A Report on the "Assessment of Blood Banks in Himachal Pradesh, India"

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

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

Table of Contents

Executive Summary ix
1. Background 1
2. Objectives 4
3. Methodology 4
4. Key Findings 7
4.1 Basic details of blood banks (n=20) 8
4.1.1 Category of Blood Banks 8
4.1.2 Ownership 8
4.1.3 Organizational Attachment 9
4.1.4 License details of blood banks 9
4.2 Annual Blood Collection and Voluntary Blood Donation 10
4.2.1 Annual Collection of Blood 10
4.2.2 Voluntary blood donation 13
4.3 Transfusion Transmitted Infections(TTIs) 15
4.3.1 Transfusion Transmitted Infections by Category of blood banks 16
4.4 Component Separation 19
4.5 Quality Management Systems 21
4.6. Reporting and Documentation 22
4.6.1. Compliance to NBTC guidelines 22
4.6.2. Reporting requirements 22
4.7. Human Resources 23
4.7.1. Availability of staff 23
4.8. Training of Blood Bank Personnel 24
4.9. Equipment and Supplies 24
4.9.1. Regular supply kits/supplies 24
4.9.2. Equipment Availability (working condition) 25
4.10. The current status of blood banks based on the assessment 26
4.10.1 Assessment score by Category of blood banks 27
4.10.2 Assessment score by Ownership 28
4.10.3 Assessment score of Private Sector Blood Banks 29
4.10.4 Assessment score by Annual Collection 29
4.10.5 Assessment score by Voluntary Blood Donation 29
4.10.6 Assessment score by participation in External Quality Assessment Scheme 30
4.10.7 Assessment score by Accreditation status 30
5. Conclusion 32
6. Reference 34
7. Annexures 35
7.1 Individual Blood Banks Summary 35
7.2 NACO/NBTC – Questionnaire for Blood Bank 37
7.3 Scoring sheet 49

Tables and Figures

Tables

Table 1 Details of technical areas included in the assessment 5

Table 2 Scoring details and weight 6

Table 3 District Wise Descriptions of Blood Banks 7

Table 4 Basic details of blood banks 8

Table 5 District wise list of blood banks by Ownership 9

Table 6 Average Annual collection 11

Table 7 Annual blood collection and percentage of VBD 11

Table 8 Transfusion Transmitted Infections (%) 15

Table 9 Transfusion Transmitted Infections by category of blood banks 16

Table 10 Total Annual Collections by BCSUS and Percentage of Component Separation 19

Table 11 Availability of Quality Parameters in Blood Banks 21

Table 12 BBs having Equipment in working condition 25

Table 13 Mean Assessment score 26

Table 14 Mean assessment score - By District (NACO supported Vs. Non-NACO) 27

Table 15 Number of Blood Banks Scored 35 to 70- by District 27

Table 16 Mean assessment score by category of blood banks 28

Table-17 Mean assessment score by Ownership 28

Table-18 Mean assessment scores categories by Ownership 29

Table-19 Mean assessment score by annual collection 29

Table-20 Mean assessment score by voluntary blood donation 30

Table-21 Distribution of Blood banks by Districts and mean assessment score categories 30

Table-22 Distribution of Blood banks by Districts and mean assessment score categories 31

Figures

Figure 1 Availability of BBs per 1,000,000 (1 million) Population 7
Figure 2 License Status (n=20) 9
Figure 3 Annual Collections and Voluntary Donation 10
Figure 4 Type of Blood Donation (Voluntary vs Replacement Donation %) 10
Figure 5 Annual Collection per 100 population- District wise 12
Figure 6 Annual Collection per 100 population Vs BBs per 1 million- District wise 13
Figure 7 Percentage of Voluntary Blood Donation by District (Overall) 13
Figure 8 Percentage of Voluntary Blood Donation by District (NACO Supported) 14
Figure 9 Percentage of Voluntary Blood Donation by District (Non-NACO) 14
Figure 10 Transfusions Transmitted Infection (%)-Jan-Dec 2015 15
Figure 11 HIV Seroreactivity- By District (%) 16
Figure 12 HCV Seroreactivity- By District (%) 17
Figure 13 HBV Seroreactivity- By District (%) 17
Figure 14 Syphilis Seroreactivity- By District (%) 18
Figure 15 Malaria Positivity- By District (%) 18
Figure 16 Total Blood Collection and Component Separation 19
Figure 17 Percentage of Component Separation- By District (All BBs) 20
Figure 18 Percentage of Component Separation- By District (NACO) 20
Figure 19 Reporting and Documentation 23
Figure 20 Percentage of BB Manpower (At least one) 23
Figure 21 Percentage of BBs having at least one trained 24
Figure 22 Regular Supply of Kits 24
Figure 23 Mean Assessment Score – By Districts (All BBs) 26
Figure 24 Blood Banks scoring between 35 to 75 28

Executive Summary

Blood Banks in Himachal Pradesh

According to Central Drugs Standard Control Organization (CDSCO), there were 22 blood banks in Himachal Pradesh in 2015. The assessment exercise identified 20 functional blood banks across the state. Of the 20 blood banks, 14 (70%) were supported by National AIDS Control Organization, Ministry of Health and Family Welfare, Government of India and the remaining 6 (30%) were Non-NACO blood banks.

Shimla (5) had the highest number of blood banks followed by Kangra (3), Solan (3) and Hamirpur (2). In terms of NACO supported blood banks, Shimla (3) had the highest number of blood banks followed by Kangra (2).

There are 12 districts in the state of Himachal Pradesh. Around 55% (11) of all the blood banks (n=20) in the state were in 3 districts that are, Shimla (5), Kangra (3), and Solan (3).

Considering the number of blood banks per one million population, districts such as, Mandi (1), Sirmaur (1.9), Una (1.9), Chamba (1.9), Kangra (2), Kullu (2.3), Bilaspur (2.6) recorded less than the State average of 2.9 blood banks per 1,000, 000 (one million) population.

For the assessment, all functional blood banks (14 NACO supported – 70% and 6 Non-NACO-30%) which submitted their complete assessment forms were included in the analysis.

Description of blood banks

- Only 25% (5) of the blood banks in the state had component separation facility.
- Majority 85% (17) of the blood banks in the state are owned by public sector followed by not for profit sector (2, 10%) and private (1, 5%).
- All (14) of NACO supported blood banks were owned by public.
- The public sector had a higher proportion (60%) of blood component separation facility than the private (20%) and not for profit sector (20%).
- All the blood banks (20) were attached to hospitals in the state. Out of which 17 blood banks belong to public sector and rest belong to not for profit (2) and private sector(1).
- The majority of the blood banks (16; 80%) had a valid and current license, and the remaining (4; 20%) had applied for renewal. Around 86% (12) of NACO supported and 67% (4) 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 39,646 of which 81.4% 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 2,087 units. The average annual collection of NACO supported blood banks was found to be higher (2,700 units) than the Non-NACO blood banks (758 units).
- The blood banks with component separation units recorded a higher average collection of 4,631 units compared to blood banks without blood component separation units which was 1,178 units.
- The NACO supported blood banks collected 88.5% (35,100 units) of the total collection, of which 85.5% (3,0001) units were through voluntary blood donation. The Non-NACO blood banks collected 4,546 (11.5%) units of which 49.7% (2,259) units were through voluntary blood donation.

Transfusion Transmitted Infections

- HIV seroreactivity was found to be 0.03%, Hepatitis-C was 0.10%, Hepatitis-B 0.38%, Syphilis 0.17% and Malaria 0.01%. However, there is a huge variation between districts.

.

Component Separation

- Around 25% 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 (26.6%) in NACO blood banks compared to Non- NACO supported blood banks (15.4%).

Quality Management Systems

- The majority of blood banks (95%) reported that they adhered to the NBTC guidelines.
- Availability of document control system was reported by less than 40% of the blood banks in the state. Around 36% NACO supported blood banks and 50% Non-NACO blood banks reported they had a document control system.
- 95% of blood banks reported to have standard operating procedures (SOPs) for technical processes.
- Practice of internal quality control (IQC) for Immunohematology was reported by 75% of the blood banks and IQC for TTIs was reported by 30% of all the blood banks, with slight variation between NACO supported and Non-NACO blood banks.

- Around 85% of the blood banks reported carrying out quality control for kits, reagents and blood bags.
- There were no blood banks enrolled in EQAS by recognized providers for immunohematology and TTIs.
- None of the blood banks out of the total 20 blood banks that participated in the assessment were accredited by National Accreditation Board for Hospitals & Healthcare Providers (NABH).
- Designated and trained Quality Managers and Trained Technical managers were available only in 15% and 5% of the blood banks respectively.
- More than 85% of the blood banks reported that they had a regular equipment maintenance programme and around 80% 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 55.4 (SD: 9.0). The Non-NACO supported blood banks scored slightly higher (57.4; SD: 7.9) than the NACO supported blood banks (54.5; SD: 9.6)
- All the blood banks in the state (n=20) scored between 35 to 70. Five districts scored above the state average. More than half of the blood banks (55%) were located in these districts.
- Among the 12 districts, Kangra (64.5) scored the highest and Sirmaur (40) scored the least.
- The mean score of blood banks with component facilities (58.40; SD: 9.05) was found to be slightly higher than the mean score of those without component facilities (54.40; SD: 9.08).
- The mean assessment score of public owned blood banks (55.68; SD: 9.07) was found to be higher than NGO/Trust/Charitable owned blood banks
- However, Non- NACO blood banks run by public sector had scored higher (61.00; SD: 3.00) compared to NACO blood banks (54.54; SD: 9.58).
- The mean assessment score of blood banks that collected more than 5000 blood units (61.75; SD: 3.18) was found to be higher than 3000 blood units (54.97; SD: 8.98).
- No blood bank was enrolled in EQAS for IH and TTI in the state of Himachal Pradesh.
- None of the blood banks were accredited by National Accreditation Board of Hospitals and Health care Providers (NABH).

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

Assessment of Blood Banks in Himachal Pradesh

1. Background

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

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

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

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

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

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

Since the inception of the National AIDS Control programme in 1992, the blood safety programme in India under the National AIDS Control Organization has been making significant strides towards ensuring access to safe, and quality blood and blood products to all those who are in need of a transfusion. The goals and objectives of the programme are to ensure provision of safe and quality blood even to the most remote areas of the country. NACO has been taking continuous steps to strengthen the blood banks across the country by providing equipment, consumables, manpower and capacity building. The efforts to modernizing blood-banks, establishing model blood banks, and setting up blood storage centres in rural areas have improved the quality of blood transfusion services in the country. The current phase of the NACP IV (2012 -2017) focuses on blood safety that aims to support

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

Due to the continuous efforts in India, the availability of safe blood increased from 44 lakh units in 2007 to 100 lakh units by 2014-15; during this time HIV seroreactivity also declined from 1.2% to 0.2%, and Voluntary Blood Donation increased substantially (NACO, 2016). 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 to 5,000 units and district level blood banks collect up to 3,000 units annually.

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

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=5) and, 2. Blood banks without component separation facility (n=15). 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

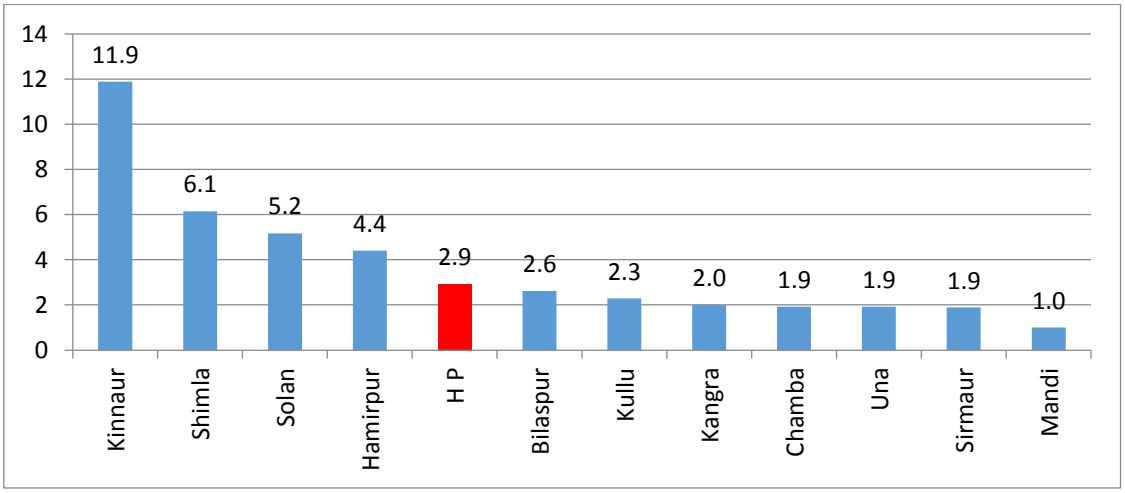
According to CDSCO, there were 22 blood banks in the state of Himachal Pradesh in 2015 (CDSCO, 2015).However, the assessment exercise identified 20 functional blood banks across the state. All functional blood banks (14 NACO supported – 70% and 6 Non-NACO-30%) which submitted their complete assessment forms were included in the analysis.

Table 3 District Wise Descriptions of Blood Banks

District	NACO Supported	Non-NACO	Total
Bilaspur	1	-	1
Chamba	1	-	1
Hamirpur	1	1	2
Kangra	2	1	3
Kinnaur	1	-	1
Kullu	1	-	1
Lahaul and Spiti	-	-	-
Mandi	1	-	1
Shimla	3	2	5
Sirmaur	1	-	1
Solan	1	2	3
Una	1	-	1
Himachal Pradesh	**14**	**6**	**20**

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. Shimla (5) had the highest number of blood banks followed by Kangra (3), Solan (3) and Hamirpur (2).In terms of NACO supported blood banks, Shimla (3) had the highest number of blood banks followed by Kangra (2).

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



Considering the number of blood banks per one million population, districts such as, Mandi (1), Sirmaur (1.9), Una (1.9), Chamba (1.9), Kangra (2), Kullu (2.3), Bilaspur (2.6) recorded less than the State average of 2.9 blood banks per 1,000, 000 (one million) population.

4.1 Basic details of blood banks (n=20)

As indicated earlier, 20 blood banks (14 NACO supported and 6 Non-NACO) that submitted the assessment forms were included in the analysis.

4.1.1 ***Category of Blood Banks:*** Out of 16 NACO supported blood banks 21.4% (3) blood banks had component separation facility and out of 6 Non-NACO blood banks 33.3% (2) had component separation facility.

Table 4 Basic details of blood banks

Specifics	Description	NACO Supported	Non-NACO	Total
Type of BB	With components	3 (21.4%)	2 (33.3%)	5 (25.0%)
	Without components	11 (78.6%)	4 (66.7%)	15 (75.0%)
Ownership	NGO/Trust/Charitable	0	2 (33.3%)	2 (10.0%)
	Private	0	1 (16.7%)	1 (5.0%)
	Public	14 (100.0%)	3 (50.0%)	17 (85.0%)
Licence	Valid	12 (85.7%)	4 (66.7%)	16 (80.0%)
	Under Renewal	2 (14.3%)	2 (33.3%)	4 (20.0%)
Attachment	Attached to Hospital	14 (100.0%)	6 (100.0%)	20 (100.0%)

At the District level, Solan (2) had the highest number of BCSUs followed by Shimla (1), Mandi (1) and Kangra (1).

4.1.2 ***Ownership:*** As depicted in Table:-4, majority 85 percent (17) of blood banks are owned by public sector followed by not for profit sector (2, 10%) and private (1, 5%). All (14) of NACO supported blood banks were owned by public. The public sector had a higher proportion (3, 60%) of blood component separation facility than the private (20%) and not for profit sector (20%). Among the NACO supported blood banks, the public sector had all the three BCSUs.

Around 47% of all the public owned blood banks (n=8) were in two districts that are Shimla (5) and Kangra (3). (Refer Table - 5)

Table 5 District wise list of blood banks by Ownership

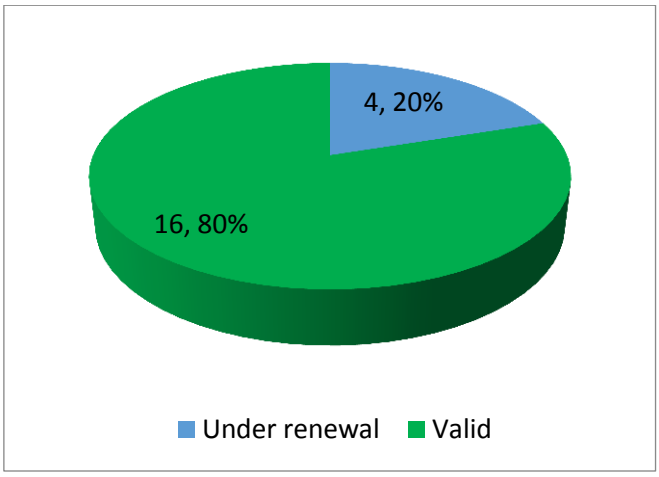
District	Public	%	Not-for-profit	%	Private	%	Total
Bilaspur	1	100	-	-	-	-	1
Chamba	1	100	-	-	-	-	1
Hamirpur	1	50	1	50	-	-	2
Kangra	3	100	-	-	-	-	3
Kinnaur	1	100	-	-	-	-	1
Kullu	1	100	-	-	-	-	1
Mandi	1	100	-	-	-	-	1
Shimla	5	100	-	-	-	-	5
Sirmaur	1	100	-	-	-	-	1
Solan	1	33.3	1	33.3	1	33.3	3
Una	1	100	-	-	-	-	1
Himachal Pradesh	**17**	**85**	**2**	**10**	**1**	**5**	**20**

4.1.3 ***Organizational Attachment:*** All the blood banks (20) were attached to hospitals. Out of which 17 blood banks belonged to public sector and rest belonged to not for profit (2) and private sector (1).

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 (16; 80%) had a valid and current license, and the remaining (4; 20%) had applied for renewal. Around 86% (12) of NACO supported and 67% (4) of Non-NACO blood banks had a valid and active license. Similarly, (13, 76.5%) of public blood banks and all private and not for profit blood banks had a valid and active license.

Figure 2 License Status (n=20)



All blood banks (n=4) which have reported as "deemed renewal" had their last inspection by licencing authority during the last one year.

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 6,833,038, currently needs around 68,330 units of blood. As per this criteria, Himachal Pradesh is producing less than what is required.

4.2.1 ***Annual Collection of Blood:*** During January 2015 to December 2015, the annual blood collection from all the blood banks that reported was 39,646 of which 81.4% units were through voluntary blood donations and the remaining were from replacement donations.

Figure 3 Annual Collections and Voluntary Donation

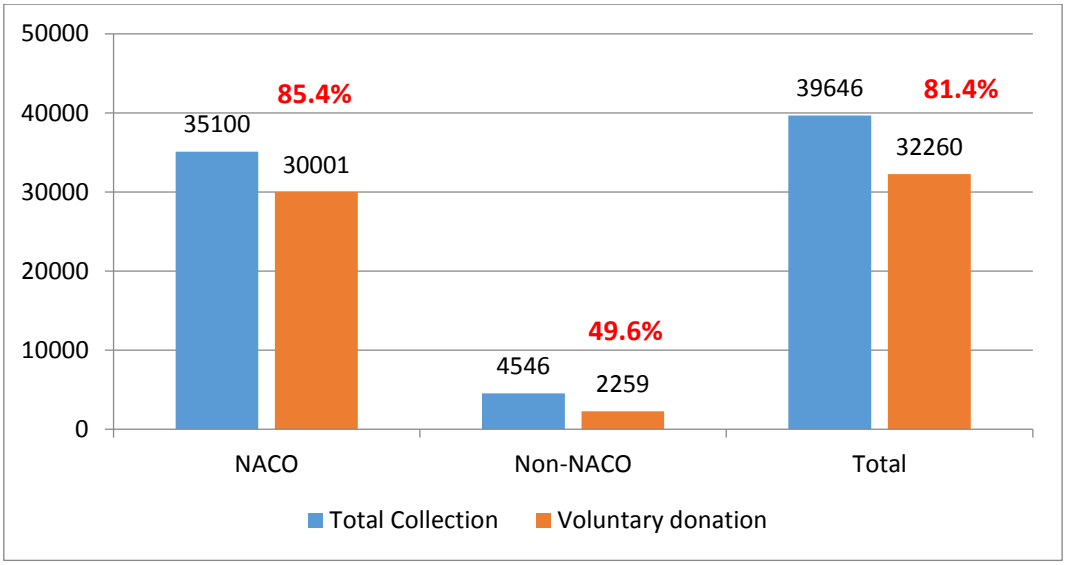
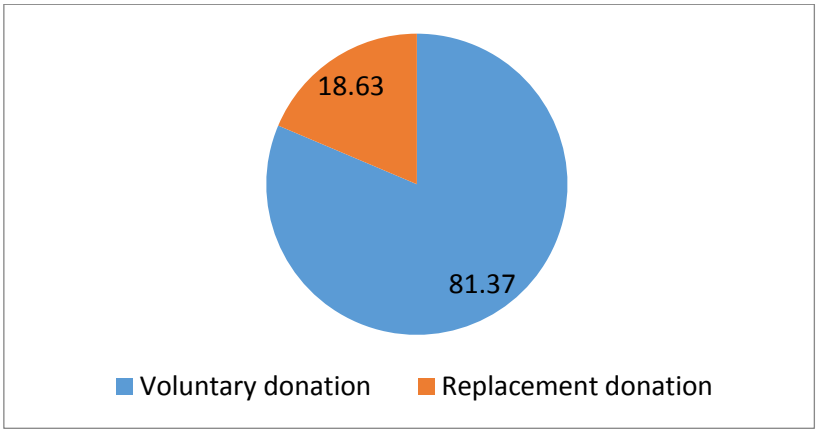


Figure 4 Type of Blood Donation (Voluntary vs Replacement Donation %)



The average annual collection of blood units of all the blood banks in the state was 2,087 units. The average annual collection of NACO supported blood banks was found to be higher (2,700 units) than the Non-NACO blood banks (758 units).

Table 6 Average Annual collection

District	NACO supported	Non-NACO	All BBs
Bilaspur	1800	-	1800
Chamba	684	-	684
Hamirpur	2274	117	1196
Kangra	4103	1189	3132
Kinnaur	-	-	-
Kullu	1398	-	1398
Mandi	3046	-	3046
Shimla	4544	418	2894
Sirmaur	720	-	720
Solan	1500	1202	1301
Una	1840	-	1840
Himachal Pradesh	**2700**	**758**	**2087**

Similarly, the blood banks with component separation units recorded a higher average collection of 4,631 units compared to blood banks without blood component separation units which was 1,178 units. However, the variation in the collection was found to be very high across and within districts.

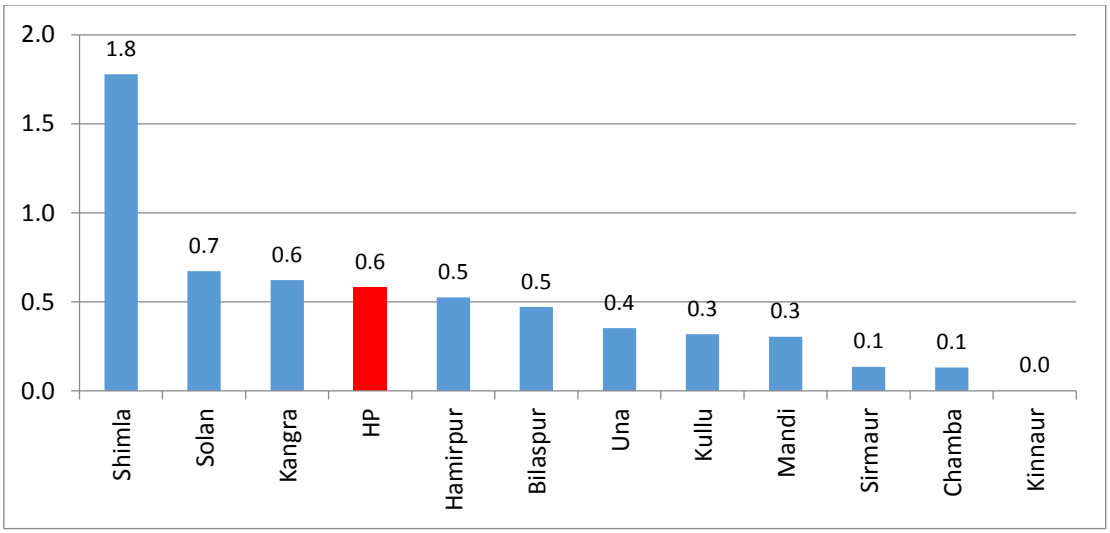
The NACO supported blood banks collected 88.5% (35,100 units) of the total collection, of which 85.5% (3,0001) units were through voluntary blood donation. The Non-NACO blood banks collected 4,546 (11.5%) units of which 49.7% (2,259) units were through voluntary blood donation. Blood banks with component separation facility collected around 58% of blood units (23,154) and the remaining 42% (67,791) were collected by blood banks without the component facility. Similarly, blood banks owned by public sector collected 93.6% (37,125) of the total collection followed by the not-for-profit sector 5.3% (2,098) and private sector blood banks (1.1%, 423).

Table-7 indicates the district-wise details of the total annual collection, voluntary and replacement donation in the state of Himachal Pradesh. Blood banks reported a varying proportion of VNRBD ranging from 30.7 to 98.9%.

Table 7 Annual blood collection and percentage of VBD

District	Voluntary Donation	Replacement Donation	Annual Collection	VBD %
Bilaspur	1572	228	1800	87.3
Chamba	210	474	684	30.7
Hamirpur	1718	673	2391	71.9
Kangra	7968	1427	9395	84.8
Kinnaur	-	-	-	-
Kullu	1200	198	1398	85.8
Mandi	2990	56	3046	98.2
Shimla	12087	2381	14468	83.5
Sirmaur	650	70	720	90.3
Solan	2045	1859	3904	52.4
Una	1820	20	1840	98.9
Himachal Pradesh	**32260**	**7386**	**39646**	**81.4**

Figure 5 Annual Collection per 100 population- District wise

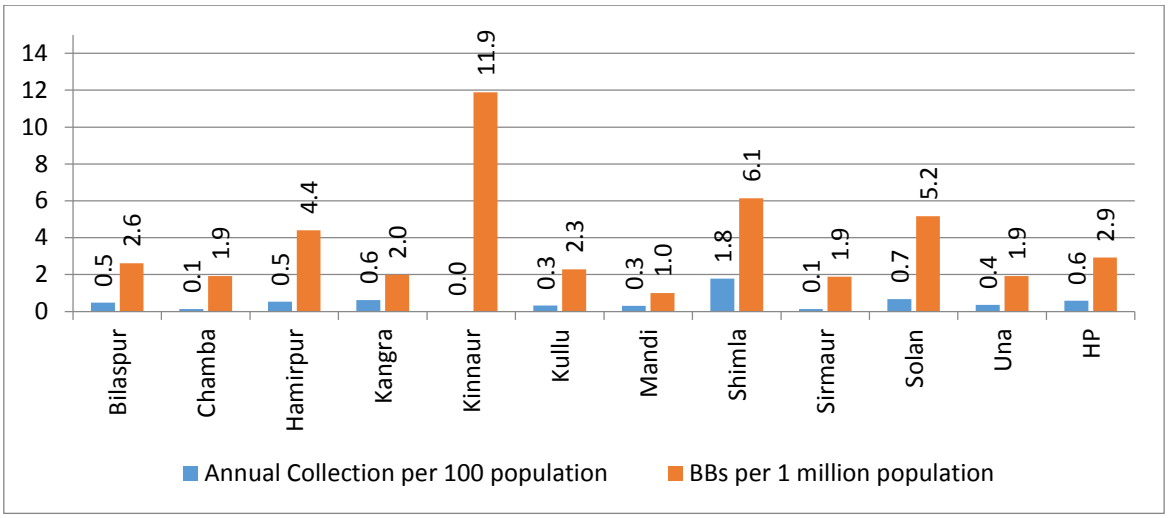


The annual collection of blood units per 100 individuals was found to be around 0.6% in the state, which is not meeting the WHO suggested requirement that 1% of the population can meet a nation's (populations) most basic requirements for blood. However, there is a huge disparity in the collection of blood between districts. Chamba (0.1), Sirmaur (0.1), Mandi (0.3), Kullu (0.3), Una (0.4), Bilaspur (0.5), Hamirpur (0.5), districts collected state average of less than 0.6 units per 100 population, Three districts in the state recorded more than the state average of 1.5 units per 100 population that are, Shimla(1.8), Solan (0.7). (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 2.9 blood banks per million population that collected around 0.6 units per

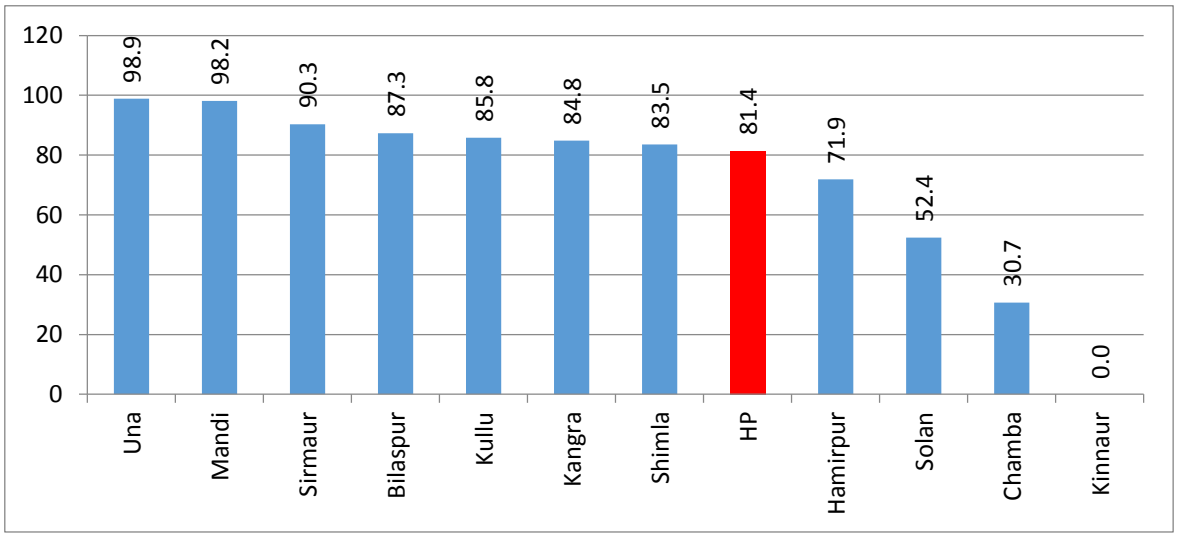
100 population at the ratio of 2.9 BB: 0.6 blood unit. The ratio was wide in Kinnaur, Shimla and Solan districts. These districts collect relatively less blood with more number of blood banks proportionate to population.

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



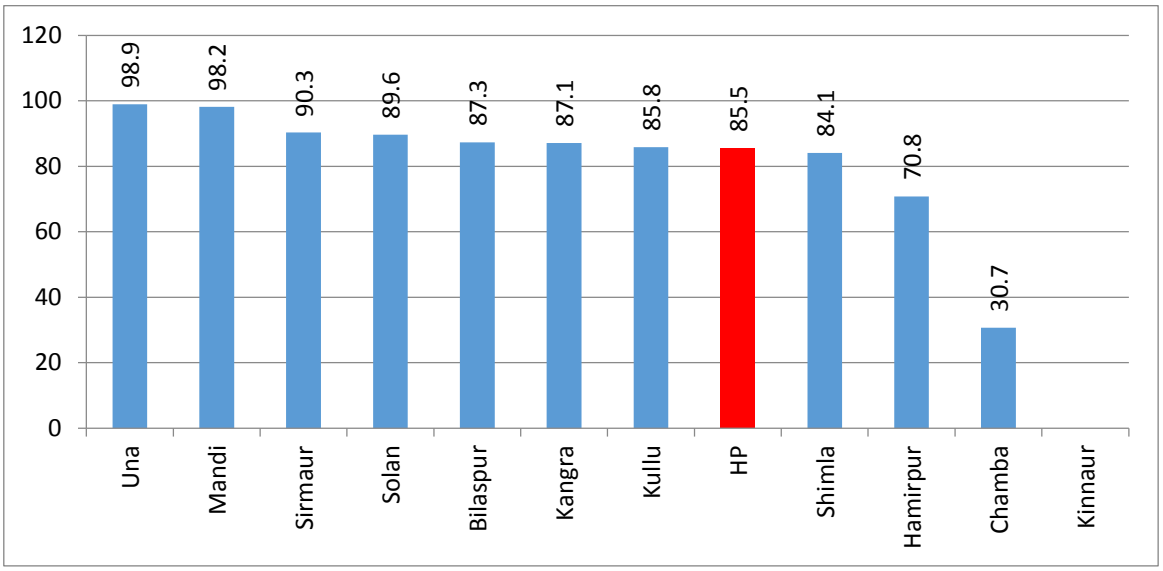
4.2.2 ***Voluntary blood donation:*** As depicted in Figure-7, nine districts have recorded more than the state average of 81.4%. Districts such as Una, Mandi and Sirmaur reported more than 90% voluntary blood donation. Chamba district recorded the lowest percentage of VBD in the state (30.7%)

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



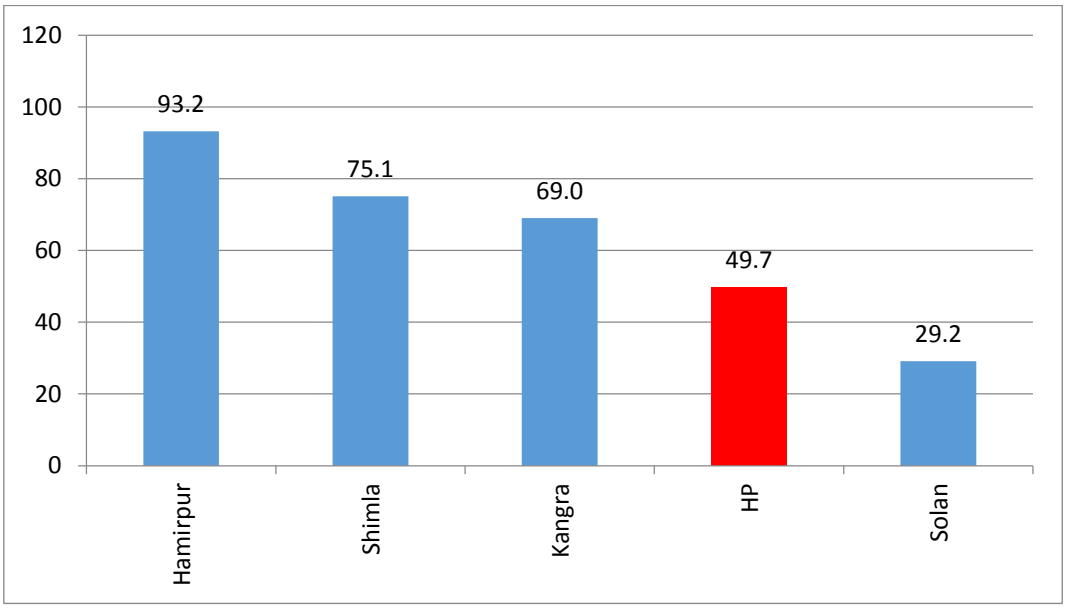
Districts such as Una, Mandi and Sirmaur recorded more than 90%, which is above the state average. Shimla, Hamirpur and Chamba districts recorded less than the state average of voluntary donation during January to December 2015.

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



Among Non-NACO blood banks, three districts recorded more than state average of 49.7%. One district recorded less than the state average. Solan district recorded the lowest VBD percentage (29.2%) in the state among Non-NACO blood banks.

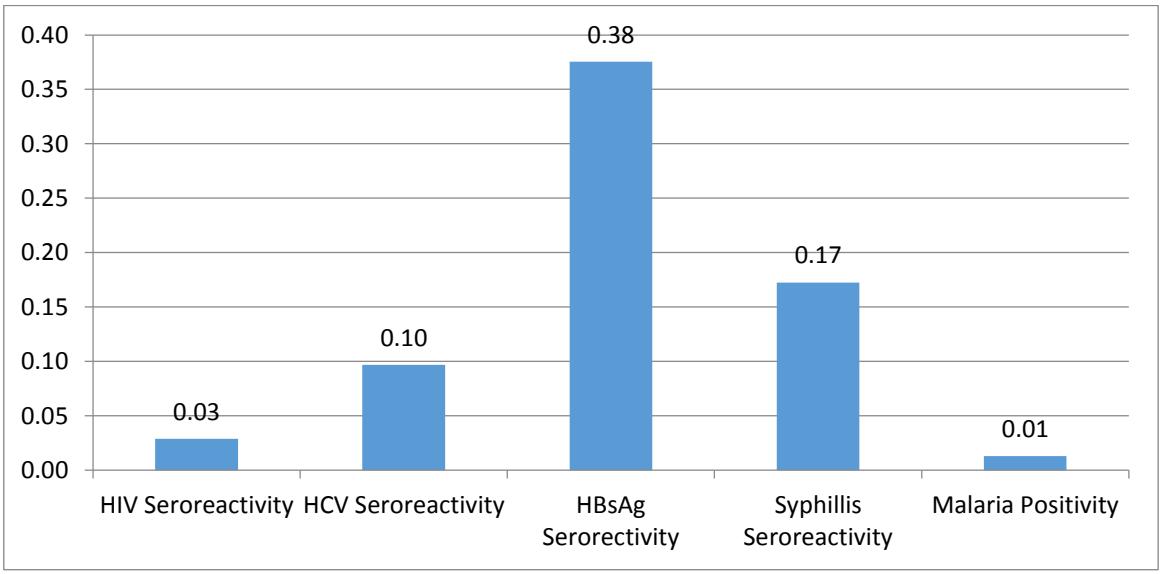
Figure 9 Percentage of Voluntary Blood Donation by District (Non-NACO)



4.3 Transfusion Transmitted Infections(TTIs)

Transfusion-Transmitted Infections (TTIs) are major problems associated with blood transfusion (Chandra, Rizvi, & Agarwal, 2014; Gupta, Singh, Singh, & Chugh, 2011). Screening for TTIs such as HIV 1, HIV 2, Hepatitis B, Hepatitis C, Malaria, and Syphilis is mandatory in India. Due to the concerted and active efforts, the 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 reactivity was found to be 0.03%, Hepatitis-C was 0.10%, Hepatitis-B 0.38%, Syphilis 0.17% and Malaria 0.01%. However, there is a huge variation between districts.

HIV, Syphilis and Malaria reactivity/positivity rates were recorded higher in NACO supported blood banks. HCV and HBV seroreactivity was found to be higher in Non-NACO blood banks.

Table 8 Transfusion Transmitted Infections (%)

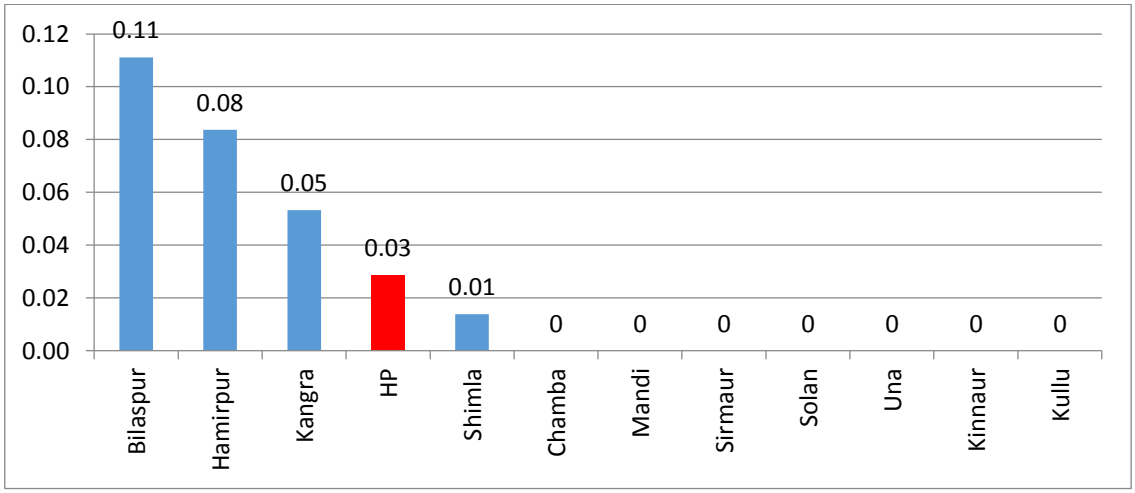
Category of BB	Transfusion Transmitted Infections %				
	HIV	HCV	HBV	Syphilis	Malaria
NACO Supported	0.03	0.09	0.37	0.18	0.01
Non-NACO	0	0.18	0.44	0.13	0
Overall	**0.03**	**0.10**	**0.38**	**0.17**	**0.01**

4.3.1 Transfusion Transmitted Infections by Category of blood banks: HCV and HBV reactivity rates were found to be higher in blood banks with component facility as compared to blood banks without component separation facility.

Table 9 Transfusion Transmitted Infections by category of blood banks

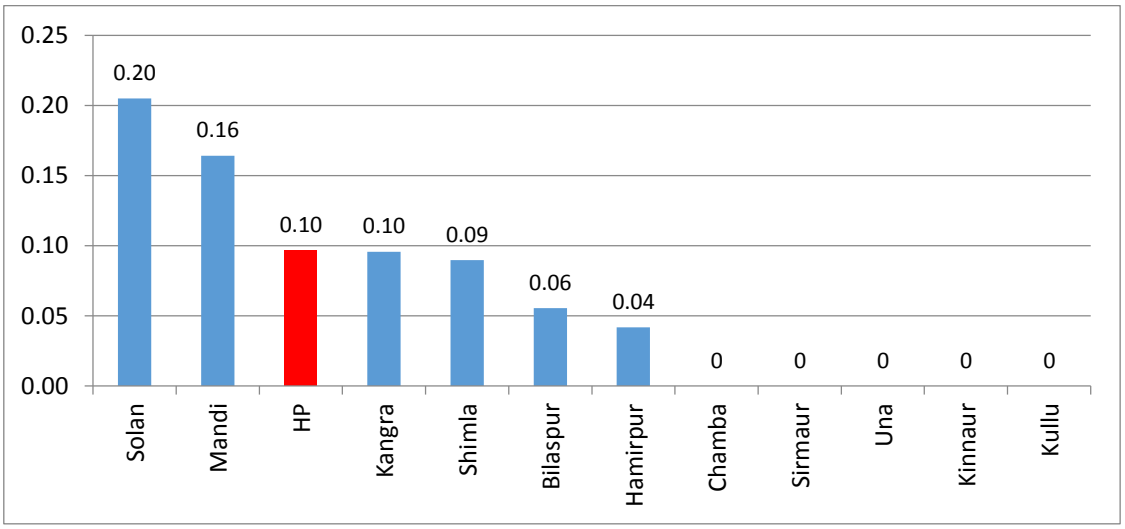
Category of BB	Transfusion Transmitted Infections %				
	HIV	HCV	HBV	Syphilis	Malaria
BBs with component facility	0	0.11	0.39	0.16	0
BBs without component facility	0.07	0.07	0.35	0.19	0.03
Overall	**0.03**	**0.10**	**0.38**	**0.17**	**0.01**

Figure 11 HIV Seroreactivity- By District (%)



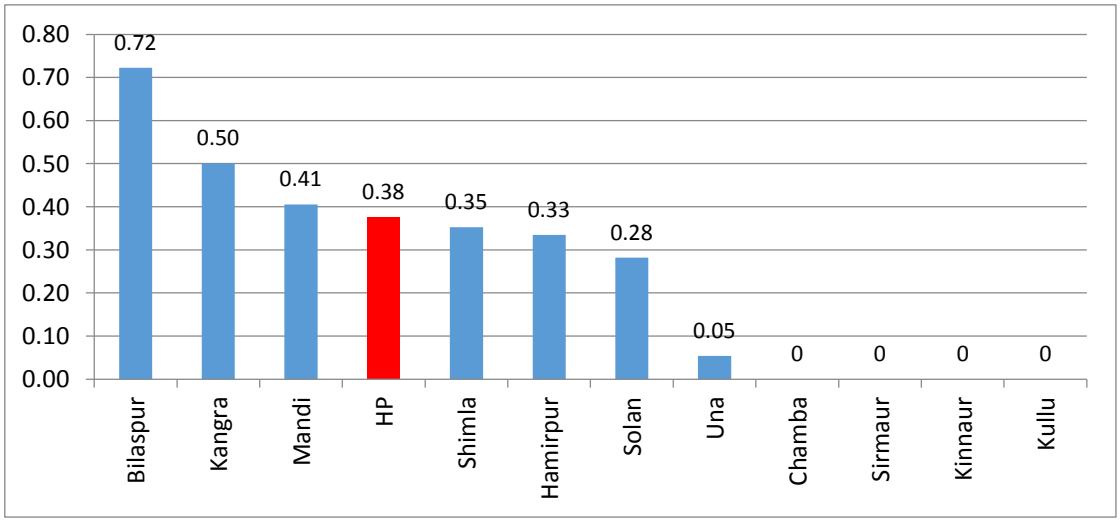
The majority of districts indicated lower HIV reactivity than the state HIV reactivity level of 0.03%. However, Bilaspur (0.11%), Hamirpur (0.08%) and Kangra (0.05%) districts recorded a higher reactivity than state average. In general, HIV reactivity in the state recorded a low reactivity as compared to other states in the country.

Figure 12 HCV Seroreactivity- By District (%)



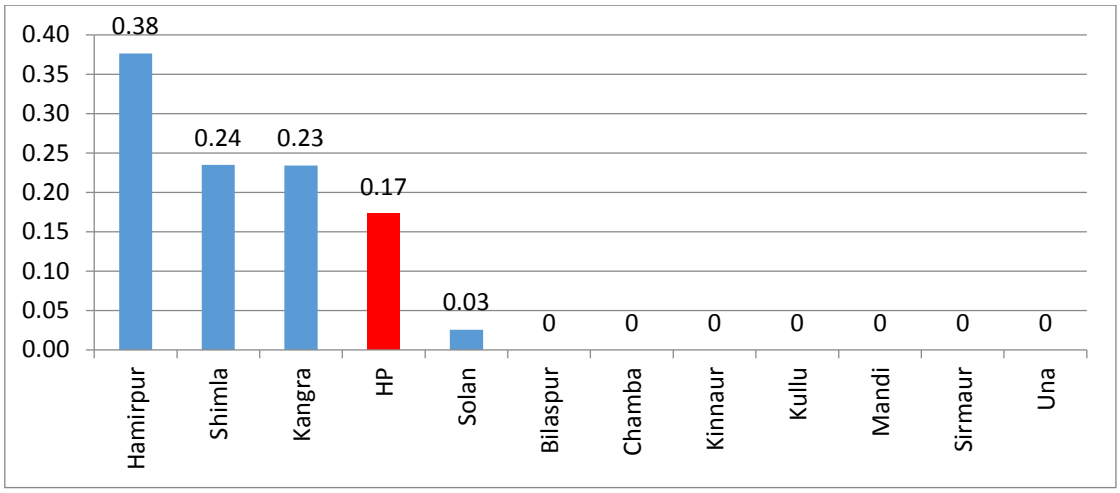
When considering Hepatitis C infection, districts like Solan (0.20%) and Mandi (0.16%) indicated a higher reactivity level as compared to the state average of 0.10%.

Figure 13 HBV Seroreactivity- By District (%)



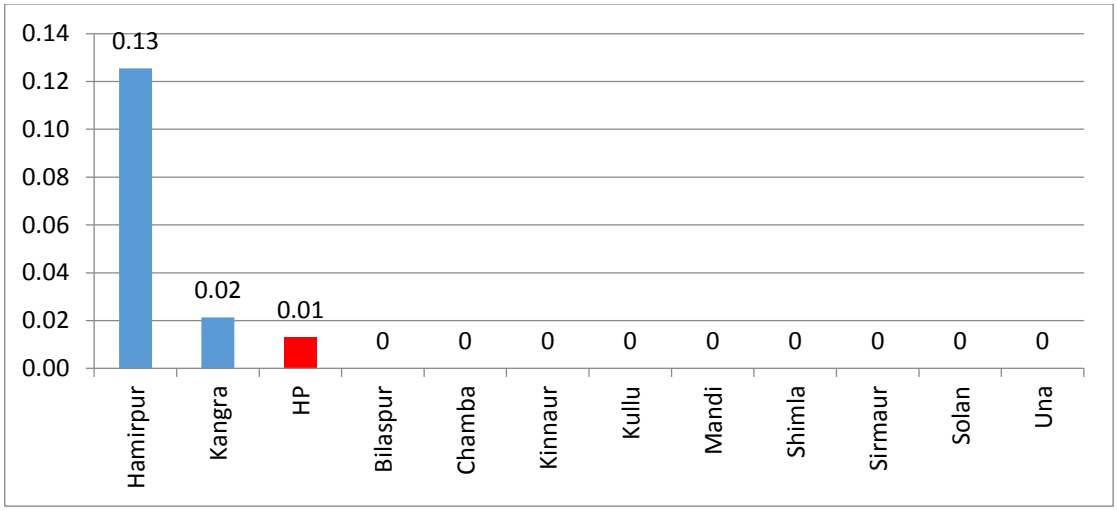
Hepatitis B seroreactivity was found to be higher than the state average of 0.38% in districts like Bilaspur (0.72%), Kangra (0.50%) and Mandi (0.41%). Four districts recorded less than the state average.

Figure 14 Syphilis Seroreactivity- By District (%)



Syphilis seroreactivity was found to be higher than the state average of 0.17% in districts like Hamirpur (0.38%), Shimla (0.24%), and Kangra (0.23%).

Figure 15 Malaria Positivity- By District (%)



The majority of the districts indicated a lower positivity rate of Malaria than the state positivity of 0.01% whereas districts like Hamirpur and Kangra recorded a higher positivity rate than the state average.

4.4 Component Separation

As depicted in Figure -16, around 25% 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 (26.6%) in NACO blood banks compared to Non-NACO supported blood banks (15.4%).

Figure 16 Total Blood Collection and Component Separation

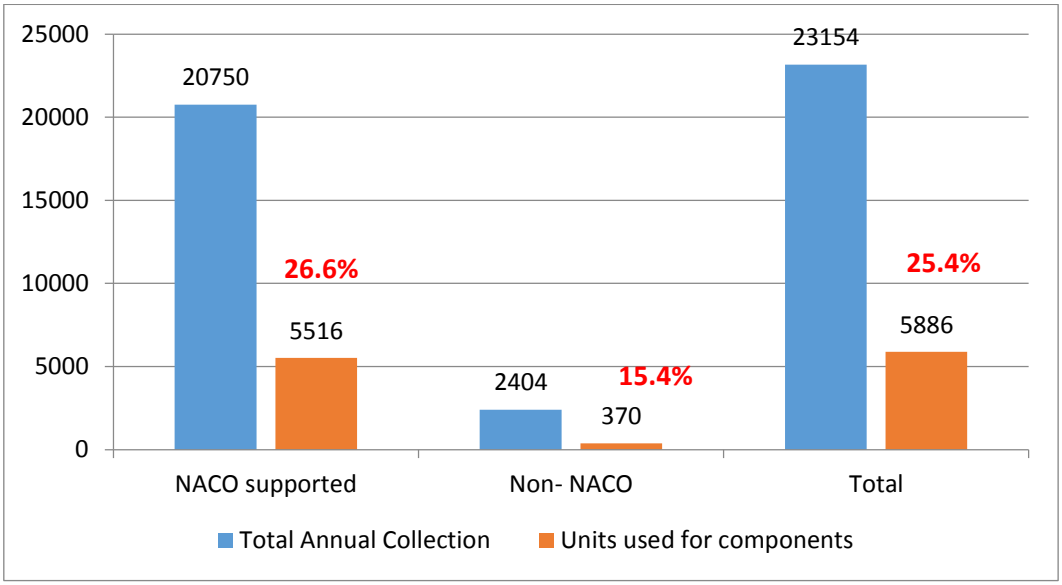
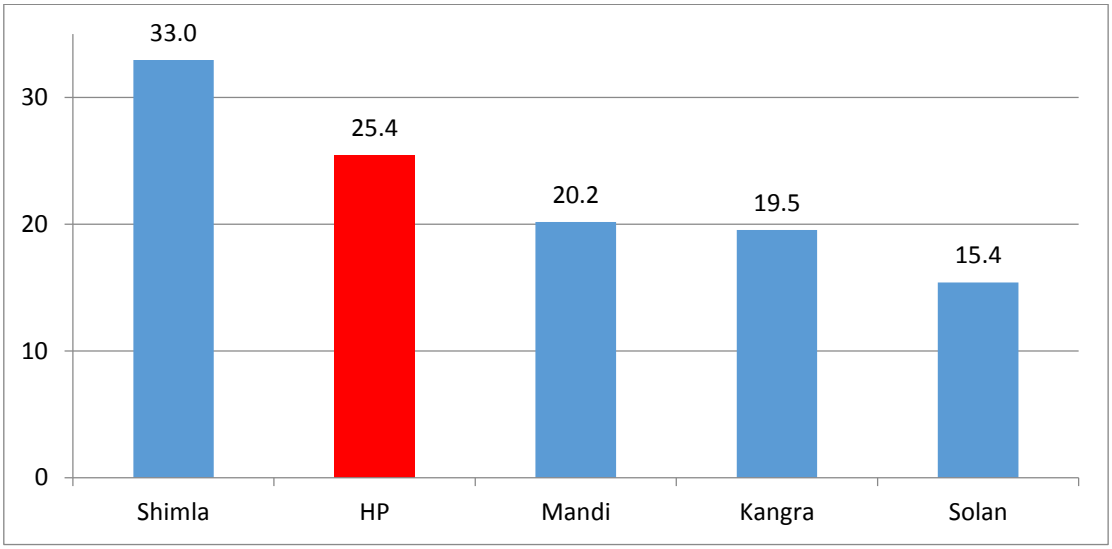


Table 10 Total Annual Collection by BCSUs and Percentage of Component Separation

District	Total Annual Collection	Total Collection by BCSUs	Percentage of component separation
Bilaspur	1800	-	-
Chamba	684	-	-
Hamirpur	2391	-	-
Kangra	9395	6940	19.5
Kinnaur	-	-	-
Kullu	1398	-	-
Mandi	3046	3046	20.2
Shimla	14468	10764	33.0
Sirmaur	720	-	-
Solan	3904	2404	15.4
Una	1840	-	-
Himachal Pradesh	**39,646**	**23,154**	**25.4**

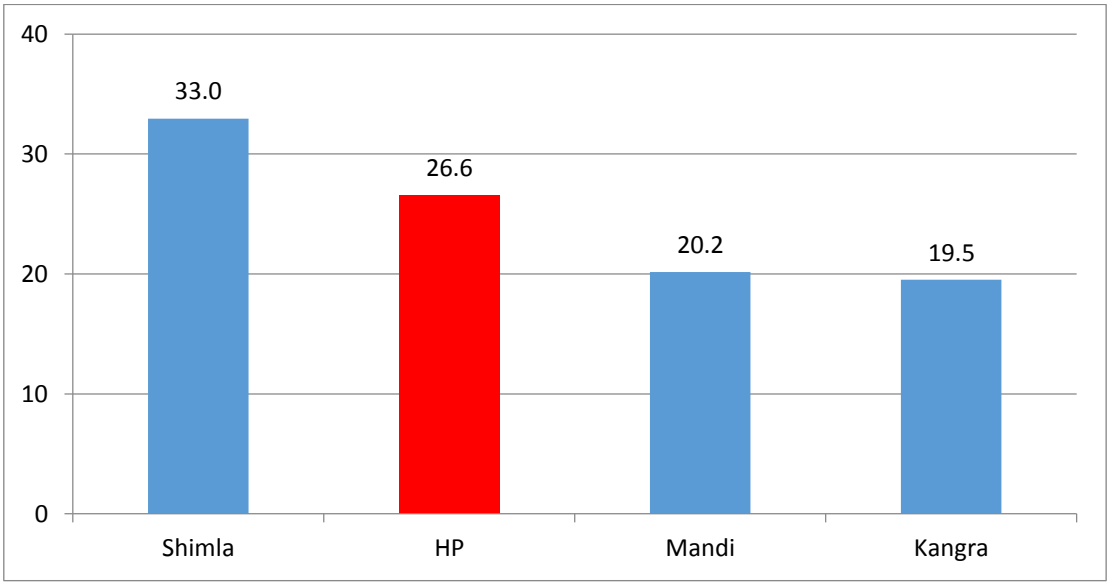
The percentage of component separation was Solan (15.4%), Kangra (19.5%), Mandi (20.2%) and Shimla (33%).

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



The percentage of component separation in NACO supported blood banks is illustrated in Figure-18 which indicates only one district recording more than the state average and two districts reporting less than the state average.

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 (95%) reported that they adhered to the NBTC guidelines. Availability of document control system was reported by less than 40% of the blood banks in the state. Around 36% NACO supported blood banks and 50% Non-NACO blood banks reported they had a document control system. In terms of Standard Operating Procedures (SOPs) for technical processes, 95% reported that they had SOPs.

Table 11 Availability of Quality Parameters in Blood Banks

Quality Parameters	NACO/NON-NACO		All Blood Banks (n=20)
	NACO supported (n=14)	Non-NACO (n=6)	
Compliance with NBTC guidelines	13	6	19
	92.9%	100%	95%
Availability of Documental Control System (DCS)	5	3	8
	35.7%	50%	40%
SOPs for Technical Processes	13	6	19
	92.9%	100%	95%
IQC for IH	11	4	15
	78.6%	66.7%	75%
IQC for TTI	4	2	6
	28.6	33.3	30
QC for kits, reagents and blood bags	11	6	17
	84.6%	100%	85%
EQAS for IH	-	-	-

	-	-	-
EQAS for TTI	-	-	-
	-	-	-
NABH accreditation for blood banks	-	-	-
	-	-	
Availability of designated and trained Quality Manager	3	0	3
	27.3%	0	15%
Availability of designated and trained Technical Manager	0	1	1
	0	16.7%	5%
Programme for regular Equipment maintenance	11	6	17
	78.6%	100%	85%
Equipment calibration as per regulatory requirement	11	5	16
	78.6%	83.3%	80%

At the state level, Internal Quality Control (IQC) for Immunohematology was reported by around 75% of the blood banks and IQC for TTIs was reported by 30% of the blood banks, with slight variation between NACO supported and Non-NACO blood banks. Around 85% of the blood banks reported carrying out quality control for kits, reagents and blood bags. There were no blood banks enrolled in EQAS by recognized providers for immunohematology and TTIs. None of the blood banks out of the total 20 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 15% and 5% of the blood banks respectively. More than 85% of the blood banks reported that they had a regular equipment maintenance programme and around 80% reported that they calibrate the equipment as per requirement.

4.6. Reporting and Documentation

4.6.1. Compliance to NBTC guidelines

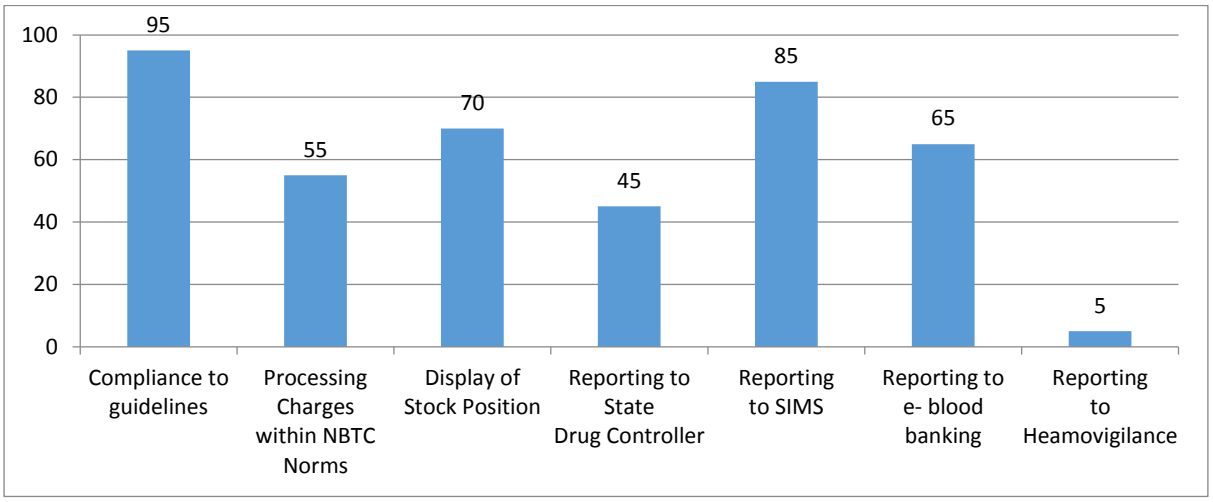
Majority of the blood banks (95%) reported to be compliant with NBTC guidelines. Around, 55% of Blood Banks reported that they were recovering processing charges within NBTC/SBTC norms. Around 70% of blood banks reported that they were displaying stock position in their Blood bank Premises.

4.6.2. Reporting requirements

In terms of reporting requirement, around 45% of the blood banks submitted regular reports to state drug controller, 85% of blood banks regularly reported in national strategic

information management systems (SIMS). However, only 65% regularly reported in E-blood banking either national or state e-blood banking. Only 5% of blood banks were members of National Haemovigilance Program.

Figure 19 Reporting and Documentation

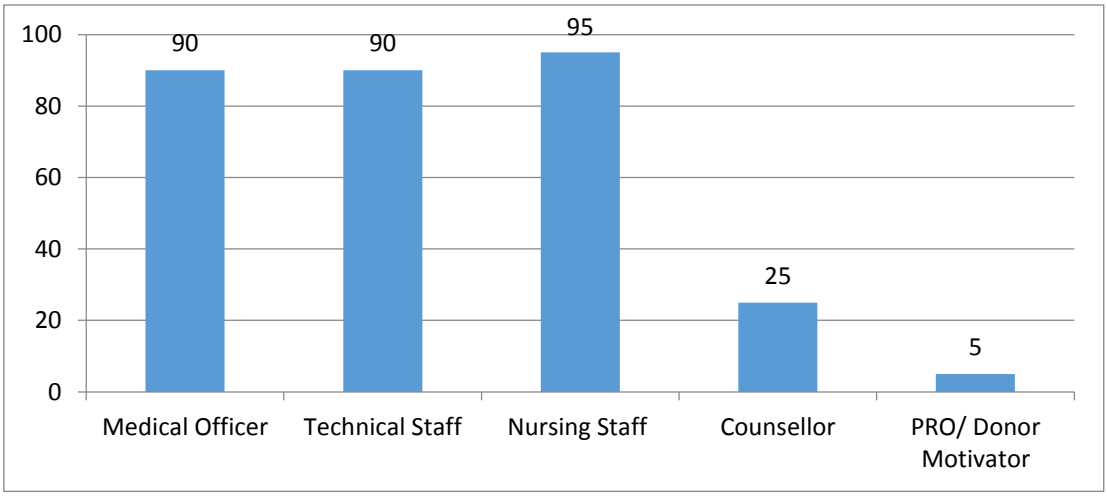


4.7. Human Resources

4.7.1. Availability of staff

The mean number of employees in the blood bank was 7.5 (SD 6.3). It ranges from 3 to 27 employees. 90% of blood banks reported to have medical officers, and technical staff and reported to have 95% nursing staff. However, only 25% had counsellors and 5% reported to have PRO/Donor motivators.

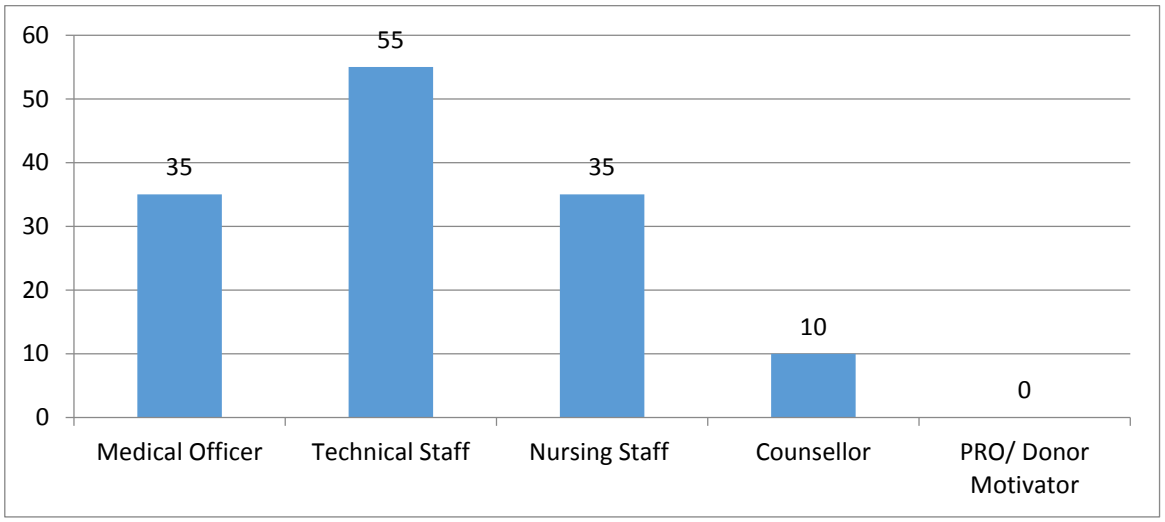
Figure 20 Percentage of BB Manpower (At least one)



4.8. Training of Blood Bank Personnel

According to the assessment, around 35% of the blood banks reported that they had at least one medical officer trained by NACO/NBTC; 55% blood banks reported they had trained technical staff, 35% reported having trained nursing staff, 10% had trained counsellors and none of the blood banks reported having trained PRO/donor motivators.

Figure 21 Percentage of BBs having at least one trained

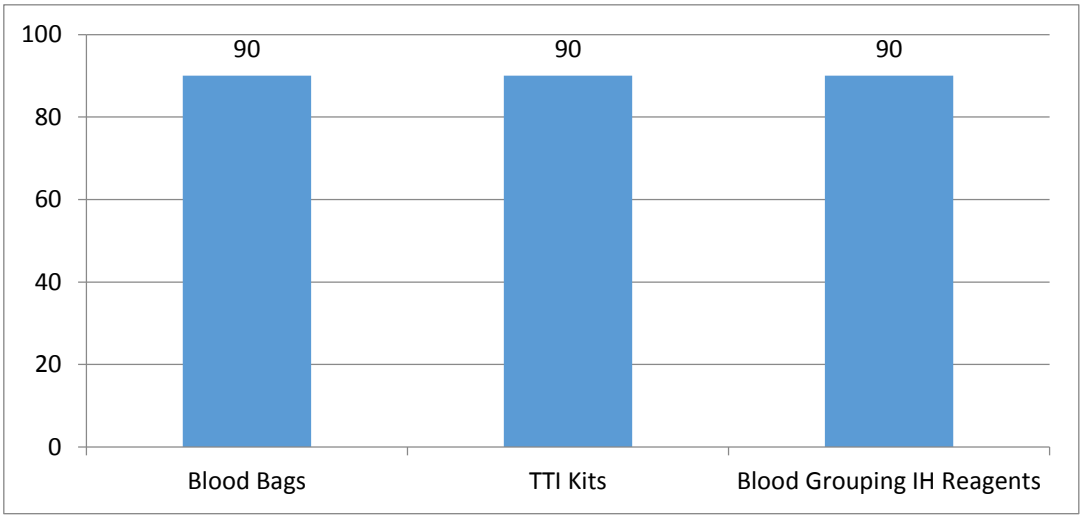


4.9. Equipment and Supplies

4.9.1. Regular supply kits/supplies

Majority of blood banks (90%) reported that they had regular supply of blood bags, TTI kits and blood grouping reagents.

Figure 22 Regular Supply of Kits



4.9.2. Equipment Availability (working condition)

Table 12 indicates the percentage of blood banks that have different equipment in working condition.

Table 12 BBs having Equipment in working condition

BBs having at least one equipment in working Condition		
Sl No	**Equipment**	**% BB**
1	Donor Couches	85
2	Instrument for Hb Estimation	85
3	Blood collection monitor	45
4	Quarantine Blood Bank Refrigerator to store untested blood	95
5	Container for safe disposal of sharps	90
6	Oxygen supply equipment	100
7	Computers with accessories and software	95
8	General lab centrifuge for samples	95
9	Bench top centrifuge for serological testing (Immunohaematology)	85
10	Blood transportation box (No. in inventory)	100
11	Emergency drugs box / Crash card	70
12	Autoclave machine	90
13	Water bath	100
14	Blood bank refrigerator (storage of tested blood) with temperature recorder	100
15	Automated pipettes	90
16	Refrigerated centrifuge	30
17	Blood container weighting device	80
18	Serology rotator	75

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

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

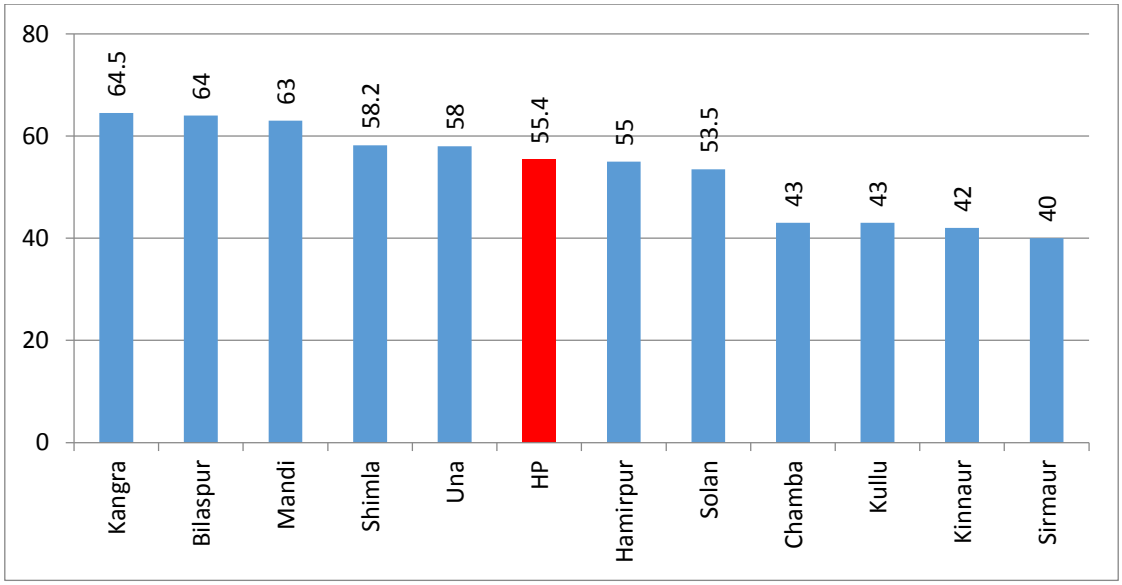
The mean assessment score of blood banks in the state was 55.4 (SD: 9.0). The Non-NACO supported blood banks scored slightly higher (57.4; SD: 7.9) than the NACO blood banks (54.5; SD: 9.6).

Table 13 Mean Assessment score

Type of BB	N	Mean	SD
NACO supported	14	54.5	9.6
Non-NACO	6	57.4	7.9
Total	**20**	**55.4**	**9.0**

All the blood banks in the state (n=20) scored between 35 to 70. Among the districts, Kangra (64.5) scored the highest and Sirmaur (40) scored the least. Five districts scored above the state average. More than half of the blood banks (55%) were located in these districts.

Figure 23 Mean Assessment Score – By Districts (All BBs)



The mean scores of NACO supported blood banks were higher than the Non-NACO blood banks in 2 districts.

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

District	NACO supported	Non-NACO	Total
Bilaspur	64	-	64
Chamba	43	-	43
Hamirpur	54	56	55
Kangra	64.8	64	64.5
Kinnaur	42	-	42
Kullu	43	-	43
Mandi	63	-	63
Shimla	57.3	59.5	58.2
Sirmaur	40	-	40
Solan	55	52.8	53.5
Una	58	-	58
Himachal Pradesh	**54.5**	**57.4**	**55.4**

Out of the 20 blood banks that scored between 35 to 70, 55% were in three districts (Shimla, Solan and Kangra).

Table 15 Number of Blood Banks Scored 35 to 70- by District

District	NACO Supported	Non-NACO	Total
Bilaspur	1	-	1
Chamba	1	-	1
Hamirpur	1	1	2
Kangra	2	1	3
Kinnaur	1	-	1
Kullu	1	-	1
Mandi	1	-	1
Shimla	3	2	5
Sirmaur	1	-	1
Solan	1	2	3
Una	1	-	1
Himachal Pradesh	**14**	**6**	**20**

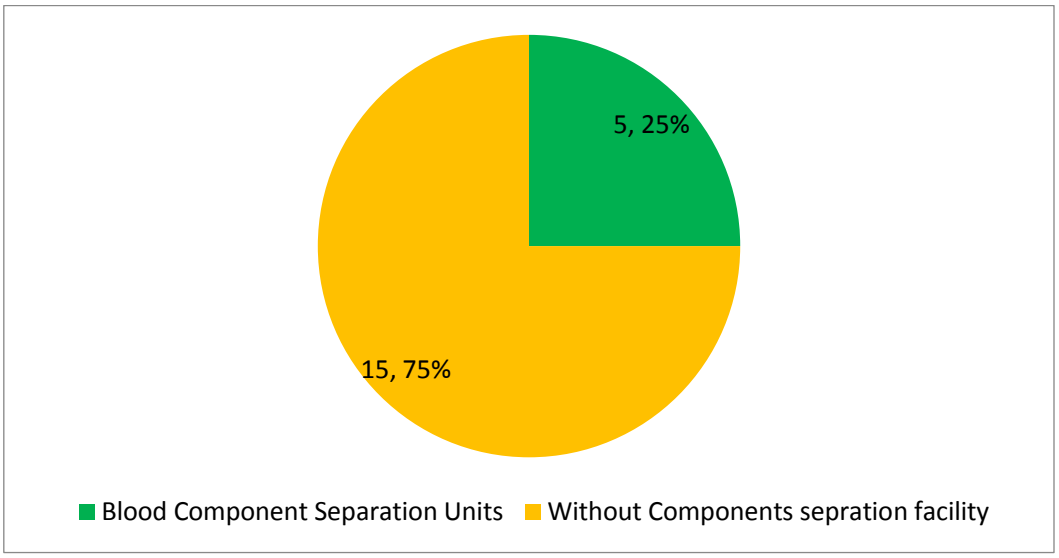
4.10.1 Assessment score by Category of blood banks: The mean score of blood banks with component facilities (58.40; SD: 9.05) was found to be slightly higher than the mean score of those without component facilities (54.40; SD: 9.08).

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	3	62.17	2.36	2	52.75	14.50	5	58.40	9.05
Without BCSU	11	52.45	9.80	4	59.75	3.50	15	54.40	9.08

Majority (75%) of blood banks that scored between 35 to 70 has component separation facility.

Figure 24 Blood Banks scoring between 35 to 75



4.10.2 Assessment score by Ownership: The mean assessment score of public owned blood banks (55.68; SD: 9.07) was found to be higher than NGO/Trust/Charitable owned blood banks (Refer Table 17).

However, Non- NACO supported blood banks run by public sector had scored higher (61.00; SD: 3.00) compared to NACO blood banks (54.54; SD: 9.58).

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	0	-	-	2	49.25	9.55	2	49.25	9.55
Private	0	-	-	1	63.00	-	1	63.00	-
Public	14	54.54	9.58	3	61.00	3.00	17	55.68	9.07

Table-18 Mean assessment scores categories by Ownership

Ownership	<=35	36 to 70	Above 70	Total
Public	0	17	0	17
	-	100%	-	100%
NGO/Trust/Charitable	0	2	0	2
	-	100%	-	100%
Private	0	1	0	1
	-	100%	-	100%
Overall	**0**	**20**	**0**	**20**
	-	**100%**	**-**	**100%**

4.10.3 Assessment score of Private Sector Blood Banks: Irrespective of the NACO support status, 15% (3) blood banks were owned by private sector, of which 2 blood banks 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 53.83 (SD: 10.42) and the mean score of public owned blood banks was 55.68 (SD 9.07).

Nevertheless, it is also important to note that the average annual collection was higher in public owned blood banks (2,320 units) compared to private blood banks (840 units). Similarly, the percentage of voluntary blood donation was higher in public owned blood banks (84.7%) compared to the private blood banks (32.1%). Of the total 3 private blood banks, 2 (66.7%) had component separation facility, whereas 17.6% (3) of total 17 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 (61.75; SD: 3.18) was found to be higher than 3000 blood units (54.97; SD: 8.98).

Table-19 Mean assessment score by annual collection

Annual Collection	NACO supported		Non-NACO		Total	
	Mean	SD	Mean	SD	Mean	SD
Up to 3000	53.50	9.66	6	57.42	54.97	8.98
3001 to 5000	63.00	-	0	-	63.00	-
Above 5000	61.75	3.18	0	-	61.75	3.18

4.10.5 Assessment score by Voluntary Blood Donation: Table -20 provides the mean assessment score of blood banks that have been categorized by percentage of voluntary blood donation which does not indicate any pattern.

Table-20 Mean assessment score by voluntary blood donation

% VBD	NACO supported		Non-NACO		Total	
	Mean	SD	Mean	SD	Mean	SD
Less than 25	-	-	1	42.50	42.50	-
25 to 49	43.00	-	0	-	43.00	-
50 to 74	56.00	2.83	2	62.50	59.25	4.27
75 to 90	57.10	8.72	2	60.50	58.07	7.45
Above 90	56.20	11.63	1	56.00	56.17	10.40

4.10.6 Assessment score by participation in External Quality Assessment Scheme (EQAS) for Immunohematology and Transfusion Transmitted Infections (TTI): No blood bank was enrolled in EQAS for IH and TTI in the state of Himachal Pradesh.

4.10.7 Assessment score by Accreditation status: None of the blood banks were accredited by National Accreditation Board of Hospitals and Health care Providers (NABH).

The list of blood banks under different categories of score is given in Table- 21 and 22

Table-21 Distribution of Blood banks by Districts and mean assessment score categories

Score Category				
District	**Upto 35**	**35 to70**	**Above 70**	**Total**
Bilaspur	-	1	-	1
Chamba	-	1	-	1
Hamirpur	-	2	-	2
Kangra	-	3	-	3
Kinnaur	-	1	-	1
Kullu	-	1	-	1
Mandi	-	1	-	1
Shimla	-	5	-	5
Sirmaur	-	1	-	1
Solan	-	3	-	3
Una	-	1	-	1
Himachal Pradesh	-	**20**	-	**20**

Table-22 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
Bilaspur	-	1	-	-	-	-
Chamba	-	1	-	-	-	-
Hamirpur	-	1	-	-	1	-
Kangra	-	2	-	-	1	-
Kinnaur	-	1	-	-	-	-
Kullu	-	1	-	-	-	-
Mandi	-	1	-	-	-	-
Shimla	-	3	-	-	2	-
Sirmaur	-	1		-	-	-
Solan	-	1	-	-	2	-
Una	-	1		-	-	-
Himachal Pradesh	-	**14**	-	-	**6**	-

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 Himachal Pradesh function subject to obtaining and maintaining a license for operations from the FDA which means compliance to basic quality standards mentioned in the Drugs and Cosmetic Act 1940 and Rules 1945 there upon. However, this assessment brings out specific gaps and possible opportunities to improve quality standards in Transfusion Services at the state.

The 14 NACO and 6 Non-NACO blood banks which were included in the review are 100% of the total blood banks (20) existing in the state. The annual collection of these blood banks was 39,646 units which is approximately 58% of the total blood requirement based on WHO's estimation that blood donation by 1% of the population can meet a nation's most basic requirements for blood (WHO, 2010). However, there is a huge variation between districts that ranges from 0.1 units to 1.8 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 (58.4%) 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 82.6% in 2015), there is still a huge variation between districts that ranges from 30.7% to 98.9%. A targeted program to increase the non-remunerated voluntary blood donors will go a long way towards ensuring a safer option for our patients.

It is also evident that the distribution of blood banks is skewed with 55% of the all the blood banks in the state relegated to only 3 districts. Seven districts of the 12 districts have less than the state average of 2.9 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.

Less than one fourth (20%) 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 65 with significant variations across the category of blood banks, ownership, voluntary blood donation, participation in proficiency testing (EQAS) and accreditation status. It is important to understand that there is a huge variation between districts on several parameters included in the assessment. This suggests the need for targeted and customized approach to address the gaps and challenges faced by the blood banks in the state. This assessment suggests that blood banks owned by trusts/charities in the private sector seemed to have performed slightly better in the quality parameters. This may be partly due to access to resources, both financial and technical, to enhance capacity and modern technology to overcome potential barriers to quality.

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

6. Reference

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7. Annexures

7.1 Individual Blood Banks Summary

District	Name of the Blood Bank	Type	Ownership	Annual Collection	Score (Out of 100)
Bilaspur	Zonal Blood Bank Bilaspur ,H.P	Non BCSU	Public	1800	64
Chamba	Blood Bank Chamba	Non BCSU	Public	684	43
Hamirpur	Blood Bank Hamirpur	Non BCSU	Public	2274	54
	Bhota Charitable Hospital	Non BCSU	NGO/Trust/ Charitable	117	56
Kangra	Blood bank Dr.RPGMC,Kangra	BCSU	Public	6940	60
	Zonal Hospital Dharamshala	Non BCSU	Public	1266	70
	Civil Hospital palampur	Non BCSU	Public	1189	64
Kinnaur	RH Reckong Peo,Kinnaur	Non BCSU	Public	#NULL!	42
Kullu	Blood Bank, Dhalpur	Non BCSU	Public	1398	43
Mandi	Netaji Subhash Chander Bose zonal hospital blood bank,Mandi	BCSU	Public	3046	63
Shimla	Indira Gandhi Medical College & Hospital, Shimla	BCSU	Public	10764	64
	Kamla Nehru State Hospital for Mother & Child, Blood Bank,Shimla	Non BCSU	Public	1755	58
	Blood bank, DDUZH,Shimla	Non BCSU	Public	1113	50
	Blood Bank MMGMSC Khaneri	Non BCSU	Public	618	58
	Blood bank Civil Hospital, Rohru	Non BCSU	Public	218	61
Sirmaur	Blood Bank , Regional Hospital, Nahan	Non BCSU	Public	720	40
	MM Medical College & Hospital	BCSU	NGO/Trust/ Charitable	1981	43

Solan	Blood bank Distt. Hospital Solan	Non BCSU	Public	1500	55
	Malhotra Super Speciality Hospital Blood Bank (A Unit of Malhotra Clinics Pvt. Ltd)	BCSU	Private	423	63
Una	Regional Hospital, Una	Non BCSU	Public	1840	58

7.2 NACO/NBTC – Questionnaire for Blood Bank

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

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

A2.	**License Information**	
1.	**BB License Number** *(Enter your license number. This should be exactly as is displayed in your license issued by the Drugs Controller Office and will be used for verification purposes. This is a mandatory field and should be entered regardless of the status of license - under-*	

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

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

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

		State	
		Others (Specify)	
11	Is there a donor database in the blood bank *(Donor database is essential to contact donors to remind them or to call during an emergency?)*	Yes	
		No	
12	If yes to Q 11, is it in electronic format or paper based?	Electronic	
		Paper	
		Both	
13	What percentage of the voluntary blood donors are repeat blood donors? (%)		
14	Does your blood bank have a mobile blood collection facility? *(Answer yes if your Blood bank has a mobile facility (bus or van with donor couches)*	Yes	
		No	
15	Source of funds for the mobile blood collection *(Indicate the source of funding for the purchase of the mobile blood donor van.)*	State	
		Central	
		Donor	
		Others	
16	Specify, other source of funds		
17	Is there a record for donor adverse reactions?	Yes	
		No	
18	Is there a referral system for HIV sero-reactive blood donors?	Yes	
		No	
19	If yes to Q 18, please specify what is the process adopted.		

Section C
Technical – Immunohematology

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

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

Section D
Technical - Screening For Transfusion Transmissible Infections (TTI)

Does the blood bank screen the following TTIs?

	Type of Test	Platform (please tick appropriate)		Method (please tick appropriate)
1	**HIV I & II**	Rapid		
		ELISA		Manual ☐ Automated ☐
		CHEMI		Manual ☐ Automated ☐
		NAT		Manual ☐ Automated ☐
1.1	Specify % of donors tested by Rapid Test?			
2	**Hepatitis B**	Rapid		
		ELISA		Manual ☐ Automated ☐
		EM		Manual ☐ Automated ☐
		NAT		Manual ☐ Automated ☐
2.1	Specify % of donors tested by Rapid Test?			

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

	you be willing to participate in future?	No	
16	If Yes to Q15, will your blood bank be able to provide financial support (about Rs. 2500 per year)	Yes	
		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	NACO/NBTC Supported in-service training	Other National Training
6	Professor				
7	Associate Professor				
8	Assistant Professor				
9	Senior Resident/Tutor				
10	Medical Officer *(include senior/Junior)*				
11	Technical Staff				
12	Nursing staff				
13	Counsellor				
14	PRO/Donor motivator				
15	Administrative staff				
16	Support staff				
	If other staff, please specify				

Total number of staff			
17	In your opinion, does the BB have adequate staff to function optimally (24x7)? This may be decided based on the volume and duration of work hours.	Yes	
		No	
18	Do you monitor Quality indicators or Key Performance indicators?	Yes	
		No	
19	If yes to above question, please specify names of indicators		
20	Do you have a designated and trained Quality manager?	Yes	
		No	
21	Do you have a designated and trained Technical Manager?	Yes	
		No	
22	If you do not have either a trained Quality manager or Technical Manager please state reasons?		

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

F2. EQUIPMENT AND SUPPLIES				
1	Does the blood bank have adequate equipment to meet regulatory requirements? *(If your blood bank has adequate equipment in working condition to meet expected workload, please answer yes.)*		Yes	
			No	
2	How is equipment purchase funded?	Local bodies		
		Central or upper (state) level agencies		
		Donors		
		Others (specify)		
3	Does the blood bank have a program for regular equipment maintenance?		Yes	
			No	
4	Are all the equipment calibrated regularly as per regulatory requirement?		Yes	
			No	
5	How are consumables purchased?	Local bodies		
		Central or state level agencies		
		Donors		
		Others (specify)		
6	Do you evaluate kits at your facility prior to procurement*? (Are kits evaluated locally (at your blood bank) prior to purchase (e.g. Titre and avidity for blood group Anti Sera?))*		Yes	
			No	
7	Is quality control for kits, reagents and blood bags carried out at your blood bank? *(Is quality control for kits performed locally (at your blood bank) Prior to use (e.g. Titre and avidity for blood group Anti Sera?))*		Yes	
			No	
8	Did you have a regular supply of the following items? (Jan to Dec 2015)			
8.1	Blood Bags		Yes	
			No	
8.2	TTI Screening Kits		Yes	
			No	
8.3	Blood grouping / IH reagents		Yes	
			No	
9	Number of staff vaccinated for Hepatitis B?			

EQUIPMENT LIST (Below is a summary equipment list (a subset of D&C list). Please specify the number in inventory and number in working condition? If you are using shared resources of hospital, you can mention that as well

		Number in inventory	**Number in working condition**
10	Donor beds/couches		
11	Any instrument for Hb Estimation *(other than CuS04*		

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

7.3 Scoring sheet

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

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

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

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