

Assessment of Blood Banks in India-2016





Ministry of Health and Family Welfare Government of India

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

National AIDS Control Organization (NACO) and National Blood Transfusion Council (NBTC), Ministry of Health and Family Welfare, Government of India in collaboration with U.S Centers for Disease Control and Prevention (HHS/CDC) Division of Global HIV and TB (DGHT), India Christian Medical College, Vellore & Christian Medical Association of India (CMAI), New Delhi 

डॉ सी.वी. धर्मा राव संयुक्त सचिव

Dr. C. V. Dharma Rao Joint Secretary



राष्ट्रीय एड्स नियंत्रण संगठन स्वास्थ्य एवं परिवार कल्याण मंत्रालय भारत सरकार

National AIDS Control Organisation Ministry of Health & Family Welfare Government of India

PREFACE

Since the inception of National AIDS Control Programme in 1992 and the creation of the National Blood Transfusion Council in 1996, the Blood Transfusion Services in India have made significant advancement in the availability and access to safe and quality Blood and Blood components to even the remotest areas of the country.

Currently, the National AIDS Control Programme is in Phase IV (2012-2017) and one of the key strategies under NACP IV is strengthening the management and structure of Blood Transfusion Services together with the implementation of Quality Management Systems in Blood Transfusion Services.

The Assessment of all licensed Blood Banks was carried out with the specific objectives of reviewing the existing situation in Blood Banks in terms of collection of blood, voluntary blood donation, quality management systems, and other areas; and to categorize and grade the Blood Banks using a scoring system, for implementation of phased quality improvement systems. This report highlights the key issues, gaps, challenges, and possible opportunities to the state health officials and programme officers of State Blood Transfusion Councils and State AIDS Control Societies.

The rich data generated from this exercise will also be further mined to generate state specific reports.

(Dr C.V Dharma Rao)

9th Floor, Chandralok Building, 36 Janpath, New Delhi -110001, Phones : 011-23325343, Fax : 011-23325335 E-mail : js@naco.gov.in, dharma.rao@nic.in, jt.secynaco@gmail.com

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Blood Transfusion Services is a lifesaving intervention in the health care system. Therefore, the Blood and Blood products must be safe and of consistent quality for clinical effectiveness. Planning and implementation of Quality Management Systems in Blood Transfusion Services across the country under the National Blood Programme require updated information at District, State & National level. This country-wide assessment was one of the unique and first assessment of its kind which captured almost all the required information on all aspects of Blood Transfusion Services across the country.

It is evident from the assessment that Blood Banks focussing on Quality Management Systems performed better than others. Therefore, it is imperative that specific programmes with targeted and customized approach are developed and implemented across the country, to improve the quality systems and patient care practices in Blood Transfusion Services.

I take this opportunity to express my heartfelt gratitude to Shri N.S Kang, President NBTC/Secretary & DG, NACO and Dr. C.V. Dharma Rao, Joint Secretary, NACO for providing constant encouragement and guidance to undertake this important activity.

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(Dr. R.S Gupta)

9th Floor, Chandralok Building, 36 Janpath, New Delhi -110001, Website : www.nblc.gov.in

Ah	previations
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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
OC	_	Ouality Control
OM	_	Ouality Manager
OMS	_	Ouality 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
TTIs	_	Transfusion Transmitted Infection
TM	_	Technical Manager
ТРНА	_	Treponema Pallidum Hemagolutination Assav
VNRBD	_	Voluntary Non-Remunerated Blood Donation
VBD	_	Voluntary Blood Donor/Donation
WHO	_	World Health Organization
SINIS SOPs TTIs TM TPHA VNRBD VBD WHO	-	Stategic Information Wanagement System Standard Operating Procedures Transfusion Transmitted Infection Technical Manager Treponema Pallidum Hemagglutination Assay Voluntary, Non-Remunerated Blood Donation Voluntary Blood Donor/Donation World Health Organization

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Executive Summary

Blood Banks in India

According to Central Drugs Standard Control Organization (CDSCO), there were 2,760 blood banks in the country in 2015. The assessment exercise identified 2,626 functional blood banks across the country excluding 46 military blood banks. Of the 2,626 blood banks, 1,131(43%) were supported by National AIDS Control Organization, Ministry of Health and Family Welfare, Government of India and the remaining 1,495 were Non-NACO blood banks.

Maharashtra (308) had the highest number of blood banks followed by Tamil Nadu (265), Uttar Pradesh (248), Karnataka (185), Kerala (166), Telangana (153), Gujarat (134), Madhya Pradesh (133), Andhra Pradesh (125), West Bengal (115) and Rajasthan (102).

Around 61% (1,592) of all the blood banks(n=2,626) in the country were in 8 states that are, Maharashtra (11.7%), Tamil Nadu (10.1%), Uttar Pradesh (9.4%), Karnataka (7%), Kerala (6.3%), Telangana (5.8%), Gujarat (5.1%), and Madhya Pradesh (5%).

Considering the number of blood banks per one million population, states such as Bihar (0.7 blood banks), Jharkhand (1.2), Uttar Pradesh (1.2), West Bengal (1.3), Rajasthan(1.5), Madhya Pradesh (1.8), Manipur (1.8), Odisha(1.9), Assam (2), Nagaland(2), Meghalaya(2) and Chhattisgarh(2) recorded less than the national average of 2.2 blood banks per 1,000,000 (one million) population.

In this assessment, 2,493 blood banks (1,119 NACO supported - 98.9% and 1,374 Non-NACO - 91.9%) that submitted the assessment forms in complete were included in the analysis.

Description of blood banks (n=2,493)

- Around 51% (1,271) of the blood banks in the country had component separation facility.
- The public and not-for-profit sector each owned 38% of the blood banks in the country and the private sector owned approximately 24% (598) of blood banks.
- The majority (876; 78.3%) of NACO supported blood banks were owned by the public sector and the remaining 21.7% (243) were run by non-profit/not-for-profit sector such as NGOs, charitable trusts, societies, foundations etc.

- The majority of the blood banks (77%; 1919) were attached to hospitals, 1% (23) were attached to laboratories and the remaining 551 (22.1%) were standalone blood banks.
- The majority of the blood banks (65.7%) had valid and current licenses while the remaining 34.3% (860) had applied for renewal. Around 55% (617) of NACO supported and 74.3% (1,021) of Non-NACO supported 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 11,645,791 of which 71.9% (8,378,692) 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 country was 4789 units. The average annual collection of NACO supported blood banks was found to be higher than (6,219 units) the Non-NACO blood banks (3,583 units).
- The blood banks with component separation units recorded a higher average collection (7,035 units) compared to blood banks without component separation units (2,432 units).
- The NACO supported Blood banks collected 59.4% (6,915,963 units) of the total collection, of which 80.5% (5,568,143) units were through voluntary blood donation. The Non-NACO Blood banks collected 4,729,828 (40.5%) units of which only 59.4% (2,810,549) units were through voluntary blood donation.

Transfusion Transmitted Infections

• HIV positivity among blood donors was found to be 0.14%, Hepatitis C 0.34%, Hepatitis-B 0.87%, Syphilis 0.17% and Malaria 0.06%. However, there is a huge variation between different states.

Component Separation

- Around 71% of blood units collected by blood banks with component separation facilities, were used for component separation in India.
- The percentage component separation was higher (75.4%) in Non-NACO blood banks compared to NACO supported blood banks (67.3%).

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 50% of the blood banks in the country. Around 42% of NACO supported blood banks and 55% of Non-NACO blood banks reported they had a document control system.
- More than 95% of blood banks reported havingstandard operating procedures (SOPs) for technical processes.
- Internal quality control (IQC) for Immunohematology was reported by 78% of the blood banks and IQC for TTIs was reported by 52% 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 12.6% and 11.2% of the blood banks in India have enrolled themselves in External Quality Control Systems (EQAS) by recognized providers for immunohematology and TTIs respectively.
- Only 73 (2.9%) 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 37.9% and 48.2% 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 country was 62 (SD: 11.19). The Non-NACO blood banks scored slightly higher (62.68; SD: 10.63) than the NACO supported blood banks.
- Around 78% of all the blood banks under NACO supported were in public sector and present across sub-divisional and divisional/district hospitals catering to all segments of the population including rural areas. Whereas, the majority (95%) of the Non-NACO blood banks were in the private and not-for-profit sector.

- At the national level, the majority of blood banks (77%) scored between 35 to 70 followed by 21% which scored above 70 and 2% scored less than or equal to 35.
- An equal proportion of 77% of NACO supported and Non-NACO blood banks scored between 35 to 70. Around 21% of NACO supported blood banks and 22% of Non-NACO blood banks scored more than 70.
- Most of the blood banks that scored less than or equal to 35 were in Uttar Pradesh (13; 5% of all blood banks), followed by Bihar (6; 8% of all blood banks) and Odisha (3; 4% of all blood banks).
- Of the 530 blood banks that scored more than 70, 297 (56%) were Non-NACO blood banks. The majority of blood banks that scored above 70 were from Maharashtra (90), followed by Gujarat (60), Karnataka (55), Tamil Nadu (53), Kerala (42), Delhi (34) and Rajasthan (22). These 6 States constitute 50% of the total blood banks that scored more than 70.
- The mean score of blood banks with component facilities was found to be higher (64.69; SD: 10.84) than the mean score of blood banks without component facilities (59.22; SD: 10.87). No significant differences were observed between NACO and Non-NACO Blood banks.
- The mean assessment score of not-for-profit (NGO/Trust/Charitable) owned blood banks (64.18; SD: 10.52) was found to be higher than the public sector blood banks (59.16; SD: 11.30).
- However, NACO supported blood banks run by not-for-profit sector had scored higher (67.30; SD: 11.27) as compared to Non-NACO blood banks run by NGO/Trust/Charitable institutions (63.11; SD: 10.03).
- The mean assessment score of blood banks that collected more than 5000 blood units (66.98; SD: 11.20) was found to be higher than those that collected between 3001 to 5000 (63.31; SD: 9.45) and those that collected less than 3000 blood units (59.39; SD: 10.48).
- 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 the blood banks that were part of EQAS for immunohematology (75.35; SD: 8.92) compared to those which were not enrolled (60.08; SD: 10.12). The similar situation was found among those blood banks that were part of EQAS for Transfusion-transmitted Infections (76.32; SD: 8.34) as compared to those which were not enrolled (60.20; SD: 10.15).

• The mean score was found to be higher among those blood banks that were accredited by National Accreditation Board of Hospitals and Health Care providers (NABH) compared to those that were not accredited.

It is evident from the assessment that those blood banks which 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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Assessment of Blood Banks in India

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 1,131 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 to 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. 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:

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

Table -1 - Details of technical areas included in the assessment

Data Handling and Analysis Management: 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 to 10,000 units of blood banks and District Level blood banks (DLBB) in NACO supported blood banks. Major blood banks collect between 3,000 to 5,000 units and district level blood banks collect up to 3,000 units annually.

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

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

Table 2 - Scoring details and weight

The scoring pattern was different based on the category of blood banks that are: 1. Blood banks with component separation facility (n=1,271) and, 2. Blood banks without component separation facility (n=1,222). 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 2,760 blood banks in the country in 2015 (CDSCO, 2015). However, the assessment exercise identified 2,626 functional blood banks across the country excluding 46 military blood banks. Of the 2,626 blood banks, 1,131(43%) were supported by National AIDS Control Organization (NACO), Ministry of Health and Family Welfare, Government of India and the remaining 1,495 were Non-NACO blood banks. There is an addition of five blood banks to the 1,126 NACO supported blood banks, recorded in the preliminary assessment of NACO supported blood banks in July 2016, as they have recently reported as being NACO supported. Of the total functional blood banks, 2,493 blood banks (1,119 NACO supported - 98.9% and 1,374 Non-NACO - 91.9%) which have submitted the assessment forms in complete were included in the analysis.

Table - 3 indicates the state wise details of all the blood banks in the country, including the description of NACO supported and Non-NACO blood banks. Maharashtra (308) had the highest number of blood banks followed by Tamil Nadu (265), Uttar Pradesh (248), Karnataka (185), Kerala (166), Telangana (153), Gujarat (134), Madhya Pradesh (133), Andhra Pradesh (125), West Bengal (115) and Rajasthan (102). In terms of NACO supported blood banks, Maharashtra (122) had the highest number of blood banks, followed by Tamil Nadu (95), Uttar Pradesh (89), Gujarat (77), Karnataka (66), West Bengal (63), Madhya Pradesh (62), Andhra Pradesh (61), Odisha (58), and Rajasthan (50).

Around 61% (1,592) of all the blood banks(n=2,626) in the country were in 8 states that are, Maharashtra (11.7%), Tamil Nadu (10.1%), Uttar Pradesh (9.4%), Karnataka (7%), Kerala (6.3%), Telangana (5.8%), Gujarat (5.1%), and Madhya Pradesh (5%).

State	NACO Supported	%	Non-NACO	%	Total
A & N	1	50.0	1	50.0	2
Andhra Pradesh	61	48.8	64	51.2	125
Arunachal Pradesh	8	80.0	2	20.0	10
Assam	26	41.9	36	58.1	62
Bihar	39	54.2	33	45.8	72
Chandigarh	4	100.0	0	0.0	4
Chhattisgarh	16	30.8	36	69.2	52
DNH	1	100.0	0	0.0	1
Daman and Diu	2	100.0	0	0.0	2
Delhi	20	30.3	46	69.7	66
Goa	3	60.0	2	40.0	5
Gujarat	77	57.5	57	42.5	134
Haryana	24	33.3	48	66.7	72
Himachal Pradesh	14	70.0	6	30.0	20

Table -3 State wise description of blood banks

Jammu & Kashmir	23	85.2	4	14.8	27
Jharkhand	23	59.0	16	41.0	39
Karnataka	66	35.7	119	64.3	185
Kerala	45	27.1	121	72.9	166
Lakshadweep	0	0.0	1	100.0	1
Madhya Pradesh	62	46.6	71	53.4	133
Maharashtra	122	39.6	186	60.4	308
Manipur	3	60.0	2	40.0	5
Meghalaya	6	100.0	0	0.0	6
Mizoram	10	100.0	0	0.0	10
Nagaland	3	75.0	1	25.0	4
Odisha	58	72.5	22	27.5	80
Puducherry	5	29.4	12	70.6	17
Punjab	43	44.8	53	55.2	96
Rajasthan	50	49.0	52	51.0	102
Sikkim	2	66.7	1	33.3	3
Tamil Nadu	95	35.8	170	64.2	265
Telangana	43	28.1	110	71.9	153
Tripura	6	50.0	6	50.0	12
Uttar Pradesh	89	35.9	159	64.1	248
Uttarakhand	18	75.0	6	25.0	24
West Bengal	63	54.8	52	45.2	115
INDIA	1,131	43.1	1,495	56.9	2,626

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



Considering the number of blood banks per one million population, states such as, Bihar (0.7 blood banks), Jharkhand (1.2), Uttar Pradesh (1.2), West Bengal (1.3), Rajasthan(1.5), Madhya Pradesh (1.8), Manipur (1.8), Odisha (1.9), Assam (2), Nagaland(2), Meghalaya(2) and Chhattisgarh(2) recorded less than the national average of 2.2 blood banks per 1,000,000 (one million) population.

4.1 Basic details of blood banks (n=2,493)

As indicated earlier, 2,493 blood banks (1,119 NACO supported and 1,374 Non-NACO) that submitted the assessment forms were included in the analysis.

4.1.1 Category of Blood Banks: Around 51% (1,271) of the blood banks in the country had component separation facility, of which, 431 (33.9%) were NACO supported blood banks. Of the 1,222 blood banks that were without component separation facility, 56.3% (688) were NACO supported blood banks.

Specifics	Description	NACO Supported	Non-NACO	Total
Type of BB	With components	431 (38.5%)	840 (61.1%)	1271 (51.0%)
Type of DD	Without components	688 (61.5%)	534 (38.9%)	1222 (49%)
	NGO/Trust/Charitable	243 (21.7%)	704 (51.2%)	947 (38%)
Ownership	Private	0 (0%)	597 (43.4%)	597 (23.9%)
	Public	876 (78.3%)	73 (5.3%)	949 (38.1%)
Licence	Valid	617 (55.1%)	1021(74.3%)	1638 (65.7%)
Licence	Under Renewal	502 (44.9 %)	353 (25.7%)	855 (34.3%)
	Attached to Hospital	964 (86.1%)	955 (69.5%)	1919(77%)
Attachment	Attached to lab	0	23 (1.7%)	23(0.9%)
	Stand alone	155(13.9%)	396(28.8%)	551(22.1%)

Table-4 Basic details of blood banks

At the state level, Delhi had the highest percentage of blood component separation units (60; 91%), followed by Maharashtra (240, 81.4%), Chandigarh (3; 75%), Karnataka (120; 65.9%), Puducherry (10; 58.8%), Uttar Pradesh (140; 56.7%), Andhra Pradesh (65; 55.1%), Haryana (34; 55.7%), Telangana (68; 55.3%), Rajasthan (53; 53.5%), Chhattisgarh (22; 53.7%).

Larger states like Jharkhand (13.5%), Odisha (17.1%), Bihar (19.4%), Assam (21.8%), Madhya Pradesh (28%), Uttarakhand (33.3%), West Bengal (41.4%), and Tamil Nadu (43%) had a low percentage of blood component separation facility. Dadra and Nagar Haveli had one blood bank that had component separation facility.

4.1.2 Ownership: The public and not-for-profit sector owned each 38% of the blood banks in the country and private sector owned around 24% (598) of blood banks. The majority (876; 78.3%) of NACO supported blood banks were owned by the public sector and the remaining 21.7% (243) 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 (47.9%) of blood component separation facility than the public (23.2%) and private sector (28.9%). Among the NACO supported blood banks, the not-for-profit sector had a higher (61.3%) proportion of component separation facilities compared to the public sector (32.2%).

Around 55% of all the not-for-profit blood banks (n=947) were clustered in five states which are Maharashtra (21.2%), Tamil Nadu (9.7%), Gujarat (8.7%), Karnataka (7.8%), and Uttar Pradesh (7.6%). Around 50% of all the public owned blood banks were clustered in seven states which are Tamil Nadu (9.7%), Uttar Pradesh (9.5%), Maharashtra (7.9%), West Bengal (7.8%), Madhya Pradesh (6.2%), Rajasthan (5.1%), and Odisha (4.7%). Similarly, 58% of all the private owned blood banks were in six states which are Uttar Pradesh (14.2%), Karnataka (10.9%), Kerala (9.7%), Tamil Nadu (9.7%), Telangana (7.2%), and Madhya Pradesh (6.4%). (Refer Table - 5)

State	Public	%	Not-for-profit	%	Private	%	Total
A & N	1	50.0	1	50.0	0	0.0	2
Andhra Pradesh	35	29.7	62	52.5	21	17.8	118
Arunachal Pradesh	8	88.9	1	11.1	0	0.0	9
Assam	30	54.5	9	16.4	16	29.1	55
Bihar	34	47.2	22	30.6	16	22.2	72
Chandigarh	3	75.0	1	25.0	0	0.0	4
Chhattisgarh	18	43.9	14	34.1	9	22.0	41
DNH0	0.0	1	100.0	0	0.0	1	
Daman and Diu	2	100.0	0	0.0	0	0.0	2
Delhi	22	33.3	20	30.3	24	36.4	66
Goa	3	60.0	0	0.0	2	40.0	5
Gujarat	27	20.5	82	62.1	23	17.4	132
Haryana	23	37.7	12	19.7	26	42.6	61
Himachal Pradesh	17	85.0	2	10.0	1	5.0	20
Jammu & Kashmir	24	88.9	2	7.4	1	3.7	27
Jharkhand	20	54.1	5	13.5	12	32.4	37
Karnataka	43	23.6	74	40.7	65	35.7	182
Kerala	35	21.5	70	42.9	58	35.6	163
Madhya Pradesh	59	44.7	35	26.5	38	28.8	132
Maharashtra	75	25.4	201	68.1	19	6.4	295

Table-5	5 State	wise	list	of	blood	banks	by	Ownersh	ip
							~		

Manipur	4	80.0	1	20.0	0	0.0	5
Meghalaya	4	66.7	2	33.3	0	0.0	6
Mizoram	7	70.0	3	30.0	0	0.0	10
Nagaland	3	100.0	0	0.0	0	0.0	3
Odisha	45	64.3	20	28.6	5	7.1	70
Puducherry	5	29.4	6	35.3	6	35.3	17
Punjab	43	44.7	25	26.0	28	29.2	96
Rajasthan	48	48.5	37	37.4	14	14.1	99
Sikkim	2	66.7	0	0.0	1	33.3	3
Tamil Nadu	92	38.0	92	38.0	58	24.0	242
Telangana	27	22.0	53	43.1	43	35.0	123
Tripura	10	83.3	0	0.0	2	16.7	12
Uttar Pradesh	90	36.4	72	29.1	85	34.4	247
Uttarakhand	16	66.7	4	16.7	4	16.7	24
West Bengal	74	66.1	18	16.1	20	17.9	112
INDIA	949	38.1	947	38.0	597	23.9	2493

4.1.3 Organizational Attachment: The majority of the blood banks (1919; 77%)) were attached to hospitals, 1% (23) were attached to laboratories and the remaining 551 (22.1%) were standalone blood banks.

The majority of the NACO supported blood banks (964; 86.1%) were attached to hospitals and only 13.9% (155) were standalone blood banks. Though 69.5% (955) of the Non-NACO supported blood banks were attached to hospitals, a significant number (396; 28.8%) of Non-NACO supported blood banks were standalone and 23 (1.7%) were attached to laboratories. Further analysis indicated that 98.6% (936) of the blood banks in the public sector, 52.8 % (500) of the blood banks in the not-for-profit sector, and 80.9%(483) of the blood banks in the private sector were attached to hospitals. In the not-for-profit sector 46.3% (438) 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 (65.7%) had a valid and current license, and the remaining 34.3% had applied for renewal. Around 55% (617) of NACO supported and 74.3% (1,021) of Non-NACO supported blood banks had a valid and active license. Similarly, 74.2% (443) of the private blood banks, 72.4% (686) of the not-for-profit blood banks, and 53.6% (509) of the public blood banks had a valid and active license.





The majority of those blood banks (66.9%) which have reported as "deemed renewal" had their last inspection by licencing authority during the last one year; 17% had their inspection between the last 1 to 2 years, 6.2% had between 2 to 3 years, 2.3% had between 3 to 4 years and 4.7% had their inspection before 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 India currently needs around 12.8 million 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 11,645,791 of which 71.9% (8,378,692) units were through voluntary blood donations and the remaining were from replacement donations.



Fig-3 Annual collection and Voluntary donation

Fig-4 Type of blood donation (Voluntary vs Replacement donation %)



The average annual collection of blood units of all the blood banks in the country was 4789 units. The average annual collection of NACO supported blood banks was found to be higher (6,219 units) than the Non-NACO blood banks (3,583 units).

State	NACO supported	Non-NACO	A11 BBs
A & N	3765.0	330.0	2047.5
Andhra Pradesh	4742.7	3640.3	4210.8
Arunachal Pradesh	619.5	77.0	559.2
Assam	5542.7	2470.9	3923.0
Bihar	2838.4	2044.9	2487.0
Chandigarh	22299.8	NA	22299.8
Chhattisgarh	5781.6	4669.8	5086.7
DNH	7497.0	NA	7497.0
Daman and Diu	849.0	NA	849.0
Delhi	15402.1	5173.3	8273.0
Goa	6479.7	187.0	4906.5
Gujarat	7943.2	3714.2	6219.0
Haryana	7228.8	4516.4	5601.4
Himachal Pradesh	2700.0	757.7	2086.6
J & K	3451.0	1031.5	3092.6
Jharkhand	5786.9	2440.9	4430.4
Karnataka	6211.7	3434.6	4434.4
Kerala	6286.2	1737.6	3008.9
Madhya Pradesh	5138.6	3008.0	4056.4
Maharashtra	6864.9	4090.5	5226.8
Manipur	6548.7	1222.0	4418.0
Meghalaya	2256.0	NA	2256.0
Mizoram	2465.8	NA	2465.8
Nagaland	3018.3	-	3018.3
Odisha	6459.8	2449.4	5587.9
Puducherry	6418.3	1269.9	2642.8
Punjab	4899.0	3807.9	4296.6
Rajasthan	8780.8	4822.2	6801.5
Sikkim	2113.5	2195.0	2140.7
Tamil Nadu	4102.0	3189.7	3550.0
Telangana	4511.5	3145.1	3635.6
Tripura	4734.8	1720.5	3981.3
Uttar Pradesh	5889.8	3762.0	4564.4
Uttarakhand	5797.6	2019.8	4812.1
West Bengal	11170.7	8316.8	9951.3
INDIA	6219.3	3,583.2	4,788.6

Table-6 Average Annual Collection

Similarly, the blood banks with component separation units recorded a higher average collection of 7,035 units compared to blood banks without blood component separation units which was 2,432 units. However, the variation in the collection was found to be very high across and within districts and states.

The NACO supported blood banks collected 59.4% (6,915,963 units) of the total collection, of which 80.5% (5,568,143) units were through voluntary blood donation. The Non-NACO supported blood banks collected 4,729,828 (40.5%) units of which 59.4% (2,810,549) units were through voluntary blood donation. Blood Banks with component separation facility collected the majority (75.2%) of blood units (87,589,98) and the remaining (2,886,793) were collected by blood banks without the component facility. Similarly, blood banks owned by public sector collected 43.5% (5,053,320) of the total collection followed by the not-for-profit sector 39% (4,542,790) and private sector blood banks (17.5%, 2,049,681).

Table-7 indicates the state-wise details of the total annual collection, voluntary and replacement donation in the country.

States	Total Voluntary donation	Replacement donation	Annual Collection	VBD %
A & N	3371	724	4095	82.3
Andhra Pradesh	335376	144657	480033	69.9
Arunachal Pradesh	5021	12	5033	99.8
Assam	103435	112331	215766	47.9
Bihar	88241	85850	174091	50.7
Chandigarh	76778	12421	89199	86.1
Chhattisgarh	90335	113133	203468	44.4
DNH	7497	0	7497	100.0
Daman and Diu	1576	122	1698	92.8
Delhi	243596	302420	546016	44.6
Goa	15333	4293	19626	78.1
Gujarat	627156	181318	808474	77.6
Haryana	229561	106520	336081	68.3
Himachal Pradesh	32260	7386	39646	81.4
Jammu & Kashmir	47643	35856	83499	57.1
Jharkhand	83659	80266	163925	51.0
Karnataka	565844	210173	776017	72.9
Kerala	400473	83964	484437	82.7
Madhya Pradesh	378906	132199	511105	74.1
Maharashtra	1481484	49962	1531446	96.7

Table -7 Annual blood collection and percentage of VBD

Manipur	9060	13030	22090	41.0
Meghalaya	5178	8358	13536	38.3
Mizoram	18543	6115	24658	75.2
Nagaland	7038	2017	9055	77.7
Odisha	277932	107636	385568	72.1
Puducherry	20745	18897	39642	52.3
Punjab	277166	135312	412478	67.2
Rajasthan	436800	229748	666548	65.5
Sikkim	4212	2210	6422	65.6
Tamil Nadu	786626	58282	844908	93.1
Telangana	265857	159507	425364	62.5
Tripura	30304	1546	31850	95.1
Uttar Pradesh	416965	660231	1077196	38.7
Uttarakhand	97352	13327	110679	88.0
West Bengal	907369	187276	1094645	82.9
INDIA	8,378,692	3,267,099	11,645,791	71.9

Fig-5 Annual collection per 100 population - State wise



The annual collection of blood units per 100 individuals was found to be around 1% in the country, which is 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 states. Bihar state collected only 0.2 units of blood per 100 population followed by Arunachal Pradesh (0.4), Meghalaya (0.5), Nagaland (0.5),
Jharkhand (0.5), and Uttar Pradesh (0.5). Nineteen states in the country recorded an annual collection of more than 1 unit per 100 population. (Refer Fig-5)

Figure 6 illustrates the state wise comparative information of annual collection per 100 population and number of blood banks per one million population. This indicates that the country had around 2.2 blood banks per million population that collected around one unit per 100 population at the ratio of 2.2 BB: 1 blood unit. The ratio was much higher in Chandigarh which was 3.8:8.5 which indicates that the state collected relatively more blood with less number of blood banks proportionate to the population. The ratio in Puducherry state had more blood banks but relatively less collection that indicates that the state collected less proportionate to the population.



Fig 6- Annual collection per 100 population Vs BBs per 1 million- State wise

4.2.2 Voluntary blood donation: As depicted in Figure-7, nineteen states have recorded more than the national average of 71.9%. States such as Dadra and Nagar Haveli, Arunachal Pradesh, Maharashtra, Tripura, Tamil Nadu, Daman and Diu, Uttarakhand, Chandigarh, West Bengal, Kerala, Andaman and Nicobar, and Himachal Pradesh reported more than 80% voluntary blood donation. States such as Meghalaya, Uttar Pradesh, Manipur, Chhattisgarh, Delhi, Assam, Bihar, Jharkhand, Puducherry, and Jammu &Kashmir reported less than 60% of voluntary blood donation during January to December 2015.



Fig-7 Percentage of voluntary blood donation by state (Overall)

In terms of NACO supported blood banks, eighteen states have recorded a higher proportion of voluntary donation which is above the national average of 80.5%. Dadra and Nagar Haveli, Tamil Nadu, Arunachal Pradesh, Maharashtra, Tripura, Haryana, Madhya Pradesh, Uttarakhand, Daman and Diu, and Kerala reported more than 90% voluntary blood donation. States such as Assam, Uttar Pradesh , Puducherry , Jammu and Kashmir, Chhatisgarh, Delhi, Manipur, and Meghalaya reported less than 60% of voluntary donation during January to December 2015.



Fig-8 Percentage of voluntary blood donation by state (NACO supported)

Among Non-NACO blood banks, only five states recorded more than 80% of voluntary donation - Arunachal Pradesh, Maharashtra, Tamil Nadu, Andaman and Nicobar, and Tripura. However, states such as Himachal Pradesh, Uttarakhand, Telangana, Punjab, Puducherry, Madhya Pradesh, Haryana, Chhattisgarh, Delhi, Goa, Bihar, Manipur, Assam, Uttar Pradesh, and Jharkhand reported less than 50% of voluntary blood donation during January to December 2015.



Fig-9 Percentage of voluntary blood donation by state (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 seropositivity percentage of TTIs has come down significantly over the years.



Fig-10 Transfusion Transmitted Infections (%) - Jan-Dec 2015

The seropositivity of TTI among blood donors in the year 2015 is depicted in Fig-10. HIV positivity was found to be 0.14%, Hepatitis C was 0.34%, Hepatitis-B 0.87%, Syphilis 0.17% and Malaria 0.06%. However, there is a huge variation between states.

Though HIV and HCV positivity rates did not indicate much difference between NACO and Non-NACO blood banks. The HBV positivity was found to be higher in NACO supported blood banks. Syphilis and Malaria positivity rates were recorded higher in Non-NACO blood banks.

	Transfusion Transmitted Infections %					
Category of BB	HIV	HCV	HBV	Syphilis	Malaria	
NACO Supported BBs	0.14	0.32	0.93	0.14	0.04	
Non-NACO	0.14	0.36	0.79	0.22	0.09	
Overall	0.14	0.34	0.87	0.17	0.06	

Table-8 Transfusion Transmitted Infections (%)

4.3.1 Transfusion Transmitted Infections by Category of blood banks: The blood banks with component facility indicated a higher positivity of HIV (0.15%), HCV (0.37%) and HBV (0.91%). However, Syphilis (0.18%) and Malaria (0.17) were found to be higher in blood banks without component facility compared to blood banks with the component facility.

	Transfusion Transmitted Infections %					
Category of BB	HIV	HCV	HBV	Syphilis	Malaria	
BBs with component facility	0.15	0.37	0.91	0.17	0.02	
BBs without component facility	0.11	0.23	0.75	0.18	0.17	
Overall	0.14	0.34	0.87	0.17	0.06	

Table-9 Transfusion Transmitted Infections by category of blood banks

Fig-11 HIV seropositivity – By state (%)



The majority of states indicated lower HIV positivity than the national HIV positivity level of 0.14%. However, Puducherry(0.37%), Mizoram(0.30%), West Bengal(0.26%), Nagaland(0.26%), Maharastra(0.21%), Delhi (0.2%), Andhra Pradesh(0.18%), Meghalaya(0.16%), Bihar (0.16%), and Manipur(0.15%) recorded a higher positivity than national average. States like, Himachal Pradesh, Arunachal Pradesh, Jammu and Kashmir, Tamil Nadu, Kerala, Chandigarh, Sikkim, Madhya Pradesh, Jharkhand, Dadra and Nagar Haveli, Tripura, and Rajasthan recorded less than 0.1% HIV positivity.

When considering Hepatitis C infection, states like Punjab (1.35%), Mizoram (1.24%), Manipur (0.83%), Haryana (0.80%), Uttarakhand (0.67%), Chandigarh (0.56%), Puducherry (0.55%), Delhi (0.54%), West Bengal (0.52%), Uttar Pradesh (0.49%), Meghalaya (0.47%), and Daman and Diu (0.35%) recorded a positivity level higher than the national average of 0.34%.





Hepatitis B was found to be higher than the national average of 0.87% in states like Puducherry (2.12%), Dadra and Nagar Haveli(1.79%), Bihar(1.42%), Andhra Pradesh(1.39%), Tripura(1.25%), Rajasthan(1.21%), Madhya Pradesh(1.14%), Delhi(1.06%), Maharashtra(1.02%), Mizoram (0.94%), Karnataka (0.94%), West Bengal (0.90%), and Uttar Pradesh (0.90%). Twenty states have recorded a positivity level less than the national average of 0.87%. Specifically, Kerala, Jammu and Kashmir, Nagaland, and Goa recorded less than 0.50%.



Fig-13 HBV seropositivity – By state (%)

Syphilis seropositivity was found to be higher than the national average of 0.17% in states like Arunachal Pradesh(0.97%), Meghalaya(0.73%), Punjab(0.49%), Madhya Pradesh(0.36%), West Bengal (0.35%), Rajasthan(0.31%), Chhattisgarh(0.30%), Assam(0.30%), Dadra and Nagar Haveli(0.28%), Jammu and Kashmir(0.23%), Delhi (0.22%), Gujarat(0.20%) and Sikkim (0.19%). Twenty one states recorded less than the national average.



Fig-14 Syphilis seropositivity- By State (%)

The majority of the states indicated a lower positivity of Malaria than the national positivity of 0.06% whereas states like Andaman and Nicobar Islands, Arunachal Pradesh, Madhya Pradesh, Telangana, Uttarakhand, Odisha, Jharkhand, and Bihar recorded a higher positivity than the national average.





4.4 Component Separation

As depicted in Figure -16, around 71% of blood units collected by blood banks with component separation facilities, were used for component separation in India. The percentage of component separation was higher (75.4%) in Non-NACO blood banks compared to NACO supported blood banks (67.3%).



Fig-16 Total blood collection and component separation

State	Total Annual Collection	Total annual collection by BCSUs	Percentage of component separation
A & N	4095	3765	29.0
Andhra Pradesh	480033	376355	42.0
Arunachal Pradesh	5033	0	0
Assam	215766	107608	37.6
Bihar	174091	85325	47.3
Chandigarh	89199	84984	96.9
Chhattisgarh	203468	136447	42.4
DNH	7497	7497	100
Daman and Diu	1698	1568	26.4
Delhi	546016	536181	87.8
Goa	19626	16249	44.1
Gujarat	808474	633787	79.8
Haryana	336081	223907	67.8
Himachal Pradesh	39646	23154	25.4
J & K	83499	63985	49.4
Jharkhand	163925	92756	66.8

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

Karnataka	776017	704560	80.2
Kerala	484437	415748	83.2
Madhya Pradesh	511105	235200	67.7
Maharashtra	1531446	1395065	84.9
Manipur	22090	14670	97.4
Meghalaya	13536	8326	72.7
Mizoram	24658	16321	79.9
Nagaland	9055	6462	0.0
Odisha	385568	171528	36.3
Puducherry	39642	34733	96.9
Punjab	412478	298146	54.1
Rajasthan	666548	471405	79.1
Sikkim	6422	2195	69.7
Tamil Nadu	844908	570309	72.8
Telangana	425364	340840	68.3
Tripura	31850	16423	48.0
Uttar Pradesh	1077196	896693	63.4
Uttarakhand	110679	74137	85.0
West Bengal	1094645	692669	54.9
INDIA	11,645,791	8,758,998	70.9

The percentage of component separation out of the total collection was more than 80% in Dadra and Nagar Haveli, Manipur, Puducherry, Chandigarh, Delhi, Uttarakhand, Maharashtra, Kerala, and Karnataka. This was reported less than 50% in states like Nagaland, Himachal Pradesh, Daman and Diu, Andaman and Nicobar, Odisha, Assam, Andhra Pradesh, Chhattisgarh, Goa, Bihar and Tripura.



Fig-17 Percentage of component separation - By state (All BBs)

The percentage of component separation in NACO supported blood banks is illustrated in Figure-18 which indicates 9 states recording more than 80% and 11 states reporting less than 50% of component separation.



Fig-18 Percentage of component separation – By state (NACO supported)

States such as Sikkim and Arunachal Pradesh did not have any NACO supported blood banks with component separation facility.

4.5 Quality Management Systems

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

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

The assessment captured several parameters that influence the quality of service provision. Some of the key parameters are mentioned in Table -11. The majority of blood banks (91.5%) reported that they adhered to the NBTC guidelines. Availability of document control system was reported by less than 50% of the blood banks in

the country. Around 42% of NACO supported blood banks and 55% 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.

Quality Parameters	NACO/N	ON-NACO	All Blood
	NACO supported	Non-NACO	Banks
Compliance with NBTC guidelines	1050	1231	2281
	93.8%	89.6%	91.5%
Availability of Documental Control System (DCS)	467	756	1223
	41.7%	55.0%	49.1%
SOPs for Technical Processes	1055	1345	2400
	94.3%	97.9%	96.3%
IQC for IH	794	1149	1943
	71.0%	83.6%	77.9%
IQC for TTI	609	690	1299
	54.4%	50.2%	52.1%
QC for kits, reagents and blood bags	882	1268	2150
	78.8%	92.3%	86.2%
EQAS for IH	79	236	315
	7.1%	17.2%	12.6%
EQAS for TTI	88	192	280
	7.9%	14.0%	11.2%
NABH accreditation for blood banks	25	48	73
	2.2%	3.5%	2.9%
Availability of designated and trained Quality	243	702	945
Manager	21.7%	51.1%	37.9%
Availability of designated and trained Technical	308	894	1202
Manager	27.5%	65.1%	48.2%
Programme for regular Equipment maintenance	834	1319	2153
	74.5%	96.0%	86.4%
Equipment calibration as per regulatory requirement	874	1335	2209
	78.1%	97.2%	88.6%
Total no of blood banks	1,119	1,374	2,493
	100.0%	100.0%	100.0%

Table -11 Availability of quality parameters in blood banks

At the national level, Internal Quality Control (IQC) for Immunohematology was reported by 78% of the blood banks and IQC for TTIs was reported by 52% 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 12.6% for immunohematology and 11.2% for TTIs. Only 73 (2.9%) blood banks out of the total 2493 blood banks that participated in the assessment were accredited by National Accreditation Board for Hospitals & Healthcare Providers (NABH).

Designated and trained Quality Managers and Technical managers were available only in 37.9% and 48.2% 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. 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 country was 62 (SD: 11.19). The Non-NACO supported blood banks scored slightly higher (62.68; SD: 10.63) than the NACO supported blood banks (Refer Table - 12). It is important to understand that around 78% of all the blood banks under NACO supported were in the public sector and present across sub-divisional and divisional/district hospitals catering all segments of the population including rural areas. Whereas, the majority (95%) of the Non-NACO blood banks were in the private and not-for-profit sector. Essentially all the private sector blood banks were coming under the Non-NACO category which could be a reason for the minor difference in the score.

Type of BB	Ν	Mean	SD
NACO supported	1119	61.18	11.79
Non-NACO	1374	62.68	10.63
Total	2493	62.00	11.19

Table-12	Mean	Assessment	score
Table-12	Mean	Assessment	scot

At the national level, the majority of blood banks (1920; 77%) scored between 35 to 70, followed by 21% (530) which scored above 70, and 2% (43) scored less than or equal to 35.



Fig-19 Categorisation of blood banks (n=2493)

An equal proportion of 77% of NACO supported and Non-NACO blood banks scored between 35 and 70. Around, 21% of NACO supported blood banks and 22% of Non-NACO blood banks scored more than 70 Score or Percentage? (Refer Figure 20; Figure 21)



Among the states, Chandigarh (80.9) scored the highest and Arunachal Pradesh (41.9) scored the least. Excluding Chandigarh and Arunachal Pradesh, the mean scores of all the other states ranged from 69.3 to 50.3 with relatively less variations between states. Although only 13 had mean scores over the national average, a majority (59.6%) of the blood banks were located in these states/UTs.



Fig-22 Mean assessment score - By state (All BBs)

Though the difference in the mean score at the national level was only 1.5 between NACO and Non-NACO supported blood banks, the mean scores of NACO supported blood banks were higher than the Non-NACO blood banks in 15 states.

The difference in the score was more than 5 in NACO supported blood banks in states such as Goa, Haryana, Jammu & Kashmir, Sikkim, and Uttarakhand. Among the 15 states that scored higher mean score than the Non-NACO blood banks, the difference was more than 5 in states such as Bihar, Chhattisgarh, Punjab, Tamil Nadu and Uttar Pradesh.

State	NACO Supported	Non-NACO	TOTAL
Andaman & Nicobar	52.0	51.0	51.5
Andhra Pradesh	61.3	61.7	61.5
Arunachal Pradesh	41.6	44.0	41.9
Assam	59.5	64.0	61.9
Bihar	46.8	54.4	50.3
Chandigarh	80.9	NA	80.9
Chhattisgarh	49.2	56.7	53.8
DNH	62.5	NA	62.5
Daman and Diu	50.3	NA	50.3
Delhi	71.0	68.6	69.3
Goa	64.0	54.5	60.2
Gujarat	70.5	65.5	68.4
Haryana	68.6	63.4	65.5
Himachal Pradesh	54.5	57.4	55.4
Jammu & Kashmir	59.6	52.5	58.5
Jharkhand	61.2	60.6	60.9
Karnataka	67.8	65.3	66.2
Kerala	66.3	64.5	65.0
Madhya Pradesh	59.5	59.7	59.6
Maharashtra	66.7	65.5	66.0
Manipur	57.7	61.5	59.2
Meghalaya	65.0	NA	65.0
Mizoram	57.4	NA	57.4
Nagaland	55.2	NA	55.2
Odisha	56.1	58.8	56.7
Puducherry	56.9	59.6	58.8
Punjab	57.4	64.6	61.4
Rajasthan	63.9	60.5	62.2

Table -13 Mean assessment score - By state (NACO supported Vs Non-NACO)

Sikkim	62.5	57.0	60.7
Tamil Nadu	58.9	64.2	62.1
Telangana	62.1	62.1	62.1
Tripura	58.7	46.8	52.8
Uttar Pradesh	52.5	58.7	56.5
Uttarakhand	60.2	52.3	58.2
West Bengal	62.1	63.9	62.9
INDIA	61.2	62.7	62.0

The number of blood banks (by state) that scored less than or equal to 35 is mentioned in Table-14. Most of the blood banks were in Uttar Pradesh (13; 5% of all blood banks), followed by Bihar (6; 8% of all blood banks) and Odisha (3; 4% of all blood banks).

State	NACO supported	Non-NACO	Total
Uttar Pradesh	10	3	13
Bihar	4	2	6
Odisha	3	-	3
Arunachal Pradesh	2	-	2
Punjab	2	-	2
Gujarat	-	2	2
Karnataka	-	2	2
Andhra Pradesh	1	-	1
Chhattisgarh	1	-	1
Jharkhand	1	-	1
Madhya Pradesh	1	1	2
Maharashtra	1	-	1
Rajasthan	1	-	1
Tamil Nadu	-	1	1
Haryana	-	1	1
Kerala	-	1	1
Telangana	-	1	1
Tripura	-	1	1
Uttarakhand	-	1	1
TOTAL	27	16	43

Table-14 Number of blood banks scored <=35

The number of blood banks (by state) that scored more than 70 is mentioned in Table-15. Of the 530 blood banks that scored more than 70 score, 297 (56%) were Non-NACO supported blood banks. The majority of

blood banks that scored above 70 were from Maharashtra (90) followed by Gujarat (60), Karnataka (55), Tamil Nadu (53), Kerala (42), Delhi (34), and Rajasthan (22). These 6 States constitute 50% of the total blood banks that scored more than 70.

Among these states, the proportion of NACO supported blood banks that scored above 70 were relatively higher in Delhi (65%) and Gujarat (54.5%).

State	NACO Supported	Non-NACO	TOTAL
Maharashtra	44	46	90
Gujarat	42	18	60
Karnataka	22	33	55
Tamil Nadu	8	45	53
Kerala	12	30	42
Delhi	13	21	34
Rajasthan	13	9	22
West Bengal	11	11	22
Uttar Pradesh	6	15	21
Punjab	5	14	19
Haryana	10	8	18
Telangana	6	12	18
Madhya Pradesh	9	8	17
Andhra Pradesh	6	10	16
Assam	3	9	12
Jharkhand	6	1	7
Odisha	5	2	7
Uttarakhand	5	1	6
Chandigarh	4	-	4
J & K	2	-	2
Puducherry	-	2	2
Bihar	-	1	1
Manipur	-	1	1
Meghalaya	1	-	1
TOTAL	233	297	530

Table-15 Number of blood banks scored above 70 – by state

4.6.1 Assessment score by Category of blood banks: The mean score of blood banks with component facilities was found to be higher (64.69; SD: 10.84) than the mean score of those without component facilities (59.22; SD: 10.87). No significant differences are observed between NACO and Non-NACO supported Blood banks.

Type of BBs	NACO Supported		Non-NACO			Total			
	Ν	Mean	SD	Ν	Mean	SD	Ν	Mean	SD
Blood Component Separation Units	431	64.58	11.70	840	64.75	10.38	1271	64.69	10.84
Without Components separation facility	688	59.05	11.35	534	59.43	10.22	1222	59.22	10.87

Table-16 Mean assessment score by category of blood banks

Among blood banks that scored <=35, the majority were without blood component separation facility (34), as compared to only 9 blood banks with component separation facility (Refer figure 23 and 24). Blood banks with component preparation facility were twice as likely to score more than 70 as compared those without component facility.

Fig-23 BBs with component –Score (n=1271) Fig-24 BBs without component-Score (n=1222)



4.6.2 Assessment score by Ownership: The mean assessment score of not-for-profit (NGO/Trust/Charitable) owned blood banks (64.18; SD: 10.52) was found to be higher than the public sector blood banks (59.16; SD: 11.30). It was also found that there were more public sector blood banks (24 blood banks) in the less than or equal to 35 category compared to only 10 blood banks from not-for-profit owned blood banks.

However, NACO supported blood banks run by not-for-profit sector had scored higher (67.30; SD: 11.27) compared to Non-NACO supported blood banks NGO/Trust/Charitable blood banks (63.11; SD: 10.03).

Ownership	NA	NACO Supported		Non-NACO			Total		
	Ν	Mean	SD	Ν	Mean	SD	Ν	Mean	SD
NGO/Trust/charitable	243	67.30	11.27	704	63.11	10.03	947	64.18	10.52
Private	-	-	-	597	63.09	11.11	597	63.09	11.11
Public	876	59.48	11.37	73	55.25	9.62	949	59.16	11.30

Table-17 Mean assessment score by Ownership

Table-18 Mean assessment scores categories by Ownership

Ownership	<=35	36 to 70	Above 70	Total
Public	24	779	146	949
	2.5%	82.1%	15.4%	100.0%
NGO/Trust/Charitable	10	695	242	947
	1.1%	73.4%	25.6%	100.0%
Private	9	446	142	597
	1.5%	74.7%	23.8%	100.0%
Overall	43	1920	530	2493
	1.7%	77.0%	21.3%	100.0%

4.6.3 Assessment score of Private Sector blood banks: Irrespective of the NACO support status, 62% (1544) blood banks were owned by private sector, of which, 947 (61.3%) were owned by not-for-profit sector such as, NGO, Trust, and charitable organizations. The mean score of private sector owned blood banks including not-for-profit sector was 63.75 (SD: 10.76) and the mean score of public owned blood banks was 59.15 (11.29). Among the private sector, not-for-profit sector (64.18; SD: 10.51) scored slightly higher than the other private blood banks (63.09; SD: 11.11).

Nevertheless, it is also important to note that the average annual collection was higher (5,405 units) in public owned blood banks compared to private blood banks (4,404 units). Similarly, the percentage of voluntary blood donation was higher in public owned blood banks (78.2%) compared to the private blood banks (67.2%). Of the total private blood banks, 976(63.2%) had component separation facility whereas only 295 (31%) of public blood banks had component separation facility.

4.6.4 Assessment score by Annual collection: The mean assessment score of blood banks that collected more than 5000 blood units (66.98; SD: 11.20) was found to be higher than those which collected between 3001 to 5000 (63.31; SD: 9.45) and less than 3000 blood units (59.39; SD: 10.48).

Annual Collection	NA supp	CO orted	Non-NACO		Tot	tal
	Mean	SD	Mean	SD	Mean	SD
Up to 3000	57.29	11.22	60.68	9.78	59.39	10.48
3001 to 5000	60.08	9.34	65.66	8.84	63.31	9.45
Above 5000	66.14	11.51	68.34	10.58	66.98	11.20

Table-19 Mean assessment score by annual collection

4.6.5 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 supported blood banks have marginally scored higher than the NACO supported blood banks across all the categories.

% VBD	NACO supported		Non-NACO		Tot	tal
	Mean	SD	Mean	SD	Mean	SD
Less than 25	51.93	12.68	60.78	11.02	59.69	11.60
25 to 49	59.14	11.62	61.19	9.28	60.41	10.25
50 to 74	58.95	11.61	65.03	9.51	62.20	10.95
75 to 90	59.60	11.36	62.84	9.06	61.05	10.50
Above 90	63.45	11.21	65.57	10.00	64.32	10.78

Table-20 Mean assessment score by voluntary blood donation

4.6.6 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 the blood banks that were part of EQAS for immunohematology (75.35; SD: 8.92) as compared to those who were not enrolled (60.08; SD: 10.12). Similar situation was found among those blood banks that were part of EQAS for Transmitted Infections (76.32; SD: 8.34) as compared to those who were not enrolled (60.20; SD: 10.15).

Although more number of Non-NACO supported blood banks were enrolled in IH and TTI-EQAS, NACO supported blood banks had higher scores under IH-EQAS (78.54;SD:9.46) and TTI-EQAS (78.14;SD:8.54).

IH - EQAS	NAG	NACO Supported			Non-NACO			Total	
	Ν	Mean	SD	Ν	Mean	SD	Ν	Mean	SD
YES	79	78.54	9.46	236	74.29	8.48	315	75.35	8.92
NO	1040	59.86	10.87	1138	60.27	9.38	2178	60.08	10.12
TTI - EQAS	Ν	Mean	SD	Ν	Mean	SD	Ν	Mean	SD
YES	88	78.14	8.54	192	75.49	8.14	280	76.32	8.34
NO	1031	59.73	10.87	1182	60.60	9.47	2213	60.20	10.15

Table-21 Mean assessment score by EQAS enrolment

4.6.7Assessment score by Accreditation status: The mean score was found to be higher among blood banks that were accredited by National Accreditation Board of Hospitals and Health care Providers (NABH) in comparison to those that were not accredited. NACO supported blood banks accredited by NABH scored higher than Non-NACO NABH accredited blood banks.

Table-22 Mean assessment score by Accreditation

NABH	NAC	CO Suppor	rted	Non-NACO			,	Total	
Accreditation	Ν	Mean	SD	Ν	Mean	SD	Ν	Mean	SD
YES	25	87.12	5.85	48	83.25	6.17	73	84.58	6.30
NO	1094	60.59	11.21	1326	61.94	10.00	2420	61.33	10.58

However, only 25 out of the 1,119 NACO supported blood banks and 48 out of 1,374 Non-NACO blood banks have been accredited by NABH. Maharashtra (22), Gujarat (12), and Delhi (11) had the highest number of accredited blood banks.

The list of blood banks under different categories of score is given in Table- 23

	Score	category		
State	Up to 35	35 to 70	Above 70	TOTAL
A&N	0	2	0	2
Andhra Pradesh	1	101	16	118
Arunachal Pradesh	2	7	0	9
Assam	0	43	12	55
Bihar	6	65	1	72
Chandigarh	0	0	4	4
Chhattisgarh	1	40	0	41
DNH	0	1	0	1
Daman and Diu	0	2	0	2
Delhi	0	32	34	66
Goa	0	5	0	5
Gujarat	2	70	60	132
Haryana	1	42	18	61
Himachal Pradesh	0	20	0	20
J & K	0	25	2	27
Jharkhand	1	29	7	37
Karnataka	2	125	55	182
Kerala	1	120	42	163
Madhya Pradesh	2	113	17	132
Maharashtra	1	204	90	295
Manipur	0	4	1	5
Meghalaya	0	5	1	6
Mizoram	0	10	0	10
Nagaland	0	3	0	3
Odisha	3	60	7	70
Puducherry	0	15	2	17
Punjab	2	75	19	96
Rajasthan	1	76	22	99
Sikkim	0	3	0	3
Tamil Nadu	1	188	53	242
Telangana	1	104	18	123
Tripura	1	11	0	12
Uttar Pradesh	13	213	21	247
Uttarakhand	1	17	6	24
West Bengal	0	90	22	112
INDIA	43	1920	530	2493

Table-23 Distribution of blood banks by state and mean assessment score categories

Score								
States	N	ACO supp	orted		Non-NA	1CO		
	Up to 35	35 to 70	Above 70	Up to 35	35 to 70	Above 70		
A & N	0	1	0	0	1	0		
Andhra Pradesh	1	53	6	0	48	10		
Arunachal Pradesh	2	6	0	0	1	0		
Assam	0	23	3	0	20	9		
Bihar	4	35	0	2	30	1		
Chandigarh	0	0	4	0	0	0		
Chhattisgarh	1	15	0	0	25	0		
DNH	0	1	0	0	0	0		
Daman and Diu	0	2	0	0	0	0		
Delhi	0	7	13	0	25	21		
Goa	0	3	0	0	2	0		
Gujarat	0	35	42	2	35	18		
Haryana	0	14	10	1	28	8		
J & K	0	21	2	0	4	0		
Jharkhand	1	15	6	0	14	1		
Karnataka	0	42	22	2	83	33		
Kerala	0	33	12	1	87	30		
Madhya Pradesh	1	52	9	1	61	8		
Maharashtra	1	75	44	0	129	46		
Manipur	0	3	0	0	1	1		
Meghalaya	0	5	1	0	0	0		
Mizoram	0	10	0	0	0	0		
Nagaland	0	3	0	0	0	0		
Odisha (Orissa)	3	46	5	0	14	2		
Puducherry	0	5	0	0	10	2		
Punjab	2	36	5	0	39	14		
Rajasthan	1	35	13	0	41	9		
Sikkim	0	2	0	0	1	0		
Tamil Nadu	0	86	8	1	102	45		
Telangana	0	37	6	1	67	12		
Tripura	0	6	0	1	5	0		
Uttar Pradesh	10	73	6	3	140	15		
Uttarakhand	0	13	5	1	4	1		
West Bengal	0	52	11	0	38	11		
TOTAL	27	859	233	16	1061	297		

Table-24 Distribution of blood banks by state and mean assessment score categories

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 country-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 country. All blood banks in India 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 and national level.

The 1,119 NACO and 1,374 Non-NACO blood banks which were included in the review are approximately 95% of the total blood banks excluding the military blood banks existing in the country. The annual collection of these blood banks was 11.6 million (One crore and sixteen lakhs) units which is approximately 95% of 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 states that ranges from 0.2 units to 8.5 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 states 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 (70%) 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 72% in 2015), there is still a huge variation between states that ranges from 38.3% to 100%. A targeted program to increase the non-remunerated voluntary blood donors will go a long way towards ensuring a safer option for our patients.

It is also evident that the distribution of blood banks is skewed with 61% of the all the blood banks in the country relegated to only 8 states. Almost a third of the states (13) have less than the national average of 2.2 blood banks per million population. The potential impact of this distribution of blood banks and collection of blood on other health indices may be further studied.

Almost a third 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 country.

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 states 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 62 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 states and within states 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 country. 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 NACO/NBTC - Questionnaire for Blood Banks

	NACO/NBTC - Question	aire for Blood Banks	
Data	Filled by		
Mob	ile Phone Number		
(Per	son filled the data)		
	Section A –	GENERAL	
A1	Basic Information		
1	Name of the Blood Bank (as mentioned in the licence)		
2	Address 1 (Institution name)		
3	Address 2 (Door number & Street name – if applicable)		
4	Address 3 (Important land mark - if applicable)		
5	City/Town		
6	District		
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 medical officer?	in the Licence, the current	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)	MB	BS
		N	ID
		N	15
		Dinlon	na
16	Specify branch/Broad speciality	Sipion	
17	Email ID: (Official/Personal Email where the medical officer can be directly contacted). This is apart from the blood bank email ID provided above.		

18	Fax number		
19	Telephone number 1 – Medical Officer (Mobile)		
20	Telephone number 2 – Medical Officer (Landline including STD code)		
21	Type of blood bank as per NACO category	Model blood	Bank
22	·//	Blood Component Separation	Units
		Major Blood	Bank
		District level bloor	i hank
		District Crefer blood	Others
22	Who is the blood bank owned by?	Public (Central/State	/Local
66	who is the blood ballk owned by	Fublic (Centraly State)	ment)
		Bublic (Other than ministry of I	menty
		Public (Other than ministry of)	nearth
		e.g. PSU, Arm	y etc.)
		NGO/Trust/Charitable -	NACO
		Supp	orted
		NGO/Trust/Cha	ritable
		Private - C	Others
23	Is the Blood Bank attached to any of the	Ho	ospital
	following?		Lab
		Stand	alone
24	If attached to Private Hospital, specify level	Medical College Ho	ospital
	of hospital	Tertiary care ho	spital
		(other than medical co	ollege)
		Secondary care ho	spital
25	If attached to public/govt, hospital, specify	Sub-District ho	ospital
	the level of the hospital	District level ho	ospital
		Medical College ho	ospital
		Tertiary care ho	ispital
		(other than Medical Co	llege)
26	If the blood bank is attached to a bornital in	are specify the number of input	tiont
20	beds available	lease specify the number of inpa	nieni
27	Are you permitted to conduct Blood donation	camp?	Yes
			No
28	How many Blood storage centres are linked to your blood bank?		.)e
29	BB working hours (Specify hours per day)		
A2	License Information	bio	
1.	BB License Number		
	(Enter your license number. This should be exa	ictly as is	
	displayed in your license issued by the Drugs C	ontroller	
	Office and will be used for verification purpose	es. This is	
	a mandatory field and should be entered read the status of license - under-renewal etc.	rdless of You will	
	have to submit a self-attested photocopy currently displayed license along with this fo	of the rm.)	

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
43	Basic Statistics (Date of reporting	n from 1an-2015-	>4 years
~~	busic statistics (suce of reporting		Dec 2010)
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. Tra statis	insfusion Transmissible Infections - Annual tics	Number tested	Number positiv
	HIV(Anti-HIV I & II)		
T	HCV (Anti-HCV)		
	HBV(HBs Ag)		
	Syphilis (RPR/TPHA/ELISA)		-
-	Positive for Malaria (Any method)		
A4.	Reporting Summary		
1	Are you in compliance with NBTC guidelines?	,	Yes
			No
2	Are you recovering processing charges for blo	od/components	Yes
	within NBTC/SBTC norms?		No
3	Are you displaying stock position in the blood	bank premises?	Yes
			No
4	Are you submitting statistics to the State Drug	s controller?	Regular
			Occasional
		A192 11	No
5	Are you reporting in SIMS (strategic Information	on Management	Regular
-	Surfam NACON		Occasional
-	System- NACOJ?		

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

	SECTION	B					
B1	Blood Donor(Reporting from Jan 2015- Dec 2015)						
Defini	tion of VBD = Close relatives should NOT be cou	nted as VBD					
1	Are you recruiting voluntary blood donors?		Yes				
			No				
2	Is donor selection performed as per regulatory r	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 fo	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 con reporting period? (Provide numbers of VBD cam during the period January - December 2015.)	ducted in the ps conducted					
8	Does the blood bank have dedicated staff for th	Yes					
	Voluntary blood donors? (If your blood bank has dedicated staff for camps, answer yes.)		No				
8 a.	if Yes to 8, select as applicable (More than one	Don	or Motivator				
	may be selected)	Public relations	tions officer (PRO)				
		5	Social Worker				
9	Is there a specific budget for donor program?		Yes				
			No				
10	If Yes, Specify budget source	Central					
	1.51.151.151.151.24551.24558.251.251.251.251.251.251.25	State					

11	Is there a donor database in the blood bank (Donor database is essential to contact donors to remind them or to call during an		ase is g an	Yes No	
12	If yes to Q 11, is it in electronic format or paper		ic		
	based?	Paper	377. 		
13	What percentage of the voluntary blood donors are repeat blood don			mors? (%)	
14	(Answer yes if your Blood bank have a mobile blood coll (Answer yes if your Blood bank has a mobile for with donor couches)	ection facili acility (bus	tyr or van	No	
15	Source of funds for the mobile blood collection	on (Indicate	the	State	
	source of funding for the purchase of the mol	oile blood d	onor	Central	
	van.)			Donor	
				Others	
16	Specify, other source of funds			·	
17	Is there a record for donor adverse reactions?			Yes	
800- 				No	
18	Is there a referral system for HIV sero-reactive	blood dono	rs?	Yes	
	Section				
C1.	Technical – Immur	ohemat	ology		
	Technical – Immur Which of the following tests are performed	ohemat	ology	Rh	Type
	Technical – Immur Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed?	nohemat Bloc (Tick as	ology od Group applicab	le) Rh	Type ick as
C1.1.	Technical – Immur Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed? Slide	Tick as Forward	ology od Group applicab Reverse	le) (Ti appl	Type ick as licable)
C1.1. C1.2	Technical – Immur Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed? Slide Tube	Tohemat Bloc (Tick as Forward	ology od Group applicab Reverse	le) (Ti appl	Type ick as licable)
C1.1. C1.2 C1.3	Technical – Immur Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed? Slide Tube Micro plate	Tick as Forward	ology od Group applicab Reverse	le) (Ti appl	Type ick as licable)
C1.1. C1.2 C1.3 C1.4	Technical – Immur Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed? Slide Tube Micro plate Column agglutination Gel/Microparticle)	Tick as	ology od Group applicab Reverse	le) (Ti e appl	Type ick as licable)
C1.1. C1.2 C1.3 C1.4 C1.5	Technical – Immur Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed? Slide Tube Micro plate Column agglutination Gel/Microparticle) Solid phase	Forward	ology od Group applicab Reverse	le) (Ti appl	Type ick as licable)
C1.1. C1.2 C1.3 C1.4 C1.5 C1.6	Technical – Immur Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed? Slide Tube Micro plate Column agglutination Gel/Microparticle) Solid phase Other Specify	Forward	ology od Group Reverse	le) (Ti appl	Type ick as icable)
C1.1. C1.2 C1.3 C1.4 C1.5 C1.6	Technical – Immur Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed? Slide Tube Micro plate Column agglutination Gel/Microparticle) Solid phase Other Specify How do you perform RhD typing?	Forward	ology od Group applicab Reverse	le) (Ti appl	Type ck as licable)
C1.1. C1.2 C1.3 C1.4 C1.5 C1.6	Technical – Immur Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed? Slide Tube Micro plate Column agglutination Gel/Microparticle) Solid phase Other Specify How do you perform RhD typing?	Forward	ology od Group Reverse	clonal reagent Both	Type ick as icable)
C1.1. C1.2 C1.3 C1.4 C1.5 C1.6	Technical – Immur Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed? Slide Tube Micro plate Column agglutination Gel/Microparticle) Solid phase Other Specify How do you perform RhD typing? Do you perform irregular antibodies screening	on blood do	ology od Group applicab Reverse	clonal reagent Ional reagent Yes	Type ck as licable)

Do you perform direct antiglobulin test (DAT/DCT)?			Yes	
(If you are performing Direct Antiglobulin test (DAT) - earlier called as Direct Coombs Test (DCT), answer yes.)		lled	No	
If yes to previous question, please specify	Tube			
method	Column agglutin	nation		
	Solid phase	1-1		
Do you perform indirect antiglobulin test (IAT/ICT)?			Yes	
	ST 9 76 76		No	
If yes, to previous question please specify	Tube			
method	Column agglutir	nation		
	Solid phase	100000		
Number of group and type tests performed in reporting period (Jan - Dec 2015) (Specify the number of group and type tests performed - Total of all patient and donor tests in the reporting period - January to December 2015.)			176	
Number of compatibility testing performed in (Specify number of compatibility tests perfor period January to December 2015)	n reporting period. med in the report	ing		
Total Number of DAT/DCT tests performed in (Specify number of DAT/DCT tests performed period (January to December 2015)	n the reporting per I in the reporting	iod		
Total Number of IAT/ICT tests performed in t (Specify number of DAT/DCT tests performed period (January to December 2015)	the reporting perio I in the reporting	d		
Total Number of antibody screening performed in reporting period (If you answered YES to Q2, Speafy number of antibody screening tests performed in the reporting period (January to December 2015).				
Do you have automation for Immunohematology testing? (If you have implemented any kind of automation, please indicate		nte	Yes	
so.) Do you perform Internal QC for all immunohematology tests (blood group/DAT/IAT str.)2			Yes	
(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.)		il le	No	
Do you participate in an external quality asse	essment program o	r	Yes	
scheme (EQAS) for Immunohematology tests your laboratory?	s usually performe	d in	No	
If yes to 14, Specify name of program/provid	ler			
If yes to 14, EQAS MembershipID number/ P	PIN#.			
			Inter-lab	_
If yes 14, specify Highest level of EQAS progr participant in	ram	Inte	National rnational	
If you are not participating in EQAS for immu	unohematology, wi	11	Yes	
you be willing to do so in the future?			100000	_
you be willing to do so in the future?			No	
you be willing to do so in the future? If Yes to above question, will your blood bank	k be able to allocat	e	No Yes	
	 Do you perform direct antiglobulin test (DAT (<i>If you are performing Direct Antiglobulin test</i> <i>as Direct Coombs Test (DCT), answer yes.</i>) If yes to previous question, please specify method Do you perform indirect antiglobulin test (IA) If yes, to previous question please specify method Number of group and type tests performed (Jan - Dec 2015) (Specify the number of group performed - Total of all patient and donor to performed - Total of all patient and donor to period - January to December 2015.) Number of compatibility testing performed in (Specify number of compatibility tests performed period January to December 2015) Total Number of DAT/DCT tests performed in (Specify number of DAT/DCT tests performed period (January to December 2015) Total Number of IAT/ICT tests performed in (Specify number of DAT/DCT tests performed period (January to December 2015) Total Number of IAT/ICT tests performed in (Specify number of antibody screening period (January to December 2015) Total Number of antibody screening perform (If you answered YES to Q2, Spedfy number of tests performed in the reporting period (Janu 2015). Do you have automation for Immunohematod (If you have implemented any kind of autom so.) Do you perform Internal QC for all immunoh (blood group/DAT/IAT etc.)? (Please answer yes if you are performing inter (IQC) for the immunohematology tests listed daily QC on reagents and cells.) Do you participate in an external quality asses scheme (EQAS) for Immunohematology tests your laboratory? If yes to 14, EQAS MembershipID number/ If yous 14, specify Highest level of EQAS prog participant in If yes 14, specify Highest level of EQAS prog participant in If yes 14, specify Highest level of EQAS prog 	Do you perform direct antiglobulin test (DAT/DCT)? (If you are performing Direct Antiglobulin test (DAT) - earlier car as Direct Coombs Test (DCT), answer yes.) If yes to previous question, please specify method Tube Do you perform indirect antiglobulin test (IAT/ICT)? Tube If yes, to previous question please specify method Tube Column agglutin Solid phase Number of group and type tests performed in reporting period (Jan - Dec 2015) (Specify the number of group and type tests performed - Total of all patient and donor tests in the reportin period - January to December 2015.) Number of compatibility testing performed in reporting period. (Specify number of compatibility tests performed in the reporting period (January to December 2015) Total Number of IAT/DCT tests performed in the reporting period (January to December 2015) Total Number of IAT/DCT tests performed in the reporting period (January to December 2015) Total Number of IAT/DCT tests performed in the reporting period (January to December 2015) Total Number of antibody screening performed in reporting period (January to December 2015) Total Number of antibody screening performed in reporting period (January to December 2015) Do you perform Internal QC for all immunohematology testing? (If you have automation for Immunohematology tests (blood group/DAT/IAT etc.)? (Please answer yes if you are performing internal quality controd (Jacl) for the immunohematology tests	Do you perform direct antiglobulin test (DAT/DCT)? (If you are performing Direct Antiglobulin test (DAT) - earlier called as Direct Coombs Test (DCT), answer yes.) If yes to previous question, please specify method Tube Do you perform indirect antiglobulin test (IAT/ICT)? Itube If yes, to previous question please specify method Tube Number of group and type tests performed in reporting period (Jan - Dec 2015) (Specify the number of group and type tests performed in reporting period - January to December 2015.) Number of compatibility testing performed in reporting period. (Specify number of compatibility tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (January to December 2015) Total Number of IAT/ICT test performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (Specify number of AT/ICT test performed in the reporting period (Specify number of AT/ICT test performed in the reporting period (Specify number of AT/ICT test performed in the reporting period (Specify number of AT/ICT test performed in the reporting period (Specify number of AT/ICT test performed in the reporting period (Specify number of AT/ICT test performed in the reporting period (Specify number of AT/ICT test performed in the reporting period (Into answered YES to Q2, Spedfy number of antibody screening tests performed in the	Do you perform direct antiglobulin test (DAT/DCT)? Yes (If you are performing Direct Antiglobulin test (DAT) - earlier called as Direct Corombs Test (DCT), answer yes.) No If yes to previous question, please specify method Tube No Do you perform indirect antiglobulin test (IAT/ICT)? Yes No If yes, to previous question please specify method Tube No If yes, to previous question please specify method Tube No Number of group and type tests performed in reporting period (Jan - Dec 2015) (Specify the number of group and type tests performed - Tatal of all patient and donor tests in the reporting period - January to December 2015.) Number of compatibility tests performed in the reporting period. (Specify number of CAT/DCT tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (Specify number of DAT/DCT tests performed in the reporting period (If you answered YES to Q2, Specify number of antibody screening tests performed in the reporting period (January to December 2015). No Do you have automation for Immunohematology tests listed above. They include daily QC on reagents and cells.] 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 Ir	ndia	Yes	
	(HVPI)?		No	
22	If yes, provide HVPI ID Number			
23	If not, would you be willing to participate in HVPI in the near	-	Yes	
	future?		No	
24	Are you reporting all adverse events to the National		Yes	
	Haemovigilance Program of India?		No	
25	Number of adverse reactions recorded in the reporting period			
26 Does your hospital have regular transfusion commi	Does your hospital have regular transfusion committee meet	tings?	Yes	
			No	
27	What is the frequency of Transfusion committee meetings?		Annual	
			Half-yearly	
			Quarterly	
		Occasion	ccasional	

Те	chnical - Screen	Section D ing For Transfusion Transmi	ssible Infections (TTI)	
Does t	the blood bank screen	the following TTIs?		
	Type of Test	Platform (please tick appropriate)	Method (please tick appropriate	
1	HIVI&II	Rapid		
		ELISA	Manual Automated	
		CHEMI	Manual Automated	
		NAT	Manual Automated	
1.1	Specify % of donors	tested by Rapid Test?		
2	Hepatitis B	Rapid		
		ELISA	Manual Automated	
		EM	Manual Automated	
	1. 	NAT	Manual Automated	
2.1	Specify % of donors	tested by Rapid Test?		

3	Hepatitis C	Rapid		
		ELISA	Manual	
		CHEM	Manual	
		0.7437.207	Automated	
		NAT	Manual	
			Automated	
3.1	Specify % of dono	rs tested by Rapid Test?		
4	Syphilis	RPR	Manual	
		10.10.223	Automated	
-		TPHA	Manual	
			Automated	
		ELISA	Manual 📃	
			Automated	
5	Malaria	Rapid		
		Fluorescent	Manual	
		the state of the s	Automated	
		Slide microscopy		
		ELISA	Manual	
	103 N 208 0		Automated	
6	Does the blood ba POSITIVE in initial	nk have an algorithm for units that test I screening?	Yes	
	(If you have a met positive on the scr	hod of verifying a sample that has tested eening test please answer yes.)	No	
7	If yes to Q6 , Repe	at testing with same test/ technique	Yes	
			No	
8	If Yes to Q6, Repea	at testing with different test/technique	Yes	
			No	
9	If yes to Q6, Recal	ling donor for repeat sample	Yes	
			No	
10	Do you perform in	dependent internal QC (Third party	Yes	
	controls) with TTI	testing?	No	
11	Do you participate	in an external quality assessment	Yes	
	program or schem	e (EQAS) for TTI(Viral Markers, Malaria,	1.000	
	and Syphilis) testir	ng?	No	
12	If yes, Specify pro	gram/provider		
13	Membership ID ou	umber (PIN)		
	Contraction and the state	1999 - 1999 - 1997 - 19		
14	Level of EQAS	Level of EQAS		
			National	
			International	
15	If you are not part	icipating in EQAS for TTI screening, will	Yes	
	you be willing to participate in future?		No	

16	If Yes to Q15, will your blood bank be able to provide financial support (about Rs. 2500 per year)		Yes	1	
			No		
17	If your answer to Q 15 is NO, when do you think you will be ready for EQAS (TTI screening)	Ne:	Next 6 months Later than 6 months		
	participation?	Lat			
	Section E Technical - Component Preparation	i (Appli	cable onl	y to BCS	5U)
1	Does your blood bank prepare components?			Yes	
				No	
If you	r answer to Q1 is NO, SKIP TO SECTION F			- (1)	
If Yes,	List the components and number prepared and iss	sued in th	e period Jan	to Decemb	er 2015
2	Number of donated blood that was used for cor	nponent			
	preparation during the period Jan- December 20	015.			
Ĩ		Numbe	er prepared	No. issu	ed (utilized)
3	Packed red cells IP (With or without Additive)			1	
4	Platelet concentrate IP				
5	Fresh frozen plasma (FFP)				
6	Cryoprecipitated antihaemophilic factor IP				
7	Human plasma IP				
8	Other (specify)	1		6.0	8
9	Do you perform apheresis for components?			Yes	
				No	
	If yes to above question, Specify the following d	etails			
		Numbe	r prepared	No. issi (utilize	ued d)
10	Platelet concentrate IP				V.C.
11	Fresh frozen plasma (FFP)				
12	Granulocytes concentrates				
13	Other (specify)				
14	Do you perform QC for the components prepare quality control for all components, answer yes.)	perform QC for the components prepared? (If you perform control for all components, answer yes.)		Yes	
15	If yes to above, Are the Factor assays on Fresh Frozen plasma/Cryoprecipitate performed at your Blood Bank?		Yes		
16	If yes for above question, do you participate in external quality assessment scheme (EQAS)?			Yes	
1029-12				No	
17	If yes, to above question, Specify agency				

SECTION F Quality Management Systems					
F1	Are you aware of quality management systems for Blood bank	Yes			
		No			
1	Is the blood bank accredited?				
---	--	-----	---		
		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	Yes			
	processes?	No			
5	Do you have written responsibilities for all levels of staff?				
			-		

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/N Support in-servi trainin	BTC ed ce g	Other National Training
6	Professor					
7	Associate Professor				- 7	
8	Assistant Professor					
9	Senior Resident/Tutor					
10	Medical Officer (include senior/Junior)					
11	Technical Staff					
12	Nursing staff					
13	Counsellor					
14	PRO/Donor motivator					
15	Administrative staff					
16	Support staff					-
17	In your opinion, does the BB have a (24x7)? This may be decided based hours.	adequate sta I on the volur	ff to function o me and duratio	ptimally n of work	Yes No	
18	Do you monitor Quality indicators	or Key Perfor	mance indicate	ors?	Yes	
					No	
19	If yes to above question, please spontaneous of indicators	ecify				
20	Do you have a designated and trained Quality manager?		Yes	9 T		
21.02			No			
21	Do you have a designated and trained Technical Manager?		Yes			
			No	2		
22	If you do not have either a trained Quality manager or Technical Manager please state reasons?					

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

F2.	EQUIPMENT AND SUPPLIES		
1	Does the blood bank have adequate equipment to meet regulatory requirements? (If your blood bank has adequate equipment in working		Yes
	condition to meet expected workload, please answ	ver yes.)	No
2	How is equipment purchase funded?	Local bodies	
		Central or upper (st	ate)
		level agencies	1011020
		Donors	
		Others (specify)	33
3	Does the blood bank have a program for regular e	quipment maintenance?	Yes
			No
4	Are all the equipment calibrated regularly as per r	regulatory requirement?	Yes
			No
5	How are consumables purchased?	Local bodies	
		Central or state leve agencies	el
	Donors		
5	Do you evaluate kits at your facility prior to procu	rement? (Are kits	Yes
	evaluated locally (at your blood bank) prior to pur avidity for blood group Anti Sera?))	chase (e.g. Titre and	No
7	Is quality control for kits, reagents and blood bags	s carried out at your	Yes
	blood bank? (Is quality control for kits performed locally (at your blood bank) Prior to use (e.g. Titre and avidity for blood aroup Anti Serg?))		No
8	Did you have a regular supply of the following iter	ms? (Jan to Dec 2015)	
8.1		Blood Bags	Yes
1212			No
8.2		TTI Screening Kits	Yes
			No
8.3	Blood grouping / IH reagents		Yes
	21.02		No
			12.0 X.1

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		

Any instrument for Hb Estimation (other than CuS04 method)	2
Blood collection monitor (Blood agitator)	
Quarantine Blood bank refrigerator to store untested units with temperature recorder	
Container for safe disposal of sharps	
Oxygen supply equipment	
Computer with accessories and software	
General lab centrifuge for samples	
Bench top centrifuge for serological testing	
Blood transportation box	
Emergency drugs box/Crash card	
Autoclave machine (shared resource should be specified)	
Water bath	
Blood bank refrigerator (storage of tested blood) with temperature recorder	
Automated pipettes	
Refrigerated centrifuge (BCSU)	
Blood container weighting device	
Serology rotator	
	Any instrument for Hb Estimation (other than CuS04 method) Blood collection monitor (Blood agitator) Quarantine Blood bank refrigerator to store untested units with temperature recorder Container for safe disposal of sharps Oxygen supply equipment Computer with accessories and software General lab centrifuge for samples Bench top centrifuge for serological testing Blood transportation box Emergency drugs box/Crash card Autoclave machine (shared resource should be specified) Water bath Blood bank refrigerator (storage of tested blood) with temperature recorder Automated pipettes Refrigerated centrifuge (BCSU) Blood container weighting device Serology rotator Serology rotator

7.2 Scoring Pattern

GENERAL	General Summany	WEIGHTAGE	Total
Liconco	Under renewal	1 INTERNA	Tota
Licence	Valid	1	
Subtatal	valid	3	
Subtotal			3
collection	Below 1000	0	
concention	1000 to 2000	0.5	
-	2000 to 2000	1	
	5000 to 3000	10	
	About 0 1000	1.5	-
Cubbabal	Above 10,000	2	-
Subtotal	an El transmitte		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
TECHIH	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 IOC for IH	3	
	BB Participating in EOAS for IH	3	
	Direct antiglobulin test (DAT/DCT) Direct Coombs Test		
	(DCI)	2	-
	Indirect antigiobulin test (IAI/ICT)	4	-
	Automation for Immunohematology testing	1	
Subtotal			18
TECH-TTI	BB performing IQC for TTI	3	
	BB Participating in EQAS for TTI	3	
	BB with follow up program for HIV Sero-positive		
	donors	3	-
HIV Testing	Rapid	1	
	Elisa	2	
	Advanced	3	
Нер В	Rapid	1	
	Elisa	2	
	Advanced	3	

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

Indiv	idual Scoring Sneet - Without Blood Component Separ	ation Units	
GENERAL	General Summary	WEIGHTAGE	Tota
Licence	Under renewal	2	-
	Valid	3	3
Subtotal			
Annual collection			
	500 - 1000	1	
0	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	
inepreur D'O'II	pre donation counselling - regular	2	-
Counselling	post donation counselling - regular	2	-
Subtotal	post donation courseling regular		11
теснин	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 IOC for IH	3	-
	BB Participating in EOAS for IH	3	-
	Direct antiglobulin test (DAT/DCT)- Direct Coombs Test		-
	(DCT)	2	-
	Automation for Immunohomatology testing	2	
Fuhtatal	Automation for immunohematology testing	1	10
Subtotal			18
TECH- TTI	BB performing IQC for TTI	3	
	BB Participating in EQAS for TTI	3	
	PR with follow up, program for UNV Care positive descent		
HIV Tection	Boold	3	
niv lesting	Rapid	1	-
	ELISA	3	

ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 QMS B8 MO with relevant PG Qualification 3 Lab technician with NACO/NBTC training 3 Lab technician with NACO/NBTC training 3 B8 with SOPs 2 B8 with SOPs 2 B8 with Colynent control system 2 B8 with Cor equipment functional 2 B8 with Cor 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 B10od bank accredited by NABH 5 Subtotal 35 GEN Control Programme 3 B8 Participating in Haemovigilance Program of India 1 E blood banking participation - State level 1 E blood banking participation - State level 1 Compliance with NBTC norms 1	SCORES	TOTAL		100
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 QMS BB MO with relevant PG Qualification 3 Lab technician with NACO/NBTC Training 3 BB with designated TM/QM 2 BB with bOcument control system 2 BB with Document control system 2 BB with calibration of equipment 4 Quarantine Blood bank with regular supply 2 Quaratine Blood bank with temperature recorder 3 BB od bank accredited by NABH 5 Subtotal 3 BB ortic Iprogramme 3 BB Participating in Haemovigilance Program of India 1 E blood banking participation – State level 1 Compliance with NBTC norms 1	Subtotal	More than 50% of the staff are vaccinated for Hep B	1	8
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 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 Cor equipment 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 supply 2 Quarantine Blood bank refrigerator to store untested units with temperature recorder 3 Blood bank accredited by NABH 5 Subtotal 35 BB Participating in Haemovigilance Program of India 1 E blood banking participation NBTC/NHP 1 E blood banking participation NBTC/NHP 1 E blood banking participation - State level 1<			-	
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 QMS B8 MO with relevant PG Qualification 3 Staff Nurse with NACO/NBTC Training 3 Lab technician with NACO/NBTC training 3 B8 with designated TM/QM 2 B8 with SOPs 2 B8 with cournent control system 2 B8 with cournent control system 2 B8 with correquipment 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 B8 Participating in Haemovigilance Program of India 1 E blood banking participation NBTC/NHP 1 E blood banking participation STMS Level 1		Compliance with NBTC norms	1	_
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 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 ADC or equipment functional 2 BB with calibration of equipment 4 Quality control for kits, reagents and blood bags carried out at blood bank with regular supply 2 Quarantine 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 BB Participating in Haemovigilance Program of India 1 BB Participating in Haemovigilance Program of India 1 BB Participating in Haemovigilance Program of India 1		E blood banking participation - State level	1	
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 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 calibration of equipment functional 2 BB with AMC for equipment 4 Quality control for kits, reagents and blood bags carried out at blood bank refrigerator to store untested units with temperature recorder 3 Blood bank accredited by NABH 5 Subtotal 35 BB reporting regularly on SIMS underNational AIDS 35 GEN B8 reporting regularly on SIMS underNational AIDS 35		BB Participating in Haemovigilance Program of India	1	
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 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 calibration of equipment functional 2 BB with calibration of 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 5 BB reporting regularly on SIMS underNational AIDS 35	GEN	Control Programme	3	·
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 COMP Not applicable 20 QMS BB MO with relevant PG Qualification 3 Staff Nurse with NACO/NBTC Training 3 Lab technician with NACO/NBTC training 3 BB with SOPs 2 BB with SOPs 2 BB with SOPs 2 BB with calibration of equipment functional 2 BB with calibration of equipment functional 2 BB with AMC for 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 Quality control for kits, reagents and blood bags carried units with temperature recorder 3 Blood bank accredited by NABH 5 Subtotal 5 5		BB reporting regularly on SIMS underNational AIDS		
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 COMP Not applicable 20 QMS BB MO with relevant PG Qualification 3 Staff Nurse with NACO/NBTC Training 3 Lab technician with NACO/NBTC training 3 BB with SOPs 2 BB with SOPs 2 BB with SOPs 2 BB with calibration of equipment functional 2 BB with calibration of equipment 4 BB with AMC for 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
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 QMS B8 MO with relevant PG Qualification 3 Staff Nurse with NACO/NBTC Training 3 Lab technician with NACO/NBTC training 3 B8 with designated TM/QM 2 B8 with SOPs 2 B8 with Document control system 2 B8 with calibration of equipment 4 B8 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	
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 QMS BB MO with relevant PG Qualification 3 Staff Nurse with NACO/NBTC Training 3 3 Lab technician with NACO/NBTC training 3 3 BB with designated TM/QM 2 3 BB with Document control system 2 3 BB with nore than 75% equipment functional 2 3 BB with calibration of equipment 4 4 BB with AMC for equipment 4 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	
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 1 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	
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 1 20 COMP Not applicable 1 QMS BB MO with relevant PG Qualification 3 Staff Nurse with NACO/NBTC Training 3 3 Lab technician with NACO/NBTC training 3 3 BB with designated TM/QM 2 2 BB with SOPs 2 2 BB with Document control system 2 2 BB with calibration of equipment functional 2 3		BB with AMC for equipment	4	
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 QMS BB MO with relevant PG Qualification 3 Staff Nurse with NACO/NBTC Training 3 3 Lab technician with NACO/NBTC training 3 3 BB with designated TM/QM 2 3 BB with Document control system 2 3 BB with more than 75% equipment functional 2 3		BB with calibration of equipment	4	
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 1 20 COMP Not applicable 1 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	
ELISA 3 Hep C Rapid 1 ELISA 3 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 QMS BB MO with relevant PG Qualification 3 Staff Nurse with NACO/NBTC Training 3 3 Lab technician with NACO/NBTC training 3 3 BB with designated TM/QM 2 3		BB with Document control system	2	
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 20 QMS BB MO with relevant PG Qualification 3 Staff Nurse with NACO/NBTC Training 3 BB with designated TM/QM 2		BB with SOPs	2	
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 3 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 1 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	
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 1 QMS BB MO with relevant PG Qualification 3 Staff Nurse with NACO/NBTC Training 3		Lab technician with NACO/NBTC training	3	
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 1 QMS BB MO with relevant PG Qualification 3		Staff Nurse with NACO/NBTC Training	3	
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20 COMP Not applicable 1	QMS	BB MO with relevant PG Qualification	3	-
ELISA 3 Hep C Rapid 1 ELISA 3 3 Syphilis RPR 1 Malaria Slide/Rapid 1 Subtotal 20	СОМР	Not applicable		
ELISA 3 Hep C Rapid 1 ELISA 3 Syphilis RPR 1 Malaria Slide/Rapid 1	Subtotal			20
ELISA 3 Hep C Rapid ELISA 1 ELISA 3 Syphilis RPR	Malaria	Slide/Rapid	1	
Hep C Rapid 1 ELISA 3	Syphilis	RPR	1	
Hep C Rapid 1	-	ELISA	3	
ELISA 3	Нер С	Rapid	1	
ELISA 3			-	
	TTEP D	FLISA	3	



Disclaimer

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