

A Report on the “Assessment of Blood Banks in Gujarat, India”

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Abbreviations

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

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Executive Summary

Blood Banks in Gujarat

According to Central Drugs Standard Control Organization (CDSCO), there were 136 blood banks in Gujarat in 2015. The assessment exercise identified 134 functional blood banks across the state. Of the 134 blood banks, 77 (57.5%) were supported by National AIDS Control Organization, Ministry of Health and Family Welfare, Government of India and the remaining 57 (42.5%) were Non-NACO blood banks.

There are 33 districts in the state of Gujarat of which only 30 districts are included in the analysis as there are no blood banks in three districts. Ahmedabad (23) had the highest number of blood banks followed by Banaskantha (10), Vadodara (10) and Rajkot (9).

Around 49% (65) of all the blood banks (n=134) in the state were in 6 districts that are, Ahmedabad (17.2%), Banaskantha (7.5%), Vadodara (7.5%), Rajkot (6.7%), Surat (5.2%) and Anand (4.5%).

Considering the number of blood banks per one million population, 15 districts such as, Morbi(10.3 blood banks), Dwarka(7.9), Porbandar(5.1), Gandhinagar (3.6), Ahmedabad(3.3), Banaskantha(3.2), Patan(3.0), Valsad(3.0), Anand(2.9), Junagadh(2.7), Tapi(2.5), Vadodara(2.4), Rajkot (2.4), Kutch (2.4) and Navsari (2.3) recorded more than the State average of 2.2 blood banks per 1,000, 000 (one million) population.

In the assessment 132 blood banks (77 NACO supported- 58.3 % and 55 Non –NACO- 41.7%) that submitted the assessment forms in complete were included in the analysis.

Description of blood banks

- Around 49% (65) of the blood banks in the state had component separation facility.
- Majority of Blood banks (82, 62.1%) are owned by not-for-profit sector followed by public (27, 20.5%) and private (23, 17.4%).
- The majority (50; 64.9%) of NACO supported blood banks were owned by the non-profit/not-for-profit sector such as NGOs, charitable trusts, societies, foundations, etc. and the remaining (27, 35.1%) were owned by public sector.
- The majority of the blood banks (71; 53.8%) were standalone blood banks, (56; 42.4%) were attached to hospitals and the remaining (5; 3.8%) were attached to laboratories.
- The majority of the blood banks (95; 72%) had a valid and current license, and the remaining (37; 28%) had applied for renewal. Around (74%, 57) of NACO supported and (38; 69.1%) of Non-NACO blood banks had a valid and active license.

Annual Collection and Voluntary Blood Donation

- During January 2015 to December 2015, the annual blood collection from all the blood banks that reported was 808,474 of which 77.6% units were through voluntary blood donations and the remaining were from replacement donations.
- The average annual collection of blood units of all the blood banks in the state was 6219 units. The average annual collection of NACO supported blood banks was found to be higher (7,943 units) than the Non-NACO blood banks (3,714 units).
- The blood banks with component separation units recorded a average higher collection of 10060 units compared to blood banks without blood component separation units which was 2607 units.
- The NACO supported blood banks collected 75.7% (611,624 units) of the total collection, of which 83.6% (511,481) units were through voluntary blood donation. The Non-NACO blood banks collected 24.3% (196,850) units of which 58.8% (115,675) units were through voluntary blood donation.

Transfusion Transmitted Infections

- HIV seroreactivity was found to be 0.10%, Hepatitis-C was 0.13%, Hepatitis-B 0.59%, Syphilis 0.20% and Malaria 0.01%. However, there is a huge variation between districts.

Component Separation

- Around 80% of blood units collected by blood banks with component separation facilities were used for component separation in Gujarat.
- The percentage of component separation was higher (82.3%) in Non-NACO blood banks compared to NACO supported blood banks (79.2%).

Quality Management Systems

- The majority of blood banks (94.7%) reported that they adhered to the NBTC guidelines.
- Availability of document control system was reported by 53% of the blood banks in the state. Around 51% of NACO supported blood banks and 56% of Non-NACO blood banks reported they had a document control system.
- In terms of Standard Operating Procedures (SOPs) for technical processes, 98% reported that they had SOPs.
- Practice of internal quality control (IQC) for Immunohematology was reported by 85% of the blood banks and IQC for TTIs was reported by 59% 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 22% and 22.7% of the blood banks in state have enrolled themselves in External Quality Control Systems (EQAS) by recognized providers for immunohematology and TTIs respectively.
- Only 12 (9%) blood banks out of the total 132 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 53% and 62.1% of the blood banks respectively.
- More than 94% of the blood banks reported that they had a regular equipment maintenance programme and around 94% reported that they calibrate the equipment as per requirement

The current status of blood banks based on the assessment

- The mean assessment score of blood banks in the state was 68.4 (SD: 11.1). The NACO supported blood banks scored higher (70.5; SD: 10.1) than the Non-NACO blood banks (65.5, SD: 11.8).
- Around 65% of all the blood banks under the support of NACO were in not-for-profit sector. Whereas, the majority (58%) of the Non-NACO blood banks were in not-for-profit sector and (41.8%) were in the private sector.
- At the state level, the majority of blood banks (70; 53%) scored between 35 to 70, followed by 45% (60) which scored above 70, and only two blood bank scored less than or equal to 35. All of the NACO supported blood bank scored more than 35.
- Around 45% of NACO supported and 63% Non-NACO blood banks scored between 35 and 70. Around, 55% of NACO supported blood banks and 33% of Non-NACO blood banks scored more than 70.
- Among the districts, Surat (79.4) scored the highest and Narmada (31) scored the least. Thirteen districts scored above the state average.
- Of the 60 blood banks that scored more than 70 score, 42 (70%) were NACO supported blood banks. The majority of blood banks that scored above 70 were from Ahmedabad (14) followed by Surat (6), Rajkot (5), Banaskantha (4), Valsad (4), Anand (3), Gandhinagar (3) and Vadodara (3). These 8 districts constitute 70% of the total blood banks that scored more than 70.
- The mean score of blood banks with component facilities (71.22; SD: 11.59) was found to be higher than the mean score of those without component facilities (65.70; SD: 9.95).
- The mean assessment score of not-for-profit (NGO/Trust/Charitable) owned blood banks (67.57; SD: 11.76) was almost equal to the private sector blood banks (67.85; SD: 9.85).
- However, NACO supported blood banks run by not-for-profit sector had scored higher (69.98; SD: 10.35) compared to Non-NACO NGO/Trust/Charitable blood banks (63.80; SD: 12.97).

- The mean assessment score of blood banks that collected more than 5000 blood units (74.46; SD: 11.27) was found to be higher than those which collected between 3001 and 5000 (66.43; SD: 9.39) and less than 3000 blood units (65.00; SD: 9.47).
- The mean score was found to be higher among the blood banks that were part of EQAS for immunohematology (79.07; SD: 9.77) as compared to those who were not enrolled (65.42; SD: 9.52). Similar situation was found among those blood banks that were part of EQAS for Transfusion-Transmitted Infections (80.10; SD: 8.36) as compared to those who were not enrolled (64.99; SD: 9.34).
- 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.

It is evident from the assessment that blood banks that focussed on quality improvement systems performed better than others. Considering the deleterious effect of poor quality practices on patient care, it is imperative that specific programmes and strategies to improve quality systems in blood transfusion services are developed and implemented across the state.

Assessment of Blood Banks in Gujarat

1. Background

Blood Transfusion Service (BTS) is an essential part of modern health care system without which medical care is impossible (Pal, Kar, Zaman, & Pal, 2011). Adequate measures to ensure blood safety play a major role in preventing the transmission of HIV, Hepatitis and other bloodborne pathogens in health care settings. The blood and its products must not only be safe but must be clinically effective, and of appropriate and consistent quality (WHO, 2012). Ensuring the safety and availability of blood and blood products is an essential public health responsibility which is primarily the responsibility of the government or the appropriate national health authority of each country (Ramani, Mavalankar, & Govil, 2007). Therefore, it is important to establish a sustainable national blood system that should be supported by a national blood policy, strategic plan, and appropriate legal instruments (WHO, 2011). The Twenty-eighth World Health Assembly resolution number WHA 28.72 of 1975 urged member countries to promote the development of national blood services based on voluntary non-remunerated blood donation (VNRBD); to enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products (WHO, 1975).

However, provision of safe and quality blood for a country like India involves a highly complex operation involving various stakeholders, and the magnitude and complexity of issues raise several challenges (GOI, 2003). This requires a holistic and comprehensive approach to planning, designing and operationalizing the BTS. It is important to ensure coordination between blood transfusion services, health services and hospitals, educational institutes, religious, social and industrial organizations, mass media, and other stakeholders including the general public. The system should ensure adequate resources and inputs into the legislative, regulatory, technical, social, and cultural aspects of making this life-saving product accessible and safe.

The need for blood is paramount and universal. However, millions of patients requiring transfusion do not have timely access to safe blood, and there is a major imbalance between developing and industrialized countries in access to safe blood (WHO, 2009). There is a huge inequity in the availability of blood within countries, with the urban areas having more access to the majority of blood available. Even if sufficient blood is available, many are exposed to avoidable, life-threatening risks through the transfusion of unsafe blood. In order to ensure universal access to safe and quality blood, achieve 100% voluntary blood donation and quality-assured testing of donated blood, strengthening the blood transfusion services with evidence-based, innovative and result-oriented strategies are essential. It is also imperative to optimize blood usage, develop quality systems in the transfusion chain, strengthen the workforce, adopt new developments, and build effective partnerships (WHO, 2008).

The National AIDS Control Organization(NACO), under the Ministry of Health and Family Welfare, and the National Blood Transfusion Council (NBTC), which is the apex policy making body, are the prime bodies responsible for the functioning of blood transfusion services and blood safety in India at the national level. At the state level, the respective state AIDS Control societies (SACS) and State Blood Transfusion Councils (SBTCs) are responsible for the smooth functioning of blood transfusion services. As blood and blood products are considered as drugs, the Central Drug Standard Control Organisation (CDSCO) and State Drug Control Organisations play a vital role in key aspects such as, approval of licenses, and enforcement of standard transfusion practices to ensure safe, quality and efficacious blood and blood components in clinical practices.

Several directions, guidelines, and legal measures during the last two decades facilitated the significant improvement of blood transfusion services in the country. The Supreme Court verdict in 1996 directed the government to improve the blood transfusion services that resulted in establishing the National and State Blood Transfusion Councils. The Drugs and Cosmetics Rules, 1945, framed under the Drugs and Cosmetics Act, 1940 were amended in 1993, as a result of which the licensing of blood banks was brought under the dual authority of the state and central government (MoHFW, 2013). The state licensing authority issues the license, while the Drug Controller General (India) is the central license approving authority. In 2002, the WHO Guidelines on the Clinical Use of Blood was adopted by NACO. In the same year, the Government of India framed and adopted the National Blood Policy (NBP) (NACO, 2007a).

In 2007, the National AIDS Control Organization developed standards for blood banks and blood transfusion services. This clearly spelled out the need for mandatory licensing and compliance to all regulatory norms; compliance to policies/ guidelines of NBTC; donor selection/ recruitment/ retention/ counseling based on voluntary non-remunerated regular repeat blood donors; appropriate blood collection procedures; mandatory testing of all donated Blood units for HIV, HBV, HCV, Syphilis and Malaria; transportation of blood and blood components ensuring cold chain maintenance; manpower requirements; maintenance of quality assurance system; regular maintenance and calibration of equipment; biosafety; waste disposal mechanisms; documentation, record keeping and regular reporting under the national programme (NACO, 2007b).

Since the inception of the National AIDS Control programme in 1992, the blood safety programme in India under the National AIDS Control Organization has been making significant strides towards ensuring access to safe, and quality blood and blood products to all those who are in need of a transfusion. The goals and objectives of the programme are to ensure provision of safe and quality blood even to the most remote areas of the country. NACO has been taking continuous steps to strengthen the blood banks across the country by providing equipment, consumables, manpower and capacity building. The efforts to modernizing blood-banks, establishing model blood banks, and setting up blood storage centres in rural areas have improved the quality of blood transfusion services in the country.

The current phase of the NACP IV (2012 -2017) focuses on blood safety that aims to support 1,300 blood banks, and achieve 90,00,000 blood units from NACO supported Blood Banks and 95% Voluntary Blood Donation in 2016-17. The key strategies under NACP IV are strengthening management structures of blood transfusion services, streamlining the coordination and management of blood banks and blood transfusion services, and developing new initiatives such as the establishment of Metro Blood Banks and Plasma Fractionation Centre (NACO, 2014).

Due to the continuous efforts in India, the availability of safe blood increased from 44 lakh units in 2007 to 100 lakh units by 2014-15; during this time HIV seroreactivity also declined from 1.2% to 0.2%, and Voluntary Blood Donation increased substantially (NACO, 2016). NACO has been providing technical and operational support to improve the efficiency and effectiveness of these blood banks, thereby, increasing the availability and accessibility of safe and quality blood and blood products to those who are in need. Though there has been a substantial improvement in BTS in India over a period of time, there are still gaps in ensuring access to quality blood and blood products that needs to be addressed at the district, state and regional levels through an evidence-based approach.

In order to have evidence-based programmes, and policies, accurate and updated information at the district, state and national level is an essential prerequisite. Lack of updated information is one of the key barriers affecting the planning and implementation of blood transfusion services across the country. Though current programmes emphasize Quality Management Systems (QMS) including EQAS and accreditation in blood banks, not much information is available related to this area. In particular, information on the existing practices of blood banks, their potential, and willingness to get involved in the programmes on QMS are critical factors that will facilitate developing appropriate strategies and programmes related to QMS at the National level.

Therefore, facility-wise updated information on structural and programmatic components, the gaps, and challenges are required which will not only facilitate in developing better programmes and policies in BTS, but also serve as a baseline for specific programmes that are being, and will be implemented at the district, state, regional, and national levels. Considering the above factors, a nationwide assessment of all the blood banks was conducted.

2. Objectives

The overall purpose of this assessment was to understand the current situation of blood banks, in terms of facilities, services, practices, performance, gaps, and challenges.

The specific objectives were:

- To review the existing situation in blood banks in terms of collection of blood, voluntary blood donation, quality management systems, and other programme areas.
- To categorize and grade the blood banks using a scoring system, for implementation of phased quality improvement systems.
- To provide evidence for the formulation of evidence-based policies and programs for blood transfusion services in India.
- To develop an updated database with basic essential details of blood banks in the country.

3. Methodology

This assessment was a cross-sectional survey that captured the current situation of all the blood banks that are owned by the government, private, non-profit and not-for-profit organizations in the state during the reporting period – January to December 2015. In order to create a comprehensive and accurate list of functional blood banks in the state, data (list of blood banks) from multiple sources were obtained which included NACO, NBTC, CDSCO, state drugs control organizations, SACS, and SBTCs. These were further reviewed for duplication, errors in name and other necessary details, and triangulated to arrive at a comprehensive list of district wise functional blood banks.

Following this, an assessment tool was designed as a web-based survey tool in REDCap Software - Version 6.11.2 which was developed by an informatics core at Vanderbilt University with support from National Center for Research Resources (NCRR) and National Institute of Health (NIH) grants. An exclusive online survey link for each blood bank, generated from REDCap, was sent to all the blood banks. This online link was linked to the email ID of the blood bank and Unique IDs created for each blood bank. Since many blood banks did not have adequate internet facility, a paper format was also developed which was sent to all the blood banks by post with a pre-stamped and self-addressed envelope. The data from the completed paper forms were then entered into REDCap.

Tool: A self-assessment questionnaire that included all the below-mentioned components was developed in consultation with programme officials and experts from the areas of public health, epidemiology, bio-statistics, and transfusion medicine.

The review focused on the following components:

Table 1 - Details of technical areas included in the assessment

S No	Component	Description
1	General	Basic details, Ownership, Category, License, etc.
2	Collection and VBD	Annual Collection, VNRBD and donor management
3	Technical – IH, TTIs, components	Methods, Performances
4	Quality Management System	Check for compliance to guidelines and standards
5	HR, Training, and Equipment	Availability and Participation

Data Management and Analysis: The database for this study was developed and maintained by Clinical Data Management Centre (CDMC), Department of Biostatistics, Christian Medical College, and Vellore, India. In-built validation checks were incorporated in the system to confirm that all study related parameters are captured completely and accurately.

Data were analyzed using SPSS Version 21 for Windows. The data were screened for outliers and extreme values using histograms, frequency distribution and Box plots. To summarize the whole data, frequency distributions and bar/pie charts were done for qualitative (categorical) variables such as ownership, type of blood banks etc., and descriptive statistics like mean, standard deviation (SD), median, minimum, and maximum were done for quantitative variables such as annual collection, voluntary blood donation, etc.

Categorisation of blood banks and scoring: In order to study variables that impact quality, the blood banks have been categorized into two groups based on the availability of component separation facility. The first category comprises of blood banks with component separation facility that includes Model Blood Banks and Blood Component Separation Units (BCSU) in NACO supported blood banks. Model blood banks collect more than 10,000 units and BCSUs collect between 5,000 to 10,000 units of blood annually. The second category includes blood banks without component separation facility that covers major blood banks and District Level blood banks (DLBB) in NACO supported blood banks. Major blood banks collect between 3,000 and 5,000 units and district level blood banks collect up to 3,000 units annually.

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

Table 2 - Scoring details and weight

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

The scoring pattern was different based on the category of blood banks that are: 1. Blood banks with component separation facility (n=65) and 2. Blood banks without component separation facility (n=67). 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 136 blood banks in the state of Gujarat in 2015 (CDSCO, 2015). The assessment exercise identified 134 functional blood banks across the state. Of the total functional blood banks, 132 blood banks (77 NACO supported – 58.3% and 55 Non-NACO- 41.7%) which have submitted the assessment forms in complete were included in the analysis.

Table 3 - District Wise Descriptions of Blood Banks

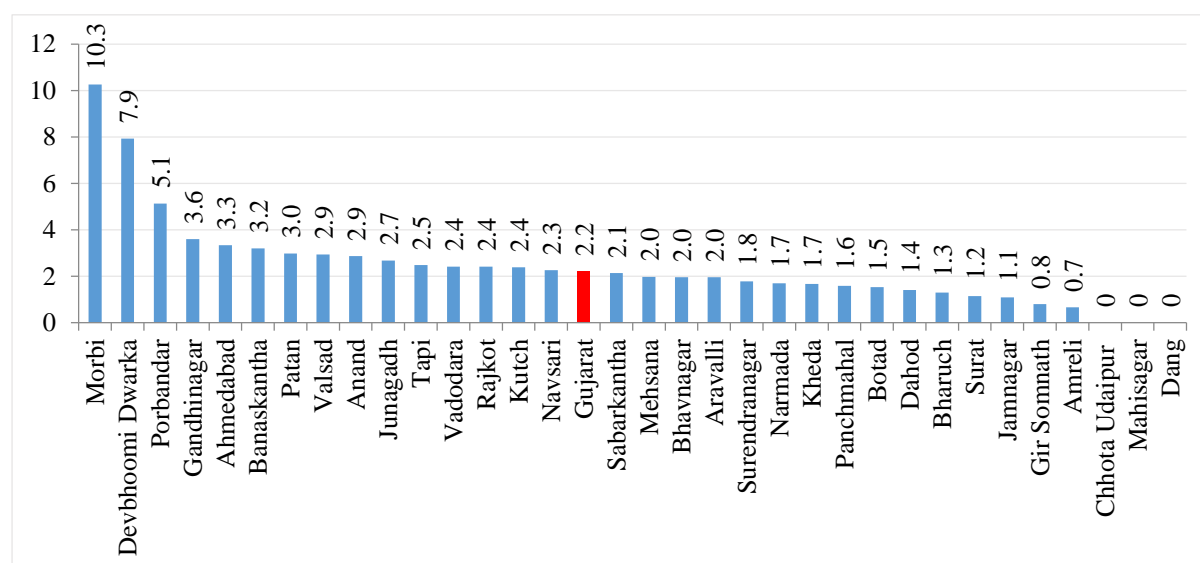
District	NACO Supported	Non-NACO	Total
Ahmedabad	10	13	23
Amreli	1	0	1
Anand	3	3	6
Aravalli	0	2	2
Banaskantha	4	6	10
Bharuch	1	1	2
Bhavnagar	4	1	5
Botad	0	1	1
Dahod	1	2	3
Devbhoomi Dwarka	1	1	2
Gandhinagar	3	2	5
Gir Somnath	0	1	1
Jamnagar	2	0	2
Junagadh	1	3	4
Kheda	2	1	3
Kutch	3	2	5
Mehsana	4	0	4
Morbi	1	1	2
Narmada	0	1	1
Navsari	2	1	3
Panchmahal	2	1	3
Patan	3	1	4
Porbandar	2	1	3
Rajkot	5	4	9
Sabarkantha	2	1	3
Surat	7	0	7
Surendranagar	2	1	3
Tapi	1	1	2
Vadodara	5	5	10
Valsad	5	0	5
Gujarat	77	57	134

Table - 3 indicates the district wise details of all the blood banks in the state, including the description of NACO supported and Non-NACO blood banks. Ahmedabad (23) had the

highest number of blood banks followed by Banaskantha (10), Vadodara (10), Rajkot (9). In terms of NACO supported blood banks, Ahmedabad (10) had the highest number of blood banks, followed by Surat (7), Rajkot (5), Vadodara (5) and Valsad (5).

Around 49% (65) of all the blood banks (n=134) in the Gujarat were in 6 districts that are, Ahmedabad (17.2%), Banaskantha (7.5%), Vadodara (7.5%), Rajkot (6.7%), Surat (5.2%) and Anand (4.5%).

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



Considering the number of blood banks per one million population, 15 districts such as, Morbi (10.3 blood banks), Dwarka (7.9), Porbandar (5.1), Gandhinagar (3.6), Ahmedabad (3.3), Banaskantha (3.2), Patan (3.0), Valsad (3.0), Anand (2.9), Junagadh (2.7), Tapi (2.5), Vadodara (2.4), Rajkot (2.4). Kutch (2.4) and Navsari (2.3) recorded more than the State average of 2.2 blood banks per 1,000,000 (one million) population.

4.1 Basic details of blood banks (n=132)

As indicated earlier, 132 blood banks (77 NACO supported and 55 Non-NACO) that submitted the assessment forms were included in the analysis.

4.1.1 Category of Blood Banks: Out of 77 NACO supported blood banks 57.1% (44) of the blood banks had component separation facility. Out of 55 Non-NACO blood banks only 38.2% (21) were with component separation facility.

Table 4 - Basic details of blood banks

Specifics	Description	NACO Supported	Non-NACO	Total
Type of BB	With components	44 (57.1%)	21(38.2%)	65(49.2%)
	Without components	33(42.9%)	34(61.8%)	67(50.8%)
Ownership	NGO/Trust/Charitable	50(64.9%)	32(58.2%)	82(62.1%)
	Private	-	23(41.8%)	23(17.4%)
	Public	27(35.1%)	-	27(20.5%)
Licence	Valid	57(74%)	38(69.1%)	95(72%)
	Under Renewal	20(26%)	17(30.9%)	37(28%)
Attachment	Attached to Hospital	43(55.8%)	13(23.6%)	56(42.4%)
	Attached to lab	-	5(9.1%)	5(3.8%)
	Stand alone	34(44.2%)	37(67.3%)	71(53.8%)

At the District level, Ahmedabad had the highest percentage of blood component separation units (15, 23.1%), followed by Vadodara (9, 13.8%), Surat (7, 10.8%) and Rajkot (6, 9.2%). All the blood banks in Surat (7) had component separation facility.

4.1.2 Ownership: As depicted in Table:-4, majority of Blood bank (82, 62.1%) are owned by not-for-profit sector followed by public (27, 20.5%) and private (23, 17.4%) sectors. The majority (50; 64.9%) of NACO supported blood banks were owned by the non-profit/not-for-profit sector such as NGOs, charitable trusts, societies, foundations, etc. and the remaining (27, 35.1%) were owned by public sector . The not-for-profit sector had a higher proportion (67.7%) of blood component separation facility than the public (18.5%) and private sector (13.8%). Among the NACO supported blood banks, the not-for-profit sector had a higher (64%) proportion of component separation facilities compared to the public sector (44.4%).

Around 51% of all the not-for-profit blood banks (n=82) were clustered in seven districts which are Rajkot (9.8%), Ahmedabad (8.5%), Anand (7.3%), Banaskantha (7.3%), Vadodara (7.3%), Surat (6.1%) and Valsad (4.9%). Around 48% of all the public owned blood banks were clustered in four districts which are Ahmedabad (25.9%), Patan (7.4%), Surat (7.4%), and Vadodara (7.4%). 82.6% of all the private owned blood banks were in six districts which are Ahmedabad (34.8%), Banaskantha (13%), Aravalli (8.7%), Gandhinagar (8.7%), Kutch (8.7%) and Vadodara (8.7%) (Refer Table - 5).

Table 5 - District wise list of blood banks by Ownership

District	Public	%	Not-for-profit	%	Private	%	Total
Ahmedabad	7	31.8	7	31.8	8	36.4	22
Amreli	-	-	1	100	-	-	1
Anand	-	-	6	100	-	-	6
Aravalli	-	-	-	-	2	100	2
Banaskantha	1	10	6	60	3	30	10
Bharuch	-	-	2	100	-	-	2
Bhavnagar	1	25	3	75	-	-	4
Botad	-	-	1	100	-	-	1
Dahod	-	-	2	66.7	1	33.3	3
Devbhoomi Dwarka	1	50	-	-	1	50	2
Gandhinagar	1	20	2	40	2	40	5
Gir Somnath	-	-	-	-	1	100	1
Jamnagar	1	50	1	50	-	-	2
Junagadh	1	25	3	75	-	-	4
Kheda	-	-	3	100	-	-	3
Kutch	-	-	3	60	2	40	5
Mehsana	1	25	3	75	-	-	4
Morbi	1	50	1	50	-	-	2
Narmada	-	-	1	100	-	-	1
Navsari	-	-	3	100	-	-	3
Panchmahal	1	33.3	2	66.7	-	-	3
Patan	2	50	2	50	-	-	4
Porbandar	1	33.3	2	66.7	-	-	3
Rajkot	1	11.1	8	88.9	-	-	9
Sabarkantha	1	33.3	2	66.7	-	-	3
Surat	2	28.6	5	71.4	-	-	7
Surendranagar	1	33.3	1	33.3	1	33.3	3
Tapi	-	-	2	100	-	-	2
Vadodara	2	20	6	60	2	20	10
Valsad	1	20	4	80	-	-	5
Gujarat	27	20.5	82	62.1	23	17.4	132

4.1.3 Organizational Attachment: The majority of the blood banks (71; 53.8%) were standalone blood banks, 42.4% (56) were attached to hospitals and the remaining 3.8% (5) were attached to laboratories.

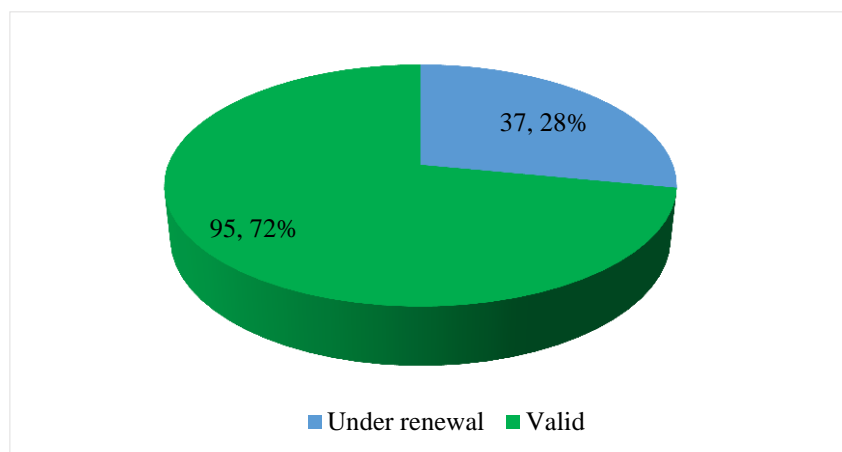
The majority of the NACO supported blood banks (43; 55.8%) were attached to hospitals and only 44.2% (34) were standalone blood banks. Majority (37; 67.3%) of the Non-NACO blood banks were standalone, 23.6% (13) of Non-NACO blood banks were attached to hospitals

and 9% (5) were attached to laboratories. Further analysis indicated that all the blood banks (27) in the public sector, 30.4% (7) of the blood banks in the private sector, and 26.8% (22) of the blood banks in the not-for-profit sector were attached to hospitals. In the not-for-profit sector 72% (59) 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 (95; 72%) had a valid and current license, and the remaining 28% (37) had applied for renewal. 74% (57) of NACO supported and 69% (38) of Non-NACO blood banks had a valid and active license. Similarly 72% (59) of the not-for-profit blood banks, 78% (21) of the public blood banks and 65% (15) of the private blood banks had a valid and active license.

Figure 2 - License Status (n=132)



The majority of those blood banks (21; 56.8%) which have reported as “deemed renewal” had their last inspection by licencing authority during the last one year; 24.3% (9) had their inspection between the last 1 to 2 years.

4.2 Annual Blood Collection and Voluntary Blood Donation

According to WHO, it is estimated that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2016b), which means that the state with a population of 60,439,692, currently needs around 604,397 units of blood. But since Gujarat is producing 808,474 units of blood, it is exceeding the basic requirement of blood by 33.7%.

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 808,474 of which 77.6% units were through voluntary blood donations and the remaining were from replacement donations.

Figure 3 - Annual Collections and Voluntary Donation

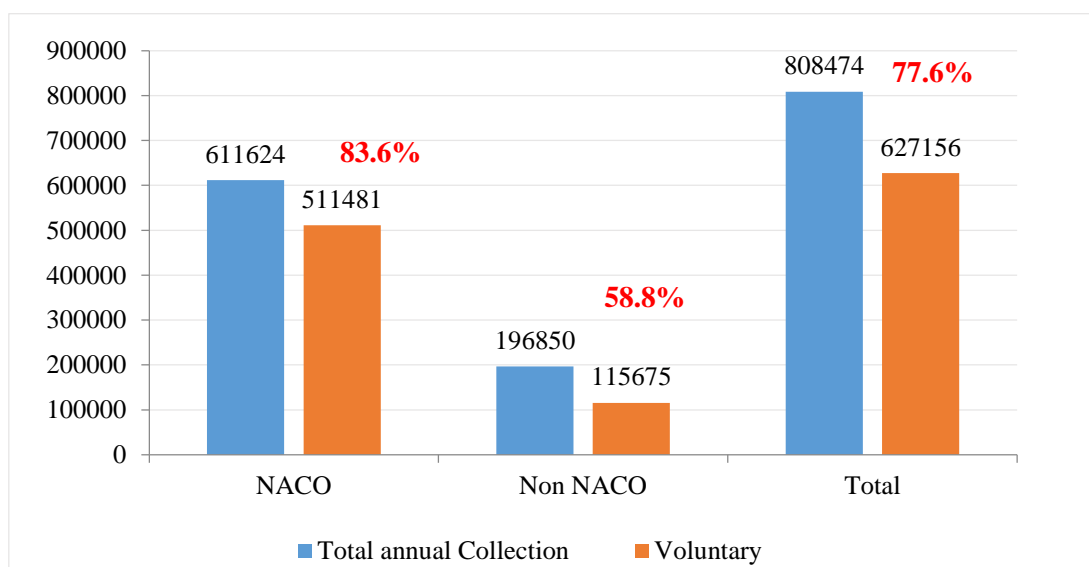
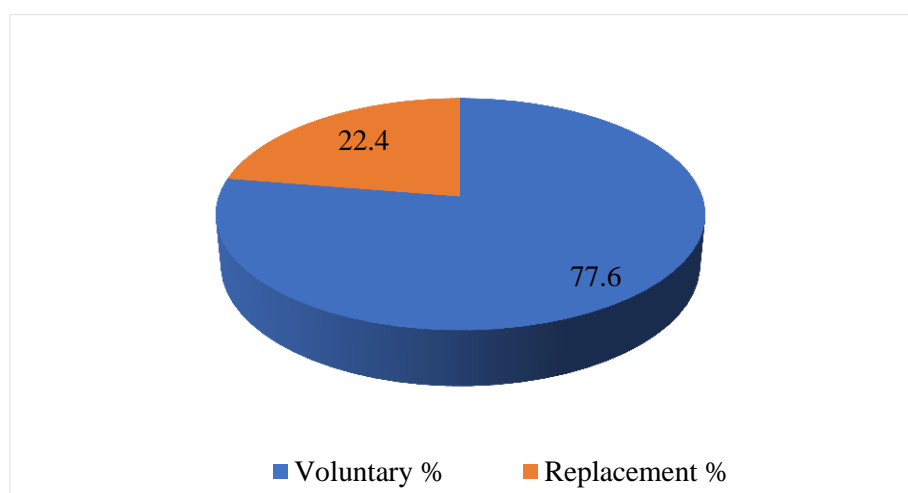


Figure 4 - Type of Blood Donation (Voluntary vs Replacement Donation %)



The average annual collection of blood units of all the blood banks in the state was 6,219 units. The average annual collection of NACO supported blood banks was found to be higher (7,943 units) than the Non-NACO blood banks (3,714 units).

Table 6 - Average Annual collection

District	NACO Supported	Non-NACO	All BBs
Ahmedabad	13512	5471	9491
Amreli	7250	-	7250
Anand	6136	2031	4083
Aravalli	-	3188	3188
Banaskantha	2389	2945	2723
Bharuch	12208	2667	7437
Bhavnagar	8432	-	8432
Botad	-	3684	3684
Dahod	2566	4327	3740
Devbhoomi Dwarka	1313	40	676
Gandhinagar	3002	3278	3112
Gir Somnath	-	3335	3335
Jamnagar	13983	-	13983
Junagadh	6541	2813	3745
Kheda	5120	4586	4942
Kutch	5771	4642	5320
Mehsana	4740	-	4740
Morbi	304	4140	2222
Narmada	-	247	247
Navsari	9355	2803	7171
Panchmahal	3951	2061	3321
Patan	4352	2881	3984
Porbandar	2596	714	1968
Rajkot	13285	2137	8331
Sabarkantha	5282	4296	4953
Surat	13148	-	13148
Surendranagar	4374	778	3175
Tapi	9090	40	4565
Vadodara	8438	7647	8043
Valsad	5440	-	5440
Gujarat	7943	3714	6219

Similarly, the blood banks with component separation units recorded a average higher collection of 10,060 units compared to blood banks without blood component separation units which was 2,607 units. However, the variation in the collection was found to be very high across and within districts.

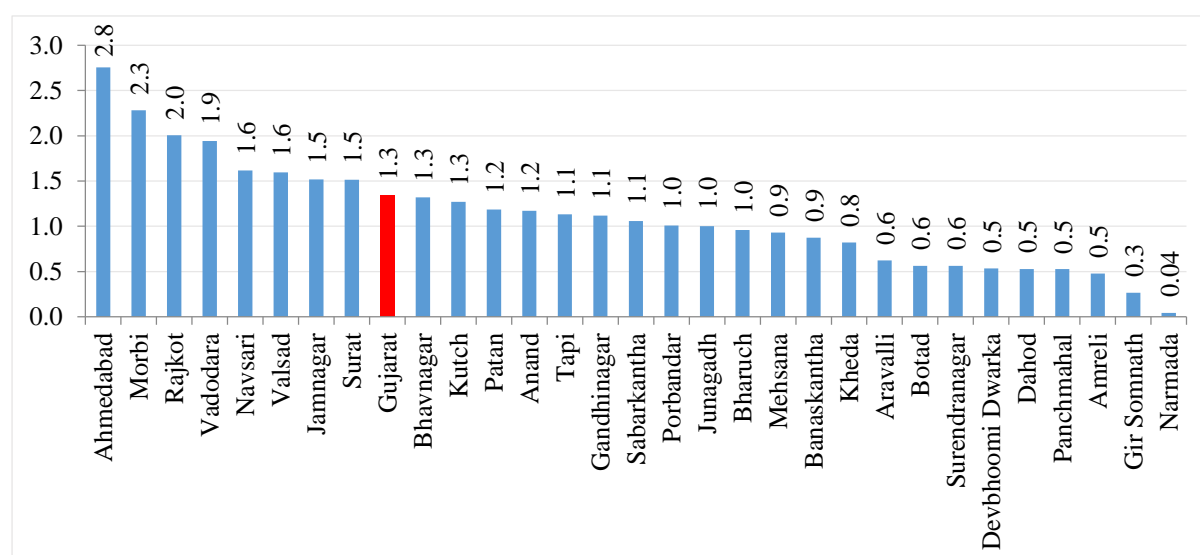
The NACO supported blood banks collected 75.7% (611,624 units) of the total collection, of which 83.6% (511,481) units were through voluntary blood donation. The Non-NACO blood banks collected 24.3% (196,850) units of which 58.8% (115,675) units were through voluntary blood donation. Blood banks with component separation facility collected the majority (78.4%) of blood units (633,787) and the remaining 21.6% (174,687) were collected by blood banks without the component facility. Similarly, blood banks owned by the not-for-profit sector collected 65.9% (532,387) of the total collection followed by public sector blood banks 23.4%, (189,559) and private sector 10.7% (86,528).

Table 7 - Annual blood collection and percentage of VBD

District	Voluntary Donation	Replacement Donation	Annual Collection	VBD %
Ahmedabad	131246	58590	189836	69.1
Amreli	5291	1959	7250	73.0
Anand	19277	5226	24503	78.7
Aravalli	3254	3122	6376	51.0
Banaskantha	14217	13014	27231	52.2
Bharuch	12875	2000	14875	86.6
Bhavnagar	32981	750	33731	97.8
Botad	3074	610	3684	83.4
Dahod	5300	5921	11221	47.2
Devbhoomi Dwarka	1338	15	1353	98.9
Gandhinagar	8285	7278	15563	53.2
Gir Somnath	1212	2123	3335	36.3
Jamnagar	23464	4502	27966	83.9
Junagadh	9248	5732	14980	61.7
Kheda	9366	5461	14827	63.2
Kutch	23645	2955	26600	88.9
Mehsana	16847	2116	18963	88.8
Morbi	3978	466	4444	89.5
Narmada	98	149	247	39.7
Navsari	20824	689	21513	96.8
Panchmahal	8736	1228	9964	87.7
Patan	8228	7711	15939	51.6
Porbandar	5869	37	5906	99.4
Rajkot	73456	1524	74980	98.0
Sabarkantha	11422	3438	14860	76.9
Surat	91345	693	92038	99.2
Surendranagar	3667	5859	9526	38.5
Tapi	1293	7837	9130	14.2
Vadodara	52620	27812	80432	65.4
Valsad	24700	2501	27201	90.8
Gujarat	627156	181318	808474	77.6

Table-7 indicates the district-wise details of the total annual collection, voluntary and replacement donation in the state of Gujarat. Blood banks reported a varying proportion of VNRBD ranging from 14% to 99%.

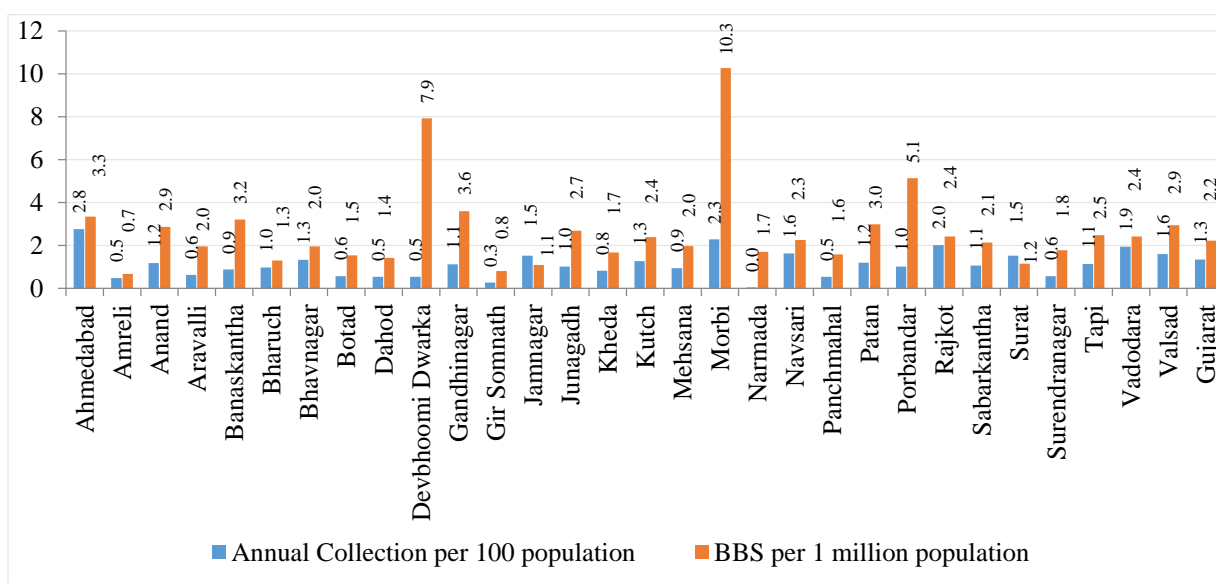
Figure 5 - Annual Collection per 100 population- District wise



The annual collection of blood units per 100 individuals was found to be around 1.3% in the state, which is slightly higher than the WHO suggested requirement that 1% of the population can meet a nation's most basic requirements for blood. However, there is a huge disparity in the collection of blood between districts. Narmada collected only 0.04 units of blood per 100 population followed by Gir Somnath (0.3), Amreli (0.5), Panchmahal(0.5), Dahod(0.5), Devbhoomi Dwarka (0.5). Eight districts in the state recorded an annual collection of more than 1.3 units per 100 populations. (Refer Fig-5).

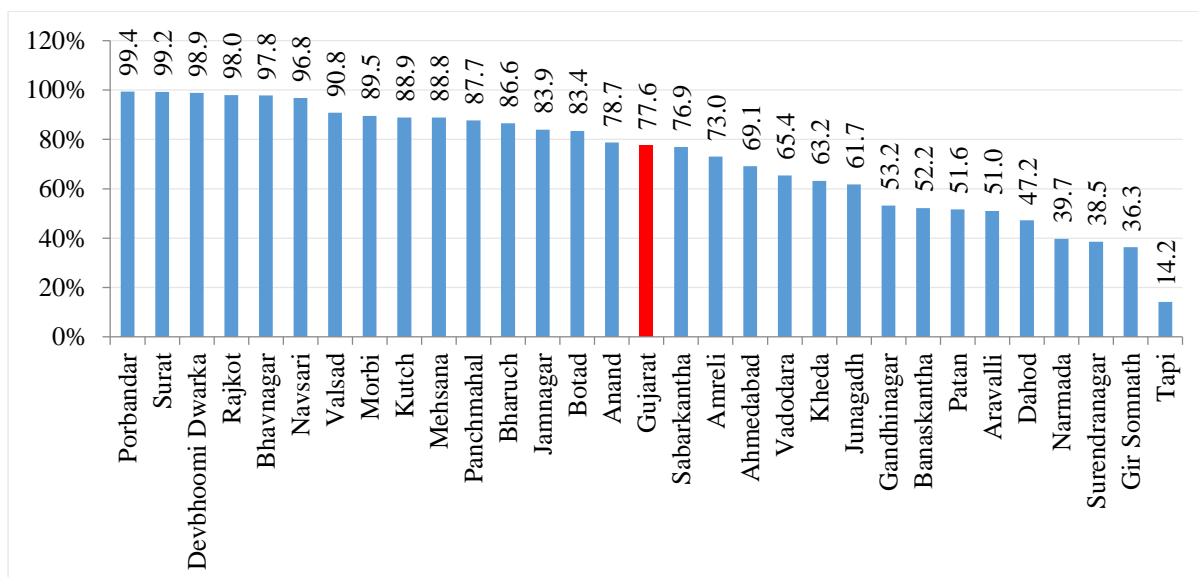
Figure 6 illustrates the district wise comparative information of annual collection per 100 population and number of blood banks per one million populations. This indicates that the state had around 2.2 blood banks per million populations that collected around 1.3 units per 100 population at the ratio of 2.2 BB: 1.3 blood unit. The ratio is wide in Morbi 10.3:2.3 and Devbhoomi Dwarka districts 7.9:0.5 which indicate that these districts collect relatively less blood with more number of blood banks proportionate to population.

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



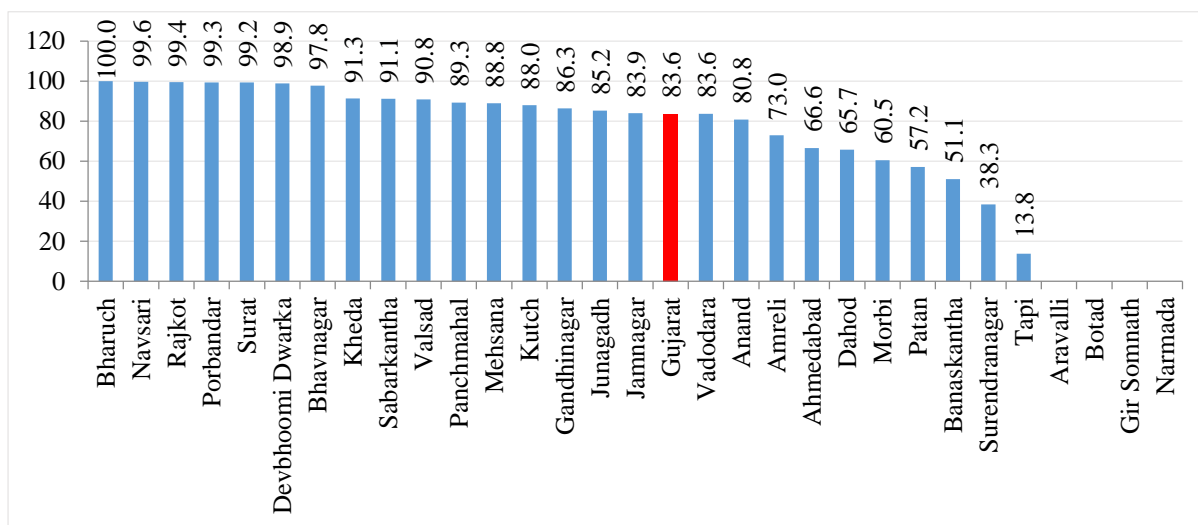
4.2.2 Voluntary blood donation: As depicted in Figure-7, fifteen districts have recorded more than the state average of 77.6%. None of the Districts reported 100% voluntary blood donation. Nine districts reported less than 60% of voluntary donation during January to December 2015.

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



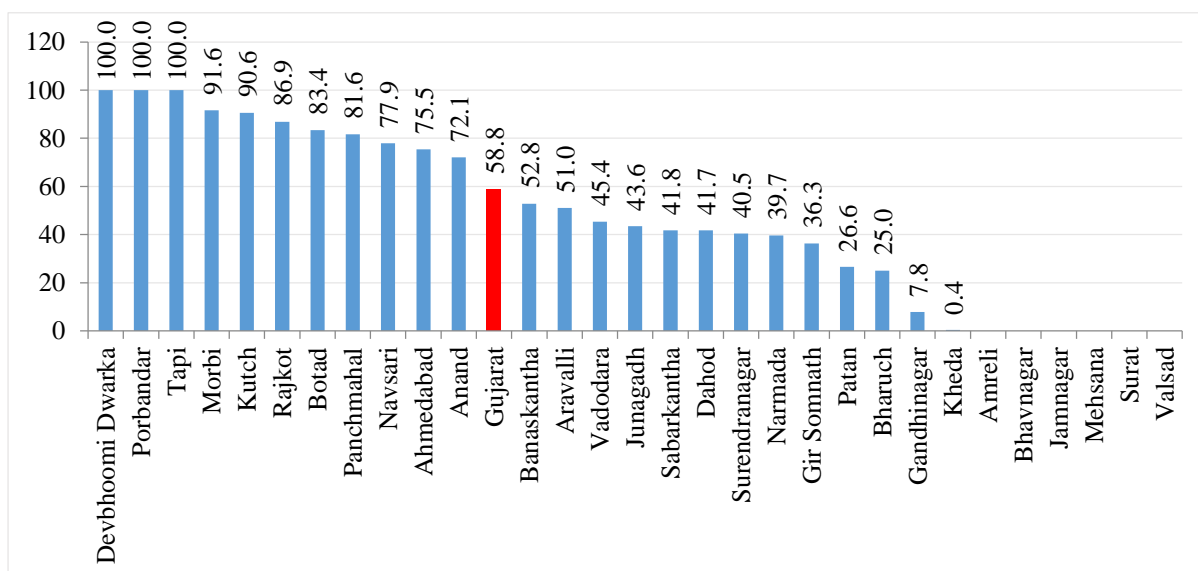
In terms of NACO supported blood banks, sixteen districts have recorded a higher proportion of voluntary donation which is above the state average of 83.6%. Only Bharuch reported 100% voluntary blood donation.

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



Among Non-NACO blood banks, eleven districts recorded more than state average of 58.8%. Three districts Devbhoomi Dwarka, Porbandar and Tapi recorded 100% of voluntary donation. However, eleven districts reported less than 50% of voluntary donation.

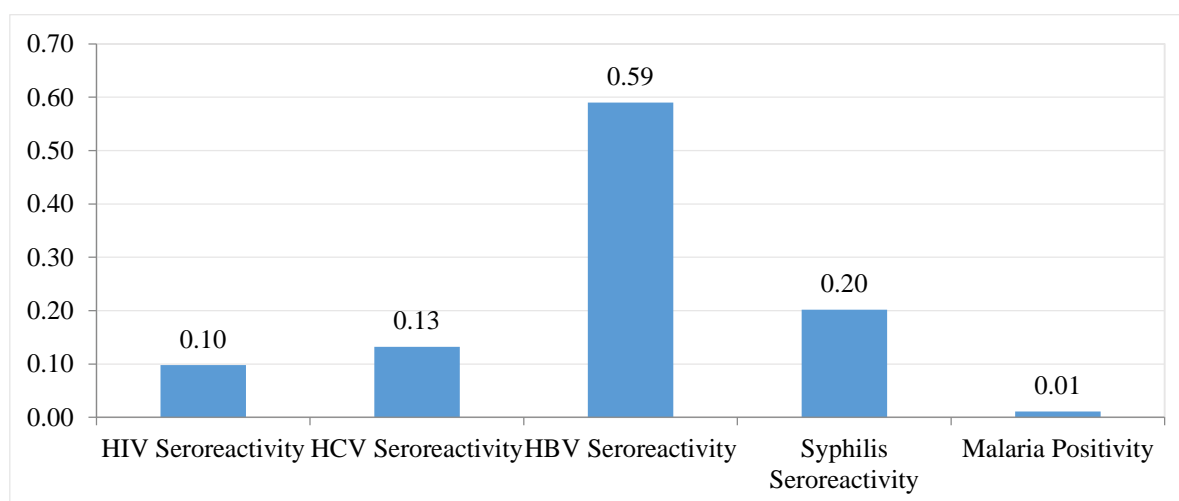
Figure 9 - Percentage of Voluntary Blood Donation by District (Non-NACO)



4.3 Transfusion Transmitted Infections(TTIs)

Transfusion-Transmitted Infections (TTIs) are major problems associated with blood transfusion (Chandra, Rizvi, & Agarwal, 2014; Gupta, Singh, Singh, & Chugh, 2011). Screening for TTIs such as HIV 1, HIV 2, Hepatitis B, Hepatitis C, Malaria, and Syphilis is mandatory in India. Due to the concerted and active efforts, the seroreactivity percentage of TTIs has come down significantly over the years.

Figure 10 - Transfusions Transmitted Infection (%) -Jan-Dec 2015



The seroreactivity of TTI among blood donors in the year 2015 is depicted in Fig-10. HIV seroreactivity was found to be 0.10%, Hepatitis-C was 0.13%, Hepatitis-B 0.59%, Syphilis 0.20% and Malaria 0.01%. However, there is a huge variation between districts.

Except Malaria all the TTIs -HIV, HCV, HBV and Syphilis reactivity rates were recorded higher in NACO supported blood banks than Non NACO blood banks.

Table 8 - Transfusion Transmitted Infections (%)

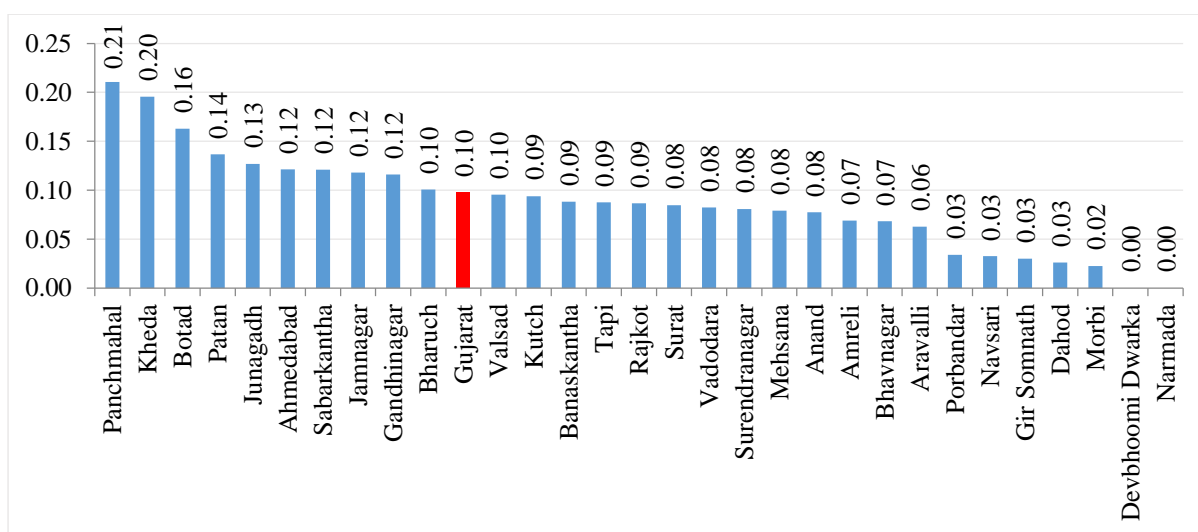
Category of BB	Transfusion Transmitted Infections %				
	HIV	HCV	HBV	Syphilis	Malaria
NACO Supported	0.11	0.15	0.64	0.18	0.01
Non-NACO	0.07	0.07	0.44	0.27	0.01
Overall	0.10	0.13	0.59	0.20	0.01

4.3.1 Transfusion Transmitted Infections by Category of blood banks: HIV, Malaria and Syphilis reactivity rates did not indicate much difference between blood banks with component and without component separation facility. The blood banks with component facility indicated a slightly higher reactivity of HCV (0.15%) and HBV (0.62%).

Table 9 - Transfusion Transmitted Infections by category of blood banks

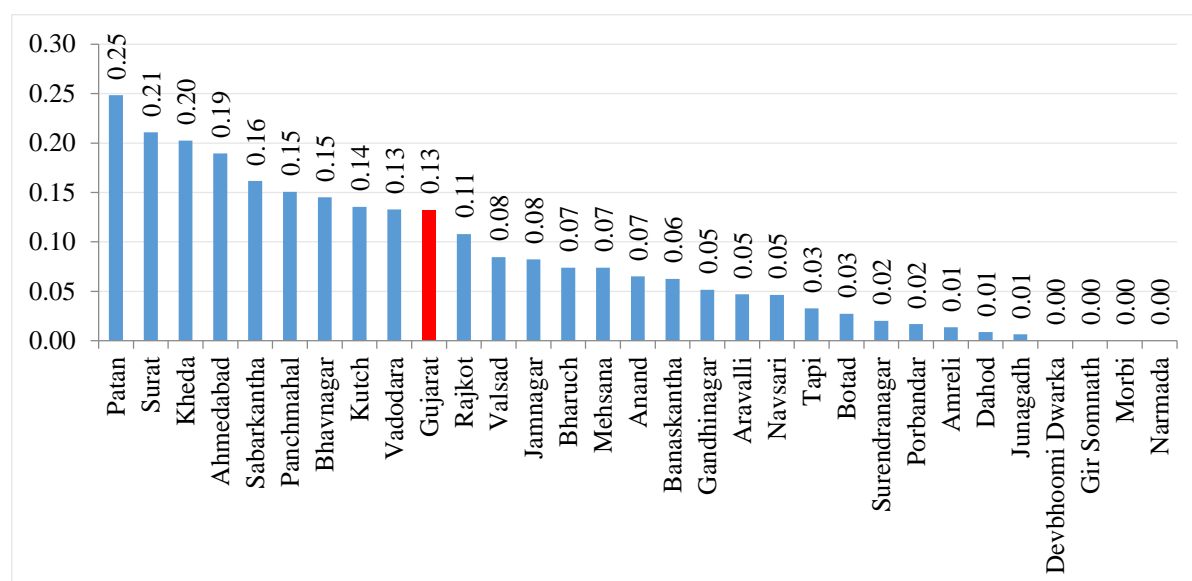
Category of BB	Transfusion Transmitted Infections %				
	HIV	HCV	HBV	Syphilis	Malaria
BBs with component facility	0.10	0.15	0.62	0.20	0.01
BBs without component facility	0.09	0.06	0.47	0.22	0.01
Overall	0.10	0.13	0.59	0.20	0.01

Figure 11 - HIV Seroreactivity- By District (%)



Nine districts Panchmahal (0.21%), Kheda (0.20%), Botad (0.16%), Patan (0.14%), Junagadh (0.13%), Ahmedabad (0.12%), Sabarkantha (0.12%), Jamnagar (0.12%) and Gandhinagar (0.12%) recorded a higher reactivity than state average of 0.10%.

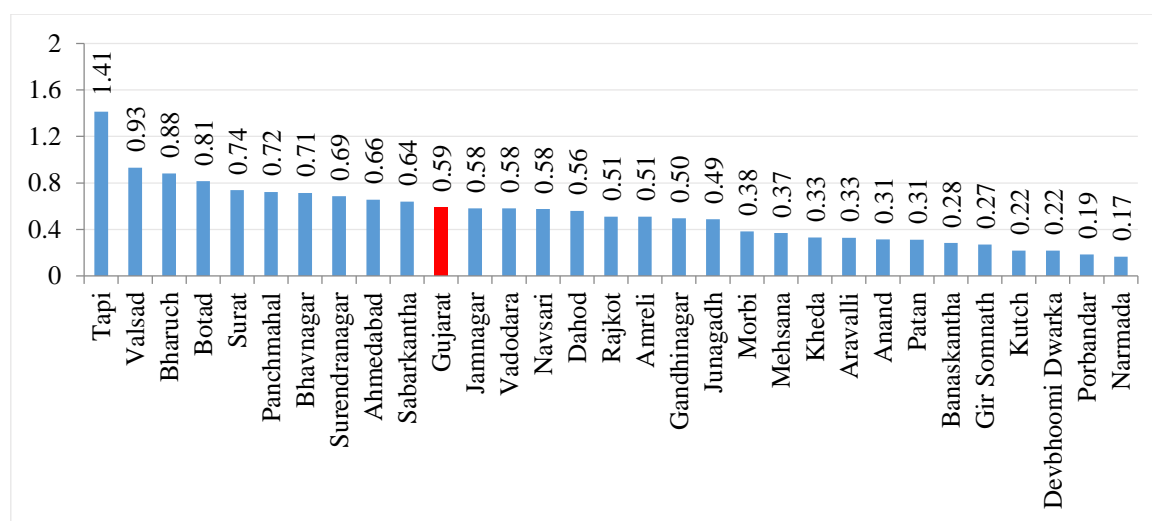
Figure 12 - HCV Seroreactivity- By District (%)



When considering Hepatitis C infection, majority of districts reported less than the state average of 0.13%. However, districts like Patan (0.25%), Surat (0.21%), Kheda (0.20%), Ahmedabad (0.19%), Sabarkantha (0.16%), Panchmahal(0.15%), Bhavnagar(0.15%) and Kutch (0.14%) recorded a reactivity level higher than the state average of 0.13%.

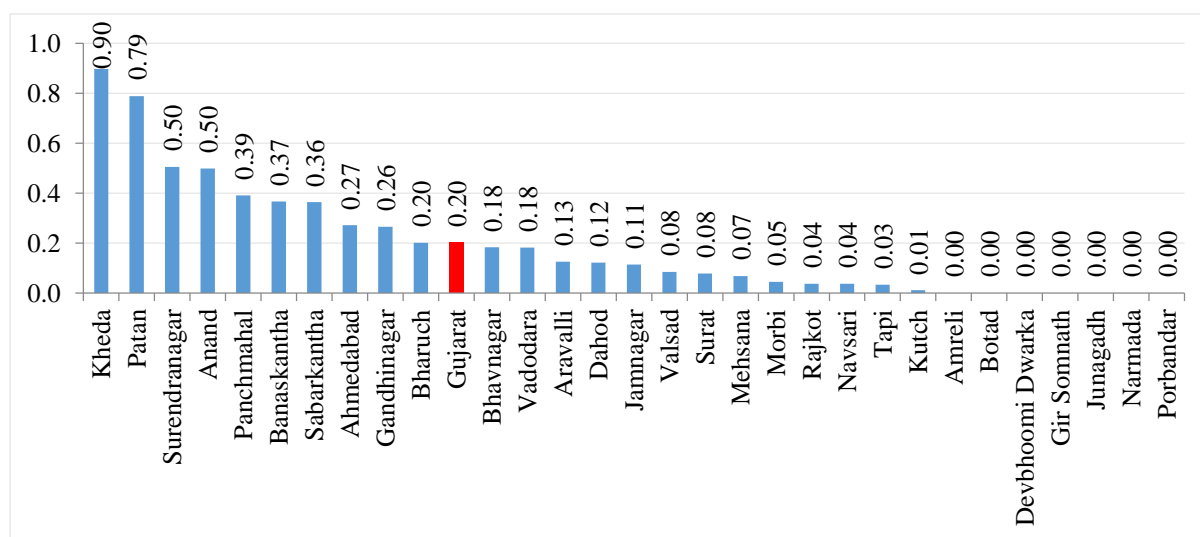
Hepatitis B seroreactivity was found to be higher than the state average of 0.94% in districts like Tapi (1.41%), Valsad (0.93%), Bharuch (0.88%), Botad (0.81%), Surat (0.74%), Panchmahal (0.72%), Bhavnagar (0.71%), Surendranagar (0.69%), Ahmedabad (0.66%) and Sabarkantha (0.64%).

Figure 13 - HBV Seroreactivity- By District (%)



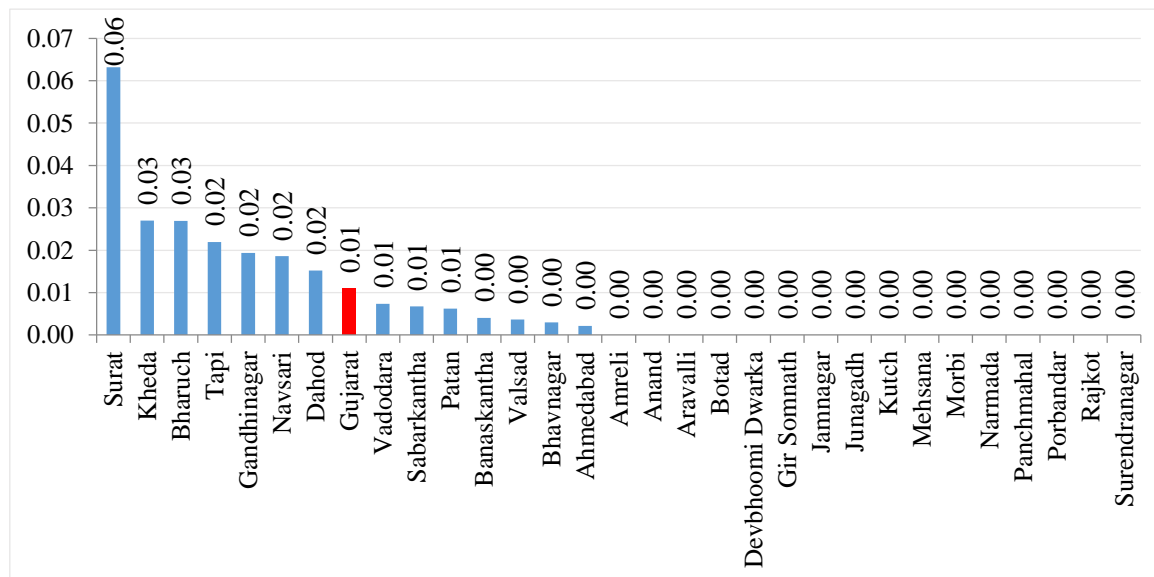
Syphilis seroreactivity was found to be higher than the state average of 0.20% in districts like Kheda (0.90%), Patan (0.79%), Surendranagar (0.50%), Anand (0.50%), Panchmahal (0.39%), Banaskantha (0.37%), Sabarkantha (0.36%), Ahmedabad (0.27%) and Gandhinagar (0.26%). Twenty districts recorded less than the state average.

Figure 14 - Syphilis Seroreactivity- By District (%)



Malaria positivity was recorded 0.01% in the state, however districts like Surat (0.06%), Kheda (0.03%), Bharuch (0.03%), Tapi (0.02%), Gandhinagar (0.02%), Navasari (0.02%) and Dahod (0.02%) reported higher than state average.

Figure 15 - Malaria Positivity- By District (%)



4.4 Component Separation

As depicted in Figure-16, around 80% of blood units collected by blood banks with component separation facilities, were used for component separation in state. The percentage of component separation was higher (82.3%) in Non-NACO blood banks compared to NACO supported blood banks (79.2%).

Figure 16 - Total Blood Collection and Component Separation

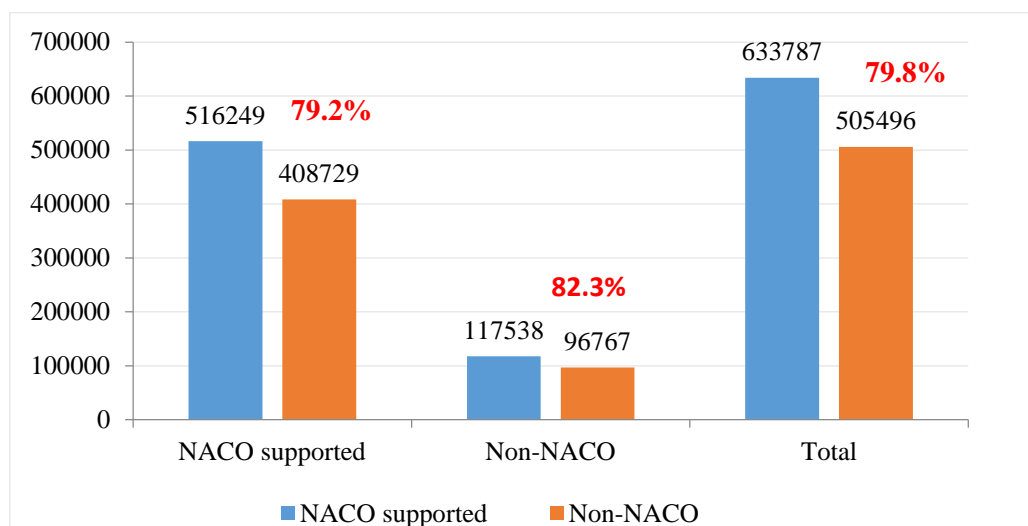


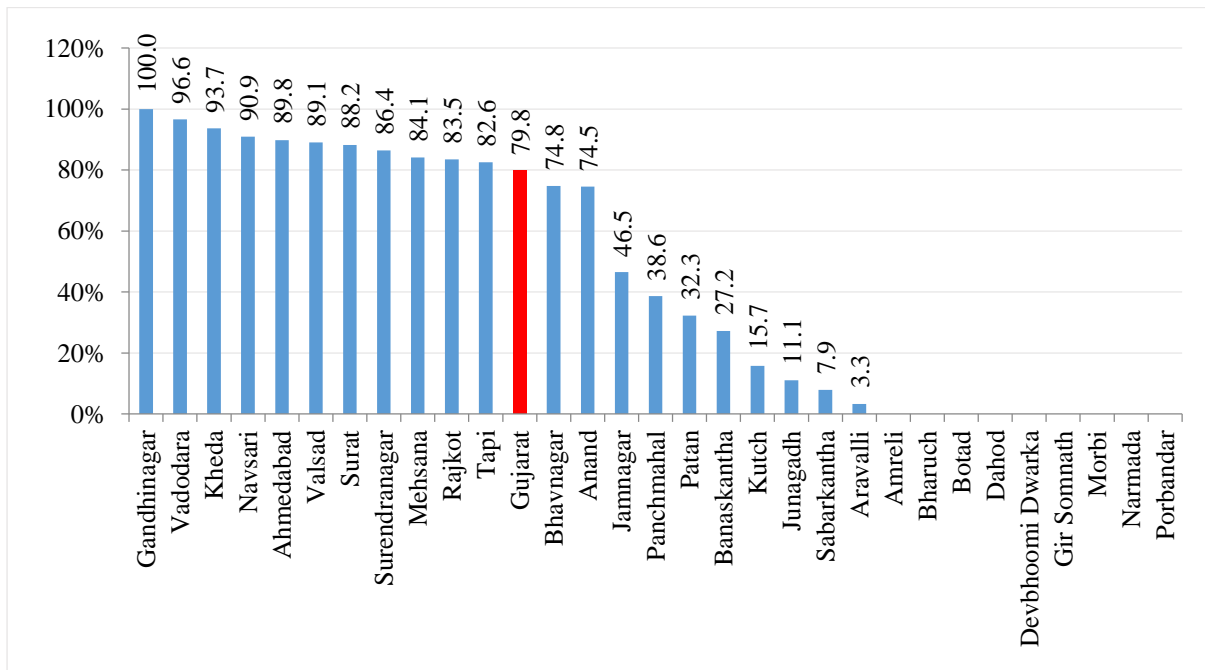
Table 10 - Total Annual Collection by BCSUs and Percentage of Component Separation

District	Total Annual Collection	Total Collection by BCSUs	Percentage of component separation
Ahmedabad	189836	175587	89.8%
Amreli	7250	-	-
Anand	24503	16563	74.5%
Aravalli	6376	3053	3.3%
Banaskantha	27231	7326	27.2%
Bharuch	14875	-	-
Bhavnagar	33731	33731	74.8%
Botad	3684	-	-
Dahod	11221	-	-
Devbhoomi Dwarka	1353	-	-
Gandhinagar	15563	4605	100.0%
Gir Somnath	3335	-	-
Jamnagar	27966	21117	46.5%
Junagadh	14980	2388	11.1%
Kheda	14827	4586	93.7%

Kutch	26600	23631	15.7%
Mehsana	18963	11956	84.1%
Morbi	4444	-	-
Narmada	247	-	-
Navsari	21513	16560	90.9%
Panchmahal	9964	9065	38.6%
Patan	15939	10643	32.3%
Porbandar	5906	-	-
Rajkot	74980	70121	83.5%
Sabarkantha	14860	9914	7.9%
Surat	92038	92038	88.2%
Surendranagar	9526	8399	86.4%
Tapi	9130	9090	82.6%
Vadodara	80432	79316	96.6%
Valsad	27201	24098	89.1%
Gujarat	808474	633787	79.8%

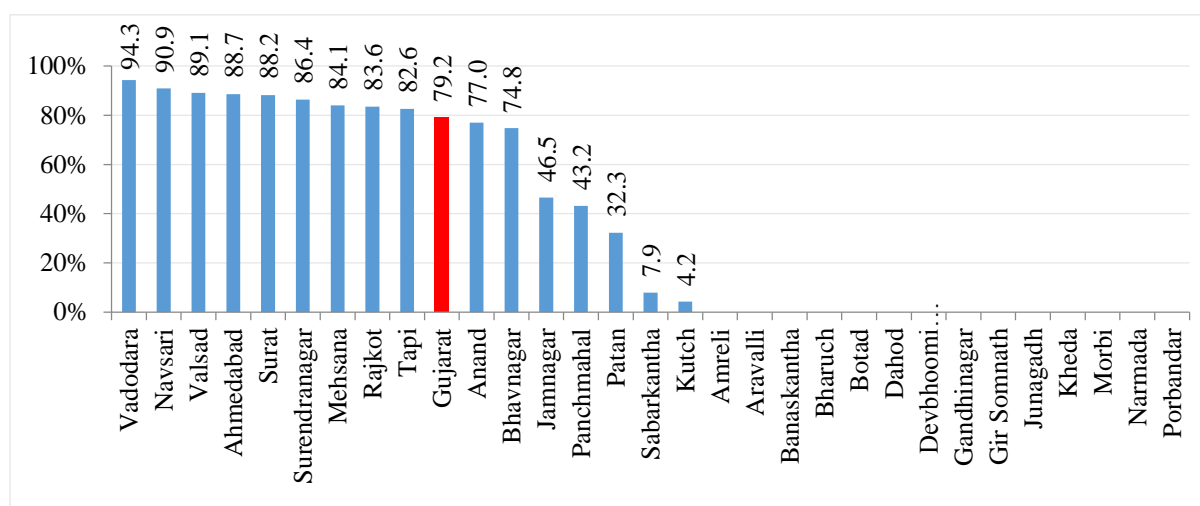
The percentage of component separation out of the total collection by BCSUs was more than 90% in Gandhinagar, Kheda, Navsari and Vadodara.

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



The percentage of component separation in NACO supported blood banks is illustrated in Figure-18 which indicates 7 districts Anand, Bhavnagar, Jamnagar, Panchmahal, Patan, Sabarkantha and Kutch recorded less than State average of 79.2% and 5 districts reported less than 50% of component separation.

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



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 (94.7%) reported that they adhered to the NBTC guidelines. Availability of document control system was there in 53% of the blood banks in the state. Around 51% of NACO supported blood banks and 56.4% of Non-NACO blood banks reported they had a document control system. In terms of Standard Operating Procedures (SOPs) for technical processes, 97.7% reported that they had SOPs.

Table 11 - Availability of Quality Parameters in Blood Banks

Quality Parameters	NACO/NON-NACO		All Blood Banks (n=132)
	NACO supported (n=77)	Non-NACO (n=55)	
Compliance with NBTC guidelines	73	52	125
	94.8%	94.5%	94.7%
Availability of Documental Control System (DCS)	39	31	70
	50.6%	56.4%	53.0%
SOPs for Technical Processes	76	53	129
	98.7%	96.4%	97.7%
IQC for IH	67	45	112
	87.0%	81.8%	84.8%
IQC for TTI	41	37	78
	53.2%	67.3%	59.1%
QC for kits, reagents and blood bags	69	45	114
	89.6%	81.8%	86.4%
EQAS for IH	22	7	29
	28.6%	12.7%	22.0%
EQAS for TTI	24	6	30
	31.2%	10.9%	22.7%
NABH accreditation for blood banks	9	3	12
	11.7%	5.5%	9.1%
Availability of designated and trained Quality Manager	41	29	70
	53.2%	52.7%	53.0%
Availability of designated and trained Technical Manager	49	33	82
	63.6%	60.0%	62.1%
Programme for regular Equipment maintenance	73	52	125
	94.8%	94.5%	94.7%
Equipment calibration as per regulatory requirement	73	51	124
	94.8%	92.7%	93.9%
Total no of blood banks	77	55	132
	100%	100%	100%

At the state level, Internal Quality Control (IQC) for Immunohematology was reported by 84.8% of the blood banks and IQC for TTIs was reported by 59.1% 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 22% for immunohematology and 22.7% for TTIs. Only 12 (9.1%) blood banks out of the total 132 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 53% and 62.1% of the blood banks respectively.

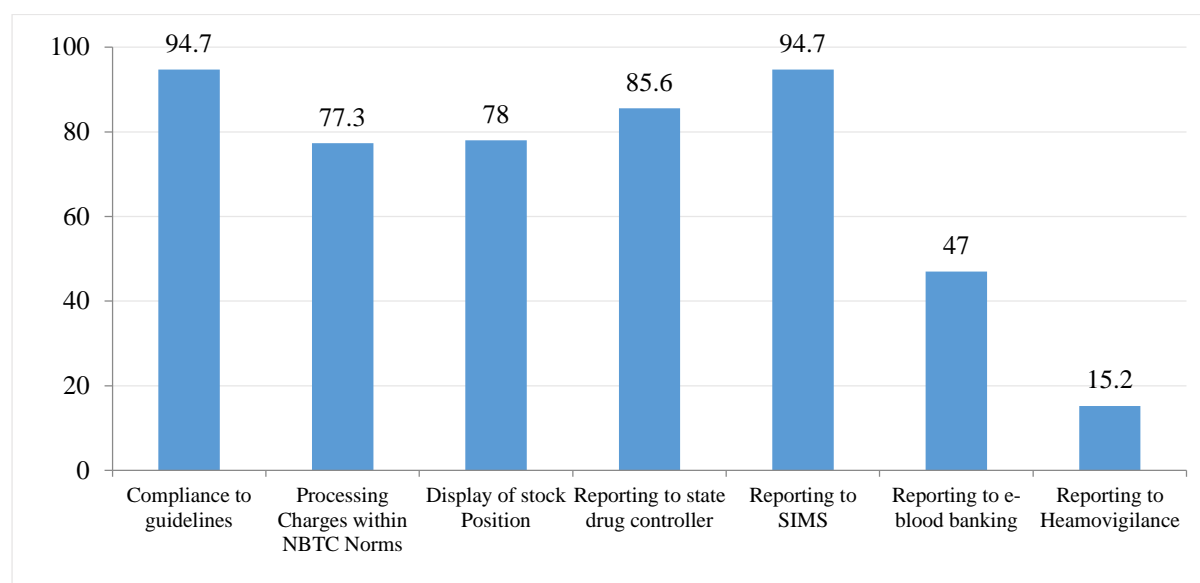
More than 94% of the blood banks reported that they had a regular equipment maintenance programme and around 94% reported that they calibrate the equipment as per requirement.

4.6. Reporting and Documentation

4.6.1. Compliance to NBTC guidelines

Majority of the blood banks (94.7%) reported to be compliant with NBTC guidelines. Around, 77% of Blood Banks reported that they were recovering processing charges within NBTC/SBTC norms. Most of the blood banks (78%) reported that they were displaying stock position in their Blood bank Premises.

Figure 19 - Reporting and Documentation



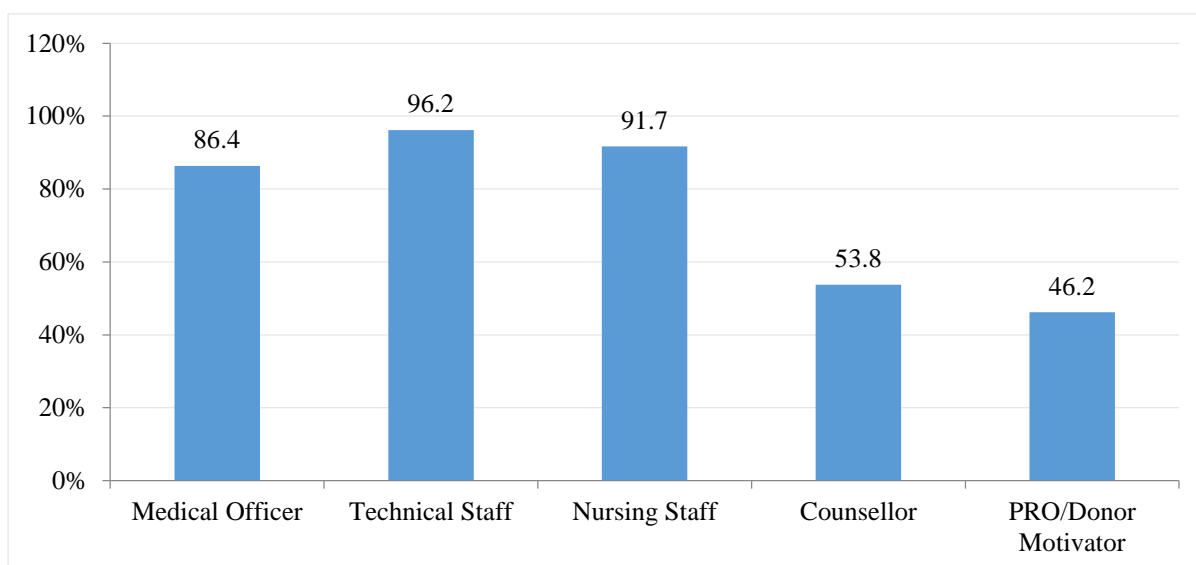
Reporting requirements: In terms of reporting requirement, 85.6% of the blood banks submitted regular reports to state drug controller, 94.7 % of blood banks regularly reported in national strategic information management systems (SIMS). However, only 47 % regularly reported in E-blood banking either national or state e-blood banking. Only 15.2 % of the Blood banks were members of National Haemovigilance Program.

4.7. Human Resources

4.7.1. Availability of staff

The mean number of employees in the blood bank was 16.1 (SD 16). It ranges from zero employees to 116 employees.

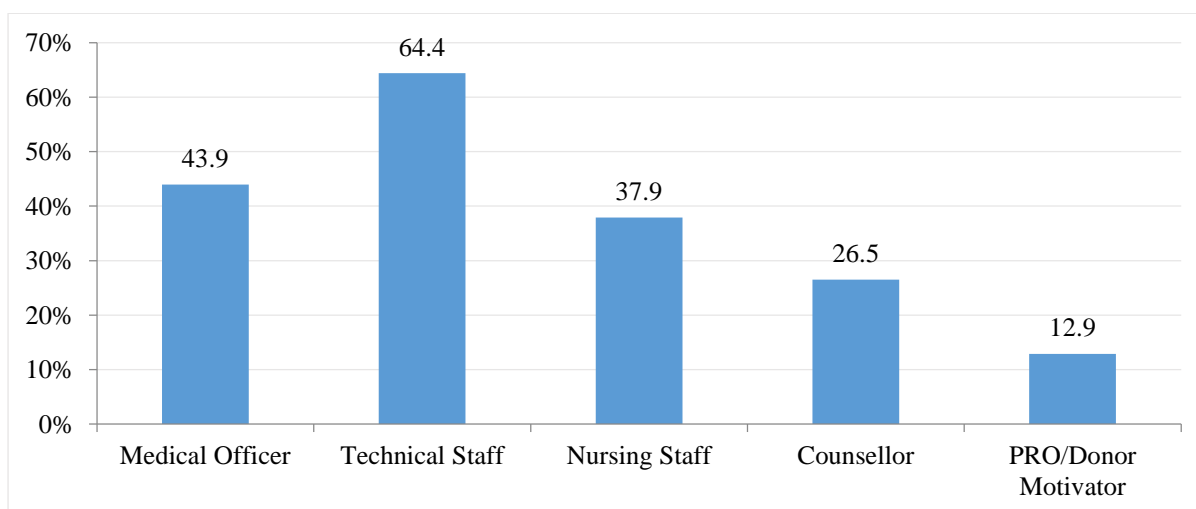
Figure 20 - Percentage of BB Manpower (At least one)



The above graph depicts that majority of the blood banks 96.2% had at least one technical staff and 86.4% had one medical officer. 92% had nursing staff. Only 53.8 % of the blood banks had at least one counsellor and 46.2% had a donor motivator.

4.8. Training of Blood Bank Personnel

Figure 21 - Percentage of At least one trained



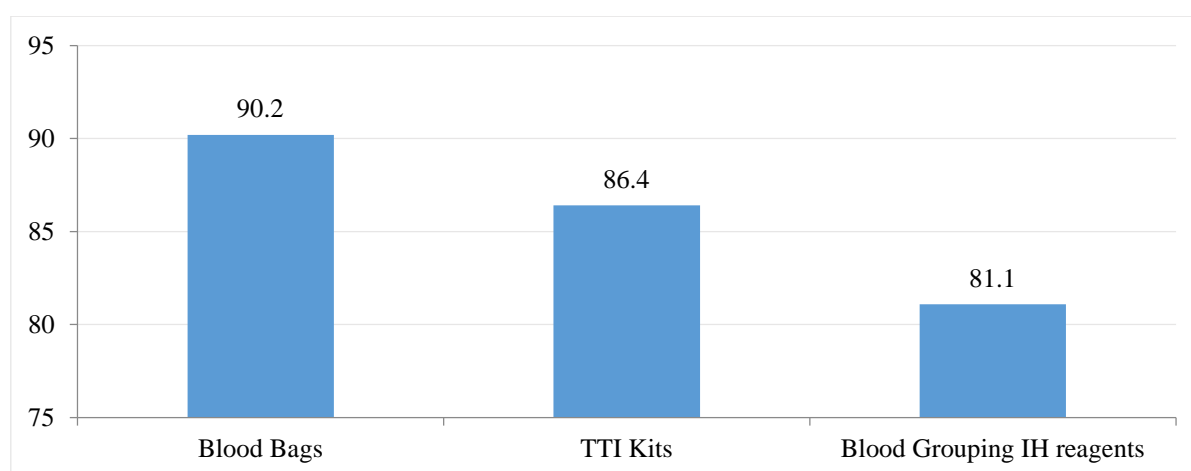
64.4% of blood banks had at least one trained technical staff followed by 43.9% of the blood banks with trained medical officer. 38% blood banks had at least one trained nursing staff. Only 26.5% had one trained counsellor and 12.9 % of blood banks had at least one trained donor motivator.

4.9. Equipment and Supplies

4.9.1. Regular supply kits/supplies

Majority of blood banks (90.2%) reported that they had regular supply of blood bags, 86.4% reported that they had regular supply of kits and 81% reported to have regular supply of blood grouping reagents.

Figure 22 - Regular Supply of Kits



4.9.2. Equipment Availability (working condition)

Table 12 indicates the availability of the different equipment in blood banks. 98.5% of blood banks in the state reported that they had donor couches, 82.6% reported that they had instrument for haemoglobin estimation. Similarly, only 52.3% of blood banks had refrigerated centrifuge in working condition.

Table 12 - BBs having Equipment in working condition

BBs having Equipment in Working Condition		
S.No	Equipment	% BB
1	Donor Couches	98.5
2	Instrument for Hb Estimation	82.6
3	Blood collection monitor	97.0
4	Quarantine Blood Bank Refrigerator to store untested blood	97.7
5	Container for safe disposal of sharps	91.7
6	Oxygen supply equipment	95.5
7	Computers with accessories and software	91.7
8	General lab centrifuge for samples	94.7
9	Bench top centrifuge for serological testing (Immunohaematology)	82.6
10	Blood transportation box (No. in inventory)	88.6
11	Emergency drugs box / Crash cart	93.9
12	Autoclave machine	95.5
13	Water bath	86.4
14	Blood bank refrigerator (storage of tested blood) with temperature recorder	98.5
15	Automated pipettes	90.2
16	Refrigerated centrifuge	52.3
17	Blood container weighting device	69.7
18	Serology rotator	81.8

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

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

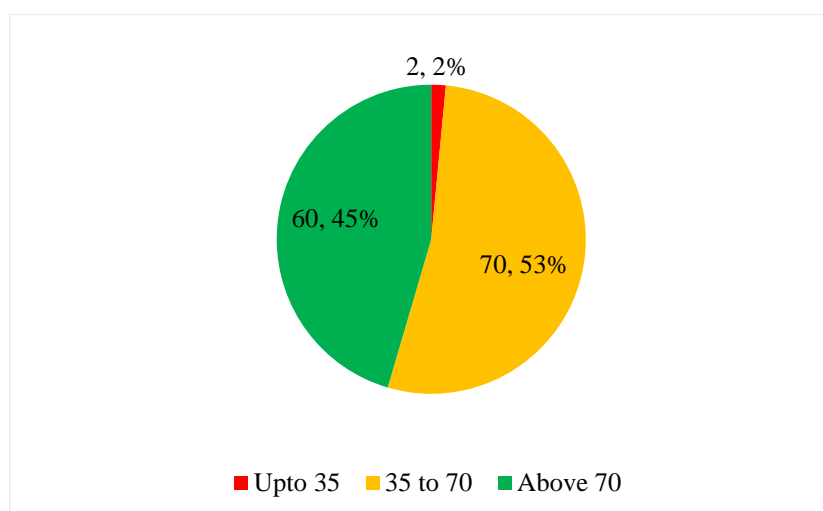
The mean assessment score of blood banks in the state was 68.4 (SD: 11.1). The NACO supported blood banks scored higher (70.5; SD: 10.1) than the Non-NACO blood banks (65.5, SD: 11.8).

Table 13 - Mean Assessment score

Type of BB	N	Mean	SD
NACO supported	77	70.5	10.1
Non-NACO	55	65.5	11.8
Total	132	68.4	11.1

At the state level, the majority of blood banks (70; 53%) scored between 35 and 70, followed by 60 blood banks (45%) which scored above 70, and only two blood banks scored less than or equal to 35. All of the NACO supported blood bank scored more than 35.

Figure 23 - Categorisation of Blood banks (n=132)



Around 45% of NACO supported and 63% Non-NACO blood banks scored between 35 and 70. Around, 55% of NACO supported blood banks and 33% of Non-NACO blood banks scored more than 70 (Refer Figure 24 and Figure 25).

Figure 24- Categorisation of NACO Supported BBs (n=77)

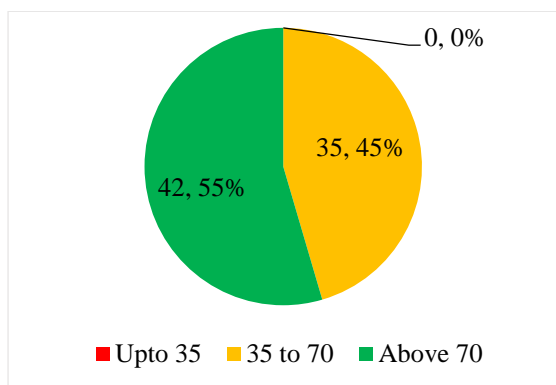
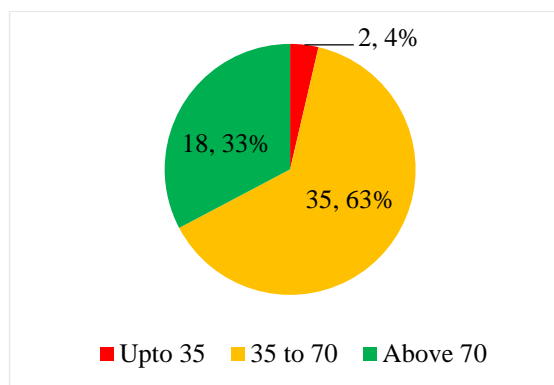
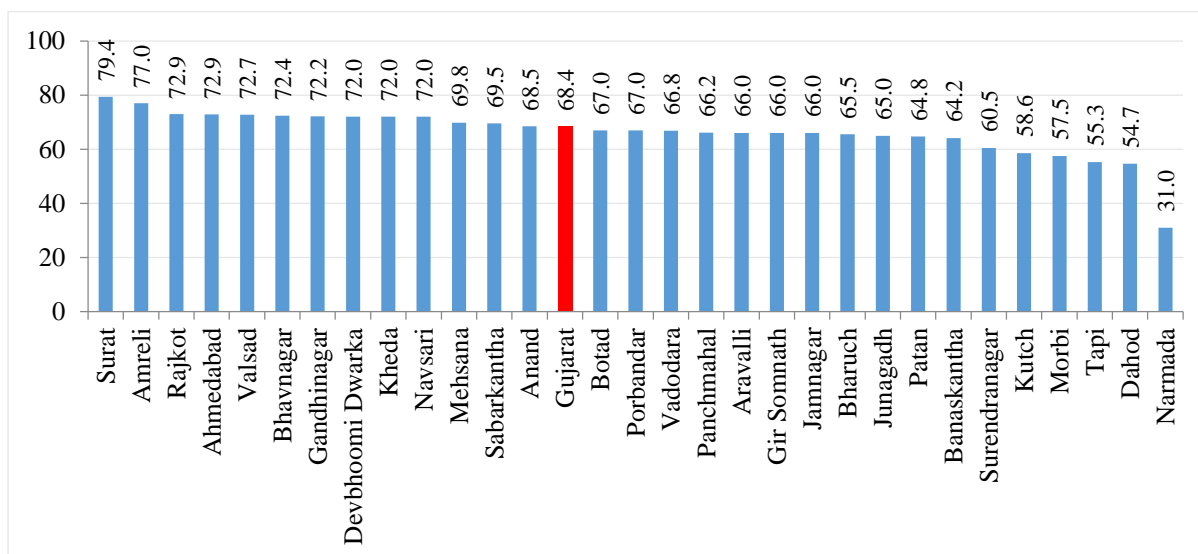


Figure 25 - Categorisation of Non-NACO BBs (n=55)



Among the districts, Surat (79.4) scored the highest and Narmada (31) scored the least. Thirteen districts scored above the state average. More than half of the blood banks (56%) were located in these districts.

Figure 26 - Mean Assessment Score – By Districts (All BBs)



Though the difference in the mean score at the state level was 5 between NACO and Non-NACO blood banks, the mean scores of NACO supported blood banks were higher than the Non-NACO blood banks in 12 districts.

The difference in the score was more than 5 in NACO supported blood banks in seven districts. The difference in the score was more than 5 in Non-NACO blood banks in three districts Kutch, Sabarkantha and Tapi.

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

District	NACO supported	Non-NACO	Total
Ahmedabad	73.8	72.1	72.9
Amreli	77.0	-	77.0
Anand	74.3	62.7	68.5
Aravalli	-	66.0	66.0
Banaskantha	64.0	64.3	64.2
Bharuch	68.0	63.0	65.5
Bhavnagar	72.4	-	72.4
Botad	-	67.0	67.0
Dahod	56.0	54.0	54.7
Devbhoomi Dwarka	71.0	73.0	72.0
Gandhinagar	70.7	74.5	72.2
Gir Somnath	-	66.0	66.0
Jamnagar	66.0	-	66.0
Junagadh	67.0	64.3	65.0
Kheda	77.5	61.0	72.0
Kutch	55.2	63.8	58.6
Mehsana	69.8	-	69.8
Morbi	66.0	49.0	57.5
Narmada	-	31.0	31.0
Navsari	76.0	64.0	72.0
Panchmahal	67.3	64.0	66.2
Patan	64.0	67.0	64.8
Porbandar	67.0	67.0	67.0
Rajkot	78.5	66.0	72.9
Sabarkantha	64.8	79.0	69.5
Surat	79.4	-	79.4
Surendranagar	63.8	54.0	60.5
Tapi	48.5	62.0	55.3
Vadodara	69.1	64.5	66.8
Valsad	72.7	-	72.7
Gujarat	70.5	65.5	68.4

Only two blood banks, one each from Banaskantha and Narmada district scored less than or equal to 35. The number of blood banks (by district) that scored more than 70 is mentioned in Table-15. Of the 60 blood banks that scored more than 70 score, 42 (70%) were NACO supported blood banks. The majority of blood banks that scored above 70 were from Ahmedabad (14) followed by Surat (6), Rajkot (5), Banaskantha (4), Valsad (4), Anand (3), Gandhinagar (3) and Vadodara (3). These 8 districts constitute 70% of the total blood banks that scored more than 70.

Table 15 - Number of Blood Banks Scored above 70- by District

District	NACO Supported	Non-NACO	Total
Ahmedabad	6	8	14
Amreli	1	-	1
Anand	2	1	3
Aravalli	-	1	1
Banaskantha	1	3	4
Bharuch	-	-	-
Bhavnagar	2	-	2
Botad	-	-	-
Dahod	-	-	-
Devbhoomi Dwarka	1	1	2
Gandhinagar	2	1	3
Gir Somnath	-	-	-
Jamnagar	1	-	1
Junagadh	-	1	1
Kheda	2	-	2
Kutch	-	-	-
Mehsana	2	-	2
Morbi	-	-	-
Narmada	-	-	-
Navsari	2	-	2
Panchmahal	1	-	1
Patan	1	-	1
Porbandar	-	-	-
Rajkot	4	1	5
Sabarkantha	1	1	2
Surat	6	-	6
Surendranagar	-	-	-
Tapi	-	-	-
Vadodara	3	-	3
Valsad	4	-	4
Gujarat	42	18	60

4.10.1 Assessment score by Category of blood banks: The mean score of blood banks with component facilities (71.22; SD: 11.59) was found to be higher than the mean score of those without component facilities (65.70; SD: 9.95).

Table 16 - Mean assessment score by category of blood banks

Type of Blood Bank	NACO Supported			Non-NACO			Total		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
BCSUs	44	72.56	11.41	21	68.43	11.75	65	71.22	11.59
Without Component facility	33	67.79	7.36	34	63.68	11.71	67	65.70	9.95

Among the blood banks that scored ≤ 35 , there was none of the blood bank with component separation facility. (Refer figures 27 and 28). There were 55% of Blood banks with component preparation facility that scored more than 70, as compared to 36% of blood banks without component facility.

Figure 27 - BBs with Component-Score (n=65)

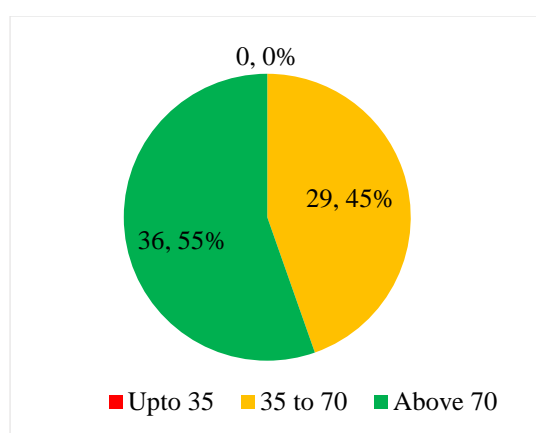
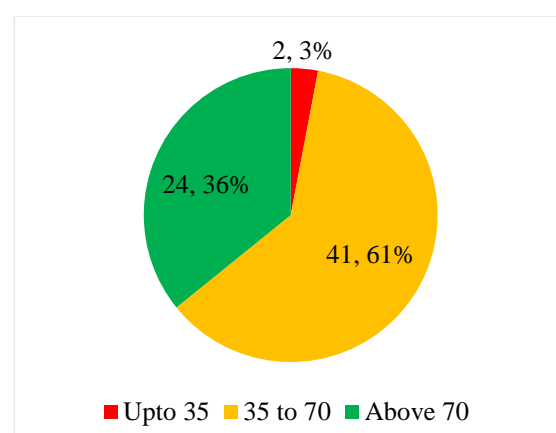


Figure 28 - BBs without Component-Score (n=67)



4.10.2 Assessment score by Ownership: The mean score of public sector blood banks (71.50; SD: 9.75) was more than not-for-profit and private blood banks. The mean assessment score of not-for-profit (NGO/Trust/Charitable) owned blood banks (67.57; SD: 11.76) was almost equal to the private sector blood banks (67.85; SD: 9.85). It was also found that there was more not-for-profit (NGO/Trust/Charitable) blood banks (35 blood banks) in the more than 70 category compared to 15 blood banks from public sector and 10 in private owned blood banks.

However, NACO supported blood banks run by not-for-profit sector had scored higher (69.98; SD: 10.35) compared to Non-NACO NGO/Trust/Charitable blood banks (63.80; SD: 12.97).

Table 17 - Mean assessment score by Ownership

Ownership	NACO supported			Non-NACO			Total		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
NGO/Trust/charitable	50	69.98	10.35	32	63.80	12.97	82	67.57	11.76
Private	0	-	-	23	67.85	9.85	23	67.85	9.85
Public	27	71.50	9.75	0	-	-	27	71.50	9.75

Table 18 - Mean assessment scores categories by Ownership

Ownership	<=35	36 to 70	Above 70	Total
Public	0	12	15	27
	0.0%	72.1%	27.9%	100%
NGO/Trust/Charitable	2	45	35	82
	2.4%	54.9%	42.7%	100%
Private	0	13	10	23
	0.0%	56.5%	43.5%	100%
Overall	2	70	60	132
	1.5%	53.0%	45.5%	100%

4.10.3 Assessment score of Private Sector Blood Banks: Irrespective of the NACO support status, 79.5% (105) blood banks were owned by private sector, of which, 82 (78%) 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 67.63 (SD: 11.33), the mean score of public owned blood banks was 71.50 (SD: 9.75). Among the private sector, not-for-profit sector (67.57; SD: 11.76) scored almost similar to other private blood banks (67.85; SD: 9.85).

Nevertheless, it is also important to note that the average annual collection was higher (7020 units) in public owned blood banks compared to private blood banks (6008 Units). The percentage of voluntary blood donation was higher in private owned blood banks (80%) compared to the public blood banks (20%). Of the total private blood banks, 53(50.5%) had component separation facility whereas only 12 (44.4%) of public blood banks had component separation facility.

4.10.4 Assessment score by Annual Collection: The mean assessment score of blood banks that collected more than 5000 blood units (74.46; SD: 11.27) was found to be higher than those which collected between 3001 and 5000 (66.43; SD: 9.39) and less than 3000 blood units (65.00; SD: 9.47).

Table 19 - Mean assessment score by annual collection

Annual Collection	NACO supported		Non-NACO		Total	
	Mean	SD	Mean	SD	Mean	SD
Up to 3000	67.20	7.27	62.88	10.91	65.00	9.47
3001 to 5000	65.78	7.05	66.74	10.91	66.43	9.39
Above 5000	73.90	11.28	78.90	10.91	74.46	11.27

4.10.5 Assessment score by Voluntary Blood Donation: Table -20 provides the mean assessment score of blood banks that have been categorized by percentage voluntary blood donation. The NACO supported blood banks had reported a higher mean assessment score than the Non NACO blood banks in the categories 25 to 49 and above 90%. Non-NACO blood banks have scored higher than the NACO supported blood banks in less than 25 categories, 50 to 74 categories and 75 to 90 categories.

Table 20 - Mean assessment score by voluntary blood donation

% VBD	NACO supported		Non-NACO		Total	
	Mean	SD	Mean	SD	Mean	SD
Less than 25	58.50	9.06	67.00	10.91	64.57	10.38
25 to 49	68.94	7.73	56.00	10.91	61.18	13.50
50 to 74	67.19	7.84	71.88	10.91	69.44	7.45
75 to 90	65.75	9.82	68.75	10.91	66.88	8.28
Above 90	74.12	9.84	66.85	10.91	72.40	10.53

4.10.6 Assessment score by participation in External Quality Assessment Scheme (EQAS) for Immunohematology and Transfusion Transmitted Infections (TTI): The mean score was found to be higher among the blood banks that were part of EQAS for immunohematology (79.07; SD: 9.77) as compared to those who were not enrolled (65.42; SD: 9.52). Similar situation was found among those blood banks that were part of EQAS for Transfusion-Transmitted Infections (80.10; SD: 8.36) as compared to those who were not enrolled (64.99; SD: 9.34).

Although more number of Non-NACO blood banks were enrolled in IH and TTI-EQAS, NACO supported blood banks had higher scores under IH-EQAS (83.40;SD:8.51) and TTI-EQAS (85.17; SD:9.36).

Table 21 - Mean assessment score by EQAS enrolment

IH-EQAS	NACO Supported			NON-NACO			Total		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
YES	22	78.98	9.78	7	79.36	10.91	29	79.07	9.77
NO	55	67.13	8.10	48	63.47	10.91	103	65.42	9.52
TTI-EQAS									
YES	24	79.52	8.64	6	82.42	10.91	30	80.10	8.36
NO	53	66.43	7.86	49	63.42	10.91	102	64.99	9.34

4.10.7 Assessment 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 Accreditation	NACO Supported			Non-NACO			Total		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
YES	9	87.56	7.29	3	87.83	10.91	12	87.63	6.78
NO	68	68.26	8.08	52	64.20	10.91	120	66.50	9.51

Only 9 out of the 77 NACO supported blood banks and 3 out of 55 Non-NACO blood banks have been accredited by NABH. Ahmedabad (5) had the highest number of accredited blood banks.

The list of blood banks under different categories of score is given in Tables 23 and 24.

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

District	Score Category			Total
	Up to 35	35 to70	Above 70	
Ahmedabad	-	8	14	22
Amreli	-	-	1	1
Anand	-	3	3	6
Aravalli	-	1	1	2
Banaskantha	1	5	4	10
Bharuch	-	2	-	2
Bhavnagar	-	2	2	4
Botad	-	1	-	1
Dahod	-	3	-	3
Devbhoomi Dwarka	-	-	2	2
Gandhinagar	-	2	3	5
Gir Somnath	-	1	-	1
Jamnagar	-	1	1	2
Junagadh	-	3	1	4
Kheda	-	1	2	3
Kutch	-	5	-	5
Mehsana	-	2	2	4
Morbi	-	2	-	2
Narmada	1	-	-	1
Navsari	-	1	2	3
Panchmahal	-	2	1	3
Patan	-	3	1	4
Porbandar	-	3	-	3
Rajkot	-	4	5	9
Sabarkantha	-	1	2	3
Surat	-	1	6	7
Surendranagar	-	3	-	3
Tapi	-	2	-	2
Vadodara	-	7	3	10
Valsad	-	1	4	5
Gujarat	2	70	60	132

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

Score Category						
District	NACO Supported			Non-NACO		
	Up to 35	35 to 70	Above 70	Up to 35	35 to 70	Above 70
Ahmedabad	-	4	6	-	4	8
Amreli	-	-	1	-	-	-
Anand	-	1	2	-	2	1
Aravalli	-	-	-	-	1	1
Banaskantha	-	3	1	1	2	3
Bharuch	-	1	-	-	1	-
Bhavnagar	-	2	2	-	-	-
Botad	-	-	-	-	1	-
Dahod	-	1	-	-	2	-
Devbhoomi Dwarka	-	-	1	-	-	1
Gandhinagar	-	1	2	-	1	1
Gir Somnath	-	-	-	-	1	-
Jamnagar	-	1	1	-	-	-
Junagadh	-	1	-	-	2	1
Kheda	-	-	2	-	1	-
Kutch	-	3	-	-	2	-
Mehsana	-	2	2	-	-	-
Morbi	-	1	-	-	1	-
Narmada	-	-	-	1	-	-
Navsari	-	-	2	-	1	-
Panchmahal	-	1	1	-	1	-
Patan	-	2	1	-	1	-
Porbandar	-	2	-	-	1	-
Rajkot	-	1	4	-	3	1
Sabarkantha	-	1	1	-	-	1
Surat	-	1	6	-	-	-
Surendranagar	-	2	-	-	1	-
Tapi	-	1	-	-	1	-
Vadodara	-	2	3	-	5	-
Valsad	-	1	4	-	-	-
Gujarat	-	35	42	2	35	18

5. Conclusion

Considering the importance of blood transfusion services in the provision of medical care, ensuring quality systems and standards in blood banks are vital, as the blood and its products must not only be safe but also clinically effective and of appropriate and consistent quality. From the programmatic perspective, adequate, accurate and updated information at the district, state and national level is essential for planning and implementation of quality management systems in blood transfusion services across the country. Generation of accurate and essential data from blood banks at regular intervals is imperative to effectively monitor the progress, gaps and challenges in the service provision which would not only facilitate appropriate corrective measures but also facilitate the development of evidence-based policies and programmes.

This state-wide assessment captured most of the required information related to the structure, services, facilities, availability of human resources, equipment, quality management system and practices in blood banks across the state. All blood banks in Gujarat function subject to obtaining and maintaining a license for operations from the FDA which means compliance to basic quality standards mentioned in the Drugs and Cosmetic Act 1940 and Rules 1945 there upon. However, this assessment brings out specific gaps and possible opportunities to improve quality standards in Transfusion Services at the state.

The 77 NACO and 55 Non-NACO blood banks which were included in the review are approximately 98.5% of the total blood banks. The annual collection of these blood banks was eight lakhs units (808,474) which is approximately 33.7% more than the total blood requirement based on WHO's estimation that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2010). However, there is a huge variation between districts that ranges from 0.04 units to 2.8 units per 100 population. Clinical demand for blood and blood products can happen only when there is a health care facility with adequate infrastructure in proximity to a blood bank. The relatively lower collection of blood in the few districts could be due to the fact that there is lower demand for blood because of the gaps in availability, accessibility, and affordability of health care services.

The review also revealed that the majority of blood collection (78.4%) was by blood banks with the component facility compared to smaller blood banks without component facility. Though there has been an increase in the percentage of voluntary blood donation over the years (around 96.7% in 2015), there is still a huge variation between districts that ranges from 14% to 99%. 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 48% (almost half) of the all the blood banks in the state relegated to only 6 districts. More than half (54.5%) of the districts (18) have less than the state 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.

Though most of the blood banks have a valid license still 28% of the blood banks having their licensing status in pendency may be an indication of an opportunity to strengthen the regulatory system by modern technological modalities to ensure a standardized, timely and transparent licensing process. It is also essential to review and update the regulatory framework to keep up with recent scientific developments and modernize the transfusion practice in the state.

The provision of a blood component separation unit in the blood bank and the volume of collection apparently have a positive influence on the quality. The inequity in the distribution of component separation facilities across districts and region is very evident. However, it is important to note that in the absence of reliable laboratory support, it will not be possible to ensure rational use of blood and its components. It is difficult to sustain cost-effective component production when the volume of operations is low without compromising the quality of the blood provided to the patients who access this service. Given that the provision of safe and high-quality blood in areas where access is a challenge is still the remit of the state, it is essential to explore new cost effective innovative methods in partnership with non-governmental agencies.

For the first time, a quality score system has been created and applied to the blood banks. This review indicated a mean score of 68.4 with significant variations across the category of blood banks, ownership, voluntary blood donation, participation in proficiency testing (EQAS) and accreditation status. It is important to understand that there is a huge variation between districts on several parameters included in the assessment. This suggests the need for targeted and customized approach to address the gaps and challenges faced by the blood banks in the state. This assessment suggests that blood banks owned by trusts/charities in the private sector seemed to have performed slightly better in the quality parameters. This may be partly due to access to resources, both financial and technical, to enhance capacity and modern technology to overcome potential barriers to quality.

It is evident from the assessment that blood banks that focussed on quality improvement systems performed better than others. Considering the deleterious effect of poor quality practices on patient care, it is imperative that specific programmes and strategies to improve quality systems in blood transfusion services are developed and implemented across the state.

6. Reference

- CDSKO. (2015). LIST OF LICENSED BLOOD BANKS IN INDIA * (February, 2015). Retrieved from <http://www.cdsko.nic.in/writereaddata/BLOOD%20BANKS%20INDIAfeb2015.pdf>
- Chandra, T., Rizvi, S. N. F., & Agarwal, D. (2014). Decreasing Prevalence of Transfusion Transmitted Infection in Indian Scenario. *The Scientific World Journal*, 2014, 4. doi:10.1155/2014/173939
- GOI. (2003). *Transfusion Medicine, Technical Manual*. New Delhi: Director General of Health Services, Government of India.
- Gupta, R., Singh, B., Singh, D. K., & Chugh, M. (2011). Prevalence and trends of transfusion transmitted infections in a regional blood transfusion centre. *Asian J Transfus Sci*, 5(2), 177-178. doi:10.4103/0973-6247.83250
- ISO-8402. (1994). *Quality Management and Quality Assurance - Vocabulary*. Retrieved from Geneva, Switzerland.:
- NACO. (2007a). *National Blood Policy (India)*. Retrieved from New Delhi: <http://upsacs.nic.in/bs%20doc/bs%20National%20Blood%20Policy.pdf>
- NACO. (2007b). *Standards For Blood Banks & Blood Transfusion Services*. Retrieved from New Delhi: http://www.iapsmgc.org/userfiles/10_Standards_for_Blood_Banks_and_Blood_Transfusion_Services.pdf
- NACO. (2014). *National AIDS Control Programme Phase-IV (2012-2017) Strategy Document*. Retrieved from New Delhi: <http://www.naco.gov.in/upload/NACP%20-%20IV/NACP-IV%20Strategy%20Document%20.pdf>.
- NACO. (2016). *Annual Report 2015-16*. Retrieved from New Delhi:
- Pal, R., Kar, S., Zaman, F. A., & Pal, S. (2011). The quest for an Indian blood law as of blood transfusion services regulatory framework. *Asian J Transfus Sci*, 5(2), 171-174. doi:10.4103/0973-6247.83246
- Ramani, K. V., Mavalankar, D., & Govil, D. (2007). *Management of Blood Transfusion Services in India: An Illustrative Study of Maharashtra and Gujarat States*. Retrieved from
- Schlickman, J. J. (1998). *ISO 9000 quality management system design: optimal design rules for documentation, implementation, and system effectiveness*: ASQ Quality Press.
- WHO. (1975). *World Health Assembly resolution WHA28.72. Utilization and supply of human blood and blood products*. Retrieved from <http://www.who.int/entity/bloodsafety/en/WHA28.72.pdf>
- WHO. (2008). *Universal Access to Safe Blood Transfusion*. Retrieved from Geneva:
- WHO. (2009). *GDBS Summary Report 2009*. Retrieved from Geneva: http://www.who.int/bloodsafety/global_database/GDBS_Summary_Report_2009.pdf
- WHO. (2011). *Developing a National Blood System*. Retrieved from Geneva: http://www.who.int/entity/bloodsafety/publications/am_developing_a_national_blood_system.pdf?ua=1
- WHO. (2012). More voluntary blood donations essential [Press release]. Retrieved from http://www.who.int/mediacentre/news/releases/2012/blood_donation_20120614/en/
- WHO. (2016a). *Quality systems for blood safety*. Retrieved from <http://www.who.int/bloodsafety/quality/en/>
- WHO. (2016b). *World Blood Donor Day 2016: Blood connects us all*. Retrieved from <http://www.who.int/campaigns/world-blood-donor-day/2016/en/>

7. Annexures

7.1 Individual Blood Banks Summary

District	Name of the Blood Bank	Type	Ownership	Annual Collection	Score (Out of 100)
Ahmedabad	Indian Red Cross Society	BCSU	NGO/Trust /Charitable	46641	93
	Department of IHBT, Civil Hospital Ahmedabad	BCSU	Public	38399	83
	Prathama Blood Center	BCSU	NGO/Trust /Charitable	30307	95
	Sheth L.G General hospital blood bank,Ahemdabad	BCSU	Public	14097	71
	The Gujarat Cancer & Research Institute,Blood Bank	BCSU	Public	13383	81
	Institute of Kidney diseases and research center	BCSU	Public	7689	70.5
	Supratech Voluntary Blood Bank	BCSU	NGO/Trust /Charitable	7052	85.5
	Sheth L.G General hospital ,Ahemdabad	BCSU	Public	4374	68
	Help voluntary blood bank	BCSU	NGO/Trust /Charitable	4279	73
	Cross World Blood Bank (Voluntary) & Sankalp Diagnostics	Non BCSU	Private	3833	79
	Adarsh Voluntary Blood Bank	BCSU	Private	3704	75
	Gujrat Blood Bank	Non BCSU	Private	3636	64
	Sterling Addlife India Limited	BCSU	Private	2887	78
	GCS Medical College Hospital & Research Centre Blood Bank	BCSU	NGO/Trust /Charitable	2724	59
	White Cross Blood Bank	Non BCSU	NGO/Trust /Charitable	2325	72
	Smt. Laxmiben Chimanbhai Lalbhai blood Bank	Non BCSU	Public	1979	70
	Civil Hospital, Ahmedabad	Non BCSU	Public	1561	69
	Gujarat Blood Bank (Vol.)& Pathology Laboratory	Non BCSU	Private	524	72
	Ami Pathology Laboratory and bloodbank	Non BCSU	Private	391	64

	Lions Blood Bank Ognaj	BCSU	NGO/Trust /Charitable	51	65
	Zyodus Hosp Healthcare Res	BCSU	Private	-	74
	Karnavati Blood Bank (Vol) & Path. Lab	BCSU	Private	-	42
Amreli	Indian Red Cross Society	Non BCSU	NGO/Trust /Charitable	7250	77
Anand	Indian Red Cross Society	BCSU	NGO/Trust /Charitable	9516	61.5
	A.D. Gorwala blood bank	BCSU	NGO/Trust /Charitable	6422	88.5
	Shree Ghanshyam Path.Lab&Blood Bank	Non BCSU	NGO/Trust /Charitable	3145	77
	Indian Red Cross Society Blood bank,Anand	Non BCSU	NGO/Trust /Charitable	2470	73
	The Secretary Lions Club (Society)	Non BCSU	NGO/Trust /Charitable	2325	58
	Indu Voluntary Blood Bank	BCSU	NGO/Trust /Charitable	625	53
Aravalli	Patel Voluntary Blood Bank	Non BCSU	Private	3323	73
	Late M H Ramani Memo Voluntary Blood Bank	BCSU	Private	3053	59
Banaskantha	Bhoomi Voluntary Blood Bank	BCSU	NGO/Trust /Charitable	7326	76.5
	Gayatri Voluntary Blood Bank	Non BCSU	Private	4481	81
	Shree Sarawati trust Sanchalit Adarssh voluntry blood bank	Non BCSU	NGO/Trust /Charitable	3766	60
	N S Gandhi - Lincoln Hospital Blood bank	Non BCSU	NGO/Trust /Charitable	2978	77
	Vikas Voluntary Blood Bank And Computerized Pathology Lab	Non BCSU	Private	2408	65
	M.U. Voluntary Blood Bank	Non BCSU	NGO/Trust /Charitable	2260	58
	Dharti Voluntary Blood Bank	Non BCSU	NGO/Trust /Charitable	2084	29
	Gayatri Voluntary Blood Bank And Laboratory	Non BCSU	Private	1368	77
	G.H. Palanpur blood bank	Non BCSU	Public	554	61
	Saraswati Voluntary Blood Bank	Non BCSU	NGO/Trust /Charitable	6	57
Bharuch	Red Cross Blood Bank,Gujarat	Non BCSU	NGO/Trust /Charitable	12208	68
	Kumarpal Gnadhi Blood Bank	Non BCSU	NGO/Trust /Charitable	2667	63
Bhavnagar	Sir T General Hospital, Bhavnagar	BCSU	Public	17391	94
	Blood Bank, Bhavanagar	BCSU	NGO/Trust /Charitable	9893	65.5

	Navkar Charitable Trust	BCSU	NGO/Trust /Charitable	3463	59
	Bambhaniya Blood Bank	BCSU	NGO/Trust /Charitable	2984	71
Botad	Omkur Paramedical & Charitable Trust	Non BCSU	NGO/Trust /Charitable	3684	67
Dahod	Kiran Voluntary Blood Bank	Non BCSU	Private	4661	54
	Samarth Raktdan Kendra	Non BCSU	NGO/Trust /Charitable	3994	54
	Indian Red Cross Society Sanchalit Dr.Mohsin Bhai S.Lenwala Voluntary Blood Bank	Non BCSU	NGO/Trust /Charitable	2566	56
Devbhoomi Dwarka	Blood Bank General Hospital	Non BCSU	Public	1313	71
	Tata Chemicals limited Mithapur	Non BCSU	Private	40	73
Gandhinagar	Apollo Hospitals International Limited	BCSU	Private	4605	83
	Indian Red Cross Society, Kalol	Non BCSU	NGO/Trust /Charitable	3015	61
	General Hospital Blood Bank	Non BCSU	Public	3000	71
	IMA Mansa Charitable trust Sanchalit Blood Bank	Non BCSU	NGO/Trust /Charitable	2992	80
	Shradhadeep Blood Bank	Non BCSU	Private	1951	66
Gir Somnath	Navjeevan Blood Bank and Clinical Laboratory	Non BCSU	Private	3335	66
Jamnagar	S P Mehta blood bank	BCSU	Public	21117	76
	Jamnagar Voluntary Blood Bank	Non BCSU	NGO/Trust /Charitable	6849	56
Junagadh	General and CMZ Hospital Blood Bank	Non BCSU	Public	6541	67
	Navdeep Voluntary Blood Bank	Non BCSU	NGO/Trust /Charitable	3513	54
	Sardar Patel Voluntary Blood Bank	Non BCSU	NGO/Trust /Charitable	2538	67
	Shree Jivanprakash Foundation Voluntary Blood Bank	BCSU	NGO/Trust /Charitable	2388	72
Kheda	Indian Red Cross Society,Kheda	Non BCSU	NGO/Trust /Charitable	7794	82
	Gujarat Methodist Church Cardiac Care & Research Society	BCSU	NGO/Trust /Charitable	4586	61
	C.R.Parikh Blood Bank	Non BCSU	NGO/Trust /Charitable	2447	73
	Rajabhai Patel Blood Bank	BCSU	NGO/Trust /Charitable	10232	47
	Jivan Jyot Blood Bank	BCSU	Private	6963	68.5

Kutch	Blood Bank GAIMS GK General Hospital	BCSU	NGO/Trust /Charitable	6436	61.5
	Mayur Blood Bank	Non BCSU	Private	2322	59
	Shri Kutchi Leva Patel Education & Medical Trust Sanchalit Matrushri Meghabai Premji Jetha Hospital & Reseach Centre	Non BCSU	NGO/Trust /Charitable	647	57
Mehsana	Mehsana Jaycees Charitable Trust Voluntary Blood Bank	BCSU	NGO/Trust /Charitable	11956	64
	Visnagar Voluntary Blood Bank	Non BCSU	NGO/Trust /Charitable	4289	69
	Blood Bank, Mehsana	Non BCSU	Public	1469	72
	Sardar Seva Trust ' Sanchalit Urjha Nagrik Sahakari Bank Ltd	Non BCSU	NGO/Trust /Charitable	1249	74
Morbi	Shiv Voluntary Blood Bank	Non BCSU	NGO/Trust /Charitable	4140	49
	General Hospital Blood Bank	Non BCSU	Public	304	66
Narmada	Indian Red Cross Society	Non BCSU	NGO/Trust /Charitable	247	31
Navsari	Indian Red Cross Society	BCSU	NGO/Trust /Charitable	16560	75
	Lions Club Bilimora Charitable Foundation Sponsored NMP Blood Bank	Non BCSU	NGO/Trust /Charitable	2803	64
	Lions Medical Research & Education Cheritable Trust	Non BCSU	NGO/Trust /Charitable	2150	77
Panchmahal	Indian Red Cross Society Voluntary Blood Bank And Blood Component Center	BCSU	NGO/Trust /Charitable	7004	77.5
	Raktdan Kendra Voluntary Blood Bank	BCSU	NGO/Trust /Charitable	2061	64
	General Hospital Blood Bank Godhra	Non BCSU	Public	899	57
Patan	S.K Blood Bank	BCSU	NGO/Trust /Charitable	8955	70.5
	Raktadan Kendra Radhanpur	Non BCSU	NGO/Trust /Charitable	2881	67
	Medical Superintendent GMERS Medical College And Hospital	Non BCSU	Public	2415	66
	Chief District Medical Officer cum Civil Surgeon	BCSU	Public	1688	55.5

Porbandar	Asha Blood bank	Non BCSU	NGO/Trust /Charitable	4825	67
	Shree Ram Voluntary Blood Bank	Non BCSU	NGO/Trust /Charitable	714	67
	Bhavsinhji General Hospital	Non BCSU	Public	367	67
Rajkot	Rajkot Voluntary Blood Bank & Research Centre	BCSU	NGO/Trust /Charitable	16988	88
	Medical Superintendent, Pandit Dindayal Upadhyay Hospital	BCSU	Public	16604	80
	Saurashtra Voluntary Blood Bank & Research Center,	BCSU	NGO/Trust /Charitable	15100	82
	Red Cross Blood Bank	BCSU	NGO/Trust /Charitable	10073	74
	Nationality Development Foundation Organised Field Marshal Blood Bank	BCSU	NGO/Trust /Charitable	7664	68.5
	Nuthani Voluntary Blood Bank	BCSU	NGO/Trust /Charitable	3692	63
	Astha Blood bank	Non BCSU	NGO/Trust /Charitable	3016	71
	Jetpur Medical Foundation	Non BCSU	NGO/Trust /Charitable	1025	63
	Jagruti vol. Blood Bank	Non BCSU	NGO/Trust /Charitable	818	67
Sabarkantha	Indian Red Cross Society	BCSU	NGO/Trust /Charitable	9914	70.5
	Shrimati Dahiben Ratilal Charitable Trust Sanchalit M/S Trimurti Voluntary Blood Bank	Non BCSU	NGO/Trust /Charitable	4296	79
	Chief District Medical Officer cum Civil Surgeon, Sir Pratap General Hospital	Non BCSU	Public	650	59
Surat	Surat Raktadan Kendra and Research Centre	BCSU	NGO/Trust /Charitable	32916	93
	Lok Samarpan Raktadan Kendra	BCSU	NGO/Trust /Charitable	22436	72
	Voluntary Blood Bank, Surat	BCSU	Public	10007	75
	Blood Bank, New Civil Hospital	BCSU	Public	9095	94.5
	Shri B.D Mehta Mahavir Cardiac Hospital Blood Bank	BCSU	NGO/Trust /Charitable	6578	67.5
	SHRC Sardar Smarak Hospital Blood Bank	BCSU	NGO/Trust /Charitable	6274	75.5
	Aminaben Gangat & Ayeshaben Patel Blood Bank	BCSU	NGO/Trust /Charitable	4732	78

Surendranagar	C.U Shah Blood Bank	BCSU	NGO/Trust /Charitable	8399	68.5
	Shraddha Voluntary Blood Bank & Pathology Laboratory	Non BCSU	Private	778	54
	Civil Hospital, Surendranagar	Non BCSU	Public	349	59
Tapi	Smt Laxmiben Khushulbhai Patel Raktdan Kendra	BCSU	NGO/Trust /Charitable	9090	48.5
	Maliba Raktdan Kendra	Non BCSU	NGO/Trust /Charitable	40	62
Vadodara	Indu Voluntary Blood Bank	BCSU	Private	31373	69
	Suraktam Blood Bank	BCSU	NGO/Trust /Charitable	17280	62
	Blood Bank Old Gynaecology Building, S.S.G Hospital	BCSU	Public	11480	81
	Medical Care Centre Trust, Shri Jalarm Blood Bank	BCSU	NGO/Trust /Charitable	9046	72.5
	Dhiraj Blood Bank	BCSU	NGO/Trust /Charitable	4037	59
	Kailash Cancer Hospital & Research Centre Blood Bank	BCSU	NGO/Trust /Charitable	3272	57
	Bhailal Amin General Hospital	BCSU	NGO/Trust /Charitable	1798	60.5
	Blood Bank, GMERS General Hospital & Medical College	Non BCSU	Public	1116	73
	Narhari Hospital Blood Bank	BCSU	Private	892	65
	Parul Sevashram Hospital Blood Bank	BCSU	NGO/Trust /Charitable	138	69
Valsad	Valsad Raktdan Kendra	BCSU	NGO/Trust /Charitable	15669	82
	Nukem Blood Bank and Rotary Suzlon Blood Component Centre	BCSU	NGO/Trust /Charitable	6097	71.5
	Sardar Bhiladwala Pardi People's Co.Op Bank Foundation Blood Bank of Manav Aarogya Seva Kendra	BCSU	NGO/Trust /Charitable	2332	66
	GMERS Medical College Hospital	Non BCSU	Public	1718	73
	Smt Puriben Popat Lakha Lions Blood Bank	Non BCSU	NGO/Trust /Charitable	1385	71

7.2 NACO/NBTC – Questionnaire for Blood Banks

NACO/NBTC - Questionnaire for Blood Banks						
Data Filled by						
Mobile Phone Number (Person filled the data)						
Section A – GENERAL						
A1	Basic Information					
1	Name of the Blood Bank (as mentioned in the licence)					
2	Address 1 (Institution name)					
3	Address 2 (Door number & Street name – if applicable)					
4	Address 3 (Important land mark - if applicable)					
5	City/Town					
6	District					
7	State					
8	Pin code					
9	Blood Bank Phone number (Land line including area code)					
10	Blood bank Email ID					
11	Do you have internet facility?				Yes	
					No	
12	Name of the Blood Bank In-charge (This should be the name of the current Medical Officer in charge)					
13	Is the name of the Medical officer mentioned in the Licence, the current medical officer?				Yes	
					No	
14	Designation (Please enter designation of the Medical Officer in the blood bank (e.g. Civil surgeon, or academic like Asst. Prof etc.)					
15	Highest Qualification (Tick only one)	MBBS				
		MD				
		MS				
		Diploma				
16	Specify branch/Broad speciality					
17	Email ID: (Official/Personal Email where					

	<i>the medical officer can be directly contacted). This is apart from the blood bank email ID provided above.</i>		
18	Fax number		
19	Telephone number 1 – Medical Officer (Mobile)		
20	Telephone number 2 – Medical Officer (Landline including STD code)		
21	Type of blood bank as per NACO category	Model blood Bank	
		Blood Component Separation Units	
		Major Blood Bank	
		District level blood bank	
		Others	
22	Who is the blood bank owned by?	Public (Central/State/Local government)	
		Public (Other than ministry of health e.g. PSU, Army etc.)	
		NGO/Trust/Charitable – NACO Supported	
		NGO/Trust/Charitable	
		Private - Others	
23	Is the Blood Bank attached to any of the following?	Hospital	
		Lab	
		Stand alone	
24	If attached to Private Hospital, specify level of hospital	Medical College Hospital	
		Tertiary care hospital (other than medical college)	
		Secondary care hospital	
25	If attached to public/govt. hospital, specify the level of the hospital	Sub-District hospital	
		District level hospital	
		Medical College hospital	
		Tertiary care hospital (other than Medical College)	
26	If the blood bank is attached to a hospital, please specify the number of inpatient beds available		
27	Are you permitted to conduct Blood donation camp?	Yes	
		No	
28	How many Blood storage centres are linked to your blood bank?		
29	BB working hours (Specify hours per day)		
A2	License Information		
1.	BB License Number (Enter your license number. This should be exactly as is displayed in your license issued by the Drugs Controller Office and will be used for verification purposes. This is a mandatory field and should be entered regardless of the status of license - under-		

	<i>renewal etc. (You will have to submit a self-attested photocopy of the currently displayed license along with this form.)</i>			
2	Status of Current License	Valid		
		Under renewal		
3	Date of issue of current licence DD/MM/YYYY			
4	Last Inspection by licensing authority	< 1 year		
		1-2 years		
		2-3 years		
		3-4 years		
		>4 years		
A3	Basic Statistics (Date of reporting from Jan-2015- Dec-2015)			
1	Number of voluntary donations			
2	Number of replacement donations			
3	Number of autologous deposits			
4	Total Annual collection for reporting period (Jan - Dec 2015) Total Annual collections (sum of A3.1+A3.2+A3.3)			
5. Transfusion Transmissible Infections - Annual statistics		Number tested	Number positive	
	HIV (Anti-HIV I & II)			
	HCV (Anti-HCV)			
	HBV (HBs Ag)			
	Syphilis (RPR/TPHA/ELISA)			
	Positive for Malaria (Any method)			
A4.	Reporting Summary			
1	Are you in compliance with NBTC guidelines?	Yes		
		No		
2	Are you recovering processing charges for blood/components within NBTC/SBTC norms?	Yes		
		No		
3	Are you displaying stock position in the blood bank premises?	Yes		
		No		
4	Are you submitting statistics to the State Drugs controller?	Regular		
		Occasional		
		No		
5	Are you reporting in SIMS (strategic Information Management System- NACO)?	Regular		
		Occasional		
		No		
6	If yes to Q5, please provide your SIMS ID			

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

SECTION B			
B1	Blood Donor(Reporting from Jan 2015- Dec 2015)		
Definition of VBD = Close relatives should NOT be counted as VBD			
1	Are you recruiting voluntary blood donors?	Yes	
		No	
2	Is donor selection performed as per regulatory norms?	Yes	
		No	
3	Do you maintain records of donor deferral?	Yes	
		No	
4	Is pre-donation counselling being performed for blood donors?	Regular	
		Occasional	
		No	
5	Is post donation counselling being performed for blood donors?	Regular	
		Occasional	
		No	
6	Are you conducting Blood donor drives/Blood collection camps?	Regular	
		Occasional	
		No	
7	If you conduct camps, how many have been conducted in the reporting period? (<i>Provide numbers of VBD camps conducted during the period January - December 2015.</i>)		
8	Does the blood bank have dedicated staff for the promotion of Voluntary blood donors? (<i>If your blood bank has dedicated staff for camps, answer yes.</i>)	Yes	
		No	
8 a.	if Yes to 8, select as applicable (<i>More than one may be selected</i>)	Donor Motivator	
		Public relations officer (PRO)	
		Social Worker	
9	Is there a specific budget for donor program?	Yes	
		No	
10	If Yes, Specify budget source	Central	

		State		
		Others (Specify)		
11	Is there a donor database in the blood bank (<i>Donor database is essential to contact donors to remind them or to call during an emergency?</i>)	Yes		
		No		
12	If yes to Q 11, is it in electronic format or paper based?	Electronic		
		Paper		
		Both		
13	What percentage of the voluntary blood donors are repeat blood donors? (%)			
14	Does your blood bank have a mobile blood collection facility? (<i>Answer yes if your Blood bank has a mobile facility (bus or van with donor couches)</i>)	Yes		
		No		
15	Source of funds for the mobile blood collection (<i>Indicate the source of funding for the purchase of the mobile blood donor van.</i>)	State		
		Central		
		Donor		
		Others		
16	Specify, other source of funds			
17	Is there a record for donor adverse reactions?	Yes		
		No		
18	Is there a referral system for HIV sero-reactive blood donors?	Yes		
		No		
19	If yes to Q 18, please specify what is the process adopted.			
Section C				
Technical – Immunohematology				
C1.	Which of the following tests are performed for determination of ABO and Rh (D) groups and what techniques are followed?	Blood Group (Tick as applicable)		Rh Type (Tick as applicable)
		Forward	Reverse	
C1.1.	Slide			
C1.2	Tube			
C1.3	Micro plate			
C1.4	Column agglutination Gel/Microparticle)			
C1.5	Solid phase			
C1.6	Other Specify			
1	How do you perform RhD typing?	Monoclonal reagent		
		Polyclonal reagent		
		Both		

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

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

Section D					
Technical - Screening For Transfusion Transmissible Infections (TTI)					
Does the blood bank screen the following TTIs?					
Type of Test		Platform (please tick appropriate)		Method (please tick appropriate)	
1	HIV I & II	Rapid			
		ELISA		Manual	<input type="checkbox"/>
				Automated	<input type="checkbox"/>
		CHEMI		Manual	<input type="checkbox"/>
				Automated	<input type="checkbox"/>
		NAT		Manual	<input type="checkbox"/>
				Automated	<input type="checkbox"/>
1.1	Specify % of donors tested by Rapid Test?				
2	Hepatitis B	Rapid			
		ELISA		Manual	<input type="checkbox"/>
				Automated	<input type="checkbox"/>
		EM		Manual	<input type="checkbox"/>
				Automated	<input type="checkbox"/>
		NAT		Manual	<input type="checkbox"/>
				Automated	<input type="checkbox"/>
2.1	Specify % of donors tested by Rapid Test?				
3	Hepatitis C	Rapid			

		ELISA		Manual	<input type="text"/>	
				Automated	<input type="text"/>	
		CHEM		Manual	<input type="text"/>	
				Automated	<input type="text"/>	
		NAT		Manual	<input type="text"/>	
				Automated	<input type="text"/>	
3.1	Specify % of donors tested by Rapid Test?					
4	Syphilis	RPR		Manual	<input type="text"/>	
				Automated	<input type="text"/>	
		TPHA		Manual	<input type="text"/>	
				Automated	<input type="text"/>	
		ELISA		Manual	<input type="text"/>	
				Automated	<input type="text"/>	
5	Malaria	Rapid				
		Fluorescent		Manual	<input type="text"/>	
				Automated	<input type="text"/>	
		Slide microscopy				
		ELISA		Manual	<input type="text"/>	
				Automated	<input type="text"/>	
6	Does the blood bank have an algorithm for units that test POSITIVE in initial screening? <i>(If you have a method of verifying a sample that has tested positive on the screening test please answer yes.)</i>			Yes		
				No		
7	If yes to Q6 , Repeat testing with same test/ technique			Yes		
				No		
8	If Yes to Q6, Repeat testing with different test/technique			Yes		
				No		
9	If yes to Q6, Recalling donor for repeat sample			Yes		
				No		
10	Do you perform independent internal QC (Third party controls) with TTI testing?			Yes		
				No		
11	Do you participate in an external quality assessment program or scheme (EQAS) for TTI (<i>Viral Markers, Malaria, and Syphilis</i>) testing?			Yes		
				No		
12	If yes, Specify program/provider					
13	Membership ID number (PIN)					
14	Level of EQAS		Inter-lab			
			National			
			International			
15	If you are not participating in EQAS for TTI screening, will you be willing to participate in future?			Yes		
				No		

16	If Yes to Q15, will your blood bank be able to provide financial support (about Rs. 2500 per year)	Yes	
		No	
17	If your answer to Q 15 is NO, when do you think you will be ready for EQAS (TTI screening) participation?	Next 6 months	
		Later than 6 months	
Section E			
Technical - Component Preparation (Applicable only to BCSU)			
1	Does your blood bank prepare components?	Yes	
		No	
If your answer to Q1 is NO, SKIP TO SECTION F			
If Yes, List the components and number prepared and issued in the period Jan to December 2015			
2	Number of donated blood that was used for component preparation during the period Jan- December 2015.		
		Number prepared	No. issued (utilized)
3	Packed red cells IP (With or without Additive)		
4	Platelet concentrate IP		
5	Fresh frozen plasma (FFP)		
6	Cryoprecipitated antihaemophilic factor IP		
7	Human plasma IP		
8	Other (specify)		
9	Do you perform apheresis for components?	Yes	
		No	
	If yes to above question, Specify the following details		
		Number prepared	No. issued (utilized)
10	Platelet concentrate IP		
11	Fresh frozen plasma (FFP)		
12	Granulocytes concentrates		
13	Other (specify)		
14	Do you perform QC for the components prepared? (If you perform quality control for all components, answer yes.)	Yes	
		No	
15	If yes to above, Are the Factor assays on Fresh Frozen plasma/Cryoprecipitate performed at your Blood Bank?	Yes	
		No	
16	If yes for above question, do you participate in external quality assessment scheme (EQAS)?	Yes	
		No	
17	If yes, to above question, Specify agency		

SECTION F			
Quality Management Systems			
F 1	Are you aware of quality management systems for Blood bank	Yes	
		No	
1	Is the blood bank accredited?	Yes	
		No	
2	If yes, provide Name of Accrediting Body		

3	Do you have a document control system - other than mandatory registers as D&C act?	Yes	
		No	
4	Do you have Standard Operating Procedures (SOPs) for all technical processes?	Yes	
		No	
5	Do you have written responsibilities for all levels of staff?	Yes	
		No	
How many staff are currently employed in each of the following categories and how many of them have been trained during the reporting period Jan 2015 - Dec 2015? (Questions 6 - 15)			
Staff Details		Total number of staff	Number on contract
6	Professor		
7	Associate Professor		
8	Assistant Professor		
9	Senior Resident/Tutor		
10	Medical Officer (<i>include senior/Junior</i>)		
11	Technical Staff		
12	Nursing staff		
13	Counsellor		
14	PRO/Donor motivator		
15	Administrative staff		
16	Support staff		
If other staff, please specify			
Total number of staff			
17	In your opinion, does the BB have adequate staff to function optimally (24x7)? This may be decided based on the volume and duration of work hours.	Yes	
		No	
18	Do you monitor Quality indicators or Key Performance indicators?	Yes	
		No	
19	If yes to above question, please specify names of indicators		
20	Do you have a designated and trained Quality manager?	Yes	
		No	
21	Do you have a designated and trained Technical Manager?	Yes	
		No	
22	If you do not have either a trained Quality manager or Technical Manager please state reasons?		
23	Please specify if you have a plan for recruitment in the future?		

F2. EQUIPMENT AND SUPPLIES			
1	Does the blood bank have adequate equipment to meet regulatory requirements? <i>(If your blood bank has adequate equipment in working condition to meet expected workload, please answer yes.)</i>	Yes	
		No	
2	How is equipment purchase funded?	Local bodies	
		Central or upper (state) level agencies	
		Donors	
		Others (specify)	
3	Does the blood bank have a program for regular equipment maintenance?	Yes	
		No	
4	Are all the equipment calibrated regularly as per regulatory requirement?	Yes	
		No	
5	How are consumables purchased?	Local bodies	
		Central or state level agencies	
		Donors	
		Others (specify)	
6	Do you evaluate kits at your facility prior to procurement? <i>(Are kits evaluated locally (at your blood bank) prior to purchase (e.g. Titre and avidity for blood group Anti Sera?))</i>	Yes	
		No	
7	Is quality control for kits, reagents and blood bags carried out at your blood bank? <i>(Is quality control for kits performed locally (at your blood bank) Prior to use (e.g. Titre and avidity for blood group Anti Sera?))</i>	Yes	
		No	
8	Did you have a regular supply of the following items? (Jan to Dec 2015)		
8.1	Blood Bags	Yes	
		No	
8.2	TTI Screening Kits	Yes	
		No	
8.3	Blood grouping / IH reagents	Yes	
		No	
9	Number of staff vaccinated for Hepatitis B?		
EQUIPMENT LIST (Below is a summary equipment list (a subset of D&C list). Please specify the number in inventory and number in working condition? If you are using shared resources of hospital, you can mention that as well			
		Number in inventory	Number in working condition
10	Donor beds/couches		
11	Any instrument for Hb Estimation <i>(other than CuSO4 method)</i>		
12	Blood collection monitor (Blood agitator)		
13	Quarantine Blood bank refrigerator to store untested units with temperature recorder		
14	Container for safe disposal of sharps		

15	Oxygen supply equipment		
16	Computer with accessories and software		
17	General lab centrifuge for samples		
18	Bench top centrifuge for serological testing		
19	Blood transportation box		
20	Emergency drugs box/Crash card		
21	Autoclave machine (shared resource should be specified)		
22	Water bath		
23	Blood bank refrigerator (storage of tested blood) with temperature recorder		
24	Automated pipettes		
25	Refrigerated centrifuge (BCSU)		
26	Blood container weighting device		
27	Serology rotator		

7.3 Scoring sheet

Individual Scoring Sheet - Blood Component Separation Units			
GENERAL	GENERAL SUMMARY	WEIGHTAGE	TOTAL
Licence	Under renewal	1	
	Valid	3	
Subtotal			3
Annual collection	Below 1000	0	
	1000 to 2000	0.5	
	2000 to 5000	1	
	5000 to 10000	1.5	
	Above 10,000	2	
Subtotal			2
VNRBD	BB by VNRBD (%)	0	
	<25%	0	
	25-49%	1	
	50 - 74%	3	
	75-90%	4	
	Above 90	5	
Repeat DON	Repeat donation >25%	2	
Counselling	Pre and post donation counselling - Regular	2	
Subtotal			9
TECH-IH	BB performing only slide grouping (forward typing)	0	
	BB using tube method for forward typing	2	
	BB performing reverse grouping (Serum group)	2	
	BB performing tube method for compatibility testing	3	
	BB performing IQC for IH	3	
	BB Participating in EQAS for IH	3	
	Direct antiglobulin test (DAT/DCT)- Direct Coombs Test (DCT)	2	
	Indirect antiglobulin test (IAT/ICT)	2	
	Automation for Immunohematology testing	1	
Subtotal			18
TECH - TTI	BB performing IQC for TTI	3	
	BB Participating in EQAS for TTI	3	
	BB with follow up program for HIV Sero-positive donors	3	
HIV Testing	Rapid	1	
	Elisa	2	
	Advanced	3	
Hep B	Rapid	1	
	Elisa	2	
	Advanced	3	

Hep C	Rapid	1	
	Elisa	2	
	Advanced	3	
Syphilis	RPR	1	
Malaria	Slide/Rapid	1	
Subtotal			20
COMP			
	Component separation < 25	0	
	Component separation < 25-50%	1	
	Component separation 51 to 80%	2	
	Component separation > 80%	3	
	BB that performs component QC	2	
Subtotal			5
QMS	BB MO with relevant PG Qualification	3	
	Staff Nurse with NACO/NBTC Training	3	
	Technician with NACO/NBTC training	3	
	BB with designated and trained QM	2	
	BB with designated and trained TM	2	
	BB with Document control system	4	
	BB with calibration of equipment	4	
	BB with AMC for equipment	4	
	Quality control for kits, reagents and blood bags carried out at blood bank with regular bags supply	2	
	Quarantine Blood bank refrigerator to store untested units with temperature recorder	3	
	Blood bank accredited	5	
Subtotal			35
GEN	BB reporting regularly on SIMS under National AIDS Control Programme	3	
	BB Participating in Haemovigilance Program of India	1	
	E blood banking participation NBTC/NHP	1	
	E blood banking participation – State level	1	
	More than 50% of the staff are vaccinated for Hep B	1	
	Compliance with NBTC norms	1	
Subtotal			8
SCORES	TOTAL		100

Individual Scoring Sheet - Without Blood Component Separation Units			
GENERAL	GENERAL SUMMARY	WEIGHTAGE	TOTAL
Licence	Under renewal	2	
	Valid	3	
Subtotal			3
Annual collection			
	500 - 1000	1	
	1001 to 2000	2	
	2001 to 3000	3	
	3001 - 5000	4	
	>5000	5	
Subtotal			5
VNRBD	BB by VNRBD (%)		
	25-49%	1	
	50 - 74%	3	
	75-90%	4	
	Above 90	5	
Repeat DON	Repeat donation >25%	2	
	pre donation counselling - regular	2	
Counselling	post donation counselling - regular	2	
Subtotal			11
TECH-IH	BB performing slide ONLY for forward grouping	1	
	BB performing TUBE for forward grouping	2	
	BB performing reverse grouping (Serum group)	2	
	Compatibility testing with tube	3	
	BB performing IQC for IH	3	
	BB Participating in EQAS for IH	3	
	Direct antiglobulin test (DAT/DCT)- Direct Coombs Test (DCT)	2	
	Indirect antiglobulin test (IAT/ICT)	2	
	Automation for Immunohematology testing	1	
Subtotal			18
TECH - TTI	BB performing IQC for TTI	3	
	BB Participating in EQAS for TTI	3	
	BB with follow up program for HIV Sero-positive donors	3	
HIV Testing	Rapid	1	
	ELISA	3	
Hep B	Rapid	1	

	ELISA	3	
Hep C	Rapid	1	
	ELISA	3	
Syphilis	RPR	1	
Malaria	Slide/Rapid	1	
Subtotal			20
COMP	<i>Not applicable</i>		
QMS	BB MO with relevant PG Qualification	3	
	Staff Nurse with NACO/NBTC Training	3	
	Lab technician with NACO/NBTC training	3	
	BB with designated TM/QM	2	
	BB with SOPs	2	
	BB with Document control system	2	
	BB with more than 75% equipment functional	2	
	BB with calibration of equipment	4	
	BB with AMC for equipment	4	
	Quality control for kits, reagents and blood bags carried out at blood bank with regular supply	2	
	Quarantine Blood bank refrigerator to store untested units with temperature recorder	3	
	Blood bank accredited by NABH	5	
Subtotal			35
GEN	BB reporting regularly on SIMS under National AIDS Control Programme	3	
	BB Participating in Haemovigilance Program of India	1	
	E blood banking participation NBTC/NHP	1	
	E blood banking participation – State level	1	
	Compliance with NBTC norms	1	
	More than 50% of the staff are vaccinated for Hep B	1	
Subtotal			8
SCORES	TOTAL		100