Assessment of NACO Supported blood banks
A Preliminary Report 2016

NACO

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FOREWORD

Blood Transfusion Service is an indispensable part of a health care system. It is essential to ensure the provision of adequate, safe, appropriate and consistent quality of blood and blood components to all those who are in need of a transfusion. This requires a comprehensive approach in planning, designing and operationalizing of Blood Transfusion Services in India which is centrally coordinated and based on voluntary non-remunerated blood donation.

During the last two decades, the National Blood Transfusion Council (NBTC) and National AIDS Control Organization (NACO) have been making significant efforts to ensure access to safe and quality blood and blood products. There has been a substantial improvement in blood transfusion services; however, it is essential to ensure the quality of service delivery at the district, state and regional levels through an evidence-based approach.

This preliminary report would definitely be a useful guide and a reference material that would explain the current situation of blood transfusion services, the gaps, challenges and recommendations to improve the blood transfusion services in the country. This report will also serve as a baseline for assessing the effectiveness of future programmatic interventions.

I would like to congratulate the team at National Blood Transfusion Council and National AIDS Control Organization for taking this initiative. I would also like to thank the US Centers for Disease Control and Prevention (HHS/CDC) Division of Global HIV and TB (DGHT) India, Christian Medical College (CMC), Vellore and Christian Medical Association of India (CMAI) for their support.

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PREFACE

Since the inception of National AIDS Control programme in 1992, followed by the formation of National Blood Transfusion Council, the Blood Safety Programme in India has been making significant advancement in availability and access to safe and quality blood and blood components even to far-flung remote areas of the country. Some of the key strategies under NACP IV (2012-17) are, strengthening management structure of blood transfusion services and implementing quality management practices in blood transfusion services.

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

I take this opportunity to extend my sincere appreciation to the team at NACO and NBTC for their valuable support. I also wish to express my thanks to the US Centers for Disease Control and Prevention (HHS/CDC) Division of Global HIV and TB (DGHT) India, Christian Medical College (CMC), Vellore and Christian Medical Association of India (CMAI) for providing technical assistance and support in completing the assessment and developing the report.

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Deputy Director General (BTS)

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Abbreviations

BB	-	Blood Bank
BCSU	-	Blood Component Separation Units
CHEMI	-	Chemiluminescence
DAT	-	Direct Antiglobulin Test
DCT	-	Direct Coombs Test
ELISA	-	Enzyme Linked Immuno Sorbent Assay
EQAS	-	External Quality Assessment Scheme
FDA	-	Food and Drug Administration
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
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 Units
QC	-	Quality Control
QMS	-	Quality Management Systems
RPR	-	Rapid Plasma Reagin
SBTC	-	State Blood Transfusion Council
SD	-	Standard deviation
SIMS	-	Strategic Information Management System
SOPs	-	Standard Operating Procedures
TTI	-	Transfusion Transmitted Infection
TPHA	-	Treponema Pallidum Hemagglutination Assay
VNRBD	-	Voluntary, Non-Remunerated Blood Donation
VBD	-	Voluntary Blood Donor/Donation
WHO	-	World Health Organization

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Assessment of NACO supported Blood Banks

1.   Background

Access to adequate, safe and quality blood and blood products is vital for any health care system which is primarily the responsibility of the government/national health authority of each country (Ramani, Mavalankar, & Govil, 2007). It is essential to establish a sustainable national blood system that should be supported by a national blood policy, strategic plan and appropriate legal instruments (WHO, 2011). In India, the National AIDS Control Organization (NACO) under the Ministry of Health and Family Welfare, and 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 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.

The Supreme Court verdict in 1996 directed the government to improve the blood transfusion services (BTS) that resulted in establishing the National and State Blood transfusion Councils (NBTC/SBTC) for bringing about improvements in blood transfusion services. The Drugs and Cosmetics Rules, 1945, framed under the Drugs and Cosmetics Act, 1940 were amended in 1993 through 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, Government of India framed and adopted the National Blood Policy (NBP) (NACO, 2007a).

In 2007, the National AIDS Control Organization(NACO) 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, 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 blood the national programme (NACO, 2007b).

Since the inception of National AIDS Control programme in 1992, the blood safety programme in India under the National AIDS Control Organization (NACO) 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 far-flung 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 centers in rural areas have improved the quality of blood transfusion services in the country. The current phase of the National AIDS Control Programme (NACP IV 2012 -2017) emphasizes blood safety that aims to support 1,300 blood banks and aims to 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 structure of blood transfusion services, streamlining the coordination and management of blood banks and blood transfusion services; and new initiatives such as the establishment of Metro Blood Banks and Plasma Fractionation Centre (NACO, 2014).

India has 1,126 National AIDS Control Organization (NACO), Ministry of Health and Family Welfare (MoHFW) supported blood banks out of the total 2,760 blood banks in the country (CDSCO, 2015). NACO has been providing technical and operational support to improve the efficiency and effectiveness of these blood banks thereby, increasing the availability and accessibility of safe and quality blood and blood products to those who are in need. Though there has been a substantial improvement in BTS in India over a period of time, there

are still gaps in ensuring access to quality blood and blood products to all those who are in need, that need to be addressed at the district, state and regional level 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 emphasise quality management systems including EQAS and accreditation in blood banks, not much information is available related to this area. In specific, information on the existing practices of blood banks, their potential, and willingness to get involved in the programmes on quality management systems (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 better programmes and policies in BTS, but also serve as a baseline for specific programmes that are being and will be implemented at district, state, region, and national level. Considering the above factors, an assessment of all NACO supported Blood Banks was conducted in the country.

2. Objectives

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

The specific objectives were,

- To develop an updated database with basic essential details of NACO supported blood banks in the country.
- To review the existing situation of blood banks in terms of collection of blood, voluntary blood donation, quality management systems, and other programme areas.
- To categorise 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 programmes for blood transfusion services in India.

3. Methodology

This assessment was a cross-sectional survey that captured the current situation of NACO supported blood banks in the country. All NACO supported blood banks (1126) were included in the survey. 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	Methodology, Performances
4	Quality Management System	Compliance to Quality System Essentials (QSE)
5	HR, Training, and Equipment	Availability and Participation

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

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

Data were analysed 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, median, IQR, minimum, and maximum were done for quantitative variables such as, annual collection, voluntary blood donation, etc. Comparison of the mean of different variables was done using an independent t-test or ANOVA if the distribution was normal. Mann-Whitney or Kruskal-Wallis test was done if the data was not normally distributed.

Categorisation of blood banks and scoring: The blood banks have been categorized into two categories based on the availability of component separation facility and annual collection. The first category is blood banks with component separation facility that includes Model Blood banks and Blood component separation Units (BCSU). 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 is blood banks without component separation facility that includes Major blood banks and District level blood banks (DLBB). Major blood banks collect between 3,000 to 5,000 units and district level blood banks collect up to 3,000 units annually.

Each component of the tool was given a weight based on the programmatic and quality priorities. The maximum achievable sum of all weighted scores under each component totalled 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=427; Model blood bank and Blood component separation units) and, 2. Blood banks without component separation facility (n=674; District level blood banks and Major blood banks). Marks 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 categorised 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

Out of 1126, NACO supported blood banks in the country, 1101 blood banks that reported were considered for analysis. Table- 3 indicates the state-wise details of NACO supported blood banks (n= 1126). Maharashtra (120) had the highest number of NACO supported blood banks followed by Tamil Nadu (95), Uttar Pradesh (89), Gujarat (77) and Karnataka (66).

Table -3–State wise description of NACO supported blood banks (n=1126)

State	No of BBs	%
Andaman and Nicobar	1	0.09
Andhra Pradesh	59	5.24
Arunachal Pradesh	8	0.71
Assam	26	2.31
Bihar	39	3.46
Chandigarh.	4	0.36
Chhattisgarh	16	1.42
Dadra & Nagar Haveli	1	0.09
Daman and Diu	2	0.18
Delhi	20	1.78
Goa	3	0.27
Gujarat	77	6.84
Haryana	24	2.13
Himachal Pradesh	14	1.24
Jammu & Kashmir	23	2.04
Jharkhand	23	2.04
Karnataka	66	5.86
Kerala	45	4.00
Madhya Pradesh	62	5.51
Maharashtra	120	10.66
Manipur	3	0.27
Meghalaya	6	0.53
Mizoram	10	0.89
Nagaland	3	0.27
Odisha	58	5.15
Puducherry	5	0.44
Punjab	43	3.82
Rajasthan	49	4.35
Sikkim	2	0.18
Tamil Nadu	95	8.44
Telangana	43	3.82
Tripura	6	0.53
Uttar Pradesh	89	7.90
Uttarakhand	18	1.60
West Bengal	63	5.60
India	**1126**	**100.00**

Considering the number of NACO supported blood banks in terms of population size, states such as, Bihar (0.4 blood bank), UP (0.4), Chhattisgarh (0.6), West Bengal (0.7), Jharkhand (0.7), Rajasthan(0.7), Assam(0.8) and Madhya Pradesh (0.9) recorded less number of blood banks per 1,000, 000 (one million) population whereas the national average was 0.9 blood bank per 1 million population.

Fig 1- Availability of NACO supported BBs per 1,000,000 (1 million) population
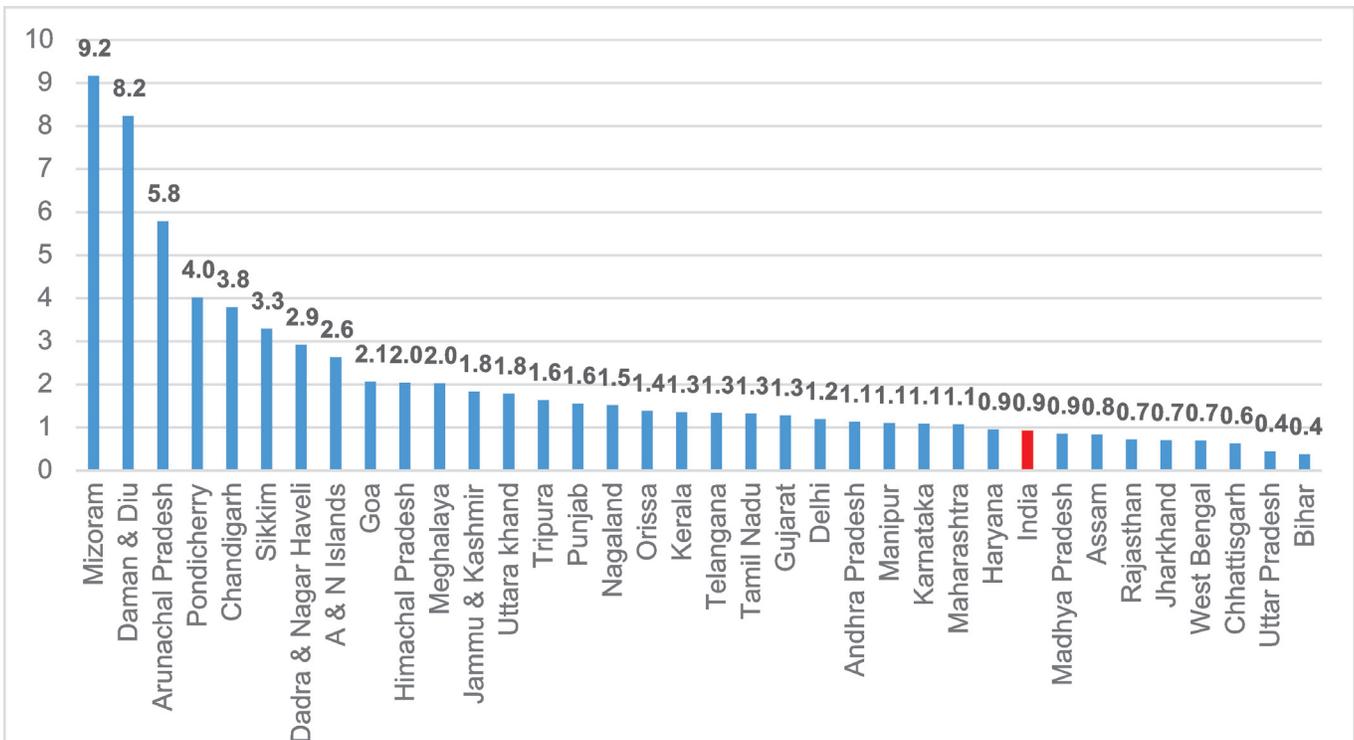
4.1   Basic details of blood banks (n = 1101)

Category of Blood Banks: Thirty-nine percent (427) of NACO supported blood banks had component separation facility and the remaining 61% (674) blood banks did not have component separation facility.

At the state level, Delhi state had the highest percentage of blood component separation units (95%) out of the total available blood banks in the state, followed by Chandigarh (75%), Maharashtra (71.6%), Karnataka (61.5%), Gujarat (58.7%), and Kerala (57.8%). States like Odisha (9.6%), Madhya Pradesh (16.1%), Assam (19.2%), Bihar (17.9%), Tamil Nadu (23.2%), West Bengal (23.8%), Rajasthan (25.5%), Chhattisgarh (25%), and Uttarakhand (27.8%) had a low proportion of blood component separation facility. Andaman & Nicobar and Dadra Nagar Haveli had one each NACO supported blood banks that had component separation facility.

Ownership: The majority (867; 79%) of NACO supported blood banks were owned by the public sector and 21% (234) were owned by non-profit/not-for-profit sector such as NGOs, charitable trusts, societies, foundations etc. The non-governmental sector had a higher proportion (62.8 %) of component separation facilities compared to the public sector (32.3%).

Organizational Attachment: The majority of NACO supported blood banks (950; 86%) were attached to hospitals and only 14% (151) were stand-alone blood banks. Around 98.8% (857) of public sector blood banks were attached to hospitals whereas 39.7% (93) of charitable blood banks were attached to hospitals.

The majority of standalone blood banks (72.2%; 109) had blood component separation facilities, and only 33.5% (318) of blood banks that were attached to hospitals had blood component separation facilities.

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Table -4–Basic details of blood banks

Content	Specifics component	BBs with component	BBs without BBs	Total
Ownership				
	Public	280 (32.3%)	587 (67.7%)	867
	NGO/Trust/Charitable	147 (62.8%)	87 (37.2%)	234
Organizational Attachment				
	Attached to Hospitals	318 (33.5%)	632 (66.5%)	950
	Standalone	109 (72.2%)	42 (27.8%)	151
Licence				
	Valid	306 (50.2%)	303 (49.8%)	609
	Deemed renewal	121 (24.6%)	371 (75.4%)	492
Total		**427 (39%)**	**674 (61%)**	**1101**

Licence details of blood banks: The licence status was categorised as "valid" which means that the blood bank has current and active licence; and "deemed renewal" which means that the blood bank had applied for renewal which is pending. Around 55% (609) of blood banks had a valid and current licence and the remaining 45% (492) had applied for renewal. The majority of those blood banks (67.7%) that reported as "deemed renewal" had their last inspection by licencing authority during the last one year; 18.3% had their inspection between the last 1 to 2 years, 6.3% had between 2 to 3 years, 2.4% had between 3 to 4 years and 5.3% had their inspection before 4 years.

Fig -2–Licence status

Licence status

492 (45%)
609 (55%)

■ Valid ■ Deemed renewal
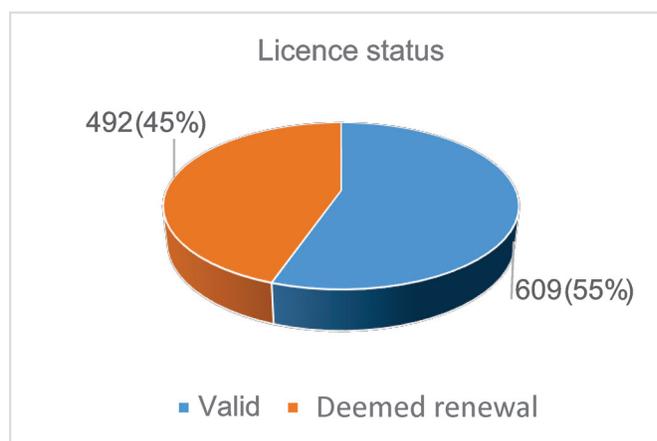
4.2 Annual Blood collection and Voluntary blood donation

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, 2010), which means India currently needs around 12.8 million units of blood.

During January 2015 to December 2015, the annual blood collection from 1101 blood banks (39.8%) out of 2760 blood banks in the country was 6,828,055, of which 80.5% (5,499,823) units were through voluntary blood donations and the remaining from replacement donations. Blood banks with component separation facility (n=427) collected around 70% of blood units (4,788,493) and the remaining (2,039,562) were collected by blood banks without component separation facility (n=674). Besides, blood banks with component separation facility collected 79.8% of the total collection through voluntary blood donation whereas, blood banks without component facility collected slightly higher percentage (82.3%) though voluntary blood donation.

## Fig -3–Annual collection and Voluntary donation
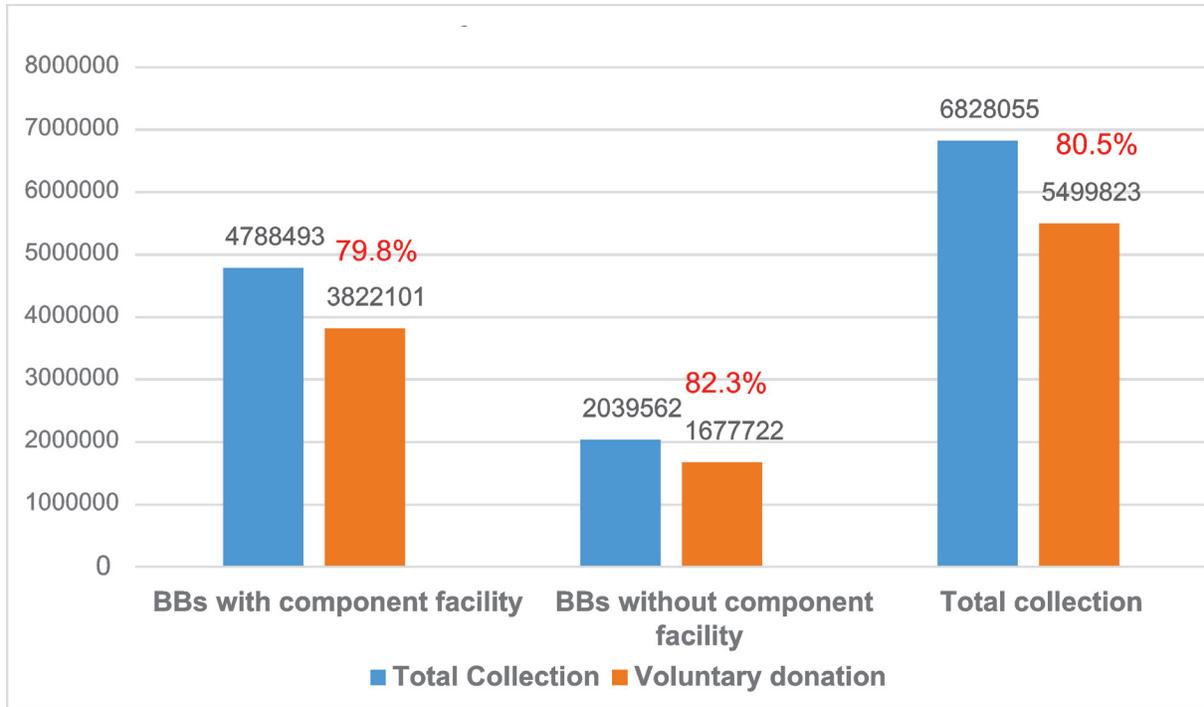

Fig 4- Type of blood donation
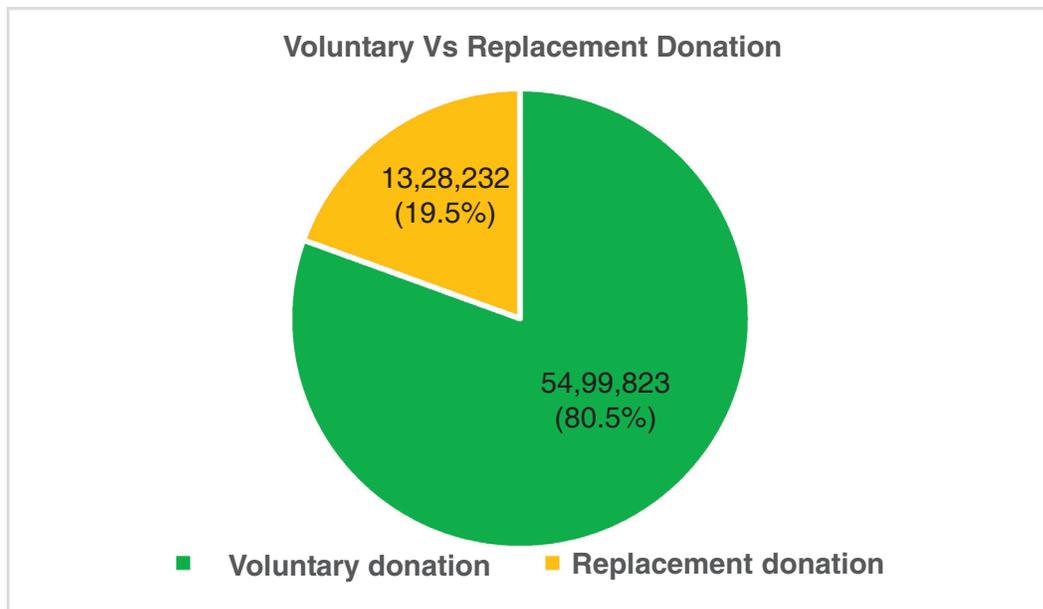
Fig 5–Percentage of voluntary blood donation by state
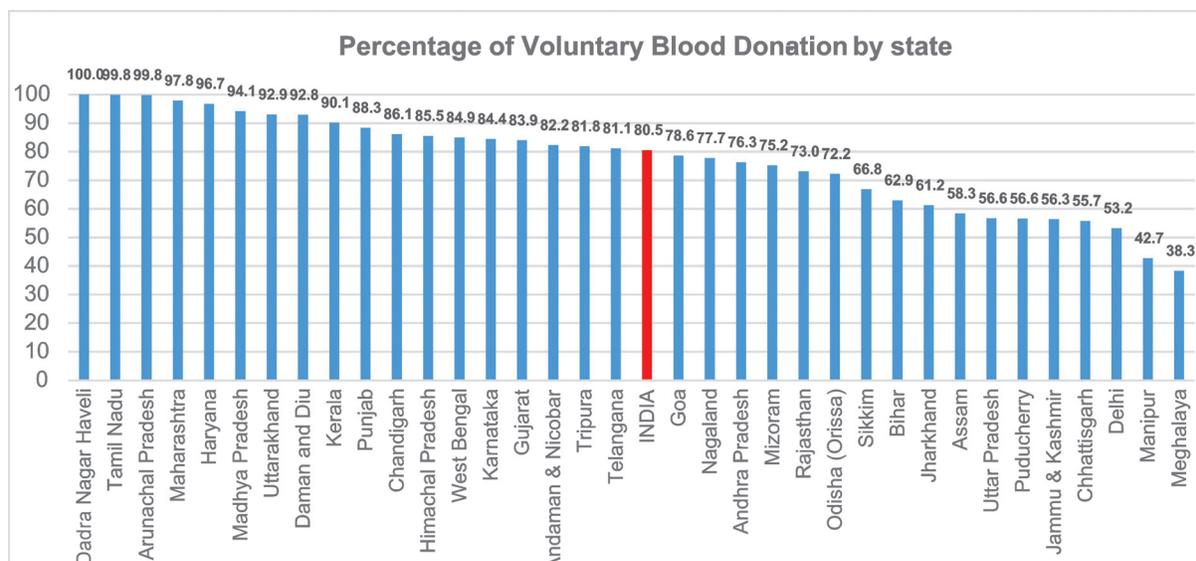
The state-wise details of voluntary, replacement and total donation are mentioned in Table-5.

Eighteen states have recorded more than 80% voluntary blood donation which is above the national average of 80.5%. States such as Dadra Nagar Haveli, Tamil Nadu, Arunachal Pradesh, Maharashtra, Haryana, Madhya Pradesh, Uttarakhand, Daman and Diu and Kerala reported more than 90% voluntary blood donation. States such as Meghalaya, Manipur, Delhi, Chhattisgarh, Jammu & Kashmir, Puducherry, Uttar Pradesh and Assam reported less than 60% of voluntary blood donation during January to December 2015.

Table -5–Annual blood collection and percentage of VBD

States	Total Voluntary donations	Total replacement donations	Total Collection (Jan - Dec 2015)	% VBD
Andaman & Nicobar	3,095	670	3,765	82.2
Andhra Pradesh	2,09,634	65,259	2,74,893	76.3
Arunachal Pradesh	4,944	12	4,956	99.8
Assam	84,043	60,066	1,44,109	58.3
Bihar	69,675	41,023	1,10,698	62.9
Chandigarh	76,778	12,421	89,199	86.1
Chhattisgarh	48,341	38,383	86,724	55.7
Dadra Nagar Haveli	7,497	–	7,497	100.0
Daman and Diu	1,576	122	1,698	92.8
Delhi	1,63,781	1,44,261	3,08,042	53.2
Goa	15,273	4,166	19,439	78.6
Gujarat	5,09,012	97,671	6,06,683	83.9
Haryana	1,67,745	5,747	1,73,492	96.7
Himachal Pradesh	30,001	5,099	35,100	85.5
Jammu & Kashmir	44,674	34,699	79,373	56.3

Jharkhand	77,882	49,383	1,27,265	61.2
Karnataka	3,30,583	61,318	3,91,901	84.4
Kerala	2,54,827	28,054	2,82,881	90.1
Madhya Pradesh	2,99,824	18,771	3,18,595	94.1
Maharashtra	7,87,548	17,778	8,05,326	97.8
Manipur	8,390	11,256	19,646	42.7
Meghalaya	5,178	8,358	13,536	38.3
Mizoram	18,543	6,115	24,658	75.2
Nagaland	7,038	2,017	9,055	77.7
Odisha (Orissa)	2,22,696	85,935	3,08,631	72.2
Puducherry	14,522	11,151	25,673	56.6
Punjab	1,85,996	24,661	2,10,657	88.3
Rajasthan	3,00,092	1,10,946	4,11,038	73.0
Sikkim	2,824	1,403	4,227	66.8
Tamil Nadu	3,88,636	689	3,89,325	99.8
Telangana	1,50,103	34,959	1,85,062	81.1
Tripura	23,238	5,171	28,409	81.8
Uttar Pradesh	2,96,938	2,27,250	5,24,188	56.6
Uttarakhand	91,603	6,957	98,560	92.9
West Bengal	5,97,293	1,06,461	7,03,754	84.9
INDIA	**54,99,823**	**13,28,232**	**68,28,055**	**80.5**

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 prevalence of TTIs has come down significantly over the years.

**Fig-6 Transfusion Transmitted Infections (%)**

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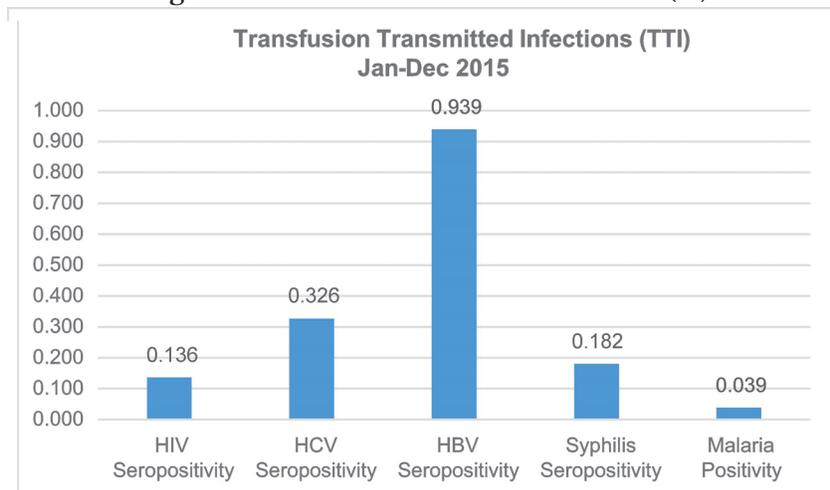
The seropositivity of transfusion transmitted infections (TTI) among blood donors in the year 2015 is depicted in Fig-6. HIV positivity was found to be 0.136%, Hepatitis C was 0.326%, Hepatitis B-0.939%, Syphilis 0.182% and Malaria 0.039%. However, there is a huge variation between states.

Transfusion Transmitted Infections by Category of blood banks: The blood banks with component facility indicated a higher positivity of HIV (0.141); HVC (0.363) and HBV (0.969). However, Syphilis (0.309) and Malaria (0.053) were found to be higher in blood banks without component facility compared to blood banks with the component facility.

Table-6 Transfusion Transmitted Infections by Category of blood banks

Category of BB	Transfusion Transmitted Infections %				
	HIV	HCV	HBV	Syphilis	Malaria
BBs with component facility	0.141	0.363	0.969	0.127	0.033
BBs without component facility	0.126	0.241	0.867	0.309	0.053
Overall	**0.136**	**0.326**	**0.939**	**0.182**	**0.039**

Fig-7 HIV seropositivity – By state (%)
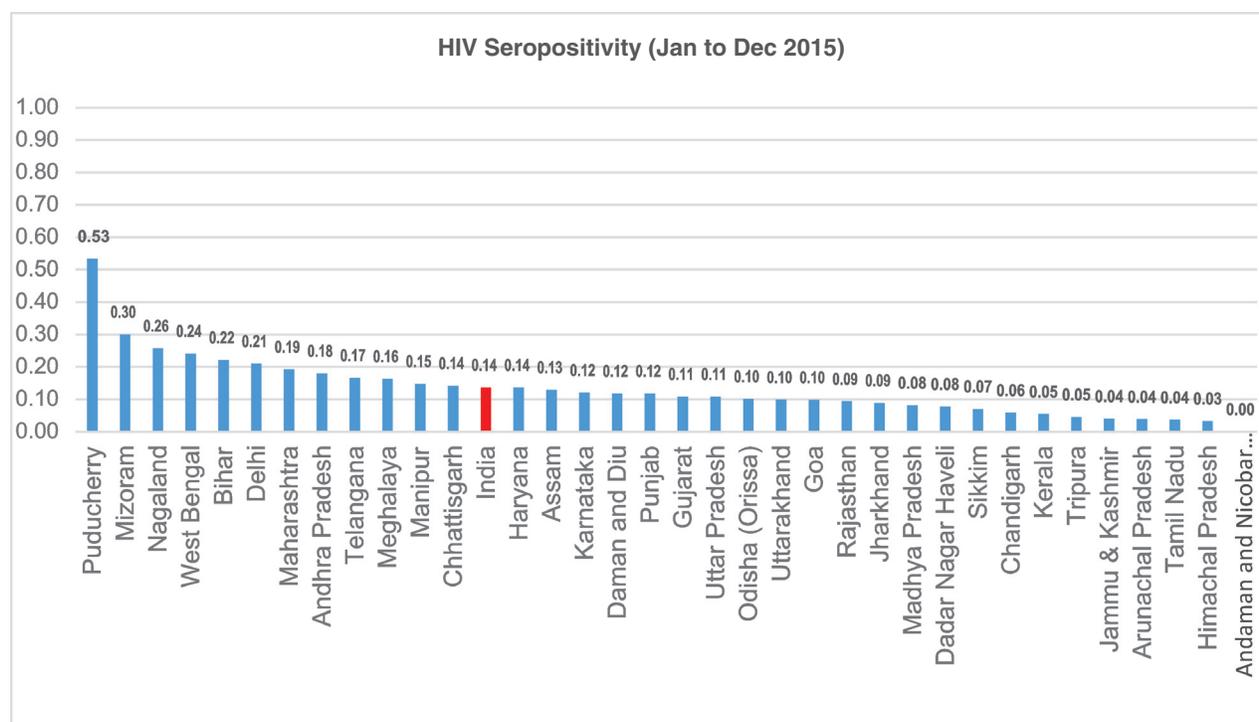
The majority of states indicated lower positivity than the national HIV positivity level which was 0.136%. However, Puducherry (0.53%), Mizoram (0.30%), Nagaland (0.26%), West Bengal (0.24%), Bihar (0.22%), Delhi (0.21%), Maharastra (0.19%), Andhra Pradesh (0.18%), Telangana (0.17%), Meghalaya (0.16%), Manipur (0.15%) and Chattisgarh (0.14%) recorded a higher positivity than national positivity level.

Fig-8 HCV seropositivity – By state (%)

HCV Seropositivity (Jan to Dec 2015)
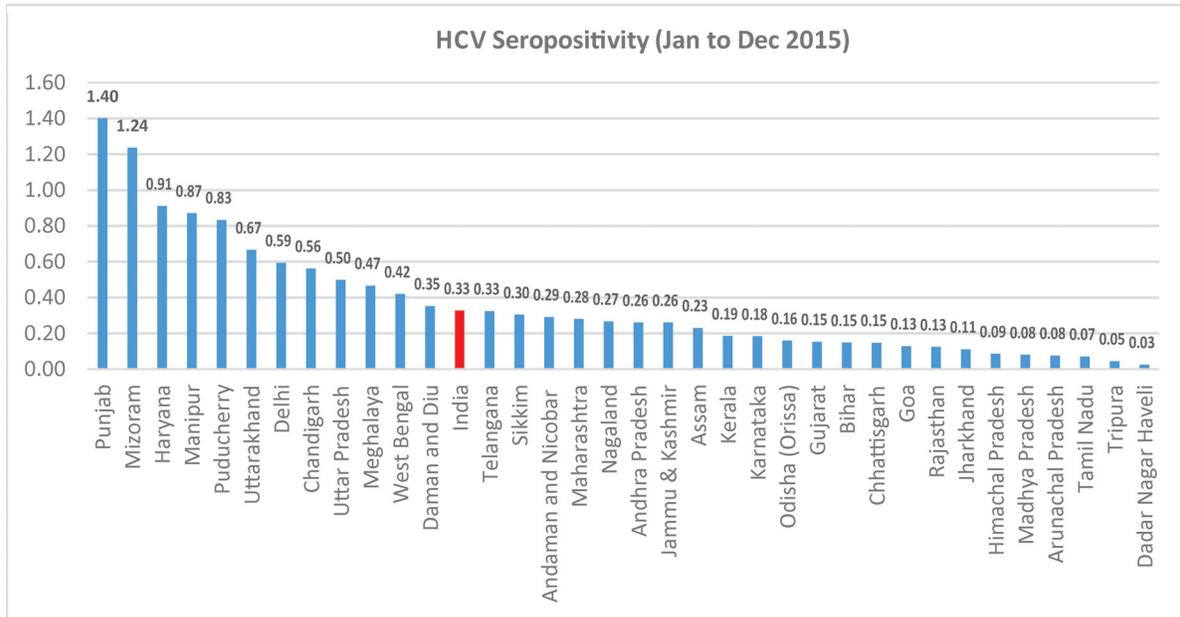
In terms of Hepatitis C, States like, Punjab(1.40%), Mizoram(1.24%), Haryana(0.91%), Manipur(0.87%), Puducherry(0.83%), Uttarakhand(0.67%), Delhi(0.59%), Chandigarh(0.56%), UP(0.50%), Meghalaya(0.47%), West Bengal(0.42%), and Daman and Diu(0.35%) recorded higher positivity level than the national average of 0.326%.

Fig-9 HBV seropositivity – By state (%)

HBV Seropositivity (Jan to Dec 2015)
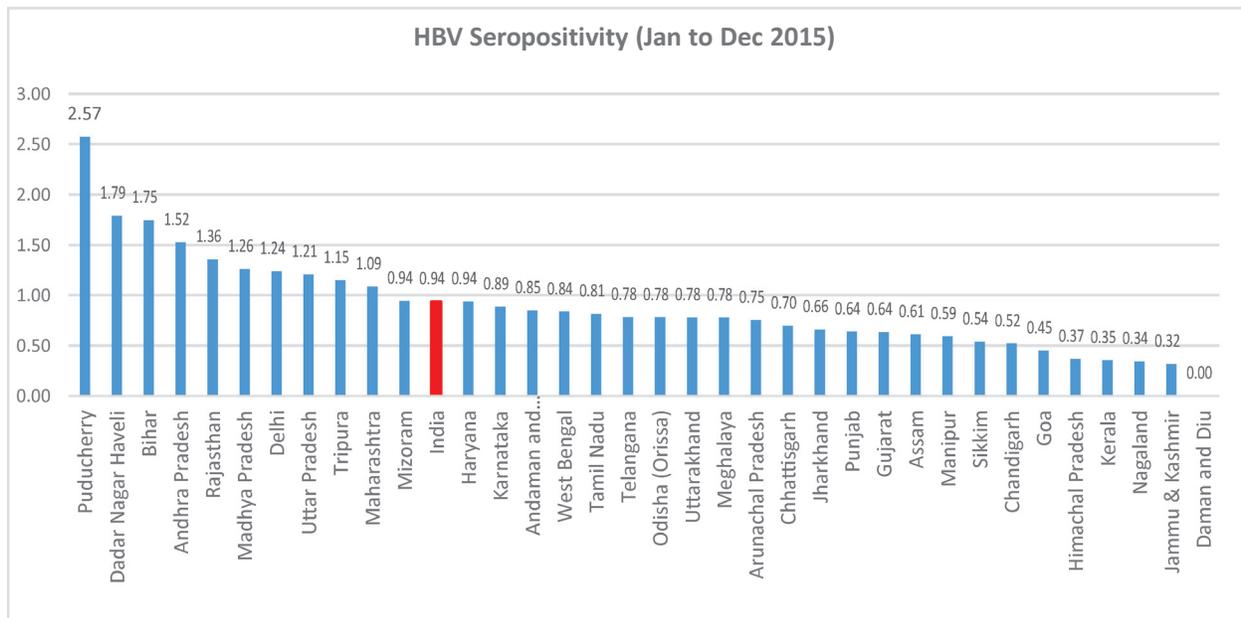
Hepatitis B was found to be higher than the national average of 0.94% in states like Puducherry(2.57%), Dadra Nagar Haveli(1.79%), Bihar(1.75%), Andhra Pradesh(1.52%), Rajasthan(1.36%), Madhya Pradesh (1.26%), Delhi(1.24%), U.P(1.21%), Tripura(1.15%) and Maharashtra(1.09%).

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Fig-10 Syphilis seropositivity- By State (%)

Syphilis Seropositivity (Jan to Dec 2015)
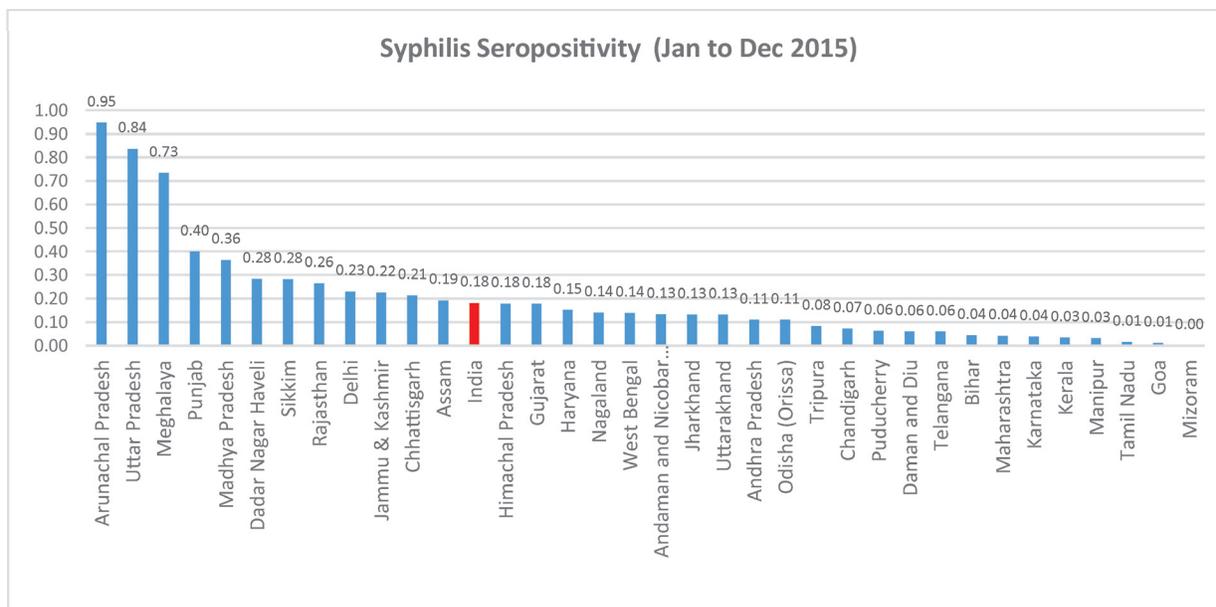
Syphilis sero-positivity was found to be higher than the national average of 0.18% in states like Arunachal Pradesh(0.95%),Uttar Pradesh (0.84%), Meghalaya(0.73%), Punjab(0.40%), Madhya Pradesh(0.36%), Dadra Nagar Haveli(0.28%), Sikkim(0.28%), Rajasthan(0.26%), Delhi(0.23%), Jammu &Kashmir(0.22%), Chhattisgarh(0.21%) and Assam(0.19%).

Fig-11 Malaria Positivity– By state (%)

Malaria Positive (Jan to Dec 2015)
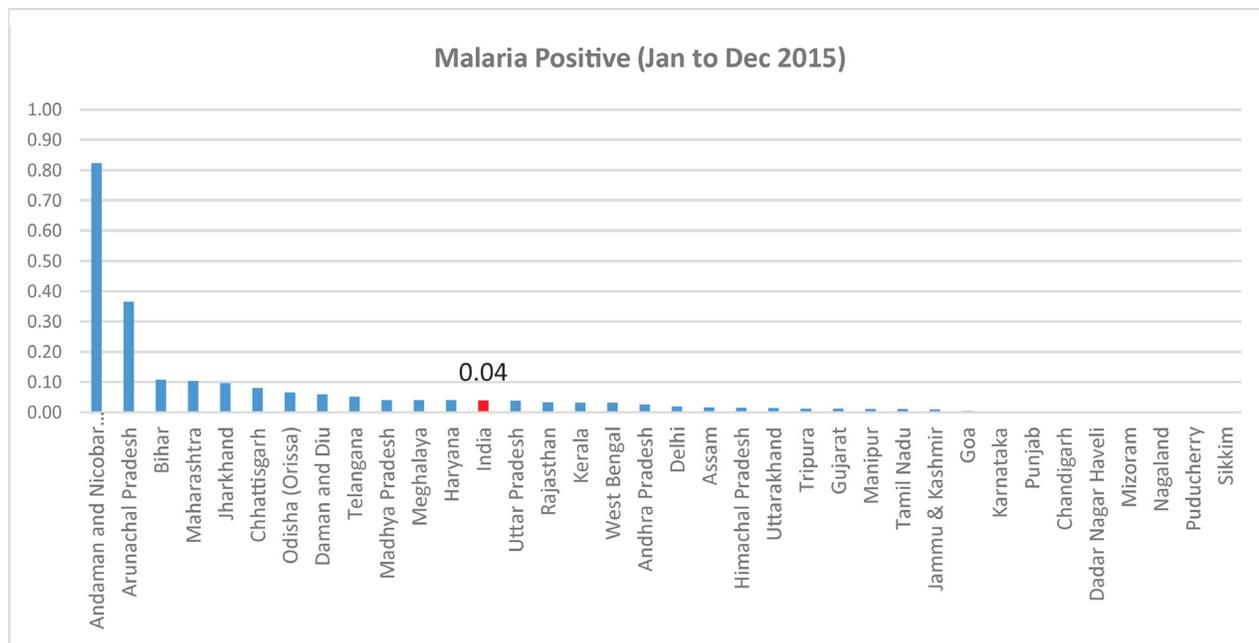
The majority of the states indicated a lower positivity of Malaria than the national positivity of 0.04%, whereas states like Andaman and Nicobar Islands, Arunachal Pradesh, Bihar,Maharashtra, Jharkhand, Chattisgarh,Odisha, Daman and Diu, Telangana, Madhya Pradesh, Meghalaya, Haryana recorded a higher positivity.

4.4   Component Separation

At the country level, 64.34% of blood units collected by blood banks with component facilities were used for component preparation.

Fig-12 Total blood collection and component separation

Total collection vs Components

Fig-13 Percentage of component separation – By state
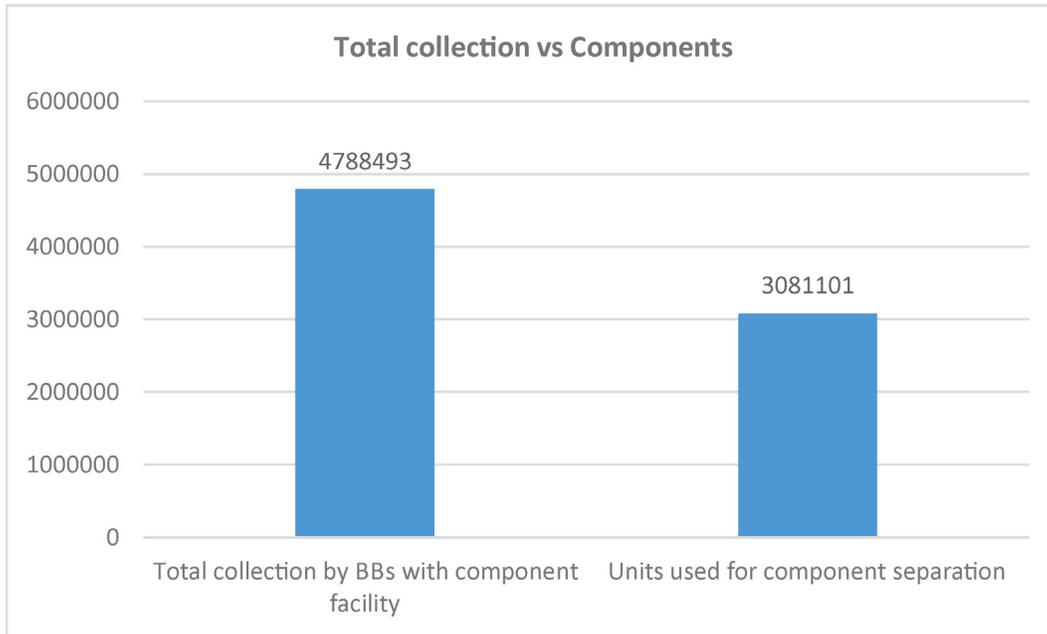
Percentage of component separation   - By state
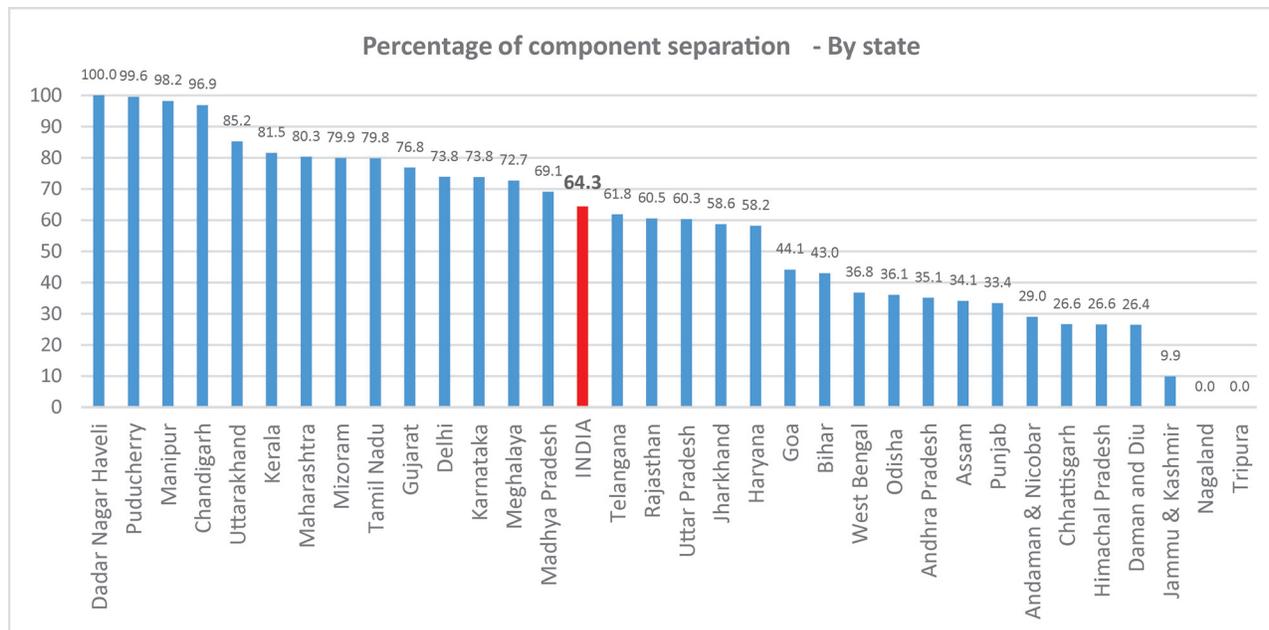
The percentage of component preparation was higher than the national average of 64.3% in Dadra Nagar Haveli, Puducherry, Manipur, Chandigarh,Uttarakhand, Kerala, Maharashtra, Mizoram, Tamil Nadu, Gujarat, Delhi, Karnataka, Meghalaya and Madhya Pradesh. States such as Sikkim and Arunachal Pradesh did not have any NACO supported blood banks with component separation facility.

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4.5 Quality Management Systems

As mentioned in the methodology section, the blood banks were assessed and categorised based on the scores obtained. Adequate importance and weight were given to technical aspects and adherence to quality management systems. At the national level, the majority of blood banks (78%) scored between 36 to 70; 19% scored above 70 and 3% scored less than or equal to 35. The mean score was 60.27 (SD: 12.05).

Fig-14 Categorisation of blood banks by assessment score
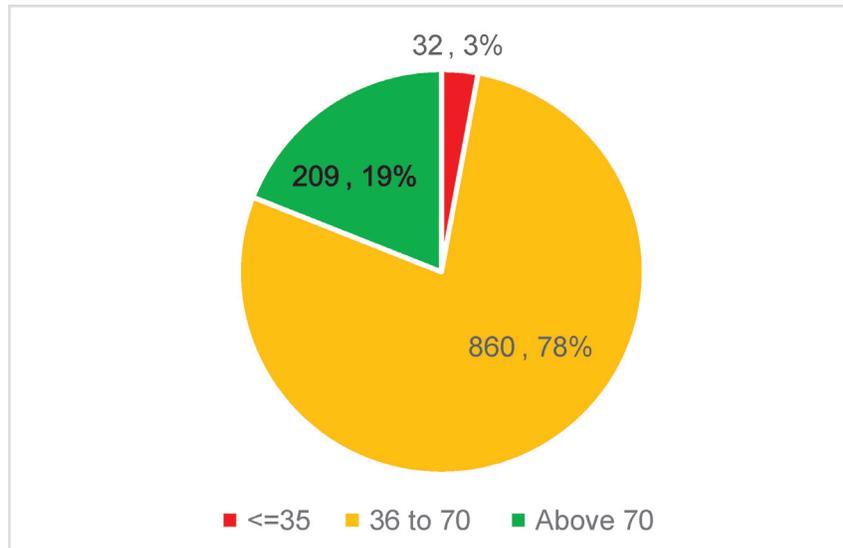
**Fig-15 - Mean assessment score- By state**
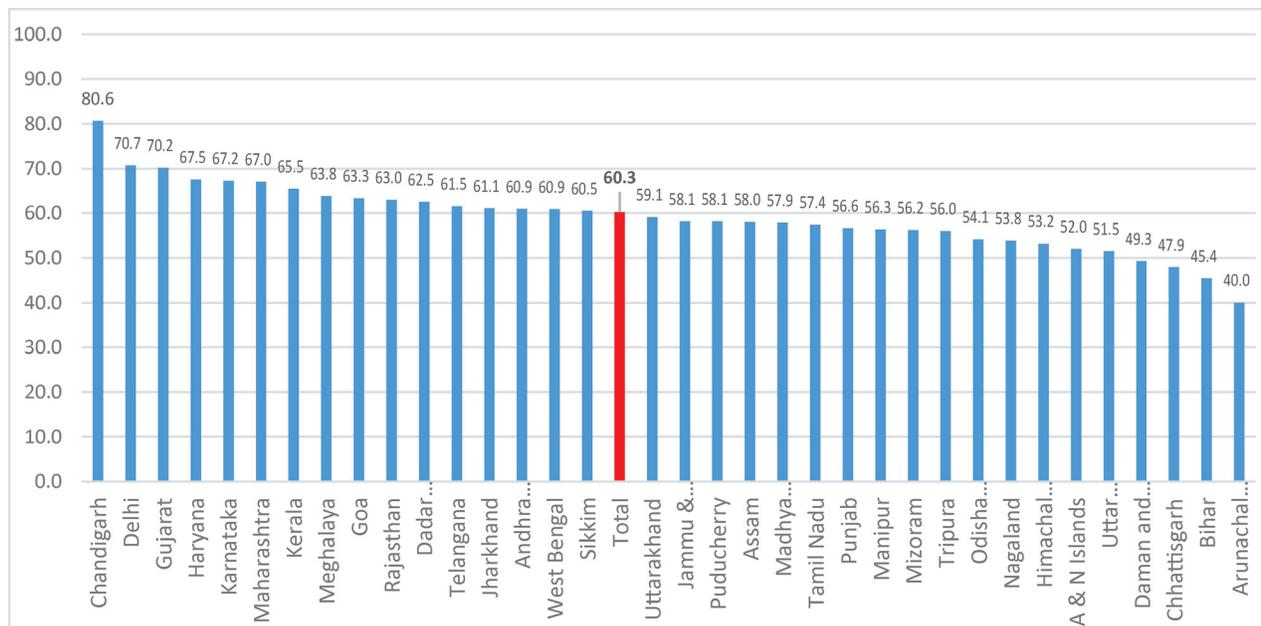
Sixteen states in the country scored more than the national average of 60.27, of which, states such as Chandigarh (80.6), Delhi (70.7) and Gujarat (70.2) scored more than 70. Nineteen states in the country scored less than the national average, of which, Arunachal Pradesh (40), Bihar (45.4), Chhattisgarh (47.9) and Daman and Diu (49.3) scored less than 50.

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The number of blood banks (by state) that scored less than or equal to 35 is mentioned in Table-7. Most of the blood banks were in Uttar Pradesh (11), followed by Bihar (7) and Odisha (3).

Table-7 – Number of blood banks scored <=35

State	No of BBs
Uttar Pradesh	11
Bihar	7
Odisha (Orissa)	3
Arunachal Pradesh	2
Punjab	2
Tamil Nadu	2
Andhra Pradesh	1
Chhattisgarh	1
Jammu & Kashmir	1
Madhya Pradesh	1
Rajasthan	1
Total	**32**

The number of blood banks (by state) that scored more than 70 is mentioned in Table-8. The majority of blood banks that scored above 70 was from Maharashtra (42), followed by Gujarat (39), Karnataka(21), Delhi(13), Rajasthan (12) and Kerala (10).

Table-8 – Number of blood banks scored above 70

State	No of BBs
Maharashtra	42
Gujarat	39
Karnataka	21
Delhi	13
Rajasthan	12
Kerala	10
Haryana	8
West Bengal	8
Madhya Pradesh	7
Tamil Nadu	7
Jharkhand	6
Uttar Pradesh	6
Andhra Pradesh	5
Odisha (Orissa)	5
Punjab	5
Telangana	5
Chandigarh	4
Uttarakhand	3
Assam	2
Jammu & Kashmir	1
TOTAL	**209**

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Assessment score by Category of blood banks: The mean score of blood banks with component facilities was found to be higher (64.72; SD: 11.57) than the mean score of blood banks without component facilities (57.45; SD: 11.50).

Table-9 Mean assessment score by category of blood banks

Category of blood banks	Mean	SD
BBs with component facility (427)	64.72	11.57
BBs without component facility (674)	57.45	11.50
Overall	**60.27**	**12.05**

Further analysis indicated that there were more blood banks (28 blood banks) who scored less than or equal to 35 among blood banks without component separation facility, compared to only 4 blood banks with component separation facility.

Fig-16 BBs with component- score
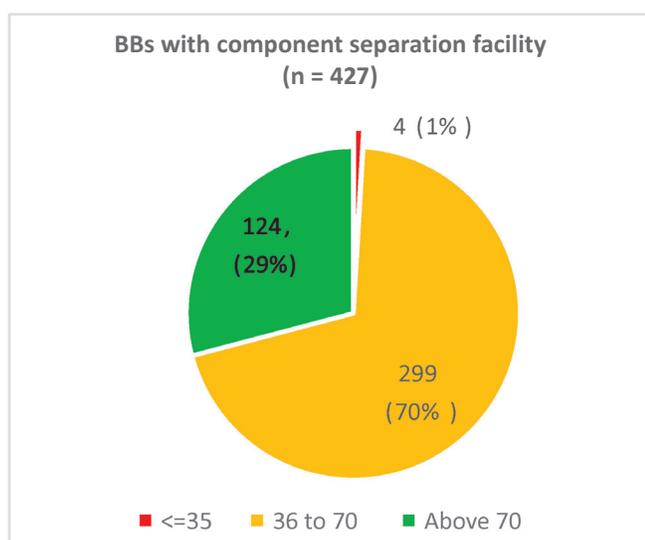
Fig-17 BBs without component- score
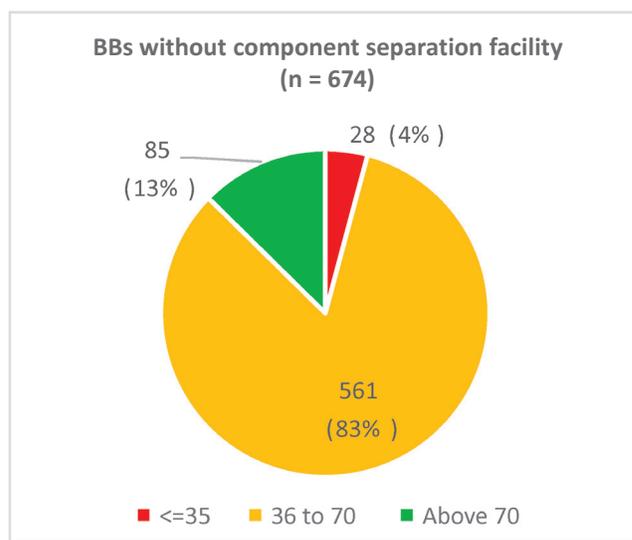
Table-10 Assessment score (categories) by Category of blood banks

Category of blood banks	<=35	36 to 70	Above 70	Total
BBs with component facility	4	299	124	427
	.9%	70.0%	29.0%	100.0%
BBs without component facility	28	561	85	674
	4.2%	83.2%	12.6%	100.0%
Overall	**32**	**860**	**209**	**1101**
	2.9%	**78.1%**	**19.0%**	**100.0%**

Assessment score by ownership: The mean assessment score of NGO/Trust/Charitable owned blood banks (67.27; SD: 11.21) was found to be higher than the public sector blood banks(58.38; SD: 11.57). It was also found that there were more public sector blood banks (29 blood banks) in the less than or equal to 35 category compared to only 3 blood banks from NGO/Trust/Charitable owned blood banks.

Table-11 Mean assessment score by Ownership

Ownership	Mean	SD
Public (867)	58.38	11.57
NGO/Trust/Charitable (234)	67.27	11.21
Overall	**60.27**	**12.05**

Table-12 Assessment score (Categories) by Ownership

Ownership	<=35	36 to 70	Above 70	Total
Public	29	715	123	867
	3.3%	82.5%	14.2%	100.0%
NGO/Trust/Charitable	3	145	86	234
	1.3%	62.0%	36.8%	100.0%
Overall	32	860	209	1101
	2.9%	78.1%	19.0%	100.0%

Assessment score by Annual blood collection: The mean assessment score of blood banks that collected more than 5000 blood units (65.79; SD: 11.46) was found to be higher than blood banks that collected between 3001 to 5000(58.88; SD: 9.48) and less than 3000 blood units (55.91; SD: 11.43).

Table-13 Mean assessment score by annual collection

Annual collection	Mean	SD
Up to 3000 (483)	55.91	11.43
3001 to 5000 (183)	58.88	9.48
Above 5000 (435)	65.79	11.46
Overall	**60.27**	**12.05**

Assessment score by voluntary blood donation: Table -14 provides the mean assessment score by percentage of voluntary blood donation. The blood banks that reported a higher proportion of voluntary blood donation indicated higher mean assessment score.

Table-14 Mean assessment score by voluntary blood donation

% VBD	Mean	SD
<25% (58)	51.07	13.01
25-49% (92)	57.77	11.87
50 - 74% (149)	57.89	11.78
75-90% (182)	58.59	11.57
Above 90 (620)	62.65	11.47
Overall	**60.27**	**12.05**

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 (78.45; SD: 9.55) compared to those who were not enrolled in EQAS (58.86; SD: 11.05). The similar situation was found among those blood banks that were part of EQAS for Transfusion-transmitted Infections as well.

<div align="center">Table-15 Mean assessment score by EQAS participation</div>

EQAS for IH	Mean	SD
Enrolled (79)	78.45	9.55
Not enrolled (1022)	58.86	11.05
EQAS for TTI		
Enrolled(88)	78.02	8.57
Not enrolled(1013)	58.73	11.04

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) compared to those that were not accredited.

<div align="center">Table-16 Mean assessment score by Accreditation</div>

NABH	Mean	SD
No accreditation(926)	59.64	11.43
Accreditation(25)	89.12	5.85
Overall	**60.27**	**12.05**

However, only 25 blood banks among the 1101 blood banks have been accredited by NABH. Maharashtra (9) and Gujarat(9) had the highest number of accredited blood banks.

The list of blood banks under different categories of score is given in Table- 17

Table-17 Distribution of Blood banks by state and assessment score categories.

State	Score			
	<=35	36 to 70	Above 70	Total BBs
Andaman & Nicobar	0	1	0	1
Andhra Pradesh	1	50	5	56
Arunachal Pradesh	2	6	0	8
Assam	0	24	2	26
Bihar	7	32	0	39
Chandigarh	0	0	4	4
Chhattisgarh	1	15	0	16
Dadra Nagar Haveli	0	1	0	1
Daman and Diu	0	2	0	2
Delhi	0	7	13	20
Goa	0	3	0	3
Gujarat	0	36	39	75
Haryana	0	16	8	24
Himachal Pradesh	0	14	0	14
Jammu & Kashmir	1	21	1	23
Jharkhand	0	15	6	21
Karnataka	0	44	21	65
Kerala	0	35	10	45
Madhya Pradesh	1	54	7	62
Maharashtra	0	74	42	116
Manipur	0	3	0	3
Meghalaya	0	6	0	6
Mizoram	0	10	0	10
Nagaland	0	3	0	3
Odisha (Orissa)	3	44	5	52
Puducherry	0	4	0	4
Punjab	2	36	5	43
Rajasthan	1	34	12	47
Sikkim	0	2	0	2
Tamil Nadu	2	86	7	95
Telangana	0	34	5	39
Tripura	0	6	0	6
Uttar Pradesh	11	72	6	89
Uttarakhand	0	15	3	18
West Bengal	0	55	8	63
Total	**32**	**860**	**209**	**1101**

5.   Conclusion

Considering the importance of blood transfusion services in the provision of medical care, maintaining standards and ensuring quality systems are vital in blood banks. From the programmatic perspective, adequate, accurate and updated information at the district, state and national level is essential for planning and implementation of blood services across the country. This assessment captured all the required information related to the structure, services, and facilities, availability of human resources, equipment, quality management system and practices in blood banks across the country. All blood banks function subject to obtaining and maintaining a licence for operations from the FDA which means compliance to basic quality standards mentioned in the Drugs and cosmetic act and rules. However, this assessment brings out specific gaps and possible opportunities to improve quality standards in Transfusion Services.

The 1101 NACO supported blood banks which were included in the review is approximately 39.8% of total blood banks (2760) existing in the country. However, the annual collection of these blood banks was 6,828,055 units which is approximately 60% of blood requirement based on WHO's estimation that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2010). The review also revealed that the majority of blood collection (70%) was by blood banks with component separation facility (427) compared to smaller blood banks without component separation facility (624).

This review indicated a mean score of 60.27 with variations across the category of blood banks, ownership, voluntary blood donation, EQAS participation and accreditation status. It is evident that blood banks with component separation facility performed well in most parameters. It is important to note that there is a huge variation between states and within states on several parameters included in the assessment. This suggests the need for targeted and customised approach to address the gaps and challenges faced by the blood banks in the country.

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

6.   Reference

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