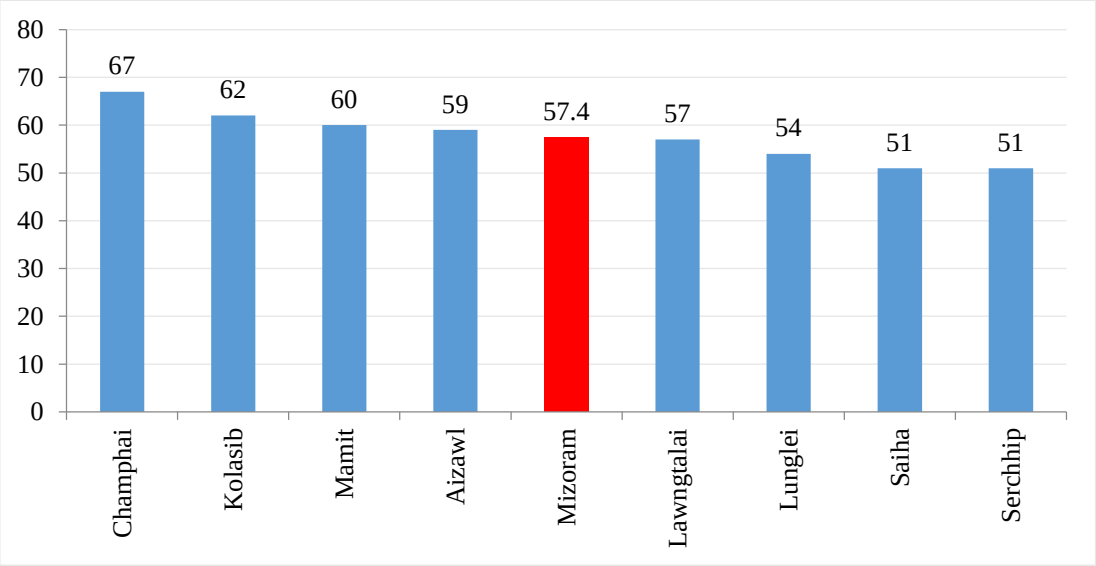
As mentioned in the methodology section, the blood banks were assessed and categorized based on the scores obtained. Though the assessment captured all aspects of blood transfusion services in blood banks, adequate importance and weightage were given to technical aspects and adherence to quality management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

Table 13-Mean Assessment score

Type of BB	N	Mean	SD
NACO supported	10	57.40	6.47
Non-NACO	-	-	-
Total	**10**	**57.40**	**6.47**

The mean assessment score of blood banks in the state was 57.40 (SD: 6.47).

Figure 17- Mean Assessment Score – By Districts (All BBs)



There were 4 districts which scored above the state average of 57.4 with Champhai district (67) scoring the highest followed by Kolasib (62), Mamit (60) and Aizawl (59). Out of the remaining 4 districts which had scored lower than the state average, Serchhip and Saiha (51) had scored the lowest.

Table 14- Mean assessment score - By District

District	BBs
Aizawl	59
Champhai	67
Kolasib	62
Lawngtalai	57
Lunglei	54
Mamit	60
Saiha	51
Serchhip	51
Mizoram	**57.4**

Table 15 - Number of Blood Banks Scored 35 to 70 - by District

District	BBs
Aizawl	2
Champhai	1
Kolasib	1
Lawngtalai	1
Lunglei	2
Mamit	1
Saiha	1
Serchhip	1
Mizoram	**10**

All the blood banks in Mizoram had scored between 35 to 70.

4.10.1 Assessment score by Category of blood banks: The mean score of blood banks with component facilities (59; SD: 4.24) was found to be higher than the mean score of those without component facilities (57; SD: 7.09). Further analysis shows that among the BCSU's, the public sector blood bank had a higher mean score of 62 than not-for-profit blood bank (56).

Table 16- Mean assessment score by category of blood banks

Type of Blood Bank	BBs		
	N	**Mean**	**SD**
BCSUs	2	59.00	4.24
Without BCSU	8	57.00	7.09

4.10.2 Assessment score by Ownership: The mean assessment score of public owned blood banks (57.86; SD: 7.20) was found to be higher than the NGO/Trust/Charitable (56.33; SD: 5.51). (Refer Table 17).

Table 17- Mean assessment score by Ownership

Ownership	BBs		
	N	Mean	SD
NGO/Trust/charitable	3	56.33	5.51
Private	0	0	0
Public	7	57.86	7.20

Table 18-Mean assessment scores categories by Ownership

Ownership	<=35	36 to 70	Above 70	Total
Public	-	7	-	7
	-	100%	-	100%
NGO/Trust/Charitable	-	3	-	3
	-	100%	-	100%
Private	-	-	-	-
	-	-	-	-
Overall	**0**	**10**	**0**	**10**
	0	**100%**	**0**	**100%**

4.10.3 Assessment score of Private Sector Blood Banks: Irrespective of the NACO support status, 30% (3) blood banks were owned by private sector, of which, all of them were owned by not-for-profit sector such as, NGO, Trust, and charitable organizations.

Nevertheless, it is also important to note that the average annual collection was higher in public owned blood banks (2,702 units) compared to private owned blood banks (1,916 units). The percentage of voluntary blood donation was higher in private owned blood banks (84.1%) compared to the public blood banks (72.5%). Of the total private blood banks, 33.3% had component separation facility whereas 14.3% of public blood banks had component separation facility.

4.10.4 Assessment score by Annual Collection: Majority of the blood banks had an annual collection up to 3000 units of blood. There was one blood bank which had an annual collection between 3001-5000 units and one blood bank which collected above 5000 units of blood. The mean assessment score of blood banks that collected above 5000 blood units (62) was found to be higher than those which collected between 3001 to 5000 (56) and up to 3000 units of blood (57:00; SD: 7.09).

Table 19- Mean assessment score by annual collection

Annual Collection	BBs	
	Mean	SD
Up to 3000	57.00	7.09
3001 to 5000	56.00	-
Above 5000	62.00	-

4.10.5 Assessment score by Voluntary Blood Donation: Table -20 provides the mean assessment score of blood banks that have been categorized by percentage of voluntary blood donation which does not indicate any pattern.

Table 20- Mean assessment score by voluntary blood donation

% VBD	BBs		Total	
	Mean	SD	Mean	SD
Less than 25	-	-	-	-
25 to 49	-	-	-	-
50 to 74	56.50	9.68	56.50	9.68
75 to 90	56.50	4.51	56.50	4.51
Above 90	61.00	1.41	61.00	1.41

4.10.6 Assessment score by participation in External Quality Assessment Scheme (EQAS) for Immunohematology and Transfusion Transmitted Infections (TTI): There were no blood banks which were enrolled in EQAS for Immunohematology or TTI.

Table 21- Mean assessment score by EQAS enrolment

IH-EQAS	BBs			TOTAL		
	N	**Mean**	**SD**	**N**	**Mean**	**SD**
YES	-	-	-	-	-	-
NO	10	57.40	6.47	10	57.40	6.47
TTI-EQAS	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**
YES	-	-	-	-	-	-
NO	10	57.40	6.47	10	57.40	6.47

4.10.7 Assessment score by Accreditation status: There were no blood banks in the state of Mizoram which are accredited by National Accreditation Board of Hospitals and Health care Providers (NABH).

Table 22- Mean assessment score by Accreditation

NABH Accreditation	BBs		
	N	Mean	SD
YES	-	-	-
NO	10	57.40	6.47

The list of blood banks under different categories of score is given in Table- 24

Table 23- Distribution of Blood banks by Districts and mean assessment score categories

Score Category				
District	Upto 35	35 to 70	Above 70	Total
Aizawl	-	2	-	2
Champhai	-	1	-	1
Kolasib	-	1	-	1
Lawngtalai	-	1	-	1
Lunglei	-	2	-	2
Mamit	-	1	-	1
Saiha	-	1	-	1
Serchhip	-	1	-	1
Mizoram	**0**	**10**	**0**	**10**

Table 24- Distribution of Blood banks by Districts and mean assessment score categories

Score Category			
District	NACO Supported		
	Upto 35	35 to 70	Above 70
Aizawl	-	2	-
Champhai	-	1	-
Kolasib	-	1	-
Lawngtalai	-	1	-
Lunglei	-	2	-
Mamit	-	1	-
Saiha	-	1	-
Serchhip	-	1	-
Mizoram	**0**	**10**	**0**

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 Mizoram 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.

There were 10 NACO supported blood banks which were included in the review. The annual collection of these blood banks was 24,658 units which exceeds 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 0.4 units to 4.1 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.

The review also revealed the blood collected by blood banks with the component facility (66.2%) was much higher than the collection collected by blood banks without component facility (33.8%). Though there has been an increase in the percentage of voluntary blood donation over the years (around 75.2% in 2015), there is still a variation between districts that ranges from 63.1% to 95.8%. A targeted program to increase the non-remunerated voluntary blood donors will go a long way towards ensuring a safer option for our patients.

There were 5 districts which recorded more than the State average of 9.1 blood banks per 1,000, 000 (one million) population. Saiha (17.7) recorded the highest followed by Serchhip (15.4), Lunglei (12.4), Kolasib and Mamit (11.6). The potential impact of this distribution of blood banks and collection of blood on other health indices may be further studied.

60% of the blood banks having 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 57.40 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 of the Blood Bank	Type	Ownership	Annual Collection	Score (Out of 100)
Aizawl	Model Blood Bank, Civil Hospital	BCSU	Public	12686	62
	Synod Hospital	BCSU	NGO/Trust/Charitable	3635	56
Champhai	Blood Bank Dist Hospital	Non BCSU	Public	1118	67
Kolasib	Blood Bank District Hospital	Non BCSU	Public	753	62
Lawngtalai	District Hospital Lawngtalai	Non BCSU	Public	459	57
Lunglei	Lunglei Civil Hospital Blood Bank	Non BCSU	Public	2496	46
	Christian Hospital, Serkawn	Non BCSU	NGO/Trust/Charitable	1353	62
Mamit	Blood Bank, District Hospital	Non BCSU	Public	405	60
Saiha	Civil Hospital	Non BCSU	Public	994	51
Serchhip	J N Hospital Blood Bank	Non BCSU	NGO/Trust/Charitable	759	51

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**