Rapid Situation Assessment of Blood Transfusion Services in India

2014

National AIDS Control Organization (NACO)),
Ministry of Health and Family Welfare, Government of India
in collaboration with
U.S Centers for Disease Control and Prevention (HHS/CDC/CGH)
Division of Global HIV/AIDS, India
and
Christian Medical Association of India (CMAI)

FOREWORD

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FOREWORD

Blood Transfusion Service is a vital part of modern health care system without which medical care is impossible. It is essential to ensure provision of safe, clinically effective and of, appropriate and consistent quality of blood and blood products to all those who are in need of transfusion. This involves a highly complex operation that requires a holistic and comprehensive approach in planning, designing and operationalizing Blood Transfusion Services in India.

The advent of National AIDS Control Programme in India, has made substantial improvements in blood transfusion services during the last two decades in terms of, availability of quality blood and blood products, infrastructure, equipment, and service delivery that resulted in, increased access to safe and quality blood and blood products across the country. Due to the concerted efforts, availability of safe blood increased from 44 lakh units in 2007 to 93 lakh units by 2013; during this time HIV sero-reactivity declined from 1.2% to 0.2%; and Voluntary blood donation increased substantially. However, there are still gaps and challenges in ensuring availability and accessibility of blood to all those are in need that need to be reviewed and analyzed.

Therefore, a comprehensive of the review of the existing situation of Blood Transfusion Services in the country is required which will help the country to take corrective measures and to develop appropriate programmes and policies in the future, so that universal access to safe blood and blood products and work towards self-sufficiency will be a reality.

This report on “Rapid Situation Assessment of Blood Transfusion Services in India” will definitely be a useful guide and reference material that explains the current situation of blood transfusion services, the gaps, challenges and recommendations to improve the blood transfusion services in the country.

I would like to congratulate Dr. S D Khaparde, DDG, the BTS team at NACO and other organizations who contributed to the development of this report.

(**Shri. LovVerma I.A.S**

PREFACE

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PREFACE

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

The current phase of the NACP IV (2012 -2017)emphasizes blood safety that aims to support 1,300 blood banks and aims to achieve 90,00,000 blood units from DAC supported Blood Banks and 95% voluntary blood donation in 2016-17. The key strategies under NACP IV are, strengthening management structure of blood transfusion services and implementing National EQAS for all participating labs at district and above for HIV related diagnostic services. NACP-IV also aims to explore the possibilities of streamlining the coordination and management of blood banks and blood transfusion services; and new initiatives such as, the establishment of Metro Blood Banks and Plasma Fractionation Centre are also planned.

The Rapid Situation Assessment of Blood Transfusion Services in India was carried out with the specific objectives of reviewing and understanding the existing structure, systems, programmes, services, legal and policy environment; the extent to which the programmes have achieved its expected outcomes; the factors facilitating or hindering achievements; gaps and challenges; and formulate recommendations that can inform programmes and policies.

This report includes the results of a comprehensive desk review and assessment carried out through site visits across the country. Besides, the report highlights the key issues, challenges and recommendations especially, the recommendations of the experts and state programme officers.

I take this opportunity to extend my sincere appreciation to the U.S. Centers for Disease Control and Prevention-Division of Global HIV/AIDS (CDC-DGHA), India Office, and Christian Medical Association of India (CMAI) for providing technical assistance and support in completing the assessment and developing the report.

(Dr Sunil D. Khaparde)

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I would like to acknowledge my appreciation and thanks to all those who have reviewed and provided their valuable comments. I take this opportunity to express my sincere thanks to all the experts who were part of the assessment through site visits.

I am pleased to extend my sincere thanks to the U.S. Centers for Disease Control and Prevention-Division of Global HIV/AIDS (CDC-DGHA), India and Christian Medical Association of India (CMAI) for providing technical assistance and support in completing the assessment and developing this report.

Dr Sunil D. Khaparde,
Deputy Director General,
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Acronyms

ADR	:Adverse Drug Reaction
BB	: Blood Banks
BCT	: Blood Components for Transfusion
BCSU	: Blood Components Separation Unit
BSC	: Blood Storage Centers
BTS	: Blood Transfusion Service
CDSCO	: Central Drugs standard Control Organization
CLAA	: Central License Approving Authority
CHC	: Community Health Centre
DAC	:Department of AIDS Control
DLBB	: District Level Blood Bank
ELISA	: Enzyme Linked Immuno sorbent Assay
EQAS	: External Quality Assessment System
FRU	: First Referral Units
GDBS	:Global Database on Blood Safety
GOI	: Government of India
HBV	: Hepatitis B Virus
HCV	: Hepatitis C Virus
HIV	: Human Immunodeficiency Virus
ICTC	: Integrated Counselling and Testing Centre
IPC	:Indian Pharmacopoeia Commission
PvPI	: Pharma covigilance Program of India
INR	: Indian Rupee
NRL	:National Reference Laboratory
NACO	: National AIDS Control Organization
NACP	: National AIDS Control Programme
NGO	: Non-Governmental Organization
NRHM	: National Rural Health Mission
SRL	: State Reference Laboratory
PCR	: Polymerase Chain Reaction
PEP	: Post Exposure Prophylaxis
PPTCTC	: Prevention of Parent to Child Transmission
PDMP	: Plasma-derived medicinal products
PFF	: Plasma for fractionation
PHC	: Primary Health Care Centre
QA	: Quality Assurance
RNA	: Ribonucleic acid
SOP	: Standard Operative Procedure
SIMS	: Strategic Management Information System
TQM	: Total Quality Management
TTI	: Transfusion Transmitted infection(s)
VNRD	: Voluntary Non-Remunerated Donation
WHA	: World Health Assembly
WHO	: World Health Organization

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Blood Transfusion Services in India

1. Background

Blood Transfusion Service (BTS) is an essential part of modern health care system without which medical care is impossible (Pal, Kar, Zaman, & Pal, 2011). The provision of safe and adequate blood and blood products at national level is the responsibility of the government/national health authority of each country (Ramani, Mavalankar, & Govil, 2007). Blood safety is essential to ensure that a patient who comes for treatment is not made sicker by another illness (Hemogenomics, 2013). These products must be safe, clinically effective and of appropriate and consistent quality (WHO, 2012b). 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 donation of blood; 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 raises several challenges(GOI, 2003). This requires a holistic and comprehensive approach in planning, designing and operationalizing the BTS services. It is important to ensure coordination between the blood transfusion services, health services and hospitals, educational institutes, religious, social and industrial organizations, mass media and other stakeholders including general public. The system should also ensure adequate input into the legislative, regulatory, technical, social and cultural aspects of making this life saving product accessible and safe.

While the need for blood is universal, 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, 2009a). Besides, there is a huge inequity in the availability of blood within countries, with 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 to ensure 100% quality-assured testing of donated blood, strengthening the implementation of key strategies is 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, 2008a).

Though Blood Transfusion services in India have advanced significantly over the last 50 years, the AIDS pandemic has, in fact, brought into focus the importance of safe blood transfusion(Ray, Chaudhary, & Choudhury, 2000a). Especially, since the inception of National AIDS Control Programme Phase one (NACP 1992-1999) that had 30 per cent of its project cost focussing on blood safety, there have been significant improvements in the availability of quality of blood/blood products, infrastructure, equipment, and service delivery in India. Though the screening of donated blood was made mandatory since 1989, an estimated 85% of the nation's blood supply was not being screened for HIV (Baweja H, 1992). In 1993, infected blood and blood products accounted for the second largest number(13%) of recorded AIDS cases (Correa; & Gisselquist, 2005); Blood banks in remote areas did not have access to screening facilities and the employees did not have skills to undertake testing themselves. A significant 24% of the country's blood supply was from the private sector that heavily relied on professional blood donors for 94% of blood collected (NACO, 1993) (Asthana, 1996). The situations have changed dramatically now. Several legislative changes and court directions during the last two decades have significantly improved the situation, and the National Blood Policy adopted in 2002 gives overall direction for the effective functioning of Blood Transfusion Services (BTS) in the country(NACO, 2007d).

Over the years, the World Health Assembly resolutions such as, Utilization and supply of human blood and blood products in 1975; Global health-sector strategy for HIV/AIDS in 2003; Blood safety: proposal to establish World Blood Donor Day in 2005; the Melbourne declaration on 100% voluntary non-remunerated donation of blood and blood components availability, safety and quality in 2010; and the Rome Declaration on achieving self-sufficiency in safe blood and blood products, based on voluntary non-remunerated donation of blood products in 2013 have guided the principles and key elements for

developing the current national blood transfusion system in the country and reaffirmed the achievement of self-sufficiency in blood and blood products based on voluntary non-remunerated blood donation(VNRD) (WHO, 2013c) (WHO, 2010d) (WHO, 2010a) (WHO, 2009b) (WHO, 2005) (WHO, 1975). In specific, the recent Rome declaration reiterated the national authorities to incorporate the goal of self-sufficiency in safe blood based on VNRD into national health policies; introduce appropriate legislation; provide sufficient financial and other resources; and introduce strategies and measures to establish appropriate quality systems (WHO, 2013b).

Due to the continuous efforts in India, the availability of safe blood increased from 44 lakh units in 2007 to 93 lakh units by 2013; during this time HIV sero-reactivity also declined from 1.2% to 0.2%; and Voluntary blood donation increased substantially (NACO, 2013). Nevertheless, there are still gaps and challenges in ensuring availability and accessibility of blood to all those are in need. For instance, some districts in the country still do not have government supported blood centers. India is able to collect only 9 million units against an annual demand of 12 million units; only around 70% is from voluntary blood donors (Agarwal, 2012); Lack of human resources and lack of adequate quality management systems in the majority of blood banks continue to be areas requiring further attention (Lowalekar & Ravichandran, 2013; Singh, 2007). There are several organizational and management issues hindering the effective service provision in the country (Nanu, 2001). In addition, there is inequity in the availability, accessibility and quality of blood transfusion services in India. This calls for a review of the existing situation of Blood Transfusion Services in the country which will help the country to take corrective measures and to develop and implement programmes and policies in the future.

2. Purpose and Objectives

The purpose of this assessment is to understand the existing situation of blood transfusion services in India, identify gaps, best practices, emerging challenges and provide inputs to evidence based inputs to National Programme.

The specific objectives are,

- To review the existing structure, systems, programmes, services, legal and policy environment.
- To review and document the extent to which the programmes have achieved its outputs and contributed to its intended outcomes
- To understand the factors facilitating or hindering achievements
- Document lessons learned and challenges
- Formulate recommendations that can inform programmes and policies.

The key areas such as, the structure; systems (organizational/management and operational); programmes; resources (human, financial and materials), strategies, services/activities, policies, legislation, regulations, social, ethical and cultural dimensions were reviewed based on the following framework or guiding principles.

- Availability and its distribution. Are they available? Is there need based distribution? Factors hindering or facilitating the availability or non- availability?
- Adequacy - Are they adequate? – Are they adequate to all? Factors hindering or facilitating the adequacy?
- Appropriateness and Relevance - Are the structure or services appropriate/relevant? Are they meeting the needs of the different situation and demands?
- Accessibility - Are those who are in need of it, able to access services? (Economic, geographical, social and cultural access). Factors hindering or facilitating the adequacy?
- Quality - Is the quality up to the standard? Is quality equally distributed? Reasons for lack of quality? Factors hindering or facilitating quality?
- Effectiveness of service provision and efficiency- Factors hindering or facilitating the effectiveness or efficiency?
- Sustainability- Are the existing service provision sustainable?
- In addition these, this review also looked at the Supply side issues such as human resources, financial resources, supply chain management issues, policy and legal environment and health system related issues and challenges.

3. Methodology

In order to achieve the objectives, a two pronged strategy of desk review and site specific observations has been adopted.

3.1 Desk Review

The desk review is mainly dependent on the secondary sources that include,

- Analysis of secondary data
    - SIMS data provided by Department of AIDS Control(DAC)
    - Data extracted from the DAC Annual Reports
    - Data from other M and E reports, documents on the topic
    - CMIS reports

The SIMS data provided from the Department of AIDS Control was analyzed in terms of total units collected, voluntary blood donation, TTIs, components separated and utilized, etc. These were analyzed for the blood banks in the country including both Private and Public sector; as well as for the DAC supported Blood banks.

- Review of documents at both global and country levels. Global documentation included
    - World Health Statistics Report.
    - Blood safety and availability Fact Sheet.
    - WHO Global Strategic Plan 2008-15
    - Global database on blood safety – WHO
    - UN Reports, Guidelines etc.,

Country level documents are drawn from a number of sources, including

- The thematic reviews, presentations
- Documents and guidelines developed by DAC and other multilateral and bilateral agencies.
- Annual work-plans,

- Country programme documents, programme review meeting reports, national surveys, national reviews, annual and quarterly reports by DAC and other relevant organizations.
- Published journal articles in peer-reviewed journals.
- Other unpublished documents

3.2 Site visits by DAC approved experts

The site specific observations included site visits to 15 facilities across five zones covering nine states. A sample of 3 DAC supported blood banks per zone was selected for the assessment. Blood banks in each zone were identified from three levels of health care delivery systems such as Tertiary, Secondary and Primary. Wherever possible, the FRUs linked to mother blood bank were also visited. Adequate attention was given in the selection of blood banks to ensure geographical distribution and representation of government and voluntary/charitable blood banks.

The site specific observations also included interviews with a Joint Director – Blood Safety and a State Drug Controller in each zone. The tools used for the Assessment were,

- Check List for Blood Banks
- Checklist for Blood Storage Centres
- Interview Schedule for Joint Director-Blood Safety
- Interview Schedule for State Drug Controller.

3.3 Challenges and limitations

The desk review has limitation in terms of establishing the counterfactuals and attribution of outputs as there are constraints for comparison that might lead to possible biases. These limitations were addressed through triangulation of information and data wherever possible.

Other limitations are,

1. The total DAC supported blood banks are 1137 (NACO, 2014b), however, 1039 blood banks were found as DAC supported in the SIMS data, based on the cross verification with the list of Blood banks provided by DAC. During the course of this exercise, it is found that the information available at the periphery, state and at the national level is in variance. Efforts are being made by DAC to address these information gaps.

2. Lack of baseline and end line data at output and outcome levels
3. Reports are very often descriptive.

3.4 Data Analysis

The quantitative data were analyzed using SPSS version 20. The Population Census 2011 of India by Government of India was used for analysis. The qualitative part of the assessment explored to understand the various aspects of blood transfusion services. Thematic analysis was done for qualitative data. The predetermined themes and the themes that emerged significantly from the interviews were listed, and the contents/concepts/views under each theme were extracted systematically.

Time period for Onsite Assessment

13th February to 5th March 2014

SECTION – A

Desk Review Results

4. Review Results

4.1 The Evolution Blood Transfusion Services India

The evolution of blood transfusion services was one of the most important of medical advances derived from World War I (Hess & Thomas, 2003). A well-organized Blood Transfusion Service (BTS) is a vital component of any health care delivery system. For quality, safety and efficacy of blood and blood products, well-equipped blood centers with adequate infrastructure and trained manpower are essential requirements (Sarkar, Philip, Kumar, & Yadav, 2012).

Since the advent of the HIV epidemic, blood services in India have come under increased scrutiny, much resources have been spent, and services have improved considerably over the last two decades (Bray & Prabhakar, 2002). The Blood Safety Programme in India began to take shape in 1992 with the establishment of the National AIDS Control Organization (NACO) with three major focus areas that were, surveillance; health education & information; and screening of blood and blood products. This was the time the Transfusion transmitted HIV/AIDS in mid-1980s raised the several questions of blood safety (Das B K, 2011). In 1989-90, a program on "Prevention of infection and modernization of blood banking services" was commenced. In the same year, under the Drugs and Cosmetics Act HIV Testing was made mandatory prior to blood transfusion (Dhot, 2003). Three laboratories viz. National Institute of Communicable Diseases (NICD) Delhi, National Institute of Virology (NIV), Pune, and Christian Medical College Hospital (CMCH), Vellore were notified to test HIV antibodies in human blood and human blood products. Since trained technicians were not immediately available in blood banks to carry out the test for HIV 1 & 2 antibodies, the Ministry of Health & Family Welfare notified Zonal Blood Testing Centres, to act as testing labs for the blood banks to comply with this new requirement.

During 1992-93, the Drugs Controller General, India was vested with the power of Central License Approving Authority (CLAA) to approve the license of notified drugs viz., blood and blood products, fluids, vaccines and sera. The Drugs and Cosmetics Rules, 1945, framed under the Drugs and Cosmetics Act, 1940 were amended in 1993 through which the

licensing of blood banks was brought under the dual authority of the state and central government. The state licensing authority issues the license, while the Drug Controller General (India) is the central license approving authority. The Drugs and Cosmetics Rules, 1945 were further amended in the years 1996, 1999 and 2001. In December 2001, a notification was issued to regulate and streamline the blood storage centres, which helped community health centres, small hospitals / nursing homes whose requirement is less than 2000 units of blood per annum.

The Supreme Court verdict in 1996 that directed the government to improve the blood transfusion service resulted in establishing the National and State Blood transfusion Councils (NBTC / SBTC) to develop policies and programs for bringing about improvements in blood centres. In 1997, HIV counselling and testing services were started in India. In 2001, Testing of blood for Hepatitis C Virus (HCV) antibodies was made mandatory. In 2002, the WHO Guidelines on the Clinical Use of Blood was adopted by NACO. In the same year, Government of India framed and adopted the National Blood Policy (NBP) (NACO, 2007d).

National AIDS Control Programme and Blood Safety

Each of the three phases of the National AIDS Control Programme(NACP) in India focused on and emphasized, blood safety in the country (Prasannakumar, 2008). The NACP paved way for revamping the blood collection, processing, and storage and distribution system in the country. National and state blood transfusion councils were established; the National Blood Transfusion Policy was formulated, and guidelines were developed covering all aspects of blood donation, testing and storage. The NACP took initiatives and provided funds to states to modernize existing blood banks and Zonal blood testing centres were set up. Professional blood donation was banned. Component separation units were set up in very large blood banks in order to address the increasing demand for safe blood.

Under ***NACP Phase I (1992-99),*** the NACO modernized 815 blood-banks and also set up 40 blood component separation facilities to promote the rational use of blood (Ramani, Mavalankar, & Govil, 2009). NACO launched a scheme to modernize blood-banks by providing assistance to states to upgrade and provide minimum facilities to blood-banks in

the public sector and those run by charitable organizations, such as Indian Red Cross Society. NACO has also constituted Technical Resource Group (TRG) in 1997 to seek guidance, advice and policy directions on various aspects of Blood Safety programme which helped in improving the quality of blood transfusion services in the country

During ***NACP Phase II (1999-2004),*** efforts were taken to modernizing more blood-banks, establishing model blood-banks, and setting up blood-storage centres in rural areas. By the end of the second phase, the number of licensed blood banks increased to 1,230 including 82 blood component separation centres; and HIV transmission through blood was reduced to less than two per cent from eight per cent when surveillance first started in the late 1980s. In addition to HIV testing, blood banks were required to test all donated blood for Hepatitis C and an external quality assurance system for HIV testing was set up.

The specific objective of ***NACP phase III (2007-12)*** was to ensure the reduction in the transfusion associated with HIV transmission to 0.5 %, while making safe and quality blood available within one hour of its requirement in a health facility. The programme aimed to bridge the gap between the demand for blood (8.5 million units annually) and supply (4.4 million units, of which only 52 % is through voluntary donation), and improve the quality of blood. This was achieved by improving the quality, infrastructure for blood storage and component separation; ensuring optimum use of blood and blood products as well as autologous blood donation; promoting voluntary blood donation; and through a regulatory and monitoring structure.

The current phase of the ***NACP IV (2012 -2017)*** also lays emphasis on blood safety that aims to support 1,300 blood banks and aims to achieve 90,00,000 blood units from DAC supported Blood Banks and 95% voluntary blood donation in 2016-17 (NACO, 2014d). The key strategies under NACP IV are, strengthening management structure of blood transfusion services and implementing National EQAS for all participating labs at district and above for HIV related diagnostic services. NACP-IV aims to explore the possibilities of streamlining the coordination and management of blood banks and blood transfusion services and new initiatives such as the establishment of Metro Blood Banks and Plasma Fractionation Centre are also planned with a budget of INR 818.80 crore for the period of 5 years (NACO, 2014f).

4.2. Current Blood Transfusion Programmes in India

4.2.1. The Structure and systems of Blood Transfusion Services in India

The Blood Safety Program in India has developed as a component of the National AIDS Control Programme that has led to several advancements in terms of better policies, increased infrastructure, facilities, quality and access to blood transfusion services. In contrast to many western countries, Blood services have been a highly decentralized and fragmented structures and operations in India (Ramani et al., 2007).

The Department of AIDS Control (DAC) under the Ministry of Health and Family Welfare, Government of India and SACS aim at preventing the transmission of HIV and ensure 100% screening of all collected blood units, providing training and financial assistance to blood-banks for technical modernization for ensuring the quality of blood-banks (Ashavaid, 2012). The National Blood Transfusion Council (NBTC) is the apex policy making body and has a major role in the formulation of policy on safe blood-transfusion services in India. The National and State Blood Transfusion Councils were established as registered societies (Sarin, 2003) which are provided with necessary funds through National AIDS Control Programme as well as by respective state governments. The National Blood Transfusion Council provides policy direction and its decisions are implemented by the State Blood Transfusion Councils. Licensing and monitoring of the blood-banks in India is the responsibility of the Drug Controller General of India (Pal et al., 2011).

Currently, there are several types of blood banks in India which are licensed by Central License Approving Authority (CLAA-DCG(I)) and State Licensing Authorities (SLA) of respective States of the Country for safe blood supply under the requirements of Schedule F part XII B and C of Drugs and Cosmetics Act 1940 and rules there under (Ramkishan et al., 2012). There has been a different mix of competing independent and hospital-based blood-banks of different levels of sophistication, serving different types of hospitals and patients. These blood banks can be either in the government or the private sector. The public bodies concerned with the organization and administration of blood services include Central, State, and autonomous government institutes, municipal corporations, cantonment boards, railway services, employee state insurance authorities, and the armed forces. In the

private sector, there are blood-banks run by, charitable trusts, independent commercially-oriented private organizations, and specific non-government health organizations, such as the Indian Red Cross Societies (IRCSs) (Ramani et al., 2009).

Functionally, blood transfusion services may be broadly categorized as,

- Hospital based blood bank
- Stand-alone blood bank
- Blood storage centres.

The key structures and their key function are mentioned below*, (Refer Figure 1)*

National Blood Transfusion Council

The National Blood Transfusion Council (NBTC), established and registered as societies in 1996, has the major advisory role in the formulation of policy on safe blood-transfusion services in India, and it is supported by the Department of AIDS Control(DAC) (Ramani et al., 2009). The NBTC is responsible for,

- Promoting Accreditation of blood banks
- Establishment of proper institutional mechanism for planning and implementation of blood safety such as Regional Blood Transfusion Centres in every state
- Development of guidelines for constitution of hospital transfusion committee & development of guidelines for operationalization of plasma fractionation facility in the country (NACO, 2007d).

The national council in collaboration with the state blood transfusion councils inspects all the blood banks at Public and Private sector facilities regularly for implementation of "National Blood Safety Programme.

State Blood Transfusion Council

The State Blood Transfusion Council (SBTC)is also an autonomous body that is responsible for formulation of policy, regulation and implementation of the entire range of activities related to operation and requirements of blood banking system in the state and blood transfusion services starting from grouping, cross matching, donor selection, collection of blood, proper preservation, transportation, utilization, component separation and apheresis

(GOO, 2014);(GOM, 2005). The training of Blood Bank Officers, Laboratory Technicians, Motivators and counsellors including the officials of RBTCs and rational use of blood are the responsibility of the Council. Quality control of whole blood and blood products is one of the activities of the Council (SBTC, 2013). However, Maharashtra and Nagaland are different when it comes to the functioning of SBTC. Generally, SBTCs are operating under SACS except in these states (Ramani et al., 2009).

Regional Blood Transfusion Centers (RBTCs)

RBTC is a blood bank approved by the SBTC taking into consideration the regional needs of blood & components and the ability of RBTC in terms of premises, personnel and equipment (Ramani et al., 2007). The objective of a regional blood transfusion centre (RBTC) is to ensure a safe and quality blood and blood components to meet the needs of the patients in the region and to assist health centres/hospitals in their appropriate use. As a mother blood bank, the RBTC are mandated to support and strengthen the blood storage centres of the region/area. The RBTCs will send regular and complete reports to SBTCs and they in turn, direct them in planning regional blood programmes and in the use of standardized techniques and procedures (GSBTC, 2013). The regional blood transfusion centre is identified based on the amount of blood collected (more than 15,000 units per year) (Ramani et al., 2009). 142 RBTC have been established so far, however, several states such as Puducherry, Andaman and Nicobar Island, Dadra and Nagar Haveli, Daman and Diu, and all northeastern states except Assam do not have any Regional Blood Transfusion Centres.

Table – 1: Types of Blood Transfusion Facilities

(DAC Supported)

Type of Facility	2008 -09	2009-10	2010 -11	2011-12	2012 - 13	2013 -2014
Blood Bank	1092	1103	1127	1,149	1118	1137
Model blood Bank	10	10	28	28	34	34
Blood Component Separation Units	104	130	155	171	175	258
Major Blood Bank	0	0	0	0	167	180
District level blood bank	0	0	0	0	742	665

DAC supported Blood Banks

Based on the volume, geographical coverage and the availability of blood transfusion facilities, the DAC supported facilities are categorized as follows,

- Model blood Bank
- Blood Component Separation Units
- Major Blood Bank
- District level blood bank
- Regional Blood Transfusion Centre

Model Blood Banks

Model Blood Banks are higher level structures in the blood banking system which functions as demonstration centres for the State in that they are set-up. According to DAC, blood banks which collect more than 10,000 blood units per annum with training facilities for Medical officers, Technicians and Nurses can be categorized as Model Blood Banks. Currently, there are 34 Model blood banks are functioning. A state of art blood mobile van has also been issued to each model blood bank to improve Voluntary collection in the states within 200 kms of the model blood bank (NACO, 2013).

Blood Component Separation Units (BSCUs)

Blood banks that collect 5000 to 10000 blood units per annum with facilities for component separation are categorized as BCSUs. The Blood Component Separation Units are primarily aimed at component separation. During NACP II & III many district headquarters hospitals blood banks (Major Blood banks) were upgraded as BCSU with the provision of infrastructure and equipment for blood component separation. Currently, there are 258 Blood Component Separation Units *(*BCSU*)* functional in the country. Of these facilities, 34 facilities have additional facilities and are designated as Model blood banks. However Goa, Daman and Diu and five out of seven northeastern states (Manipur, Nagaland, Mizoram, Arunachal Pradesh, Sikkim, and Tripura) still do not have any BCSUs**.**

Major Blood Banks

Blood banks that collect 3000 to 5000 blood units per annum are categorized as major blood banks. The number of Major Blood Banks (MBB) increased from 167 in 2012-13 to 180 in 2013-14. However several state including Puducherry, Ahmedabad, Andaman and Nicobar Islands, Dadra and Nagar Haveli, Daman and Diu, Meghalaya, still do not have any MBB.

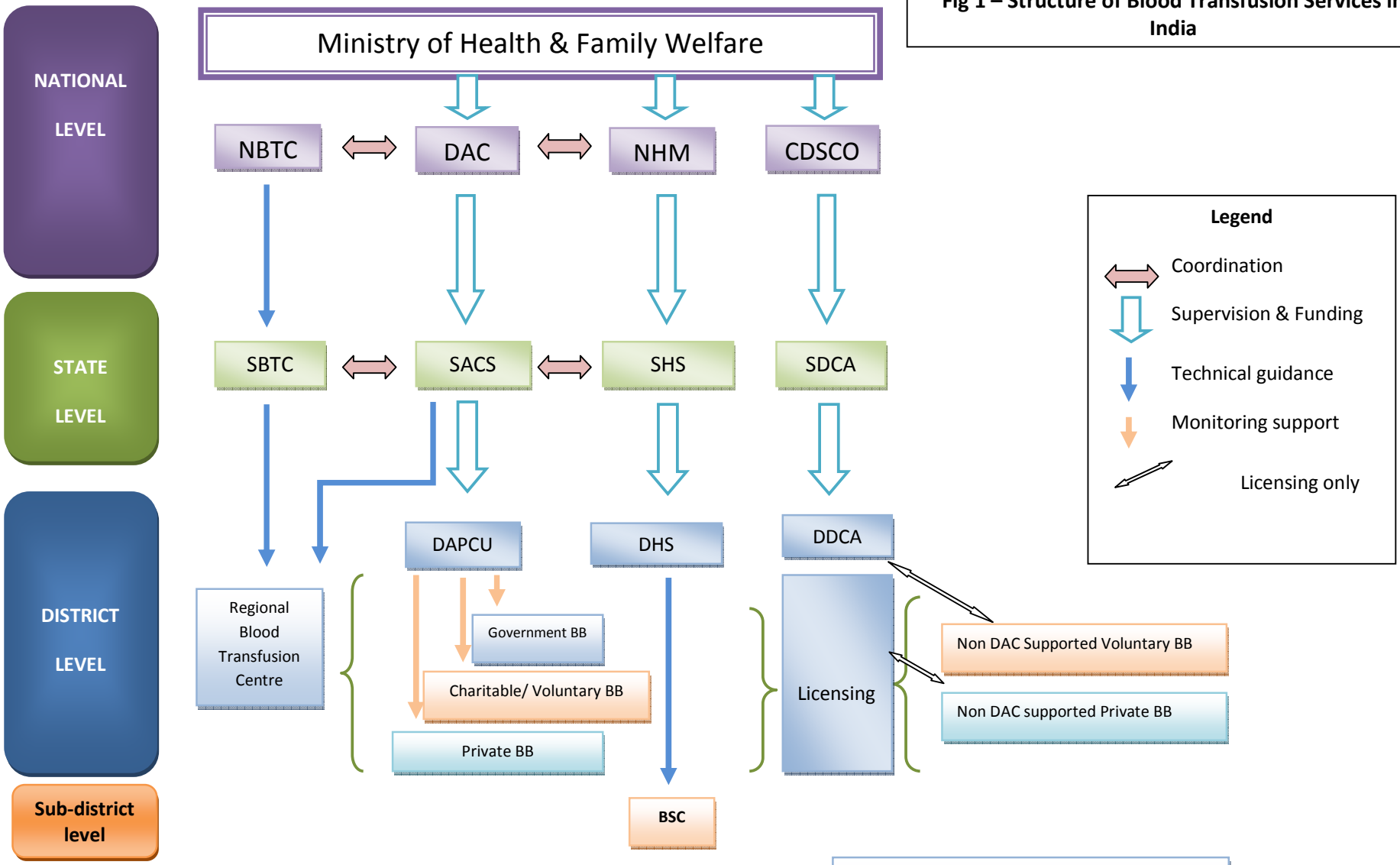
District level Blood Banks

Blood banks that collect less than 3000 blood units are categorized as District level Blood banks, usually located at district hospitals. During NACP-I and NACP-II, blood banks in all districts of the country were taken up under the scheme for modernization of blood banks. Currently, 665 district level blood banks are functional throughout the country. Chandigarh, Dadra and Nagar Haveli still do not have District level Blood Bank (DLBB) supported by DAC.

Metro Blood Banks

DAC has proposed to set up four Metro Blood Banks as Centres of Excellence in transfusion medicine, in the cities of New Delhi, Mumbai, Kolkata and Chennai to improve the BTS in India. These proposed blood banks will have State of the Art facilities with 100% Voluntary Blood Donation, 100% blood components preparation, and capacity to process more than one lakh units of blood annually.

Fig 1 – Structure of Blood Transfusion Services in India



NBTC – National Blood Transfusion Council
DAC – Department of AIDS Control
NHM – National Health Mission
CDSCO – Central Drugs Standard Control Organisation

SBTC – State Blood Transfusion Council
SACS – State AIDS Control Society
SHS – State Health Society
SDCA – State Drug Control Administration

DAPCU – District AIDS Prevention Control Unit
DHS – District Health Society
DDCA – District Drug Control Administration
BSC –Blood Storage Centres
BB – Blood Bank

Blood Storage Centres (BSC)

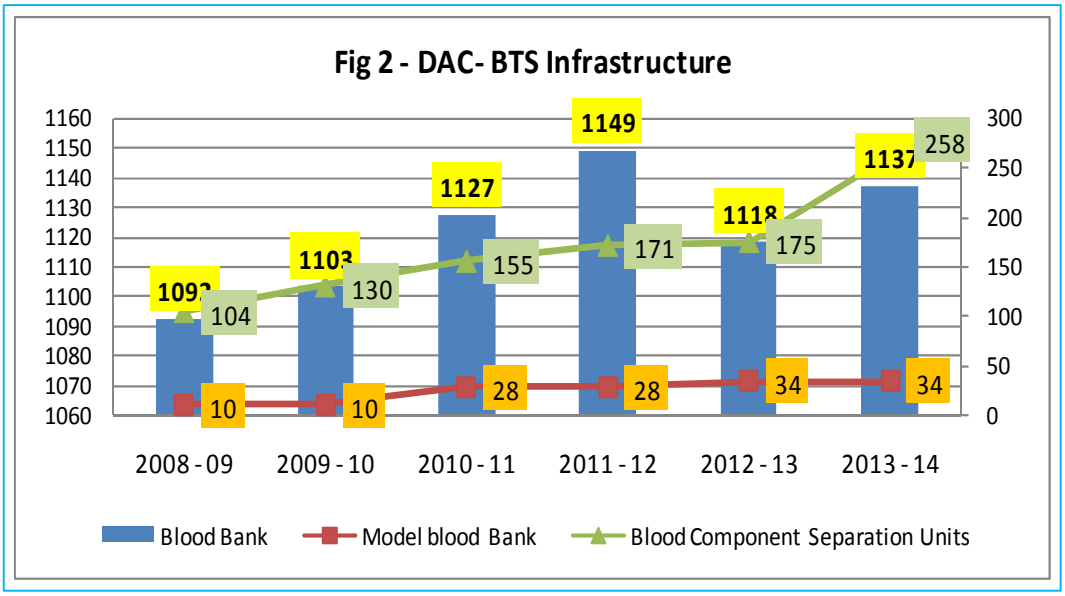
In order to address the lack of availability of blood in rural areas, the policy was modified in 2001, allowing the establishment of blood-storage units in rural regions. It has provided the exemption from obtaining the license to store, cross-match and issue Whole Human Blood I. P. and / or its components to the First Referral Unit, Community Health Centre, Primary Health Centre and any Hospital. Currently, there are Blood storage centres (BSCs). However, there is still a lot to be achieved as it is given low priority in the states.

According to the FRU guidelines, blood-storage facility is one of the three critical determinants as First Referral Units (FRUs) have been identified to deliver EmOC services (GOI, 2004). As of March 2011, there were 2,891 FRUs (574 DH + 826 SDH+1491 CHCs) in the country (GOI, 2011). The NACP phase III aimed to establish blood storage centres in 3222 CHCs with the equipment grant by RCH-II & annual recurrent grant by DAC and make available refrigerated vans in 500 districts for networking with blood storage centres (NACO, 2007g). But, there are only 745 blood storage centres functioning across the country (NACO, 2013). It was reported that FRUs were not fully operational due to lack of specialist staff, infrastructure, equipment, medicines, and blood-transfusion facilities in 2001(Ramani et al., 2009). It is estimated that if FRUs were equipped with the proper blood supply, they could reduce maternal mortality by 30% (HINDU, 2007).

As per the Concurrent Evaluation of National Rural Health Mission (NRHM) in 2009, only 14% of the CHC were having blood storage facility, 74.1% of the District Hospitals have Blood Bank/ Blood storage unit (GOI, 2013). According to Facility Survey 2007-08, though 52% of Community Health Centres (CHC) were designated as FRUs, only 9.1% had blood storage facilities (IIPS, 2010) which indicated the huge gap in making blood accessible to the rural population. Though the creation of blood storage centres in sub district level and first referral units have resulted in better access to blood than previously, these are still not available to all due to licensing and regulations as these blood storage centres are not authorized to supply blood to other facilities.

Plasma Fractionation Centre

As envisaged by NACP phase III strategy plan, a large Plasma Fractionation Centre at Chennai with processing capacity of 1.5 lakh litres annually is under process and expected to function shortly. This is an INR 250-crore project which aims to ensure access of plasma derivatives to those who are in need at affordable costs; that would also reduce the dependence on importing from other countries. Through this initiative, the surplus plasma will not be wasted and will be sent to the fractionating centres. However, the country needs standards and guidelines for testing, processing and logistics; National guidelines on Clinical use of plasma derived products (NACO, 2014c).



Voluntary Organizations in Blood Transfusion Services

Civil Society Organizations such as, NGOs, charitable and voluntary organizations play an active role in Blood Transfusion Services in India. There are several blood banks in the country being run by charitable and voluntary organization and, in specific; they are quite active in promoting voluntary donation of blood.

Indian Red Cross Society

Red Cross/Red Crescent Societies in many countries, as auxiliaries to their governments, play an important role in promoting safe and sustainable blood programmes. The Indian Red Cross Society established in 1920 follows the same mandate. Their activities range from the

provision of the national blood service to systematic recruitment of voluntary blood donors, the promotion of blood donation and advocacy for VBD, etc. They are involved in blood-related activities at three levels such as, full blood services (collecting, testing, processing, and distribution); Systematic recruitment of blood donors to the blood service; Promotion and advocacy of blood donation. Promote safe, sustainable and equitable practices in the development and administration of blood programmes. Indian Red Cross Society is one of the important players in the Blood Transfusion Services in India. As of now, they have 166 blood banks across 14 states in India. IRCS provides blood to government hospitals and the needy free of charge as well as to thalassemia children (IRCS, 2014).

Safe Blood Saves Lives Project

GIZ (Deutsche Gesellschaft für Internationale Zusammenarbeit) and the National AIDS Control Organisation collaborated through the project titled "Safe Blood Saves Lives" in ensuring the provision of adequate, safe and quality blood to every patient in the need of a transfusion through a well-coordinated National Blood Transfusion System. GITEC CONSULT GmbH - One of Germany's leading consulting companies in development projects was the implementing partner for the project. Stakeholders include the Government of India, in particular the DAC, along with the National Blood Transfusion Council and the State Blood Transfusion Council (GIZ, 2012). The key strategic areas of support were,

Plasma Fractionation Centre: To support the establishment of India's first public-owned plasma fractionation centre in Chennai.

Metro Blood Banks: To support the establishment of Support was provided for the establishment of the four metro blood banks in Mumbai, Delhi, Kolkata and Chennai to serve as centres of excellence for the blood transfusion system in India..

Private Sector Blood banks in India

Indian blood transfusion service is the largest in the South Asia region, and private sector contributes a significant proportion of blood supply in the country (Choudhury, 2011). According to Central Drugs Standard Control Organization, 61.2% (1564) of the blood banks in the country were private blood banks which can be classified as follows from an administrative point of view,

- Private hospital based
- Private stand-alone

Like private health care, blood transfusion service in the private sector is also unregulated. Though private blood banking in India has philanthropy motive, it is not so in many cases (Choudhury, 2009). Private sector heavily relied on professional blood donors, and there are commercial motives, as well. The blood banks including private blood banks in India is also reported having shortage of technical capability and lack of quality standards (Choudhury, 2009). While the Department of AIDS Control supported blood banks are required to follow specific guidelines and adhere to quality standards, supported by regular monitoring and supervision, the private blood banks lack in these areas. Several licensed private blood banks in the states do not report their blood collection details to the respective SACS that lead to lack of monitoring and supervision of blood supply from the blood banks to health care institutions (Ramani et al., 2009) (Ramani et al., 2007). This calls for regulatory measures for collection and supply chain of blood and its components in order to ensure adequate, safe and quality blood and blood products to those who access private blood transfusion services.

4.2.2. Resource Availability

Ever since the National AIDS Control Programme Phase one (NACP 1992-1999) was initiated, blood safety has been given much attention by the Government of India. The National AIDS Control Organization (NACO) is responsible for blood safety while providing financial assistance along with adequate training to staff and doctors. In addition to this, staffing and materials (test kits, equipment, reagents) support are being provided to the DAC supported blood banks in the country.

Financial Resources

The first phase of the Programme had INR 250.02 crore out of the INR 657.55 crore (38% per cent of its project cost) focussing on blood safety (CAG, 2004). The third phase of the project proposed INR 955 crore (8.24 percent of the project cost). Around INR 41 Crore were exclusively proposed for blood safety promotional activities in NACP III phase (NACO, 2006). The current National AIDS Control Programme NACP IV has allocated substantial resources

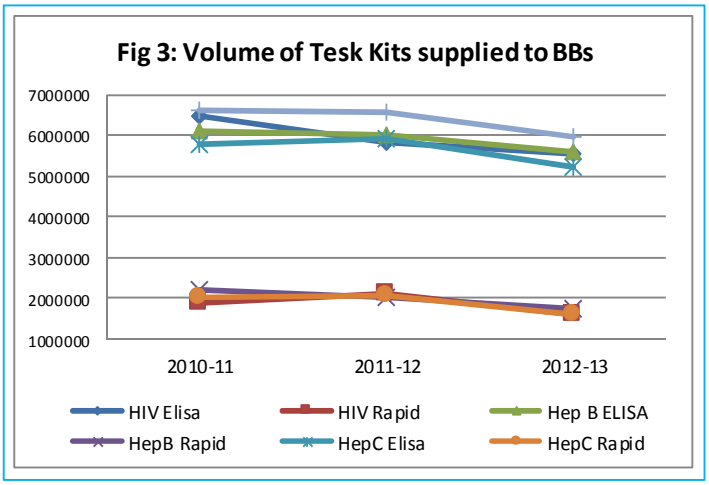
for Blood Transfusion Services that comes around INR 818 crore(6.09 percent) out of the INR 13,414 crore with the targets of supporting 1300 blood banks through which aiming to achieve 90 percent of the total volume of blood collected in the country (NACO, 2014e).

Human Resources

The National AIDS Control Programme provides human resources support to all the DAC supported blood banks that includes, Quality Assurance Manager, Technical Assistant, Lab Technician and Counsellor. In addition to this, several training programmes on all aspects of Blood Transfusion Services that aim to strengthen the capacity of the individual and institutions involved in Blood Transfusion Services. The department of AIDS Control identified 17 centres across the country to build the capacity of Blood Bank Medical Officers, Technicians, Counselors, Nurses, Clinicians, Donor Motivators and Programme Officers of SACS (NACO, 2013).

Equipment and Materials:

The DAC supports the blood banks in terms of procurement of equipment, blood bags, Testing Kits and Reagents (HIV, HBsAg, and HCV, Syphilis & group regents) as well as the recurring expenditure of government blood banks and those run by voluntary/charitable organizations, which were modernized. In addition, it provides IEC materials such as, Donor-group Cards, Donor and camp organizer appreciation certificates, Voluntary Blood Donation posters, Hand-outs etc. It also provides donors refreshment and camp expenses support to all DAC supported blood banks for their Voluntary Blood Donation Promotion programmes (NACO, 2013).

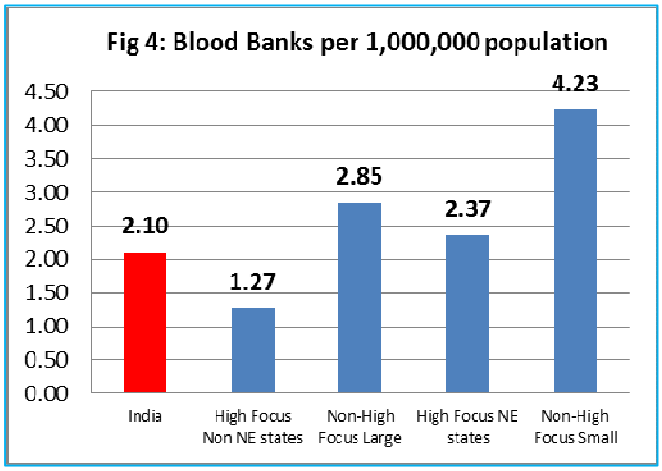


However, literature highlights that Blood Transfusion Services in India is highly decentralized and the Country lack many essential resources like manpower, adequate infrastructure and financial resources which emphasizes the need for more allocation of resources (NACO, 2007d) (NACO, 2007h)

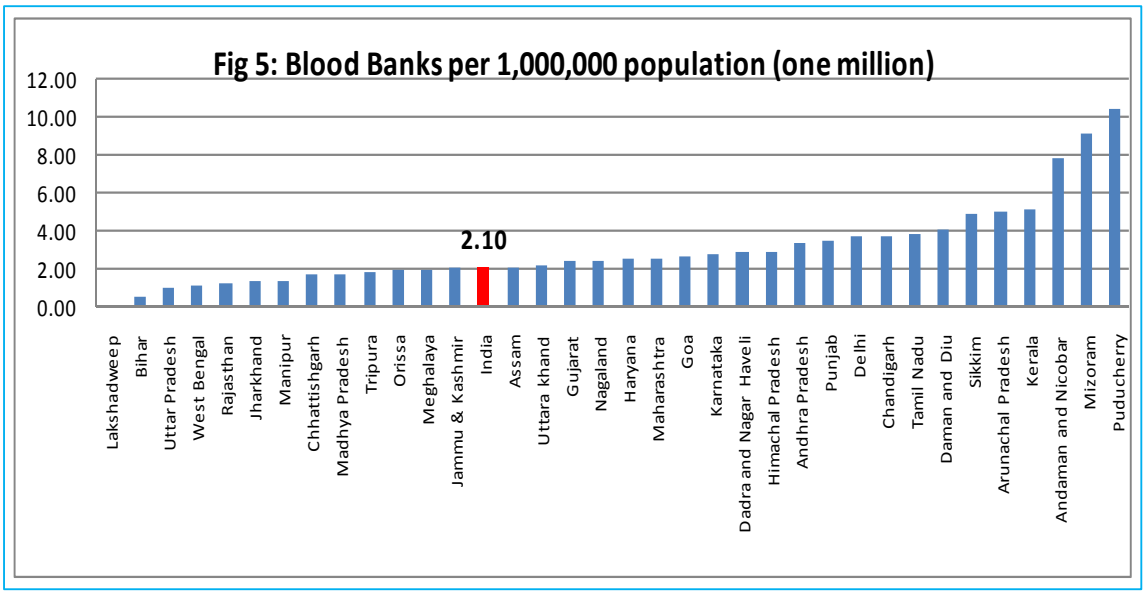
4.2.3. Blood Banks and the volume of blood collected

According to Central Drugs Standard Control Organization, there are 2,545 licensed blood-banks up to November 2012, of which 1564(61.5%) were private blood banks and the remaining 981(38.5%) are government blood banks (CDSCO, 2014). Currently, Department of AIDS Control is supporting 1,137 blood banks across the country (2013-14) that increased from 1,118 in 2012-13(NACO, 2014b).

Further analysis indicates that the country has 2.10 blood banks per one million populations with a huge disparity across the states. The high focus Non North-East states[1] that include, Bihar, Madhya Pradesh, Chhattisgarh, Odisha, Himachal Pradesh, Rajasthan, Jammu & Kashmir, Uttar Pradesh, Jharkhand and Uttarkhand has the lowest number of blood banks per 1,000,000 populations. As indicated in Figure 5, there is a disparity among states, as well. BTS in India is fairly in the advanced stage that is mainly concentrated in urban areas. BTS at sub-urban and rural areas need improvement (Choudhury, 2011; Ramkishan et al., 2012). Though population size is a key factor, areas with difficult terrain and other impediments of physical access need special consideration while planning for blood banks.

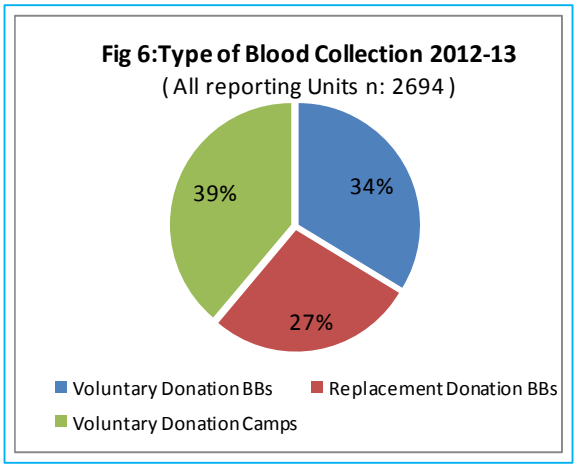


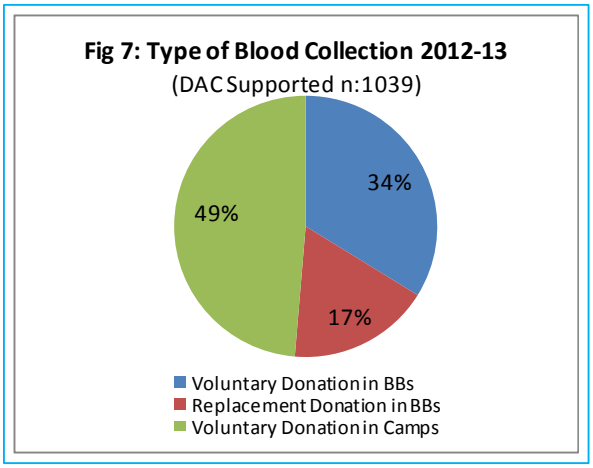
[1] ***High Focus - Non NE States:*** Bihar, Madhya Pradesh, Chhattisgarh, Odisha, Himachal Pradesh, Rajasthan, Jammu & Kashmir, Uttar Pradesh, Jharkhand and Uttarakhand
Non High Focus – Large: Andhra Pradesh, Kerala, Goa, Maharashtra, Gujarat, Punjab, Haryana, Tamil Nadu, Karnataka, West Bengal
High Focus – NE: Arunachal Pradesh, Manipur, Assam, Nagaland, Meghalaya, Tripura, Mizoram, Sikkim
Non High Focus - Small & UT: Dadra & Nagar Haveli, Delhi, Chandigarh, Lakshadweep, Daman & Diu, Puducherry, Andaman & Nicobar Islands

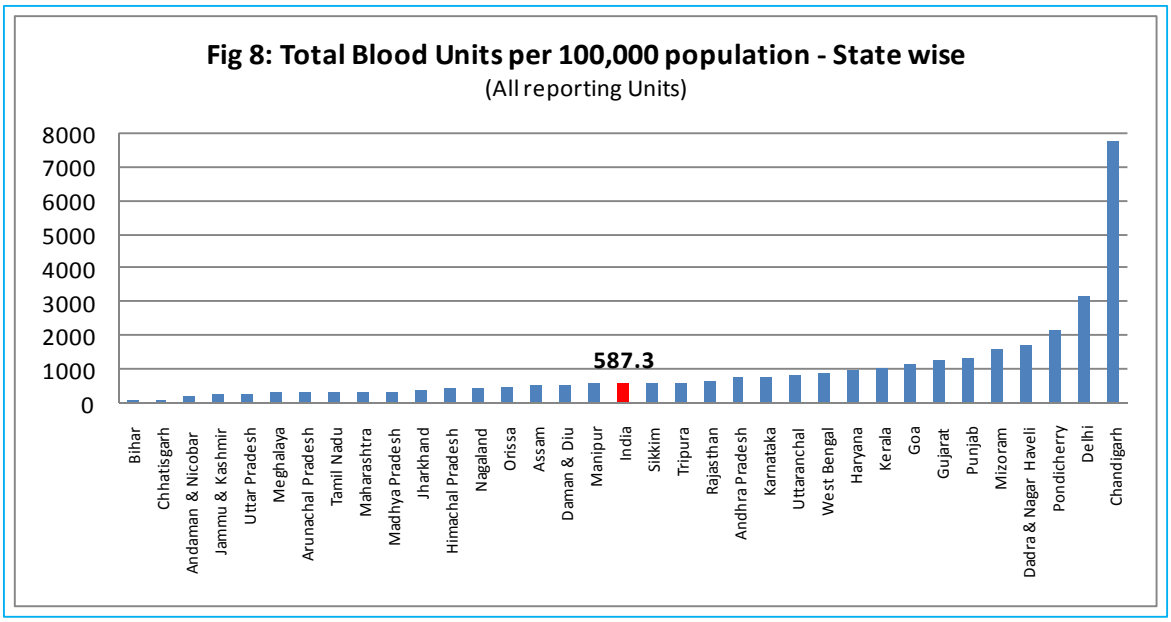


Volume of Blood Units Collected

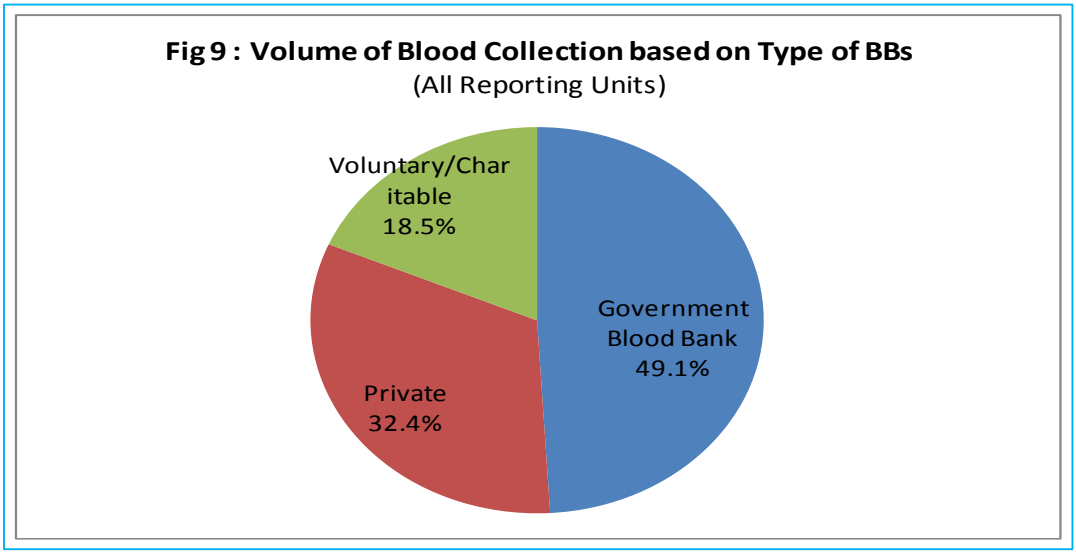
According to SIMS data(2012-13), the total units of blood collected in 2012-13 was 7,106,884 from all reporting units across the country, of which, 73% were from voluntary donation (34% (2,394,363) from voluntary donation in blood banks, 39% (2,764,192) from voluntary donation in camps and a significant 27%(1,948,329) was from replacement donations in Blood banks (fig 6). The DAC supported blood banks recorded a higher proportion of voluntary blood donation of 83% (fig 7). The Total blood units per 100,000 populations for the country were 587.3 units in 2012-13.

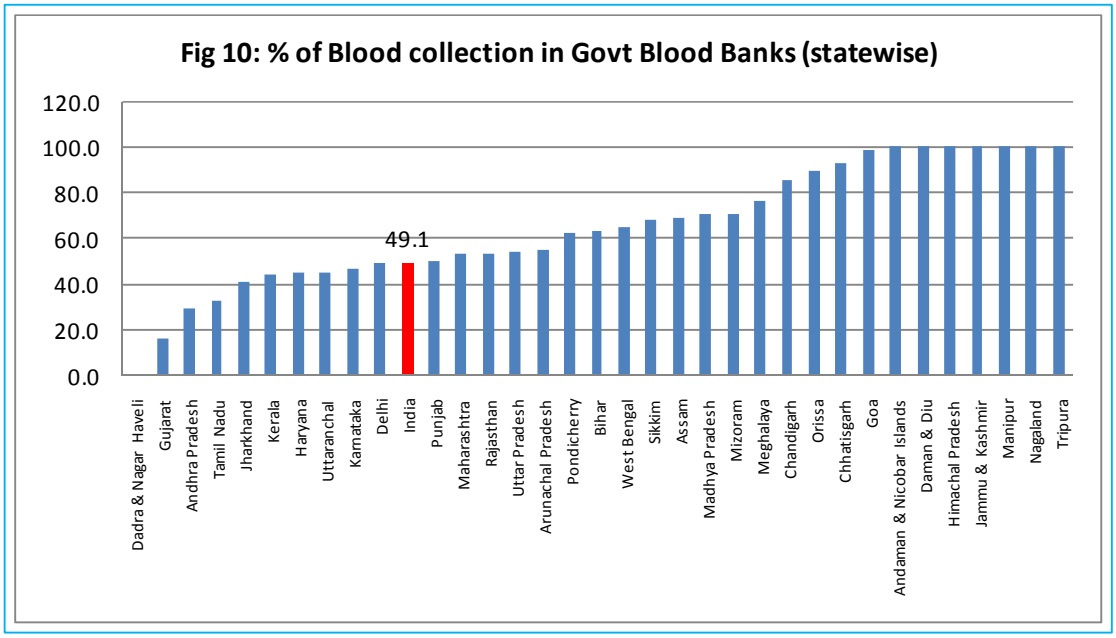






The SIMS Data 2012-13 indicated that the Government Blood banks recorded around 49% (3,487,571) of the total blood collection in the country followed by private (32.4% - 2,302,134) and voluntary/charitable blood banks 18.5% (1,317,179).





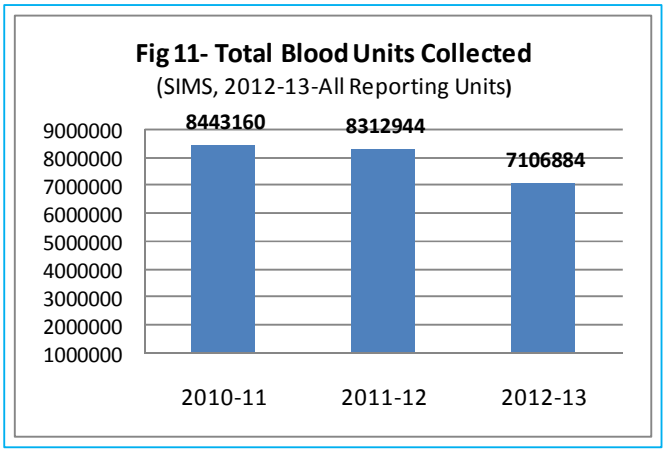
A greater proportion of blood collection was from private and voluntary/charitable blood banks in states such as, Delhi, Karnataka, Uttaranchal, Haryana, Kerala, Jharkand, Tamil Nadu and Gujarat.

4.2.4. The demand and supply

It is the responsibility of the state to ensure timely access to safe and sufficient supplies of blood and blood products and good transfusion practices to meet the patients' needs. Ensuring universal access to safe blood and blood products and work towards self-sufficiency in safe blood and blood products based on voluntary unpaid blood donation is vital to achieving universal health coverage (WHO, 2013a). National requirements for blood are, in part, determined by the capacity of the country's health care system and its coverage of the population (WHO, 2010c). In developed countries with advanced health systems, the demand for blood continues to rise to support increasingly sophisticated medical and surgical procedures, trauma care and the management of blood disorders. An increase in ageing populations requiring more medical care has also led to increased requirements for blood. According to WHO estimates, blood donation by 1% of the population is generally the minimum needed to meet a nation's most basic requirements for blood; the requirements

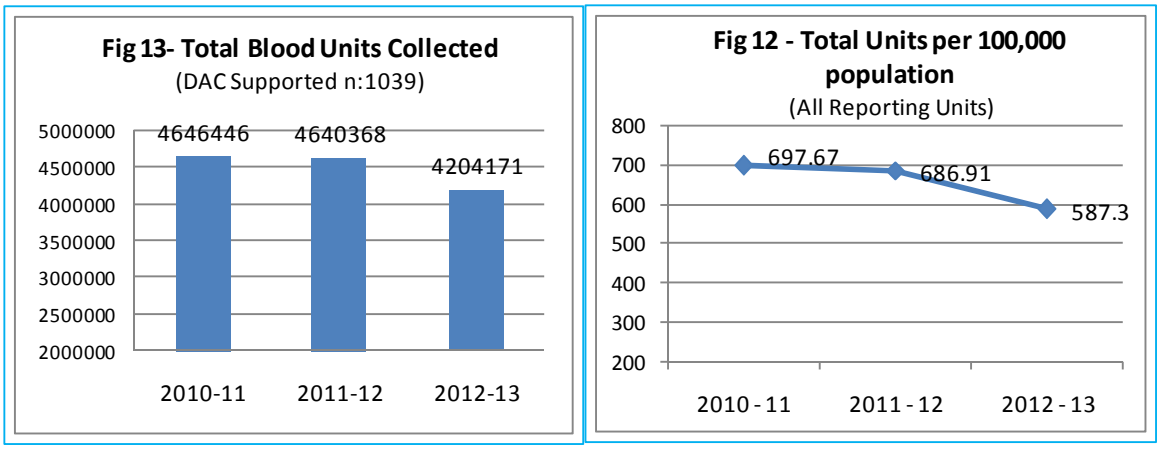
are higher in countries with more advanced health care systems. As per WHO standards, India's demand for blood and blood components should be one percent of the total population which is around 12 million blood units (1% of 1.2 billion populations). The annual requirement of blood for the country is estimated at 80 lakh units of blood in 2012-13 by the Department of AIDS Control (DAC, 2013).

However, there are several reports indicating different volume of blood units collected per annum. In 2007, the reported collection of blood units in India was reported to be 4 million against the need of 10 million (WHO, 2008c). In 2011, it was reported that Indian Blood banks were able to 5.5 million blood units against the requirement of 9 to 9.5 million per year which is a serious mismatch in the demand and availability(Kora S.A., 2011). Another report says that India has 2,433 blood banks that can collect 9 million units of blood annually, but collects only 7 million (Aggarwal S, 2012). The requirement of blood for the country is estimated to be 85 lakh to 1 crore units/year, whereas the available supply is only 74 lakh units/year (Umakanth Siromani et al., 2013). According to the Central Drugs Standard Control Organization (CDSCO), India has a total of 2545 licensed blood banks and the annual blood collection was approximately 8.2 million units but requirement was close to 10 million units leading to a shortage of 2 million blood units. Another report says that, against an annual demand of 8,500,000 units/year, the availability of blood in government supported blood banks is 4,400,000 units/year in 2009-10 and the remaining is reported to be addressed through private hospital/private commercial blood banks (Bachani & Sogarwal, 2010).



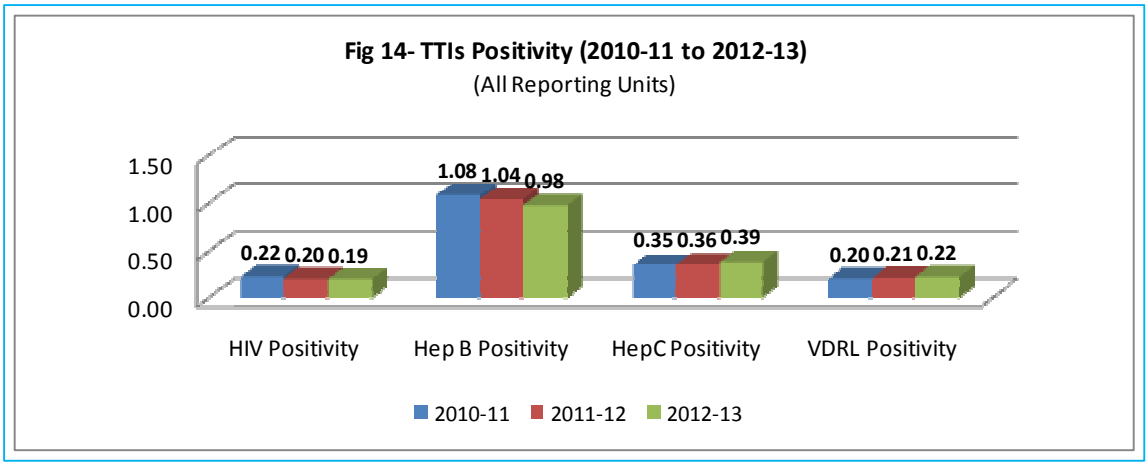
The recently launched National AIDS Control program, Phase IV (NACP-IV) sets an annual target of 9 million blood units by 2017 through the DAC supported blood banks. According to SIMS data in 2013, the total units of blood collected in 2012-13 were 7,106,884 that again indicate a shortage of 30%. It is also important to note that the volume of blood collection is indicating a decreasing trend (around 16% decline

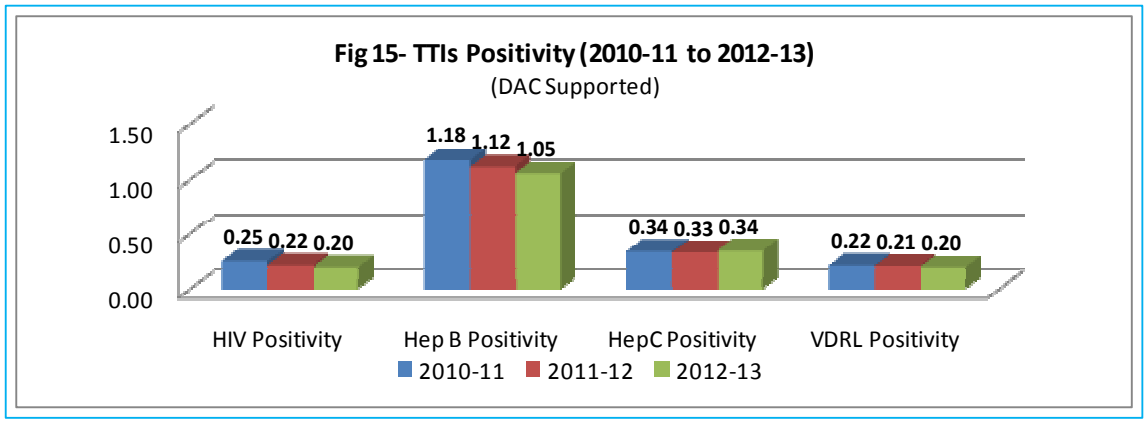
from 2010-11 to 2012-13) both at the country level as well as in the DAC supported blood banks and the reasons for the declining trend may be explored. Literature says that if 1-3% of a country's population donate blood, it would be sufficient for the country's needs for a year. Though there are several reports indicating different numbers, it is evident that India faces a blood deficit of approximately 30-35 per cent annually. The SIMS data also indicated that there is a decline in the total number of blood units collected over the years.

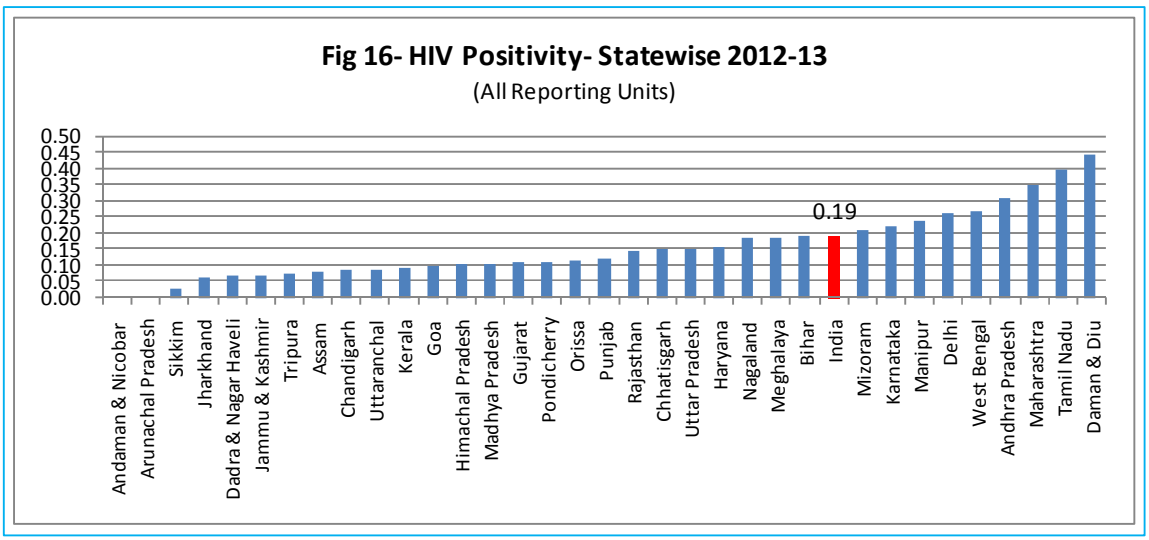


4.2.5. Transfusion Transmitted Infections

Transfusion transmitted infections (TTIs) are a major problem associated with blood transfusion (Chandra, Rizvi, & Agarwal, 2014; Gupta, Singh, Singh, & Chugh, 2011). Accurate estimates of the risk of TTIs are essential for monitoring the safety of blood supply and evaluating the efficacy of the screening procedures. The major concern is due to the prevalence of asymptomatic carriers and the donations during the window period of infections. However, there have been active efforts to provide safe and quality blood and blood products by improving the screening procedures world-wide. Screening for TTIs such as, HIV 1, HIV 2, Hepatitis B, Hepatitis C, Malaria and Syphilis is mandatory in India. Because of the active efforts, the prevalence of TTIs has come down significantly over the years.

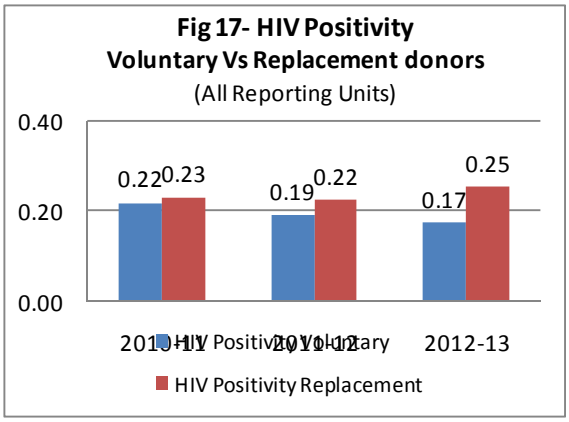


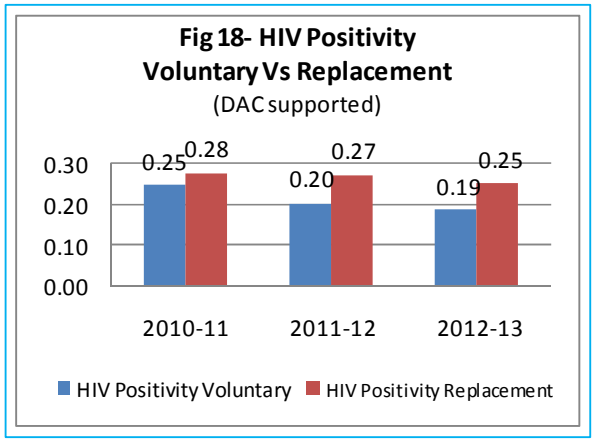




The positivity of TTIs among the donors in the country over the years is depicted in Fig 12. Though there is a decline in HIV and Hepatitis B positivity, a slightly increased positivity is seen in HepC and VDRL but DAC supported blood banks reported a decline in all TTIs.

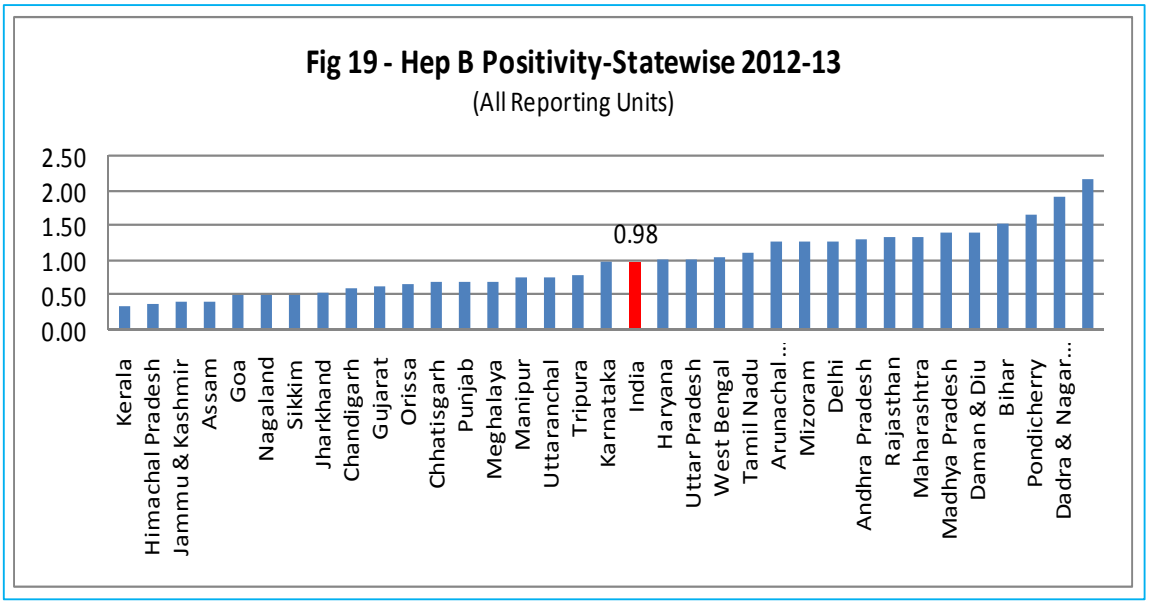
Malaria positivity was found to be 0.04% in 2012-13. Though the majority of the states are indicating lower HIV positivity levels comparing to the national positivity levels, the high prevalence states like Karnataka, Manipur, Andhra Pradesh, Maharashtra and Tamil Nadu are indicating higher positivity level than the national level. Similarly, around 16 states in the country indicated a higher positivity level of Hep B comparing with the national average.

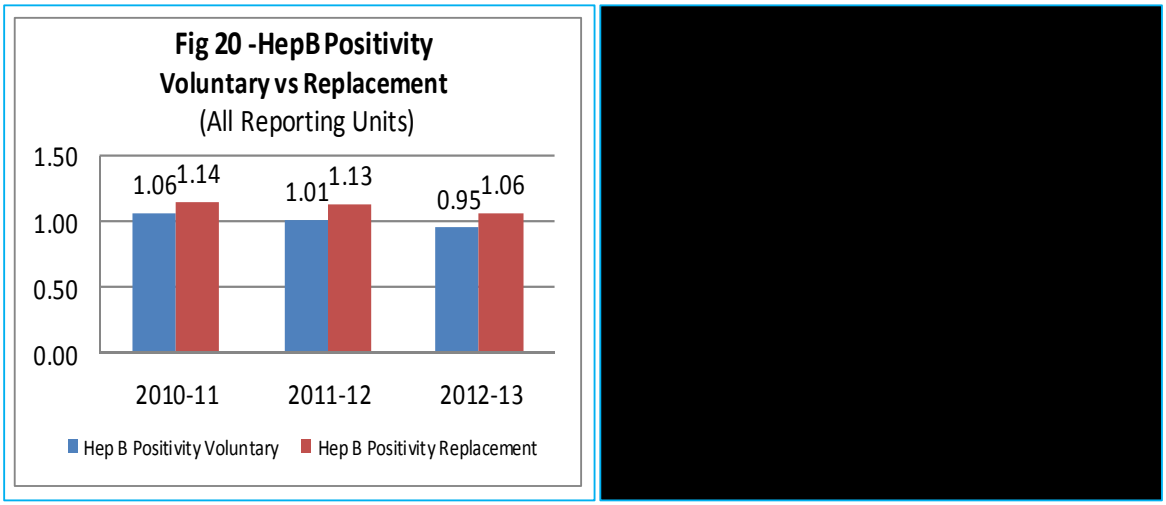


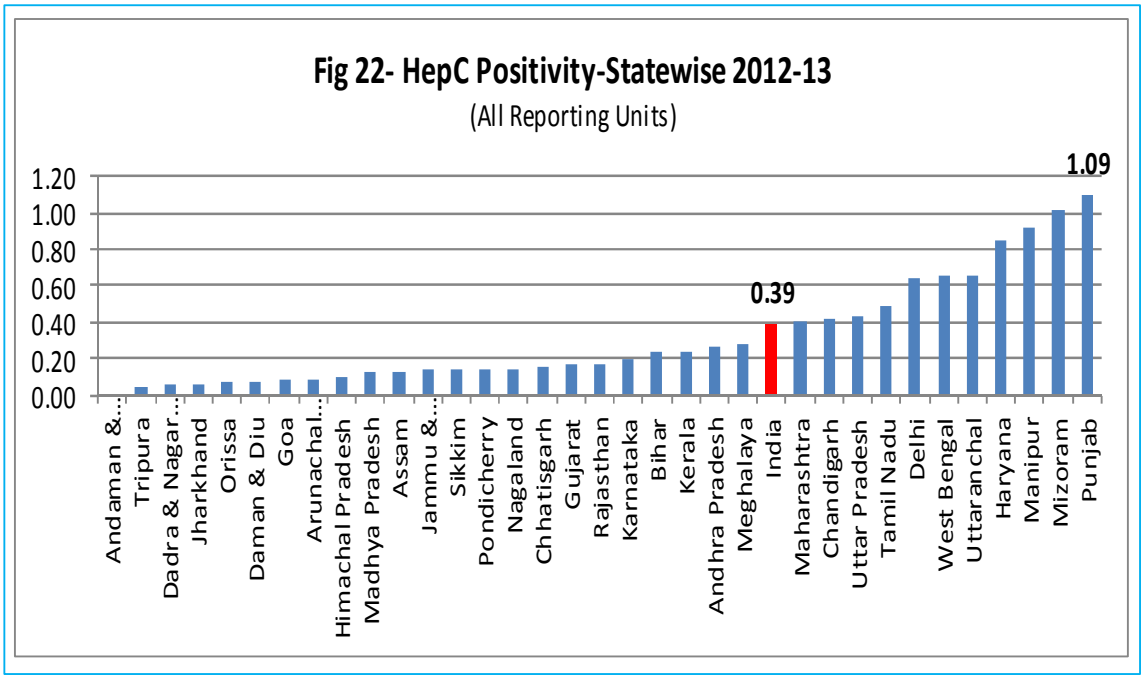


It is important to note that different types testing processes and methods with different levels of sensitivity and specificity are in place across the institutions/states/country that might influence the testing outcomes.

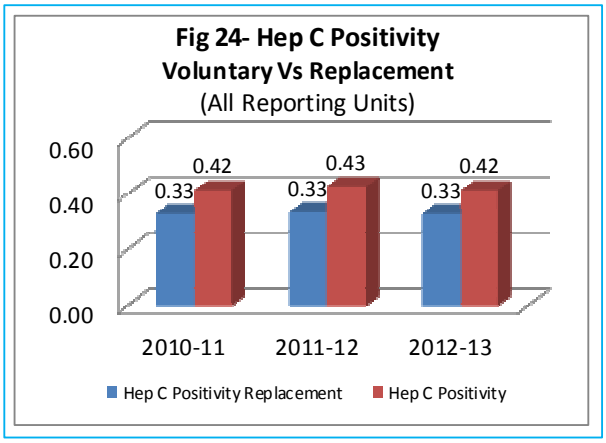
As proved earlier, the positivity among replacement donors is found to be relatively higher that indicates the need for promoting voluntary donation.

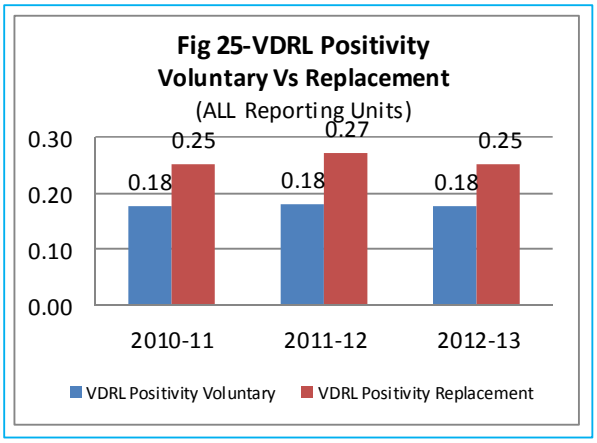




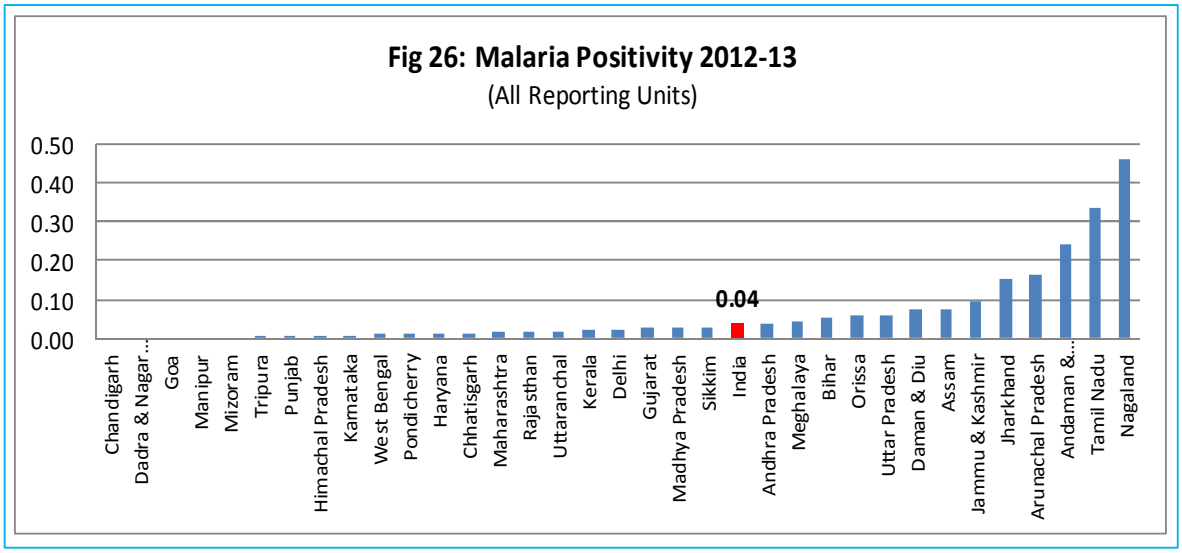


In terms of Hepatitis C, States like, Punjab(1.09%), Mizoram(1.01%), Manipur(0.92%), Haryana(0.85%), Uttaranchal(0.65%), West Bengal(0.65%), Delhi(0.63%), Tamil Nadu(0.48%, UP(0.43%), Chandigarh(0.41%) and Maharashtra(0.40%) have recorded higher positivity level than the national average of 0.39 percent.





All TTI infections such as HIV, Hep B, Hep C and VDRL are indicating higher positivity among replacement donors.



4.2.6. Blood Transfusion Services Components under National AIDS Control Programme – A Review

India gave utmost importance to Blood safety since the beginning of HIV epidemic that can be understood from the fact that, in 1986, the Indian Council of Medical Research (ICMR) in collaboration with the Directorate General of Health Services (DGHS) and individual State Governments initiated a national programme of serological surveillance (ICMR, 1987). They had also initiated blood safety and AIDS case management programmes whereby existing medical colleges and institutes had been designated as regional centres for the clinical treatment of AIDS that paved the way for the creation of National AIDS Control Organization in 1992 for coordinating a broader range of AIDS-related Programme and policies.

After that, recognizing the urgency of improving blood safety in India, the first phase of the NACP (1992-99) focused on screening all blood units collected for blood transfusions and decrease the practice of professional blood donations. NACO has undertaken initiatives to improve testing of blood and blood products, strengthen existing government facilities and external quality control, promote voluntary blood donation, develop and improve facilities for plasma fractionation, and to improve the management, monitoring and evaluation of blood transfusion services.

The second phase (1999-2007) focused on scaling up the services carried out in phase I. The NACP II also focused on quality management systems (EQAS for HIV testing, Accreditation), strengthening capacity building initiatives, and appropriate clinical use of blood and promotion of voluntary non remunerated blood donation.

The third phase of the National AIDS Control Programme III (2007-12) aimed to ensure the provision of safe and quality blood to the remote areas of the country in the shortest possible time through a well-coordinated National Blood Transfusion Service(NACO, 2007g). This was planned to be achieved by, Strengthening infrastructural facilities and establishing blood storage centers in the primary health care system for availability of blood in remote areas; ensuring that regular (repeat) voluntary non-remunerated blood donors constitute the main source of blood supply; promoting appropriate use of blood, blood components and blood products; developing long-term policy for capacity building to achieve efficient and self-sufficient blood transfusion services; mandatory testing of each unit of blood for

HIV, Hepatitis B and C, Syphilis and Malaria and voluntary blood donation for which camps are organized with the help of various organizations.

This section of review of blood transfusion services will be based on the broad components that the National AIDS Control Programme envisaged over the years, that are,

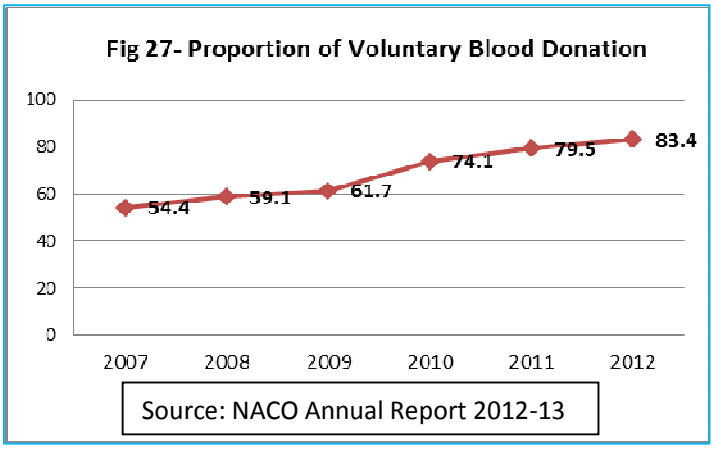
i. Augmentation of Voluntary Blood Donation
ii. Access to safe and quality blood
iii. Appropriate Use of Blood and Blood Products - Clinical use of Blood and Blood products
iv. Quality Assurance in Blood Transfusion Services
    - Hemovigilance
v. Monitoring and Evaluation System of Blood Transfusion Services in India
vi. Efficient Supply Chain Management and Quality Assurance
vii. Convergence with NRHM, other departments and Ministries
viii. Legal, regulatory and Policy Issues
ix. Ethical Issues of Blood Transfusion

4.2.6. (i). Augmentation of Voluntary Blood Donation (VBD)

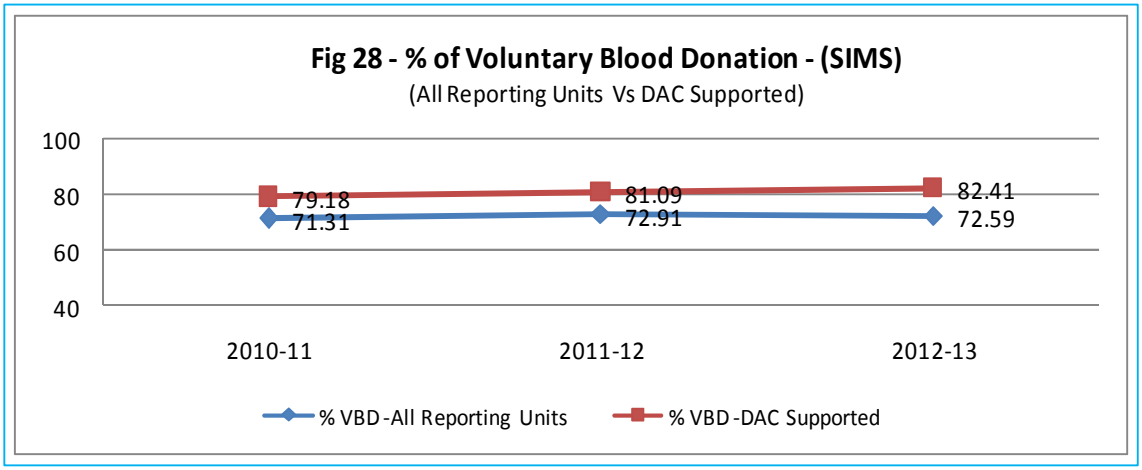
It has been recognized world over that collection of blood from regular (repeat) voluntary non remunerated blood donors should constitute the main source of blood supply, as Voluntary non-remunerated donation has been shown to be the cornerstone of a safe and sufficient blood supply and is the first line of defense against the transmission of infectious diseases through transfusion(WHO, 2010c). Besides, meeting the transfusion requirements through replacement donation by the family and friends are rarely able to meet the demands for blood and paid commercial donation poses serious threats to the health and safety of the recipients, as well as the donors themselves. In 2010, the World Health Assembly defined self-sufficiency in the supply of safe blood and blood products based on Voluntary Non-Remunerated Donation (VNRD), and the security of that supply, as important national goals to prevent blood shortages and meet the transfusion requirements of the patient population (WHO, 2013b). The resolution WHA63.12 urged Member States "to take all necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes according to the

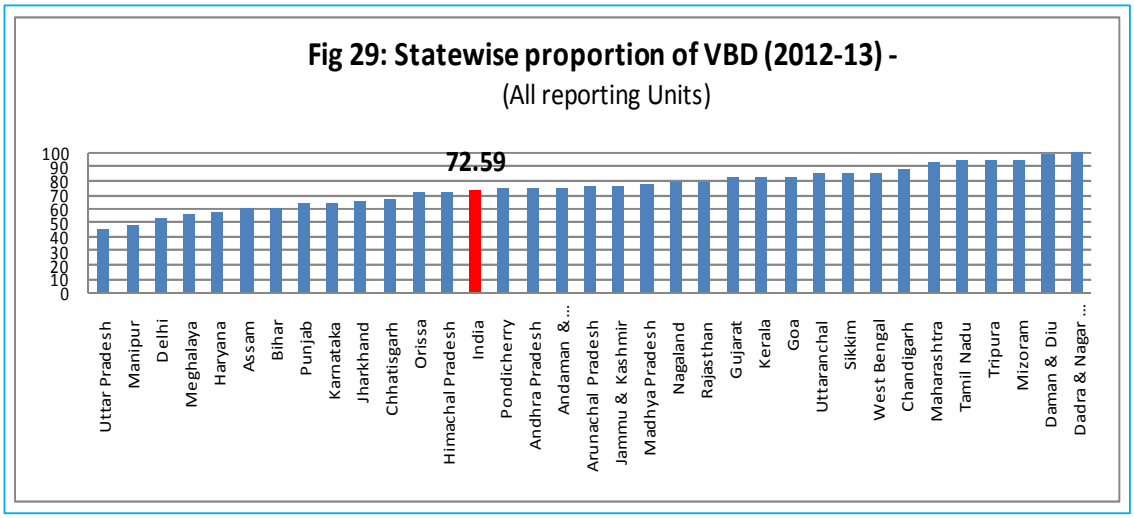
availability of resources, with the aim of achieving self-sufficiency" (WHO, 2010d). There were major blood system reforms in many countries to secure national blood supplies through voluntary, non-remunerated donation and self-sufficiency in meeting national blood needs (WHO, 2013b).

In 2011, the median donation rate was 39.2 donations/1000 population in high-income countries, 12.6 in middle-income countries, and 4.0 in low-income countries. Especially, some developed countries such as Switzerland and Japan, the number of voluntary blood donors per 1,000 population was reported to be 113 and 70 respectively, but in India it was still very low, 8 for every 1,000 population (Agarwal, 2012).

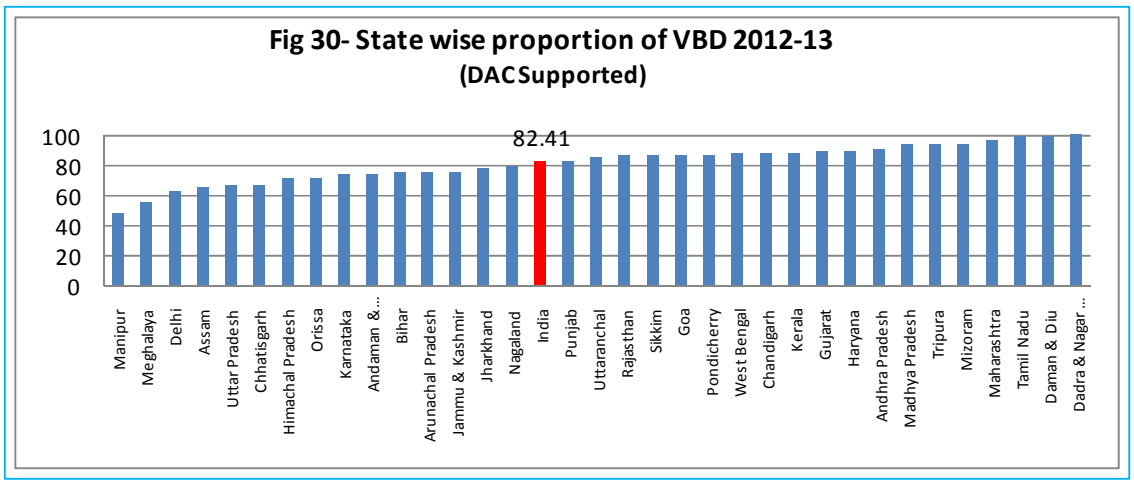


The DAC supported blood banks indicated a significant increase in voluntary blood donation, from 54.4% in 2007 to 83.4% in 2012 (NACO, 2013). Promotion of voluntary blood donation has also enabled reducing transmission of HIV infection through contaminated blood from about 6.07% in 1999 to 0.2% in 2012. However, according to SIMS data, the VBD status for the entire country showed a plateau trend from 2010-11 to 2012-13(Figure 28). Out of the total units of blood collected from both blood banks and camps, 72.6% was from voluntary donation. However, there is a disparity in the proportion of voluntary donation across states. (Fig-9)

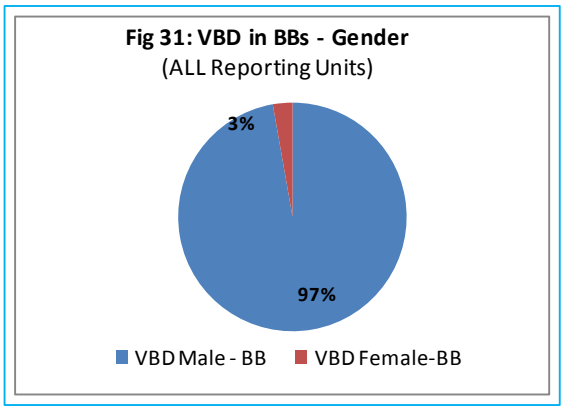


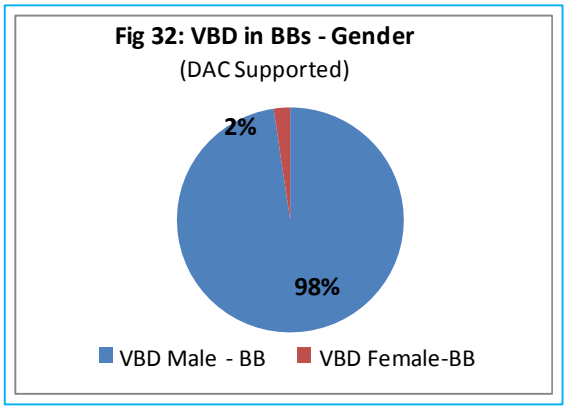


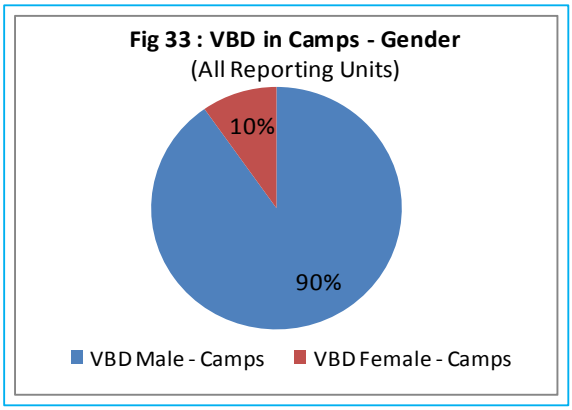
UP, Manipur, Delhi, Meghalaya, Haryana, Karnataka, Assam, Bihar, Punjab, and Jharkhand. Chhattisgarh, Orissa, HP were the states that recorded lower level of VBD than the national average. Maharashtra, Tripura, Tamil Nadu, Mizoram, Daman and Die, Dadra Nagar Haveli recorded more than 90% VBD.

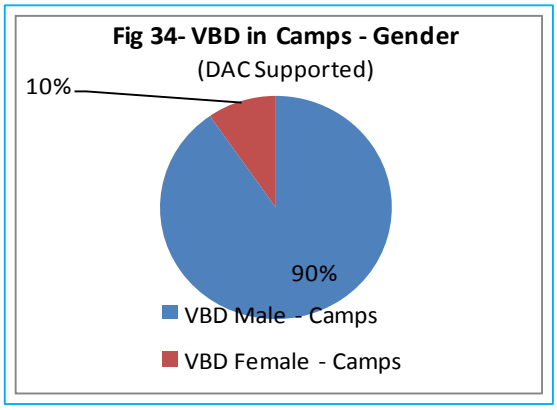


According to the SIMS data for the entire country, majority of blood donation was from the male (93%) that is corroborating with the World Health Organization's (WHO) global database on blood safety updated in June 2011 that reported mind-boggling gender disparity among blood donors that was 94 percent of blood donations in the county by men. However, a higher proportion of the female population voluntarily donated blood through camps. Only 2% of total replacement donation was from females.

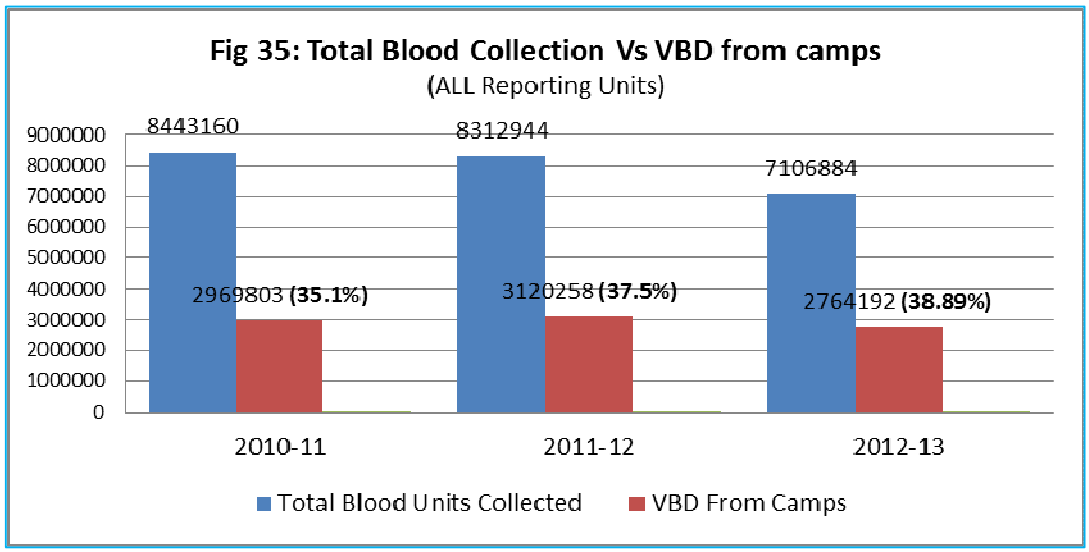


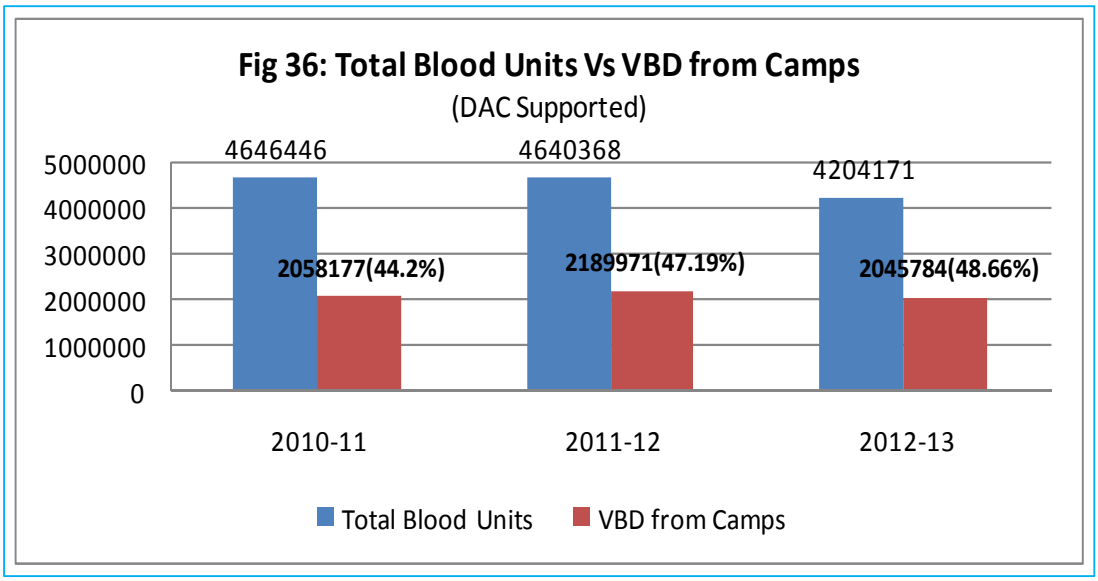




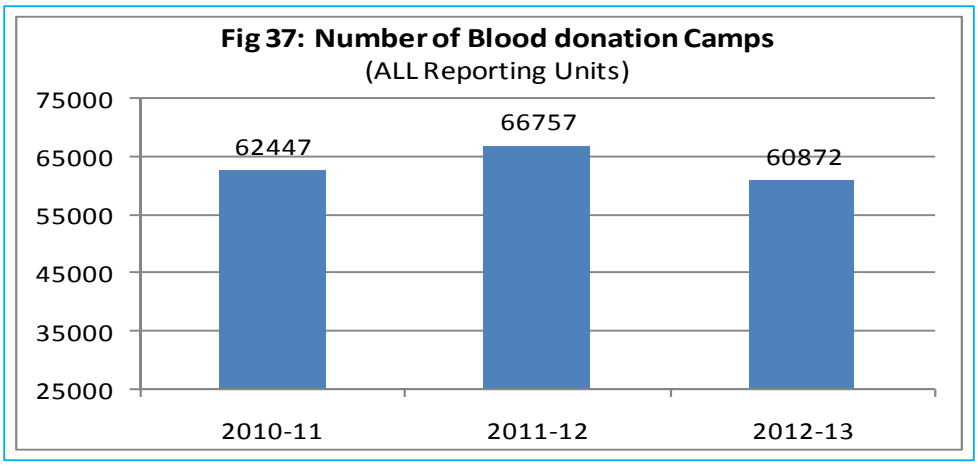


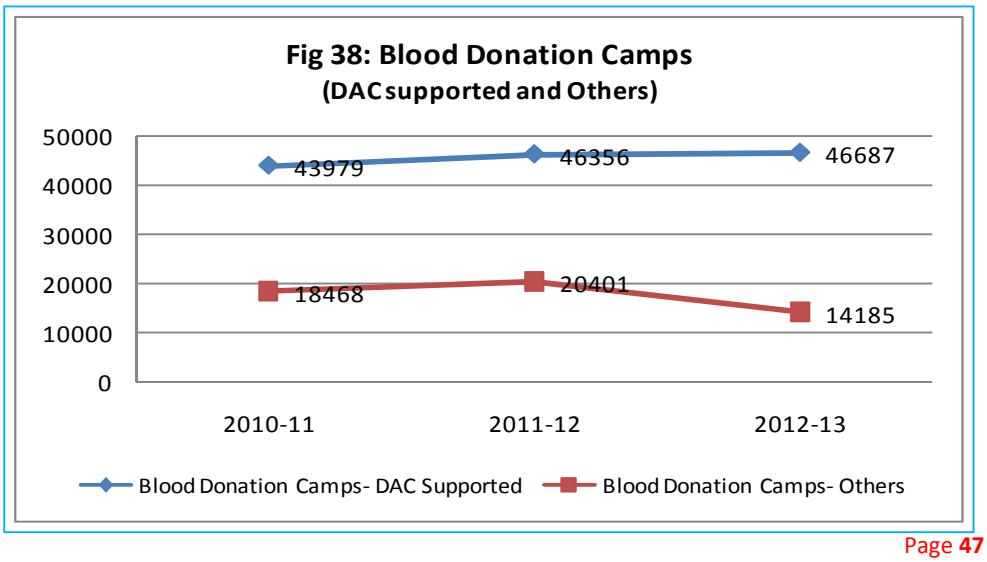
Blood donation camps play a major role in the Blood transfusion services in India. Figures 35 and 36 clearly indicate that a significant proportion (35 to 38%) of blood collection in the country is from camps. The proportion is higher among DAC supported blood banks.





According to SIMS, the number of camps conducted during the 2012-13 was 60,872, out of which, 46687 (76.6%) were by DAC supported blood banks.

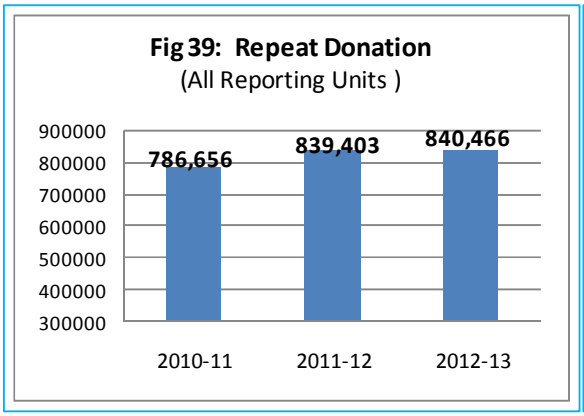


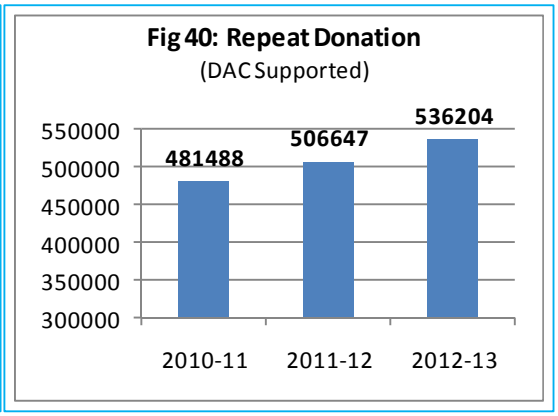


The number of camps conducted during 2012-13 decreased from 2011-12, however, that is primarily due to the reduction in the number of camps conducted by non DAC supported blood banks.

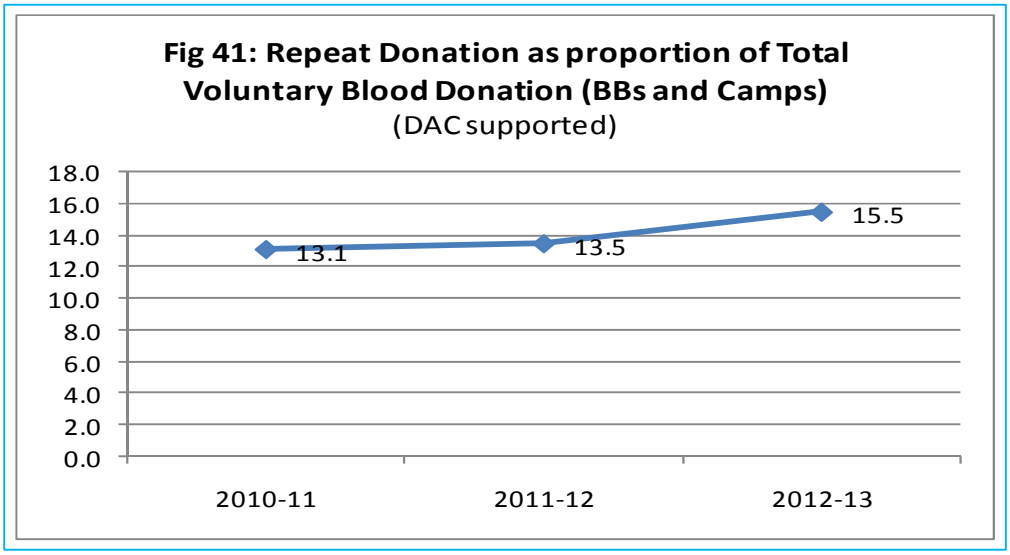
Repeat Voluntary Blood Donation

Voluntary non-remunerated repeat blood donors are perceived to be safer than the first time blood donors (Choudhury et al., 2011). By improving the repeat voluntary donors, the reliability of blood supply and safety of blood and blood products can be assured (WHO, 2012a). Literature suggests that the repeat donors, irrespective of family, replacement or volunteer non-remunerated donors are considered as the most viable alternative to ensure safe blood (Allain, 2011; Tagny, 2012).





The SIMS data indicated an increasing trend in repeat donation in the country and the proportion of repeat donation out of total voluntary donation (blood banks and Camps) showed an increasing trend from 13 percent in 2010-11 to 16.3 percent in 2012-13. However the current level is low when comparing with countries like Iran that achieved 75.2% of its donation through regular and repeat donors in 2012(IBTO, 2013). The DAC supported blood banks also indicated a similar proportion of repeat donations comparing with total voluntary donation (13.1; 13.5 and 15.5% from 2010-11 to 2012-13). So, it is important to increase donation rates among the younger generation, increase the number of repeat donors and to secure wider community support for blood donation.



4.2.6. (ii). Access to safe and Quality Blood

The availability and accessibility of safe blood and blood products are vital for the prevention of HIV infection and to the achievement of the health-related Millennium Development Goals to reduce child mortality, improve maternal health, combat HIV and other infections (WHO, 2008b). However, access to safe and effective blood products is a major challenge in low and middle income countries like India due to various reasons such as lack of basic facilities and systems, low quality and safety standards need to be established or strengthened, and insufficient supply.

In India, access to safe blood is mandated by law (NACO, 2014a) and it is the primary responsibility of the government (WHO, 2002). The blood safety programme in India aims to make available safe and quality blood within one hour of requirement in a health facility (NACO, 2014a). Over the years, access to safe and quality blood has increased significantly due several factors such as, increased number of blood banks, increased voluntary blood donation, appropriate use of blood and products, reduction in wastages, increased quality, improved infrastructure and service delivery. Nevertheless, the need for blood continues to grow due to, changes in population demographics and disease patterns, expansion and development of health systems, improvements in diagnostic and treatment options and advances in surgical and medical procedures requiring blood transfusion(WHO, 2013c).

According to Department of AIDS Control, the availability of safe blood increased from 44 lakh units in 2007 to 93 lakh units by 2012(NACO, 2013). The gradual increase of the number of blood banks, Blood Component Separation Units (BCSUs) and blood storage centres (BSC) in the country has indeed increased the access to blood and blood products. However, as per World Health Organization (WHO) guidelines, there is 31 percent deficit of available blood at national level; in rural areas this proportion is much higher in India (Pandey, 2014).

The safety of blood and blood products are ensured through the following,

- Department of AIDS Control provides all test kits to all the government and charitable blood banks like Red Cross;
- The Drugs & Cosmetics Act provides a legal framework under which the blood banks are inspected and issued a proper license
- The blood banks are jointly inspected by the Drug Inspectors of the Food and Drug Administration and by the SACS of the respective states
- Blood safety training program by DAC to ensure an uniform training curriculum for all aspects of blood transfusion. This will impart training on all aspects of blood safety involving Blood Bank Medical Officers, Technicians, Counselors, Nurses, clinicians, donor Motivators and Programme Officers of SACS through 17 centers identified across the country. Voluntary blood donation trainings were held in four regions to augment voluntary blood donation in the country.

But there are still gaps; and lack of access to safe blood still remains a major cause of maternal mortality in all parts of the country (Vora et al., 2009).

The lack of access to safe blood services due to both supply side and demand side factors is given in (Table 2).

Table 2. Factors contributing to Lack of access to safe blood and blood products in India

Supply Side Factors	Demand Side factors
• Shortage of blood supply • Skewed distribution of service delivery units such as blood banks, BSUs. • Stock-out of test kits and reagents • Minimal Infrastructure (Ramani et al., 2009) • Obsolete equipment • Insufficient and Lack of trained human resources • Poor supply chain management system, • Lack of cold chain transportation • Huge costs in carrying blood from remote banks • In appropriate use of blood and blood products, • Quality Management System • Lack of institutional coordination and coordination between health systems. • Unclear roles and responsibilities between structures.	• Poor as socio-economic and cultural factors. • Lack of awareness, knowledge, myths and misconception • Poor physical access to service delivery points such as blood banks. Poor availability of transportation, long distance. • User Fee (Processing Fee) • Lack of free availability of components.

All these factors, in fact, lead to lack of and inequitable access to blood and blood products in the country. Especially, the shortages also contribute to increased risk of infection transmission by forcing a reliance on unsafe replacement or paid donors and greater pressure to issue untested blood (WHO, 2008a)

4.2.6. (iii). Quality Assurance in Blood Transfusion Services

The quality systems in Blood Transfusion Services cover the entire transfusion process, from donor recruitment to the follow-up of the recipients of transfusion (CDC, 2011), which requires the establishment of well-organized, nationally-coordinated blood transfusion services to ensure the timely availability of safe blood and blood products for all those who require transfusion services (WHO, 2008c). The Quality Assurance includes the collection of blood from voluntary unpaid blood donors from low-risk populations to quality-assured testing for transfusion-transmissible infections, blood grouping and compatibility testing.

The overall aim is to promote safe and appropriate use of blood and to reduce unnecessary transfusions (CDC, 2011).

Over the years a fragmented mix of competing independent and hospital-based blood-banks of different levels of sophistication, different level of quality levels, serving different types of hospitals and patients have emerged in India (Ramani et al., 2009). The population explosion and the expansion of poorly regulated health care market propagate this fragmented evolution in blood banking with different quality levels. Nevertheless, assured quality services in blood storage and transfusion services are extremely important in transfusion services.

In order to these concerns of Quality Assurance, the Quality Management Project (QMP) has been implemented in all the WHO regions since 2001 that aims to introduce and strengthen the quality aspects of Blood Transfusion Services (BTS) with the objective to improve the safety, adequacy and quality of blood. In India, the National Quality Management Training Course was conducted in October 2001 where the State Program Officers were sensitized regarding QMP and its utility to assure quality, safety and adequacy of blood(Pal et al., 2011). The Department of AIDS Control in India emphasize certain practices such as, licensing of blood storage and transfusion facilities, supervisory visits, Internal Quality Control Procedures and the External Quality Assessment Schemes (EQAS)/Proficiency Testing to ensure quality of the BTS at all levels. The DAC also developed and disseminated a "Manual on quality standards for HIV Testing laboratories" for practicing quality assurance required for HIV testing on a day today basis, training, implementation of quality assurance programmes in all the HIV testing facilities including blood banks across the country (NACO, 2007c)

a. Licensing of blood storage and transfusion facilities

The first step of quality assurance is ensured through mandatory licensing of all the blood storage and transfusion facilities in the country which need to be obtained from the State/Union Territory licensing authority after satisfying the conditions and facilities through inspection. The approval is valid up to a period of five years from the date of issue unless sooner suspended or cancelled. An application for renewal is to be made three months prior to the date of expiry of the approval. Even in case of FRUs/ CHCs/ PHCs before

applying for the approval, the storage centre have to identify and obtain consent from the blood bank from where they will get the supply of blood/blood components(GOI, 2001). These could be licensed blood banks run by Government Hospitals/Indian Red Cross/Regional Blood Transfusion Centres only. In case the license of the parent blood bank/centre is cancelled, the license of the storage centre is also automatically cancelled. The storage centres, can however, get affiliated to more than one blood bank/centre to ensure un-interrupted supplies, but a separate approval is required in each case

b. Supervisory Visits to DAC- supported Blood Banks

A team in every State that comprises of four members namely one Blood Safety Official of SACS, director of State Blood Transfusion Council (SBTC), one nominated expert in the field of Transfusion Medicine and a member of State drug control, carries out the inspection of all blood banks and voluntary blood donation camps (NACO, 2013). The team makes periodic supervisory visits to and prepares reports identifying various constraints and the methods to rectify them. Officers of DAC also undertake supervisory visits to blood banks in various States.

c. Internal Quality Control Procedures

Internal Quality Control (IQC) consists of a set of procedures that are undertaken by the staff for continuous and concurrent assessment of laboratory work and emergent results (Jain, Sharma, & Gupta, 2013) (Bharucha et al., 2006). It facilitates the professionals to check their own performance and to help them monitor the reliability of their techniques. In India, the internal quality control is maintained in blood banks by going through a complete checklist of items or tests daily to make sure that all systems are being monitored and in control. Immediate decisions are also taken to accept or reject results/ products on daily basis.

d. External Quality Assessment Scheme (EQAS) (NACO, 2013)

One of the most important aspects of accreditation is to continue checking performance by way of participation in External Quality Assessment Schemes (EQAS)/Proficiency Testing which provides an opportunity to any blood bank to compare its results with other blood banks. It ensures that the blood bank is not only selecting the right method but also following it properly. The department of AIDS Control in 1999 initiated the External Quality

Assessment Scheme (EQAS) for HIV testing for the Blood Banks and laboratories with the objective of bringing qualitative improvement in the Blood banks and laboratories for HIV testing. The programme has emphasized on quality practices and documentation of EQAS.

The National External Quality Assurance Scheme (NEQAS) for HIV has categorized the laboratories in the country into four tiers as follows(NACO, 2013),

1. Apex laboratory (first tier) - National AIDS Research Institute, Pune,
2. Thirteen National Reference Laboratories (NRLs) located in all parts of India undertake EQAS in their respective geographical areas including apex (second tier).
3. State level: 117 State Reference Laboratories (SRLs) (third tier)
4. Districts level, i.e., all ICTC & Blood banks (fourth tier).

Each NRL has been allotted specific states. The NRL mentors SRLs under them; and the SRL in turn, monitor and mentors the ICTCs and blood banks under them. Sera panels are distributed to the linked blood banks by the SRLs biannually.

Training of all the four tiers has been conducted. Blood Bank Medical Officers and Technicians of around 1200 Blood Banks have also been trained in the country(NACO, 2013).

e. Accreditation

In order to ensure quality assurance in Blood Transfusion Services, DAC has been pursuing the task of accreditation of blood banks through the National Blood Transfusion Council (NBTC). In order to get NABH accreditation, all lab testing done in the Blood banks (including TTIs and Immunohematology) should be covered under a formal EQA programme.

4.2.6. (iv). Monitoring and Evaluation System of Blood Transfusion Services in India

The National AIDS Control Programme established “one nationwide monitoring and evaluation framework" under the "Three Ones” principle which ensures effective use of information generated by government agencies, NGOs, CBOs, private and development partners. The data generation originates from service delivery level to district, state and national level. Currently, there are around 12,000 reporting units that include blood banks across the country. The data flow for collecting data involves multiple points where data

quality is verified and further improved by State and National Strategic Information management Units (SIMU).

The monitoring and evaluation of Blood banks are through the information generated from Strategic Information Management System (SIMS). The establishment of Strategic Information Management Units (SIMU) at the state and national level intensified the efforts on improving data quality at all levels and brought together Monitoring and Evaluation, surveillance, and operations research. Clear roles and responsibilities, validation (using a validation checklist) and feedback at different levels, have ensured overall data quality. The SIMS has sections of data collection that are, volume and profile of blood donors; results of testing and separation; infrastructure and inventory management; storage unit linkages to blood banks (NACO, 2007e). At state level, reports are compiled by the 5th of every month, and feedback is given to the regional health officers by the 15th of every month. At the start of each year, monthly analysis of blood collection of the previous year is done to formulate strategies to compensate for the deficit in blood collection in a particular month (Ramani et al., 2009).

Supervision

At the District Level, the existing District Nodal Officer in charge of AIDS Control Programme in the district visits each and every blood donation camp organized in the district to ensure effective coordination. A monthly review of the implementation of blood bank using a check-list is also undertaken. At the state level, SACS officials such as Joint Director (Blood Safety) or Dy. Director (Blood Safety); Drug Inspector (FDA); SBTC official and an external technical expert develop a joint supervisory plan and undertake periodic supervisory visits to the blood banks in the state to assess the functional status, identify the constraints and methods to rectify them. At the National Level, a threefold supervision framework exists that includes the blood safety division at DAC; National Blood Transfusion Council (NBTC) and Technical Resource Group (TRG) on Blood Safety. Based on the performance, the states are categorized into, poor performing; Average performing; and Better performing states as per laid down indicators. The poor performing states are visited by the Consultant/Technical Expert once in a quarter, while other states will be randomly selected for supervisory visit. Officers of DAC also undertake supervisory visits to blood banks in

various States to review the status. Members of NBTC as well as members of TRG are assigned one state to give feedback to Department of AIDS Control on the overview of Blood Transfusion Services twice a year.

4.2.6. (v). Appropriate Use of Blood and Blood Products – Clinical use of Blood and Blood products

WHO recommends for the safe and rational use of blood to reduce unnecessary and unsafe transfusions and to improve patient outcomes and safety, thus minimizing the risk of adverse events including errors, transfusion reactions and transmission of infections (WHO, 2009a, 2014b). It is also suggested that blood and blood components should be administered only when clinically indicated at the lowest effective dose and frequency. Safer alternatives should always be used first whenever possible(MOH, 2009). Rational or appropriate use of blood means providing the right blood product, in the right quantity, for the right patient (WHO, 2002). It can help in bridging the gap between demand and supply of the precious blood or blood products. Patients who require blood or blood products, whether in life-threatening acute situations or as a supportive therapy in chronic hematological disorders, must receive the required components only (WHO, 2006). The safety, adequacy and effectiveness of blood supply can only be achieved if there are no unnecessary transfusions.

Strategies ensuring rational use of blood includes, Developing guidelines and dissemination at various levels; organizing clinical awareness training programmes; Setting up hospital transfusion committees (HTC) to promote strategies for rational use of blood; Promoting blood component therapy; Encouraging autologous transfusions and managing inventory of blood in order to avoid wastage and transfusion of untested or improperly screened blood (Bharucha et al., 2006).

In India, it is reported that the inappropriate use of blood is very common as single-unit transfusion is often given which is not very much useful. Many a times, transfusion of blood and blood products happen even there are safer alternative therapies(Kaur, Basu, Kaur, & Kaur, 2013). With no monitoring system in place, it is found to be difficult to ensure the rational use of blood as the use of blood in hospitals is hardly audited in India. WHO

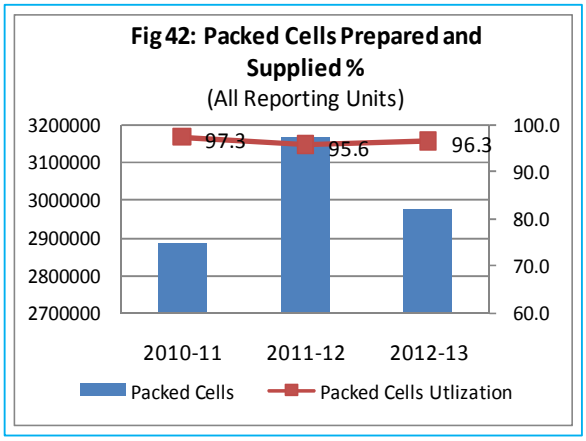
recommends that the ratio of the use of blood components and whole blood should be 90:10 since only a limited category of clinical interventions require whole blood. The use of blood-component therapy allows four patients to benefit from one unit of blood collected(Ramani et al., 2009). In India, 80 percent of blood is used as whole blood, only and 20 per cent units are utilized as components (NACO, 2007a). Choudhury (2011) reported that about 37% blood units are separated into components, and all collected units are tested for five transfusion-associated infections as on record. It was also reported that demand for components are not very high due to lack of awareness(Choudhury, 2011).

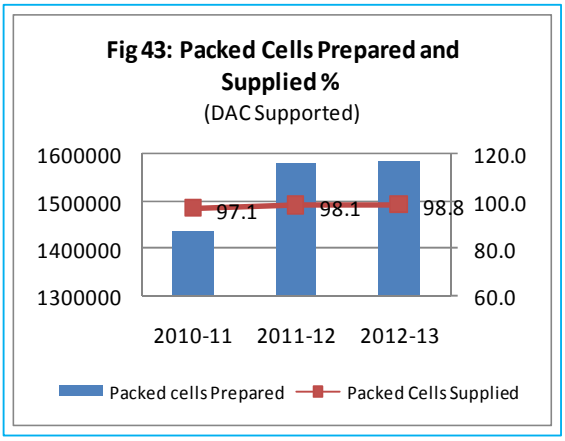
Though the Clinical use of blood is widely discussed in India, majority of blood banks collect and stock whole blood. Licensing requirements do not have mandates to suggest the blood banks to process the blood it collects into components or for institutions to introduce blood-use audits. India is continuing to request for single units of fresh whole blood, ignoring the fact that fresh blood is much more likely to transmit infection (Nanu, 2001). It is reported that around 30% of the blood units are wasted or inappropriately used in India (Gupte, 2002). Drugs and Cosmetics Act 1940 and Rules 1946 which forbids the transfer of blood from one bank to other under ordinary circumstances that really prevents the transfer of blood and blood products to high volume blood banks to other places in need of it.

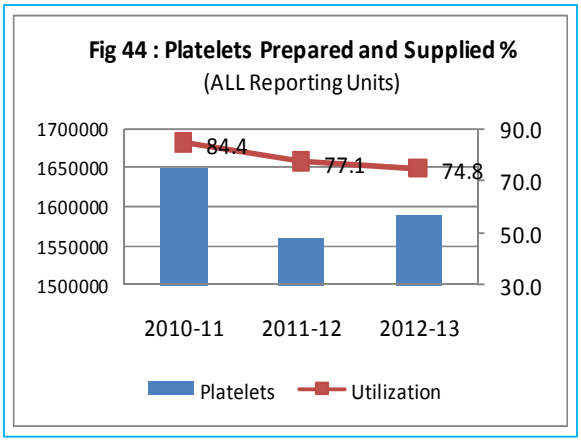
However, Department of AIDS Control reports that the practice of appropriate clinical use of blood amongst the clinicians has seen a definite rise due to the dengue epidemic, and training of clinicians on the rational use of blood (NACO, 2013). Blood Component Separation Units are being started and started working in their respective States, and the proportion of blood units processed for component separation has increased. Quality management modules were also prepared by Technical Resource Group to increase Blood Component separation in the BCSUs. A national guidelines on appropriate use of blood and blood products has been prepared and circulated (Gupte, 2002). Besides, Medical Council of India has made it mandatory that all Medical Colleges with post graduate training programme should possess a blood separation facility.

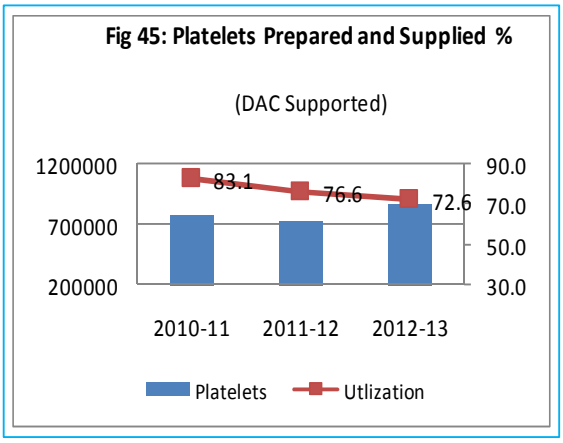
According to SIMS data, though whole blood and its components are prepared, the utilization per annum (supplied in the year is considered as utilization in this report) per annum indicates lower levels. For examples, utilization of platelets over three years is

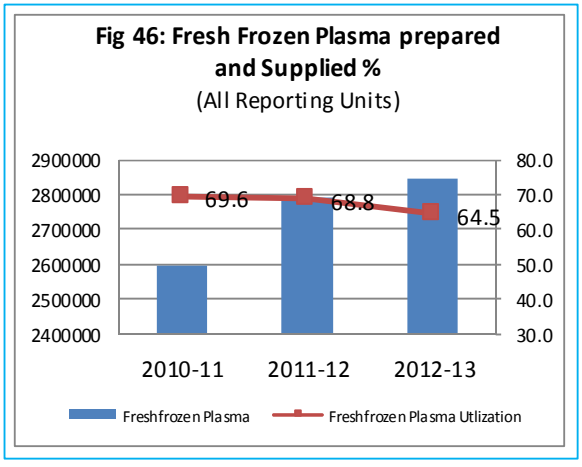
around 75 to 85%; fresh frozen plasma utilization is around 65 to 75% during the last three years. It is essential to develop and establish a systematic approach and operational guidelines to assess and ensure quality and quantity of blood components prepared across the country. Strategies also need to be planned to maximize the utilization rates of blood and blood components.

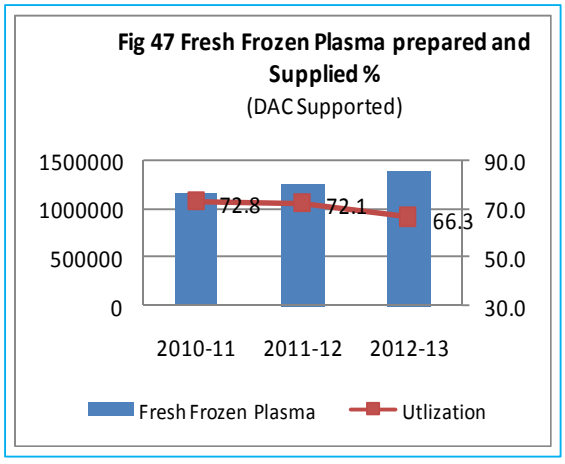


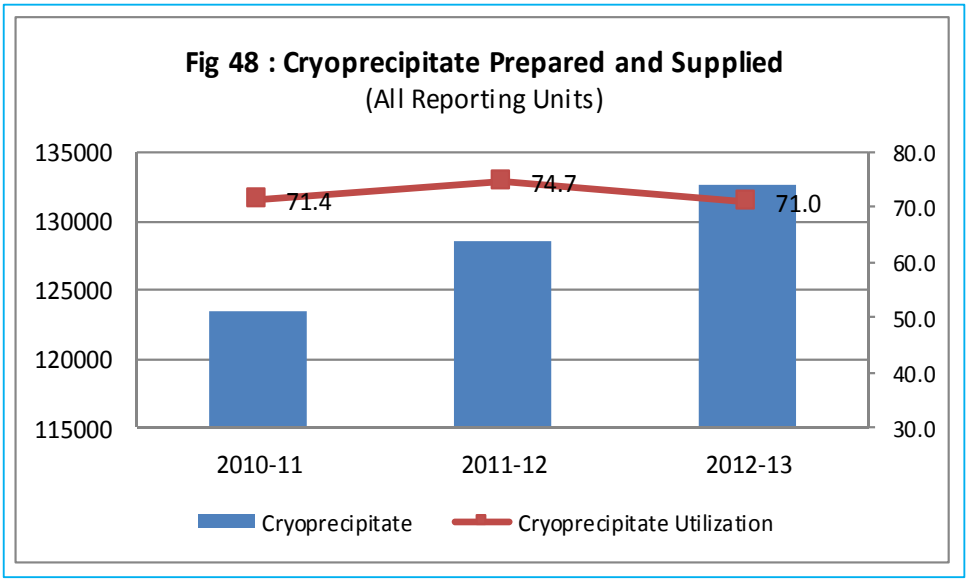












Haemovigilance

Monitoring clinical use of blood and blood products in India is weak, and there is no systematic analysis to measure adverse reactions following blood transfusion. Besides, Blood-banks lack registering or monitoring of total demand for blood and blood products for each blood group that could not be met due to the non-availability of blood or blood products. They do not report systematically the proportion of stored blood that expired due to non-use as well. This calls for Haemovigilance system which is required to identify and prevent occurrence or recurrence of transfusion related undesirable events, increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient (WHO, 2014a). The system includes monitoring, identification, reporting, investigation and analysis of adverse events including, reactions related to transfusion and manufacturing. These systems are designed in a way that it will define problems encountered in the entire chain of the transfusion process which in turn will facilitate to direct the efforts and resources appropriately; ensure that the endpoint of a safe and effective transfusion is achieved; and enable to collect, interpret and use information on the long and short term effects of transfusion.

Haemovigilance in India

The centralised Haemovigilance programme in India to assure patient safety and to promote public health, was lunched on 10th December, 2012 in 90 Medical Colleges along with a well-structured program for monitoring adverse reactions associated with blood transfusion and blood product administration. This program is being implemented under overall ambit of Pharmacovigilance Program of India (PvPI), coordinated by Indian Pharmacopoeia Commission (IPC). Currently there are 142 Centers under Haemovigilance Programme of India (HvPI) across the country. This programme has been launched with the objectives of, monitoring transfusion reactions; create awareness among health care professionals; generate evidence-based recommendations; advise Central drugs standard control organization (CDSCO) for safety related regulatory decisions; Communicate findings to all key stakeholders and to Create national and international linkages (Bisht, Singh, & Marwaha, 2013). In 2012, a guideline document for reporting Serious Adverse Reactions in Blood Transfusion Services was also developed by the National Institute of Biologicals (NIB), Ministry of Health and Family Welfare, Government of India. These guidelines are proposed for reporting the serious adverse reactions in transfusion medicine by the Adverse Drug Reaction (ADR) Monitoring Centers under Pharmacovigilance Programme of India (NIB, 2012).

The key characteristics of Haemovigilance Programme in India are, non-punitive, confidential, independent, expert analysis, credible, system oriented and responsive to the need. This programme in India has three phases. The Initiation phase (2012-13) that aims to develop systems & procedures; develop software; enroll participants; start data collection; conducting zonal workshops for awareness and publication of newsletter. The expansion and consolidation phase (2013-15) aims to continue enrollment; training of staff; continue zonal workshops; publication of newsletter etc. The expansion and maintenance phase (2015-17) is aiming for, maintenance and optimization; Identify gaps & address through appropriate training; assess feasibility of donor vigilance; rapid alerts and epidemiological surveillance for TTIs. There are clearly defined roles and responsibilities for each HvPI units. The Medical Colleges/Institutions/Blood banks are responsible for, collection and causality assessment of Transfusion Reactions, data entry into “Haemo-Vigil” Software, transmission of data to HvPI-NCC, NIB. The HvPI- Haemovigilance National Coordinating Centre, National

Institute of Biologicals is responsible for, review completeness of data Quality, preparation of SOPs, guidance documents & training manuals, publication of Haemovigilance Newsletter/ IEC Literature, and communicating recommendations of Haemovigilance Advisory Committee to IPC. The PvPI, National coordinating Centre, IPC is responsible for forwarding recommendations of NCC to DCGI- CDSCO. Finally, the DCGI- CDSCO is responsible for formulate safety related regulatory decisions and communicating Blood & blood products transfusion safety related decisions to all stakeholders. There are several IEC measures to increase the awareness of Heamovigilance in India. It is also proposed that all medical colleges of the country will be enrolled in this program by the year 2016 in order to have a National Centre of Excellence for Hemovigilance at National Institute of Biologicals (NIB), which will act as a global knowledge platform.

Hemovigilance programme in India, independent of BTS under DAC, is in its initial phase and there is a need for concerted efforts to make this effective and successful.

4.2.6. (vi). Technological Innovations in Blood Transfusion Services in India

In the rapidly changing world of biomedical science, automation and continuous technical advancements are inevitable. However, technical advancements in the field of blood group serology and transfusion did not have similar rapid advancements as it was perceived that no machine could take over the highly interpretative role of the skilled serologist (IBMS, 2014). It was proved wrong later, and there have been several technical advancements and innovations in blood Transfusion Services across the world. Providing health technology has been a priority in the Millennium Development Goals (UN, 2001). The escalating demand for safer blood donation and transfusion services; and appropriate use of blood and blood products is creating the need for more automated blood collection devices, such as leukocyte reduction filters, blood cell separators, etc. (MedicalBuyer, 2014b) (MedicalBuyer, 2014a). Besides, programmatically, technological innovations are essential to ensure universal access to adequate, safe and quality blood and blood products.

The technological innovations in India have happened both in clinical and programmatic management. India has coped up well in managing increasing requirement for microbiological screening of blood donations in addition to the provision of blood grouping and antibody screening. Earlier, syphilis testing was mandatory, and now a list of screening

tests is required for hepatitis B and C, HIV, and malaria, etc. Without the technology, it would have been impossible to ensure the supply of safer and quality blood and blood products.

However, the issue is that the benefit of technology are yet to reach across the country, and the lack of access to diagnostic techniques and blood transfusion technology is not much discussed (Hazarika & Dutta, 2013). Many states within India have also been facing the shortage of technological innovations and specialist services that affect the scale up of Blood Transfusion Services. Besides, in India few hospitals like All India Institute for Medical Sciences and Technology, New Delhi; PGI, Chandigarh; SGPGI, Lucknow; Nair Hospital, Mumbai etc., have adopted new technological innovations in Blood Transfusion services whereas other smaller hospitals are not able to adapt to the situation.

The key programmatic technological adaptations in Blood Transfusion Services is,

i. ***Electronic Integrated Blood Banking System (e-Blood banking)***

Although policies and guidelines are prescribed by governing bodies at national level, the implementation and efficiency of absorption of these policies & guidelines have been dependent on state's capacities. Some of the states have gone beyond the prescribed levels by establishing a very efficient system. They are, Odisha and Maharashtra, especially Odisha's has been recognized as a model by DAC (NACO, 2013).

In 2011, National Rural Health Mission, Orissa, with the support of the State Blood Transfusion Council and the Odisha State AIDS Control Society started e-blood banking services that linked 59 government blood banks with the expansion plan of linking all 81 in the state (Mohanty, 2011). E-Blood Bank is an integrated web based blood bank automation system that interconnects all the Blood Banks into a single network. The Management Information System (MIS) refers the acquisition, validation, storage and circulation of information which will also be able to put together the diverse data into comprehensible reports to support decision making from effective donor screening to optimal blood distribution to the end user (NRHMOrissa, 2014). This process facilitates online access to group-wise blood availability in the blood banks so that they can place a requisition of a particular blood group in a blood bank near to them. People can access

the information on blood stock availability through online, SMS & IVRS System, as well. Tracking the orders of blood bags is also made easier, and the user can also check the status of blood bags issued by the respective blood banks. This system manages the entire activities from blood collection both from camps & hospitals till the issue of blood to the user (eIndia, 2012). The Odisha model of integrated e-Blood Banking system has led to increased efficiency by bringing in accountability, transparency and easy access to information. Through this initiative, the challenges in BTS have been considerably alleviated with the use of technology, a particularly web-based system which further enhances the case for adapting integrated e-Blood banking in other states.

Following the successful implementation of this initiative, e-blood banking system has been initiated in Kerala as well (NewIndianExpress, 2012). However, the effectiveness of its functioning is not known.

ii. Nucleic acid testing (NAT) in Karnataka

Nucleic Acid Testing (NAT) method is an advanced screening technology that reduces the window period of transfusion transmissible infections (TTIs) and helps improve blood safety (Chandrashekar, 2014). This method screens the genetic material of the disease-causing organisms which can detect the infection faster than the conventional serology tests. ID-NAT detects HIV-1 within 4.7 days; HCV within 2.2 days as against relatively very longer period through the conventional ELISA (Yasmeen, 2013).

In Karnataka, the blood bank at Bowring Hospital, a government run institution adopted this method of screening in coordination with a private partner, since June 2011. This bank tests an average of 300 samples every day. A total of 1.3 lakh blood samples of donors from 30 government blood banks across the State have been tested till 2013 since the inception(Phadnis, 2013; Yasmeen, 2013).

4.2.6. (vii). Integration with the Health System and Convergence with NRHM, other departments and Ministries

Access to sufficient and safe blood and blood products provided within a national blood system is a vital component in achieving universal health coverage. It is the responsibility of every government to provide effective leadership and governance in developing a national blood system that is fully integrated into the health-care system, consisting of all the organizations, institutions, and financial and human resources whose primary purpose is to meet the transfusion needs of all patients within the country (WHO, 2013c). The national government is also responsible for the provision of adequate and supply of safe blood and blood products, and their rational use and should be an integral part of the country's national health care policy and system which should be supported by a strategic plan and appropriate legal instruments (WHO, 2011). Besides, an effective national blood system requires close coordination and collaboration with relevant government ministries, national reference laboratory and agencies and institutions for public health, surveillance, regulation, accreditation and plasma fractionation (WHO, 2011). It is also essential to establish a mechanism for the coordination of all public, private and voluntary sector institutions, organizations and agencies involved in the national blood system (WHO, 2012c)

In India, the major causes of maternal deaths in India are due to antepartum hemorrhage, post-partum hemorrhage. According to a the Sample Registration Survey, postpartum hemorrhage accounted for nearly 38% of all maternal deaths(Registrar General, 2006). Hemorrhage during pregnancy is generally not predictable and blood transfusion can be helpful in management of such hemorrhage. Thus, establishing blood transfusion services at all such institutions conducting deliveries is vital. Especially, in India, the District hospitals, CHCs and FRUs are required to have direct linkage with the blood bank or blood storage facility as FRUs treat emergency cases (GOI, 2011). This requires convergence of the program with NRHM, other State health departments, ESI, CGHS hospitals, etc. Convergence is also necessary as some commentators believe due to continued governmental negligence, blood-transfusion services in India are a highly-fragmented mix of competing independent and hospital-based blood-banks, serving the needs of urban populations (Ramani et al., 2009). There is also a need for strong coordination between health care facilities and blood banks or blood storage units, as lacunae in this will be a serious hurdle towards full utilization.

The main aim of convergence with NRHM is to ensure availability of whole human blood or its components to FRUs/CHCs/PHCs. The Drug and Cosmetics Act[i], was amended with the objective of setting up blood storage/ transfusion services at these health facilities functioning under NRHM without taking a license for blood storage/ transfusion facilities. However, this exemption is applicable to those centres and identified FRUs that are transfusing blood and/or its components less than 2000 units per annum. In order to ensure the safety and quality of blood and/or its components to be stored in such blood storage centers, the Ministry of Health and Family Welfare notification[ii] laid down some conditions that have to be met before getting exemption from the purview of taking of a license from the respective State Drugs Controllers. The Staff needed for a Blood Storage Centre - one existing Medical Officer and a lab technician, trained on for three days on 'Storage and utilization of blood' from some recognized centre. Guidelines for Setting up Blood Storage centers, by Department of AIDS Control were introduced (NACO, 2007b). DAC also supplied blood bank refrigerators of different types to a number of States. Department of Family Welfare, Government of India, took up the provision of equipment and training of staff for blood storage and transfusion in health facilities at identified FRUs, where emergency obstetric care services/institutional deliveries are being conducted. DAC has linked these centers with the nearest Regional Blood Transfusion Centre (RBTC) for the supply of screened blood on a regular basis and is regularly training the staff attached to the storage centers. Also, voluntary blood donation programme has been proposed to be clubbed with Anaemia Programme (NACO, 2013).

The outcome of this convergence initiative is that, in 2013-14, there are 745 blood storage centers functioning across the country. A minimum of 10- 15 units are available at the centers according to their consumption(NACO, 2013). According to Planning Commission's NRHM evaluation report 2011, there is a need to strengthen blood storage facilities in FRUs and sub-DH health facilities. In a few states like Assam and Jammu and Kashmir, shortage of blood banks and ill- functioning blood storage units is a serious snag towards full utilization of health facilities like FRUs especially for emergency and surgical services. Blood components are still not available for patient use as per licensing regulations at these blood storage centres (GOI, 2007).

In addition, according to National Facility Report RCH II, only 67.5% of the District Hospitals, 27.2% of the FRUs and 15.8% of the CHC were having linkages with the blood banks and regular blood supply was available only in 60.5% of the District Hospital, 27.% of the FRUs and 10.5% of the CHCs which is far from satisfactory (IIPS, 2005). Kerala, Tripura and West Bengal are the only three states with all the hospitals having linkage with district blood banks. The Health and Family Welfare statistics 2013 reported that only 14% of the CHCs have BSCs in which only 11.8% of CHCs in high focus NRHM states have BSCs. This recent data indicates an increase in the Blood Bank/ Blood storage units in the district hospitals that are 74%. It also indicates that only 42% of the functioning FRUs have facilities for blood transfusion (GOI, 2013). According to the District Level Household and Facility Survey 2007-08, only 9.1% of the CHCs have blood storage facilities which are designated as First Referral Units (FRUs); fully operational blood bank is available in 69 percent of the district hospitals. (IIPS, 2010).

4.2.6. (viii). Efficient Supply Chain Management and Quality Assurance

The blood transfusion service should have an efficient supply chain management in place to monitor and manage stocks in order to maintain an uninterrupted supply. Continuity in the supply of the assays reagents and consumables required for testing depends on reliable procurement and supply systems (WHO, 2010b). A national procurement system will require the development of specifications for equipment, test kits, reagents and consumables and assessment of the quantity and types required. The implementation of centralized bulk procurement with an efficient distribution system is likely to provide significant cost savings, simplify stock management and enable an uninterrupted supply of assays and reagents to be maintained.

In India, DAC supports the procurement of equipment, test kits and reagents as well as the running expenditure for government blood banks, and those supported by DAC (NACO, 2013). Most of the key items required for the programme - equipment, blood bags, reagents, including test kits (HIV-Rapid), HIV-Elisa), HBs Ag-Rapid), HBs Ag-Elisa), HCV-Rapid, HCV-Elisa and other items such as ARV drugs, STI drug kits, etc. are centrally procured by Department of AIDS Control and supplied to peripheral units and State AIDS Control Societies (SACS)(NACO, 2013). A consortium of 5 laboratories is responsible for quality

assurance of reagent kits-HIV, HBsAg, and HCV. In order to ensure quick maintenance, most of the equipment procured by DAC are under comprehensive maintenance or warranty. Procurement of goods is done through bids and minutes of pre-bid meeting and bid opening minutes are uploaded on the websites in order to ensure transparency. After central procurement, the goods are all distributed to the facilities directly. A comprehensive "Procurement Manual for National AIDS Control Programme (NACP III)" has been developed, and the respective officers' have been continuously trained on Procurement (NACO, 2007f) .

Supply Chain Management of blood and blood products is vital in blood transfusion services. Usually, the problems in India arise in terms of storage capability over time and the ability to move units from low demand to high demand centres to avoid outdating (Tirupathi, 2013). Central blood banks need to visualize the trends to meaningfully identify demand and set up a dependable supply chain system for effective utilization. In order to ensure quality, guidelines for supply chain management of blood and blood products is essential in terms of maintenance and use of blood cold chain equipment and management.

Few initiatives in India which strengthened the supply chain process of BTS services India, one among them is Blood Transportation Vans which are used for,

- Transportation of collected blood from Voluntary Blood Donations (VBD) camps to mother blood bank for processing; after processing, blood is being transported in these vans from mother blood bank to storage centres in FRUs in order to ensure blood availability in the remote areas (NACO, 2011a, 2013)
- Transportation of blood from the linked RBTC to the Blood Storage Centre. Each RBTC is linked to 6-8 BSCs in order to supply blood units under proper conditions and storage. DAC provided 250 refrigerated Blood Transportation vans to the RBTCs/district Blood Banks during NACP-III. These vans transfer blood units to the BSC on a regular basis and also on demand/ emergency situations.
- Blood collection and storage vans - With a capacity to stock 300 bags of blood and space to accommodate four blood donors simultaneously, donating blood has become little easier in the rural areas. The blood is then transported for processing in the same vans (NACO, 2013).

According to DAC, efforts are being made to streamline the Supply Chain Management of various supplies to consuming units includes providing training on Supply chain Management to the Procurement Officials of SACS in addition to hand-holding support to State AIDS Control Societies is being provided by the procurement division at Department of AIDS Control (UNAIDS, 2012).

4.2.6. (ix). Legal, Regulatory and Policy Dimension of Blood Transfusion Services in India

Laws and Regulations

Laws and regulations related to BTS in India are a part of the *Drugs and Cosmetics Law, 1940* under section 3(b), as Human Blood and blood components are categorised as a "drug" because of their internal administration (NACO, 2003). This Act and the Rules provide the legal framework for regulating the functioning of blood banks, which in turn determine the blood transfusion service delivery in the country (NACO, 2007a). Since initial formulation, the act has been expanded, and the rules have been frequently amended to integrate the concerns; and the amended act came into force with effect from April 5. 1999. Under this act and its rules, all blood banks in the country need to obtain a license from the Central License Approving Authority of the Ministry of Health and Family Welfare on the basis of recommendation of Director, Drug Control of the state by abiding the condition laid down in the Act and the Rules, that need to be renewed on expiry. The regulatory control is exercised under the dual authority of the State and the Central government.

A key aspect of the legal provision is that voluntary blood donation in outdoor camps can only be collected by a licensed Government Blood Bank, Indian Red Cross Society, or a licensed non-governmental organization designated by State Blood Transfusion Council constituted by the State Government. The legal framework concerning blood safety issue has been adequately outlined in the Schedule XII B of the Drugs and Cosmetics Act/Rules, which demands mandatory testing of blood for blood transmissible diseases, including HIV(SolutionExchange, 2006). The rules have been further amended providing adequate testing procedures, quality control, standard qualifications, and experience for blood bank personnel, maintenance of complete and accurate records, etc. In 2001, a notification was

issued to regulate and streamline the blood storage centres, which will help community health centres, small hospitals / nursing homes whose requirement is less than 2000 units of blood per annum.

As Blood transfusion can be lifesaving and also can be fatal, it comes under *fundamental rights of a citizen* according to Article 21 part III titled fundamental rights of the Constitution of India. Besides, the Indian Penal Code(IPC) Section 269 has provisions for fine and imprisonment for a negligent act likely to spread infectious disease dangerous to life and section 270 of the Malignant Act likely to spread infection of disease dangerous to life covers blood transfusion and blood banking in all aspects(GOM, 2014).

The consumer protection act also gives protection, whereby patients who received deficient services from medical professions and hospitals are entitled to claim damages under the Act. Blood banking service comes under this Act, and both donor and recipient may take the cover of this Act.

Few judgements and directives correspondingly gave direction to blood safety services in India. For example, the Supreme Court of India banned paid donations in 1997 and has ordered the establishment of an autonomous National Blood Transfusion Council and State Transfusion Councils (Pal et al., 2011). The Supreme Court in 1996 had directed the government to consider the advisability of enacting legislation to regulate the collection, processing, storage, distribution of blood, and the operation of blood banks. The supreme court also directed to amend the, Section 80G of the Income Tax Act, 1961 so as to make all donations to the National Blood Transfusion Council (NBTC) and to the State Blood Transfusion Councils (SBTCs) eligible for tax deductions from the taxable income of an Assesse.

In 2012, following a public interest litigation to make PCR test as mandatory, the Gujarat high court had directed the Ministry of Health and Family Welfare, Government of India, to constitute a body of experts to examine the feasibility of making PCR tests mandatory at all licensed blood banks across the country. Subsequently based on the committee's report, though the court has recognized the superiority of PCR Test compared to ELISA, it refused to

give an order to make Polymerase Chain Reaction (PCR) test or the nucleic acid amplification test (NAAT) compulsory instead of ELISA to screen HIV infection during blood transfusion.

In 2013, the Gujarat high court once again gave a landmark judgment, which clearly stated that it would be the duty of the state government to appoint sufficient number of inspectors to ensure that rules for running of blood banks are strictly complied with as per the National Blood Policy. It ordered that all blood banks should display a rate card of the blood as per NBTC rates. It also directed the committee to ensure that the blood banks in states do not indulge in profiteering or charge more than the rate prescribed by the ministry of health and family welfare and to Evolve a policy to make it clear as to what constitutes profiteering including the penal consequences of the offence of profiteering.

Following these landmark judgments, the Department of AIDS Control, Ministry of Health and Family Welfare, and the National Blood Transfusion Council, in its 24th Governing Body council approved a guidelines for recovery of processing charges for blood and blood components. The guidelines also indicated that it is mandatory to provide blood free of cost of those who needs blood transfusion regularly such as, Thalassemia, Haemophila, sickle cell anaemia, and another blood dyscrasia requiring repeated blood transfusion. All these legal measures and key decisions by the Government, helped to ensure transparent procedures in blood transfusion services and increase the access to safe and quality of blood.

Blood Transfusion Policies in India

Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP) and quality systems are the major challenges to the organization and management of blood transfusion services in order to achieve maximum safety for any nation (NACO, 2007h). Keeping these challenges in mind and to ensure quality, equity in blood transfusion services, National Blood policy was introduced in 2002 which will also ensure the implementation of the directives of Supreme Court of India - 1996.

This policy aims at ensuring easy accessibility and adequate supply of safe and quality blood and blood components collected from Voluntary and non-remunerated blood donors in

well-equipped premises, which is free from TTIs, and is stored and transported under optimum conditions. Transfusion under supervision of trained personnel for all who need it irrespective of their economic or social status through comprehensive, efficient and a total quality management approach will be ensured under the policy (NACO, 2007d). The national blood policy also defined the authority and responsibility for service, the importance of voluntary blood donation, the means of funding, and legislation required to ensure safe and quality blood transfusion services in India. Establishment of blood transfusion councils and focusing on an integrated strategy for blood safety were emphasized the National Blood Policy which is of great value.

The policy in 2002 followed by Action Plan for Blood Safety in order to operationalize the priorities and objectives set out in the national blood policy and to address the infirmities in existing systems in terms of quality, structures, linkages and procedures that govern the blood transfusion services in the country. Each Section of the Action Plan reiterated an objective mentioned in the National Blood Policy (NBP), 2002, and all objectives of the NBP were addressed. Each objective cited is followed by a listing of diverse and wide ranging operational strategies whose implementation calls for a multi-agency response from the government, the private sector, the Red Cross Society of India, the Indian Council of Medical Research, Medical Council of India, NGOs / CBOs and others.

4.2.6. (x). Ethical Issues in BTS Services

In parallel with the increasing awareness of ethical issues in every field of health care and research in India, knowledge and awareness are mounting in transfusion medicine, as well. However, the adherence to the international code of ethics is very low in India (Elhence, 2006). In 1980, the International Society of Blood Transfusion (ISBT) endorsed its first formal code of ethics that was later endorsed and adopted by the World Health Organization and the League of Red Crescent Societies. A revised code of ethics for blood donation and transfusion was endorsed in 2000, with inputs from various concerned organizations that gave recommendations regarding the ethical responsibilities of the donor, the collection agency and the prescribing authority toward the well-being of the recipient and the community at large.

The 1996 Supreme Court's order of banning professional and commercial blood sellers has made a significant impact practicing ethical principles that has also directed the government to formulate a national blood policy. The National Blood Transfusion Council, with the National Blood Policy as a tool, and the Drugs Controller, with the help of the Drugs and Cosmetics Act, now aim to ensure blood safety and ethical transfusion practices in India. According to the present guidelines, consent for testing is taken, and the donor is given the option of receiving the results. However, following the standard guidelines is not present universally which leads to ethical issues. The Code of Medical Ethics that is binding on doctors honours confidentiality. However, in a court of law in India, this privilege is not absolute but qualified. Doctors can reveal information in the interest of individual or general welfare of society and when there is no mal-intention.

Ethical issues are mostly violated in relation to the patient in India. Patients all over the country do not have access to safe blood free of charge, the option of giving consent and choosing safer alternatives. In addition, ensuring voluntary non remunerated donation, anonymity between donor and recipient, wastages, donor confidentiality, donor notification and donor consent are the areas still need improvement. It is also important address all the other issues in the international code of ethics for blood donation and transfusion to make India achieve international standards.

SECTION – B

Site Specific Observations

5. Site Specific Observations

The objective of the site specific observations was to understand the current status of the blood banks in terms of human resources, equipment, supplies (reagents, kits, etc.), performance, VBD camps, and quality management practices; the gaps, issues and challenges of blood transfusion services in their respective areas.

As mentioned in the methodology earlier, 15 blood banks from five zones were visited for observations. First Referral Units were also visited for observation wherever possible. In addition, a Joint Director of Blood safety and a state drug controller from each zone were interviewed in-depth to get their views on the management of blood transfusion services in the region.

A team of assessors comprising of two experts in Transfusion Medicine for each zone (South, North, East, West and North East), and observers from DAC, CDC and CMAI, visited the predetermined sites. The experts were selected from the panel, available with DAC who had experience of conducting such assessments in blood banks.

The key observations have been analysed thematically and presented in sequence. The differences between zones have also been captured. The key themes include, Human resource,

5. I). Human Resources

Staffing pattern: The staffing in blood banks is supported from either budget allocations from the state health services or State AIDS Control Societies. However, staff vacancy exists at different levels primarily due to lack of allocation of funds. In addition, the positions are not filled or lying vacant in many places, in spite of sanctioned positions. This situation is observed relatively higher in Government facilities compared to Voluntary / Charitable institutions. In few states, the staffing positions funded by the respective SBTCs have been withdrawn due to low workload at the facilities that is mostly due to a reduction in the number of voluntary donors. The range of staff vacancies indicate more variation on the North (0 to 75%) and South (0 to 50%) compared to the other zones where the situation is

better and 85-100% positions are filled. Moreover, vacancies are observed higher in the District level blood banks (0 to 75%) compared to higher facilities.

> *"I am a pathologist from the hospital side and on additional duty as Blood bank Medical Officer. One Sr. Lab Technician from UP Govt. is posted who is also retiring in October 2014. There is one more technical staff through UPSACS. With this manpower how do you expect us to ensure quality?"*
>
> *– A BB MO in charge*

In few facilities, medical officers exclusively for blood banks are not available and in many places, only technicians are posted. In few sites, it was also suggested have staff such as PRO, social worker, counsellor, quality manager, data entry operator and driver which would increase the effective functioning of the blood bank activities.

It was reported that there is a disparity between state government funded technicians and SACS funded technicians in terms of salary, capacity building and work load. The workload and responsibility of the SACS appointed/trained technicians were reported to be higher as they are required to carry out the data management work in addition to their technical responsibilities.

> *"We need to give power and authority to Blood Bank Medical Officer to make decision and handle local administration"*
>
> *-JD BS of SACS*

Morale of the staff: The morale of the staff appointed by SBTC/SACS was found to be lower as they perceive that they are given consolidated salary, and benefits are reported to be not on par with the other state government employees. The increased workload combined with a lack of incentives was indicated as one of the reasons for the high staff attrition in these facilities. The interviews with Joint Directors (BS) highlighted the difficulty of maintaining or retaining the trained personnel due to frequent transfers in addition to staff attrition due to perceived factors like, contractual position with consolidated pay; salaries and

> *"Whenever there is a shortage of staff, they extend our duty hours. But we do not get any benefits".*
>
> *– Lab technician, IBTM*

increments not on par with the government staff; and increased work load compared to the state government employees.

Coordination within the facilities: In few facilities, lack of active participation and involvement of the pathology department was reported.

Capacity Building: It was observed that the majority of blood bank staff have not been trained in advanced technology in Blood Transfusion Services. Many of them still follow outmoded technology for pre donation checking, Blood Grouping and compatibility testing. Though there has been improvement in the training status of staff, not all technical staff have been trained in Blood Safety under SACS. A few sites that have given information on training indicate that more than 75% of staff have been trained.

> *"The knowledge levels of Lab technicians are at diverse levels and most of them do not understand English. In addition, lack of hands on training results in poor outcomes of capacity building initiatives. CPR training is also essential for all Blood bank Staff"*
>
> *–DD BS of a SACS.*

The Joint Directors (JD) of Blood safety in the states expressed that regular capacity building programs and exposure visits have been carried out to strengthen the capacity of blood bank personnel. There are 17 DAC identified training centres, however, they are not geographically well distributed. The training centers in the state conduct an average of 3 to 4 training programs annually using the DAC approved training curriculum with the financial support from DAC. It was also perceived that capacity building component witnessed several challenges due to shortage of manpower (trainer and trainees) and, regional level coordination. Training facilities are facing challenges due to factors such as, uneven knowledge level of Lab Technicians; ability to understand language (English); short duration of Training; insufficient fund for logistics and accommodation; lack of hands on Training; and lack of updated training modules. Lack of training for Medical Officers and Nurses in rural areas has also been stated as one of the challenges. The importance of having of more training-

> *There is no structured program to follow up the training participants and observe the impact of these training programs and quantify actual change of practice.*
>
> *- Joint Director(BS) of a state*

of-trainer/trainers, and training centres; and training for private blood banks were emphasized as key requirements.

Besides, JDs of SACS mentioned that they are carrying out mentoring visits to the facilities. For instance, a minimum of one visit is being carried out by TANSACS in a year, whereas it was 2 visits with MACS. It was pointed out "training needs, pre & post counseling, cleanliness, logistics, bio-safety, equipment management and voluntary blood donation" were the key areas of focus during the supportive monitoring visits. Technical experts from medical colleges or other BCSU's, retired blood bank personnel's or core committee members were involved in the monitoring visits. Lack of staff and frequent changes in SACS staff were quoted as the challenges of having regular mentoring and monitoring visits.

5. II). Equipment and Supplies

5. II. a) Supplies

It was reported that supplies from DAC have become increasingly irregular especially over the last year that led to the shortage of supplies (2013). In these situations, the Government Blood Banks were asked to purchase supplies from local fund that is through state government budget. Besides, the blood banks were left with no choice in terms of the quality of kits and blood bags and forced to buy whatever was available. However, it was observed that the voluntary / charitable institutions were able to overcome these situations as they were able to use their own funds to avoid stock outs. Facilities in South, North & East zone, have reported having inadequate supplies compared to their western and northeastern counterparts. Most of the higher level facilities (major and model blood banks) reported having adequate supplies. There were vast differences in the supplies across zones, as mentioned above, clearly indicating the lack of initiatives by the respective SACS.

> *"Supplies are becoming increasingly erratic – especially over the last year. Most times, we are left with no choice about kits and blood bags to be purchased except to go for whatever is available at short notice that compromise the quality"*
>
> – *A Blood Bank Medical Officer.*

The Joint Directors of SACS also highlighted continuous issues of erratic supply and mostly short supply; and supply chain management issues. The blood banks in Tamil Nadu state have been addressing the issue of shortage of supplies through state government funds. .

5. II. b). Equipment and Maintenance

In few facilities, critical equipment like refrigerator, ELISA reader & washer, Serological water bath and autoclave were not adequate in number or not available. Some of the blood banks have been facing issues in transporting kits and storing. In few facilities, the bags are stored in non-a/c rooms. The Joint Directors reported that they find it difficult to cover the entire requirement of blood bank due to limited funding availability.

It was observed that there is a shortage of trained manpower to maintain the equipment internally. Most of the temperature monitoring are manual on charts that require constant human attention. Though there are annual maintenance contracts (AMC) for some equipment, there is absence monitoring mechanism to ensure quality or quantum of work to maintain the equipment. During emergency situations, Blood banks do not have an option but to go to other private operators to get machines repaired at additional cost. Facilities in South & West zone have reported having regular annual maintenance contract for most of the equipment. Other zones lack this system, leading to inefficient functioning and lack of quality service provision. Most of the higher facilities (major and model blood banks) do not have adequate maintenance facilities compared to district level facilities which have good systems. This could be due to higher cost of AMC.

> *"Most of the crucial equipment are not working as there is no AMC by SACS. So, how do we manage the equipment?"*
>
> – *Staff, Central Blood bank*

> *"There are 9 sanctioned lab technicians. Only two are qualified. Other seven are only 10th passed with CMLT qualification and on contractual pay of Rs 3,000 per month"*
>
> - *A BB Medical Officer*

Calibration of equipment is not being performed at desired frequency in many government centres as calibration is reported to be expensive. Details of equipment were also not

maintained, for instance, equipment were not having ID number and usages. It was also observed that most equipment in few sites are kept idle and not utilised at all. It is also evident that there is no structured condemnation and replacement plan for non-functioning equipment both under Government budget and DAC provision.

5. II. c). Adequacy of Blood and blood components generated

Majority of the blood banks (Model, BCSU & Major BB) are meeting the demand for blood thanks to the increasing number of blood donation camps. Facilities from almost all the zones are reporting adequate number of camps for collection of blood. Higher facilities like major, BCSU and Model blood banks collect at a range of 3,000 to 35,000 units per year. District level blood banks collect an average of 1000 to 9000 units per year with the exception of a Voluntary BB in Bangalore that collects 35,000 units/year. Though blood storage facilities do not conduct camps, few sites which were visited during this assessment *(CHC, Jowai, Meghalaya)* do have a huge potential for conducting camps and upgrading themselves to District Level Blood Bank (DLBB).

However, the blood banks lack a structured program to organize camps as well as to recruit donors. They are heavily dependent on Non-Governmental Organizations (NGO) or religious organizations to organize camps. During the time shortages especially in summer and fever seasons, medical officers are forced to request these organisations to conduct camps or to bring in donors. Though it creates a good link with the community based organizations, the over dependence of them sometimes lead to a shortage of blood availability. Facilities facing challenges in organising camps are depending on mobile donor units. However, due to shortage of staff, they use the services of trained DMLT students (technicians), nursing students, post graduates or medical students (doctors) and contract employees (support staff) which usually lead to increased rejection in the bags with reasons of “incomplete collections” and “vein/needle blocks”.

> *“We only get 5 units per month from our mother blood bank that is not enough. Our requirement is 10 per month. The mother banks find it difficult to fulfill their own requirement. We are forced to refer patients to other higher facilities in case of stock out”*
>
> – *MO in charge of a storage centre, CHC*

Component Separation: Separation of whole blood was found to be very low in certain facilities and the primary reason is lack of demand for components from the clinicians. This stresses the need for regular training of clinical staff on the rational use of components. According to interviews with JDs, a range of 45 percent to 80 percent of whole blood is separated as components; it was also mentioned that adequate facilities are available for component separation and storage in the states. However, in Meghalaya only 2 BCSU's are functioning for the entire state, but located in one district. The JDs expressed that though there are no structured program or guidelines to improve access to blood and components "Networking with Government run blood banks to transport blood with existing transport facility, inception of 'blood on call' system and process of increasing Blood Banks, BCSU's and BSC's" were the methods adopted so far to improve access of blood and blood components.

> *Effective linkages within Blood Banks and geographical mapping were the requirements to be fulfilled in order to improve the access to blood and component.*
>
> - *JD of a SACS*

5. II. d). Voluntary Blood Donation

Overall, the rate of voluntary blood donation has been increasing across facilities during the last five years. Most facilities reported a higher proportion of voluntary donation especially from camps. The volume of blood units collected under voluntary blood donation was found to be low between the month of May and July. VBD was reported to be poor in North East zone (10- 50%) followed by North zone (60 - 80%) whereas other zones reported high VBD rates (>95%).

> *"100% of our collection is from voluntary donors, and 30-40% is from repeat voluntary donors mostly from a rich source of young, healthy, educated and socially aware voluntary donors. We conduct camps 5 days a week and sometimes twice a day. We maintain a department for donor recruitment whose role is to develop and sustain the contacts required, and to organize a calendar for this intensive schedule. We have also effectively leveraged the influence of socially committed leaders in the community to organize and mobilize voluntary blood donors"*
>
> – *A charitable Rotary blood bank,*

All the facilities do not maintain the data related to repeat voluntary blood donation, however, it was observed that the rates of repeat donation vary from 2 to 40%. This was between 10- 40% in south zone facilities and 2- 7% in North zone facilities. Facilities in the other zones were not able to provide data related repeat voluntary donors. The lower rate of repeat donation could be due to the increasing number of camps organised across the cities, which leads to lack of importance on motivating repeat donors.

Few blood banks do maintain a directory of voluntary blood donors and agencies who can organize camps, which is found to be useful to approach them in times of emergency. Donor motivation and felicitation programs have been organized by SBTC in some blood banks.

Few blood banks stated that they need sufficient funds to conduct outdoor blood donation camps. It was also suggested that the Department of Education should issue directions to educational institutions (colleges) to conduct blood camps in order to increase the voluntary blood donation. In few sites, blood banks have PROs who manage and organize camps, but PROs do not exist in most district level blood banks, in the Government side. It was reported that having PROs in all the blood banks will increase the proportion of voluntary blood donation.

5. II. e). Blood screening mechanism & discard rates

It was observed that screening of blood was in conformity with standard guidelines. Screening for TTIs such as, HIV, HBV and HCV have been done by ELISA; Syphilis by RPR test; and Malaria by microscopy. Positive samples are retested by rapid test. Donor notification and referral to ICTC are happening in most facilities. However, there is no feedback or follow-up mechanism for these donors who are referred. There is not much of a variation across the types of blood banks in terms of screening for TTIs. Though all the facilities are screening for TTIs, the facilities in East zone seldom do haemoglobin estimation that is critical and require strict compliance to standard procedures.

In few zones, screening is being done before collection and the donors are deferred if they are found positive for any TTIs. This process is not confidential and unlinked. Discard rates are low in many facilities due to selective collection and appropriate use of blood. The

discard rates are consistently low due to pre-screening deferral, as well. It was observed in few facilities that seropositive blood was discarded without autoclaving. Though, it is not a mandatory requirement, donors who are tested positive for Hepatitis B and C are not being given adequate attention and guidance through counselling in most facilities that is an area of concern.

5. II. f). Standard Operating Procedures and Quality Assurance

Most blood banks across zones have written standard operating procedures (SOPs). Though North Zone has written SOPs SOP, they are not in compliance to that.

Many blood banks are not carrying out any quality assurance program for Blood screening for an infectious agent, compatibility testing, component separation, kit and reagent quality. Only, West zone facilities were observed to have a good national EQA program in place. Participation in EQA program was found to be better in District level blood banks compared to all other higher facilities. From the interviews with JDs, it was observed that they hardly get feedback on EQAS and "there is no consistent participation". In few facilities, it was observed that equipment were not being maintained properly and calibrated. Blood banks found it difficult to check the quality of reagent and antisera prior to purchasing as these are either supplied by DAC or purchased on an urgent basis when there is short supply.

Most blood banks perform internal quality control (IQC) on cells and serum using pooled donor cells and serum. Cells used are created in-house from donor blood. Facilities in South and North East zone reported having effective internal quality Control mechanism and the other did not report so. Internal Quality control was found to be better in District level blood banks compared to all other higher facilities. Biomedical waste management regulation is adhered in most sites; however, few facilities in North and East zone do not adhere to these practices.

In few sites, staffs of blood banks have not been vaccinated for Hepatitis B which raises concern on the occupational safety of them. Most blood bank staff expressed their willingness and desire to participate in EQAS programme, but they face financial restrictions.

This clearly indicates the need for strengthening the IQC, EQAS and adherence to SOPs, in all blood banks especially in the North and East Zones.

5. II. g). Referral and linkages

It was observed that there is a significant improvement in referral and linkages in blood banks. Facilities in South zones were reported to have good and effective linkages with an average of 5- 15 hospitals in the vicinity; the blood storage centres in the Northeast have good linkages with higher facilities; however, facilities in North and West zones have poor referral and linkages with PHC/ FRUs. East zone did not report the status. Most District level blood banks & Major Blood banks have better linkages with tertiary care centres. Higher level Government facilities and IRCS have good linkages with blood storage centres in hospitals, and district blood banks in the vicinity. Besides, few blood storage centres were observed to have effective linkages with their mother Blood banks, for instance CHC Jowai with mother blood banks in Shillong. However, supply of blood to BSC has always been low due to shortages in the mother blood bank itself. However, it was also observed that some blood banks are not effectively linked to any PHC/BSU/FRU, Model Blood Banks, Tertiary Hospital and NGO trust.

> *"We have linkages for the supply of blood and components to blood storage centres in 14 Hospitals and district blood banks in remote northern Karnataka. We feel that captive nature of Blood storage centres to selected facilities must be removed and there should be free access to transfer blood across facilities in the vicinity"*
>
> – *A charitable BB, Bangalore.*

> *"We have a plan to link 11 storage centers of which 2 are already functional. We also have 'Blood On call 'scheme started. We are yet to evaluate the outcome of it"*
>
> *–MO of a BB*

It was suggested by staff that blood banks should be effectively linked to other blood banks and BSUs in that area for effective utilization of excess blood and to permit transportation of blood across state borders in ensuring access to blood and components in border areas.

5. II. h). Transportation of blood and blood products

It was observed that there is a significant increase in access to blood and blood products across the country due to continuous and various efforts. According to the JDs in the states, the states have vehicles *(range: 0-18 per state)* to transport the blood during the need and to ensure efficient supply chain management. In-addition to the vehicles, blood transportation boxes, are available in states like Meghalaya. The availability of mobile blood bank (except MACS) has also improved the situation. For instance, Tamil Nadu has three mobile blood banks of which two were supported by DAC and the remaining was the state government funded; Maharashtra has two; one with GMC Nagpur and one being shared by all centers. The JDs also expressed the challenges of operating mobile blood banks with inadequate staff; underpaid drivers; poor scheduling of payment to drivers; low budget allocation for equipment maintenance; and difficulty in maintaining the cold chain. The need for customized blood mobile units that suits to terrain of few states was stressed by the JDs.

> *"Clear guidelines and rules regarding exchange of blood between blood banks are required"*
>
> *–DD BS of a SACS*

> *"Maintenance of mobile vans is not fully supported. Cold chain maintenance is also a problem"*
>
> *–DD BS of a SACS*

5. II. i). mmunohematology parameters

It was observed that there are huge variations in Immunohematology testing across facilities. In District level blood banks, primitive techniques such as, slides and tile method are used for blood grouping. Cross matching is being done by tube method and occasionally by direct and indirect coombs's test. In higher facilities, blood grouping is done by tube method in addition to reverse grouping. Coombs test is also performed if required.

Grouping & cross matching: Facilities in North and East use tile and slide method for blood grouping respectively and the remaining use tube method. Facilities in East use slide method for cross matching and all other facilities use tube method.

5. II. j). Record maintenance, Documentation, Reporting& Monitoring

In most facilities, though registers are in place as per regulatory requirements, completeness is a concern. Especially, facilities in East zone do not maintain appropriate registers and most are incomplete. Record maintenance and documentation are at below average level in BCSUs and major blood banks, and other facilities are adhering to the requirements.

In few sites, donor registration form needs revision. Referral register of sero-reactive donors to ICTC and the outcome is being maintained in many sites. Cell and serum grouping register is also not maintained in few places. Few facilities do not have computers and internet facility.

The JDs mentioned that they are using SIMS for data collection, whereas, MSACS and MACS still use CMIS. According to them, monthly reports are regularly sent to DAC, but they hardly get feedback. It was also stated that the data are helpful for program planning of SACS. Especially, the analysis facilitates the blood banks to effectively plan to improve their blood collection and component preparation during outbreak of certain diseases. It was also reported that the NERO provides technical support in program planning by facilitating analysis of monthly and quarterly CMIS outputs.

> *"Technical input requirements and the data generated is very high in all states. We are in need of technically qualified persons- preferably MD transfusion medicine to initiate and sustain research on such areas"*
>
> *- A JD-BS*

5. II. k). Regulation and Licensing

According to the drug controller in Tamil Nadu, only 40% of the blood banks' licenses were renewed in the last year, and the reasons were mainly due to the delay in rectification of defects by the blood banks, noticed during the joint inspection. It was also reported that nearly 0.5% of blood banks license is cancelled every year due to non-compliance of the rules and regulations. However, in Meghalaya 100% of blood banks' license were renewed in the last year.

The Drug controllers accompany the JD blood safety during joint supervisory visits. The visits are conducted only once a year. The coordination between SACS and SBTC for these joint visits is the key challenge expressed by the Drug controllers.

SECTION – C

Issues, Challenges and Recommendations

6. Issues, Challenges and Recommendations

6.1 The Structure and systems of Blood Transfusion Services in India

Though there is a significant improvement in the blood safety services, there are several structural and systemic issues that need to be addressed.

- In India, Blood Transfusion Services are highly fragmented and different organizations play different roles in licensing, controlling, and regulating blood-banks (Ramani et al., 2009). Two parallel systems are in place to monitor the blood-safety Programme in India—NBTC/SBTC and NACO/SACS. While the Department of AIDS Control (DAC) was responsible for ensuring the safety of blood supply, it had limited ability to enforce a ban on professional donation or even to strengthen licensing requirements. National Blood Transfusion Council is the apex policy-making body for blood transfusion services but these bodies have an advisory role and have no control over the blood banks (Pal et al., 2011). Problems and issues facing the provider and the end user in each of these settings are, therefore, unique and each one needs to be addressed in the context of our current organizational structure. Merits and demerits of working towards a centralized system need to be carefully evaluated. Implementation of any change requires a careful feasibility study and the strategy of moving towards such a system planned in exquisite detail before considering implementation.

- The absence of a centralized national transfusion service leads to lack of accountability on many fronts – from donor recruitment to component preparation, testing protocols, appropriate use of blood / components and costing. A major problem plaguing blood banks is poor monitoring and control because of the multiplicity of agencies involved (Tripathi, 2005).

- All SBTCs are functioning under the SACS except Maharashtra and Nagaland, and since SACSs have many other responsibilities, blood safety functions may not be receiving adequate attention (Ramani et al., 2009).

- Conceptually creation of the state of the art and model blood banks is ideal and the structure trickling down to the peripheries in the form of blood storage centres forms a good pyramid. However, implementation of standard practice, quality systems, teaching and research requires a tremendous amount of manpower – which we currently lack. Infrastructure will be the easiest part of the algorithm to create. Follow through to ensure accountability on all these fronts is vital.

- There is a huge disparity in the availability of BTS services at the state level. The less developed states like UP, Orissa, Jharkhand, MP have lesser number of blood banks that has a direct link with the blood units collected(Refer Fig 4 and 7). Especially availability of blood transfusion services in the geographically remote areas and difficult terrain particularly bear the brunt of this inequity.

6.2 Demand and Supply

It is evident that the gap between demand and supply is narrowing down. However, there are still issues that need to be addressed.

- It is evident that currently there is a mismatch between demand and supply of blood and its products. Literature also reveals that deaths are reported at childbirth or in accident cases, due to lack of timely availability of blood. Surgeons, obstetricians and other qualified clinicians are now available in rural areas who are handicapped in saving these lives because of non-availability of blood (CDSCO, 2013).

- It is also predicted that the demand will increase due to the ageing population, high rates of accidents and injuries(Williamson & Devine, 2013)

- New approaches to recruitment and detainment of future generations of blood donors are needed. Integrated approaches in bloodstock management between transfusion services and hospitals are critical to minimize wastage-E.g. Using supply chain solutions from industry (Williamson & Devine, 2013).

6.3 Transfusion Transmitted Infections

- Screening blood for Hep B surface antigen alone which is currently mandatory in India has little impact on reducing post transfusion Hepatitis. Hep B surface antigen is considered as less effective in screening, and there is a possibility of missing out a significant amount of cases. Whereas other developed and few other developing countries, follow core antibody screening.

- There is no standard method prescribed for Malaria screening. The current practice is screening Malaria by any acceptable method. Generally, peripheral smear is being done and very few centres are practicing ELISA. But for those centres that collect huge volume of blood, screening Malaria is labour intensive.

- In India, there is no system or an action plan for follow up if the patient is found to be positive.

6.4 Augmentation of Voluntary Blood Donation(VBD)

There are several factors hindering voluntary blood donation that need to be addressed on order to achieve the adequate, safe and quality blood and blood products

- Even though Indian law forbidden collection of blood from paid donors, many times health care facilities are forced to accept blood from paid donors as there is scarcity of voluntary blood donors (Sabu KM, 2011). There are several factors affecting the voluntary blood donation in the country. Although many individuals are eligible to donate blood, numerous awareness campaigns promote its importance and a good proportion of the population shows a positive attitude towards blood donation; only a smaller proportion actually ever donates blood voluntarily (Riley, Schwei, & McCullough, 2007). It was observed that higher the income, percentage of non-donors was high, which means it is the poor unemployed and servicing people who are the backbone of the blood donation programme (Shah, Pallavi Patil, Deepika Sawant, Madhavi Deokar, & Puranik, 2011). Physical harm, fear, possible illness, and inconvenience of giving blood were found to be the common reasons for not

donating blood (Juarez-Ocana, Pizana-Venegas, Farfan-Canto, Espinosa-Acevedo, & Fajardo-Gutierrez, 2001; Singh Bir, 2002). Another study reports that the hesitation towards blood donation is mainly due to inadequate and incorrect knowledge for its necessity and misconceptions (Shenga, Pal, & Sengupta, 2008). The interaction with staff of health facilities is also considered as One of the important factors motivating people for donating blood (Mullah, Kumar, Antani, & Gupta, 2013). Fear of learning HIV status and mistrust of confidentiality are also considered as obstacles to blood donation many places. The widely prevalent indigenous fear is ("khoon ki kami " or a volumetric deficiency of blood) one of the important reason for not donating blood (Sharma, 2011).

- Nationally, in the donor profile, youngsters and females are underrepresented. SIMS data also indicates the same. The involvement of youngsters is essential to ensure repeat donations (Sharma, 2011). Strategies to increase the donation rates among the younger generation, increase the number of repeat donors and to secure wider community support for blood donation are required.

- Strategies to increase the awareness on the importance of blood donation among young people, including high-school students and young mothers are required.

- IEC materials need to focus on providing correct knowledge and to clarify the myths and misconception prevailing in the community.

6.5 Access to safe and Quality Blood

There has been a substantial improvement in the access to safe and quality blood and blood products thanks to the increased number of blood banks, blood storage centres, etc. Nevertheless, efforts are required to achieve universal access to blood and blood products in the country.

- Though the country has ensured blood banks in all the districts, blood banks are still not available or not-functional in some districts (NACO, 2013). Several government

blood banks in India operate in hospitals with minimal infrastructure and inadequate/irregular supply of blood (Ramani et al., 2009; Vora et al., 2009)

- Especially, rural areas do not have licensed blood banks or resources to build them, and most of the licensed blood banks are urban centric that make blood and blood products inaccessible to the rural population. The Supreme Court Judgment in 1996 resulted in improvements in blood safety, but it made blood even scarcer in rural areas as more than necessary infrastructural requirements were mandated for licensing blood-banks. The policy changes to have small blood-storage facilities have not made significant advancements due the non-achievements of BSCs as planned, lack of surplus blood available at link blood-banks and lack of coordination and understating between the blood-bank and the blood-storage units (Vora et al., 2009). In addition due to high level of illiteracy, poverty and superstition, very few people are ready to donate blood in rural India (Mavalankar, 2004).

- In peripheral areas, there are few organized services, and the HIV testing facility is sometimes a considerable distance from the blood centre – the transport and screening of blood samples can take several days (Bray & Prabhakar, 2002).

- There is also evidence that there is a huge state level disparity in the availability services facilities, blood and blood products. Some of the less developed states recorded very low levels of blood units per 100,000 populations that may make the services inaccessible to a high proportion of the population.

- The recent policy changes to charge the patients the processing fee is a major barrier to accessing blood by poor women who need it, especially in emergency (Vora et al., 2009).

- The blood banks need to be also more efficient as even with less number of blood banks with efficient functioning and network; the lack of access to safe blood can be easily addressed by having more and properly trained manpower and good supply chain management system.

6.6 Quality Assurance in Blood Transfusion Services

The quality assurance related issues, challenges and recommendations are,

- In spite of several quality assurance mechanisms, the annual reports of Departments of AIDS Control in 2009-10, 2010-11 and 2012-13 have repeatedly mentioned the deficiencies based on the assessment of blood banks, such as, lack of proper infrastructure and facilities, lack of manpower, frequent transfer of trained manpower to other departments, poor accessibility, inadequacy, poor safety and poor quality maintenance, absence of Quality Management System, lack of standardization, poor maintenance of inventory of equipment, kits and consumables and improper record keeping and documentation (NACO, 2010) (NACO, 2011b) (NACO, 2013). It indicates that the above problems exist for a longer time period which may be given attention.

- Implementation of the Internal Quality Control Program should establish written policies and procedures, assign responsibility for monitoring and reviewing, train staff, collect data and set evidence based targets. In addition the need to establish and implement troubleshooting and corrective action protocols and maintain a system for documentation is also essential (Jain et al., 2013).

- Literature suggest that there is a lack of uniform quality-assurance processes like, manuals for standard operating procedures, appropriate training and competency certification programmes and continuous assessment systems, hamper good laboratory and manufacturing practices. It was also reported that BTS service units have different testing procedures and standards which hindered the exchange of blood between blood banks hence leading to wastage of blood (Ramani, Mavalankar, Tirupati, & Chand, 2008).

- It is also suggested for an ordered law for infrastructure and storage and to ensure compliance and quality assurance. Since quality assurance is a legal obligation in mandating good practices in blood banks, it is essential to update the rules, maintain a uniform approach for self-sufficient supply, product quality and transfusion safety. (Pal et al., 2011)
- As mentioned elsewhere, there are huge numbers of private blood banks available in

the country which are not strictly under the purview of Department of AIDS Control. The status of quality assurance practices are not known or nor clear. Efforts are required to bring all the blood banks under one umbrella so that monitoring, supervision and quality assurance can be ensured.

6.7 Monitoring and Evaluation System of Blood Transfusion Services in India

- Though DAC supported blood banks are being monitored and supervised at district, state and national level, private sector blood banks are not being monitored and supervised at different levels.

- Several private and voluntary blood banks are not reporting to Department of AIDS Control through Strategic Information Management Systems which prevents the country to get a national scenario of volume of blood collected, TTIs, and component separation.

6.8 Appropriate Use of Blood and Blood Produces – Clinical use of Blood and Blood products

- In terms of appropriate use of blood and blood products, India is lacking in several fronts. There is a need for comprehensive national guidelines on the appropriate clinical use of blood and blood products; a national haemovigilance system; mandatory Transfusion committees in all hospitals performing transfusions; and mandatory clinical audit in all the hospitals performing transfusion and there should be a system for reporting adverse transfusion events in all the hospital.

- The use of whole blood need to be reduced to the maximum possible extent so that the cost as well as risk due to blood transfusion can be minimized. Studies indicate that, of all blood components, Fresh Frozen Plasma showed a maximum inappropriate usage, which needs to be addressed (Gomathi & Varghese, 2012).

- Blood components can be obtained by aphaeresis rather than prepared from a standard unit of whole blood (Singhal, Patel, Kapoor, & Mittal, 2013)

- In order to reduce inappropriate use of blood and blood products, it is suggested to establish of transfusion practice guidelines; Retrospective monitoring of medical / transfusion records of the patients; Prospective monitoring of requests for blood components before they are issued; introduction of new transfusion policies or algorithms; Education of health professionals; and Peer review and self-audit (Chaudhary, 2013).

- It is evident that great proportions of wastage happen in India due to expiry, breakage and red blood cells contamination for fresh frozen plasma. A comprehensive inventory management system and up gradation of facilities and training of staff is necessary to ensure optimum utilization and minimize wastage (Singhal et al., 2013).

6.9 Technological Innovations in Blood Transfusion Services in India

- India is quick and effective in adapting newer technologies and implementing innovations. But, benefits of these reach only a smaller section of the society. There is a huge inequity in access to technology and innovations across the country. Many technological adaptations are individual hospital centric and limited to particular geographical area.

- E-blood banking is found to be effective. But, it is critical that a nationally unified system of integrated e-blood banking system is in place to regularize systems and to improve the efficiencies.

6.10 Integration with the Health System and Convergence with NRHM, other departments and Ministries

- It is evident that several health facilities including DHs, CHC and FRUs lack of blood bank/blood storage facilities (GOI, 2013; IIPS, 2005, 2010) which calls for more efforts on convergence.

- The mechanism of availability of blood in rural areas is quite weak. There is a need for networking between urban blood-banks and rural blood-storage units. And as there is no special provision for timely blood supply for maternal emergencies in rural areas, it may not be possible to reduce maternal mortality due to hemorrhage, anaemia, and abortions. The use of blood components, at least in urban areas where facilities exist for storage of components, will also enhance supply of whole blood for rural areas (Ramani et al., 2009).

- Convergence of BTS services with other National Disease Control Programmes need to be given more attention. A convergence plan between DAC and other programmes and a comprehensive blood safety plan in coordination with other departments like Social Welfare, Education, and Youth will make the implementation effective.

6.11 Efficient Supply Chain Management and Quality Assurance

- There have been many incidents of test kit stock out complaints reported in 2012 and 2013 (TheHealthsite, 2013). Due to the absence of centrally procured diagnostic kits, Department of AIDS Control has authorized local purchase by blood banks in order to maintain uninterrupted supplies (Krishnan, 2013). Decentralization of procurement will be more effective as there will be more ownership from the states.

- There is a lack of coordination between blood banks, blood storage centres and health care facilities due to the fragmented systems. Lack of clear guidelines to transfer blood and blood products to one high volume blood banks to low volume blood banks and blood storage centres.

- A centralised and a comprehensive e-Blood Bank Management System which can strengthen effective stock utilization and supply chain management. This can also facilitate easy prescription of blood transfusion, faster turnaround time from demand to issue, locating the blood components thus increasing transfusion

security. This will also ease up the monitoring, facilitate better planning and resource allocation (Wankhede, 2013)

6.12 *Legal, Regulatory and Policy Dimension of Blood Transfusion Services in India*

- In spite of the legislations, compliance with quality assurance and Good Manufacturing Practices is not ensured, 34% of blood banks are unlicensed and nearly 50% of collection is estimated to be from paid blood sellers and only 5% of voluntary donors are repeat donors. There is a need for ordered law for infrastructure and storage for compliance and quality assurance.

- Though mandated by law, all donated blood units are not screened for TTI. Testing for TTIs is unsatisfactory and poorly regulated in India. Reporting of adverse events after transfusion is poor and no stringent donor deferral system exists (Kapoor, Saxena, Sood, & Sarin, 2000; Ray, Chaudhary, & Choudhury, 2000b).

- Poor regulation, monitoring and control of blood bank exist because of the involvement of multiple agencies for licencing, regulation etc. There is a need for an independent Blood Transfusion Authority, to monitor the collection, storage, distribution and supply of safe blood in the country.

- The Supreme Court judgement in 1996 advised the government to consider the advisability of enacting legislation to regulate the collection, processing, storage, distribution of blood, and the operation of blood banks. This is yet to happen.

- India does not have a National Blood Law though there is a national policy, in order to ensure enforcements of GMP and GLP in optimal quality (Pal et al., 2011). This calls for a national blood law.

- Currently, though buying and selling of blood is banned, anecdotal evidences indicate that the business of paid blood donation continues to exist which indicate a

genuine lacuna in the law enforcement. Though the Supreme Court banned commercial blood donation, it did not stipulate any punishment.

- The Indian National Blood Transfusion Services Act 2007, prepared by the Union health ministry may be reviewed and proposed in the parliament

7. Key recommendations of experts based on site visit observations

7. I). Policy Level

- The experts expressed that guidelines need to be converted into rules with a mechanism to ensure its compliance.

- The National Blood Transfusion Council and the State Blood Transfusion Council should be bestowed with authority to take corrective measures and actions against non-conforming blood banks either directly or through the Licensing body.

- There should be some mechanism/criteria to support larger blood banks in terms of Infrastructure, human resources and automation need

- It is important to develop one or two blood banks in a specific region into major blood bank(s) with component separation facilities, and the other smaller ones to be either storage units attached to the same and/or collection centres that feed the major blood banks.

- Unbanked Direct Blood Transfusion: It is vital to assess the practice of direct donor to recipient transfusion and the reasons for that. The existing status policy, legal and regulatory mechanism in terms of this practice need to be revisited to ensure universal access to safe and quality blood and blood products.

- Transport of blood units: Policy regarding cross border transportation of blood is not very clear. Liabilities to be stated and appropriate documentation to be put in place.

7. II). Program Level

- ***Capacity Building:*** Frequent transfers of staff mandate a continuous plan in order to train the blood bank staff. In specific, advanced training especially on Internal Quality Control and External Quality Assurance System (EQAS) for the staff is very much required. Department of AIDS Control may consider periodical continuing medical education (CME) programme which may be linked with accreditation.

- **Supply of equipment:** Department of AIDS control and State AIDS Control Societies DAC/ SACS should undertake a comprehensive infrastructure needs assessment and obtain the consent of Blood Bank/ Medical Superintendent before the supply of equipment to blood banks. It will be waste of resources if equipment are dumped without assessing the requirement. There should be a clear mechanism to obtain license for certain equipment which are currently defunct in many blood banks for want of licensing.

- ***Maintenance of equipment:*** Department of AIDS Control should provide appropriate guidelines and training on maintenance of the costly equipment and planning for maintenance contracts.

- ***Voluntary blood donation:*** It is imperative that DAC should develop a strategic plan for the implementation of programs in order to accelerate the voluntary blood donation particularly in north & north eastern states.

- ***Rational use of blood and products:*** DAC needs to have a strategic plan to sensitize the clinicians on rational use of blood and products in order to increase the demand for component usage. CME and regular workshops for clinicians may be considered.

- ***Data collection & reporting:*** DAC should develop a structured plan to facilitate individual facilities to analyse the collected data and make use of them for taking corrective measures and for programme planning.

- ***External Quality Assurance System (EQAS):*** Quality assurance should be non-punitive with education. The participants in the EQAS program need to coordinate more effectively. A comprehensive EQAS programme which include TTI testing and Immunohematology is essential.

- ***Referral and Linkages: :*** There should be a clearly defined structured mechanism for networking between Government, private & charitable hospitals in order to address the needs and demands. Blood Banks should be linked with other blood banks in the

area to meet the demand in case of crisis and exchange the excess available blood which will improve the accessibility.

- ***Accreditation:*** It is very essential that Department of AIDS Control and the State AIDS Control Societies have a clearly defined strategy and action plan to motivate and facilitate accreditation of blood banks.

7. III). Institution Level

- ***Staff availability:*** The inadequacies in staff positions need to be addressed by the head of the institution.

- ***Voluntary blood donors list:*** The hospital authorities should take necessary steps to compile the list of potential repeat blood donors and develop local mechanism to remind them for donation especially during high demand seasons.

- ***Adherence to SOP:*** The hospital authorities should ensure that SOPs are regularly updated and validated by the competent authority. It should be displayed in their respective areas of activity in the blood banks. Efforts are needed to ensure compliance to SOPs.

- ***Calibration of equipment:*** The blood bank authorities should ensure that all equipments are calibrated as per the standards at required frequencies.

- ***Testing Techniques:*** It is important to ensure that that blood banks discontinue the slide/ tile method for blood grouping and opt for direct and reverse blood grouping by tube technique. Facilities should also be provided for red cell antibody identification.

- ***Universal precautions:*** Few blood banks are not aware of the percentage of hypochlorite used for disinfection and spill treatment. The SOPs for bio-safety and segregation of waste are also not available in few facilities especially for discarding of sero-reactive blood. The hospital authorities should ensure that, universal precautions and appropriate biomedical waste management practices are followed in the Blood Bank as per DAC guidelines.

- ***Coordination:*** Better coordination is required between SACS and Hospital authorities for effective utilisation of resources (e.g. linkages with ICTC for communication of sero-reactive donors, counselling of sero-reactive donors for Hep B & C, etc)

- ***Fund utilisation:*** The blood bank medical officer should be given more authority to judiciously use the funds.

- ***Renewal of license:*** The hospital authorities should ensure that the blood bank license is renewed in time.

8. Key areas for improvement and suggestions by Programme Officers of SACS

- **Manpower and responsibilities:** It was suggested that the positions in SACS need to be filled by senior Government officials on deputation, not by employing contract staff. There is an urgent need to ensure adequate doctors and lab technicians. The role of quality manager is vital that requires good knowledge on pharmacy; and should be responsible for ensuring quality of equipment/testing. Supplies for the blood banks should be managed by the hospital store keeper. The remuneration of VBD consultants and Quality Managers should be on par with Deputy Director. The JDs suggested that the blood bank medical officer needs to be given adequate authority to make decision and handle local administrative issues.

- **Training Programs:** Government staffs need training and they should be encouraged to attend training programs. It is also essential to include private blood banks in training programs.

- **Policy on Supplies:** The policy on supplies needs to be consistent and intimated to blood banks. Clear rules and guidelines on exchange of blood units between blood banks are required.

- **Reporting:** The JDs felt that it is imperative and necessary to include private blood banks in the existing reporting mechanism.

- **Up gradation of facilities:** In order to improve the access of blood and blood components, there should be at least one blood bank per district. Major blood banks/ DLBBs with greater requirement for components should be upgraded as BCSU. Storage centres need to be set-up in remote areas with mobile blood donation vehicles.

9. Conclusions

The provision of safe and adequate blood and blood products is vital to any health care system and it is the responsibility of the government to ensure safe and quality blood and blood products to those who in need. After the inception of National AIDS Control Organization in 1992, Blood safety has been given utmost improvement. Due the concerted efforts of different stakeholders, the blood transfusion services in India have improved very significantly over the last two decades. There has been huge improvement in the infrastructure, number of manpower, capacity, quality of testing kits and reagents, availability of advanced equipment which in turn improved the services provision and increased the access to safe and quality blood and blood products. In addition, there has been an improved legal, and policy environment in the country that facilitates the effective delivery of blood transfusion services. This can be very well understood from the fact that the availability of safe blood increased from 44 lakh units in 2007 to 93 lakh units by 2012; during this time HIV sero-reactivity also declined from 1.2% to 0.2%; and Voluntary blood donation increased substantially (NACO, 2013).

Nevertheless, there are still gaps in the provision of Blood transfusion Services. For instance there is an absence of a centralized management of blood services which results in lack of standardized practices and processes. There are varying levels of capacities of the personnel, poor quality standards, inadequacy of blood availability and presence of geographical, economics, physical and gender related inaccessibility of blood transfusion

services those who are in need. There are still several changes required in the legal and policy areas in order to make the blood transfusion services universally accessible to all.

It is essential that all the relevant stakeholders under the leadership of Department of AIDS Control work together to address the gaps and challenges and ensure universal access to safe and quality blood and blood products.

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[i] This notification has been inserted under Schedule K of Drugs & Cosmetics Rules, 1945 under serial no. 5B.
[ii] Ministry of Health & Family Welfare (Department of Health) vide Notification No. GSR 909(E) dated 20th Dec, 2001