

**A Report on the
“Assessment of Blood Banks in Andhra Pradesh,
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 Andhra Pradesh

According to Central Drugs Standard Control Organization (CDSCO), there were 140 blood banks in the state in 2015. The assessment exercise identified 126 functional blood banks across the state excluding one military blood bank. Of the 126 blood banks, 62 (49.2%) were supported by National AIDS Control Organization, Ministry of Health and Family Welfare, Government of India and the remaining 64 (50.8%) were Non-NACO blood banks.

The highest number of blood banks was in Guntur (18) followed by Krishna (16), Vishakhapatnam (14), West Godavari (14), East Godavari (13) and Chittoor (11). There are 13 districts in the state Andhra Pradesh. Around 60% (75) of all the blood banks (n=126) in the state were in 5 districts that are, Guntur (14.3%), Krishna (12.7%), Vishakhapatnam (11.1%), West Godavari (11.1%), East Godavari (10.3%), and Chittoor (8.7)

Considering the number of blood banks per one million population, districts such as, East Godavari(2.5), Vizianagaram (2.1), Y.S.R (2.1), Nellore (2.0), Kurnool (2.0), Prakasam(1.8), Anantapuram (1.5), and Srikakulam(1.1) recorded less than the State average of 2.6 blood banks per 1,000, 000 (one million) population.

In this assessment, 118 blood banks (60 NACO supported-50.8% and 58 Non-NACO-49.2%) that submitted the assessment forms in complete were included in the analysis.

Description of blood banks

- Around 55% (65) of the blood banks in the state had component separation facility.
- The not-for-profit sector owned 52.5% followed by public 29.7% and 17.8% of private sector blood banks.
- The majority (34; 56.7%) of NACO supported blood banks were owned by the public sector and the remaining (26; 43.3%) were owned by non-profit/not-for-profit sector such as NGOs, charitable trusts, societies, foundations etc.
- The majority of the blood banks (76; 64.4%) were attached to hospitals and the remaining (42; 35.6%) were standalone blood banks.
- The majority of the blood banks (86; 72.9%) had a valid and current license and the remaining (32; 27.1%) had applied for renewal. Around (34; 56.7%) of NACO supported and (52; 89.7%) of Non-NACO blood banks had a valid and active license.

Annual Collection and Voluntary Blood Donation

- During January to December 2015, the annual blood collection from all the blood banks that reported was 4,80,033 of which 69.9% (3,35,376) units were through voluntary blood donations and the remaining were from replacement donations.
- The average annual collection of blood units of all the blood banks in the state was 4,211 units. The average annual collection of NACO supported blood banks was found to be higher than (4,743 units) the Non-NACO blood banks (3,640 units).
- The blood banks with component separation units recorded a higher average annual collection of 6,070 units compared to blood banks without component separation units which was 1,993.
- The NACO supported Blood banks collected 58.3% (279,819 units) of the total collection, of which 76.5% (213,977) units were through voluntary blood donation. The Non-NACO blood banks collected 41.7% (200,214) units of which 60.6% (121,399) units were through voluntary blood donation.

Transfusion Transmitted Infections

- HIV seroreactivity among blood donors was found to be 0.18%, Hepatitis-C 0.23%, Hepatitis-B 1.39%, Syphilis 0.07% and Malaria 0.05%. However, there is a huge variation between districts.

Component Separation

- Around 78% of blood units collected by blood banks with component separation facilities were used for component separation in Andhra Pradesh.
- The percentage component separation was higher (89.4%) in Non-NACO blood banks compared to NACO supported blood banks (70.5%).

Quality Management Systems

- 91.5% of the blood banks reported that they adhered to the NBTC guidelines.
- Availability of document control system was reported by less than 59.3% of the blood banks in the state. Around 60.0% of NACO supported blood banks and 58.6% of Non-NACO blood banks reported they had a document control system.
- More than 95% of blood banks reported to have standard operating procedures (SOPs) for technical processes.
- Practice of internal quality control (IQC) for Immunohematology was reported by 79% of the blood banks and IQC for TTIs was reported by 56.8% of all the blood banks, with slight variation between NACO supported and Non-NACO blood banks.
- Around 86% of the blood banks reported carrying out quality control for kits, reagents and blood bags.

- Only 6.8% the blood banks in state have enrolled themselves in External Quality Control Systems (EQAS) by recognized providers for both immunohematology and TTIs.
- None of the blood banks that participated in the assessment were accredited by National Accreditation Board for Hospitals & Healthcare Providers (NABH).
- Designated and trained Quality Managers and Trained Technical managers were available only in 31.4% and 39% of the blood banks respectively.
- More than 85% of the blood banks reported that they had a regular equipment maintenance programme and around 89% reported that they calibrate the equipment as per requirement.

The current status of blood banks based on the assessment

- The mean assessment score of blood banks in the state was 61.54 (SD: 7.97). The Non- NACO supported blood banks scored slightly higher (61.74; SD: 8.15) than the NACO blood banks.
- Around 57% of all the blood banks under NACO supported were in public sector and present across sub-divisional and divisional/district hospitals catering all segments of the population including rural areas. Whereas, the (62.1%) of the Non-NACO blood banks were in not-for-profit sector.
- At the state level, the majority of blood banks (85.6%) scored between 35 and 70 and 13.6% scored above 70. One blood bank scored less than or equal to 35.
- Around 88% of NACO supported and 82.8% of Non-NACO blood banks scored between 35 and 70. Around, 10% of NACO supported blood banks and 17.2% of Non-NACO blood banks scored more than 70%.
- Among the 13 districts, Vizianagram (66.1) scored the highest and Srikakulam scored the least with the mean score of (52.3). Seven districts scored above the state average.
- Of the 16 blood banks that scored more than 70 score, 10 (62.5%) were Non-NACO blood banks. The majority of blood banks that scored above 70 were from East Godavari (4), Krishna (4), followed by Chittoor (3).
- The mean score of blood banks without component facilities was found to be higher (62; SD: 8.26) than the mean score of blood banks with component facilities (61.16; SD: 7.77)
- The mean assessment score of not-for-profit and private (NGO/Trust/Charitable) owned blood banks (61.96; SD: 8.26) and (59.33; SD: 7.66) respectively, were found to be lower than the public sector blood banks (62.11; SD: 7.63).
- However, Non- NACO supported blood banks run by not-for-profit sector had scored higher (63.11; SD: 8.32) compared to NACO blood banks NGO/Trust/Charitable blood banks.
- The mean assessment score of blood banks that collected more than 5000 blood units (63.05; SD: 9.19) was found to be higher than blood banks that collected between 3001 and 5000 (62.35; SD: 7.10) and less than 3000 blood units (61.34; SD: 7.31).

- The blood banks that reported a higher proportion of voluntary blood donation indicated higher mean assessment score.
- The mean score was found to be higher among NACO supported blood banks that were part of EQAS for Immunohematology (61.14; SD: 7.8) compared to Non-NACO blood banks. A similar situation was found among those blood banks that were part of EQAS for Transfusion-transmitted Infections (60.99; SD: 7.9) where the mean assessment for NACO supported blood banks was higher than the Non-NACO supported blood banks.

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 Andhra Pradesh

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). Currently, India has 2,760 blood banks of which 1,126 blood banks are supported by NACO, Ministry of Health and Family Welfare (MoHFW). 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 country during the reporting period – January to December 2015. In order to create a comprehensive and accurate list of functional blood banks in the country, 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 state 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, 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, interquartile range(IQR), minimum, and maximum were done for quantitative variables such as annual collection, voluntary blood donation, etc. Comparison of the means of different variables was done using an independent t-test or ANOVA, if the distribution was normal. Mann-Whitney or Kruskal-Wallis test was done if the data was not normally distributed.

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 and 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=65) and, 2. Blood banks without component separation facility (n=53). 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 140 blood banks in the state of Andhra Pradesh in 2015 (CDSCO, 2015). However, the assessment exercise identified 126 functional blood banks across the state excluding 1 military blood bank. Of the 126 blood banks, 62(49.2%) were supported by National AIDS Control Organization(NACO), Ministry of Health and Family Welfare, Government of India and the remaining 64 were Non-NACO blood banks. Of the total functional blood banks, 118 blood banks (60 NACO supported – 50.8% and 58 Non-NACO- 49.2%) which have submitted the assessment forms in complete were included in the analysis.

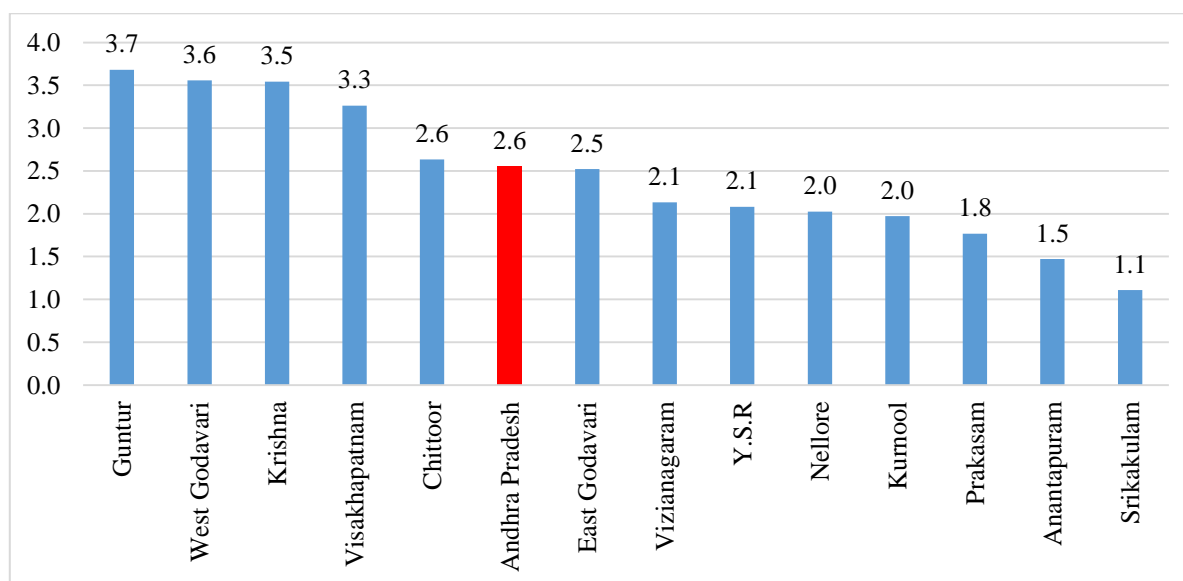
Table-3 indicates the District wise details of all the blood banks in the state, including the description of NACO supported and Non-NACO blood banks. Guntur (18) had the highest number of blood banks followed by Krishna (16), West Godavari (14), and Vishakhapatnam (14).

Table 3 - District wise description of blood banks

Districts	NACO Supported	Non-NACO	Total
Anantapur	5	1	6
Chittoor	8	3	11
East Godavari	6	7	13
Guntur	4	14	18
Krishna	7	9	16
Kurnool	4	4	8
Nellore	3	3	6
Prakasam	4	2	6
Srikakulam	1	2	3
Visakhapatnam	5	9	14
Vizianagaram	3	2	5
West Godavari	7	7	14
YSR	5	1	6
Andhra Pradesh	62	64	126

Considering the number of blood banks per one million population, districts such as, East Godavari (2.5), Vizianagaram (2.1), Y.S.R (2.1), Nellore (2.0), Kurnool (2.0), Prakasam (1.8), Anantapuram (1.5), and Srikakulam (1.1) recorded less than the State average of 2.6 blood banks per 1,000, 000 (one million) population.

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



4.1 Basic details of blood banks (n=118)

As indicated earlier, 118 blood banks (60 NACO supported and 58 Non-NACO) that submitted the assessment forms were included in the analysis.

4.1.1 Category of Blood Banks: Around 55% (65) of the blood banks in the state had component separation facility, of which, 23 (38.3%) were NACO supported blood banks. Of the 53 blood banks that were without component separation facility, 61.7% (37) were NACO supported blood banks.

Table 4 - Basic details of blood banks

Specifics	Description	NACO Supported	Non-NACO supported	Total
Type of BB	With components	23 (38.3%)	42 (72.4%)	65 (55.1%)
	Without components	37 (61.7%)	16 (27.6%)	53 (44.9%)
Ownership	NGO/Trust/Charitable	26 (43.3%)	36 (62.1%)	62 (52.5%)
	Private	-	21 (36.2%)	21 (17.8%)
	Public	34 (56.7%)	1 (1.7%)	35 (29.7%)
Licence	Valid	34 (56.7%)	52 (89.7.3%)	86 (72.9%)
	Under Renewal	26 (43.3%)	6 (10.3%)	32 (27.1%)
Attachment	Attached to Hospital	41 (68.3%)	35 (60.3%)	76 (64.4%)
	Stand alone	19 (31.7%)	23 (39.7%)	42 (35.6%)

At the District level, Srikakulam had the highest percentage of blood component separation units (3; 100%), followed by Kurnool (6, 75%), Guntur (11; 68.8%), Anantapur (4; 66.7%), Krishna (9; 60%), Visakhapatnam (8;57.1%), East Godavari (6; 50%). Prakasam district had only one blood bank that had component separation facility.

4.1.2 Ownership

The Not for Profit sector owned 52.5% of the blood banks in the state whereas the public sector owned around 30% of the blood banks followed by Private Sector which contributed only 17.8 % of the total Blood banks The majority (34; 57%) of NACO supported blood banks were owned by the public sector and the remaining 43% (26) were owned by non-profit/not-for-profit sector such as NGOs, charitable trusts, societies, foundations etc. The not-for-profit sector had a higher proportion (56.9%) of blood component separation facility than the private (24.6%) and public sector (18.4%). Among the NACO supported blood banks, the public sector had a higher (52.1 %) proportion of component separation facilities compared to the public sector (47.8%).

Around 45% of all the not-for-profit blood banks (n=62) were clustered in three districts which are Guntur (16.1%), West Godavari (16.1%) and Krishna (12.9%). Around 48% of all the public owned blood banks were clustered in four districts which are Chittoor (14.3%), East Godavari (11.4%), Vishakhapatnam (11.4%) and YSR (11.4%). Similarly, 61.9% of all the private owned blood banks were in three districts which are Guntur (23.8%), Krishna (19%) and Kurnool (19%) (Refer Table -5).

Table 5 - District wise list of blood banks by Ownership

Districts	Public	%	Not-for-profit	%	Private	%	Total
Anantapur	3	50	3	50.0	-	-	6
Chittoor	5	45.5	6	54.5	-	-	11
East Godavari	4	33.3	6	50.0	2	16.7	12
Guntur	1	6.3	10	62.5	5	31.3	16
Krishna	3	20	8	53.3	4	26.7	15
Kurnool	3	37.5	1	12.5	4	50	8
Nellore	2	40	3	60.0	-	-	5
Prakasam	3	50	3	50.0	-	-	6
Srikakulam	1	33.3	2	66.7	-	-	3
Visakhapatnam	4	28.6	6	42.9	4	28.6	14
Vizianagaram	1	20	2	40.0	2	40	5
West Godavari	1	9.1	10	90.9	-	-	11
YSR	4	66.7	2	33.3	-	-	6
Andhra Pradesh	35	29.7	62	52.5	21	17.8	118

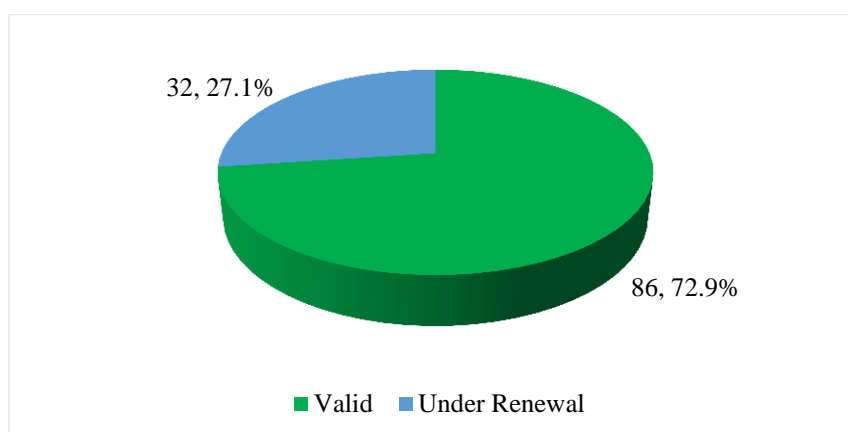
4.1.3 Organizational Attachment: The majority of the blood banks (76; 64.4%) were attached to hospitals, and the remaining (42; 35.6%) were standalone blood banks.

The majority of the NACO supported blood banks (41; 68.3%) were attached to hospitals and only (19; 31.7 %) were standalone blood banks. Though 60.3% (35) of the Non-NACO supported blood banks were attached to hospitals, a significant number (23; 39.7%) of Non-NACO blood banks were standalone. Further analysis indicated that around 97% (34) of the blood banks in the public sector, 35.5% (22) of the blood banks in the not-for-profit sector, and 95.2% (20) of the blood banks in the private sector were attached to hospitals. In the not-for-profit sector, 64.5% (40) of the blood banks are 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 (86; 72.9%) had a valid and current license, and the remaining (32; 27.1%) had applied for renewal. Around 57% (34) of NACO supported and 89.7 % (52) of Non-NACO blood banks had a valid and active license. Similarly, 95.2% (20) of the private blood banks, 74.2% (46) of the not-for-profit blood banks, and around 57% (20) of the public blood banks had a valid and active license.

Figure 2 - License status (n=118)



The majority of those blood banks (22; 68.8%) which have reported as “deemed renewal” had their last inspection by licencing authority during the last one year; one blood bank had its inspection between the last 1 to 2 years, three (9.4%) had between 2 to 3 years, one had its inspection between 3 to 4 years and three (9.4 %) had their inspection in more than 4 years.

4.2 Annual Blood Collection and Voluntary Blood Donation

According to WHO, it is estimated that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2016b), which means that Andhra Pradesh state with the population of 493,86,799 state currently needs 493,867 units of blood.

4.2.1 Annual Collection of Blood: During January 2015 to December 2015, the annual blood collection from all the blood banks that reported was 4,80,033 of which 69.9% (335,376) units were through voluntary blood donations and the remaining were from replacement donations.

Figure 3 - Annual Collection and Voluntary Donation

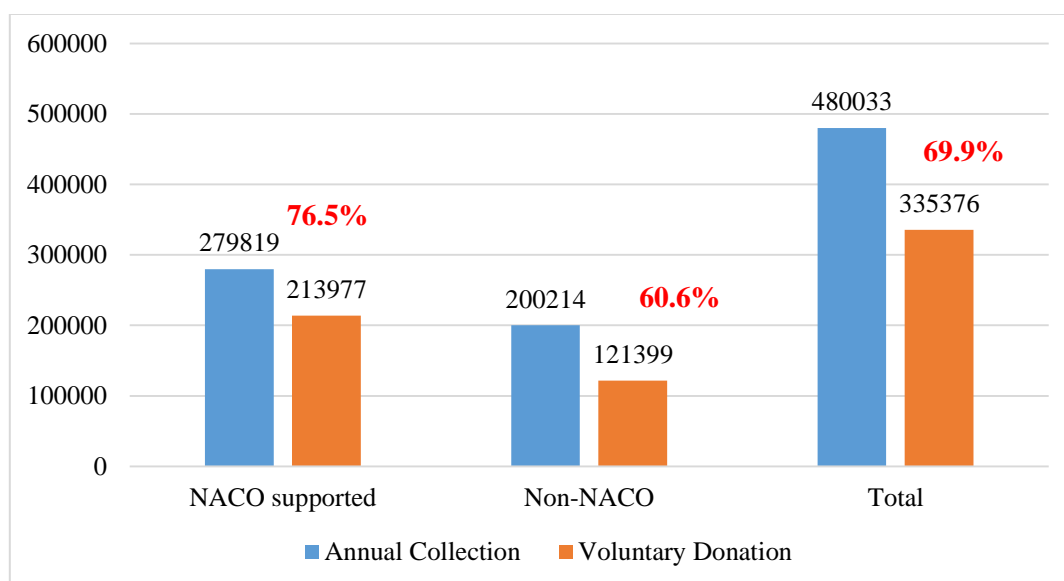
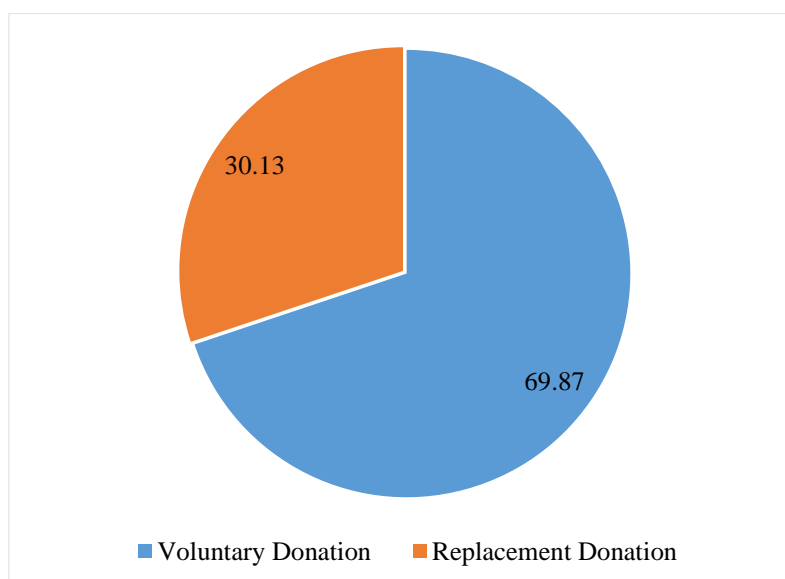


Figure 4 - Type of blood donation (Voluntary vs. Replacement Donation %)



The average annual collection of blood units of all the blood banks in the state was 4,211 units. The average annual collection of NACO supported blood banks was found to be higher(4,743 units) than (the Non-NACO blood banks (3,640 units).

Table 6 - Average Annual collection

District	NACO supported	Non-NACO	All BBs
Anantapur	4116	6401	4497
Chittoor	4673	3439	4336
East Godavari	6439	4029	5343
Guntur	4431	3575	3803
Krishna	5187	3248	4218
Kurnool	5861	3531	4696
Nellore	8634	4696	7059
Prakasam	1717	3135	2189
Srikakulam	3950	1208	2122
Visakhapatnam	6003	4777	5215
Vizianagaram	3287	1270	2480
West Godavari	2103	3806	3125
YSR	4147	730	3578
Andhra Pradesh	4743	3640	4211

Similarly, the blood banks with component separation units recorded a average higher collection of 6,070 units compared to blood banks without blood component separation units which was 1,993 units. However, the variation in the collection was found to be very high across and within districts.

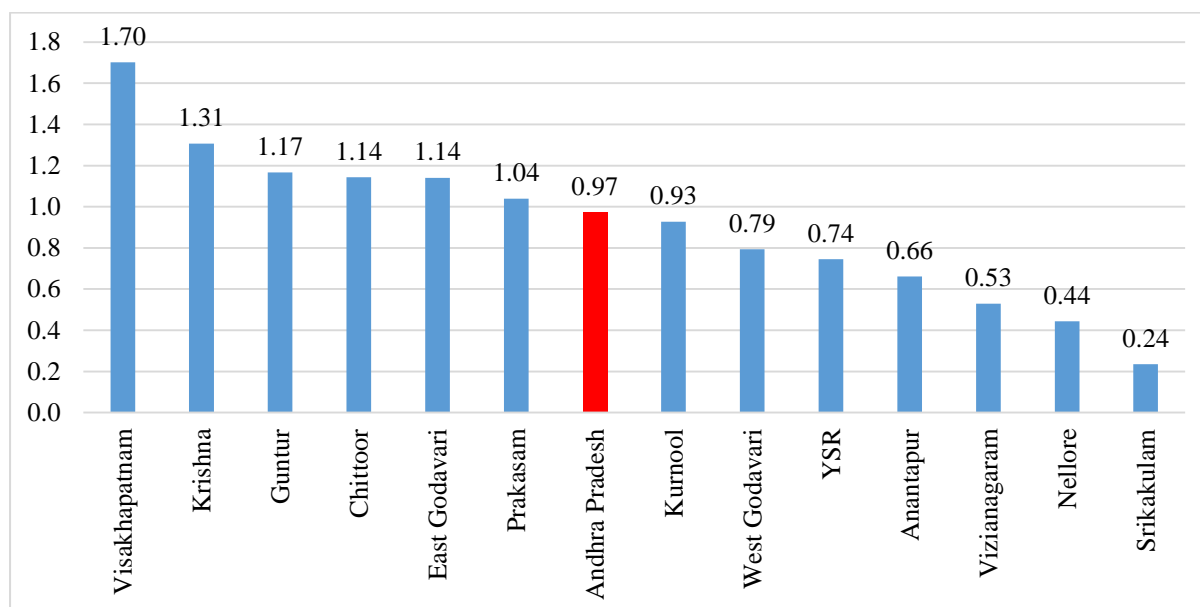
The NACO supported blood banks collected 58.3% (279,819 units) of the total collection, of which 76.5% (213,977) units were through voluntary blood donation. The Non-NACO blood banks collected 41.7% (200,214) units of which 60.6% (121,399) units were through voluntary blood donation. Blood banks with component separation facility collected the majority (78.4%) of blood units (376,355) and the remaining (103,678) were collected by blood banks without the component facility. Similarly, blood banks owned by not-for-profit sector collected 63.1% (302,985) of the total collection followed by the public sector 27.6% (132,596) and private sector blood banks 9.3% (44,452).

Table-7 indicates the district-wise details of the total annual collection, voluntary and replacement donation in the Andhra Pradesh. Blood banks reported a varying proportion of VNRBD ranging from 54.8 to 95.9%.

Table 7 - Annual blood collection and percentage of VBD

Districts	Total Voluntary donation	Replacement donation	Annual Collection	VBD %
Anantapur	14790	12192	26982	54.8
Chittoor	44705	2992	47697	93.7
East Godavari	45401	13376	58777	77.2
Guntur	42065	14981	57046	73.7
Krishna	46174	12874	59048	78.2
Kurnool	18285	19282	37567	48.7
Nellore	33838	1457	35295	95.9
Prakasam	8064	5072	13136	61.4
Srikakulam	2750	3616	6366	43.2
Visakhapatnam	43207	29798	73005	59.2
Vizianagaram	9094	3307	12401	73.3
West Godavari	14642	16605	31247	46.9
YSR	12361	9105	21466	57.6
Andhra Pradesh	335,376	144,657	480,033	69.9

Figure 5 - Annual collection per 100 population – District wise



The annual collection of blood units per 100 individuals was found to be 0.97 % in the state, which is almost 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. Kurnool (0.93), West Godavari (0.79), YSR (0.74), Anantapur (0.66), Vizianagaram (0.53), Nellore (0.44), and Srikakulam (0.24). Six districts in the state recorded an annual collection of more than 1 unit per 100 populations. (Refer Fig-5).

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

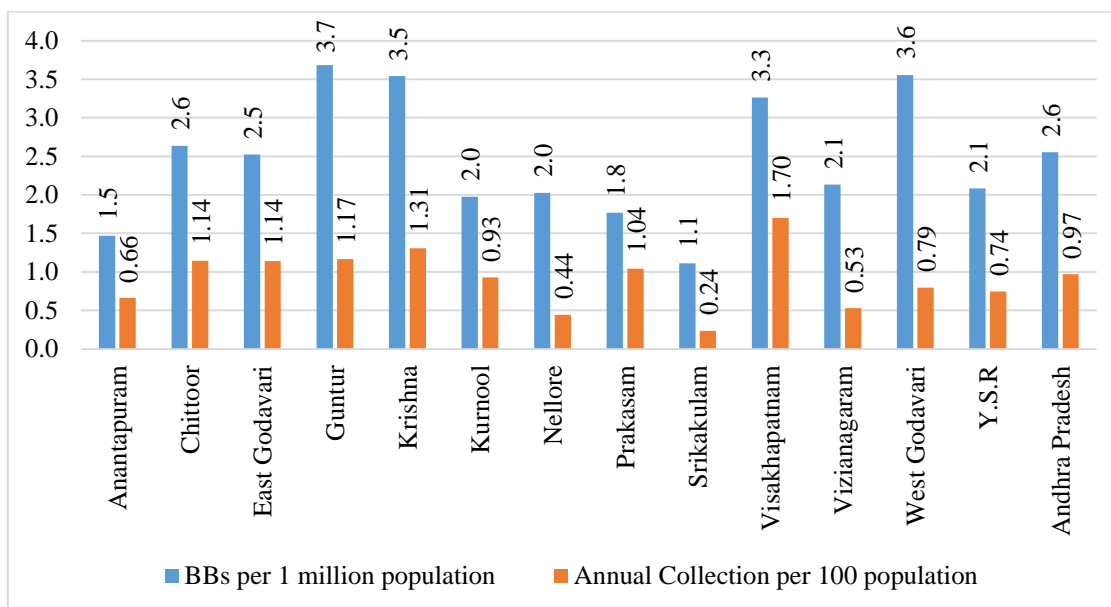
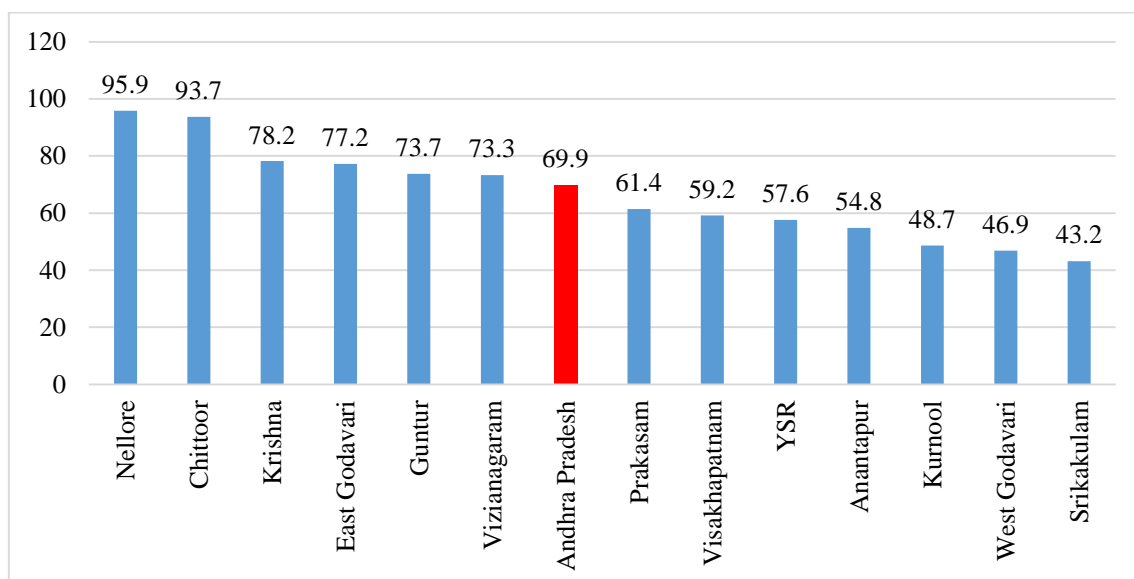


Figure-6 illustrates the district wise comparative information of annual collection per 100 population and number of blood banks per one million populations. This indicates that the state had 2.6 blood banks per million population that collected 0.97 units per 100 population at the ratio of 2.6 BB: 0.97 blood unit.

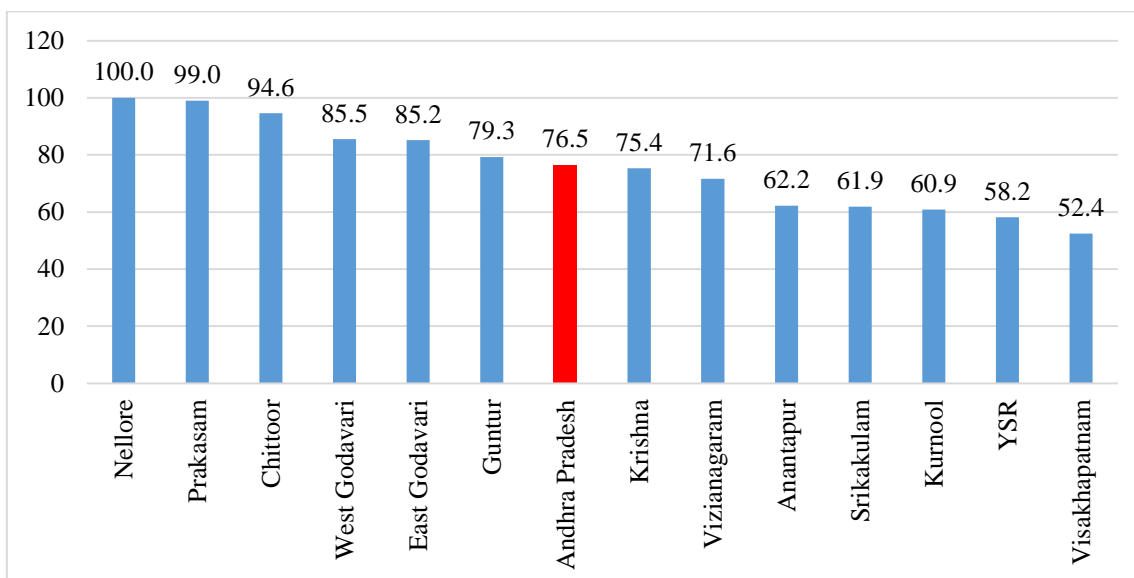
4.2.2 Voluntary blood donation: As depicted in Figure-7, six districts have recorded more than the state average of 69.9%. Districts such as Nellore, Chittoor, Krishna, East Godavari, Guntur and Vizianagaram reported more than 69.9% voluntary blood donation. Remaining Seven districts reported less than the state average of voluntary blood donation during January to December 2015.

Figure 7 - Percentage of voluntary blood donation by district (Overall)



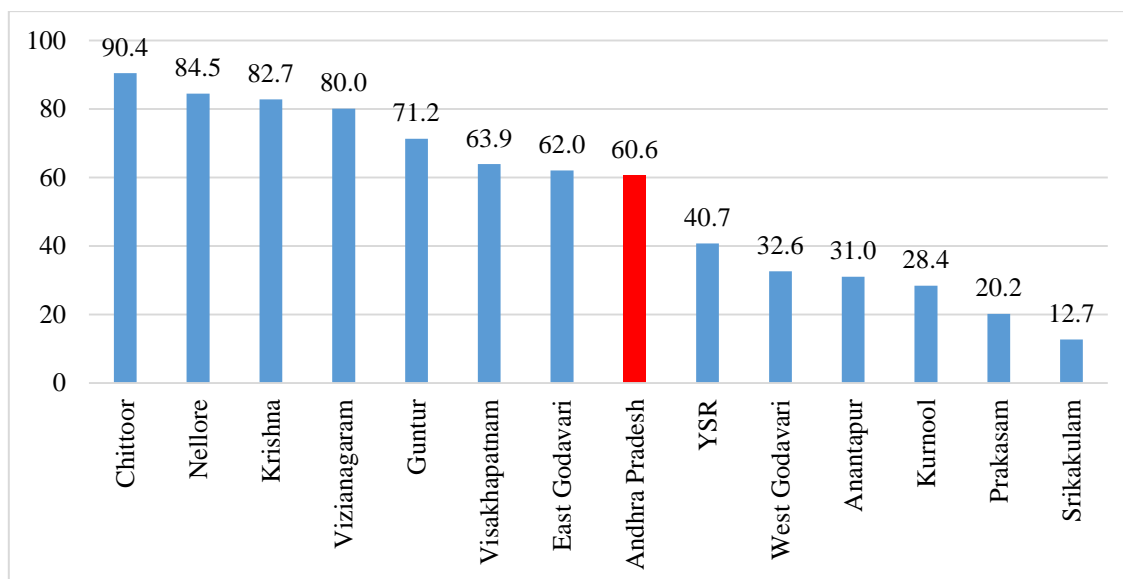
In terms of NACO supported blood banks, six districts have recorded a higher proportion of voluntary donation which is above the state average of 76.5%. Nellore, Prakasam and Chittoor reported more than 90% of Voluntary Blood donation. Only two districts YSR and Visakhapatnam reported less than 60% of voluntary donation during January to December 2015.

Figure 8 - Percentage of voluntary blood donation by district (NACO supported)



Among Non-NACO blood banks, seven districts such as Chittoor, Nellore, Krishna, Vizianagaram, Guntur, Visakhapatnam and East Godavari reported more than the state average of 60.6%. Remaining six districts recorded less than the state average.

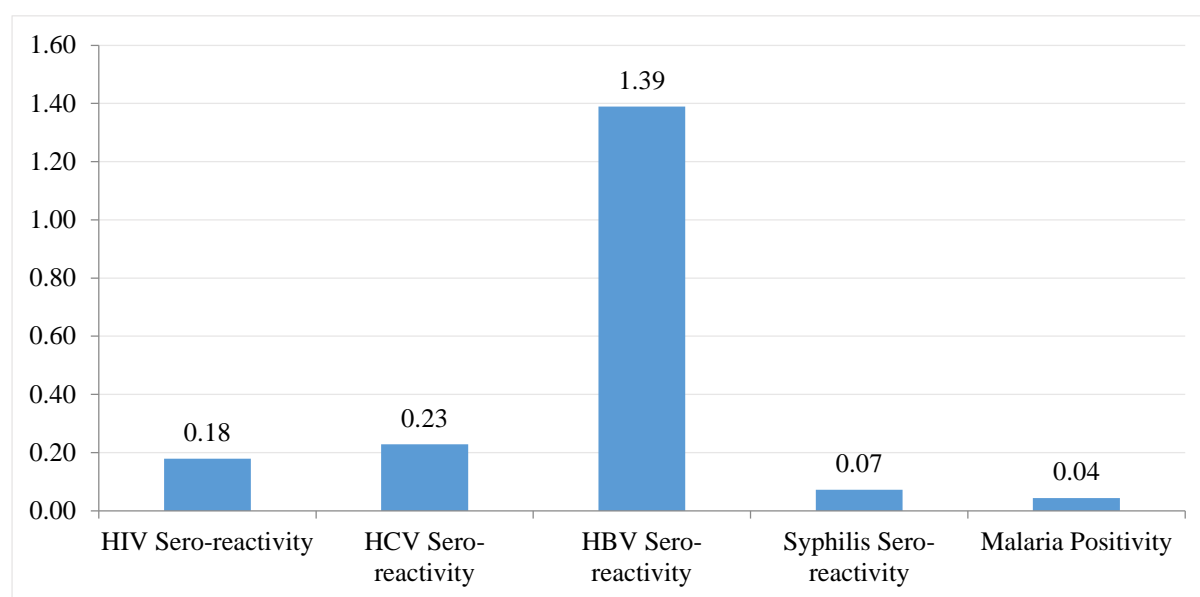
Figure 9 - Percentage of voluntary blood donation by district (Non-NACO)



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 seroreactivity percentage of TTIs has come down significantly over the years.

Figure 10 - Transfusion Transmitted Infections (%) – Jan-Dec 2015



The seroreactivity of TTI among blood donors in the year 2015 is depicted in Fig-10. HIV seroreactivity was found to be 0.18%, Hepatitis-C was 0.23%, Hepatitis-B 1.39%, Syphilis 0.07% and Malaria 0.04%. However, there is a huge variation between districts.

Table 8 depicts that all the Transfusion Transmitted Infection rates were Higher in NACO supported Blood Banks

Table 8 - Transfusion Transmitted Infections (%)

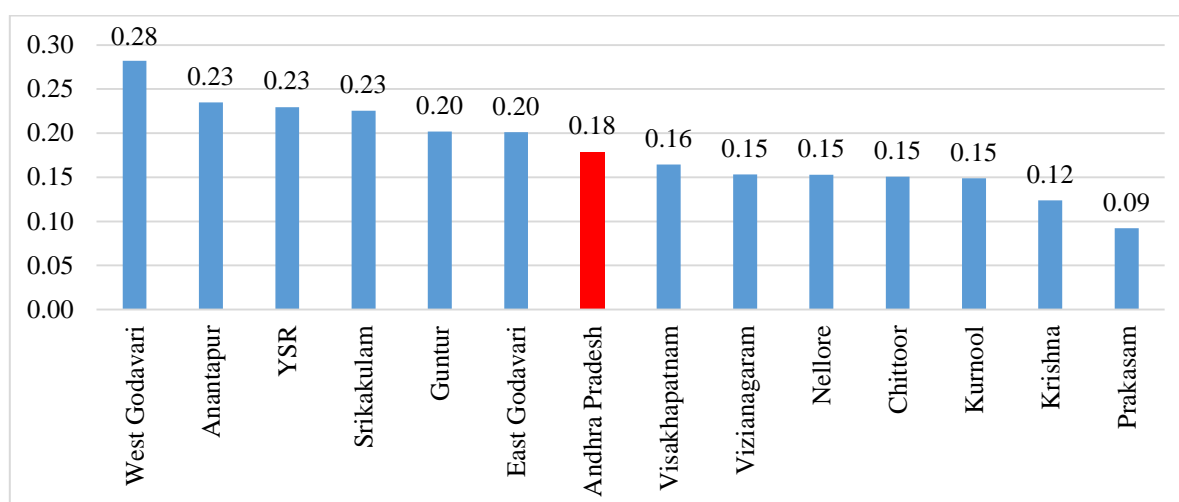
Category of BB	Transfusion Transmitted Infections %				
	HIV	HCV	HBV	Syphilis	Malaria
NACO Supported BBs	0.19	0.26	1.52	0.11	0.06
Non-NACO	0.16	0.19	1.21	0.03	0.01
Overall	0.18	0.23	1.39	0.07	0.04

4.3.1 Transfusion Transmitted Infections by Category of blood banks: The blood banks with component facility indicated higher reactivity of HIV (0.19%) and HCV (0.24%). HBV (1.45%), Syphilis (0.17) and Malaria (0.06%) were found to be higher in blood banks without component 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	0.19	0.24	1.37	0.04	0.04
BBs without component facility	0.14	0.20	1.45	0.17	0.06
Overall	0.18	0.23	1.39	0.07	0.04

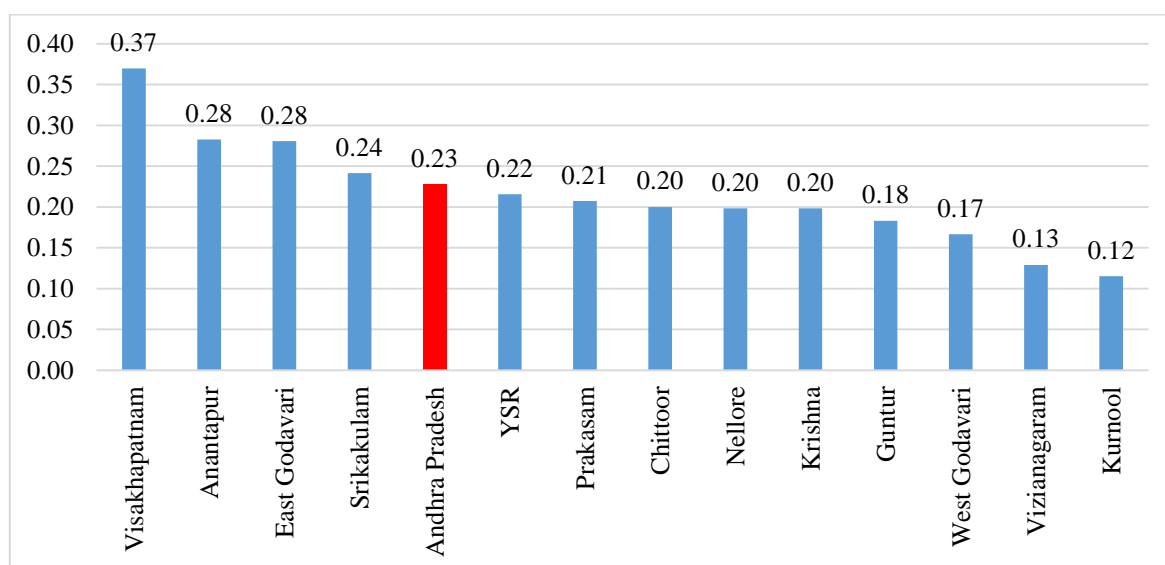
Figure 11 - HIV seroreactivity – By district (%)



The seven districts indicated lower HIV reactivity than the state HIV sero-reactivity level of 0.18%. However, West Godavari (0.28%), Anantapur (0.23%), YSR (0.23%), Srikakulam (0.23%), Guntur (0.20%), East Godavari (0.20%) recorded higher sero-reactivity than the state HIV Sero-reactivity level. Districts like Visakhapatnam (0.16%), Vizianagaram (0.15%), Nellore (0.15%), Chittoor (0.15%), Kurnool (0.15%), Krishna (0.12%) and Prakasam (0.09%) recorded less than the state sero-reactivity level.

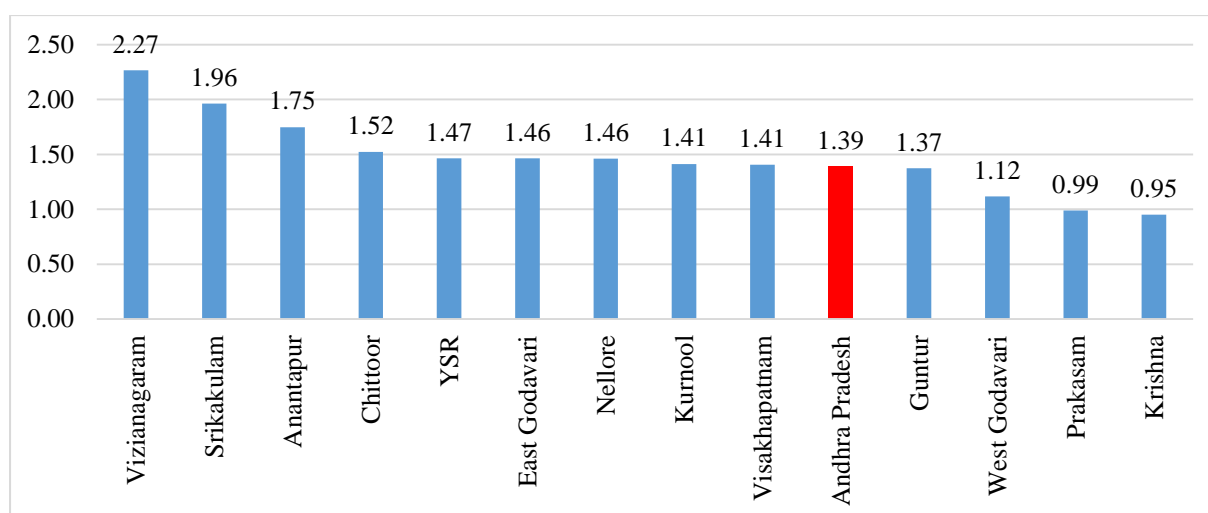
While considering Hepatitis C infection districts like Visakhapatnam (0.37%), Anantapur (0.28%), East Godavari (0.28%) and Srikakulam (0.24%) recorded a seroreactivity level higher than the state average of 0.23%.

Figure 12 - HCV seroreactivity – By district (%)



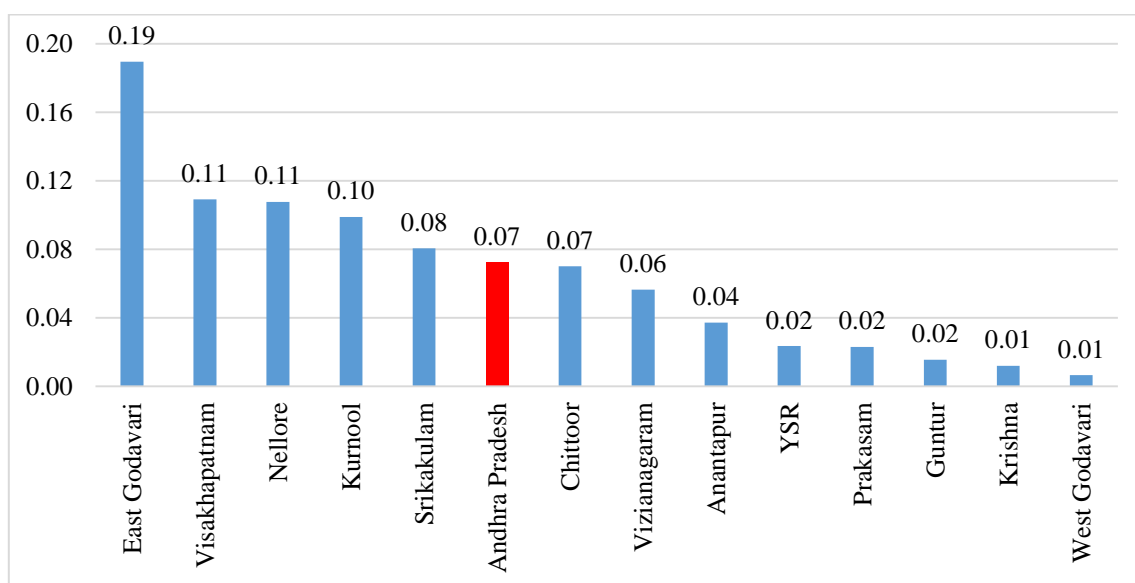
Hepatitis B was found to be higher than the state average of 1.39% in nine districts like Vizianagaram (2.27%), Srikakulam (1.96%), Anantapur (1.75%), Chittoor (1.52%), YSR (1.47%), East Godavari (1.46%), Nellore (1.46%), Kurnool (1.41%) and Visakhapatnam (1.41%).

Figure 13 - HBV seroreactivity – By district (%)



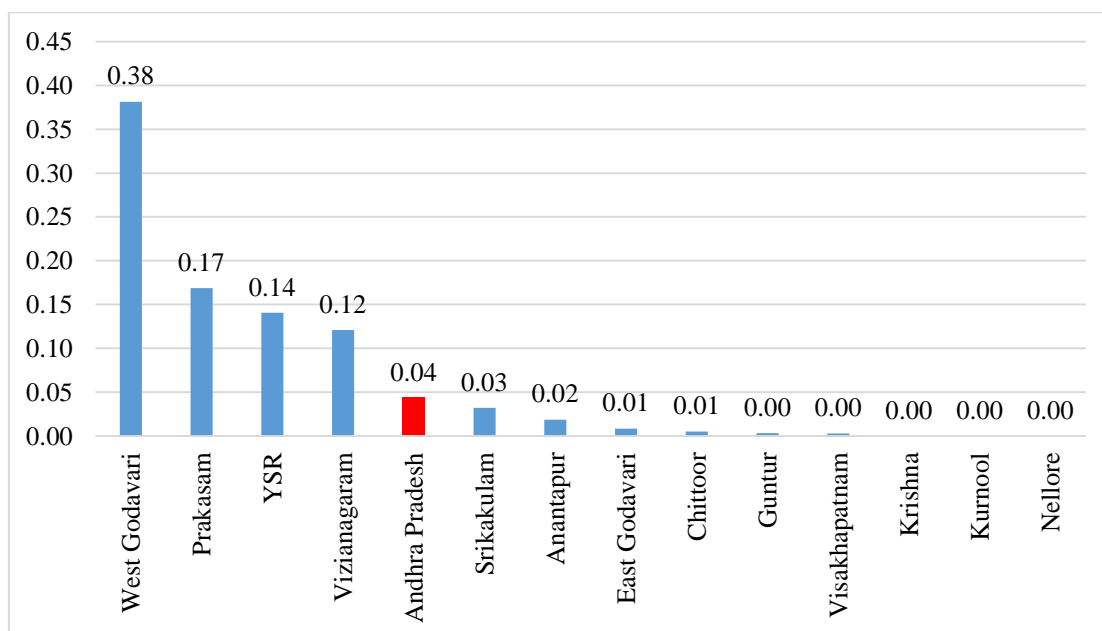
Syphilis seroreactivity was found to be higher than the state average of 0.07% in districts like East Godavari (0.19%), Visakhapatnam (0.11%), Nellore (0.11%), Kurnool (0.10%), Srikakulam (0.8%). Eight districts recorded less than the state average.

Figure 14 - Syphilis seroreactivity – By district (%)



The majority of the districts indicated a lower positivity of 0.04% whereas districts like Solapur and Gadchiroli recorded a higher positivity than the state average. Districts such as West Godavari, Prakasam, YSR and Vizianagaram recorded higher positivity than the state average.

Figure 15 - Malaria Positivity – By district (%)



4.4 Component Separation

As depicted in Figure -16, around 79% of blood units collected by blood banks with component separation facilities, were used for component separation in state. The percentage of component separation was higher (89.4%) in Non-NACO blood banks compared to NACO supported blood banks (70.5%).

Figure 16 - Total blood collection and component separation

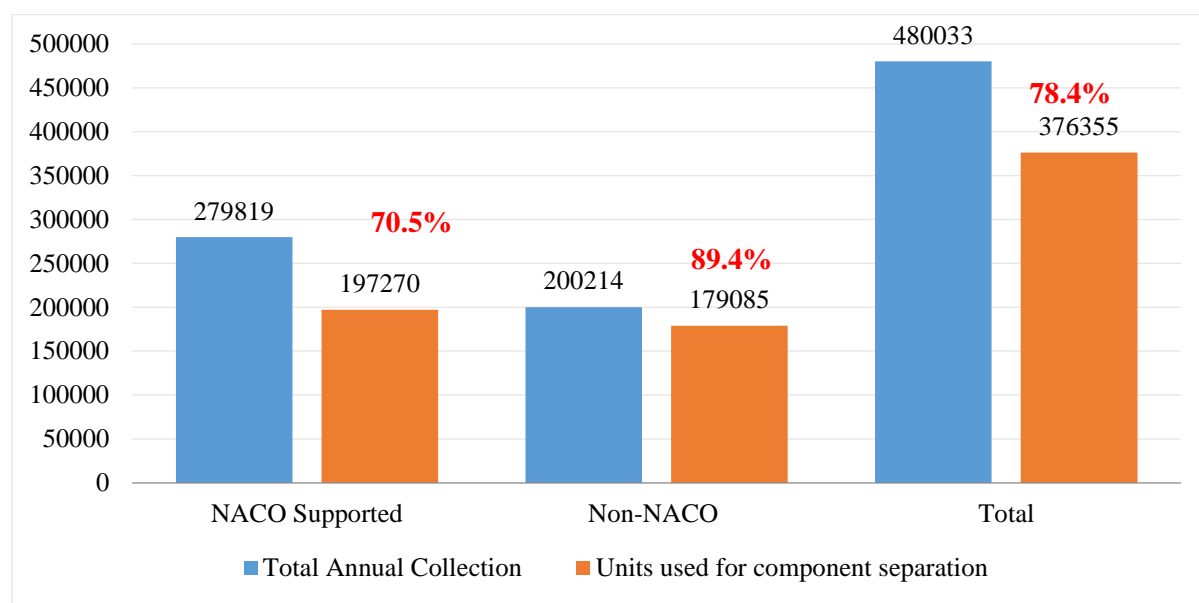
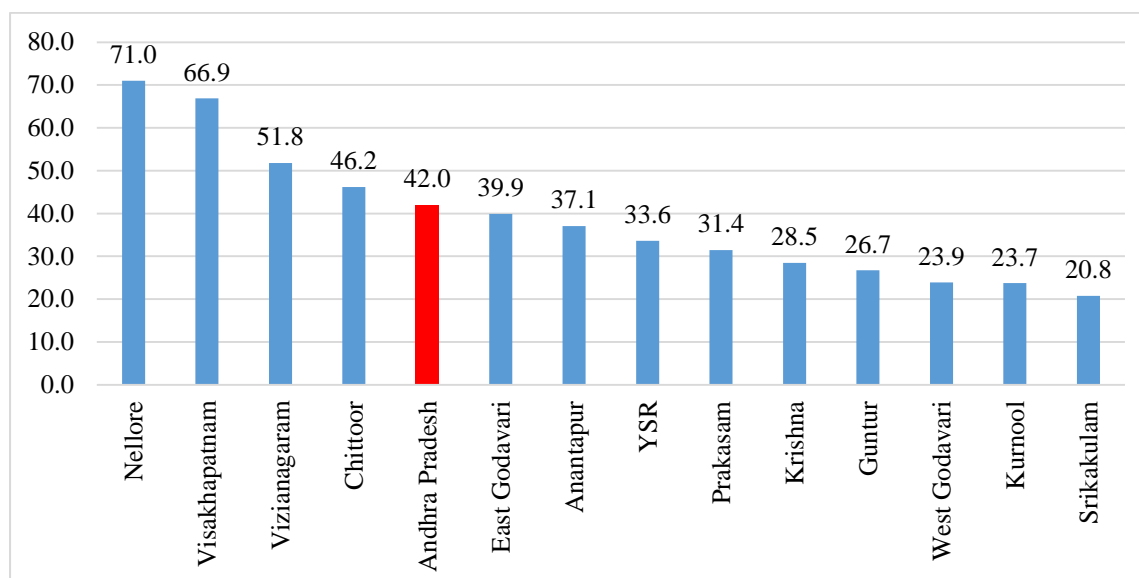


Table 10 - Total annual collection by BCSUs and Percentage of component separation

Districts	Total Annual Collection	Total annual collection by BCSUs	Percentage of component separation
Anantapur	26982	23445	37.1
Chittoor	47697	39287	46.2
East Godavari	58777	40430	39.9
Guntur	57046	48027	26.7
Krishna	59048	49737	28.5
Kurnool	37567	29923	23.7
Nellore	35295	32270	71.0
Prakasam	13136	4500	31.4
Srikakulam	6366	6366	20.8
Visakhapatnam	73005	67391	66.9
Vizianagaram	12401	3937	51.8
West Godavari	31247	22448	23.9
YSR	21466	8594	33.6
Andhra Pradesh	480,033	376,355	42.0

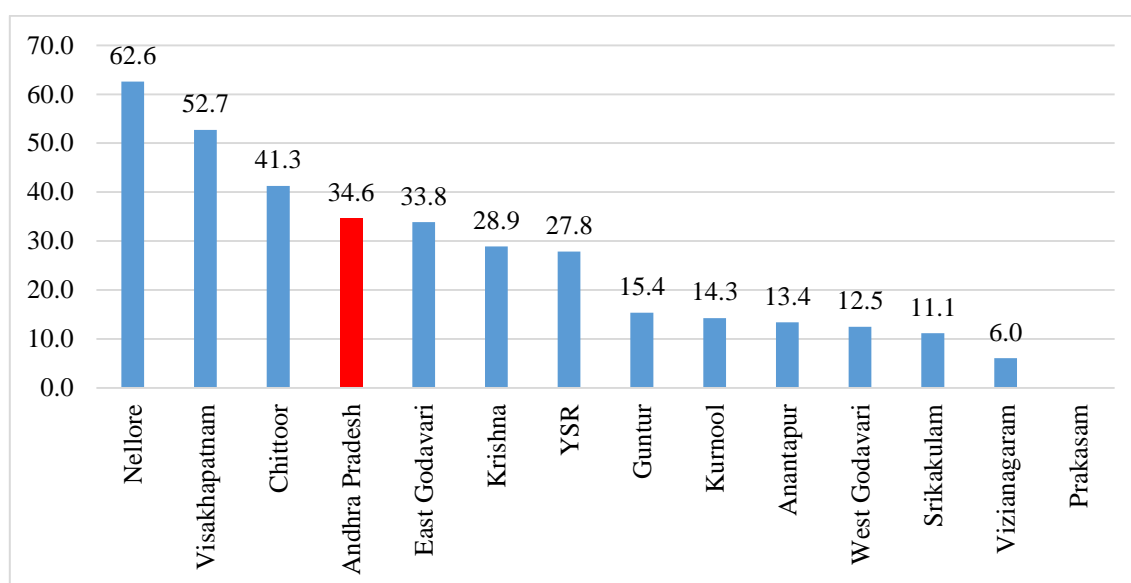
Table 10 depicts that four districts which are Chittoor (46.2%), Vizianagaram(51.8%), Vishakapatnam (66.9%), Nellore(71%) had percentage of component separation more than the state average of 42%.

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 three districts Nellore, Visakhapatnam and Chittoor recording more than State average of 34.6%.

Figure 18 - Percentage of component separation – By district (NACO supported)



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 (91.5%) reported that they adhered to the NBTC guidelines. Availability of document control system was reported by 59.3% of the blood banks in the state. Around 60% of NACO supported blood banks and 58.6% of Non-NACO blood banks reported they had a document control system. In terms of Standard Operating Procedures (SOPs) for technical processes, more than 95% reported that they had SOPs.

Table 11 - Availability of quality parameters in Blood Banks

Quality Parameters	NACO/NON-NACO		All Blood Banks
	NACO supported	Non-NACO	
Compliance with NBTC guidelines	55	53	108
	91.7%	91.4%	91.5%
Availability of Documental Control System (DCS)	36	34	70
	60.0%	58.6%	59.3%
SOPs for Technical Processes	56	58	114
	93.3%	100.0%	96.6%
IQC for IH	45	48	93
	75.0%	82.8%	78.8%
IQC for TTI	34	33	67
	56.7%	56.9%	56.8%
QC for kits, reagents and blood bags	48	54	102
	80.0%	93.1%	86.4%
EQAS for IH	1	7	8

	1.7%	12.1%	6.8%
EQAS for TTI	3	5	8
	5.0%	8.6%	6.8%
NABH accreditation for blood banks	-	-	-
	-	-	-
Availability of designated and trained Quality Manager	10	27	37
	16.7%	46.6%	31.4%
Availability of designated and trained Technical Manager	11	35	46
	18.3%	60.3%	39.0%
Programme for regular Equipment maintenance	49	56	105
	81.7%	96.6%	89.0%
Equipment calibration as per regulatory requirement	57	57	114
	95.0%	98.3%	96.6%

At the state level, Internal Quality Control (IQC) for Immunohematology was reported by 79% of the blood banks and IQC for TTIs was reported by 56.8% of the blood banks, with slight variation between NACO supported and Non-NACO blood banks. Around 86% 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 6.8% for immunohematology and 6.8% for TTIs. No blood banks that were accredited by National Accreditation Board for Hospital and Healthcare provider.

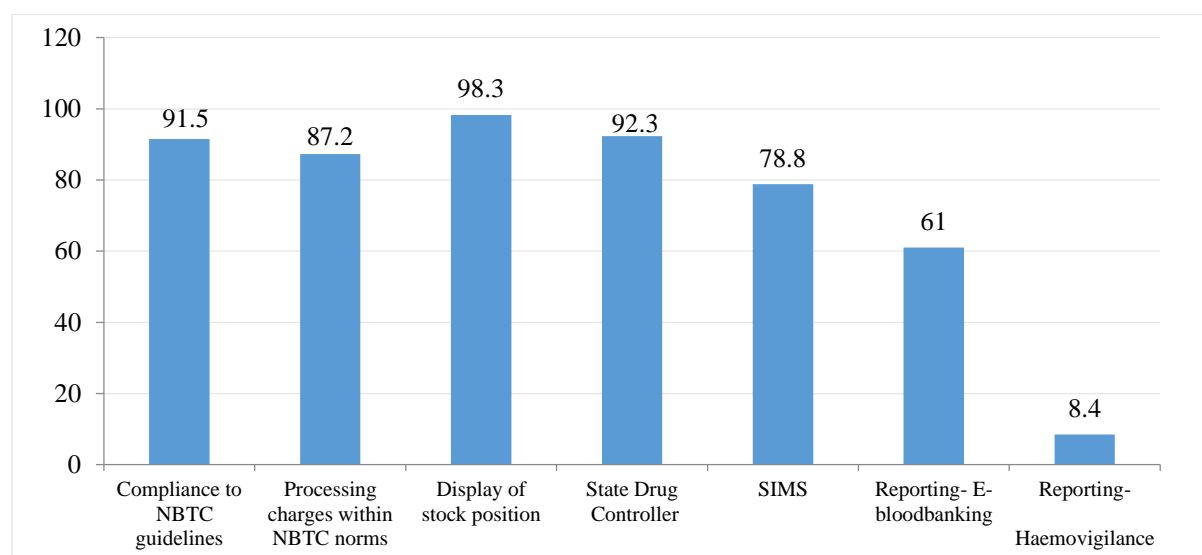
Designated trained Quality Manager and Technical manager were available only in 31.4% and 39% of the blood banks respectively. More than 85% of the blood banks reported that they had a regular equipment maintenance programme and around 89% reported that they calibrate the equipment as per requirement.

4.6. Reporting and Documentation

4.6.1. Compliance to NBTC guidelines

Majority of the blood banks (98.3%) reported that they were displaying stock in position in their Blood bank Premises. 87.2% of blood bank reported that they were recovering processing charges within NBTC/SBTC norms

Figure 19 - Reporting and Documentation



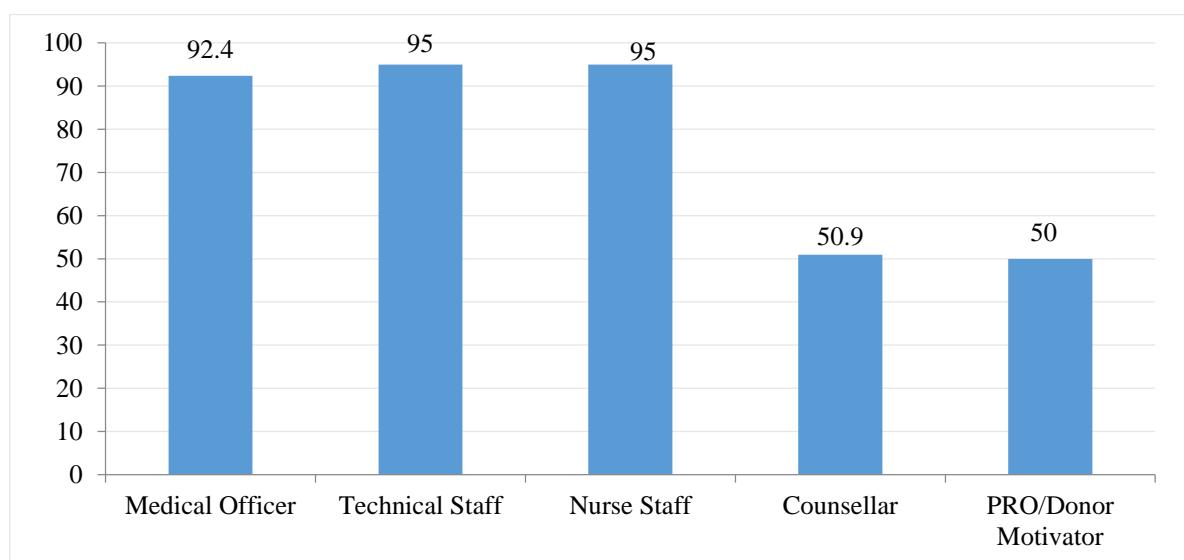
Reporting requirements: Around, 92% of Blood Banks submitted regular reports to state drug controller. 78.8% of blood banks regularly reported in national strategic information management system (SIMS). However, only 61% regularly reported in E-blood banking either national or state e-blood banking. Only 8.4% of blood banks were members of Hemovigilance Program.

4.7. Human Resources

4.7.1. Availability of staff

The mean number of employees in the blood bank was 12.9 (SD 7.3). It ranges from 2 employees to 35 employees. Around 92% of blood banks reported to have at least one Medical Officer, 95% had a technical staff, 95% had a nursing staff, 51% had counsellor and 50% had donor motivator/PRO.

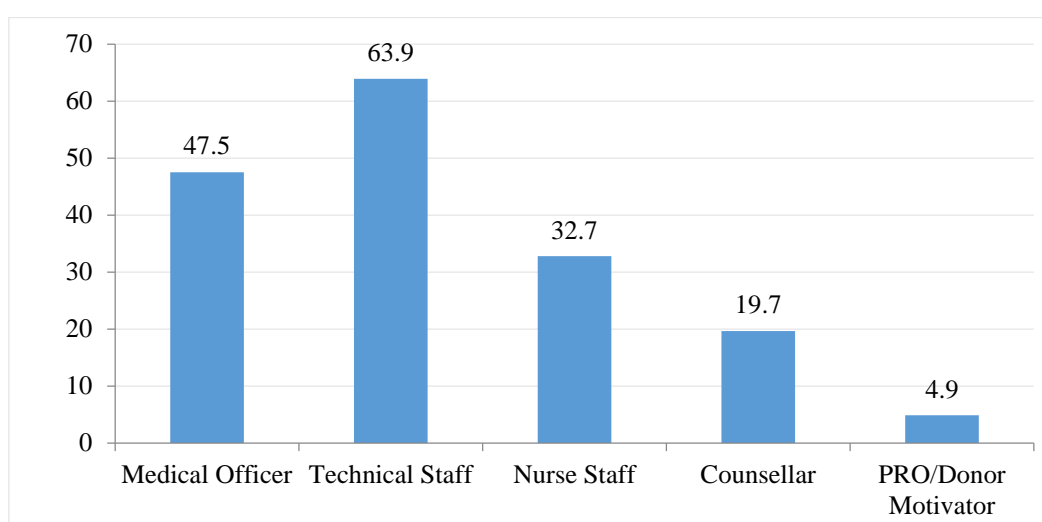
Figure 20 - Percentage of BB Manpower (At least one)



4.8. Training of Blood Bank Personnel

The assessment indicated that 47.5% of the blood banks reported to have at least one Medical Officer trained by NACO/NBTC, followed 63.9% of blood banks had at least one trained technical staff followed by 47.5 % of the blood banks with trained medical officer. Only 4.9% of blood banks had at least one trained donor motivator.

Figure 21 - Percentage of BBs having at least one trained

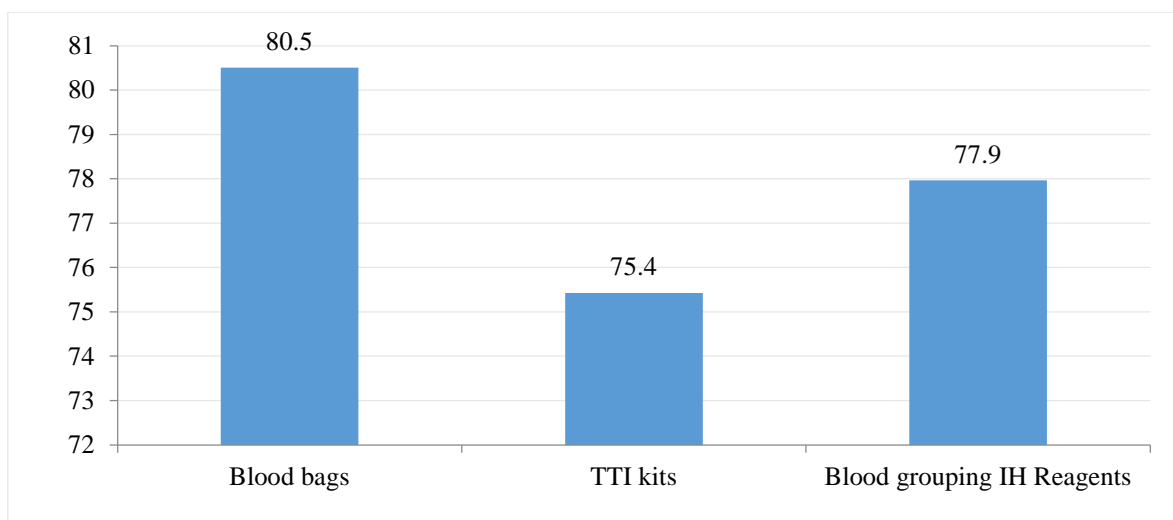


4.9. Equipment and Supplies

4.9.1. Regular supply kits/supplies

Majority of blood banks (80.5%) reported that they had regular supply of blood bags, 75.4% reported that they had regular supply of kits and 77.9% 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 availability of the different equipment in blood banks. 96.6% of blood banks in the country reported that they had donor couches, 95.8% reported that they had instrument for haemoglobin estimation, Blood collection monitor and Quarantine blood bank refrigerator to store untested blood. Similarly, only 90.7% of blood banks had refrigerated centrifuge in working condition.

Table 12 – Equipment Availability

S No	Equipment	%BB
1	Donor Couches	96.6
2	Instrument for Hb Estimation	95.8
3	Blood collection monitor	95.8
4	Quarantine Blood Bank Refrigerator to store untested blood	95.8
5	Container for safe disposal of sharps	90.7
6	Oxygen supply equipment	92.4
7	Computers with accessories and software	76.3
8	General lab Centrifuge for samples	88.1
9	Bench top centrifuge for serological testing(Immunohaematology)	83.9
10	Blood transportation box	87.3
11	Emergency drug box/Crash cart	96.6
12	Autoclave machine	94.9
13	Water Bath	94.9
14	Blood bank refrigerator(storage of tested blood)with temperature recorder	97.5
15	Automated pipettes	85.6
16	Refrigerated centrifuge	59.3
17	Blood container weighing device	80.5
18	Serology rotator	90.7

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 the aspects of blood transfusion services in blood banks, adequate importance and weightage were given to the technical aspects and adherence to quality management systems.

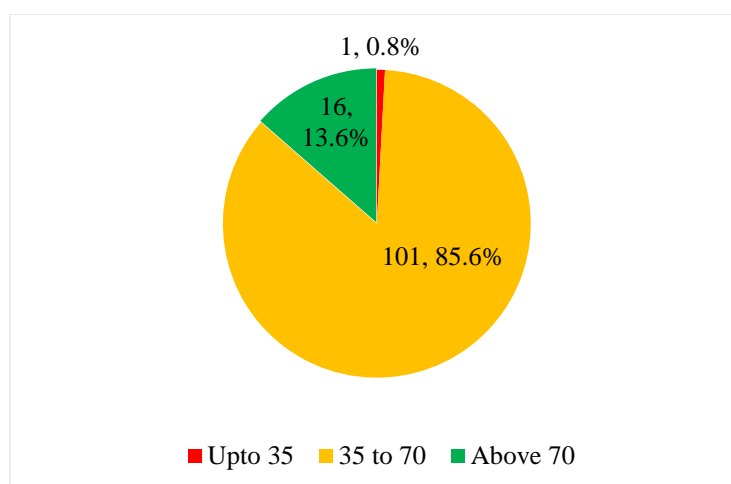
The mean assessment score of blood banks in the state was 61.54 (SD: 7.97). The Non-NACO supported blood banks scored slightly higher (61.74; SD: 8.15) than the NACO supported blood banks.

Table 13 - Mean Assessment score

Type of BB	N	Mean	SD
NACO supported	60	61.34	7.86
Non-NACO	58	61.74	8.15
Total	118	61.54	7.97

At the state level, the majority of blood banks (101; 85.6%) scored between 35 to 70, followed by (16; 13.6%) which scored above 70, and only one blood bank scored less than or equal to 35.

Figure 23 - Categorisation of blood banks (n=118)



Around 88% of NACO supported and 82.8% Non-NACO blood banks scored between 35 and 70. Around, 10% of NACO supported blood banks and 17.2% of Non-NACO blood banks scored more than 70. Only one NACO supported blood bank scored below 35. (Refer Figure 24 and 25).

Figure 24 - Categorisation of NACO BBs (n=60)

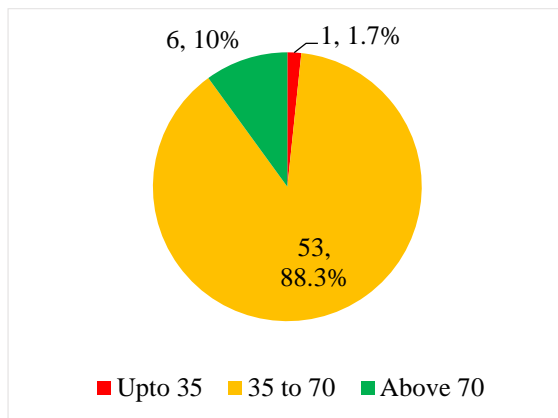
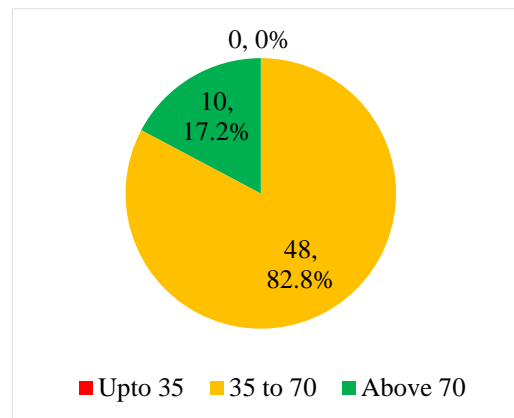
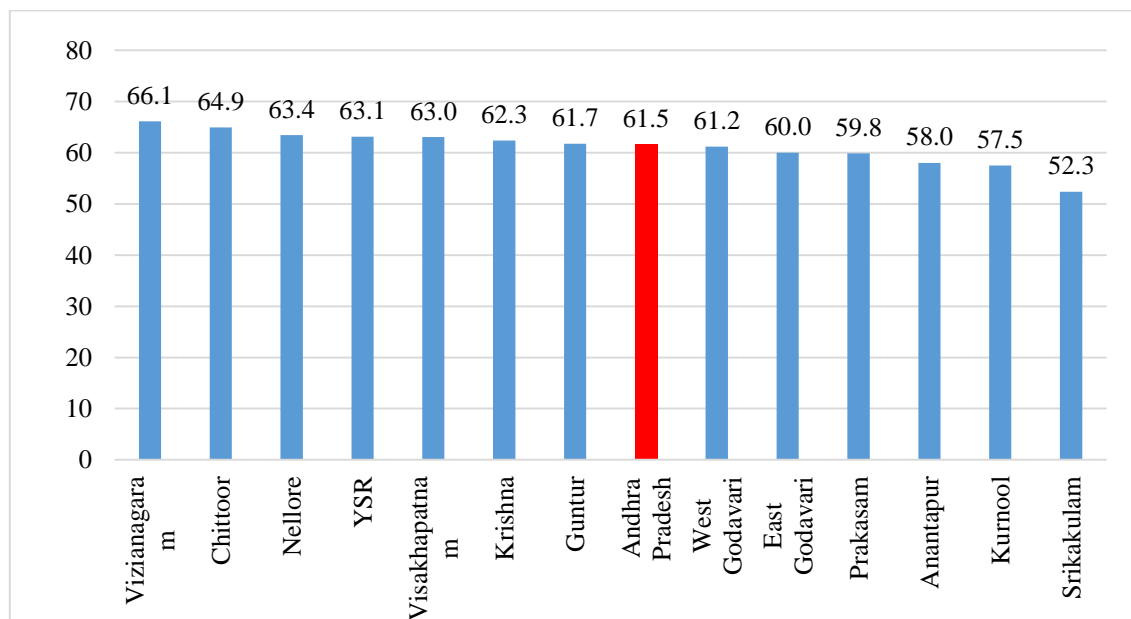


Figure 25 - Categorisation of Non-NACO BBs (n=58)



Among the districts, Vizianagram (66.1) scored the highest and Srikakulam scored the least with mean score (52.3). Excluding Vizianagram and Srikakulam the mean score of all the other districts ranges from 64.9 to 57.5. There were six districts that had mean scores less than the state average of 61.5 and seven districts scored above the state average.

Figure 26 - Mean assessment score – By district (All BBs)



Though the difference in the mean score at the state level was only 0.4 between NACO and Non-NACO blood banks, the mean scores of Non-NACO supported blood banks were higher than the NACO blood banks in 7 districts.

Seven districts such as Chittoor, Guntur, Nellore, Visakhapatnam, Vizianagram, West Godavari and YSR had higher scores in Non NACO supported blood banks than NACO

supported. Among these seven districts the difference of the mean scores was more than five in Nellore and Chittoor.

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

District	NACO Supported	Non-NACO	Total
Anantapur	58.1	57.5	58.0
Chittoor	62.9	70.2	64.9
East Godavari	64.2	55.8	60.0
Guntur	60.0	62.3	61.7
Krishna	62.6	62.1	62.3
Kurnool	59.3	55.8	57.5
Nellore	56.2	74.3	63.4
Prakasam	61.3	57.0	59.8
Srikakulam	55.0	51.0	52.3
Visakhapatnam	61.0	64.2	63.0
Vizianagaram	65.3	67.3	66.1
West Godavari	60.8	61.5	61.2
YSR	62.5	66.0	63.1
Andhra Pradesh	61.3	61.7	61.5

Only one blood bank from East Godavari district scored less than or equal to 35. The number of blood banks (by district) that scored more than 70 is mentioned in Table-15. Of the 16 blood banks that scored more than 70 score, 10 (62.5%) were Non-NACO blood banks. The majority of blood banks that scored above 70 were from East Godavari(4), Krishna(4) followed by Chittoor (3). These three districts constitutes more than 50% of the blood banks that scored above 70. Among these three districts the proportion of NACO supported blood banks that scored above 70 were higher in East Godavari (50%).

Table 15 - Number of blood banks score above 70 – By district

District	NACO Supported	Non-NACO	Total
Chittoor	1	2	3
East Godavari	3	1	4
Krishna	2	2	4
Nellore	-	2	2
Visakhapatnam	-	2	2
Vizianagaram	-	1	1
Andhra Pradesh	6	10	16

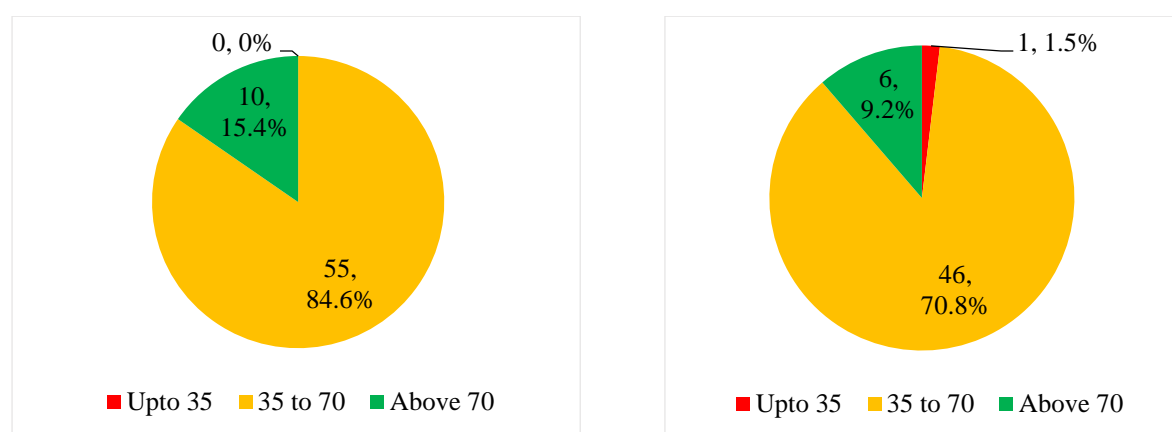
4.10.1 Assessment score by Category of blood banks: The mean score of blood banks without component facilities (62; SD: 8.26) was found to be higher than the mean score of those with component facilities (61.16; SD: 7.77).

Table 16 - Mean assessment score by category of blood banks

Type of BBs	NACO Supported			Non-NACO			Total		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Blood Component Separation Units	23	62.41	6.02	42	60.48	8.58	65	61.16	7.77
Without Components separation facility	37	60.68	8.83	16	65.06	5.94	53	62.00	8.26

Among the blood banks that scored ≤ 35 , there was only one blood bank without component separation facility. (Refer figure 29 and 30). There were 15.4% of Blood banks with component preparation facility that scored more than 70, as compared to 9.2% of blood banks without component facility.

Figure 27- BBs with component – Score (n=65) **Figure 28 - BBs without component – Score (n=53)**



4.10.2 Assessment score by Ownership: The mean assessment score of Public blood banks (62.11 SD: 7.63) was higher than not-for-profit blood banks (61.96; SD: 8.26) and Private owned blood banks (59.33;SD:7.66). It was also found that there were more not-for-profit (NGO/Trust/Charitable) blood banks (52 blood banks) in the more than 36 to 70 category compared to only 30 blood banks from public owned blood banks.

However, Non-NACO supported blood banks run by not-for-profit (63.11; SD: 8.32) and Public sector (63; SD: 0) had scored higher compared to NACO supported blood banks.

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	26	60.37	8.06	36	63.11	8.32	62	61.96	8.26
Private	0	-	-	21	59.33	7.66	21	59.33	7.66
Public	34	62.09	7.74	1	63.00		35	62.11	7.63

Table 18 - Mean assessment scores categories by Ownership

Ownership	<=35	36 to 70	Above 70	Total
Public	0	30	5	35
	0.0%	85.7%	14.3%	100.0%
NGO/Trust/Charitable	1	52	9	62
	1.6%	83.9%	14.5%	100.0%
Private	0	19	2	21
	0.0%	90.5%	9.5%	100.0%
Overall	1	101	16	118
	0.8%	85.6%	13.6%	100.00%

4.10.3 Assessment score of Private Sector Blood Banks: Irrespective of the NACO support status, 70.3% (83) blood banks were owned by private sector, of which, 52.5% (62) were owned by not-for-profit sector such as, NGO, Trust, and charitable organizations and 17.8% (21) were owned by private sector. The mean score of private sector owned blood banks including not-for-profit sector was 61.3 (SD: 8.1) the mean score of public owned blood banks was 62.1(SD: 7.6). Among the private sector, not-for-profit sector (62; SD: 8.2) scored slightly higher than the other private blood banks (59.3; SD: 7.7).

Nevertheless, it is also important to note that the average annual collection was higher (4398 units) in private owned blood banks compared to public blood banks (3788 Units). Similarly, the percentage of voluntary blood donation was higher in public owned blood banks (75%) compared to the private blood banks (68%). Of the total private blood banks, 53(64%) had component separation facility whereas only 12 (34%) 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 (63.05; SD: 9.19) was found to be higher than those which collected between 3001 and 5000 (62.35; SD: 7.10) and less than 3000 blood units (61.34; SD: 7.31).

Table 19 - Mean assessment score by annual collection

Annual Collection	NACO supported		Non-NACO		Total	
	Mean	SD	Mean	SD	Mean	SD
Up to 3000	61.27	7.51	61.42	7.23	61.34	7.31
3001 to 5000	62.78	5.26	62.00	8.57	62.35	7.10
Above 5000	61.56	9.57	65.12	8.57	63.05	9.19

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 voluntary blood donation. The blood banks that reported a higher proportion of voluntary blood donation indicated higher mean assessment score. Non-NACO blood banks have marginally scored higher than the NACO supported blood banks.

Table 20 - Mean assessment score by voluntary blood donation

% VBD	NACO supported		Non-NACO		Total	
	Mean	SD	Mean	SD	Mean	SD
Less than 25	55.50		56.67	7.63	56.58	7.31
25 to 49	58.50	6.51	60.50	5.85	59.44	6.10
50 to 74	62.75	11.90	63.92	5.34	63.19	9.73
75 to 90	60.63	10.53	65.38	7.29	63.57	8.73
Above 90	62.48	5.58	64.66	8.02	63.22	6.51

4.10.6 Assessment score by participation in External Quality Assessment scheme (EQAS) for Immunohematology and Transfusion Transmitted Infections (TTI): The mean score was found to be higher among NACO supported blood banks that were part of EQAS for immunohematology (61.14; SD: 7.8) as compared to Non-NACO blood banks. Similar situation was found among those blood banks that were part of EQAS for Transfusion-Transmitted Infections where the mean assessment score in NACO supported blood bank (60.99; SD: 7.9) was slightly higher than the Non NACO blood banks.

Although more number of Non-NACO blood banks were enrolled in IH and TTI-EQAS, NACO supported blood banks had higher scores under IH-EQAS.

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	59	61.14	7.78	51	60.32	7.40	110	60.76	7.58
NO	1	73.00		7	72.07	5.81	8	72.19	5.38
TTI - EQAS	N	Mean	SD	N	Mean	SD	N	Mean	SD
YES	57	60.99	7.86	53	60.88	7.79	110	60.94	7.79
NO	3	68.00	4.58	5	70.90	6.64	8	69.81	5.78

4.10.7 Assessment score by Accreditation status: There were no blood banks that were accredited in the state of Andhra Pradesh.

Table 22 - Distribution of Blood banks by Districts and mean assessment score categories

Districts	Score category			
	Up to 35	35 to 70	Above 70	Total
Anantapur	-	6	-	6
Chittoor	-	8	3	11
East Godavari	1	7	4	12
Guntur	-	16	-	16
Krishna	-	11	4	15
Kurnool	-	8	-	8
Nellore	-	3	2	5
Prakasam	-	6	-	6
Srikakulam	-	3	-	3
Visakhapatnam	-	12	2	14
Vizianagaram	-	4	1	5
West Godavari	-	11	-	11
YSR	-	6	-	6
Andhra Pradesh	1	101	16	118

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

Districts	Score					
	NACO supported			Non-NACO		
	Up to 35	35 to 70	Above 70	Up to 35	35 to 70	Above 70
Anantapur	-	5	-	-	1	-
Chittoor	-	7	1	-	1	2
East Godavari	1	2	3	-	5	1
Guntur	-	4	-	-	12	-
Krishna	-	5	2	-	6	2
Kurnool	-	4	-	-	4	-
Nellore	-	3	-	-	-	2
Prakasam	-	4	-	-	2	-
Srikakulam	-	1	-	-	2	-
Visakhapatnam	-	5	-	-	7	2
Vizianagaram	-	3	-	-	1	1
West Godavari	-	5	-	-	6	-
YSR	-	5	-	-	1	-
Andhra Pradesh	1	53	6	-	48	10

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 Andhra Pradesh 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 60 NACO and 58 Non-NACO blood banks which were included in the review are approximately 94% of the total blood banks excluding the military blood banks existing in the state. The annual collection of these blood banks was 4,80,033 Lakhs units which is approximately 97% of the total blood requirement based on WHO's estimation that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2010). However, there is a huge variation between districts that ranges from 0.24 units to 1.7 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 (78.4%) was by blood banks with the component facility compared to smaller blood banks without component facility. Though there has been an increase in the percentage of voluntary blood donation over the years (around 70% in 2015), there is still a huge variation between districts that ranges from 43.2% to 95.9%. A targeted program to increase the non-remunerated voluntary blood donors will go a long way towards ensuring a safer option for our patients.

It is also evident that the distribution of blood banks is skewed with 60% of the all the blood banks in the state relegated to only 5 districts. More than half the districts (8) have less than the state average of 2.6 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.

Almost one fourth (27.1%) 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 61.54 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 country.

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7 Annexures

7.1 Individual Blood Banks' Summary

District	Name of the Blood Bank	Type	Ownership	Annual Collection	Score (Out of 100)
Anantapur	Blood Bank, Anantapuramu	BCSU	Public	9536	58.5
	M/S Rural Development Trust Hospital Blood Bank	BCSU	NGO/Trust /Charitable	6401	57.5
	M/S. Indian Red Cross Society, Blood Bank, (District Branch)	BCSU	NGO/Trust /Charitable	4403	62
	M/s Sri SatyaSai Institute of Higher Medical Sciences. Blood Bank	BCSU	NGO/Trust /Charitable	3105	70
	Indian Red Cross Society Blood Bank, Anantapuram	Non BCSU	Public	1863	50
	Indian Red Cross Society Blood Bank, Anantapuram	Non BCSU	Public	1674	50
Chittoor	Sri Venkateshwara Institute of Medical Sciences Blood Bank	BCSU	Public	18366	73
	Model Blood Bank	BCSU	Public	7942	60.5
	M/s. Sri Venkata Sai Charitable Trust Blood Bank and Transfusion Centre	BCSU	NGO/Trust /Charitable	7246	71.5
	RCH II Blood bank IRCS, Chittoor	Non BCSU	NGO/Trust /Charitable	3069	58
	People Education Society Institute Of Medical Sciences And Research Blood Bank	BCSU	NGO/Trust /Charitable	3012	76
	Blood Bank, DHH, Chittoor	BCSU	Public	2721	62
	Indian Red Cross Society Blood Bank, Chittoor	Non BCSU	NGO/Trust /Charitable	2483	66
	Government Maternity Hospital, Blood Bank	Non BCSU	Public	1985	67
	T.T.D, Central Hospital Blood Bank	Non BCSU	Public	506	62
	Aswini Blood Bank	Non BCSU	NGO/Trust /Charitable	309	55

	Arogyavaram Medical College,Blood Bank	Non BCSU	NGO/Trust /Charitable	58	63
East Godavari	Dhanwantari Voluntary Blood Bank	BCSU	NGO/Trust /Charitable	12544	57
	Government General Hospital Blood Bank,East Godavari	BCSU	NGO/Trust /Charitable	12374	73
	Indian Red Cross Society Blood Bank,East Godavari	BCSU	Public	10748	67
	Rotary Blood Bank	Non BCSU	NGO/Trust /Charitable	9269	32
	G.S.L Medical College & General Hospital Blood Bank	BCSU	NGO/Trust /Charitable	2794	52
	APVVP Blood Bank	Non BCSU	Private	2739	73
	Govt Blood Bank Rajamundry	Non BCSU	Public	2317	69
	M/S Konaseema Institute Of Medical Science & Research Foundation Blood Bank & Blood Components	BCSU	Public	1970	70.5
	Swatantra Blood Bank	Non BCSU	NGO/Trust /Charitable	1768	50
	M/s Govt. Area Hospital Blood Bank,East Godavari	Non BCSU	Private	1186	71
	Sakthi Voluntary Blood Bank	Non BCSU	Public	1068	62
	Buddala Nagratnam Memorial Voluntary Blood Bank	BCSU	NGO/Trust /Charitable		43
Guntur	Needs Blood Bank	BCSU	NGO/Trust /Charitable	14514	67
	Government Blood Bank,Guntur	BCSU	NGO/Trust /Charitable	11394	62
	Indian Red Cross Society Blood Bank,Guntur	Non BCSU	Public	4637	64
	NRT Blood Bank	BCSU	NGO/Trust /Charitable	4072	57
	NTR Memorial Trust Blood Bank	BCSU	Private	3783	59
	Manipal Hospital Blood bank	BCSU	NGO/Trust /Charitable	3614	68
	Lions Club of Guntur Vision Blood	BCSU	Private	3360	70

	Bank				
	sri lakshmi blood bank	BCSU	NGO/Trust /Charitable	2050	62
	Anjireddy Multy Speciality Hospital Blood Bank Piduguralla	BCSU	Private	1942	58.5
	Rudhra Voluntary Blood Bank	BCSU	Private	1856	59.5
	Besy Rotary Blood Bank	Non BCSU	NGO/Trust /Charitable	1620	61
	Katuri Medical College and Hospital Blood Bank	BCSU	NGO/Trust /Charitable	1442	64.5
	St. Joseph`S Hospital Blood Bank	Non BCSU	Private	1068	69
	Red Cross Blood Bank, Guntur	Non BCSU	NGO/Trust /Charitable	1023	63
	APVVP, Govt Blood Bank	Non BCSU	NGO/Trust /Charitable	671	51
	Sree Welfare Society Blood Bank	BCSU	NGO/Trust /Charitable		52
Krishna	Smt Chigurupati Manjuvani Varaprasad Lions Blood Bank	BCSU	Private	15879	61
	Chaitanya Blood Bank	BCSU	NGO/Trust /Charitable	9100	71.5
	Vijaya Sri Blood Bank With Components	BCSU	NGO/Trust /Charitable	9055	72.5
	Suraksha Voluntary Blood Bank With Components	BCSU	NGO/Trust /Charitable	6044	70.5
	M/s Blood Bank aayush Hospital	BCSU	NGO/Trust /Charitable	4166	53
	Rotary Red Cross Blood Bank	BCSU	Private	3728	64
	Government General Hospital Blood Bank	Non BCSU	NGO/Trust /Charitable	3153	69
	M/s District Coordinator of Hospital Services Blood Bank	Non BCSU	Public	2039	73
	Dr Pattabhi Red Cross Blood Bank, Machilipatnam	Non BCSU	Public	1666	62
	Dr. Pinnamaneni Siddhartha Institute of Medical Sciences & Research Foundation	BCSU	NGO/Trust /Charitable	1590	57.5

	Nagarjuna Hospital Blood Bank	Non BCSU	Private	943	68
	Area Hospital,Blood Bank	Non BCSU	NGO/Trust /Charitable	792	37
	St Ann's Hospital Blood Bank	Non BCSU	Public	718	64
	Nimra Institute Of Medical Sciences	BCSU	NGO/Trust /Charitable	175	58
	M/s.Kamineni Health care Pvt. Ltd. Blood Bank	BCSU	Private		54
Kurnool	Indian Red Cross Society Blood Bank,Kurnool	BCSU	NGO/Trust /Charitable	9651	54.5
	RR Hospital Blood Bank	BCSU	Private	6356	63.5
	M/S.Government General Hospital Blood Bank	BCSU	Public	6150	68.5
	M/s Indian Red Cross Society,Kurnool	Non BCSU	Public	4997	57
	Viswabharathi Super Speciality Hospital Blood Bank	BCSU	Private	3897	49
	District Hospital, Nandyal	Non BCSU	Public	2647	57
	Viswabharathi General Hospital Blood Bank	BCSU	Private	2194	50
	Santhiram General Hospital	BCSU	Private	1675	60.5
Nellore	Indian Red Cross Society Blood Bank	BCSU	NGO/Trust /Charitable	23276	58
	Narayana Medical College Hospital Blood Bank	BCSU	NGO/Trust /Charitable	7287	76.5
	Kanamrapudi Koteswara Rao Indian Red Cross Society Blood Bank	Non BCSU	NGO/Trust /Charitable	2105	72
	DSR Dt Hq Hospital,Nellore	BCSU	Public	1707	53.5
	Govt Blood Bank,Nellore	Non BCSU	Public	920	57
Prakasam	M/S Belief Blood Bank	BCSU	NGO/Trust /Charitable	4500	52
	M/s Rajeev Gandhi Institute of Medical Sciences Hospital Blood Bank	Non BCSU	Public	2940	60
	Indian Red Cross	Non	NGO/Trust	2688	61

	Society	BCSU	/Charitable		
	Life Line Voluntary Blood Bank	Non BCSU	NGO/Trust /Charitable	1770	62
	Blood Bank, Area Hospital, Chirala	Non BCSU	Public	1110	63
	Indian Red Cross Society Blood Bank	Non BCSU	Public	128	61
Srikakulam	Rajiv Gandhi Institute of Medical Sciences General Hospital Blood Bank	BCSU	Public	3950	55
	M/S Great Eastern Medical School & Gems Hospital Blood Bank	BCSU	NGO/Trust /Charitable	1379	48.5
	GMR Varalakshmi Care Hospital Blood Bank	BCSU	NGO/Trust /Charitable	1037	53.5
Visakhapatnam	NTR Memorial Trust Blood Bank	BCSU	NGO/Trust /Charitable	18734	67
	Rotary Blood Bank	BCSU	NGO/Trust /Charitable	14434	64
	A S Raja Voluntary Blood Bank	BCSU	NGO/Trust /Charitable	13941	79
	Indian Red Cross Society Blood Bank, Visakhapatnam	BCSU	NGO/Trust /Charitable	7879	55.5
	King George Hospital Blood Bank	BCSU	Public	5883	55.5
	Lions club of Visakhapatnam Blood Bank Trust	BCSU	NGO/Trust /Charitable	5588	58.5
	Apollo Blood Bank Centre	Non BCSU	Private	1704	61
	Seven Hills Healthcare Pvt Ltd Blood Bank	Non BCSU	Private	1350	74
	NTR Vaidyalayam Blood Bank, Visakhapatnam	Non BCSU	Public	914	65
	Government Victoria Hospital for Women and Children Blood Bank, Visakhapatnam	Non BCSU	Public	903	65
	Anil Neerukonda NRI General Hospital	BCSU	Private	674	49
	M/s. Gitam Institute of Medical Sciences	Non BCSU	Private	450	70

	& Research Blood Bank, Rushikonda, Visakhapatnam				
	Visakha Steel General Hospital Blood Bank	Non BCSU	Public	293	63
	GVPIHMT Blood Bank	BCSU	NGO/Trust /Charitable	258	56
Vizianagaram	Indian Red Cross Society Blood Bank, Vizianagaram	Non BCSU	NGO/Trust /Charitable	6211	69
	District Head Quarters Hospital Blood Bank, Vizianagaram	BCSU	Public	2680	62
	Srinivasa Nursing Home	Non BCSU	Private	1282	73
	Maharajah Institute of Medical Sciences blood bank	BCSU	Private	1257	61.5
	Indian Redcross Society Blood Bank, Vizianagaram	Non BCSU	NGO/Trust /Charitable	971	65
West Godavari	Buddala Narasimha Murthy Voluntary Blood Bank	BCSU	NGO/Trust /Charitable	6143	52.5
	ASN Raju Charitable Trust Blood Bank	BCSU	NGO/Trust /Charitable	5110	54.5
	Indian Red Cross Society Blood Bank	BCSU	NGO/Trust /Charitable	4545	59
	Uddaraju Ananda Raju Foundation Blood Bank	Non BCSU	NGO/Trust /Charitable	3997	65
	Palakol Voluntary Blood Bank	BCSU	NGO/Trust /Charitable	3566	68
	Alluri Sita Rama Raju Academy of Medical Sciences Blood Bank	BCSU	NGO/Trust /Charitable	3084	65
	Dr. Mullapudi Harischandra Prasad Red Cross Blood Bank,	Non BCSU	NGO/Trust /Charitable	1710	66
	Govt Headquarters Hospital Blood bank	Non BCSU	NGO/Trust /Charitable	1378	68
	Good Samaritan Blood Bank	Non BCSU	Public	935	64
	IRCS - RCH - II Blood Bank	Non BCSU	NGO/Trust /Charitable	779	62
	Indian Red Cross Society Blood Bank	Non BCSU	NGO/Trust /Charitable		49
YSR	Rajiv Gandhi	BCSU	Public	7864	64.5

	Institute of Medical Sciences Blood Bank, Y.S.R., Kadapa				
	Indian Red Cross Society Blood Bank	Non BCSU	NGO/Trust /Charitable	5327	59
	Boga Parvathamma Blood Bank	Non BCSU	Public	3343	66
	Govt Blood Bank	Non BCSU	Public	2183	62
	APVVP Area Hospital Blood Bank	Non BCSU	Public	2019	61
	M/s Fathima Institute of Medical Sciences Blood Bank	BCSU	NGO/Trust /Charitable	730	66

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: <i>(Official/Personal Email where the medical officer can be directly contacted). This is apart from the blood bank email ID provided above.</i>		
18	Fax number		
19	Telephone number 1 – Medical Officer <i>(Mobile)</i>		
20	Telephone number 2 – Medical Officer <i>(Landline including STD code)</i>		
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 <i>(Specify hours per day)</i>		
A2	License Information		
1.	BB License Number <i>(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</i>		

	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 (<i>more than one can be selected</i>)	State
		National (NHP)
		Other(Specify
10	Please provide E Blood banking user ID (<i>State</i>)	
11	Please provide E Blood banking user ID (<i>National</i>)	
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? (<i>Provide numbers of VBD camps conducted during the period January - December 2015.</i>)		
8	Does the blood bank have dedicated staff for the promotion of Voluntary blood donors? (<i>If your blood bank has dedicated staff for camps, answer yes.</i>)	Yes	
		No	
8 a.	if Yes to 8, select as applicable (<i>More than one may be selected</i>)	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 (<i>Donor database is essential to contact donors to remind them or to call during an emergency?</i>)	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 (<i>Indicate the source of funding for the purchase of the mobile blood donor van.</i>)	State		
		Central		
		Donor		
		Others		
16	Specify, other source of funds			
17	Is there a record for donor adverse reactions?	Yes		
		No		
18	Is there a referral system for HIV sero-reactive blood donors?	Yes		
		No		
19	If yes to Q 18, please specify what is the process adopted.			
Section C				
Technical – Immunohematology				
C1.	Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed?	Blood Group (Tick as applicable)		Rh Type (Tick as applicable)
		Forward	Reverse	
C1.1.	Slide			
C1.2	Tube			
C1.3	Micro plate			
C1.4	Column agglutination Gel/Microparticle)			
C1.5	Solid phase			
C1.6	Other Specify			
1	How do you perform RhD typing?	Monoclonal reagent		
		Polyclonal reagent		

		Both		
2	Do you perform irregular antibodies screening on blood donations and patient sample?	Yes		
		No		
3	Do you perform direct antiglobulin test (DAT/DCT)? <i>(If you are performing Direct Antiglobulin test (DAT) - earlier called as Direct Coombs Test (DCT), answer yes.)</i>	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) <i>(Specify the number of group and type tests performed - Total of all patient and donor tests in the reporting period - January to December 2015.)</i>			
8	Number of compatibility testing performed in reporting period. <i>(Specify number of compatibility tests performed in the reporting period January to December 2015)</i>			
9	Total Number of DAT/DCT tests performed in the reporting period <i>(Specify number of DAT/DCT tests performed in the reporting period (January to December 2015))</i>			
10	Total Number of IAT/ICT tests performed in the reporting period <i>(Specify number of DAT/DCT tests performed in the reporting period (January to December 2015))</i>			
11	Total Number of antibody screening performed in reporting period <i>(If you answered YES to Q2, Specify number of antibody screening tests performed in the reporting period (January to December 2015)).</i>			
12	Do you have automation for Immunohematology testing? <i>(If you have implemented any kind of automation, please indicate so.)</i>	Yes		
		No		
13	Do you perform Internal QC for all immunohematology tests (blood group/DAT/IAT etc.)? <i>(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.)</i>	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 <input type="checkbox"/> Automated <input type="checkbox"/>
	CHEMI	Manual <input type="checkbox"/> Automated <input type="checkbox"/>
	NAT	Manual <input type="checkbox"/> Automated <input type="checkbox"/>
1.1	Specify % of donors tested by Rapid Test?	
2	Hepatitis B	
	Rapid	
	ELISA	Manual <input type="checkbox"/> Automated <input type="checkbox"/>
	EM	Manual <input type="checkbox"/> Automated <input type="checkbox"/>
	NAT	Manual <input type="checkbox"/> Automated <input type="checkbox"/>
2.1	Specify % of donors tested by Rapid Test?	
3	Hepatitis C	
	Rapid	
	ELISA	Manual <input type="checkbox"/>

				Automated	<input type="text"/>
		CHEM		Manual	<input type="text"/>
				Automated	<input type="text"/>
		NAT		Manual	<input type="text"/>
				Automated	<input type="text"/>
3.1	Specify % of donors tested by Rapid Test?				
4	Syphilis	RPR		Manual	<input type="text"/>
				Automated	<input type="text"/>
		TPHA		Manual	<input type="text"/>
				Automated	<input type="text"/>
		ELISA		Manual	<input type="text"/>
				Automated	<input type="text"/>
5	Malaria	Rapid			
		Fluorescent		Manual	<input type="text"/>
				Automated	<input type="text"/>
		Slide microscopy			
		ELISA		Manual	<input type="text"/>
				Automated	<input type="text"/>
6	Does the blood bank have an algorithm for units that test POSITIVE in initial screening? <i>(If you have a method of verifying a sample that has tested positive on the screening test please answer yes.)</i>			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 (<i>Viral Markers, Malaria, and Syphilis</i>) 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			
Technical - Component Preparation (Applicable only to BCSU)			
1	Does your blood bank prepare components?	Yes	
		No	
If your answer to Q1 is NO, SKIP TO SECTION F			
If Yes, List the components and number prepared and issued in the period Jan to December 2015			
2	Number of donated blood that was used for component preparation during the period Jan- December 2015.		
		Number prepared	No. issued (utilized)
3	Packed red cells IP (With or without Additive)		
4	Platelet concentrate IP		
5	Fresh frozen plasma (FFP)		
6	Cryoprecipitated antihaemophilic factor IP		
7	Human plasma IP		
8	Other (specify)		
9	Do you perform apheresis for components?	Yes	
		No	
	If yes to above question, Specify the following details		
		Number prepared	No. issued (utilized)
10	Platelet concentrate IP		
11	Fresh frozen plasma (FFP)		
12	Granulocytes concentrates		
13	Other (specify)		
14	Do you perform QC for the components prepared? (If you perform quality control for all components, answer yes.)	Yes	
		No	
15	If yes to above, Are the Factor assays on Fresh Frozen plasma/Cryoprecipitate performed at your Blood Bank?	Yes	
		No	
16	If yes for above question, do you participate in external quality assessment scheme (EQAS)?	Yes	
		No	
17	If yes, to above question, Specify agency		

SECTION F			
Quality Management Systems			
F 1	Are you aware of quality management systems for Blood bank	Yes	
		No	
1	Is the blood bank accredited?	Yes	
		No	
2	If yes, provide Name of Accrediting Body		
3	Do you have a document control system - other than mandatory	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 (<i>include senior/Junior</i>)				
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? <i>(If your blood bank has adequate equipment in working condition to meet expected workload, please answer yes.)</i>	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? <i>(Are kits evaluated locally (at your blood bank) prior to purchase (e.g. Titre and avidity for blood group Anti Sera?))</i>	Yes	
		No	
7	Is quality control for kits, reagents and blood bags carried out at your blood bank? <i>(Is quality control for kits performed locally (at your blood bank) Prior to use (e.g. Titre and avidity for blood group Anti Sera?))</i>	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 <i>(other than CuSO4 method)</i>		
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	<i>Not applicable</i>		
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