# A Report on the
# "Assessment of Blood Banks in Bihar, 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 Bihar

According to Central Drugs Standard Control Organization (CDSCO), there were 84 blood banks in Bihar in 2015. The assessment exercise identified 72 functional blood banks across the state. Of the 72 blood banks, 39 (54.2%) were supported by National AIDS Control Organization, Ministry of Health and Family Welfare, Government of India and the remaining 33 (45.8%) were Non-NACO blood banks.

Patna (20) had the highest number of blood banks followed by Muzaffarpur (4) and Rohtas (4) while Purnia, Begusarai and Bhojpur had 3 blood banks each.In terms of NACO supported blood banks, Patna (5) followed by Bhojpur and Muzzaffarpur with 2 each.

There are 38 districts in the state of Bihar. Around 24% (20) of all the blood banks (n=84) in the state was in one district that is Patna.Considering the number of blood banks per one million population, districts such as, Buxar (0.6), Gaya (0.5), East Champaran (0.4) and West Champaran (0.3) recorded less than the state average of 0.7 blood banks per 1,000,000 (one million) population while Patna (3.4), Bhojpur (1.1) and Muzaffarpur (0.8) had a recording higher than the State average. Five districts (Araria, Arwal, Banka, Sheohar and Supaul) do not have a blood bank.

For the assessment 71 blood banks (39 NACO supported- 54.9% and 32 Non–NACO - 45.1%) that submitted the assessment forms in complete were included in the analysis.

## Description of blood banks

- Around 20% of the blood banks in the state had component separation facility.
- The not-for-profit sector owned 42.9% of the blood banks in the state followed by 35.6% owned by private and 21.5% owned by public sector.
- Around 48% blood banks are owned by the public sector followed by the non-profit/not-for-profit sector (22, 31%) and private sector (15, 21%).
- The majority (34; 87.2%) of NACO supported blood banks were owned by the public sector while the non-profit/not-for-profit sector such as NGOs, charitable trusts, societies, foundations etc. had only 5 (12.8%) blood banks.
- Out of all the districts, only seven have a blood bank with BCSU facility
- The majority of the blood banks (56; 79%) were attached to hospitals and the remaining (15; 21%) were standalone blood banks.
- 65% blood banks had applied for renewal while only 35% blood banks had a valid and current license. Only 21% of NACO supported and 53% of Non-NACO blood banks had a valid and active license.

## Annual Collection and Voluntary Blood Donation

- During January 2015 to December 2015, the annual blood collection from all the blood banks that reported was 173,554 units of which 50.8% 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 2,515 units.The average annual collection of NACO supported blood banks (2,838 units) was found to be higher than the Non-NACO blood banks (2,095 units).
- The blood banks with component separation units recorded a higher average collection of 6,095 units compared to blood banks without blood component separation units which was 1,604 units.
- The NACO supported blood banks collected 64% (110,698 units) of the total collection, of which 63% (69,675) units were through voluntary blood donation. The Non-NACO blood banks collected 62,856 units (36%) of which 30% (18,566) units were through voluntary blood donation.

## Transfusion Transmitted Infections

- HIV reactivity was found to be 0.16%, Hepatitis-C was 0.14%, Hepatitis-B 1.43%, Syphilis 0.05% and Malaria 0.07%. However, there is a significant variation between districts.

## Component Separation

- Around 47.3% of blood units collected by blood banks with component separation facilities were used for component separation in the state.
- The percentage of component separation was higher (55%) in Non-NACO blood banks compared to NACO supported blood banks (44%).

## Quality Management Systems

- The majority of blood banks (93%) reported that they adhered to the NBTC guidelines.
- Availability of document control system was reported by less than 40% of the blood banks in the state. Around 38% NACO supported blood banks and 44% of Non-NACO blood banks reported they had a document control system.
- More than 94% of blood banks reported to have Standard Operating Procedures (SOPs) for technical processes.
- Internal Quality Control (IQC) for Immunohematology was reported by around 66% of the blood banks and IQC for TTIs was reported by 43% of the blood banks, with huge variation between NACO supported and Non-NACO blood banks.
- Around 61% of the blood banks reported carrying out quality control for kits, reagents and blood bags.

- The percentage of blood banks enrolled in EQAS by recognized providers was found to be only 1.4% for immunohematology and none for TTIs.
- No blood bank out of the total 71 blood banks that participated in the assessment was accredited by National Accreditation Board for Hospitals & Healthcare Providers (NABH).
- Designated and trained Quality Managers and Technical managers were available only in 32% and 38% of the blood banks respectively.
- 60% of the blood banks reported that they had a regular equipment maintenance programme and around 66% reported that they calibrate the equipment as per requirement.

### Reporting and Documentation

- Majority of the blood banks (93%) reported to be compliant with NBTC guidelines. Around 90% of blood banks reported that they were recovering processing charges within NBTC/SBTC norms. Around 91% of blood banks reported that they were displaying stock position in their blood bank premises.
- In terms of reporting requirement, around 80% of the blood banks submitted regular reports to state drug controller, 89% of blood banks regularly reported in national Strategic Information Management Systems (SIMS). 80% regularly reported in e-blood banking either national or state e-blood banking. Only 7% of blood banks were members of the National Haemovigilance Program.

### Human Resources

- 96% of blood banks reported to have medical officers, 100% had technical staff and 87% had nursing staff. However, only 38% had counsellors and 24% reported to have PRO/Donor motivators.
- According to the assessment, around 42% of the blood banks reported that they had at least one medical officer trained by NACO/NBTC; 49% blood banks reported they had trained technical staff, 21% reported having trained nursing staff, 6% had trained counsellors and only 3% blood banks reported having trained PRO/donor motivators.

### Equipment and Supplies

- For the regular supply of kits, only 86% blood banks reported that they had regular supply of blood bags, 87% reported that they had regular supply of TTI kits and 86% reported to have regular supply of blood grouping reagents.

## The current status of blood banks based on the assessment

- The mean assessment score of blood banks in the state was 50.2 (SD: 10.3). The NACO supported blood banks scored less (46.7; SD: 10) than the Non-NACO blood banks (54.4; SD: 9.2).
- At the state level, the majority of blood banks (64; 90%) scored between 35 to 70, followed by 6 blood banks (8%) which scored less than or equal to 35, and only one blood bank scored above 70.
- Around 90% of NACO supported and 91% Non-NACO blood banks scored between 35 and 70.Only one of Non-NACO blood bank scored more than 70%.
- Among the districts, East Champaran (64) scored the highest and Sheikpura (27) scored the least.
- The mean score of blood banks without component facilities (48.49; SD: 8.61) was found to be lower than the mean score of those with component facilities (57.36; SD: 48.49).
- The mean assessment score of private blood banks (54.47; SD: 9.47) was found to be slightly higher than the public and not-for-profit owned blood banks.
- However, Non-NACO blood banks run by not-for-profit sector had scored higher (54.50; SD: 9.31) compared to NACO Supported blood banks NGO/Trust/Charitable blood banks (53.60; SD: 16.52).
- The mean score of private sector owned blood banks including not-for-profit sector was 54.36 (SD: 10.19) and the mean score of public owned blood banks was 45.75 (SD 8.60).
- The mean assessment score of blood banks that collected more than 5000 blood units (56.15; SD: 11.20) was found to be slightly less than those which collected between 3001 and 5000 (56.67; SD: 9.92) and higher than 3000 blood units (47.59; SD: 9.38).
- In Bihar, only one NACO supported blood bank was enrolled in EQAS for Immunohematology. Out of the 71 blood banks which had responded, none of them were a part of the EQAS for TTI.
- The state of Bihar has no blood banks which have been accredited by the 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 Bihar

## 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 and 5,000 units and district level blood banks collect up to 3,000 units annually.

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

**Table 2 - Scoring details and weight**

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

The scoring pattern was different based on the category of blood banks that are: 1. Blood banks with component separation facility (n=14) and, 2. Blood banks without component separation facility (n=57). 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 84 blood banks in the state of Bihar in 2015 (CDSCO, 2015).However, the assessment exercise identified 72 functional blood banks across the state. Of the total functional blood banks, 71 blood banks (39 NACO supported – 54.9% and 32 Non-NACO – 45.1%) which have submitted the assessment forms in complete were included in the analysis.

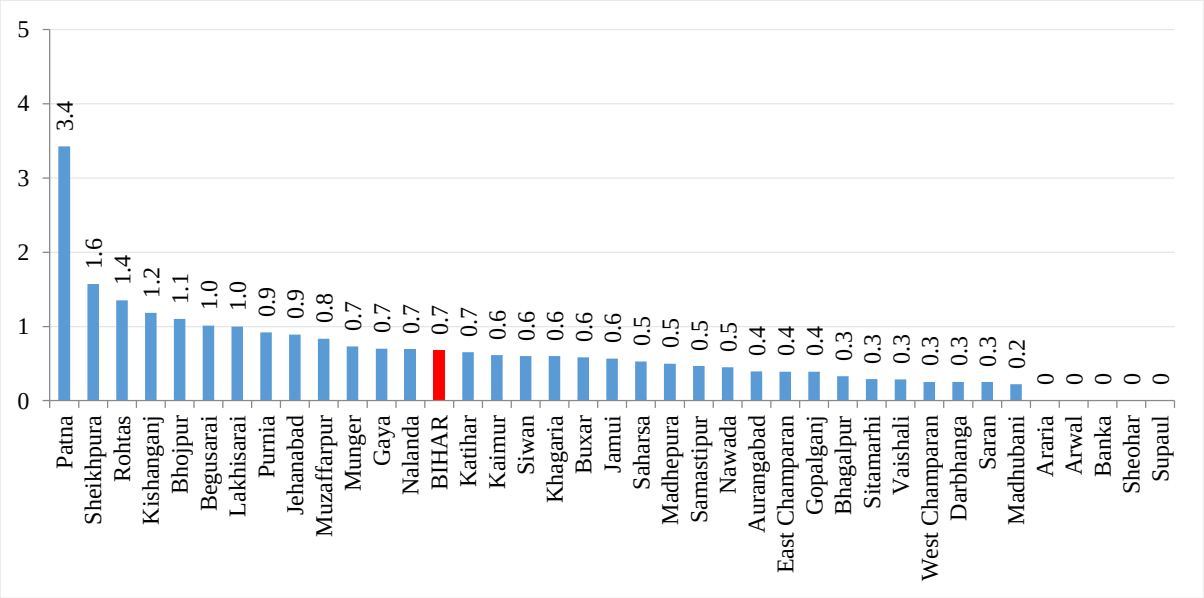
**Table 3 - District Wise Descriptions of Blood Banks**

| District | NACO Supported | Non-NACO | Total |
|---|---|---|---|
| **Aurangabad** | 1 | - | 1 |
| **Begusarai** | 1 | 2 | 3 |
| **Bhagalpur** | 1 | - | 1 |
| **Bhojpur** | 2 | 1 | 3 |
| **Buxar** | 1 | - | 1 |
| **Darbhanga** | 1 | - | 1 |
| **East Champaran** | 1 | 1 | 2 |
| **Gaya** | 1 | 2 | 3 |
| **Gopalganj** | 1 | - | 1 |
| **Jamui** | 1 | - | 1 |
| **Jehanabad** | 1 | - | 1 |
| **Kaimur** | 1 | - | 1 |
| **Katihar** | 1 | 1 | 2 |
| **Khagaria** | 1 | - | 1 |
| **Kishanganj** | 1 | 1 | 2 |
| **Lakhisarai** | 1 | - | 1 |
| **Madhepura** | 1 | - | 1 |
| **Madhubani** | 1 | - | 1 |
| **Munger** | 1 | - | 1 |
| **Muzaffarpur** | 2 | 2 | 4 |
| **Nalanda** | 1 | 1 | 2 |
| **Nawada** | 1 | - | 1 |
| **Patna** | 5 | 15 | 20 |
| **Purnia** | 1 | 2 | 3 |
| **Rohtas** | 1 | 3 | 4 |
| **Saharsa** | 1 | - | 1 |
| **Samastipur** | 1 | 1 | 2 |
| **Saran** | 1 | - | 1 |
| **Sheikhpura** | 1 | - | 1 |
| **Sitamarhi** | 1 | - | 1 |
| **Siwan** | 1 | 1 | 2 |
| **Vaishali** | 1 | - | 1 |
| **West Champaran** | 1 | - | 1 |
| **Bihar** | **39** | **33** | **72** |

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. In the state, apart from Patna which has 20 blood banks, the other districts have less than 5 blood banks each. Five districts (Araria, Arwal, Banka, Sheohar and Supaul) in Bihar have no blood banks. In terms of NACO supported blood banks, Patna (5) has the maximum number of blood banks followed by Bhojpur (2) and Muzaffarpur (2).

Considering the number of blood banks per one million population, districts such as, Buxar (0.6), Gaya (0.5), East Champaran (0.4) and West Champaran (0.3) recorded less than the State average of 0.7 blood banks per 1,000,000 (one million) population while Patna (3.4), Bhojpur (1.1) and Muzaffarpur (0.8) had a recording higher than the State average.

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



## 4.1 Basic details of blood banks (n=71)

As indicated earlier, 71 blood banks (39 NACO supported and 32 Non-NACO) that submitted the assessment forms were included in the analysis.

***4.1.1 Category of Blood Banks:*** Out of 39 NACO supported blood banks 17.9% (7) of the blood banks had component separation facility. Out of 32 Non-NACO blood banks 21.9% (7) had component separation facility.

**Table 4 - Basic details of blood banks**

| Specifics | Description | NACO Supported | Non-NACO | Total |
|---|---|---|---|---|
| **Type of BB** | With components | 7 (17.9%) | 7 (21.9%) | 14 (19.7%) |
| | Without components | 32 (82.1%) | 25 (78.1%) | 57 (80.3%) |
| **Ownership** | NGO/Trust/Charitable | 5 (12.8%) | 17 (53.1%) | 22 (31%) |
| | Private | - | 15 (46.9%) | 15 (21.1%) |
| | Public | 34 (87.2%) | - | 34 (47.9%) |
| **Licence** | Valid | 8 (20.5%) | 17 (53.1%) | 25 (35.2%) |
| | Under Renewal | 31 (79.5%) | 15 (46.9%) | 46 (64.8%) |
| **Attachment** | Attached to Hospital | 35 (89.7%) | 21 (65.6)% | 56 (78.9%) |
| | Stand alone | 4 (10.3%) | 11 (34.4%) | 15 (21.1%) |

Out of all the districts, only seven have a blood bank with BCSU facility, Patna (8), Bhagalpur (1), Darbhanga (1), Katihar (1), Kishanganj (1), Purnia (1) and Rohtas (1). The number of NACO Supported (56%) blood banks without BCSU facility is more than the Non-NACO (44%) blood banks.

***4.1.2 Ownership:*** As depicted in Table:-4, 48% (34) blood banks are owned by the public sector followed by the non-profit/not-for-profit sector (22, 31%) and private sector (15, 21%). The majority (34; 87.2%) of NACO supported blood banks were owned by the public sector while the non-profit/not-for-profit sector such as NGOs, charitable trusts, societies, foundations etc. had only 5 (12.8%) blood banks. The not-for-profit (7) as well as the public sector (7) had equal number of blood banks with component separation facility. Among the NACO supported blood banks, the public sector had a higher (86%) proportion of component separation facilities compared to the not-for profit sector (14%).

Around 28% of all the blood banks are clustered in Patna district. 68% not-for-profit blood banks (n=22) were clustered in five districts which are Patna (7), East Champaran (2), Muzaffarpur (2), Nalanda (2) and Purnia (2). Around 60% of all private owned blood banks

(n=15) were clustered in Patna and 13% (2) in Rohtas. Similarly, 18% of all the public owned blood banks (n=34) were in two districts that are, Patna (4) and Muzaffarpur (2). (Refer Table- 5)

**Table 5 - District wise list of blood banks by Ownership**

| District | Public | % | Not-for-profit | % | Private | % | Total |
|---|---|---|---|---|---|---|---|
| **Aurangabad** | 1 | 100 | - | - | - | - | 1 |
| **Begusarai** | 1 | 33.3 | 1 | 33.3 | 1 | 33.3 | 3 |
| **Bhagalpur** | 1 | 100 | - | - | - | - | 1 |
| **Bhojpur** | 1 | 33.3 | 1 | 33.3 | 1 | 33.3 | 3 |
| **Buxar** | 1 | 100 | - | - | - | - | 1 |
| **Darbhanga** | 1 | 100 | - | - | - | - | 1 |
| **East Champaran** | - | - | 2 | 100 | - | - | 2 |
| **Gaya** | 1 | 50.0 | - | - | 1 | 50 | 2 |
| **Gopalganj** | 1 | 100 | - | - | - | - | 1 |
| **Jamui** | 1 | 100 | - | - | - | - | 1 |
| **Jehanabad** | 1 | 100 | - | - | - | - | 1 |
| **Kaimur** | 1 | 100 | - | - | - | - | 1 |
| **Katihar** | 1 | 50 | - | - | 1 | 50 | 2 |
| **Khagaria** | 1 | 100 | - | - | - | - | 1 |
| **Kishanganj** | 1 | 50 | 1 | 50 | - | - | 2 |
| **Lakhisarai** | 1 | 100 | - | - | - | - | 1 |
| **Madhepura** | 1 | 100 | - | - | - | - | 1 |
| **Madhubani** | 1 | 100 | - | - | - | - | 1 |
| **Munger** | 1 | 100 | - | - | - | - | 1 |
| **Muzaffarpur** | 2 | 50 | 2 | 50 | - | - | 4 |
| **Nalanda** | - | - | 2 | 100 | - | - | 2 |
| **Nawada** | 1 | 100 | - | - | - | - | 1 |
| **Patna** | 4 | 20 | 7 | 35 | 9 | 45 | 20 |
| **Purnia** | 1 | 33.3 | 2 | 66.7 | - | - | 3 |
| **Rohtas** | 1 | 25 | 1 | 25 | 2 | 50 | 4 |
| **Saharsa** | 1 | 100 | - | - | - | - | 1 |
| **Samastipur** | 1 | 50 | 1 | 50 | - | - | 2 |
| **Saran** | 1 | 100 | - | - | - | - | 1 |
| **Sheikhpura** | 1 | 100 | - | - | - | - | 1 |
| **Sitamarhi** | 1 | 100 | - | - | - | - | 1 |
| **Siwan** | 1 | 50 | 1 | 50 | - | - | 2 |
| **Vaishali** | 1 | 100 | - | - | - | - | 1 |
| **West Champaran** | - | - | 1 | 100 | - | - | 1 |
| **Bihar** | **34** | **48** | **22** | **31** | **15** | **21** | **71** |

**4.1.3** ***Organizational Attachment:*** The majority of the blood banks (56; 79%) were attached to hospitals and the remaining (15; 21%) were standalone blood banks.

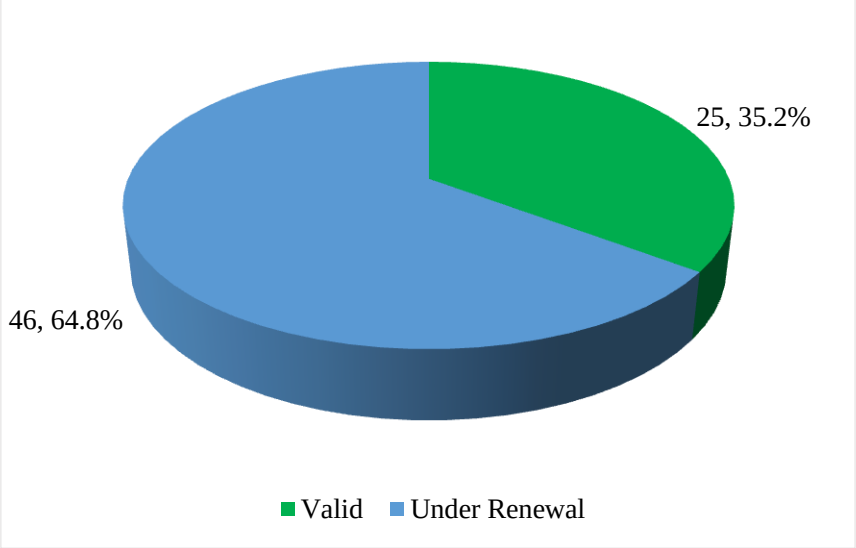
The majority of the NACO supported blood banks (35; 90%) were attached to hospitals and 4 blood banks (10.3%) were standalone.

Further analysis indicated that majority of the blood banks in the public sector (33, 97%), not-for-profit sector (15, 68%) and 8 (53%) blood banks in the private sector were attached to hospitals. In the not-for-profit sector and private, 7 blood banks each are standalone whereas only one public blood bank was a standalone.

**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 (46, 65%) had applied for renewal while only 25 (35%) blood banks had a valid and current license. Only 21% (8) of NACO supported and 53% (17) of Non-NACO blood banks had a valid and active license. The not-for-profit sector had the maximum (14 out of 8) number of blood banks with a valid and current license. However, 82% (28) of public sector and 67% (10) of the private sector blood banks had their license under renewal.

**Figure 2 - License Status (n=71)**




The majority of those blood banks (n=46) which have reported as "deemed renewal" had their last inspection by licencing authority during the last one year (21; 46%); 28% (13) had their inspection between the last 1 to 2 years, and 5 (11%) blood banks had their inspection between 3 to 4 years and 4 to 5 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 104,099,452, currently needs around 1,040,994.52 units of blood.As per this criteria, Bihar 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 173,554 of which 50.8% units were through voluntary blood donations and the remaining were from replacement donations.

**Figure 3 - Annual Collections and Voluntary Donation**

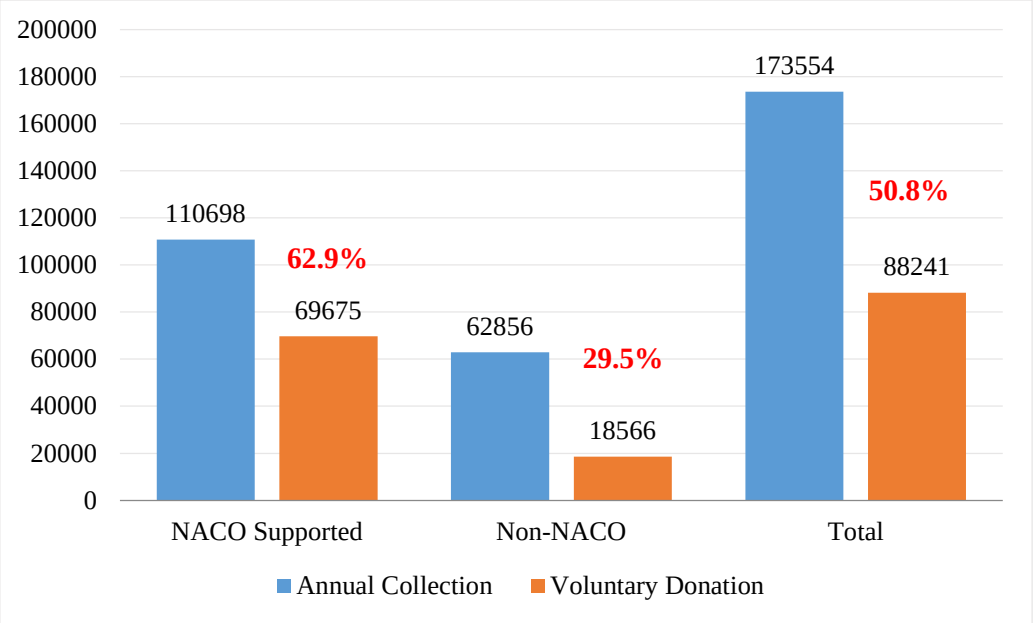
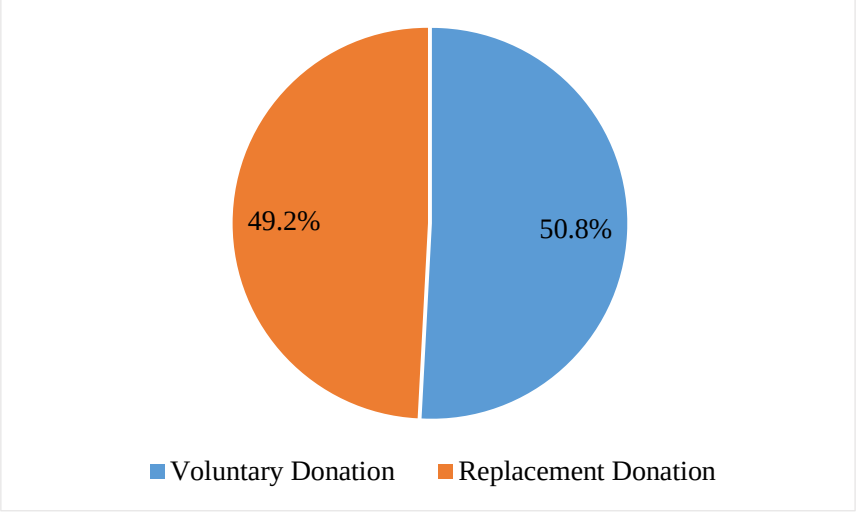



**Figure 4 - Type of Blood Donation (Voluntary vs. Replacement Donation %)**



The average annual collection of blood units of all the blood banks in the state was 2,515 units.The average annual collection of NACO supported blood banks (2,838 units) was found to be higher than the Non-NACO blood banks (2,095 units).

**Table 6 - Average Annual Collection**

| District | NACO | Non-NACO | All BBs |
|---|---|---|---|
| **Aurangabad** | 824 | - | 824 |
| **Begusarai** | 3488 | 812 | 1704 |
| **Bhagalpur** | 6281 | - | 6281 |
| **Bhojpur** | 971 | 819 | 920.3 |
| **Buxar** | 748 | - | 748 |
| **Darbhanga** | 7819 | - | 7819 |
| **East Champaran** | 5265 | 891 | 3078 |
| **Gaya** | 3434 | - | 3434 |
| **Gopalganj** | 916 | - | 916 |
| **Jamui** | 1066 | - | 1066 |
| **Jehanabad** | 234 | - | 234 |
| **Kaimur** | 155 | - | 155 |
| **Katihar** | 1332 | 1332 | 1332 |
| **Khagaria** | 1134 | - | 1134 |
| **Kishanganj** | 3027 | 4180 | 3603.5 |
| **Lakhisarai** | 4 | - | 4 |
| **Madhepura** | 710 | - | 710 |
| **Madhubani** | 443 | - | 443 |
| **Munger** | 1658 | - | 1658 |
| **Muzaffarpur** | 4067 | 1128 | 2597.8 |
| **Nalanda** | 758 | 1715 | 1236.5 |
| **Nawada** | 469 | - | 469 |
| **Patna** | 9111 | 2002.2 | 3872.9 |
| **Purnia** | 4680 | 6725 | 6043.7 |
| **Rohtas** | 51 | 2333 | 1762.5 |
| **Saharsa** | 1640 | - | 1640 |
| **Samastipur** | 995 | 622 | 808.5 |
| **Saran** | 1028 | - | 1028 |
| **Sheikhpura** | 15 | - | 15 |
| **Sitamarhi** | 1361 | - | 1361 |
| **Siwan** | 3661 | 936 | 2298.5 |
| **Vaishali** | 324 | - | 324 |
| **West Champaran** | 1546 | - | 1546 |
| **Bihar** | **28384** | **2095** | **2515** |

The blood banks with component separation units recorded a higher average collection of 6,095 units compared to blood banks without blood component separation units which was 1,604 units. However, the variation in the collection was found to be high across and within districts.

The NACO supported blood banks collected 64% (110,698 units) of the total collection, of which 63% (69,675 units) were through voluntary blood donation. The Non-NACO blood banks collected 62,856 (36%) units of which 30% (18,566 units) were through voluntary blood donation. Blood banks with component separation facility collected around 49% of blood units (85,325) and the remaining 51% (88,229 units) were collected by blood banks without the component facility.Similarly, blood banks owned by public sector collected 56% (96,845 units) of the total collection followed by the not-for-profit sector 31% (54,133 units) and private sector blood banks (13%, 22,576 units).

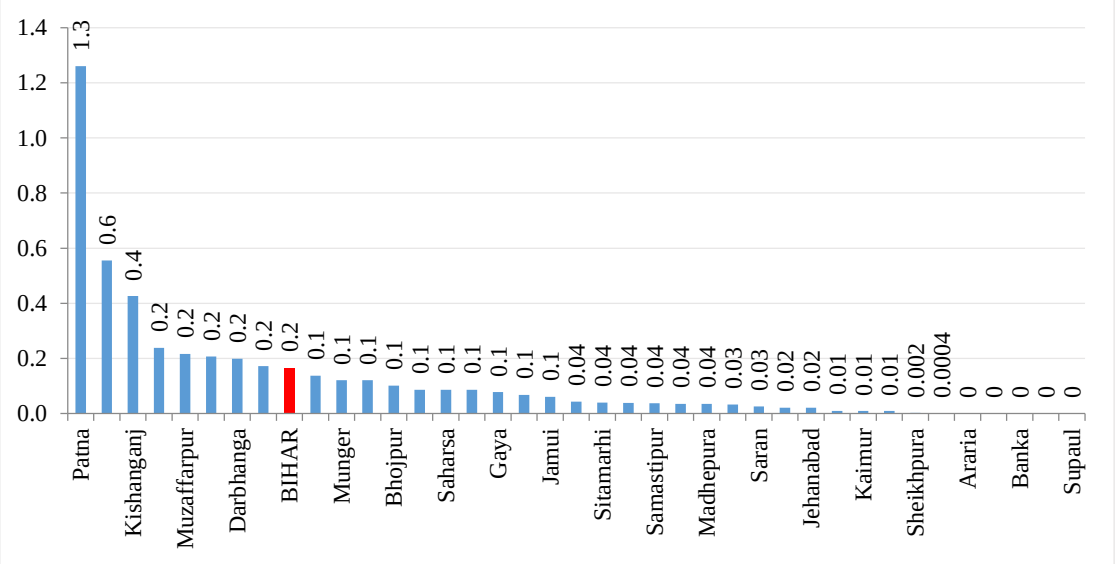
Table-7 indicates the district-wise details of the total annual collection, voluntary and replacement donation in the state of Bihar. Blood banks reported a varying proportion of VNRBD ranging from 7 to 100%.

**Table 7 - Annual blood collection and percentage of VBD**

| District | Voluntary Donation | Replacement Donation | Annual Collection | VBD % |
|---|---|---|---|---|
| **Aurangabad** | 585 | 239 | 824 | 71 |
| **Begusarai** | 3123 | 1989 | 5112 | 61.1 |
| **Bhagalpur** | 6087 | 194 | 6281 | 96.9 |
| **Bhojpur** | 529 | 2232 | 2761 | 19.2 |
| **Buxar** | 269 | 479 | 748 | 36 |
| **Darbhanga** | 6660 | 1159 | 7819 | 85.2 |
| **East Champaran** | 3816 | 2340 | 6156 | 62 |
| **Gaya** | 3265 | 169 | 3434 | 95.1 |
| **Gopalganj** | 902 | 14 | 916 | 98.5 |
| **Jamui** | 756 | 310 | 1066 | 70.9 |
| **Jehanabad** | 118 | 116 | 234 | 50.4 |
| **Kaimur** | 83 | 72 | 155 | 53.5 |
| **Katihar** | 1334 | 1330 | 2664 | 50.1 |
| **Khagaria** | 963 | 171 | 1134 | 84.9 |
| **Kishanganj** | 5315 | 1892 | 7207 | 73.7 |
| **Lakhisarai** | 2 | 2 | 4 | 50 |
| **Madhepura** | 74 | 636 | 710 | 10.4 |
| **Madhubani** | 443 | 0 | 443 | 100 |
| **Munger** | 1111 | 547 | 1658 | 67 |
| **Muzaffarpur** | 7620 | 2771 | 10391 | 73.3 |
| **Nalanda** | 1590 | 883 | 2473 | 64.3 |
| **Nawada** | 35 | 434 | 469 | 7.5 |

| | | | | |
|---|---|---|---|---|
| **Patna** | 27245 | 46341 | 73586 | 37 |
| **Purnia** | 4891 | 13240 | 18131 | 27 |
| **Rohtas** | 2415 | 4635 | 7050 | 34.3 |
| **Saharsa** | 1518 | 122 | 1640 | 92.6 |
| **Samastipur** | 482 | 1135 | 1617 | 29.8 |
| **Saran** | 1022 | 6 | 1028 | 99.4 |
| **Sheikhpura** | 11 | 4 | 15 | 73.3 |
| **Sitamarhi** | 1040 | 321 | 1361 | 76.4 |
| **Siwan** | 3269 | 1328 | 4597 | 71.1 |
| **Vaishali** | 324 | - | 324 | 100 |
| **West Champaran** | 1344 | 202 | 1546 | 86.9 |
| **Bihar** | **88241** | **85313** | **173554** | **50.8** |

**Figure 5 - Annual Collection per 100 population- District wise**

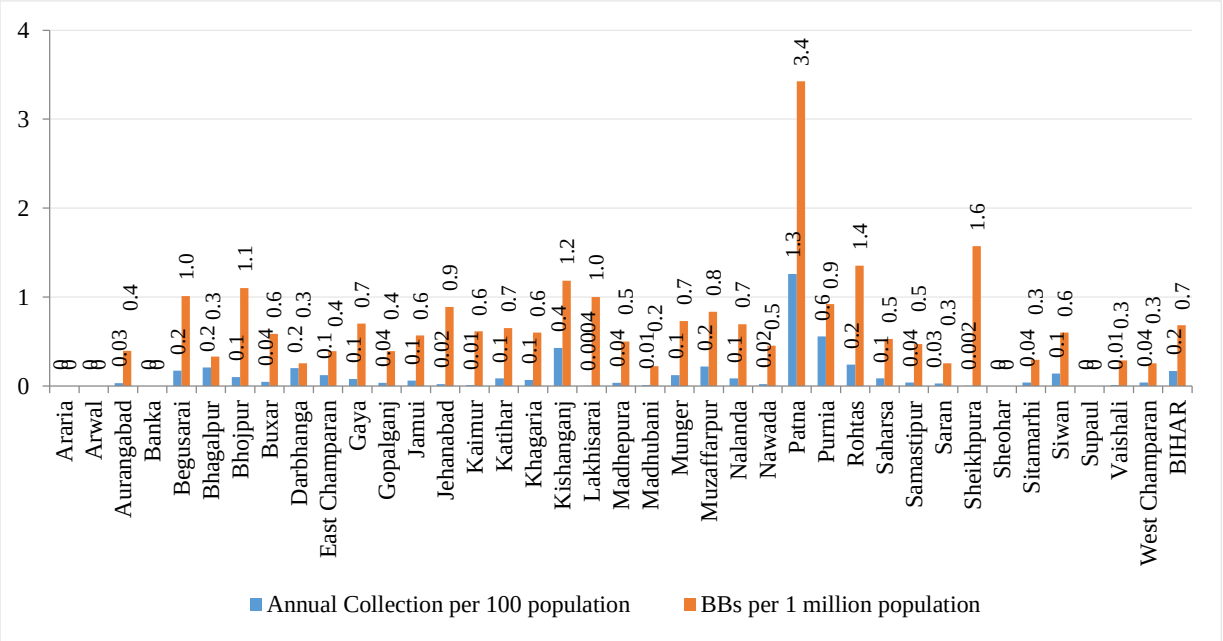



The annual collection of blood units per 100 individuals was found to be around 0.2% in the state, which is not meeting the WHO suggested requirement that 1% of the population can meet a nation's most basic requirements for blood. However, there is a huge disparity in the collection of blood between districts. Lakhisarai(0.0004), Sheikpura(0.002), Vaishali(0.01), Aurangabad(0.3), Jamui (0.1), Gaya (0.1) among others, collected a state average of less than 1.5 units per 100 population. Eight districts in the state recorded more than/equal to the state average of 0.2 units per 100 population that are, Patna (1.3), Purnia (0.6), Kishanganj (0.4), Begusarai (0.2), Darbhanga (0.2), Bhagalpur (0.2), Muzaffarpur (0.2), and Rohtas (0.2). (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 the state had around 0.7 blood banks per million population that collected around 0.2 units per

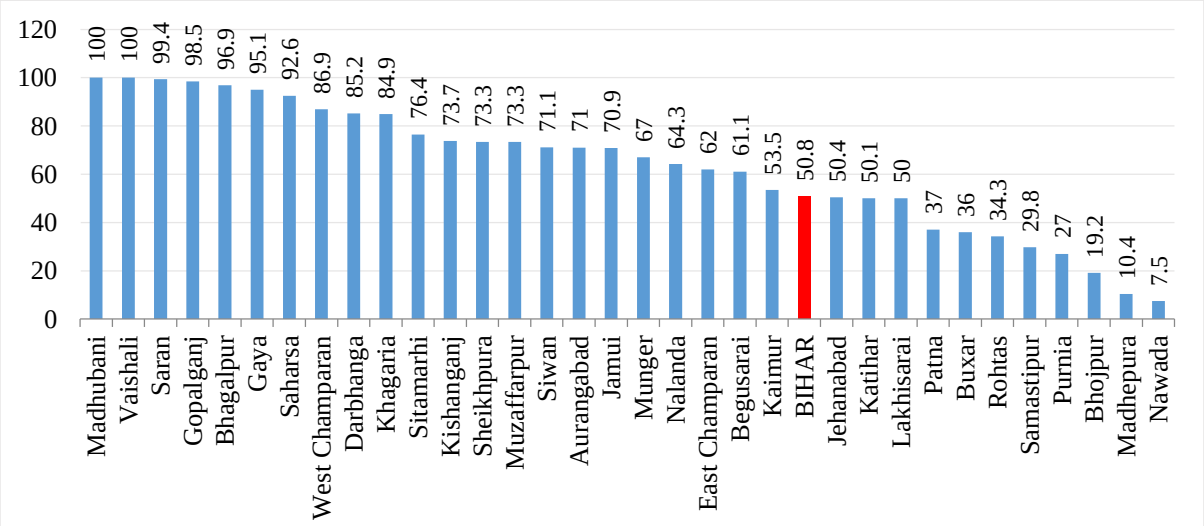
100 population at the ratio of 0.7 BB: 0.2 blood unit. The ratio was wide in Patna, Sheikpura, and Lakhisarai districts. These districts collect relatively less blood with more number of blood banks proportionate to population.

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



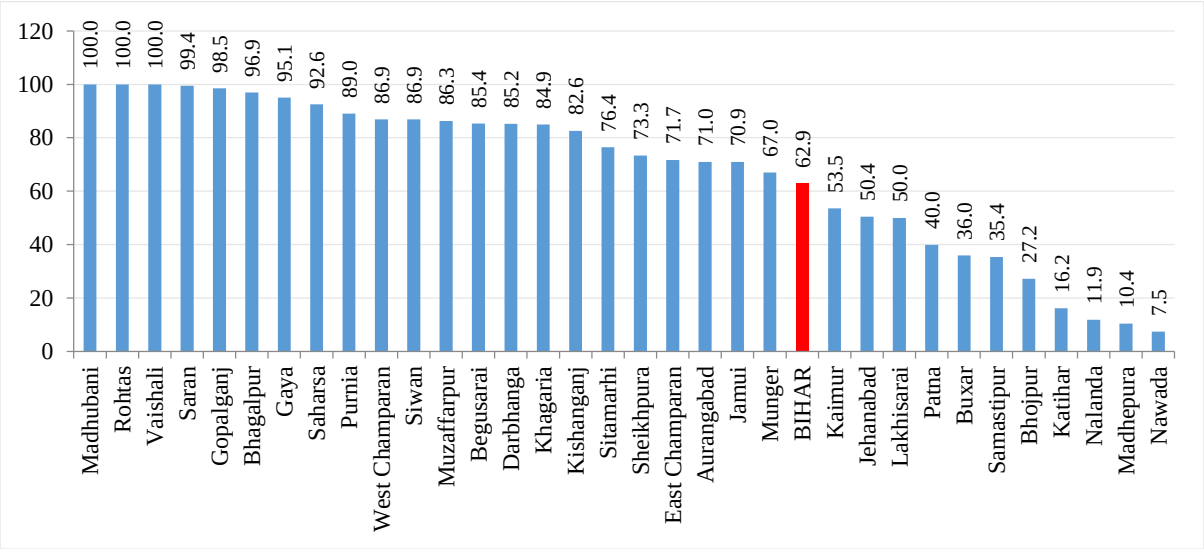

**4.2.2** ***Voluntary blood donation:*** As depicted in Figure-7, 22 districts have recorded more than the state average of 50.8%. Districts such as Saharsa, Gaya, Bhagalpur, Gopalganj and Saran reported more than 90% voluntary blood donation while Vaishali and Madhubani districts showed 100% voluntary blood donation. Nawada district recorded the lowest percentage of VBD in the state (7.5%)

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



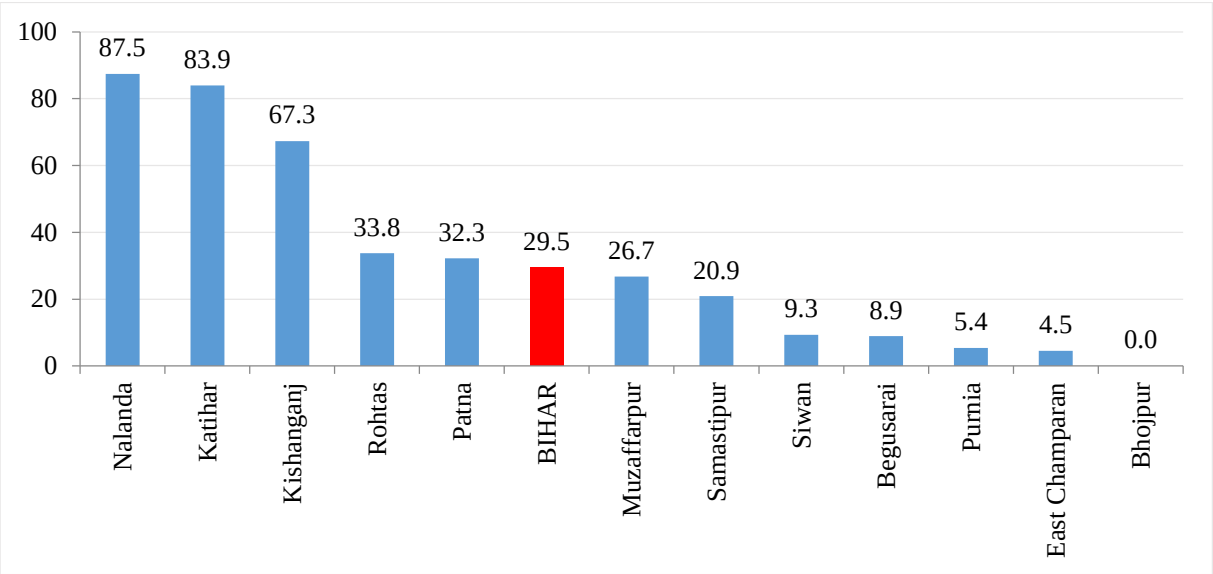
Among the NACO supported blood banks, three districts, Madhubani, Rohtas and Vaishali, recorded 100% voluntary donation. Districts such as Saharsa, Gaya, Bhagalpur, Gopalganj and Saran recorded more than 90%, which is well above the state average (62.9%).

**Figure 8 - Percentage of Voluntary Blood Donation by District (NACO Supported)**




Among Non-NACO blood banks, five districts recorded more than state average of 29.5%. Seven districts recorded less than the state average. Bhojpur district recorded the lowest VBD percentage (0%) in the state among Non-NACO blood banks.

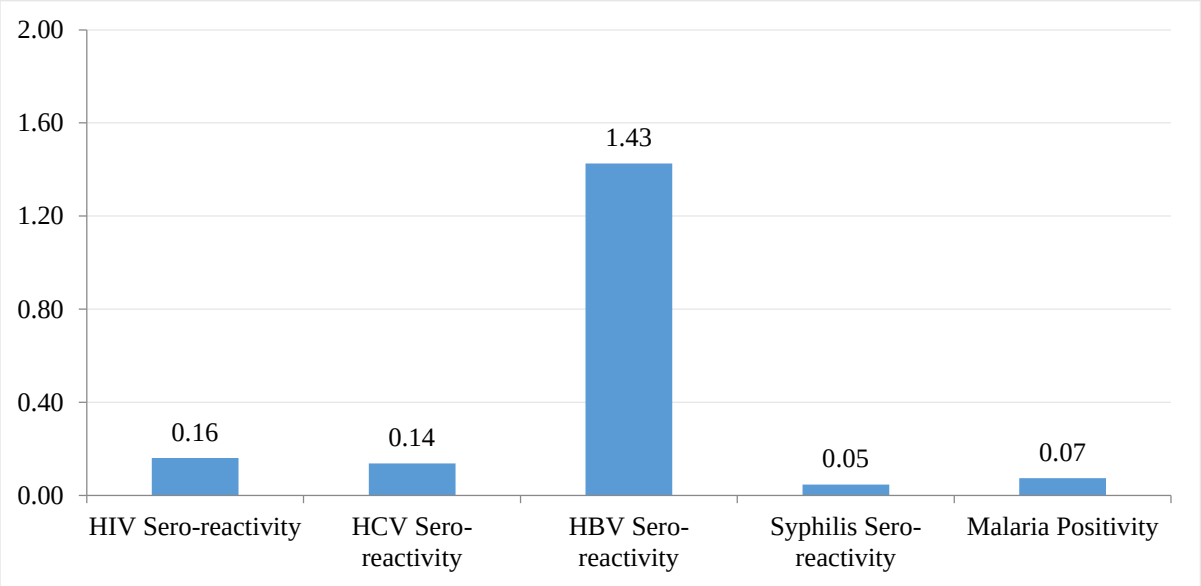
**Figure 9 - Percentage of Voluntary Blood Donation by District (Non-NACO)**



## 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 sero-reactivity percentage of TTIs has come down significantly over the years.

**Figure 10 - Transfusion Transmitted Infection (%)-Jan-Dec 2015**




The seroreactivity of TTI among blood donors in the year 2015 is depicted in Fig-10. HIV reactivity was found to be 0.16%, Hepatitis-C was 0.14%, Hepatitis-B 1.43%, Syphilis 0.05% and Malaria 0.07%. However, there is a significant variation between districts.

HIV, HCV, HBV and Malaria reactivity/positivity rates were recorded higher in NACO supported blood banks. Syphilis reactivity was found to be higher in Non-NACO blood banks. The frequency of HBV (1.75) was comparatively higher than the other TTIs.

**Table 8 - Transfusion Transmitted Infections (%)**

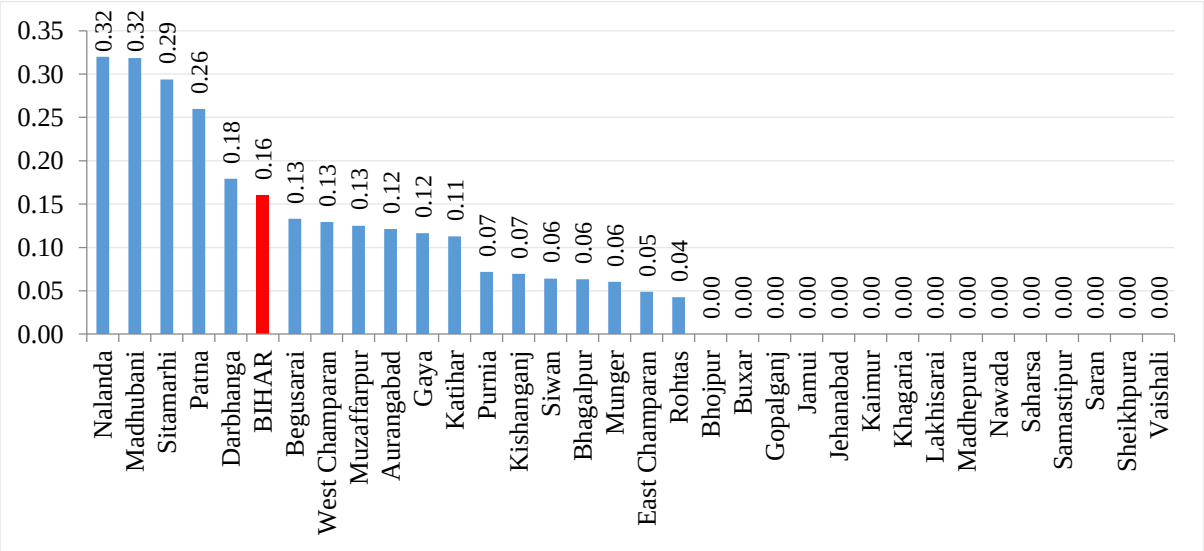
| Category of BB | Transfusion Transmitted Infections % | | | | |
|---|---|---|---|---|---|
| | HIV | HCV | HBV | Syphilis | Malaria |
| NACO Supported | 0.22 | 0.15 | 1.75 | 0.04 | 0.11 |
| Non-NACO | 0.05 | 0.12 | 0.86 | 0.05 | 0.02 |
| **Overall** | **0.16** | **0.14** | **1.43** | **0.05** | **0.07** |

**4.3.1 Transfusion Transmitted Infections by Category of blood banks**: HIV, HCV, HBV seroreactivity and Malaria positivity 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**

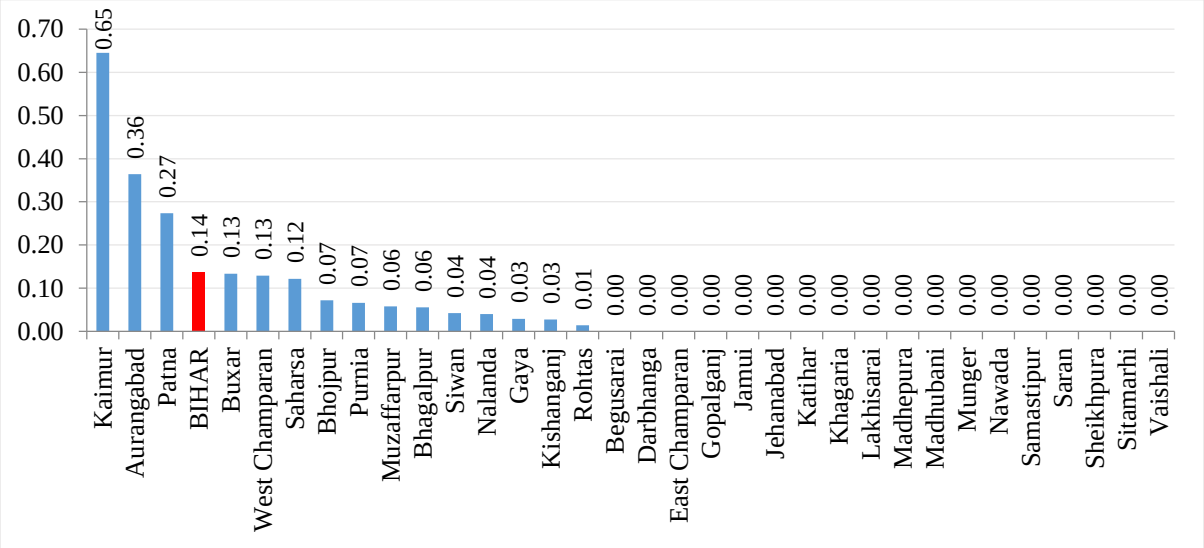
| Category of BB | Transfusion Transmitted Infections % | | | | |
|---|---|---|---|---|---|
| | HIV | HCV | HBV | Syphilis | Malaria |
| BBs with component facility | 0.25 | 0.24 | 1.84 | 0.02 | 0.05 |
| BBs without component facility | 0.08 | 0.04 | 1.03 | 0.07 | 0.09 |
| **Overall** | **0.16** | **0.14** | **1.43** | **0.05** | **0.07** |

**Figure 11 - HIV Seroreactivity- By District (%)**



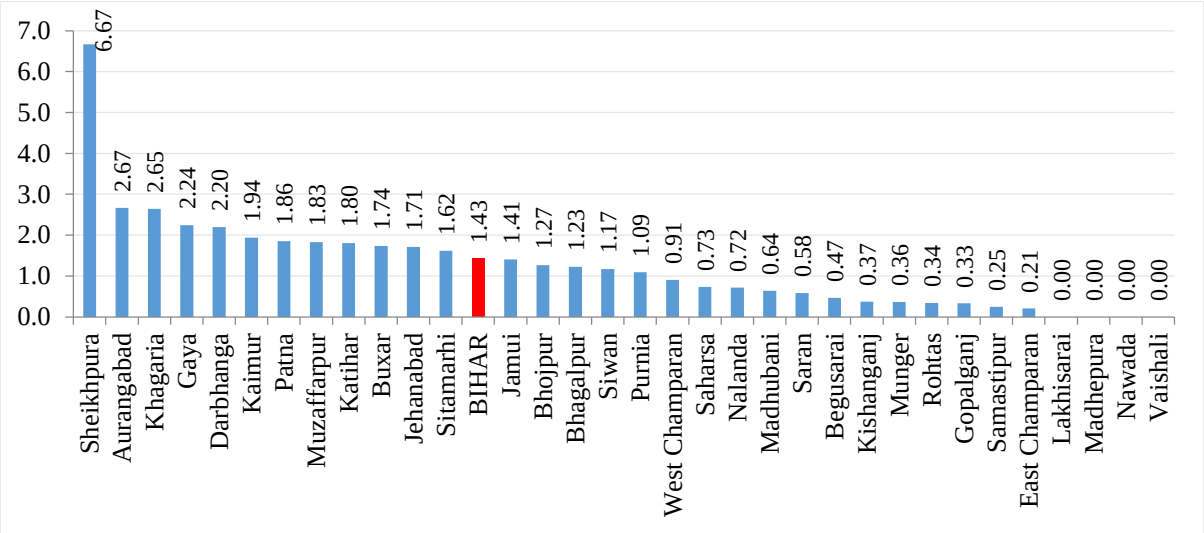

The majority of districts indicated lower HIV reactivity than the state HIV reactivity level of 0.16%. However, Nalanda (0.32), Madhubani (0.32), Sitamarhi (0.29), Patna (0.26) and Darbhanga (0.18) districts recorded a higher reactivity than state average. In general, HIV reactivity in the state recorded a low reactivity as compared to other states in the country.

**Figure 12 - HCV Seroreactivity- By District (%)**



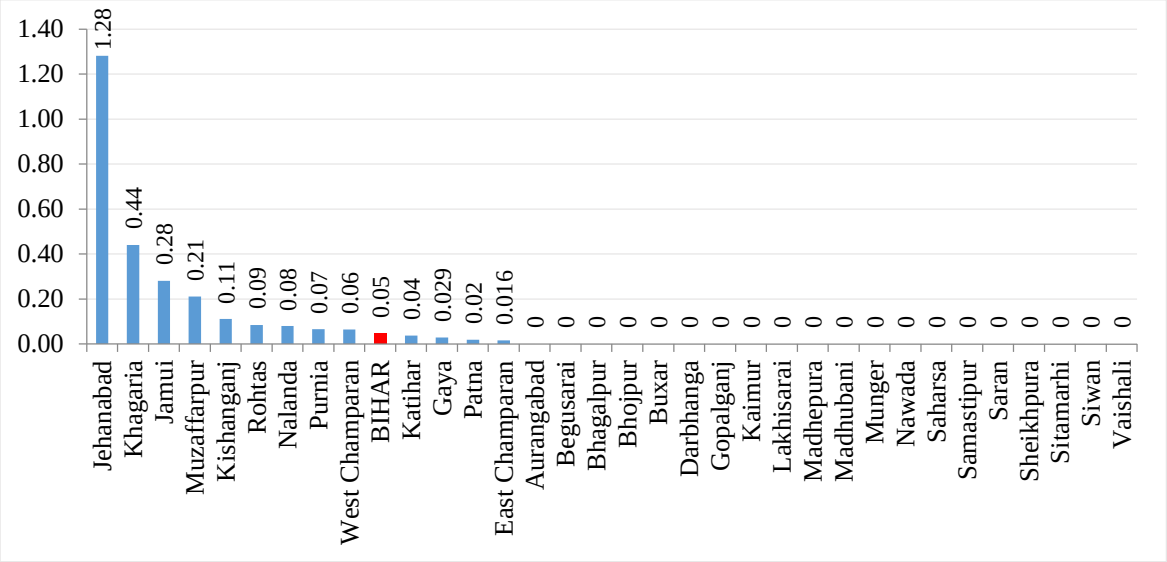

When considering Hepatitis C infection, districts like Kaimur (0.65), Aurangabad (0.36) and Patna (0.27) indicated a higher reactivity level as compared to the state average of 0.14%.

**Figure 13 - HBV Seroreactivity- By District (%)**



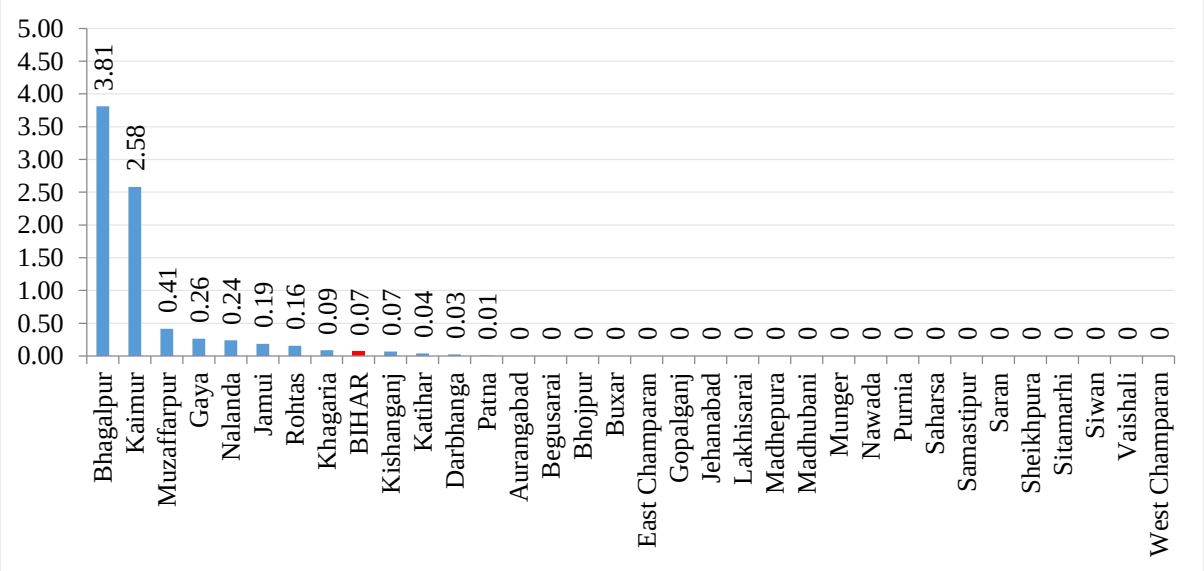

Hepatitis B seroreactivity was found to be higher than the state average of 1.43% in twelve districts with Sheikpura having the highest reactivity (6.67).Twenty-one districts recorded less than the state average.

**Figure 14 - Syphilis Seroreactivity- By District (%)**




Syphilis seroreactivity was found to be higher than the state average of 0.05% in districts like Khagaria (0.44%), Kishanganj (0.11%), Nalanda (0.08%), Purnia (0.06%) and West Champaran (0.06%), among others. Jehanabad (1.28%) recorded the highest number of syphilis reactivity among donors while East Champaran (0.016%) recorded the least. Twenty districts did not report any case of syphilis reactivity among their donors.

**Figure 15 - Malaria Positivity- By District (%)**




The majority of the districts indicated a lower reactivity of Malaria than the state reactivity of 0.07% whereas districts like Bhagalpur (3.18) and Kaimur (2.58), recorded a higher reactivity than the state average.

## 4.4 Component Separation

As depicted in Figure-16, around 47.3% of blood units collected by blood banks with component separation facilities were used for component separation in the state. The percentage of component separation was higher (55%) in Non-NACO blood banks compared to NACO supported blood banks (44%).

**Figure 16 - Total Blood Collection and Component Separation**

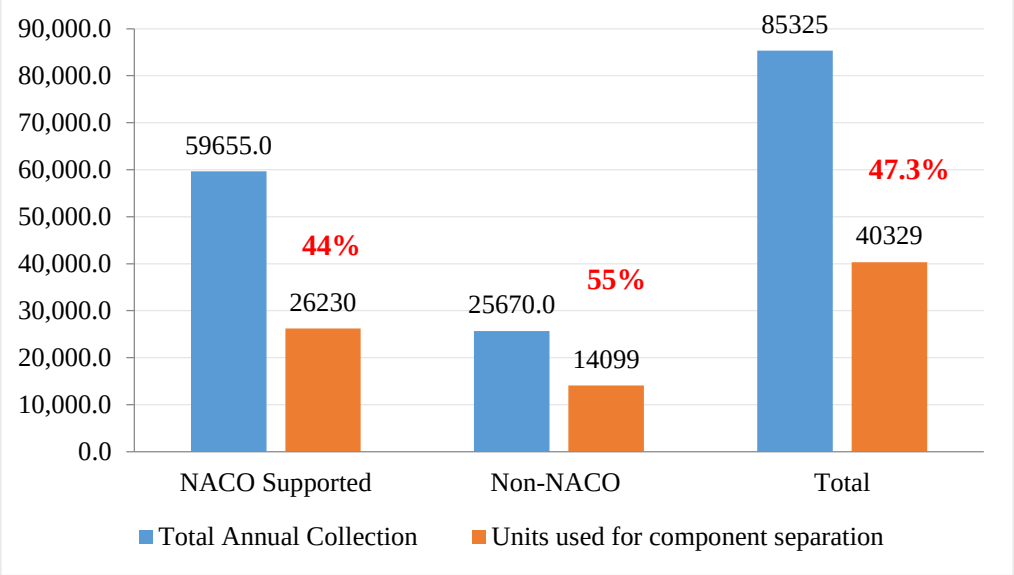


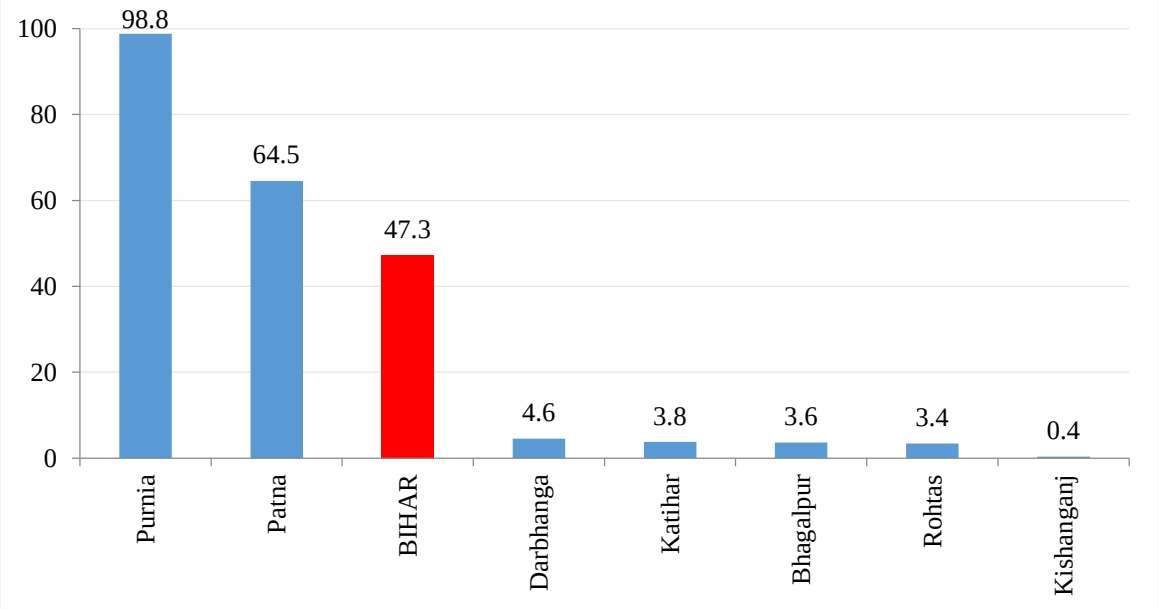

**Table 10 - Total Annual Collection by BCSUs & Percentage of Component Separation**

| District | Total Annual Collection | Total Collection by BCSUs | Percentage of component separation |
|---|---|---|---|
| **Aurangabad** | 824 | - | - |
| **Begusarai** | 5112 | - | - |
| **Bhagalpur** | 6281 | 6281 | 3.6 |
| **Bhojpur** | 2761 | - | - |
| **Buxar** | 748 | - | - |
| **Darbhanga** | 7819 | 7819 | 4.6 |
| **East Champaran** | 6156 | - | - |
| **Gaya** | 3434 | - | - |
| **Gopalganj** | 916 | - | - |
| **Jamui** | 1066 | - | - |
| **Jehanabad** | 234 | - | - |
| **Kaimur** | 155 | - | - |
| **Katihar** | 2664 | 1332 | 3.8 |
| **Khagaria** | 1134 | - | - |

| | | | |
|---|---|---|---|
| **Kishanganj** | 7207 | 4180 | 0.4 |
| **Lakhisarai** | 4 | - | - |
| **Madhepura** | 710 | - | - |
| **Madhubani** | 443 | - | - |
| **Munger** | 1658 | - | - |
| **Muzaffarpur** | 10391 | - | - |
| **Nalanda** | 2473 | - | - |
| **Nawada** | 469 | - | - |
| **Patna** | 73586 | 60600 | 64.5 |
| **Purnia** | 18131 | 407 | 98.8 |
| **Rohtas** | 7050 | 4706 | 3.4 |
| **Saharsa** | 1640 | - | - |
| **Samastipur** | 1617 | - | - |
| **Saran** | 1028 | - | - |
| **Sheikhpura** | 15 | - | - |
| **Sitamarhi** | 1361 | - | - |
| **Siwan** | 4597 | - | - |
| **Vaishali** | 324 | - | - |
| **West Champaran** | 1546 | - | - |
| **Bihar** | **173,554** | **85,325** | **47.3** |

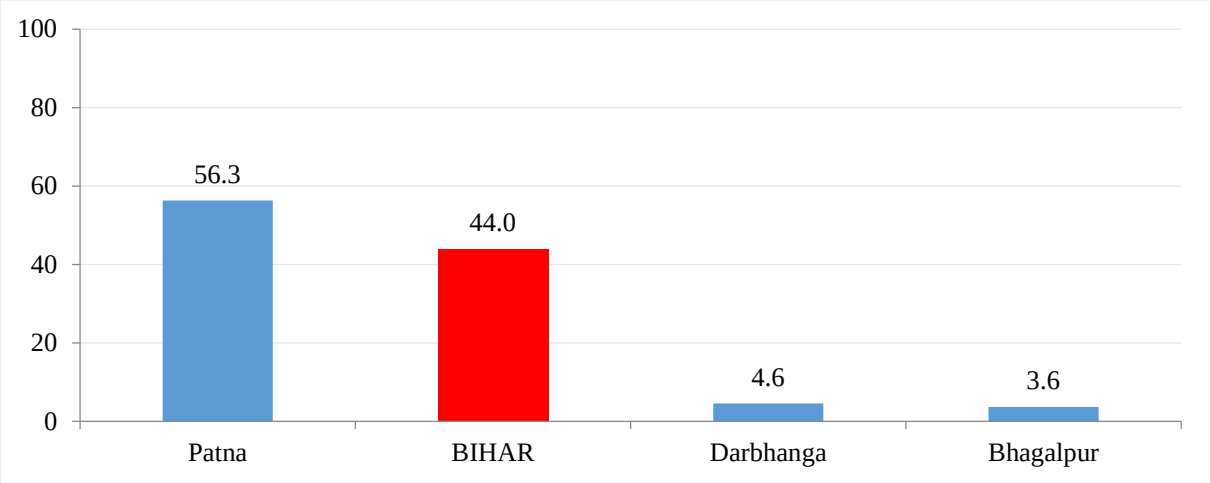
The percentage of component separation out of the total collection was more than the state average of 47.3% in Purnia (98.8%) and Patna (64.5%).

**Figure 17 - Percentage of Component Separation- By District (All BBs)**




The percentage of component separation in NACO supported blood banks is illustrated in Figure-18 which indicates only one district, Patna (56.3%) recording more than the state average and four districts reporting less than 50% of component separation.

**Figure 18 - Percentage of Component Separation- By District (NACO)**




Only three districts (Patna, Bhagalpur and Darbangha) had NACO supported blood banks with component separation facility.

## 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 (93%) reported that they adhered to the NBTC guidelines. Availability of document control system was reported by less than 40.8% of the blood banks in the state. Around 38% NACO supported blood banks and 44% Non-NACO blood banks reported they had a document control system. In terms of Standard Operating Procedures (SOPs) for technical processes, more than 94% reported that they had SOPs.

**Table 11 - Availability of Quality Parameters in Blood Banks**

| Quality Parameters | NACO/NON-NACO | | All Blood Banks (n=71) |
|---|---|---|---|
| | NACO supported (n=39) | Non-NACO (n=32) | |
| **Compliance with NBTC guidelines** | 38 | 28 | 66 |
| | 97.4% | 87.5% | 93.0% |
| **Availability of Documental Control System (DCS)** | 15 | 14 | 29 |
| | 38.5% | 43.8% | 40.8% |
| **SOPs for Technical Processes** | 35 | 32 | 67 |
| | 89.7% | 100% | 94.4% |
| **IQC for IH** | 24 | 23 | 47 |
| | 61.5% | 71.9% | 66.2% |
| **IQC for TTI** | 19 | 12 | 31 |
| | 48.7% | 37.5% | 43.7% |
| **QC for kits, reagents and blood bags** | 21 | 28 | 49 |
| | 53.8% | 87.5% | 69% |
| **EQAS for IH** | 1 | - | 1 |
| | 2.5% | - | 1.4% |
| **EQAS for TTI** | - | - | - |
| | - | - | - |
| **NABH accreditation for blood banks** | - | - | - |
| | - | - | - |
| **Availability of designated and trained Quality Manager** | 2 | 21 | 23 |
| | 5.1% | 65.6% | 32.4% |
| **Availability of designated and trained Technical Manager** | 3 | 24 | 27 |
| | 7.7% | 75% | 38% |
| **Programme for regular Equipment maintenance** | 14 | 29 | 43 |
| | 35.9% | 90.6% | 60.6% |
| **Equipment calibration as per regulatory requirement** | 16 | 31 | 47 |
| | 41% | 96.9% | 66.2% |

At the state level, Internal Quality Control (IQC) for Immunohematology was reported by around 66% of the blood banks and IQC for TTIs was reported by 43% of the blood banks, with huge variation between NACO supported and Non-NACO blood banks. Around 61% of the blood banks reported carrying out quality control for kits, reagents and blood bags. The percentage of blood banks enrolled in EQAS by recognized providers was found to be only 1.4% for immunohematology and none for TTIs. No blood bank out of the total 71 blood banks that participated in the assessment was accredited by National Accreditation Board for Hospitals & Healthcare Providers (NABH).

Designated and trained Quality Managers and Technical managers were available only in 32.4% and 38% of the blood banks respectively. 60% of the blood banks reported that they

had a regular equipment maintenance programme and around 66% reported that they calibrate the equipment as per requirement.

## 4.6. Reporting and Documentation

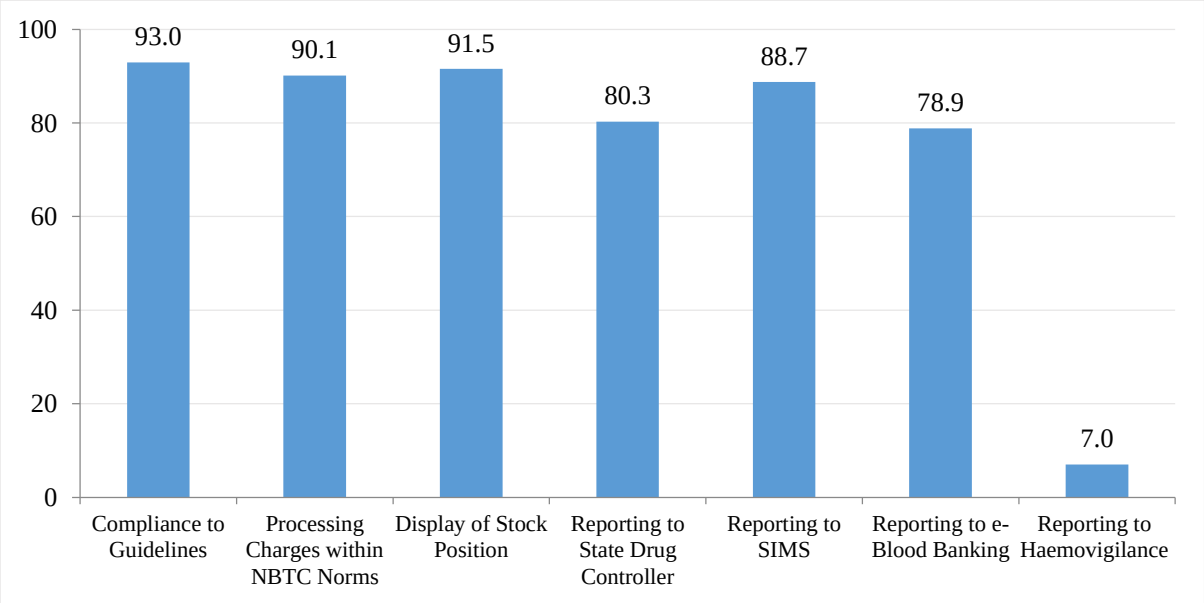
### 4.6.1. Compliance to NBTC guidelines

Majority of the blood banks (93%) reported to be compliant with NBTC guidelines. Around, 90% of Blood Banks reported that they were recovering processing charges within NBTC/SBTC norms. Around 91% 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, around 80% of the blood banks submitted regular reports to state drug controller, 89% of blood banks regularly reported in national strategic information management systems (SIMS). 80% regularly reported in e-blood banking either national or state e-blood banking. Only 7% of blood banks were members of the National Haemovigilance Program.

**Figure 19 - Reporting and Documentation**

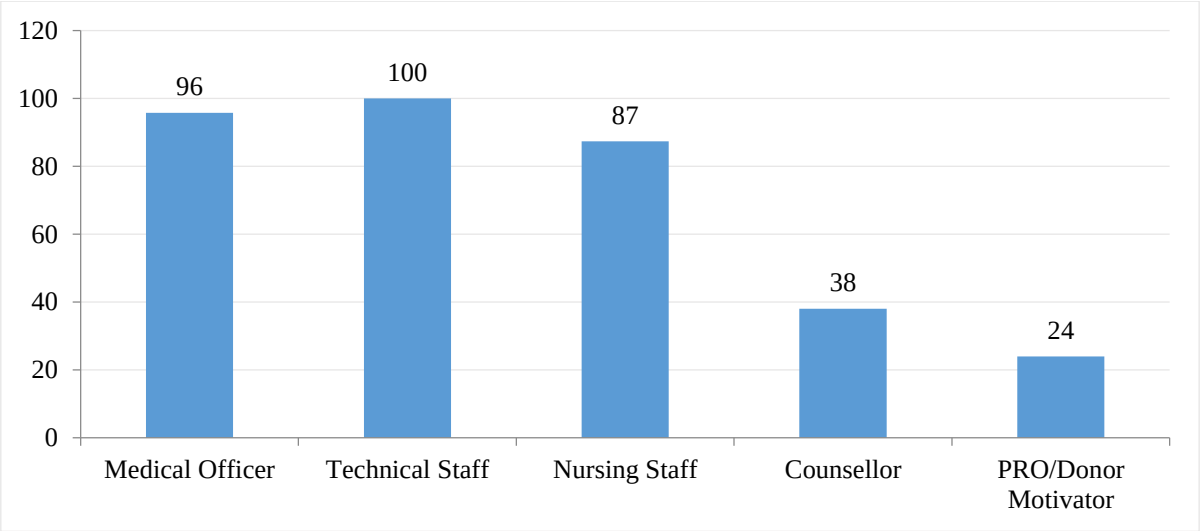


## 4.7. Human Resources

### 4.7.1. Availability of staff

The mean number of employees in the blood banks of the state was 9.6 (SD : 5.7). The number of employees ranges from 3 to 31 employees. 96% of blood banks reported to have medical officers, 100% had technical staff and 87% had nursing staff. However, only 38% had counsellors and 24% reported to have PRO/Donor motivators.

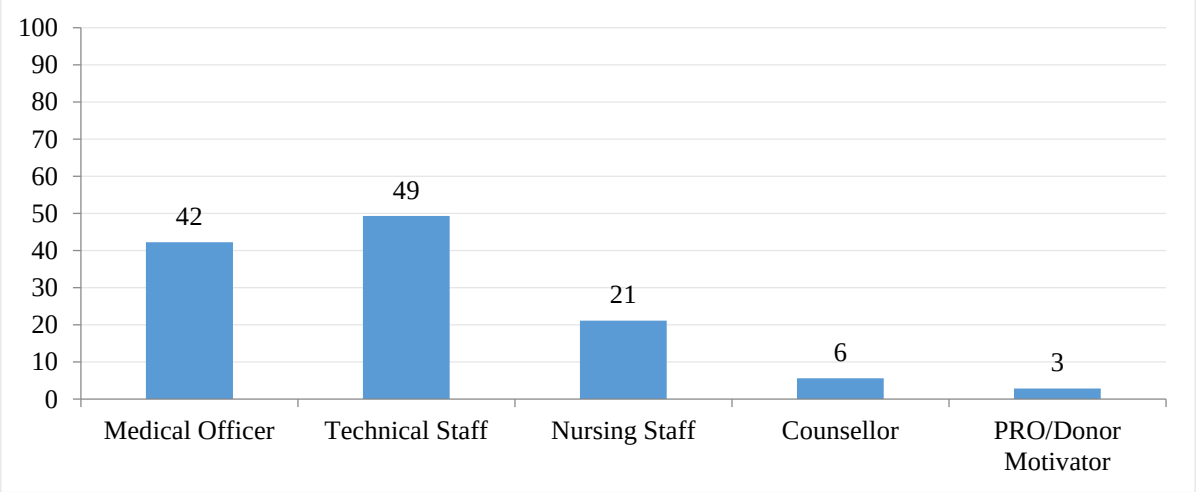
**Figure 20 - Percentage of BB Manpower (At least one)**




## 4.8. Training of Blood Bank Personnel

According to the assessment, around 42% of the blood banks reported that they had at least one medical officer trained by NACO/NBTC; 49% blood banks reported they had trained technical staff, 21% reported having trained nursing staff, 6% had trained counsellors and only 3% blood banks reported having trained PRO/donor motivators.

**Figure 21 - Percentage of BBs having at least one trained**

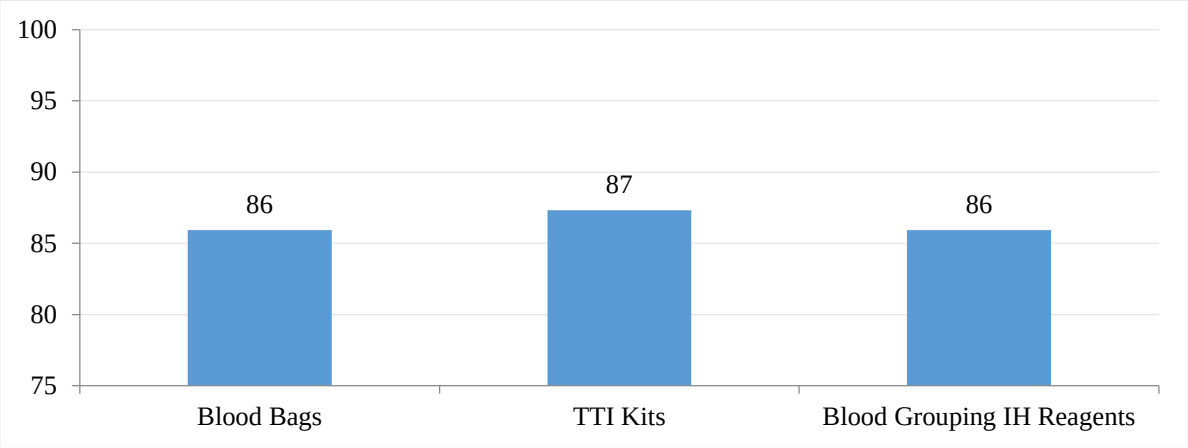


## 4.9. Equipment and Supplies

### 4.9.1. Regular supply kits/supplies

For the regular supply of kits, only 86% blood banks reported that they had regular supply of blood bags, 87% reported that they had regular supply of TTI kits and 86% reported to have regular supply of blood grouping reagents.

**Figure 22 - 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 | 85.9 |
| 2 | Instrument for Hb Estimation | 78.9 |
| 3 | Blood collection monitor | 63.4 |
| 4 | Quarantine Blood Bank Refrigerator to store untested blood | 84.5 |
| 5 | Container for safe disposal of sharps | 76.1 |
| 6 | Oxygen supply equipment | 81.7 |
| 7 | Computers with accessories and software | 50.7 |
| 8 | General lab centrifuge for samples | 76.1 |
| 9 | Bench top centrifuge for serological testing (Immunohaematology) | 83.1 |
| 10 | Blood transportation box (No. in inventory) | 87.3 |
| 11 | Emergency drugs box / Crash cart | 76.1 |
| 12 | Autoclave machine | 67.6 |
| 13 | Water bath | 71.8 |
| 14 | Blood bank refrigerator (storage of tested blood) with temperature recorder | 95.8 |
| 15 | Automated pipettes | 71.8 |
| 16 | Refrigerated centrifuge | 26.8 |
| 17 | Blood container weighting device | 56.3 |
| 18 | Serology rotator | 50.7 |

## 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.

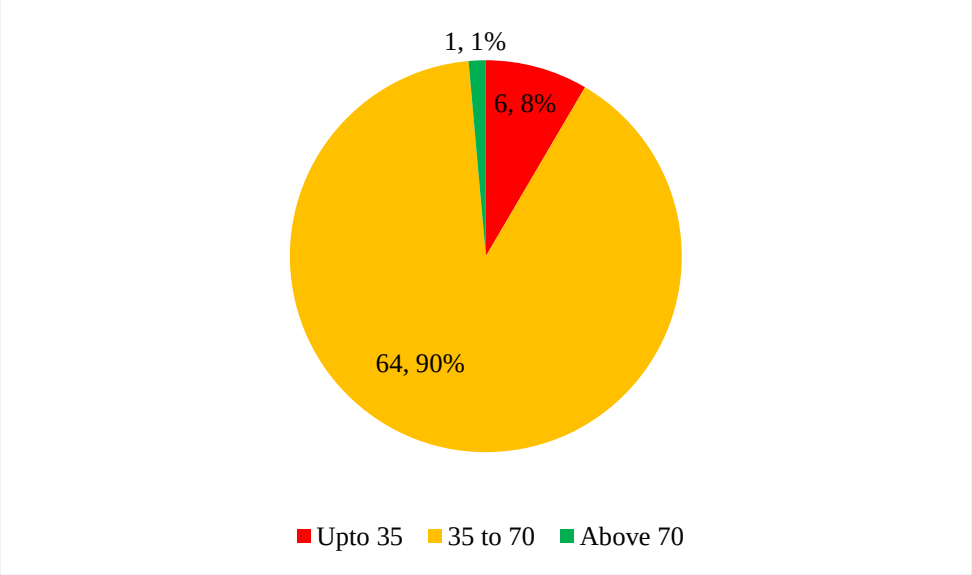
The mean assessment score of blood banks in the state was 50.2 (SD: 10.3).The NACO supported blood banks scored less (46.7; SD: 10) than the Non-NACO blood banks (54.4; SD: 9.2).

**Table 13 - Mean Assessment score**

| Type of BB | N | Mean | SD |
|---|---|---|---|
| **NACO supported** | 39 | 46.76 | 10.00 |
| **Non-NACO** | 32 | 54.48 | 9.23 |
| **Total** | **71** | **50.24** | **10.35** |

At the state level, the majority of blood banks (64; 90%) scored between 35 and 70, followed by 6 blood banks (8%) which scored less than or equal to 35 and only one blood bank scored above 70.

**Figure 23 - Categorisation of Blood banks (n=71)**




Around 90% of NACO supported and 91% Non-NACO blood banks scored between 35 and 70. Only one of Non-NACO blood bank scored more than 70%. (Refer Figure 24; Figure 25). Four NACO Supported and two Non-NACO blood banks scored below 35.

**Figure 24 -Categorisation of NACO Supported BBs (n=39)**

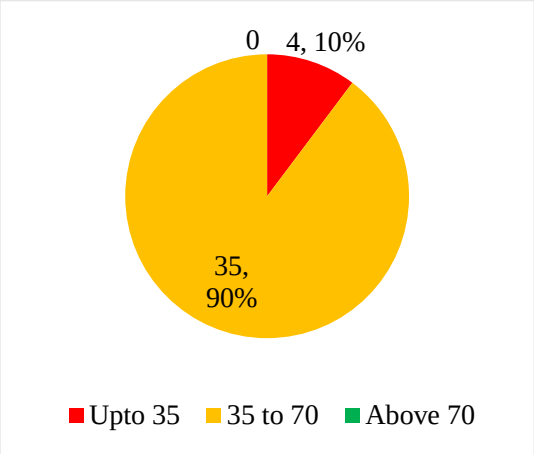
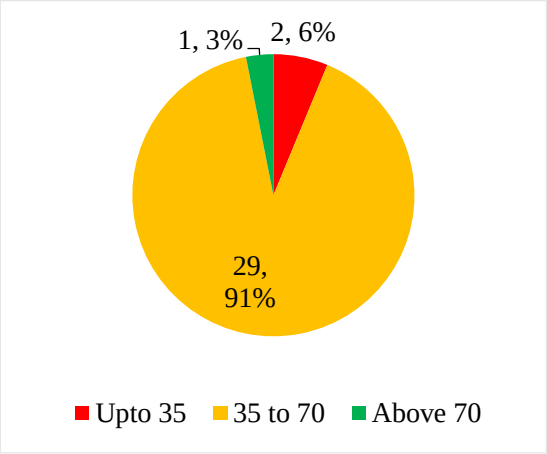
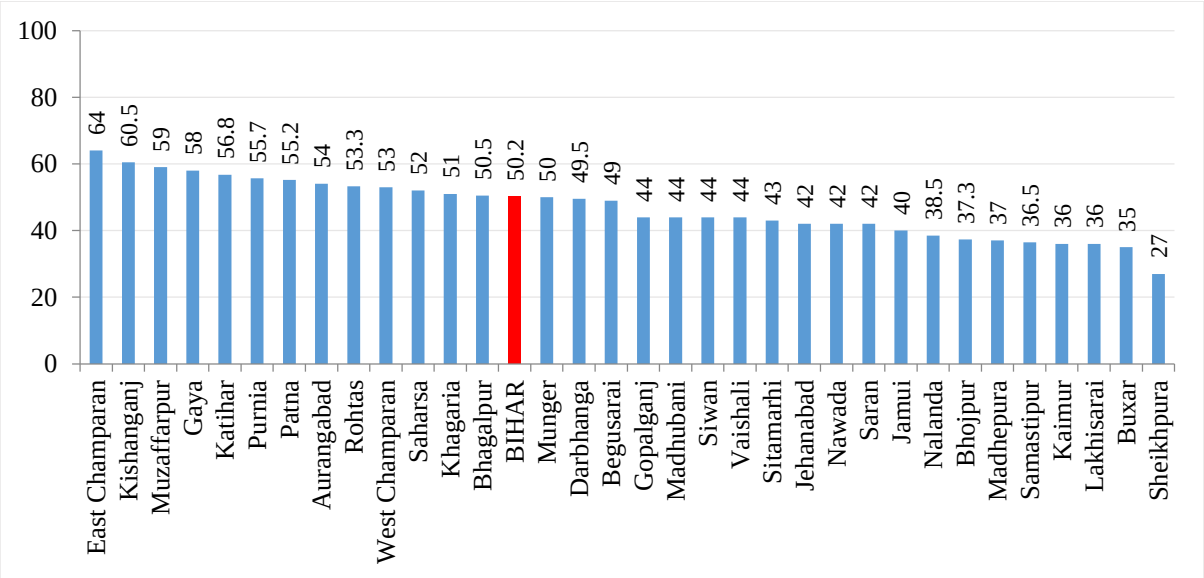



**Figure 25 Categorisation of Non-NACO BBs (n=32)**




Among the districts, East Champaran (64) scored the highest and Sheikpura (27) scored the least. Thirteen districts scored above the state average. Almost half of the blood banks were located in these districts.

**Figure 24 - Mean Assessment Score – By Districts (All BBs)**




The mean scores of Non-NACO blood banks were higher than the NACO Supported blood banks in 8 districts. The difference in the score was more than 5 in Begusarai, Gaya, Katihar, Nalanda, Rohtas and Siwan.

**Table 14 - Mean assessment score - By District (NACO supported Vs. Non-NACO)**

| District | NACO supported | Non-NACO | Total |
|---|---|---|---|
| **Aurangabad** | 54 | - | 54 |
| **Begusarai** | 45 | 51 | 49 |
| **Bhagalpur** | 50.5 | - | 50.5 |
| **Bhojpur** | 38.5 | 35 | 37.3 |
| **Buxar** | 35 | - | 35 |
| **Darbhanga** | 49.5 | - | 49.5 |
| **East Champaran** | 70 | 58 | 64 |
| **Gaya** | 52 | 64 | 58 |
| **Gopalganj** | 44 | - | 44 |
| **Jamui** | 40 | - | 40 |
| **Jehanabad** | 42 | - | 42.0 |
| **Kaimur** | 36 | - | 36 |
| **Katihar** | 51 | 62.5 | 56.8 |
| **Khagaria** | 51 | - | 51 |
| **Kishanganj** | 61 | 60 | 60.5 |
| **Lakhisarai** | 36 | - | 36 |
| **Madhepura** | 37 | - | 37 |
| **Madhubani** | 44 | - | 44 |
| **Munger** | 50 | - | 50 |
| **Muzaffarpur** | 60.5 | 57.5 | 59 |
| **Nalanda** | 31 | 46 | 38.5 |
| **Nawada** | 42 | - | 42 |
| **Patna** | 52.7 | 56 | 55.2 |
| **Purnia** | 58 | 54.5 | 55.7 |
| **Rohtas** | 42 | 57 | 53.3 |
| **Saharsa** | 52 | - | 52 |
| **Samastipur** | 42 | 31 | 36.5 |
| **Saran** | 42 | - | 42 |
| **Sheikhpura** | 27 | - | 27 |
| **Sitamarhi** | 43 | - | 43 |
| **Siwan** | 38 | 50 | 44 |
| **Vaishali** | 44 | - | 44 |
| **West Champaran** | 53 | - | 53 |
| **Bihar** | **46.8** | **54.5** | **50.2** |

Five blood banks had scored less than or equal to 35. Only one blood bank (by district) that scored more than 70 is a Non-NACO blood bank.

**Table 15 - Number of Blood Banks Scored <=35 - by District**

| District | NACO | Non - NACO | Total |
|---|---|---|---|
| **Bhojpur** | 1 | 1 | 2 |
| **Buxar** | 1 | - | 1 |
| **Nalanda** | 1 | - | 1 |
| **Samastipur** | | 1 | 1 |
| **Sheikhpura** | 1 | - | 1 |
| **Total** | **4** | **2** | **6** |

**4.10.1 Assessment score by Category of blood banks:** The mean score of blood banks without component facilities (48.49; SD: 8.61) was found to be lower than the mean score of those with component facilities (57.36; SD: 48.49).

**Table 16- Mean assessment score by category of blood banks**

| Type of Blood Bank | NACO Supported | | | Non-NACO | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| | N | Mean | SD | N | Mean | SD | N | Mean | SD |
| **BCSUs** | 7 | 51.93 | 8.09 | 7 | 62.79 | 5.12 | 14 | 57.36 | 8.61 |
| **Without BCSU** | 32 | 45.63 | 10.13 | 25 | 52.16 | 8.82 | 57 | 48.49 | 10.04 |

The blood banks that scored <=35 were without component separation facility. (Refer Figure 27 and 28). Only one blood bank with component preparation facility scored more than 70.

**Figure 27 - BBs with Component-Score (n=14)**

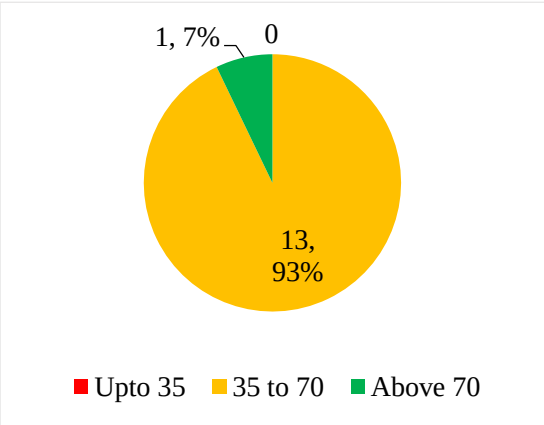
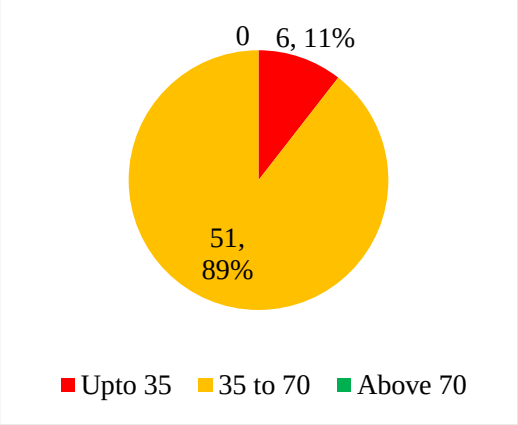



**Figure 28- BBs without Component-Score (n=57)**




**4.10.2 Assessment score by Ownership:** The mean assessment score of private blood banks (54.47; SD: 9.47) was found to be slightly higher than the public and not-for-profit owned blood banks (Refer Table 18).

However, Non-NACO blood banks run by not-for-profit sector had scored higher (54.50; SD: 9.31) compared to NACO Supported blood banks NGO/Trust/Charitable blood banks (53.60; SD: 16.52).

**Table 17 - Mean assessment score by Ownership**

| Ownership | NACO supported | | | Non-NACO | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| | N | Mean | SD | N | Mean | SD | N | Mean | SD |
| NGO/Trust/ charitable | 5 | 53.60 | 16.52 | 17 | 54.50 | 9.31 | 22 | 54.30 | 10.87 |
| Private | - | - | - | 15 | 54.47 | 9.47 | 15 | 54.47 | 9.47 |
| Public | 34 | 45.75 | 8.60 | - | - | - | 34 | 45.75 | 8.60 |

**Table 18 - Mean assessment scores categories by Ownership**

| Ownership | <=35 | 36 to 70 | Above 70 | Total |
|---|---|---|---|---|
| Public | 3 | 31 | - | 34 |
| | 8.8% | 91.2% | - | 100.0% |
| NGO/Trust/Charitable | 2 | 20 | - | 22 |
| | 9.1% | 90.9% | - | 100.0% |
| Private | 1 | 13 | 1 | 15 |
| | 6.7% | 86.7% | 6.7% | 100.0% |
| **Overall** | **6** | **64** | **1** | **71** |
| | **8.5%** | **90.1%** | **1.4%** | **100.0%** |

**4.10.3 Assessment score of Private Sector Blood Banks:** The maximum number of blood banks were in the public sector (48%) followed by the not-for-profit sector having 31% and the private sector owning 21% of the total number of blood banks in the state. The mean score of private sector owned blood banks including not-for-profit sector was 54.36 (SD: 10.19) and the mean score of public owned blood banks was 45.75 (SD 8.60). Among the private sector, not-for-profit sector (54.30; SD: 10.87) scored slightly less than the other private blood banks (54.47; SD: 9.47).

Nevertheless, it is also important to note that the average annual collection was higher in public owned blood banks(2849 units) compared to private blood banks (2191 units). Similarly, the percentage of voluntary blood donation was higher in public owned blood banks (71%) compared to the private blood banks (29%). Of the total private blood banks, 21.6% (8) had component separation facility whereas only 17.6% (6) 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 more than 5000 blood units (56.15; SD: 11.20) was found to be slightly less than those which collected between 3001 and 5000 (56.67; SD: 9.92) and higher than 3000 blood units (47.59; SD: 9.38).

**Table 19 - Mean assessment score by annual collection**

| Annual Collection | NACO supported | | Non-NACO | | Total | |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD |
| **Up to 3000** | 42.92 | 7.30 | 52.65 | 8.84 | 47.59 | 9.38 |
| **3001 to 5000** | 53.83 | 11.23 | 62.33 | 2.52 | 56.67 | 9.92 |
| **Above 5000** | 54.93 | 10.71 | 59.00 | 14.26 | 56.15 | 11.20 |

**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.

**Table 20 - Mean assessment score by voluntary blood donation**

| % VBD | NACO supported | | Non-NACO | | Total | |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD |
| **Less than 25** | 41.60 | 7.92 | 50.92 | 9.43 | 48.89 | 9.78 |
| **25 to 49** | 44.60 | 14.60 | 61.30 | 6.67 | 52.95 | 13.86 |
| **50 to 74** | 45.25 | 12.13 | 55.33 | 4.16 | 47.58 | 11.52 |
| **75 to 90** | 52.06 | 9.84 | 57.83 | 10.32 | 53.50 | 9.83 |
| **Above 90** | 47.15 | 4.27 | 65.00 | - | 48.77 | 6.74 |

**4.10.6 Assessment score by participation in External Quality Assessment Scheme (EQAS) for Immunohematology and Transfusion Transmitted Infections (TTI):** In Bihar, only one NACO supported blood bank was enrolled in EQAS for Immunohematology. Out of the 71 blood banks which had responded, none of them were a part of the EQAS for TTI.

**Table 21 - Mean assessment score by EQAS enrolment**

| IH-EQAS | NACO supported | | | NON-NACO | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| | N | Mean | SD | N | Mean | SD | N | Mean | SD |
| **YES** | 1 | 44.00 | | - | | | 1 | 44.00 | |

**4.10.7 Assessment score by Accreditation status:** The state of Bihar has no blood banks which have been accredited by the NABH.

**Table 22 - Mean assessment score by Accreditation**

| NABH Accreditation | NACO supported | | | Non-NACO | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| | N | Mean | SD | N | Mean | SD | N | Mean | SD |
| **NO** | 39 | 46.76 | 10.00 | 32 | 54.48 | 9.23 | 71 | 50.24 | 10.35 |

The list of blood banks under different categories of score is given in Tables 24 and 25.

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

| Score Category | | | | |
|---|---|---|---|---|
| **District** | **Up to 35** | **35 to70** | **Above 70** | **Total** |
| **Aurangabad** | - | 1 | - | 1 |
| **Begusarai** | - | 3 | - | 3 |
| **Bhagalpur** | - | 1 | - | 1 |
| **Bhojpur** | 2 | 1 | - | 3 |
| **Buxar** | 1 | - | - | 1 |
| **Darbhanga** | - | 1 | - | 1 |
| **East Champaran** | - | 2 | - | 2 |
| **Gaya** | - | 2 | - | 2 |
| **Gopalganj** | - | 1 | - | 1 |
| **Jamui** | - | 1 | - | 1 |
| **Jehanabad** | - | 1 | - | 1 |
| **Kaimur** | - | 1 | - | 1 |
| **Katihar** | - | 2 | - | 2 |
| **Khagaria** | - | 1 | - | 1 |
| **Kishanganj** | - | 2 | - | 2 |
| **Lakhisarai** | - | 1 | - | 1 |
| **Madhepura** | - | 1 | - | 1 |
| **Madhubani** | - | 1 | - | 1 |
| **Munger** | - | 1 | - | 1 |
| **Muzaffarpur** | - | 4 | - | 4 |
| **Nalanda** | 1 | 1 | - | 2 |
| **Nawada** | - | 1 | - | 1 |
| **Patna** | - | 19 | 1 | 20 |
| **Purnia** | - | 3 | - | 3 |
| **Rohtas** | - | 4 | - | 4 |
| **Saharsa** | - | 1 | - | 1 |
| **Samastipur** | 1 | 1 | - | 2 |
| **Saran** | - | 1 | - | 1 |
| **Sheikhpura** | 1 | - | - | 1 |
| **Sitamarhi** | - | 1 | - | 1 |
| **Siwan** | - | 2 | - | 2 |
| **Vaishali** | - | 1 | - | 1 |
| **West Champaran** | - | 1 | - | 1 |
| **Bihar** | **6** | **64** | **1** | **71** |

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

| Score Category | | | | | | |
|---|---|---|---|---|---|---|
| District | NACO supported | | | Non-NACO | | |
| | Up to 35 | 35 to 70 | Above 70 | Up to 35 | 35 to 70 | Above 70 |
| Aurangabad | - | 1 | - | - | - | - |
| Begusarai | - | 1 | - | - | 2 | - |
| Bhagalpur | - | 1 | - | - | - | - |
| Bhojpur | 1 | 1 | - | 1 | - | - |
| Buxar | 1 | - | - | - | - | - |
| Darbhanga | - | 1 | - | - | - | - |
| East Champaran | - | 1 | - | - | 1 | - |
| Gaya | - | 1 | - | - | 1 | - |
| Gopalganj | - | 1 | - | - | - | - |
| Jamui | - | 1 | - | - | - | - |
| Jehanabad | - | 1 | - | - | - | - |
| Kaimur | - | 1 | - | - | - | - |
| Katihar | - | 1 | - | - | 1 | - |
| Khagaria | - | 1 | - | - | - | - |
| Kishanganj | - | 1 | - | - | 1 | - |
| Lakhisarai | - | 1 | - | - | - | - |
| Madhepura | - | 1 | - | - | - | - |
| Madhubani | - | 1 | - | - | - | - |
| Munger | - | 1 | - | - | - | - |
| Muzaffarpur | - | 2 | - | - | 2 | - |
| Nalanda | 1 | - | - | - | 1 | - |
| Nawada | - | 1 | - | - | - | - |
| Patna | - | 5 | - | - | 14 | 1 |
| Purnia | - | 1 | - | - | 2 | - |
| Rohtas | - | 1 | - | - | 3 | - |
| Saharsa | - | 1 | - | - | - | - |
| Samastipur | - | 1 | - | 1 | - | - |
| Saran | - | 1 | - | - | - | - |
| Sheikhpura | 1 | - | - | - | - | - |
| Sitamarhi | - | 1 | - | - | - | - |
| Siwan | - | 1 | - | - | 1 | - |
| Vaishali | - | 1 | - | - | - | - |
| West Champaran | - | 1 | - | - | - | - |
| **Bihar** | **4** | **35** | **-** | **2** | **29** | **1** |

## 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 Kerala 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 39 NACO and 32 Non-NACO blood banks which were included in the review are approximately 85% of the total blood banks (84) existing in the state. The annual collection of these blood banks was 173554 units which is approximately 17% of the total blood requirement based on WHOs estimation that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2010). However, there is a huge variation between districts that ranges from 0.0004 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.

The review also revealed that the majority of blood collection (51%) was by blood banks without component facility compared to the blood banks without component facility (49%), though the variation is less. Though there has been an increase in the percentage of voluntary blood donation over the years (around 50.8% in 2015), there is still a huge variation between districts that ranges from 7.5% to 100%. A targeted program to increase the non-remunerated voluntary blood donors will go a long way towards ensuring a safer option for our patients.

In the state, apart from Patna which has 20 blood banks, the other districts have less than 5 blood banks each. Five districts in Bihar have no blood banks. 25 districts of the 38 districts have less than the state average of 0.7 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.

More than half (64.8%) 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 50.24 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.

## 6. Reference


CDSCO. (2015). LIST OF LICENSED BLOOD BANKS IN INDIA * (February, 2015). Retrieved from http://www.cdsco.nic.in/writereaddata/BLOOD%20BANKS%20INDIAfeb2015.pdf

Chandra, T., Rizvi, S. N. F., & Agarwal, D. (2014). Decreasing Prevalence of Transfusion Transmitted Infection in Indian Scenario. *The Scientific World Journal, 2014*, 4. doi:10.1155/2014/173939

GOI. (2003). *Transfusion Medicine, Technical Manual*. New Delhi: Director General of Health Services, Government of India.

Gupta, R., Singh, B., Singh, D. K., & Chugh, M. (2011). Prevalence and trends of transfusion transmitted infections in a regional blood transfusion centre. *Asian J Transfus Sci, 5*(2), 177-178. doi:10.4103/0973-6247.83250

ISO-8402. (1994). *Quality Management and Quality Assurance - Vocabulary*. Retrieved from Geneva, Switzerland.:

NACO. (2007a). *National Blood Policy (India)*. Retrieved from New Delhi: http://upsacs.nic.in/bs%20doc/bs%20National%20Blood%20Policy.pdf

NACO. (2007b). *Standards For Blood Banks & Blood Transfusion Services*. Retrieved from New Delhi: http://www.iapsmgc.org/userfiles/10_Standards_for_Blood_Banks_and_Blood_Transfusion_Services.pdf

NACO. (2014). *National AIDS Control Programme Phase-IV (2012-2017) Strategy Document*. Retrieved from New Delhi: http://www.naco.gov.in/upload/NACP%20-%20IV/NACP-IV%20Strategy%20Document%20.pdf.

NACO. (2016). *Annual Report 2015-16*. Retrieved from New Delhi:

Pal, R., Kar, S., Zaman, F. A., & Pal, S. (2011). The quest for an Indian blood law as of blood transfusion services regulatory framework. *Asian J Transfus Sci, 5*(2), 171-174. doi:10.4103/0973-6247.83246

Ramani, K. V., Mavalankar, D., & Govil, D. (2007). *Management of Blood Transfusion Services in India: An Illustrative Study of Maharashtra and Gujarat States*. Retrieved from

Schlickman, J. J. (1998). *ISO 9000 quality management system design: optimal design rules for documentation, implementation, and system effectiveness*: ASQ Quality Press.

WHO. (1975). *World Health Assembly resolution WHA28.72. Utilization and supply of human blood and blood products*. Retrieved from http://www.who.int/entity/bloodsafety/en/WHA28.72.pdf

WHO. (2008). *Universal Access to Safe Blood Transfusion*. Retrieved from Geneva:

WHO. (2009). *GDBS Summary Report 2009*. Retrieved from Geneva: http://www.who.int/bloodsafety/global_database/GDBS_Summary_Report_2009.pdf

WHO. (2011). *Developing a National Blood System*. Retrieved from Geneva: http://www.who.int/entity/bloodsafety/publications/am_developing_a_national_blood_system.pdf?ua=1

WHO. (2012). More voluntary blood donations essential [Press release]. Retrieved from http://www.who.int/mediacentre/news/releases/2012/blood_donation_20120614/en/

WHO. (2016a). Quality systems for blood safety. Retrieved from http://www.who.int/bloodsafety/quality/en/

WHO. (2016b). World Blood Donor Day 2016: Blood connects us all. Retrieved from http://www.who.int/campaigns/world-blood-donor-day/2016/en/

# 7. Annexures

## 7.1 Individual Blood Banks' Summary

| District | Name of the Blood Bank | Type | Ownership | Annual Collection | Score (Out of 100) |
|---|---|---|---|---|---|
| **Aurangabad** | Blood Bank Sadar Hospital | Non BCSU | Public | 824 | 54 |
| **Begusarai** | Rastra Kavi Dinkar Blood Bank | Non BCSU | Public | 3488 | 45 |
| | Blood Bank Research Center | Non BCSU | Private | 923 | 46 |
| | Desh Ratna Dr. Rajendra Prasad Memorial Rotary Blood Bank | Non BCSU | NGO/Trust/Charitable | 701 | 56 |
| **Bhagalpur** | Regional Blood Bank, J.L.N.M.C.H, | BCSU | Public | 6281 | 50.5 |
| **Bhojpur** | Indian Red Cross Blood Bank | Non BCSU | NGO/Trust/Charitable | 1613 | 45 |
| | Maa Vindhyawasini Blood Bank | Non BCSU | Private | 819 | 35 |
| | Sadar Hospital | Non BCSU | Public | 329 | 32 |
| **Buxar** | Blood Bank Sadar Hospital | Non BCSU | Public | 748 | 35 |
| **Darbhanga** | Regional Blood Bank D.M.C.H | BCSU | Public | 7819 | 49.5 |
| **East Champaran** | Indian Red Cross Society, Blood Bank, Motihari | Non BCSU | NGO/Trust/Charitable | 5265 | 70 |
| | Blood Bank Duncan Hospital | Non BCSU | NGO/Trust/Charitable | 891 | 58 |
| **Gaya** | A.N Magadh Medical College, Hospital Blood Bank | Non BCSU | Public | 3434 | 52 |
| | Blood Bank Abhay Institute Of Medical Sciences | Non BCSU | Private | | 64 |
| **Gopalganj** | Blood Bank Sadar Hospital | Non BCSU | Public | 916 | 44 |
| **Jamui** | Blood Bank Sadar Hospital | Non BCSU | Public | 1066 | 40 |

| | | | | | |
|---|---|---|---|---|---|
| **Jehanabad** | Sadar Hospital Blood Bank | Non BCSU | Public | 234 | 42 |
| **Kaimur** | Sadar Hospital,Bhasna | Non BCSU | Public | 155 | 36 |
| **Katihar** | Katihar Medical College Blood Bank | BCSU | Private | 1332 | 62.5 |
| | Sadar Hospital Katihar | Non BCSU | Public | 1332 | 51 |
| **Khagaria** | District Blood Bank,Sadar Hospital | Non BCSU | Public | 1134 | 51 |
| **Kishanganj** | Blood Bank, Mata Gujri Memorial Medical College & Lions Kenra Hospital | BCSU | NGO/Trust/Charitable | 4180 | 60 |
| | Blood Bank,Sadar Hospital | Non BCSU | Public | 3027 | 61 |
| **Lakhisarai** | Blood Bank Sadar Hospital | Non BCSU | Public | 4 | 36 |
| **Madhepura** | Blood Bank Sadar Hospital | Non BCSU | Public | 710 | 37 |
| **Madhubani** | Blood Bank Sadar Hospital | Non BCSU | Public | 443 | 44 |
| **Munger** | Sadar Hospital | Non BCSU | Public | 1658 | 50 |
| **Muzaffarpur** | Sri Krishna Medical College & Hospital,Blood Bank | Non BCSU | Public | 6823 | 70 |
| | Sinha Blood Bank | Non BCSU | NGO/Trust/Charitable | 1838 | 50 |
| | Blood Bank,Sadar Hospital | Non BCSU | Public | 1312 | 51 |
| | Krishna Devi Devi Prasad Kejriwal Maternity Hospital | Non BCSU | NGO/Trust/Charitable | 418 | 65 |
| **Nalanda** | Nalanda Blood Bank(A Unit Of Janta Karah Kalyan Samaj) | Non BCSU | NGO/Trust/Charitable | 1715 | 46 |
| | Red Cross Blood Bank Sadar Hospital, | Non BCSU | NGO/Trust/Charitable | 758 | 31 |
| **Nawada** | Blood Bank Sadar Hospital | Non BCSU | Public | 469 | 42 |

| | | | | | |
|---|---|---|---|---|---|
| **Patna** | Bihar State Blood Bank | BCSU | Public | 20068 | 47 |
| | State of the Art Model Blood Bank | BCSU | Public | 10316 | 44 |
| | Blood Bank, IGIMS, Sheikhpura | BCSU | Public | 8373 | 53.5 |
| | Lions Mahavir Cancer Sansthan Blood Bank | BCSU | NGO/Trust/Charitable | 6892 | 58.5 |
| | Blood Bank Paras HMRI Hospital | BCSU | Private | 6097 | 73.5 |
| | Red Cross Blood Bank,Patna | BCSU | NGO/Trust/Charitable | 4671 | 69 |
| | National Blood Bank & Research Centre | Non BCSU | Private | 4194 | 65 |
| | Nalanda Medical College Hospital | BCSU | Public | 2127 | 50 |
| | Kurji Holy Family Blood Bank | BCSU | NGO/Trust/Charitable | 2056 | 59 |
| | Bharat Blood Bank | Non BCSU | Private | 1980 | 52 |
| | Blood Bank Ruban Memorial Hospital, Ratan Stone Clinic,(Unit of Ruban Patliputra Hospital Pvt. LTD.) | Non BCSU | Private | 1352 | 55 |
| | Patli Putra Blood Bank | Non BCSU | Private | 1291 | 54 |
| | Lions Jeevan Blood Bank | Non BCSU | NGO/Trust/Charitable | 1193 | 70 |
| | Life Line Blood Bank | Non BCSU | Private | 1099 | 49 |
| | Jeevan Rekha Blood Bank | Non BCSU | NGO/Trust/Charitable | 542 | 52 |
| | Hitech Emergency Hospiatl Blood Bank | Non BCSU | Private | 527 | 48 |
| | Tripolia Social Service Hospital | Non BCSU | Private | 351 | 52 |
| | Palm View Hospital Blood Bank | Non BCSU | Private | 318 | 52 |
| | Vaatsalya Blood Bank | Non BCSU | NGO/Trust/Charitable | 139 | 48 |

| | | | | | |
|---|---|---|---|---|---|
| | Shrishti Blood Bank | Non BCSU | NGO/Trust/Charitable | | 52 |
| **Purnia** | Blood Bank (Red Cross) | Non BCSU | NGO/Trust/Charitable | 13044 | 45 |
| | Blood Bank, Sadar Hospital | Non BCSU | Public | 4680 | 58 |
| | Blood Bank, Max-7 Hospital | BCSU | NGO/Trust/Charitable | 407 | 64 |
| **Rohtas** | Blood Bank, Narayan Medical College & Hospital | BCSU | NGO/Trust/Charitable | 4706 | 62 |
| | Micro Blood Bank | Non BCSU | Private | 1365 | 61 |
| | Bose Clinic Blood Bank | Non BCSU | Private | 928 | 48 |
| | Blood Bank, Sadar Hospital | Non BCSU | Public | 51 | 42 |
| **Saharsa** | District Blood Bank | Non BCSU | Public | 1640 | 52 |
| **Samastipur** | Sadar Hospital, Blood Bank | Non BCSU | Public | 995 | 42 |
| | I.R.C.S.Samastipur | Non BCSU | NGO/Trust/Charitable | 622 | 31 |
| **Saran** | M/S Blood Bank | Non BCSU | Public | 1028 | 42 |
| **Sheikhpura** | Sadar Hospital, Blood Bank | Non BCSU | Public | 15 | 27 |
| **Sitamarhi** | District Blood Bank | Non BCSU | Public | 1361 | 43 |
| **Siwan** | Blood Bank Sadar Hospital | Non BCSU | Public | 3661 | 38 |
| | Blood Bank PNH Mahatma Budha Education Center | Non BCSU | NGO/Trust/Charitable | 936 | 50 |
| **Vaishali** | Sadar Hospital, Blood Bank, Sadar Hospital, Hajipur | Non BCSU | Public | 324 | 44 |
| **West Champaran** | Blood Bank | Non BCSU | NGO/Trust/Charitable | 1546 | 53 |

## 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** | | | | | | | | |
| **A1** | **Basic Information** | | | | | | | |
| **1** | Name of the Blood Bank (as mentioned in the licence) | | | | | | | |
| **2** | Address 1 (Institution name) | | | | | | | |
| **3** | Address 2 (Door number & Street name – if applicable) | | | | | | | |
| **4** | Address 3 (Important land mark - if applicable) | | | | | | | |
| **5** | City/Town | | | | | | | |
| **6** | District | | | | | | | |
| **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*) | | |
| **A2** | **License Information** | | |
| **1.** | **BB License Number**<br>*(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 | |
| **A3** | **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) | | |
| **A4.** | **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**

| | | **Blood Group (Tick as applicable)** | | **Rh Type** (Tick as applicable**)** |
|---|---|---|---|---|
| C1. | Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed? | 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 you be willing to participate in future? | | | Yes | |
| | | | | No | |
| 16 | If Yes to Q15, will your blood bank be able to provide | | | Yes | |

| | | | |
|---|---|---|---|
| | financial support (about Rs. 2500 per year) | No | |
| 17 | If your answer to Q 15 is NO, when do you think you will be ready for EQAS (TTI screening) participation? | Next 6 months | |
| | | Later than 6 months | |

| **Section E**<br>**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**<br>**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 | Yes | |

| | | | |
|---|---|---|---|
| | registers as D&C act? | 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 | Yes | |

| | | | | |
|---|---|---|---|---|
| | requirements? (If your blood bank has adequate equipment in working condition to meet expected workload, please answer 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** |