Part I

Internship Report

1.1 Introduction to the Organisation

As a mandatory requirement of the course curriculum for Post Graduate Diploma in Health & Hospital Management, the students have to undergo a 3 months internship in a hospital or health organization. In order to comply with this requirement, I have been placed in **ICRA Management Consulting Limited (IMaCS)** under the supervision of **Dr. (Col) Sajal Sen,** , **Assistant General Manager & Programme Leader- Healthcare, IMaCS** as our Organisational advisor. I was hired by the firm as a Contractual Consultant for the project of **ISO Certification of District Hospital Durg, Chattisgarh.** The project is of NHSRC on Quality Improvement in Public Health Facilities.

ICRA Management Consulting Services Limited (IMaCS) is a wholly-owned subsidiary of ICRA Limited, is a multi- line consulting firm with a global operating footprint. IMaCS offers Consulting Services in Health, Strategy, Risk Management, Regulatory Economics, Transaction Advisory, and Process Re-engineering. IMaCS clientele includes Banks & Financial Service Companies, Corporate Entities, Institutional Investors, Governments, Regulators, and Multilateral Agencies. Besides India, IMaCS has consulting experience across 35 countries in South East Asia, Northern Asia, West Asia, Africa, Western Europe, and North America.

District Hospital, Durg is one of the three District hospitals which have been selected for ISO certification. It was started in year 1963 as a 100 bedded hospital. On 12 February 2008, it has been up graded to 430 bedded hospital. The hospital caters to a population of about 25 Lakhs locally from the Durg district and also referrals from various Community Health Centres (CHC), Primary Health Centres (PHC). The services available in the district hospital are General Medicine, Pediatric, Obstetrics and Gynecology, General Surgery, Dental, E.N.T, Ophthalmology, Orthopedics, Anesthesiology, T.B.& Isolation, I.C.U & Dialysis. Hospital also participates in various National Programs and schemes which are as follows:

- National Immunization Programme
- Pulse Polio Programme
- National Leprosy Eradication Programme
- RNTCP Programme

- AIDS Control Programme
- Maternal & Child Health Programme
- Family Planning Programme
- Rashtriya Swasthya Bima Yojana (RSBY)

The following are the future plans of the hospital:

- CT scan installation- allocation of funds and instrument has already been done by C.G. government. It will start within 3-6 months.
- Water reservoir/ over head tank of about 1 lakh liter capacity is sanctioned by NRHM.
- Installation of high tension line- substation is sanctioned.
- M.R.I. Installation
- Central oxygen and central suction are under process at state level
- Trauma unit-20 bedded
- Component blood therapy and up gradation of blood bank
- Up gradation of Eye OT (PPP).

1.2 Introduction of the Activity

The current mandate targets the capacity building of select health care facilities, Durg, Chhattisgarh being one of them. The agenda includes:

- Mapping the As-Is Process
- Identifying the resource and process gaps
- Developing documents in line with the ISO requirements
- Developing systems for continuous evaluation, monitoring and control
- Undertaking requisite training to manage the change
- Incorporate learning and best practices from the facilities that are best in the industry
- Achieving ISO as a milestone

Among the above mentioned steps for the achievement of ISO certification by the facility, the following are the steps which are completed by me during the period of internship towards the achievement of ISO Certification:

- Formulation of As-Is Report
    - Analysis of hospital's current performance
    - Mapping of the processes in the hospital
    - Comparison of Manpower, Infrastructure and resources with IPHS and ISO guidelines
    - Identification of the gaps in the facility
- Initiation of gap closures and formulation of gap closure report
- Preparation of ISO documents for the hospital

1.3 Responsibilities Allocated

1.3.1 Formulation of As-Is Report

The As-Is Analysis has evaluated the current facilities, processes against the standards of IPHS, ISO 9001-2008 guidelines. The method of as-is mapping at the District Hospital, Durg includes the following:

- Observation of the processes and the facility
- Study of the documents available at the departments
- Data collection from the hospital records, patients & staff (survey)
- Participative brainstorming with department heads/in-charges of hospital areas

The As-Is report has revealed the current status of the facility in terms of infrastructure, manpower, resources regarding District Hospital Durg. The following are the findings obtained after the formulation of As- Is Report:

1.3.1.1 Utilization of the Facility

These are the data of utilization of the facility in past years which includes details of patient load (OPD & IPD), Surgeries, Bed Occupancy, Deliveries and Laboratory & Diagnostics Services.

- The hospital has witnessed an upward trend in the OPD utilization. There has been about 5.08% increase in the number of OPD consultations in the last 9 years. (OPD 125129 in 2001: in 2008 total OPD 185410 and in current year 2009 total OPD was 195415)
- The IPD utilization has shown increasing trend with marginal increase of CAGR 4.7% in comparison to base year 2001. (Total IPD 18088 in 2001 and in year 2009 total IPD 27410)
- The bed occupancy rate is observed to be gradually increasing over the given period (2000-2009). After a small decline from 73% to 70% in 2001, the bed occupancy rate has gradually increased during the years reaching a figure of 92% in 2009.
- The number of total surgeries has increased with a CAGR of 20.3 %. However there is a trend fluctuation in case of surgical work load. In 2004 the total surgeries carried out were 5293. Thereafter there was a sudden increase to 8570 surgeries in 2005. By the year 2006 it again rose to 9157 surgeries conducted in the hospital. In the year 2008 and 2009 the figures are again declining to 8264 and 8737 respectively.
- The number of institutional deliveries has increased with a CAGR of 7.78% from 2003 to 2009. The total number of deliveries conducted in the year 2003 was 3617. In the year 2009 the total number of deliveries conducted in the hospital was 5671.

1.3.1.2 Analysis of Gaps in Various Departments of Hospital

The various Gaps identified have been classified either as resource/infrastructure Gap or process Gap and depending upon their implications on the patient care they have been further classified as High Medium and Low. The details of the Gaps along with rationale and impact have been recorded in the subsequent section of the report. The major Gaps are briefly highlighted in the subsequent paragraphs.

Infrastructure Gaps Noticed in Casualty

1. The approach to casualty was common with main entrance. The patients had to wheel in patients in a circuitous route. These aspects have been overcome by commissioning of the new casualty block with a dedicated entrance and sufficient covered space for off loading the patients. As such most of the infrastructural gaps of the erstwhile casualty have been closed

Process Gaps Noticed in Casualty

1. It was observed that the drugs in the casualty were not stocked in a manner to facilitate easy retrieval and identification. Similarly sounding and similarly appearing drugs were stocked together which could be hazardous in emergency situation.

2. Further it was noticed that there was no clear evidence of disinfection of beds and equipment periodically although it was stated to have been carried out periodically.

3. The casualty does not have standard protocols for the information of staff to deal with common emergency situations. Similarly there is no disaster management plan to deal with mass casualty situation.

4. The Ambulance is not equipped with life support equipment and supplies. Further the charges for availing ambulance services are not displayed anywhere.

Infrastructure/Resource Gap in OPD

1. The OPD lacks in provision of amenities for the patients in the form of safe drinking water facility and toilet facility. It was observed that the drinking water facility is not in working condition. Also there are toilets common for male as well as female patients which are under insanitary condition. In the Gynecology OPD also there is no integrated toilet causing inconvenience to the woman patients who need to evacuate bladder prior to internal examination.

2. The list of Doctors available on duty in OPD is not displayed with their room/cabin numbers. The patients who are desirous to get themselves reviewed from the same Doctor who had seen them earlier have to face inconvenience in locating them.

3. There is overcrowding in and around the OPD chambers as there is no audiovisual patient calling system and all patients crowd into the chamber in apprehension of missing out their turn. There was no major process gap observed in the OPD.

Infrastructure/Resource Gap in the In-patient Department

1. The ward complex is planned on Nightingale pattern having series of beds at right angles to the side walls. However the illumination levels at the nurses station were found to be much lower than desired levels prescribed in BIS standards when measured with a lux meter. It was also noticed that there was no nurse calling system in the wards for the beds in which lying/ post operative patients are kept. This causes inconvenience to patients especially during nights when they do not have a relative/attendant nearby.

2. At multiple location seepage problem was noticed on the walls of the ward which could be source of foul odor and infection

Process Gaps in the In-patient Department

1. It was seen that there is no existing practice amongst the staff to ensure the consumption of oral medicines correctly by the admitted patients which is left for the patients to take and the compliance to medical advice in the ward could be questionable in this regard.

2. There is no evidence on pest and rodent control in the hospital and rodent nuisance was visible in the wards. The ward is always crowded with visitors and relatives in the absence of well enforced visitor control procedure.

3. The Pre-Anesthesia check-up is carried out in wards and no PA checkup form used. Use of PA check form will facilitate record of all the details and safer anaesthesia practice and is considered a prescribed method for PA check up.

4**.** There is no system for prevention and control of Hospital Associated Infections Standard precautions for safety of staff and prevention of transmission infection are not followed.

Infrastructure/Resource Gaps in Operation Theatre Complex and Labor Room

1. The Theatre Sterile Supply Unit (TSSU) was not planned in accordance with the principles of sterilization. There were multiple autoclaves spread in different user areas of the hospital and no standard system in collection distribution and ascertaining the process efficacy was in place.

2. The Operation Theatre is not planned in accordance with zone plan i.e. Protective Zone, Clean Zone, Sterile Zone and Disposal Zone.

3. In the labor room no screen/separation has been provided between delivery tables compromising privacy of the delivering mother.

4. There is no verification system in practice to ensure and evidence appropriate sterility of the operation theatre and Labor Room. There is no record of fumigation done or conduct of periodic wall swab tests.

Infrastructure/Process Gaps in Laboratory & Radiology

1. The Lab is reasonably equipped to carry out all the routine tests required by the clinicians for treating the patients. However there is no system to verify the correctness of the results by way of cross checking the results with other laboratories or participating in quality control program with some institutes of repute.

2. In the X Ray department It was observed that though there is a system of using TLD badges the same is not implemented due to absence of films for TLD. And there is no record of TLD reports.

Gaps in Hospital Stores Management

1. It was observed that the consumables like IV fluids and ORS powder are stored in a manner that is not in conformity to the storage instruction on them. They were found to be lying in bulk, exposed to sun light.

2. Different types of medical and other items are not segregated in the store and there is no system in practice for inventory management. There is no display for detection of stock levels of surgical and medical inventory and they are randomly stored on floor and shelves

available. Storage area is poorly lit and the illuminations were found to be very in comparison to prescribed BIS norms when measured with lux meter.

Biomedical Waste Management

1. The segregation of hospital waste is not as per rules. The record of waste generated and labeling of the bags is not done by respective ward and departments. There is no conformity to the rules in management of the Kerb site where the waste is temporarily stored after collection from various areas and it was found that potentially hazardous waste is not kept under lock. The waste handlers do not exercise due precautions and personal protective measures. On interaction with different categories of staff significant knowledge gap on the subject was detected amongst the staff in patient care areas and the waste handlers.

Process gaps in Dietary Services

1. It was noticed that the hospital does not have evidence of food safety measures in place while providing dietary services. The cleanliness in the kitchen and food preparation area is not maintained. The food handlers do not undergo regular medical checkup and they do not wear aprons gloves and caps. There is no system in place for regular control of insects and rodents in the kitchen.

Gaps observed in Medical Records management

1. It was observed that there is no definite system in place for storage and retention of medical records for easy retrieval. The IPD tickets are put in bundles and stored monthly. The racks and storage cabinets are grossly insufficient in comparison to the quantum of documents.

Gaps observed in General Management and Hospital Infrastructure

2. The hospital does not have a citizen charter displayed at appropriate location in the hospital premises as prescribed in IPHS.The schedule of available specialists as on day is not displayed in the OPD area of the hospital. In absence of proper information about availability of concerned specialist the patients who come from far away wait in OPD complex in vein.

3. Hospital does not have appropriate safety signage at all required installations like electrical panels, fire exit plans etc.

4. As regards the maintenance and upkeep of the complex there is no annual maintenance plan for the building and fixtures that is required to be maintained by the engineering department. No schedule for preventive maintenance of Fans, ACs Coolers, high output electric fitments and panels, sewage and plumbing lines, water purifiers etc is being maintained. Most sewage lines are open and chocked in various areas close to IPD and OT complex. The cycle time of repair and maintenance is highly unpredictable.

5. There is no maintenance schedule for Biomedical equipment. A number of Biomedical equipment like Cautery, Operating microscope, suction machines are lying idle for want of maintenance. Further here is no calibration plan for monitoring and measuring equipment.

6. Although water purifiers are installed there is no evidence of its regular cleaning and maintenance. Moreover the area around these water points is also untidy. As such there is no assurance towards quality of drinking water supplied at various water points It was also noticed that the hospital does not have any fire safety plan and there are no fire fighting points with appropriate extinguishers maintained in the hospital premises.

7. There is no plan for continuous training of all cadre of personal in order to enhance their skill sets. The human resources are deficient in comparison to the IPHS norms prescribed for hospital of bed strength 430 beds. There is no evidenced system to capture feedback from the patients. Moreover there is no complaint redressal system in place. There is a complaint box available but it is not used.

Results from Staff and Patient Satisfaction Surveys

1. Survey was conducted to ascertain the satisfaction levels of OPD/IPD patients and the Staff with the help of pre tested set of questionnaire. Each question was required to be responded by the subject in a scale of numerical marking 0 to 5. Accordingly an overall satisfaction index in each category was computed.

(a) As regards the satisfaction survey of OPD patients the overall score was 3.2.

(b) In the case of Indoor patients the overall score was found to be lower with the figure 2.7

(c) The overall score of satisfaction survey conducted amongst the staff was found to be 2.9

2. These indices would be taken as base line and the survey will be repeated after closure of the various Gaps, Staff training and implementation of the quality management system.

1.3.2 Initiation of Gap Closure and Formulation of Gap closure

The gaps identified in the facility are given priority as High, Medium and Low. A report to check the status of the gaps and the recommended action to be taken within specified timeline is prepared and updated every week. Currently gaps regarding sinages and some infrastructure are tackled.

1.3.3 Preparation of ISO Document for the Hospital

The ISO documents for hospital are being prepared which includes Clinical Manuals, Administrative Manuals, Improvement Manuals and Quality System Manuals. These manual documents all the processes being conducted in the hospital and the records & formats being prepared for each processe.

1.4 Conclusion

District Hospital Durg which is a secondary level health care service provider, centrally located in the District Headquarters has a promising infrastructure in place. All the Gaps identified can be traversed with the help of time bound action plan, training and budgetary support through allocations under existing heads. Upon implementation of Quality Management Systems as per ISO standards the facility will be a role model for the state to emulate. It has a promising infrastructure to become a teaching hospital in times to come.

Part II

Dissertation on "Study of Blood Bank Services in a Multispecialty District Hospital"

CHAPTER 1: INTRODUCTION

1.1 Introduction to Blood Transfusion Services

The necessity for blood is of utmost concern to the community as a whole. Blood transfusion is a fundamental and requisite part of any Health Care Facility for optimum management of emergency conditions like severe trauma shock and resuscitation with the optimum stock of whole blood and blood components. To run a hospital without a blood transfusion service is to invite severe difficulties in the daily operations of that institution. The reality is that no hospital can function effectively without an efficient blood supply.[1]

Blood transfusion is the process of transferring blood or blood-components from one person into the circulatory system of another. Blood transfusions can be life-saving in many situations, such as massive blood loss due to trauma, or it can be used to replace blood lost during surgery. Blood transfusions may also be used to treat severe anaemia or thrombocytopenia caused by a blood disease. People suffering from hemophilia or sickle-cell disease may require frequent blood transfusions. Early transfusions used whole blood, but modern medical practice commonly uses only components of the blood.[2]

A **blood donation** is a process when a healthy person voluntarily has blood drawn and stored as whole blood or blood component for further use. The blood is used for transfusions or made into medications by a process called fractionation [3]. There are three types of blood donors:

- **Professional Donors:** They sell their blood, which could be of very poor quality and can transmit very dangerous diseases to the recipient. It is illegal to take blood from any professional donor.
- **Replacement Donation:** Healthy relatives and friends of the patient give their blood, of any group, to the blood bank. In exchange, the required number of units in the required blood group is given.
- **Voluntary Donation:** Here a donor donates blood voluntarily. The blood can be used for any patient even without divulging the identity of the donor. This is the **best type** of blood donation where a motivated human being gives blood in an act of selfless service.[4]

1.2 Historical Development

The first attempt of transfusion of blood was described by the 17th century chronicler Stefano Infessura. Infessura describes that, in the year 1492, Pope Innocent VIII went into a coma. In order to prevent the pope to sink into coma, the blood of three children was transfused into the pope through mouth. The reason being the absence of concept of circulation and intravenous method of blood transfusion at that time. The children were ten years old. However, not only did the pope die, but so did the three children.

Harvey's experiments with the transfusion of blood which was a more sophisticated research into blood transfusion began in the 17th century. He conducted successful experiments in transfusion between animals. However, attempts on humans have produced fatal results.

The first complete documentation of blood transfusion in humans was ensured by Dr. Jean-Baptiste Denys, a prominentt physician of King Louis XIV of France. This was administered on June 15, 1667. He transfused sheep blood into a 15-year old child, who survived the transfusion. Denys performed another transfusion into a laborer, who also survived. Both instances were likely due to the small amount of blood that was actually transfused into these people. This allowed them to withstand the allergic reaction. Denys' third patient to undergo a blood transfusion was Swedish Baron Bonde. He received two transfusions. After the second transfusion Bonde died. In the winter of 1667, Denys performed several transfusions on Antoine Mauroy with calf's blood, who on the third account died.[2]

A milestone leading to the establishment of blood banks occurred in 1915, when Richard Lewison of Mount Sinai Hospital in New York City used sodium citrate as an anticoagulant. This discovery brought the revolution of indirect blood transfusion procedure by replacing direct blood transfusion. In the same year, Richard Weil showed the feasibility of storage of anticoagulated blood in the refrigerator. Two years later Francis Peyton Rous and JR Turner introduced a citrate-glucose solution which permitted storage of blood in containers for several days, thereby opening new horizons for the first "blood depot" which was established in Britain during World War I. Charles R. Drew researched in the field of blood transfusions, developing improved techniques for blood storage, and applied his expert knowledge in developing large-scale blood banks early in World War II. Oswald Hope Robertson is recognized as the creator of the first blood bank. He was a medical researcher and U.S.

Army officer who established the depots for blood storage. The University of Louisville is also credited for the Blood Bank.[5]

Blood Transfusion Services constitute a crucial part of healthcare delivery system. Adequate and safe supply of blood and blood components is essential, to enable a wide range of critical care procedures to be carried out in hospitals. Unfortunately, blood transfusion themselves can be a cause of illness like transmission of dreaded viruses like HIV, etc. While the vast majority of HIV infections in India are attributed to the sexual route of transmission, the transfusion of unsafe blood and blood products account for 2.07 percent of the HIV infections in the country in 2004-2005. When viewed against the fact that in 1999 unsafe blood and blood products accounted for over 9 percent of AIDS cases, this drop to 2.07 percent is certainly encouraging. Ensuring the widespread availability of safe and quality blood is a critical component of the National AIDS Prevention and Control Programme.[6]

1.3 Introduction: District Hospital, Durg

District Hospital, Durg was started in year 1906 as a civil hospital. It became a district hospital in 1963. On 12 February 2008, it was upgraded to a 430 bedded hospital. The hospital caters to the local population of Durg district and also referrals from various Community Health Centres (CHC), Primary Health Centres (PHC). Its distance from the bus station and railway station is about 0.5 km. & 3 km. respectively.

The Hospital building is surrounded by well defined boundary wall. The hospital building is having two floors with OPD, Casualty, Maternity, orthopedic, child ward, blood bank, ART etc present on ground floor and Operation theatre, ICU, Isolation, T.B., Operation theatre (family planning),stores etc on first floor. Essential services including Out Patient Department (OPD), Indoor Patient Services (IPD) and Emergency Services are available in the hospital. Apart from this, there are specialties like General Medicine, General Surgery, Obstetrics and Gynaecology, Emergency Anaesthesia, Ophthalmology and ENT are also available.

The inpatient department has a total of 430 beds that are functioning. Operation theatre is placed on first floor. Hospital has a pharmacy counter for dispensing drugs to OPD Patient.

The hospital has recently got newly constructed Blood Bank, NICU, Gynaecology ward and Child ward.

The Jeevan Deep Samiti (formly Rogi Kalyan Samiti) has also been established for monitoring the hospital functioning and taking decision for improvement of its services.

The hospital has started in 1963 as a 100 bedded civil hospital, since then there are many developments which took place with time. The amendments includes introduction of Eye department in 1964 and OPD in 1976, the hospital was renovated in 1987. Later the hospital started its blood bank, Air conditioned Labor Room, NICU, Telemedicine, Computerized Registration Counter and New Operation Theatre. The hospital is starting CT Scan facility shortly.

1.3.1 Patient Volume and Profile

The hospital being the oldest hospital of Durg has historically catered to high patient volumes. The hospital caters to the referral patients from nearby villages as well as from the associated Civil hospital (Supela and Bemetara). Being a district hospital offering services in the broad specialties, the hospital not only receives patients from within the district, but also from adjoining villages. The hospital primarily attracts the patients for the low income group. The hospital catered to 195415 out-patients, 27410 in-patients with a bed occupancy of 92 % in the calendar year 2009.

1.3.2 Service Availability at District Hospital, Durg

District Hospital, Durg is a combined hospital offering preventive and curative services to the community. The hospital is a general hospital and currently provides OPD services in General Medicine, Ob&G, Orthopedic, Surgery, Pediatric, E.N.T., Ophthalmology, Dental, Psychiatry, physical medicine and rehabilitation on daily, biweekly and weekly basis. The hospital provides In-Patient (IP) services through a bed-strength of 60 beds (including 10 emergency beds). The hospital provides minor and major surgical services also. A well equipped labor room and neo natal unit is also servicing patients round the clock.The hospital delivers patient care through its clinical, supportive and utility service areas. As shown

below, both core services and support services are in-house. Utility services are also available in-house. District hospital Durg is also having a Panchkarma & AYUSH clinic

Hospital also participates in various National Programs and schemes which are as follows:

- National Immunization Programme
- Pulse Polio Programme
- National Leprosy Eradication Programme
- RNTCP Programme
- AIDS Control Programme
- Maternal & Child Health Programme
- Family Planning Programme
- Rashtriya Swasthya Bima Yojana (RSBY)

1.4 Blood Bank, District Hospital, Durg

The blood bank in district hospital was present since its inception but the facilities and infrastructure was very limited. In the year 1995 the blood bank of the hospital was renovated into a modernized manner to cater the transfusion requirements of the district and the surrounding villages of other district in an efficient and effective way.

The blood bank is serving the patient visiting the hospital as well as referred patients. It provides the units of blood at Rs 175/- to the patients and free of cost to the BPL patients as well as poor patients who are in urgent need. The blood bank fulfills the requirement of blood through Voluntary donation by organizing various blood donation camps in the community as well as through Replacement donation by the attendants of the patients.

The blood bank is having a well defined Standard Operating Procedure and state of the art infrastructure and equipment for the collection, storage and distribution of whole blood and blood components. Currently the blood bank is not undertaking the component separation part and dealing with the collection, testing, storage and distribution of whole blood.

Once the blood is collected from the patient, it is then for the diseases which can be transmitted through blood such as malaria, HIV, hepatitis etc. and once it is tested and found

to be free of such diseases then it is stored. The distribution process includes the testing of the blood group of the sample of the blood collected from the patient. Donor's physical condition is evaluated and his/her blood sample is taken for grouping depending upon his/her fitness to donate blood. The donor is laid on the bleeding couch in the collection area of the blood bank and the donor is bled in a double bag pack. Patient's blood sample as would have been taken for grouping and cross matching is done. Based on the patient's blood group he/she receives a unit of whole blood. The blood unit is transfused by the nurse on duty after due checking of the blood group and expiry date mentioned on the blood bag.

The aim of the study is to understand the Procedures, Infrastructure, Manpower and Equipment availability at the facility, assessment of the performance of the facility, Identification of certain Bottlenecks and suggest recommendations.

CHAPTER 2: RESEARCH METHODOLOGY

2.1 Methodology

There are several methods that will be use to achieve research objectives. After the literature review, observation and collecting data is needed. The complete field data collection will be tested before it will be used for data analysis. The problems and nonproductive in the work process can be identified based on the data collection and their analysis. Then, the result from the data testing will be determined whether the result can be used or not and if there are any incomplete data, the data collection will be executed again until it fulfills the objective requirement.

2.2 Research Design

a) Review of Literature on Blood Bank and Blood Donation.
b) Review of Records related to Blood Bank
c) Assessment of utilization and need by analyzing past data
d) Comparison of the infrastructure, manpower and equipment requirement with the regulatory norms.

This research was conducted by collecting the data of various parameters such as equipment available, current manapower, infrastructure design. Also the data is collected for the performance review of the facility which includes the no. of blood units issued, voluntary donation, replacement donation, no. of units discarded, Rh negative donor pool and autologous blood transfusion. This data collection is followed by the mapping of the process employed in the blood bank facility. The process employed is as follows:

Process Group	Laboratory services	**Sub-Process**	Blood Banking
Process Location	Laboratory	**Process Owner**	Technician
Input(s)	Patient samples, Lab equipment, Technician	**Output(s)**	Supply of safe blood

<table>
<tr><th colspan="2">Process Flow / Process Description</th></tr>
<tr><td colspan="2">

Patient’s attendant visits the blood bank with the Emergency, OPD/IPD slip and patient’s blood sample to transfuse blood.
The blood bank charges Rs 175/- per unit of blood transfused for patients admitted in the hospital.
The hospital transfuses upon receiving a donor of the patient. If in case no donor is present then blood is given to the patient for free depending upon need and urgency (trauma, shock, excessive bleeding etc.).
Donor’s physical condition is evaluated and his/her blood sample is taken for grouping depending upon his/her fitness to donate blood.
The donor is now laid on the bleeding couch in the collection area of the blood bank and the donor is bled in a double bag pack.
Patient’s blood sample as would have been taken for grouping and cross matching is done.
Based on the patient’s blood group he/she receives a unit of whole blood.
The blood unit is transfused by the nurse on duty after due checking of the blood group and expiry date mentioned on the blood bag

</td></tr>
<tr><td>Process Records</td><td>✓ Requisition form
✓ Donor fitness form
✓ Cross-matching form
✓ Donor register
✓ Master record for donor
✓ Cross-matching and issue register
✓ Issue slip
✓ Blood grouping register
✓ Stock register (for available blood)
✓ Stock register (other than blood)</td></tr>
</table>

Table 2.2.1 Process Mapping of Blood Bank

A detailed process review is done and the data collected is compared with the regulatory norms for blood bank which are Drug and Cosmetic Act, 1940 (India), Standards for Blood Bank & Blood Transfusion Services, NACO and IPHS for 301-500 bedded district hospital. The performance assessment is done through the past data collected and bottlenecks are identified from that evaluation.

CHAPTER 3: RESULTS & FINDINGS

3.1 Human Resource: Blood Bank, District Hospital, Durg

The blood bank in the hospital is headed by the Head pathologist Dr. J. P. Meshram. The staff at the blood bank is permanent as well as contractual hired by the Jeevan Deep Samiti. The current available staff at the hospital and the comparison with IPHS standards is done as follows:

Staff currently available at Blood Bank:

(a) Medical Officer	-Dr.J.P.Meshram, MBBS.MD.
	-Dr.P.K.Chandrakar,MBBS.MD.
(b) Technical Supervisor-	-Shri Roshan Singh, DMLT
(c) Registered Nurse	-Smt.Nema Chandrakar, DMLT
(d) Blood Bank Technician	-Shri Rupesh Kumar Sarpe, DMLT
	-Shri Kirtan Deshmukh, DMLT
	-Shri Mahendra Kumar Chandrakar, DMLT
	-Shri Raju Yadav, DMLT
	-Ku.Jagrati Sinha, DMLT
	-Shri Deepak Chandrakar, DMLT
(e) A/c Officer cum store keeper	-Shri Sunil Kumar Dewangan
(f) Office assistant	-Shri Ganesh Prasad Swarnkar
(g) Computer Operator	-Shri K.Srinivas

As per the requirement of Drug and Cosmetic Act the staff available in the blood bank is almost sufficient to cater the needs of the patients in an efficient manner.[7]

Manpower required for Blood Bank according to Drug & Cosmetic Act			
		Available	Not Available
Bleeding Room			
1.	Jr. Doctor		√
2.	Nurse	√	
3.	Social worker		√
4.	Attendant	√	
Aphaeresis Room			
1.	Nurse	-	-
2.	Attendant	-	-
Laboratory			
1.	Technician Supervisor	-	-
2.	Tech. Assistant	√	
3.	Technician	√	
4.	Laboratory Asst	√	
5	Laboratory	√	
Donor organizer			
1.	Associated clerical staff	-	-
Service staff clerical staff			
1.	Clerk typist - Part time	√	
2.	Store keeper - Part time	√	
3.	Cleaner Sweeper - Part time	√	
Medical Doctor			
1.	Consultant professor	√	
2.	Asst Professor.	-	-
3.	Lecturer	-	-

Table 3.1.1 Manpower Availability in Blood Bank

The table 3.1.1 shows the manpower requirement as per Drug and Cosmetic Act, 1940 of a blood bank collecting less than 5000 units per year. As it is clear from the above table that the Blood bank, District Hospital Durg is having almost complete staff when compared to the drug and cosmetic act guidelines except for a junior doctor and a social worker. The blood bank has recruited many of the employees under Jeevan Deep Samiti to minimize the shortage of staff.

3.2 Equipment Availability at Blood Bank, District Hospital, Durg

The blood bank is having the charge of the equipment of blood bank as well as pathology of the hospital. The stock for both the facility is maintained and issued from blood bank. The equipment are purchased through Directorate Health Services, Chhattisgarh State Government or through tender process. The costlier equipment are also having their AMC/CMC. The list of equipment currently available in the facility and a comparison with IPHS requirement of equipment for 301-500 bedded hospital [8] is given as follows:

S. No.	Name of the Equipment	Equipment Required	Equipment available
1	Binocular Microscope	10	7
2	Chemical Balances	2	2
3	Simple balances	2	
4	Electric Colorimeter	2	6
5	Auto analyser *	1	1
6	Semi auto analyser	1	1
7	Micro pipettes of different volume range	10	19
8	Water bath	2	6
9	Hot Air oven*	2	6
10	Lab Incubator*	3	5

S. No.	Name of the Equipment	Equipment Required	Equipment available
11	Distilled water plant	2	-
12	Electric centrifuge table top	3	2
13	Cell Counter Electronic*	1	3
14	Hot plates	6	-
15	Rotor / Shaker	2	1
16	Counting chamber	4	8
17	PH meter	3	2
18	Paediatric Glucometer / Bilirubinometer*	1	-
19	Glucometer	2	2
20	Haemoglobinometer	3	5
21	TCDC count apparatus	2	4
22	ESR stand with tubes	6	Stands-5, tubes- 50
23	Test tube stands *	10 – 20	-
24	Test tube rack *	10 – 20	40
25	Test tube holders*	10 – 20	5
26	Spirit lamps*	10	10
27	Microtome*	1	-
28	Oven (Wax embedding)*	1	-
29	Tissue processor*	1	-
30	Timer stop watch	2	-
31	Alarm clock	2	-

S. No.	Name of the Equipment	Equipment Required	Equipment available
32	Elisa Reader cum washer	2	2
33	Blood gas analyser*	1	-
34	Blood Component Separator	1	2
35	Biosafety Cabinet	1	-
36	Refrigerators	4	13
37	Platelet Agetator	1	1
38	Platelet Thawing Machine	1	1
39	Laboratory Autoclaves	4	1
40	Laminar Flow	1	2

Table 3.2.1 Equipment Availability at Blood Bank

Table 3.2.1 depicts the current situation of the equipment available in the blood bank. It is clear from the table that the quantity of most of the equipment complies with the requirement of IPHS guidelines, however there are some equipment, the quantity of which are lagging behind the IPHS standards and some are in excess as compared to the norms. These two situations are discussed with the help some major blood bank equipment in the graphs below

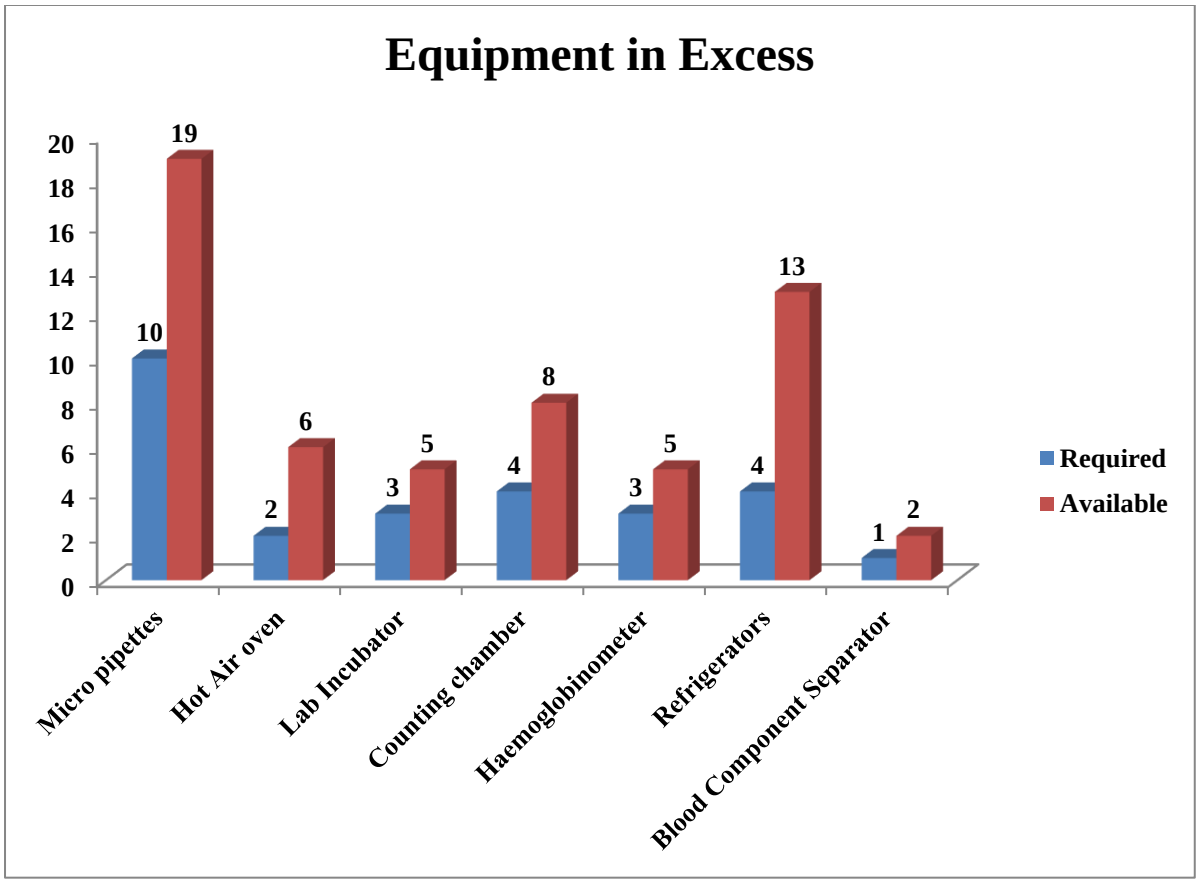


Figure 3.2.1 Equipment in Excess

The graph above shows that the quantity of the above mentioned equipment is more than the requirement of the IPHS standards. The reason being, the blood bank has not started component separation and currently dealing with only whole blood but the blood bank has equipment and all the facilities required for component separation. Also in case of the equipment acquired through Directorate Health Services, several time the condition arises that the quantity received in more than the quantity required. Another reason is the quantity of equipment sanctioned by the state government sometimes is different from IPHS standards and therefore the no of equipment increases.

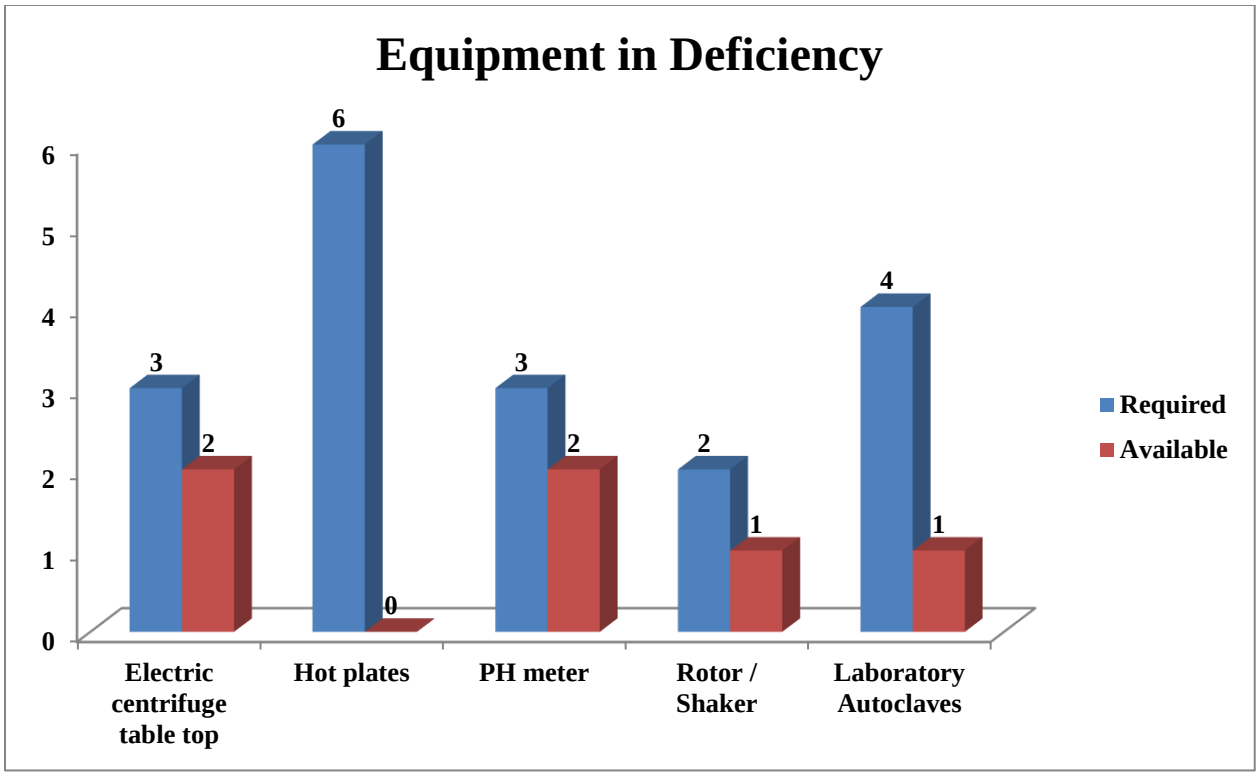


Figure 3.2.1 Deficient Equipment

Figure 3.2.1 describes the status of the equipment, the quantity of which is less than the IPHS requirements. There are no hot plates available and only one autoclave is present which is kept in pathology. The reasons are the delays in the indenting procedures and difference in the state and IPHS norms.

3.3 Infrastructure Available at Blood Bank, District Hospital, Durg

Infrastructure Requirements for Blood Banks			
Space Requirement			
		Available	Not available
1.	Reception Room	√	
2.	Bleeding Room	√	
3.	Refreshment Room		√
4.	Kitchen/Pantry	√	
5.	Aphaeresis Area	√	
Laboratory Area			
1.	Laboratory for routine work	√	
2.	Laboratory for special RBC serology quality control	√	
3.	Laboratory for specialized work Platelets HLA serology	√	
4.	Issue counter and contingency counter	√	
5.	Hepatitis, AIDS, VDRL etc	√	
6.	Wash Basin, Distillation plant etc	√	
7.	Component basis	√	
8.	Component - Advanced and Freeze Diving etc	√	
9.	Room for arrival	√	
General Area			
1.	Doctor's office	√	
2	Donor Recruitment, social worker and associated clerical staff	√	
3.	Blood Bank officer	√	
4.	Stores	√	
5.	Technical common room	√	
6.	Toilets	√	

Table 3.3.1 Infrastructure Available at Blood Bank

A detailed layout is given below.

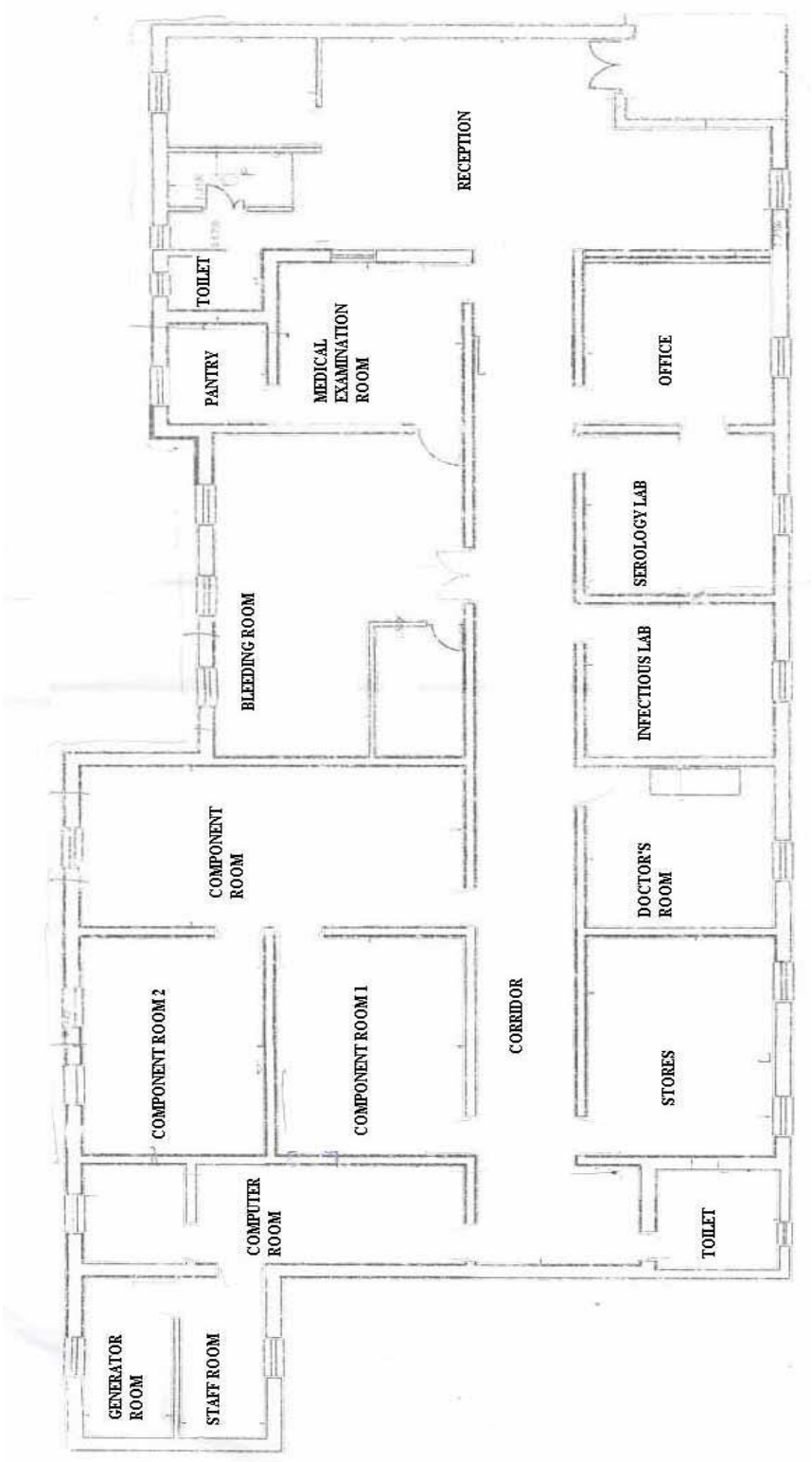


Figure 3.3.1 Layout of Blood Bank

3.4 Performance Assessment of the Blood Bank Facility

The assessment of the performance of blood bank, district hospital durg has been done by identifying certain variables and evaluating their trend over the past years. The data collected for the assessment of the performance of the facility ranges from 2001 to 2009. The analysis includes the review of the trend of the service and determination of the cause of the trend. The various indicators selected for this purpose are as follows:

(a) Voluntary Donation Versus Replacement Donation
(b) No of blood units Issued (Free Vs paid)
(c) Discard Rate
(d) Rh Negative (Rare Blood Group) Donor Pool
(e) Autologus Transfusion

3.4.1 Voluntary Donation Versus Replacement Donation:

Voluntary blood donation is the best and safest system of blood transfusion and thus it needs to be strengthened. Thus, the understanding the various factors which could change the perception of the people and awareness among the community about blood donation may prove to be useful for the successful implementation of a blood donation program in the state, especially in improving the voluntary blood donation system. Blood donation is important for not only saving people's lives but also for the pursuit of a better social and living environment, and voluntary blood donation is of great social importance. It is important that voluntary non-remunerated blood donations should be promoted, accepted and practiced for safe blood supply.[9]

The data on blood donation both voluntary and replacement has been collected and analysed. The following analysis has been deduced from the collected data:

Sr. No.	Variable	Year								
		2001	2002	2003	2004	2005	2006	2007	2008	2009
1	Voluntary Donor	113	236	192	257	473	388	391	468	1604
2	Replacement Donor	3011	3031	3437	3581	4211	4275	3893	4159	2861
3	Total Donors	3124	3267	3634	3838	4684	4663	4284	4627	4465

Table 3.4.1.2 Voluntary Donation Versus Replacement Donation

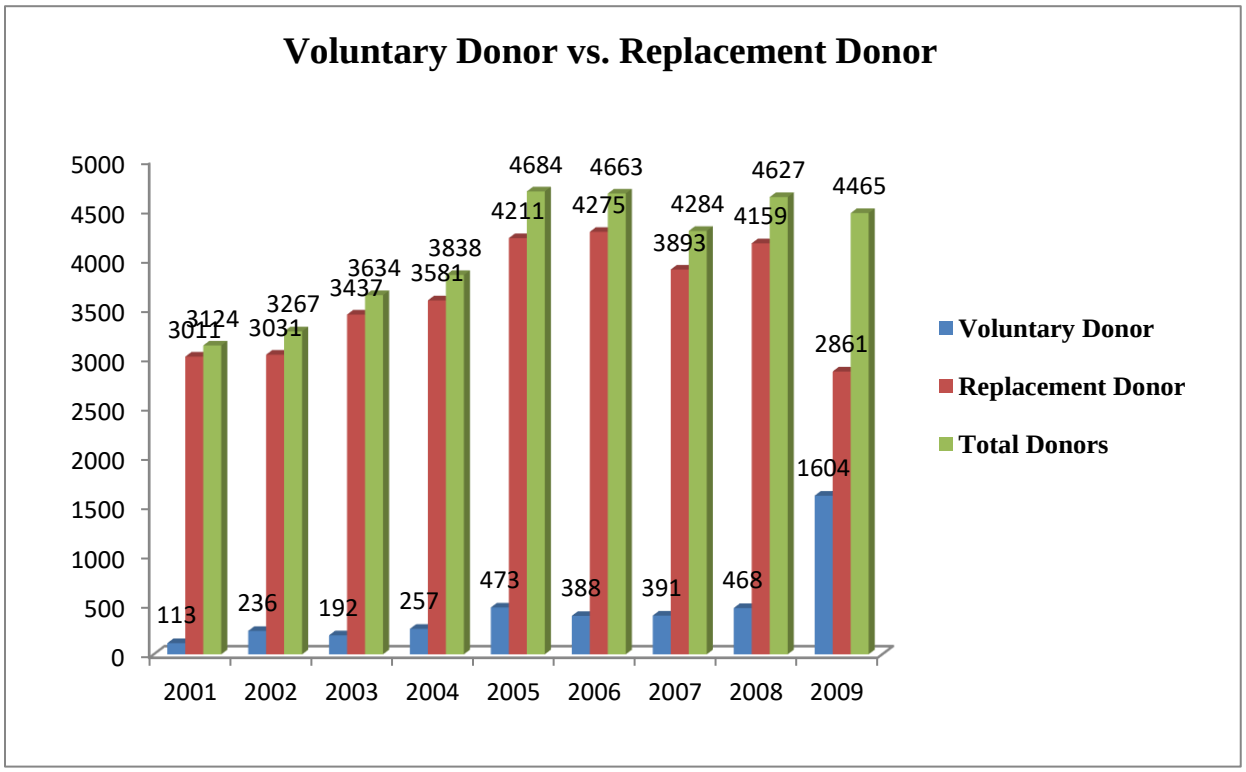


Figure 3.4.1.2 Voluntary Donation Versus Replacement Donation

Year	Blood Donation Camp
2001	12
2002	15
2003	16
2004	21
2005	36
2006	19
2007	16
2008	25
2009	21

Table 3.4.1.1 Blood Donation Camps

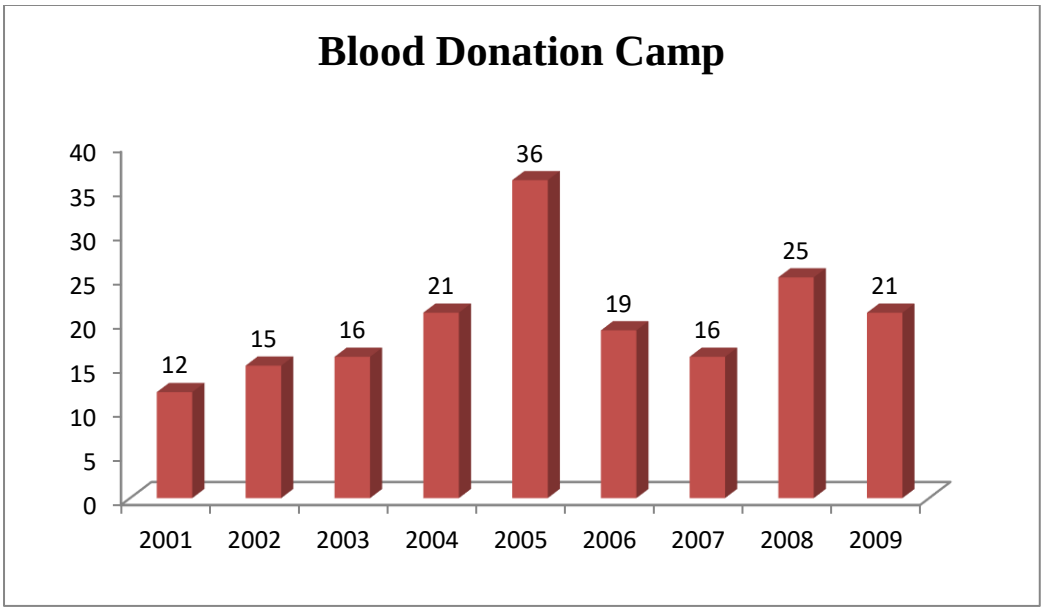


Figure 3.4.1.1 Blood Donation Camps

It has been observed from the above graphs that the blood donation through replacement has been a major the major source of blood for the blood bank. As per the current trend which suggest that the blood bank should collect 100% of the blood in the blood bank through Voluntary donation instead of replacement donation which is not the case in this blood bank as blood donation through replacement being the major source of blood for the blood bank. The major reason behind this is identified as the blood bank needs to organize more blood donation caps for voluntary blood donation camps in the community which are showing a downfall since 2006.However it is evident from the graph that though voluntary donation is less than replacement donation, but it is continuously increasing over the past years with a CAGR of 70.7% which is more as compared to Replacement donation (CAGR:-0.6%) which is showing a down trend since 2005.

3.4.2 No of blood units Issued (Free Versus paid)

Sr. No.	Variable	Year								
		2001	2002	2003	2004	2005	2006	2007	2008	2009
1	Issued	3082	3279	2924	3753	4588	4573	4221	4745	4430
2	Paid	2718	3139	2687	3263	3560	3173	3870	3122	2260
3	Free	364	340	237	490	1028	1377	351	1610	2170

Table 3.4.2.1 No of blood units Issued

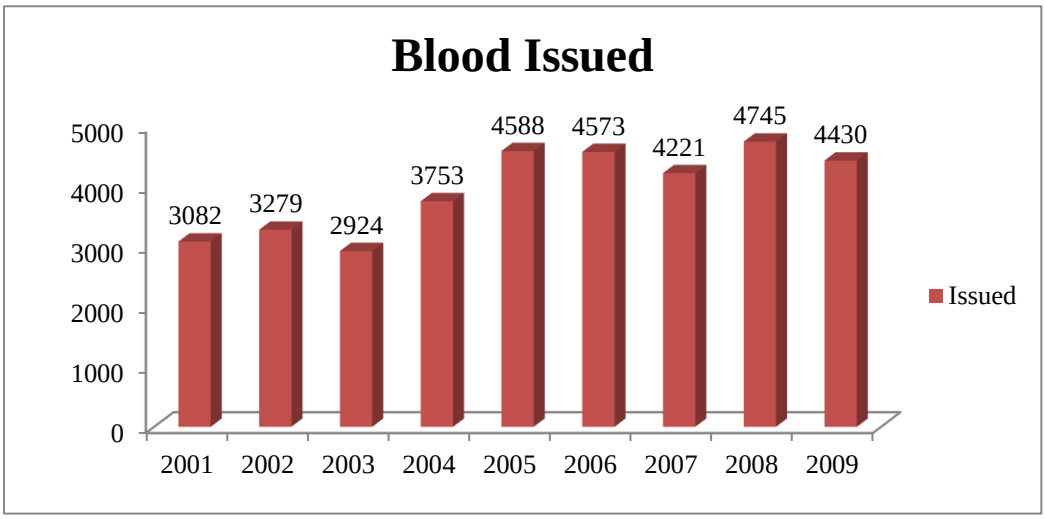


Figure 3.4.2.1 No of blood units Issued

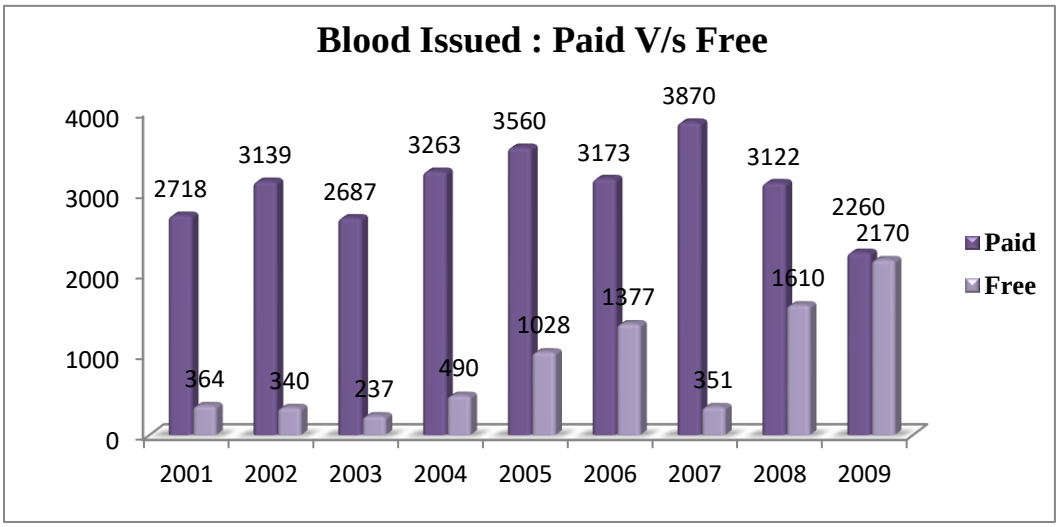


Figure 3.4.2.2 No of blood units Issued (Free versus Paid)

The no. of units issued has showing a continuous trend and maintained itself above 4000 units distributed per year since 2005 with a CAGR of 4.1%. it is clearly evident from the graph that no of BPL patients have increased since past years as the no of units distributed for free has increased with a CAGR of 21.9% where as paid distribution of blood is showing a downtrend which consecutively indicates that the utilization of services by BPL group in increasing.

3.4.3. Discard Rate

Sr. No.	Variable	Year								
		2001	2002	2003	2004	2005	2006	2007	2008	2009
1	Blood Discarded	44	22	56	62	116	141	131	90	115
2	Haemolisis	7	9	12	5	15	24	22	14	17
3	HIV Positive	2	8	5	7	15	25	19	24	20
4	HBsAg Positive	31	32	23	45	70	66	77	56	53
5	HCV Positive	2	1	3	0	0	2	1	3	3
6	V.D.R.L. Positive	2	2	13	3	16	24	12	7	22
7	Malaria	0	0	0	0	0	0	0	0	0

Table 3.4.3.1 Discard Rate

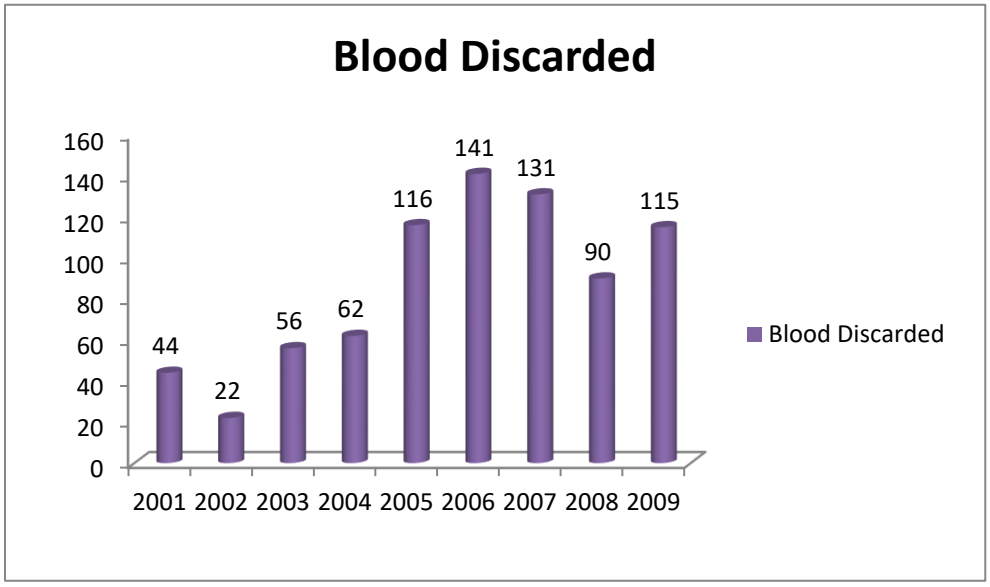


Figure 3.4.3.1 Discard Rate

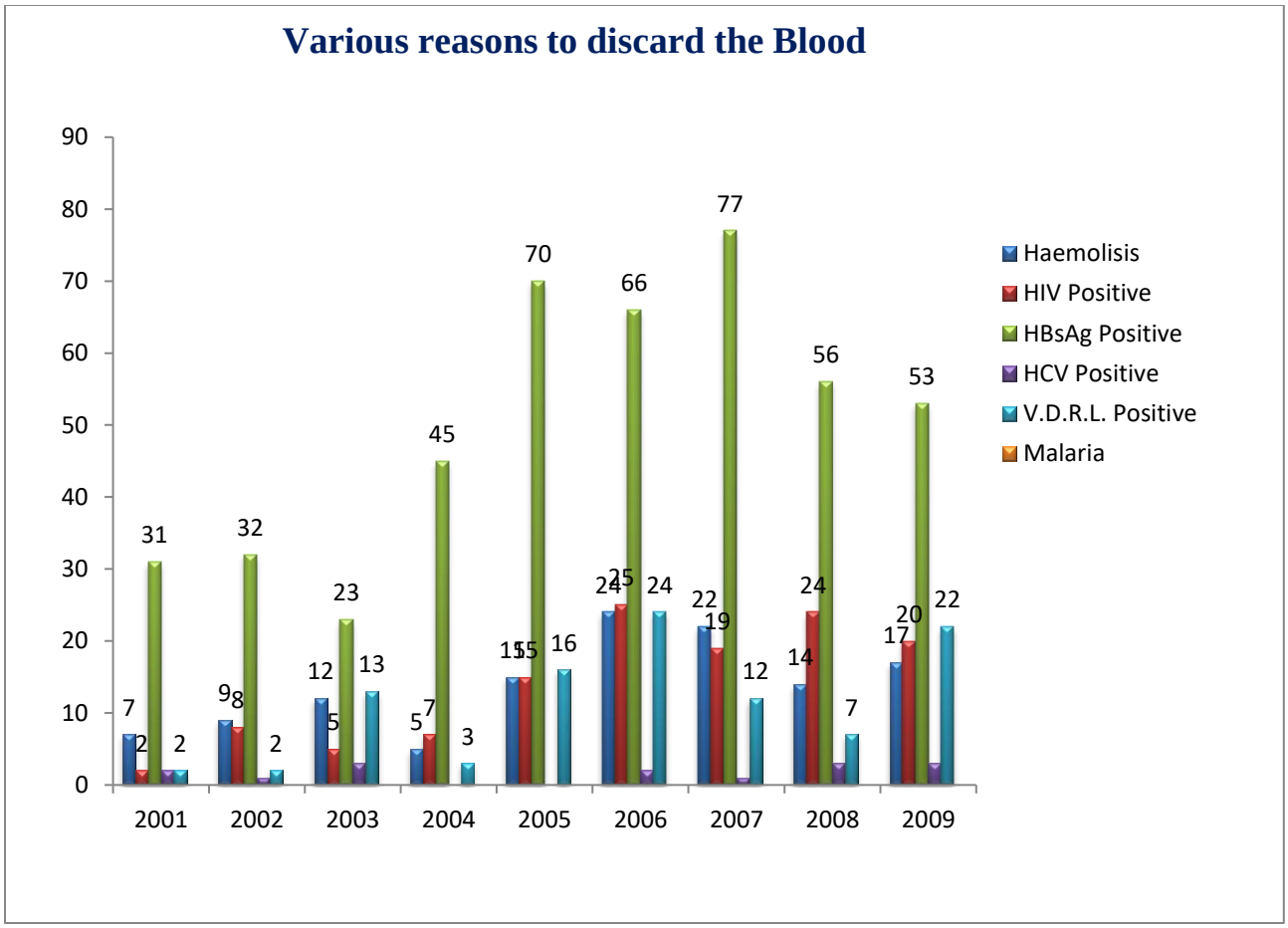


Figure 3.4.3.2 Reasons to discard the Blood

The discard rate is showing an initial uptrend followed by a downfall in the no. of blood units discarded. The discard rate has been increased with a CAGR of 11.2% since 2001. The major cause of discard is identified as HBs Ag Positive followed by HIV Positive, VDRL Positive and Haemolysis. In Chhattisgarh, Durg district has the maximum HIV burden[10] and hence the it becomes one of the significant reason to discard blood.

3.4.4. Rh Negative (Rare Blood Group) Donor Pool

The blood bank maintains a single unit of each Rh negative blood group available in the storage in order to deal with any emergent requirement. They claim that the requirement arises at less frequent intervals so carrying more no. of Rh negative blood units will increase their inventory and discard rates as the requirement is less so there are chances of expiry of the blood.

3.4.5. Autologus Transfusion

Autologous Blood transfusion is the process of collecting and re-infusing patient's own Blood or Blood components. Although this kind of transfusion is not completely free of risk but then also autologous Blood is the safest form of Blood transfusion. Use of a patient's own Blood eliminates reactions due to donor recipient incompatibility and precludes exposure to transfusion transmitted infection. Despite reduction of the risk of transmitting viruses such as the human immunodeficiency virus (HIV) or hepatitis B or C (HCV) autologous blood transfusion remains safer than allogeneic blood transfusion and appropriate for properly selected patients. Use of autologous blood can eliminate or reduce many adverse effects of transfusion. [11]

The blood bank is currently not undertaking the procedure of autologous blood transfusion since the physicians in the facility are not recommending the procedure. This results in the utilization of the blood bank resources which could have been minimized if the autologous transfusion would have started. There is a need of starting autologous blood transfusion services in the facility.

CHAPTER 4: CONCLUSION & RECOMMENDATION

4.1 Identification of Bottlenecks in the Facility

The blood bank, district hospital, durg is serving the community in an efficient manner catering to the blood requirements in a well managed manner. It meets all the necessary guideline required for a blood bank. The following are the bottlenecks identified in the Blood Bank, District Hospital, Durg.

1. Lack of autologous blood donation in the facility:

2. No provision of refreshments to the blood donors after their bleeding

3. Delay between Indent and receipt of consumables

4. Component separation has not started

5. Technicians do not have authority to sign and verify crossmatching report

6. Requirement of Class II medical officer on duty

7. Necessity to increase Voluntary Blood Donation

8. Necessity to increase Rh negative (rare blood group) donor pool.

4.2 Recommendations

After the analysis of all the data of the blood bank facility and identification of the bottlenecks in the facility, the following recommendations can be made in order to increase the efficiency of the facility and satisfaction among the donors and receivers of blood:

1. The facility should start autologous blood transfusion in the facility in order to optimize the utilization of resources and stored blood. The autologous transfusion is safer than indirect transfusion. The top management is informed to take necessary steps for the implementation of this procedure.

2. There is no refreshment area in the facility, which is a mandatory requirement of the blood bank facility. For this purpose a space near reception area is identified where the donors will be allowed to relax after blood donation and provided with refreshments. The blood bank is having a pantry in it where the refreshment can be stored.

3. The delays in the receipt of consumable could produce disastrous consequences. Hence there is a need to develop a mechanism for proper inventory control. They need to keep certain buffer stock of consumables which can be utilized during the lead time. Also there is need to identify the suppliers and make a list of supplier followed by setting a lead time for the indent and receipt of material.

4. There is perennial shortage of blood and blood components in most of the developing world. The resources are inadequate in terms of meeting the ever growing demand of blood components. The facility is having all the resources available for the component separation but still it has not got the approval for starting the same. The facility will be getting approval and then a formal inauguration of blood component separation.

5. There is an absence of class II medical doctor in the facility which is a mandatory requirement of regulatory norms. This gap has been identified and intimated to the top management. They will try to hire the same through Jeevan Deep Samiti Fund.

6. In order to increase voluntary donation awareness campaign has been suggested to the blood bank and there is a need to increase no. of blood donation camps. For awareness campaign sinages, charts and leaflets can be used.

4.3 Conclusion

The blood bank, District Hospital Durg is already performing at an exceptionally well by complying most of the regulatory requirements. There are some lacunas in the facility on which improvement is needed to be done in order to achieve maximum efficiency. Among the identified gap, the corrective action has already started. After the fulfillment of the entire requirement the facility will possess the potential become a role model for the other blood bank facility in district hospitals.

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Annexure 1

1. STANDARD OPERATING PROCEDURES: BLOOD BANK, DISTRICT HOSPITAL DURG

1. Criteria for donor selection

Accept only voluntary/replacement non-remunerated blood donors if following criteria are fulfilled.

The interval between blood donations should be no less than three months. The donor shall be in good health, mentally alert and physically fit and shall not be a jail inmate or a person having multiple sex partners or a drug-addict. The donors shall fulfil the following requirements, namely:-

(a) The donor shall be in his age group of 18 to 60 years.

(b) The donor shall not be less than 45 kilograms.

(c) Temperature and pulse of the donor shall be normal.

(d) The systolic and diastolic blood pressures are within normal limits without medication.

(e) Hemoglobin shall be more than 12.5 g/dl.

(f) The donor shall be free from acute respiratory disease.

(g) The donor shall be free any skin diseases at the site of phlebotomy.

(h) The donor shall be free from any diseases transmissible by blood transfusion, in so far as can be determined by history and examination indicated above.

(i) The arms and forearms of the donor shall be fee from skin punctures or scars indicative of professional blood donors or addiction of self-injected narcotics.

2. Donor Screening

Medical Examination:

(a) General Appearance: Defer a donor who appears ill, under the influence of drugs/alcohol or do not appear to be providing reliable answers to medical history.

(b) Check and enter donor's WEIGHT. The weight should be >50 kg. To collect 450 ml and between 45 and 50 kg to collect 350 ml blood.

(c) Check if the BLOOD PRESSURE, PULSE AND TEMPERATURE are within the acceptable limits :

- Systolic blood pressure not >160 mm of Hg.
- Diastolic pressure not > 100 mm of Hg.
- Pulse regular, between 60 and 100 beats/minute.
- Oral Temperature 37.5 C +/-0.2 C (98.6 F=/-0.5F).
- HAEMOGLOBIN ESTIMATION: Blood donation can be accepted only if the Haemoglobin is > 12.5 g/dl. Test for Haemoglobin by $CuSO_4$ specific gravity method.

3. Qualifying Test for Blood Donation

Principle:

This is a qualitative test based on specific gravity. The drop of donor's blood dropped into copper sulphate solution becomes encased in a sac of copper proteinate, which prevents any change in the specific gravity for about 15 seconds. If the haemoglobin is equal to or more than 12.5 gm/dl the drop will sink within 15 seconds and the donor is accepted.

N.B. : -Do not depend on colour of tongue or conjunctiva.

-Accept a donor only if haemoglobin is >12.5g/dL.

Method:

(a) 30 ml copper sulphate working solution (Sp.gr.1.053) in a clean, dry coplin jar is used for determining hemoglobin. The jar is kept covered with a lid when not in use. The working solution is changed after every 25 tests.

(b) The fingertip is cleaned thoroughly with a spirit swab & allowed to dry.

(c) The finger is punctured firmly near the tip with a sterile disposable lancet. A good free flow of blood is ensured. The finger is not to be squeezed repeatedly since it may dilute the drop of blood with excess tissue fluid and give false low results.

(d) The first drop of blood is wiped and ¾ of the micro capillary is allowed to fill with blood sample by capillary force, without any bubbles.

(e) Allow one drop of blood to fall gently from the capillary from a height of about 1 cm above the surface of the copper sulphate solution, into the coplin jar.

(f) The drop of blood is observed for 15 seconds.

(g) The lancet and capillaries are disposed off in a container with 1% sodium hypochlorite solution.

Interpretation:

(a) If the drop of blood sinks within 15 seconds (i.e. donor's haemoglobin is more than 12.5 gm/dl), the donor is accepted for blood donation.

(b) However, if the blood drop sinks midway (i.e. haemoglobin level is less than 12.5 gm/dl), and then comes up, the donation or donor is deferred.

(c) If the drop sinks slowly, hesitates and then goes to the bottom of the jar, confirm the haemoglobin of this donor.

(d) If the donor fails the $CuSO_4$ test, repeat haemoglobin by Sahli's/Drabkin's/Automated Cell Counter.

(e) In case if the haemoglobin is lower than 12.5 gm/dl, prescribe haematinics and ask the donor to come for a recheck after one month.

4. Haemoglobin Estimation: Preparation of $CuSO_4$ Solution

Stock solution is made as follows and kept in a jar or bottle.

(a) Dissolve 170 gm crystalline $CuSO_4$, $5H_2O$ in 1000 ml distilled water working solution.

(b) Every morning prepare fresh solution.

(c) Add 51 ml stock solution to 49 ml distilled water.

(d) Check specific gravity which should be 1.053, if not, adjust it using either stock solution or Distilled Water.

5. Copper Sulphate Solution: Quality Control

Check the copper sulphate solution against a light source for the presence of precipitate/cloudiness.

↓

Check the specific gravity of the solution using a urinometer.

↓

Copper sulphate being a colored solution, the marking of the urinometer corresponding to the upper meniscus of the solution should be 1.053=12.5 g% of haemoglobin.

↓

Arrange the blood samples according to haemoglobin concentration in a rack.

↓

Obtain samples of known Hb values.

↓

Transfer 30 ml copper sulphate working solution in a Coplin jar.

↓

Mix the blood sample of known haemoglobin concentration by inversion.

↓

Fill heparinized capillary upto ¾ capacity with the blood sample.

↓

Allow the drop of blood to fall gently into the copper sulphate solution.

↓

Repeat the procedure for all the blood samples.

↓

Note the result.

↓

Record the results in the copper sulphate record book

6. Blood Collection: Solutions & method for preparing Phlebotomy Site

After selection of the vein for venipuncture, apply spirit, povidone-iodine (loprep) and finally spirit swab, in this order, to the skin at the phlebotomy site. Start disinfection of the skin of about an area of 5 cm diameter from the centre outwards in a circular motion. Scrub the providone-iodine vigorously for at least 30 seconds or till froth forms. Do not touch the site prepared for venipuncture. Should it be necessary, touch the skin away from the point of needle insertion? If the puncture site is touched, repeat skin preparation procedure as detailed earlier.

Discreetly check the used swab. If it is physically soiled/ contaminated, take a new swab and repeat skin preparation, procedure as detailed earlier.

Dispose off used swab(s) into a waste bin meant for bio-hazardous materials. Allow the skin to air dry. Do not wipe the area with cotton wool, fan or blow on it.

`

7. Selection of Bags: Choice of Bag depending on component to be prepared

Select the bag as per the following chart:

DONOR		**COMPONENTS**	**BAGS**	
Weight	**Asprin intake**	**Required**	**Type**	**Qty.(ml) of Blood**
>55 kg	No	PC+FFP+PLT	Triple or Quadruple	450 ml
>55 kg	Yes	PC+FFP PC+FVIIID+CRYO	Double	350/450 ml
45-55 kg	No	PC+FFP PC+FVIID+CRYO PC+PLT	Double	350 ml
45-55 kg	Yes	PC+FFP PC+FVIIID PC+FVIIID+CRYO	Double	350 ml

PC: Packed Cells, **FFP**: Fresh Frozen Plasma, **PLT**: Platelets, **FVIIID**: Factor VIII deficient plasma, **Cryo**: Cryoprcipitate

- Check the bag visually.
- In case of puncture, discolouration, do not use.
- Check the expiry date of the bag.
- Use single bag when.

1. Components are not to be separated from that unit.

2. When autologous blood is collected for patients e.g. elective surgery.
3. Therapeutic phlebotomy is being performed on a patient.

8. **Blood Collection**

(a) Mark the donor lie down with a pillow under the head or recline in a comfortable donor chair. Loosen tight garments.

(b) Identify the donor by name. Enter the bag and segment numbers on the donor card/form.

(c) Ask the donor if he/she is in a comfortable position. Give the donor a hand roller/squeeze to hold.

(d) Select a bag for blood collection.

(e) Clean the venipuncture site.

(f) Set the bio mixer for the required volume of blood (350/450 ml) to be collected and place the bag on it.

(g) Apply the tourniquet on donor arm.

(h) Clamp the bleed line of the blood bag using plastic forceps to ensure that no air enters the tubing or bag once the needle cover is removed.

(i) Keep the level of the needle facing upward and the shaft at an angle of 15^0 to the arm.

(j) Once the needle is beneath the skin, release the clamp.

(k) Insert the blood bag needle into the vein for about 1 to 1.5 cms by a bold single prick to ensure smooth flow of blood and secure on the arm with adhesive strips.

(l) Advise the donor to gently squeeze the hand roller to improve blood flow.

(m) If the venipuncture is unsuccessful do not make further attempt in the same arm. Take the donor's permission for a second attempt. Use a new bag.

(n) Once blood enters the bag tubing, press the bio mixer 'start' switch to allow the blood to flow into the bag. After the programmed volume of blood is collected, the bio mixer automatically clamps the tubing.

(o) Clamp the bloodline at 2 sites and cut in the middle. Collect blood in the pilot tubes from the tubing so that blood flows directly into the tubes from the donor arm.

(p) Release the tourniquet and remove the needle gently from the donor's vein pressing the phlebotomy site. Fasten a Velcro cuff around the donor's arm in a flexed position.

(q) Seal the blood bag tubing with the tube sealer.

(r) Burn the needle of the bag in the needle incinerator. Discard the tubing with the burnt needle in a container of sodium hypochlorite solution.

9. Blood Collection (Post Donation Care)

(a) To prevent adverse reactions like giddiness ask the donor not to get up from the chair/cot for 5 minutes even if he feels perfectly all right.

(b) Observe for another 10 minutes in the refreshment area whilst having coffee.

(c) Inspect the venipuncture site before the donor leaves the donor room. Apply an adhesive tape only after oozing stops. If there is persistent oozing at the site of venipuncture, apply pressure with a dry, sterile cotton swab. If there is haematoma apply Thrombophob ointment gently over the area after 5 minutes. Inform the donor about the expected change in skin colour. If the pain persists, ask him/her to apply ice.

(d) Instruct the donor to drink adequate fluid in the day and avoid strenuous activities.

10. Blood Collection (Management of adverse reactions in a donor)

(a) Giddiness/Syncope (vasovagal syndrome).

Raise feet and lower head end.

Loosen tight clothing (belt, tie etc.)

Ensure adequate airway

Check pulse and blood pressure

Apply cold compresses to forehead and back

Administer inhalation of spirit of ammonia if needed. The donor should respond by coughing which will elevate the blood pressure.

If there is bradycardia and hypotension-

- Administer inj. Atropine 1 ml IM, if bradycardia continues for more tan 20 minutes.
- Administer IV normal saline or dextrose saline infusions if hypotension is prolonged.

(b) **Convulsions:** Keep the head tilted to the side; prevent the tongue bite; keep the airway patent by inserting a tongue blade or gauze between the teeth.

(c) **Vomiting:** Usually this provides relief. If the donor feels nauseous or if vomiting is severe, inject Stemetil. Usually subsides on its own.

(d) **Tetany/Nyscykarsoasn/twitching:** These are usually due to hyperventilation in an apprehensive donor. Ask the donor to breath in a paper bag, which provides prompt relief. Do not give oxygen.

(e) **Haematoma:** Release the tourniquet/pressure cuff immediately. Apply pressure on the venipuncture site and withdraw the needle from the vein. Raise the arm above the head for a few minutes. Apply Thrombophob ointment gently around the phlebotomy site after about 5 minutes. Advise the donor to apply ice if there is pain and inform about the expected change in skin colour.

(f) Eczematous reactions of the skin around venipuncture site : Apply steroid ointment.

(g) Delayed syncope: These may occur as late as 30 minutes to 1 hour after donation, usually after the donor has left the blood bank. Permanently defer any donor who gives history of such attacks more than twice.

11. Trace ability of Blood Bags

(a) Give each donor a unique number and once his blood is collected, identify by that number only.
(b) Do not write donor's name on his/her blood bag or sample tube. This maintains the donor's confidentiality.
(c) Affix pre printed number labels on the primary bag on both sides, on all the satellite bags in case of multiple bags and the three pilot tubes (2 plain and one with CPD anticoagulant).
(d) Verify the donor's identity by tallying with the name on the master registration card.
(e) Affix the unit number label, which is loosely attached to the bag now to the card.
(f) Cross check the numbers on the bag, pilot tubes and master registration card to ensure identity. Record the entry in the donor register using the same number.
(g) Transcribe this number on all records hence forth for storage, testing and distribution.

(h) Whilst issuing the unit, use the same number on issue record.

12. Blood Component Separation

A. Preparation of packed cells and FFP or FVIII deficient plasma using double bags :

(a) Keep the units vertical on the laminar flow table for 30 to 45 minutes (Process all units within 6 hours of blood collection).

(b) Keep the bags in the buckets and balance them. Keep the equally balanced buckets with bags diagonally opposite in the refrigerated centrifuge ensuring that the position of the bags in buckets in parallel to the direction of the spin.

(c) After centrifugation, gently remove the bags from the bucket and place them on the expresser stand under the laminar flow. Break the integral seal of the tube connecting it to the satellite bag/s manually and express the supernatant plasma into the satellite bag. In case of double bag, leave 50-60 ml of plasma back along with the red cells in the primary bag and this component is Packed Red Cells (PC).

(d) Label the plasma in the satellite bag, as Fresh Frozen Plasma (FFP) if separated within 6 hours of collection and stored immediately below 30^0C.

(e) If plasma is separated after 6 hours of collection label as factor VIII deficient plasma (FVIIID).

(f) Cut the segment of FFP and FVIIID bags short.

B. Preparation of packed cells, platelet concentrates and FFP using triple bags with or without additive solution:

(a) Process the blood collected within 6 hours.

(b) Keep the bags erect on the laminar flow for 30-40 minutes.

(c) Note the weight of the primary bag and record in the register.

(d) Balance the bags in the buckets using dry rubber or unused bags.

(e) Keep equally balanced buckets diagonally opposite each other in the refrigerated centrifuge.

(f) Position the bags in buckets parallel to the direction of the spin. Centrifuge the bags at 3500 rpm* for 10 minutes at 4^0C.

(g) Keep the bag on the separator on the laminar flow. Break the seal of the tubing connecting to the satellite bag. And express the plasma into the satellite bag leaving 50-60 ml plasma along with the red cells. If the bag with additive solution is used, remove all plasma in satellite bag before clamping. Remove the clamp of the bag containing additive solution and let the additive solution slowly pass into the primary bag containing red cells.

(h) Mix the contents thoroughly and seal the tubing and detach the bags.

(i) Keep the primary bags containing packed cells with additive solution in quarantine storage in the blood bank refrigerator kept in the component room?

(j) Label the bag and take it on the inventory after the testing is over.

(k) Spin the satellite bag containing platelet rich plasma(PRP) and connecting bag from which additive solution was empties, at 22^0C in refrigerated centrifuge at 500 rpm* for 10 minutes after balancing the buckets.

(l) Place the bag containing PRP on the expresser stand.

(m) Express the plasma into the empty bag leaving 50-60 ml plasma along with the platelets.

(n) Seal the tubing and cut the tubing of the plasma bag short (1") to avoid breakage during frozen storage.

(o) A small segment of tube containing platelets (about 8 cms long) is prepared after mixing of the bag contents as and when requested by quality control laboratory.

(p) Leave the platelet concentrates on the laminar flow for 30 minutes, keeping the label side down. Mix the contents of the bag manually before transferring the units to quarantine storage in the incubator at 22^0C on the lower shelf.

(q) After the required test results are available place the platelet concentrates on the agitator in the upper shelf for use.

(r) Keep the plasma bag in the quarantine storage in the deep freezer kept in the component room and transfer to deep freezer in issue area when the tests are completed after labelling and entering in the inventory.

(s) Standardise the speed of the centrifuge as it depends on the type of bag, the amount of blood collected and centrifuge in use.

C. Preparation of Cryoprecipitate :

(a) The basic material is platelet poor fresh frozen plasma. The plasma should be free of red cell. Use the plasma frozen at 80^0C preferably within a day or two of freezing.

(b) Keep the segment of the bags for potential cryo-preparation longer.

(c) Fill the cry bath with double distilled water.

(d) Maintain the temperature of water in continuous circular motion at 9^0C.

(e) Keep the frozen plasma bags in this cryo bath. When the plasma is thawed, place the bags in centrifuge buckets and balance the buckets on weighing scale.

(f) Keep the position of the bags in buckets parallel.

(g) Spin the buckets at 5000 rpm for 15 minutes at 4^0C.

(h) Connect empty transfer bag to the bag containing plasma and cryoprecipitate using sterile connecting device. Under laminar flow.

(i) Place the plasma bag on expresser and separate plasma into the transfer bag leaving approximately 15-25 ml as cryoprecipitate suspension in the original bag.

(j) Seal the tubing and separate the cryoprecipitate and the cryopoor plasma bags.

(k) Weight, the cryo and plasma bags and record.

(l) The plasma separated is F-VIII deficient plasma. Both the bags are kept in quarantine till tests are completed.

(m) Label, enter the inventory and place than in deep freezer in issue area after test results are available.

D. Washed Packed Red Cell

(a) Undertake the washing procedure only after the compatibility test is over.

(b) If a single bag is used for blood collection attaches a transfer bag using sterile connecting device.

Balance the blood bag in the centrifuge bucket with another empty bucket.

Spin the bag at 3500 rpm for 10 minutes at 4^0C.

(e) Remove the supernatant plasma completely in a transfer bag using expresser under laminar flow. Before washing the unit, red cell serology laboratory should perform the compatibility tests. The washing procedure is undertaken only after the proposed unit is found to be compatible with recipient.

(f) The proposed blood unit is balanced in the centrifuge bucket with another empty bucket. The buckets are centrifuged as per programme.

(g) The bag is removed and supernatant plasma is completely removed in a transfer bag using an expresser under laminar flow.

(h) Connect the bag with a sterile 0.9% saline bag using a transfer set.

(i) Record batch number and expiry dates of saline in use.

(j) Introduce approximately 200 ml of saline into the packed cell bag and mix thoroughly and centrifuge again.

(k) Transfer the supernatant saline with some plasma into a transfer bag using the expresser under laminar flow.

(l) Disconnect the transfer bag, seal and discard.

(m) Repeat the washing with saline twice more (total three times) exactly in the same manner as described above. In the end keep 25-30 ml saline with the red cells in the bag.

(n) Seal the final thrice washed red cell unit.

(o) Weight the bag and record details in the register.

(p) Store the washed packed red cell unit at 1-6^{0}C and use within 24 hours of washing.

(q) Use this blood only for the patient for which requested. If not used discard after 24 hours with standard disposal protocol, after subjecting small sample for bacteriological examination.

13. ABO Blood Group (Cell & Serum Testing –Tube Method)

Principal:

ABO system is the only system in which there is a reciprocal relationship between the antigen on the red cells and the naturally occurring antibodies in the serum. Routine grouping of donors and patients must therefore include both RBC and serum tests, each serving as check on the other. The procedure is based on the principle of agglutination of antigen positive red cells in the presence of antibody directed towards the antigen.

RBC Testing:

(a) Label tubes with donor/patient and test identification.

(b) Prepare cell suspension for cells being tested (Refer SP015).

(c) Place two drops of anti-A, anti-B and anti-AB reagent in the appropriately labelled tubes.

(d) Add to each tube one drop of 2-5% cell suspension (in normal saline, serum or plasma) of the red cells to be tested.

(e) Mix the contents of the tubes gently and incubate at room temperature for 15 minutes.

(f) Centrifuge at 1000 rpm for 1 minute.

(Note: Always follow manufacturer's instructions from package insert)

Serum Testing:

(a) Label tubes with donor-patient and test identification.

(b) Add 2 drops of test serum in all tubes in the corresponding column.

(c) Prepare cells for testing of A,B and O groups by pooling 3 samples of each group.(Refer SP015).

(d) Add 1 drop of 2% pooled A red cell suspension in tube labelled A.

(e) Add 1 drop of 2% pooled B red cell suspension in tube labelled B.

(f) Add 1 drop of 2% pooled O red cell suspension in tube labelled O.

(g) Mix the contents of the tubes gently and incubate the test for minimus 15 minutes at room temperature.

(h) Centrifuge all tubes at 1000 rpm for 1 minute.

(i) Gently resuspend the red cell button & examine for agglutination.

Results:

(a) Depending on presence (+) or absence (-) of agglutination, the position of the tubes is changed or remains unaltered as shown below.

(b) Confirm the cell grouping results with those obtained in serum grouping and vice versa.

Test	**Initial Position**	**Tube Position**	**After Result**
		Aggin +	Aggin –
Anti-A	Row 1	Row 3	Row 1
Anti-B	Row 2	Row 4	Row 2
Anti-AB	Row 3	Row 5	Row 3
A_c	Row 1	Row 3	Row 1

B_c O_c	Row 2 Row 3	Row 4 Row 5	Row 2 Row 3

Interpretation:

(a) Agglutination in any tube of RBC tests and agglutination or haemolysis in serum test constitutes a positive test result. The expected agglutination reaction for positive tests are 3*to4*.

(b) A smooth suspension of RBCs after resuspension of RBC button is a negative test result. All negative results must be verified under microscope. Cells should be separate without any clumping.

(c) The interpretation of ABO group is as follows :

Cell Typing			Serum Typing			Interception of ABO Group
Anti-A	Anti-B	Anti-AB	AC	BC	OS	
C	-	C	-	C/L	-	AB
-	C	C	C/L	-	-	B
C	C	C	-	-	-	AB
-	-	-	+	+	-	O
C=Clumps, L=Lysis						

(d) Resolve any discrepancies between cell and serum typing tests before the patient's or donor's ABO group is interpreted.

14. Rh D Typing (Tube test for Rh testing)

Principle:

Testing with anti-D is necessary to determine if red blood cells possess or lack D blood group antigen. Absence of agglutination is a negative test result, which indicates that the D antigen

is not demonstrable. Agglutination of red blood cells with an anti-D reagent is a positive test result, which indicates the presence of the D antigen on the red blood cells.

D Typing:

(a) Label tubes with patient/unit and test identification.
(b) Prepare cells for testing in accordance with the preparation of cell suspension (SOP 015).
(c) Add one drop of reagent anti-D to the test tube.
(d) Using a pipette, and one drop of the cell suspension to each test tube.
(e) Mix well (incubation temperature and time depends on manufacturer's instructions).

Results:

(a) Centrifuge all tubes at 1000 rpm for 1 minute (or as specified by manufacturer).
(b) Gently resuspend the red cell button and examine for agglutination.
(c) Grade and record test results.

Interpretation:

(a) Agglutination of the red blood cells in the presence of reagent is a positive test result and indicates the presence of the D antigen.
(b) A smooth suspension of RBCs after resuspension of RBC button is a negative test result. All negative result must be verified under microscope. Cells should appear separate without and agglutination.
(c) The interpretation of Rh D type is as follows :

Cell Typing Anti-D Biclonal	**Cell Typing Anti-D Monoclonal**	**Interpretation of Rh D Type**
V	V	Positive*
-	-	Negative*
V	-	?*
-	V	?*
V=Visible Clumps		

(d) Proceed with weak D(Du) Typing using indirect anti-globulin technique in case of blood donor sample.

* Hand over sample to Advanced Red Cell Serology Laboratory for further workup.

N.B.:

(a) Invalid test results may be obtained with this reagent if the blood tested is from a person with autoantibodies or abnormal serum proteins. Concurrent testing for the ABO blood group serves as a Rh hr control is required only when the cells under test are found to be reactive with anti-A, anti-B, anti-D. If the use of an additional control is necessary, isotonic saline or 6% to 8% albumin in isotonic saline or a patient auto control may be used. If the control gives a positive result, a valid interpretation cannot be made. Cord red blood cells heavily sensitised with anti-D may demonstrate a false negative test result.

15. Preparation of Red Cell Suspensions

Principle:

The ration of serum to red cells may dramatically affect the sensitivity of agglutination tests. Consistent preparation of either 2 to 5% red cell suspension is critical to any agglutination test.

Pooled Cell Suspension:

(a) Label tubes with A, B and O groups.

(b) Place 1 drop of red cells each from 3 of A group sample tubes or segment into the A labelled tube.

(c) Place 1 drops of red cells each from 3 of B group sample tubes or segment into the labelled tube.

(d) Place 1 drop of red cells each from 3 of O group sample tubes or segment into the labelled tube.

(e) Fill the tube ¾ full with 0.9% saline to resuspend the cells.

(f) Centrifuge the tubes for at least 2 to 3 minutes on high speed. Decant the supernatant fluid.

(g) Remove any debris or fibrin with the pipette. Add enough saline to produce as cherry red colour comparable to that of the reagent red cell suspension.

(h) If the colour is too dark, add additional isotonic saline to the tube until the suspension colour is right.

(i) If the colour is too light, repeat steps 6 and 7.

(j) The the pooled cells prepared using the antisera (anti-A, B, AB and D) in use.

(k) Proceed to use the same procedure to prepare cell suspension of particular donor or patient sample for grouping and cross matching.

16. Antibody Screen (Detection of Unexpected Blood group Antibodies)

Principle:

The antibody screen test is used in the detection of unexpected blood group antibodies. In this test, pooled O cells or the antibody-screening reagent red blood cells are combined with serum under investigation. The addition of a potentiating medium enzyme/albumin helps to promote the interaction of red cells and antibodies allowing antibody/antigen reactions to occur. Positive reactions (haemolysis or agglutination) in any tests indicate the presence of allo anibody or auto antibody in the serum.

Antibody Screen:

(a) Label tubes with donor/patient and test identification.

(b) Add two drops of test serum to each tube.

(c) Add 1 drop of papain cystein to all tube labelled 'enzyme' (if enzyme method is being followed).

(d) To each of the tubes labelled 'saline' of 'enzyme/albumin', add 1 drop of 2% pooled O red cell suspension (or 2% suspension of the antibody- screening reagent red cells).

(e) Add 1 drop of 22% abovine albumin to tubes labelled 'albumin' (if albumin method is being followed).

(f) Add 1 drop of 5% pooled O red cell suspension (or 5% suspension of antibody-screening reagent red cells) to tubes labelled 'IAT' followed by 2 drops of 22% bovine albumin.

(g) Mix the contents of the tubes gently and incubate for minimum 15 minutes.

Test	Incubation Temperature	Ideal Incubation Time

Saline	Room Temperature	1 hour
Enzyme	37^0C	45 minutes
Albumin	37^0C	45 minutes
IAT	37^0C	1 hour
Follow manufacturer's directions when using commercial reagents.		

Either enzyme or albumin method may be followed for detection of incomplete antibodies.

Results:

(a) Centrifuge saline, enzyme and albumin tests at 1000 rpm for 1 minute.

(b) Examine for haemolysis.

(c) Gently resuspend the red cell button and examine for agglutination.

(d) Examine all visually negative tests microscopically.

(e) Grade and record test results immediately.

(f) Proceed to perform antiglobulin phase of the indirect antiglobulin test on tubes labelled 'IAT'.

(g) Wash the cells 3 times with saline. Decant completely after last wash. (washing can be done manually or using automated cell washer).

(h) Add 2 drops antihuman globulin reagent to the dry cell button.

(i) Mix well and centrifuge at 1000 rpm for 1 minute.

(j) Read and record results.

(k) Add drop IgG sensitised cells to all negative results. This shows a positive agglutination.

Interpretation:

(a) Hemolysis or agglutination in any test may indicate the presence of an unexpected antibody.

(b) The absence of agglutination and hemolysis in all tests in a negative test result.

(c) After addition of IgG sensitised cells to a negative test, the presence of agglutination indicates that the AHG serum added was capable of reacting and that the negative antiglobulin test is valid.

(d) If IgG- sensitised cells added to confirm the activity of the anti-IgG show only weak or no agglutination after centrifugation, the test is invalid and must be repeated.

Limitations:

If tests with all reagent red cells are reactive, the possibility of spontaneous agglutination should be considered. A control of cells washed three to four times added to two drops of saline must be non-reactive.

17. Detection of incompatibility between patient & donor (Saline/Enzyme Cross-match)

Principle:

The major cross-match is used to detect unexpected blood group antibodies in patient's serum against antigens on door cells. Positive reaction in any test indicates incompatibility.

Cross-match:

(a) Label 3 tubes with patient/donor test identification.
(b) Add 2 drops of patient's serum to each tube.
(c) Prepare 5% cell suspension in 0.9% saline from each donor unit segment.
(d) Add 1 drop 5% donor red cell suspension to the tubes containing patient's serum.
(e) Add 1 drop pap-cysteine to tubes labelled enzyme.
(f) Add 1 drop of 22% albumin to the tubes labelled albumin.
(g) Mix the contents of of tubes gently and incubate for minimum 15 minutes.(Saline tubes at room temperature and Enzyme/Album at 37^0C)
(h) Centrifuge the tubes at 1000 rpm for 1 minute.
(i) Examine for hemolysis.
(j) Gently resuspend red cell button and examine for agglutination.
(k) Examine all visually negative reactions under microscope.
(l) Grade and record test results immediately.
(m) Let a second technician check the results.

Interpretation:

(a) Hemolysis or agglutination in any test indicates incompatibility.

(b) Absence of hemolysis/agglutination in all tests indicates compatibility.

Limitation:

The saline/enzyme cross match will not :-

(a) Detect error in Rh typing.

(b) Prevent isoimmunization of the recipient.

(c) Ensure normal red blood cell survival.

(d) Detect some weakly reactive antibodies.

18. Antiglobulin Cross-match

Principle:

The cross match through the anti-globulin phase permits detection of clinically significant incompatibilities caused by incomplete antibodies that sensitise cells at 37^0C, but do not directly cause agglutination.

Anti-Globulin Cross-match:

(a) Label tube with patient/unit and test identification.

(b) Add two drops of patient serum to each tube.

(c) Prepare a 5% cell suspension in saline from each donor unit segment.
(SP 015)

(d) Add 1 drop of donor's 5% red cell suspension to the tube.

(e) Add 2 drops of 22% bovine albumin & mix well.

(f) Incubate at 37^0C for minimum 15 minutes. (Follow manufacturer's directions when using commercial reagents).

(g) Wash the cells a minimum of 3 times with saline. Decant completely after last wash. (washing can be done manually or in automated cell washer)

(h) Add two drops of antihuman globulin reagent to the dry cell button.

(i) Mix well and centrifuge at 1000 rpm for 1 minute.

(j) Resuspend and read for agglutination. Grade and record test results immediately.

(k) To all negative antiglobulin tests add 1 drop of IgG-sensitised control cells. Centrifuge, resuspend and read for agglutination. Grade and record test results. After the addition of

IgG-sensitised control cells to a negative test, the presence of agglutination indicates that the AHG serum added was capable of reacting and that the negative antiglobulin test is valid.

Interpretation:

(a) Hemolysis or agglutination indicates the presence of a serologically incompatible cross-match. This result is interpreted as incompatible.

(b) Absence of agglutination and hemolysis is a negative test result and indicates a serologically compatible cross match. This result is interpreted as compatible.

If the IgG-sensitised control cells added to confirm the activity of the poly specific reagent show only weak or no agglutination the test is invalid and must be repeated.

Limitation:

The anti-globulin cross match will not :-

(a) Detect error in Rh typing.

(b) Prevent isoimmunization of the recipient.

(c) Ensure normal red blood cell survival.

(d) Detect some weakly reactive antibodies.

19. Transfusion Transmitted Infections (VDRL Test)

Principle:

(b) Venedex is an antigenic cardiolipin based emulsion for detecting syphilis regains (antibodies) in serum, plasma and spinal fluid.

(c) Venedex emulsion contains cardiolipin, lecithin and cholesterol as its active components which produces a flocculation reaction with serum or plasma that contain syphilis antibodies (regains).

Reagent Storage:

Reagent is stable at 2-8^{0}C. Bring to room temperature before use and gently stir the reagent.

Method:

(a) Samples do not need in activation.

(b) Centrifuge the samples to be tested.
(c) Take a VDRL slide i.e. slide with twelve concave depressions, thoroughly clean and dry it.
(d) Arrange samples to be tested in tube rack and label them serially.
(e) Using a pipette transfer 0.05 ml of serum or plasma of the 1st sample on the concave depression.
(f) Discard the tip.
(g) Attack a new tip to the pipette and deliver 0.05 ml of the 2nd sample.
(h) Repeat this step for all the samples.
(i) Note the position of the samples added.
(j) Lastly add the negative and positive controls.
(k) Mix the Venedex reagent and add one drop to all the test samples, negative and positive controls contained in a VDRL slide.
(l) Rotate the VDRL slide at 180 rpm for four minutes.
(m) Examine macroscopically and microscopically for flocculation.
(n) Repeat reactive and doubtful results again along with controls.

Interpretation:

Test results are reported by comparing it with positive control and negative control results.

(a) REACTIVE: Presence of flocculation indicates the presence of anti-lipoidal antibodies in test samples. Strength of flocculation depends upon the degree of positivity of the test samples.

(b) NON-REACTIVE: Absence of flocculation indicates the absence of anti-lipoidal antibodies in test samples. Strength of flocculation depends upon the degree of positivity of the test samples.

20. HBsAg Testing(Samples tested for Hepatitis B Surface Antigen by ELISA method)

Principle:

In the monoclonal EIA procedures micro plate wells are coated with monoclonal antibody to Hepatitis B Surface Antigen (Anti HBs) are incubate with serum of plasma and Anti-HBs peroxidase (Horse radish) conjugate in one step assay. During the incubation period HBsAg if present is bound to the conjugate (Anti-HBs-HRPO). Unbound material is aspirated and washed away. On the addition of substrate colour develops in proportion to the amount of HBsAg which is bound. The enzyme reaction is stopped by the addition of stopping solution.

Method:

(a) Carry out the test as per manufacturer's instructions given in the package insert.

(b) Remove reagents from the friage 30 minutes prior to testing. Mix the reagents gently by inverting the vials without foaming.

(c) Bring reagents and samples to room temperature before testing.

(d) Arrange all donor unit test tube samples, apheresis samples, serially in ascending order in a test tube rack. Add required number of internal kit controls and external lab controls.

(e) Discard all disposable tips into hypochlorite solution.

(f) Place the tray in front of the test tube rack.

- Dispense test sample 100 volume using an auto pipette and fresh disposable tip for every sample.
- Add kit internal positive control.
- Add kit internal negative control.
- Add Lab. External negative control.
- Add Lab. External strong positive control.
- Add Lab. External weak positive control.
- Agitate using micro shaker speed 900 rpm for 15 seconds.
- Incubate at 37^0C for 90 minutes.
- Wash and soak each well four times with PO4 buffer. Check buffer before use. If salt crystals have formed, resolubilise by warming at 37^0C until crystals dissolve.
- Pipette 100 I substrate in each well. Do not mix or agitate discard any unused substrate.
- Incubate at 5-300 for 30 minutes.

- Stop reaction by adding 100 I 1 mol/L Sulphuric Acid to each well.
- Ensure thorough mixing by aping side of plate.
- Read the plates within 15 minutes.
- Blank the reader or air and read the absorbance in each well at 450 ±5nm.

Validation:

If the run fails to meet criteria as per package insert consider the test is invalid and repeat the whole test again. Examine absorbance values of the controls before the sample results can be interpreted.

I.P.C.: Reactive (Internal Kit Positive Control).

I.N.C.: Non Reactive (Internal Kit Negative Control).

E.P.C.1: Reactive (Lab. External Strong Positive Control).

E.P.C.2: Reactive (Lab. External Weak Positive Control).

E.N.C.Non Reactive (Lab. External Negative Control).

The record is then transferred to donor grouping register.

21. Anti HIV Testing (Sample tested for Anti HIV antibodies by EIA)

Principle:

Human serum or plasma diluted in specimen diluent and incubated with proteins of HIV 1 HIV 2, coated auto micro plate wells and incubated. If the HIV antibodies are present in the sample that are tested, it will bind with the proteins coated on the microwell. After washing off the unbound analyte, horse radish peroxidase conjugated with anti human IgG antibodies is added. Enzyme conjugate binds through antigen antibody complex if present. Unbound analyte is washed and substrate solution is added. Colour will develop in proportion to the amount of HIV antibodies present in the specimen. Stopping solution is added at the end of the incubation to stop the reaction. The reaction is read by EIA reader.

Method:

The anti HIV antibody test is carried out as per the instruction given in the package insert of the kit.

(a) Remove reagents from the fridge 30 minutes prior to testing. Mix the reagents gently by inverting the vials without foaming.

(b) Bring the samples to room temperature before testing.

(c) Arrange all samples to be tested serially in ascending order in which they are to be tested in a test tube rack.

(d) Place the plate in front of the test tube rack.

- Add 100 I of the sample diluent to A -1 well as blank.
- Add 100 I negative control in each well No. B-1, C-1 respectively.
- Add 100 I positive control in D-1, E-1 and F-1 wells.
- Add 100 I of each sample diluted in sample diluent (1:11) in each well, starting from G1 well.
- Apply cover seal.
- Incubate at $37^{o}C \pm 2^{0}C$ for 30 min. ±2 min.
- While the samples are incubating, prepare working wash solution and working conjugate as specified in package insert.
- Take out the plate from the incubator after the incubation time is over & wash the wells five times with working wash solution.
- Add 100 I of working conjugate solution in each well including A-1.
- Apply cover seal.
- Incubate at $37^{0}C \pm 2^{o}C$ for 30 min. ± 2 min.
- Aspirate and wash as described in step No.(h).
- Add 100 I of working substrate solution in each well including A-1.
- Incubate at room temperature ($20\text{-}30^{o}C$) for 30 min. in dark.
- Add 50 I of stop solution.
- Read absorbance at 450 nm within 30 minutes in Elisa Reader after blanking A-1 well.
- Printer prints out all nos. fed in and their OD values. Reactive is printed across that particular reactive sample number according to the O.D. value of the cut off.

Validation:

(a) Check the validity of the Blank (if used) as well as negative & positive control absorbance values as per pack insert of the kit.

(b) Examine absorbance values of the controls before the sample results can be interpreted. If the run fails to meet the criteria as per package insert consider the test as invalid & repeat the whole test again.

(c) Cut off O.D. is automatically calculated.

Interpretation:

Check the print out carefully for absorbance values:

(a) The samples below the cut off are considered non-reactive.

(b) Equal to cut off are considered initially reactive (I.R.).

(c) Above cut off are considered I.R.

(d) Sample close to cut off value 10% below cut off (grey zone).

(e) Samples with grey zone results are repeated in one well.

22. Anti HCV Testing (Sample tested for HCV antibodies by EIA Method)

Principle:

In HCV Eia, the micro well are coated with recombinant Hepatitis C Virus encoded antigens as the solid phase. If the HCV antibody is present, it becomes bound to the solid phase and can be detected by a complementary anti-human IgG conjugated to an enzyme (capable of acting on a chromogenic substrate). When substrate is added to the bound complex, the presence of antibody can be detected by development of a coloured end product.

Method:

Anti-HCV EIA test is carried out as per kit manufacturer's instructions. The details of the kit procedure and interpretation of results are as per the pack insert of the kit in use. Remove reagents from fridge 30 minutes prior to testing. Mix the reagents gently by inverting the vials without foaming.

(a) Bring samples to room temperature before testing.

(b) Prepare wash buffer solution as per pack insert.

(c) Discard all disposable tips in a container with hypochlorite solution.

(d) Arrange the samples so that well I A is blank I B, C & D as negative control and I E + F as positive controls.

(e) Dispense 100 ul diluent to each well except the blank well.

(f) Add 10 ul of controls and specimens to appropriate wells.

(g) Mix the plate gently and cover with a seal.

(h) Incubate at 37^0C for 60 minutes.

(i) Remove seal and wash 5 times.

(j) Invert the plate and tap on clean paper towel to remove excess wash buffer.

(k) Dispense 100 ul conjugate to all wells except blank.

(l) Cover the piate with sealer and incubate at 37^0C for 30 minutes 3.

(m) Prepare substrate 10 minutes prior to use.

(n) Wash wells 5 times.

(o) Dispense 100 ul of substrate to all wells including blank.

(p) Incubate at 15-30^0C in dark for 30 minutes.

(q) Dispense 100 ul of 4 N sulphuric acid to all wells.

(r) Remove moisture from bottom of plate and read at wavelength of 490 nm.

Validation:

(a) Cut off O.D. is automatically calculated.

(b) Examine absorbance values of the controls before the sample result.

(c) Check the validity of the Blank (if used) Negative and positive control absorbance value as per pack insert of the kit.

(d) If the run fails to meet the criteria as per package insert consider the test invalid and repeat the whole test.

(e) Check the validity of the blank (if used) Negative and Positive control absorbance value as per package insert of the kit.

Interpretation:

Check the printout carefully for absorbance value.

(a) The samples below the cut off are considered non-reactive.

(b) Equal to cut off are considered initial reactive.

(c) Above cut off are considered initial reactive.

(d) Those with asterik are in grey zone. Repeat all samples showing grey zone result

23. Labeling of Blood Bags & Blood Components

(a) After collection and processing whole blood and component units remain in quarantine storage areas.

(b) Once all the reports of blood group and TTI testing are ready, place the bags on a table in chronological order.

(c) Segregate those which are found reactive for any TTI or found unsuitable for use and keep them in the area for disposal. Leave those found suitable for use on the bench for labelling.

(d) Write clearly the unit number, date of collection and expiry and the volume on each label as per the grouping resister records.

(e) Date of collection and date of expiry is very important. The expiry date depends on the type of bag and component. In case of a triple and quadruple bag with additive solution, the expiry date is 42 days, and for double and single bags, it is 35 days. In case of a triple or quadruple bag if for some reason, the components could not be separated, then label the expiry date as 21 or 35 days depending on the anticoagulant present in the primary bag. The day of blood collection is considered the day zero for calculating the expiry dates.

(f) After the bags are labelled ask a second technician to double check the number and group on the bags tallying them with the records.

(g) Enter all labelled bags group wise in the stock book which is also maintained group wise. In the stock book keep a footnote for any autologous blood that is reserved for the patient's own use.

(h) Lable FFP and Cryo deficient plasma, and platelet concentrates in the same manner. Cryoprecipitate labels do not indicate blood groups.

(i) All plasma components have an expiry date of one year. The expiry date of platelet concentrate is 3 days with PVC bags and 5 days if special bags are in use.

24. Preservation of Blood and Blood Components

(a) All untested units should be kept in the quarantine area.

(b) After testing is over, release the fully tested. Transfer those deemed suitable for clinical use from quarantine area to the stock area after labelling.

(c) Label those found unsuitable for use with a biohazard label and keep for disposal.

(d) Store whole blood and Red Cell concentrates on metal rack stand in the Cold Room (4-6^{0}C). These stands have shelves. Each shelf is reserved for a particular group having its label stuck on the outer side. Arrange the blood bags in chronological order, group wise and according to the expiry dates in trays and then stack the trays on the shelves. This makes it very easy for the technologists on duty to remove the bags for issuing, whenever required.

(e) Store blood collected in CPD-A1 and the red cells separated in a closed system up to 35 days. Store the red cells suspended in additive solutions up to 42 days. Use red cells prepared in open system within 24 hours of preparation.

(f) Keep Fresh Frozen Plasma, cryoprecipitate and FVIII deficient plasma bags in over wrap bags and then arrange in plastic trays in the Deep Freezer (-40^{0}C) immediately after separation. The shelf life of all these plasma components is 1 year. FFP once thawed and then refrozen is used only as FVIII deficient plasma.

(g) Place Random donor platelets (RDP), Single Donor Platelets (SDP) in a platelet incubator at 20-22^{0}C on a agitator which has shelves to store them. Store the concentrates prepared in PVC bags up to 3 days and those prepared in special platelet bags up to 5 days.

(h) Take due care to maintain sterility of all components by keeping all storage areas clean.

(i) Monitor to ensure the storage conditions to be appropriate and correct for each product. Monitor the temperature of all storage areas with continuous graphic recorder. Change the charts every week, and achieve them. Check the alarm system every month.

(j) Similarly, after labelling the plasma bags, enter the unit numbers group wise in the stock register. Make FFP entries on the right hand page of the stock register, whereas Factor VIII-D plasma & Cryo units on the left hand page. Carry out physical stock taking every night and rewrite the inventory.

25. Inventory of Blood Bags and Blood Components

(a) Inventory is maintained on a day to day basis. After labelling the units, enter the numbers of whole blood or packed cells numbers group wise on the right hand page of the inventory register kept in the main red cell laboratory. In case of packed cells units, write the alphabet "PC" above the unit number. PC denotes packed cells without additive solutions. PCS denotes packed cells with additive solution. The inventory bears columns for A group, B group, AB group, O group as well as negative group of these four groups.

(b) Enter the units group wise and according to the date of collection in the inventory register (daily stock). The technologist on night duty is responsible for physical checking of the printed number tag with the hand written number on the label and enters in the inventory.

(c) After labelling the FFP, enter the donor units numbers group wise in the stock register of FFP similar to blood units.

(d) Enter FVIII Deficient Plasma units labelled group wise in the stock register similar to plasma register.

(e) Enter the labelled cryoprecipitate unit numbers in the register.

(f) Clearly mark the inventory of bags that have less volume of blood collected or are reserved for specific patients with specific instructions.

26. Supply of Safe Blood Transfusion

(a) When blood is released from the Blood Bank to operation theatre or ward of the hospital or outside for transfusion, some times for some reason or the other, it may not be required by the patient and it is returned to the blood bank. If this unit of blood or blood component arrives within half an hour, it could be reused for another patient. Take care to see that this unit of blood is kept erect in the cold room to look out for hemolysis. If there is no hemolysis seen after spinning or standing, issue this unit safely to another patient.

(b) In case of FFP, which comes to the blood bank unused, issue to another patient if there is a demand for that particular group immediately within 6 hours of the first issue. If no arises, then use it later as FVIII deficient plasma.

27. Issue of blood for transfusion

(a) In order to avoid outdating, implement FIFO policy.

(b) Carry out compatibility testing.

(c) Ensure that the compatible units are tested for TTI and found suitable for use.

(d) Remove the correct unit from blood bank refrigerator and keep it in the thermal box for transport.

(e) Make entries in the issue register.

(f) Instruct the individual to take the unit straight to OT/Ward for transfusion.

28. Investigation of Transfusion Reaction

Principle:

Red Cell Serological tests are based on the principle of agglutination and help to identify haemolytic transfusion reactions caused either by ABO incompatible transfusion or irregular red cell antibodies in patient's blood.

Leuco-agglutinations, if present are detected by agglutination of random donor leucocytes in cases of febrile transfusion reaction. Serum bilirubin total and indirect is raised in case of haemolysis. The sulfosalicylic acid test helps to differentiate between haemoglobin and non-protein pigment, probably porphyrin in the urine. The ammonium sulphate precipitation test is based on the fact that haemoglobin and myoglobin are precipitated in urine at different degrees of ammonium sulphate saturation.

Serological Tests:

(a) Perform a direct antiglobulin test (DAT) on post-transfusion EDTA sample before refrigeration immediately on receipt. If test is positive, perform DAT on pre-transfusion sample to verify whether sensitisation is due to transfusion or it pre-existed.

(b) Repeat grouping and antibody screening of patient's pre-transfusion sample.

(c) Repeat grouping and antibody screening of patient's post-transfusion sample.

(d) Repeat grouping and antibody screening of donor sample.

(e) Repeat grouping of unit from bag. In case of packed cell unit, do only cell grouping. In case of FFP, do only serum grouping.

(f) Repeat cross matching of donor with patient's pre and post transfusion samples using saline/enzyme/ IAT. Use donor cells from blood bag and not the pilot tube.

Leucocyte Test:

(a) In case of febrile transfusion reaction and hypotension, look for leukocyte antibodies.

Biochemical Tests:

(a) Note colour of plasma. Plasma is pink, if haemoglobin is present and icteric if bilirubin is present.

(b) Separate the patient's pre and post transfusion serum and send to biochemistry department in a 5 ml screw cap plastic vial bearing the date, patient and test identification for estimation of serum bilirubin total, direct and indirect and estimation of plasma haemoglobin.

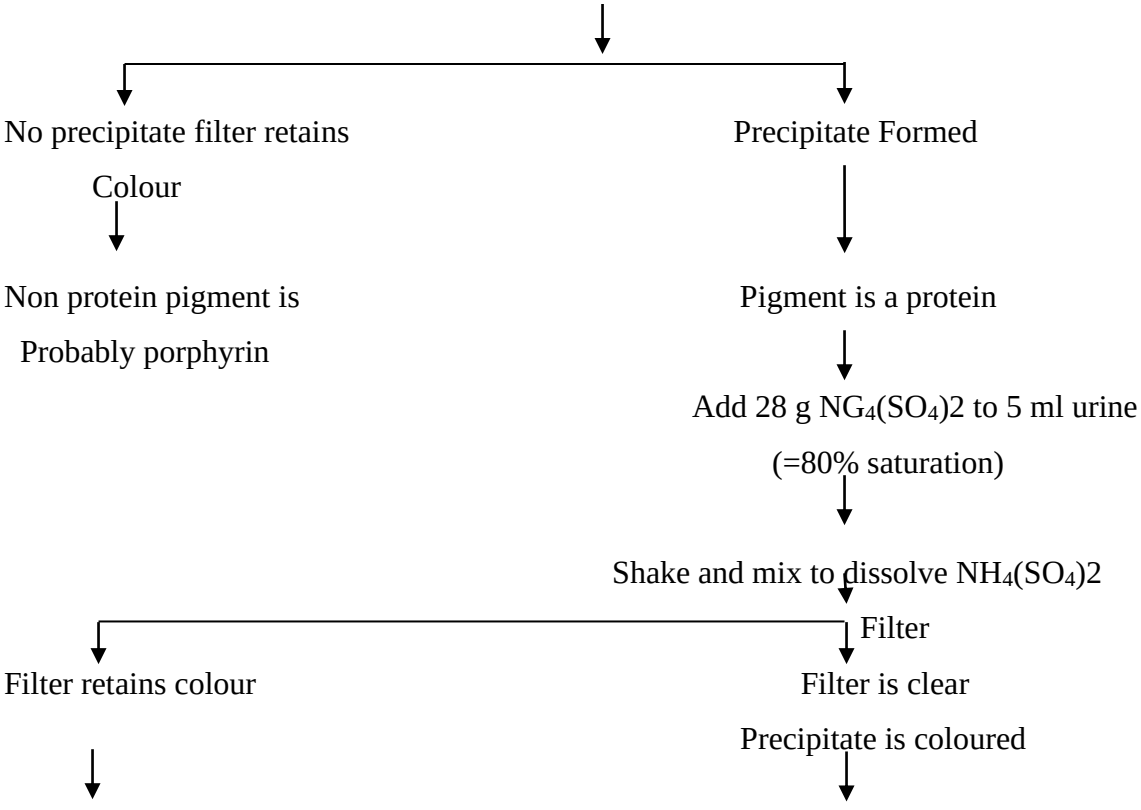
(c) Send the biochemistry request form with proper entries along with the sample.

(d) Collect the report from biochemistry lab.

Tests on post-transfusion urine sample:

Red colour indicates haematuria or haemaglobinuria.

Add 3ml of 30g/l solution of sulfosalicylic acid to 1 ml urine. Mix well and filter.



Myoglobin Haemoglobin

Microbiology:

(a) Send the donor unit for smear and culture (at 37^0C, room temperature and 4^0C) to bacteriology department.

(b) Make proper entries in the bacteriology despatch book and bacteriology request form and send along with the unit.

(c) Collect the report from bacteriology lab.

(d) If donor unit reveals bacteremia, then request attending doctor to get the patient's blood culture done and report the findings to the blood bank officer.

Interpretation:

(a) Any red cell incompatibility found during the investigation explains a haemolytic transfusion reaction.

(b) The DAT will be positive and a mixed field reaction will be seen if in vivo sensitisation of transfused red cell has occurred.

(c) The DAT may be negative even in cases of haemolytic transfusion reaction, if the cell destruction is severe.

(d) If any antibody is detected in patient's serum, the donor cells should be positive for the corresponding antigen.

(e) Detection of leucoagglutination explains a febrile reaction or hypotension.

(f) Serum bilirubin total and indirect is raised in case of haemolysis.

(g) Haemoglobinemic and haemoglobinuric are highly suggestive of red cell destruction, but are not necessarily caused by antigen-antibody reaction, unless confirmed.

Limitation:

The non serologic possibilities of haemoglobinemia and haemoglobinuria are :-

(a) Hemolysis of blood before transfusion.

(b) Poor technique of collecting post transfusion sample.

(c) Myoglobinuria following major surgery.

(d) Infusion of distilled water during prostatectomy.

(e) Hemolysis due to artificial valve.

(f) Patient's clinical condition; autoimmune haemolytic anaemia or paroxysmal nocturnal hemoglobinuria.

(g) Use of glucose or dextrose through the same line before starting blood.

(h) Addition of certain drugs to blood such as ethacrynic acid, hydrocortisone or diphenyl hydantoin.

29. To ensure reliability and reproductively of blood group results

Principle:

Test for reactivity and specificity is based on the principle of agglutination of antigen positive red cells in the presence of antibody directed towards the antigen.

Quality Control Checks:

A. Visual Inspection:

Examine each vial carefully for precipitate, gel formation, turbidity or change in colour.

B. Reactivity and specificity:

I. Add one drop of 3 5% suspension of the appropriate red cells to the one-drop of antiserum in micro tube.

II. Mix well and incubate (as per manufacturer's instruction).

(a) Cleaning :

a. Frequency.

b. Referenced documents.

Maintain a list of all equipment and instruments used in all sections/departments in the QC lab to ensure all equipment within the department are documented.

Maintenance Schedules:

Draw up suitable schedules by maintenance type and frequency or by equipment type. Define forward dates for the completion of maintenance and record the date of actual performance in the schedule.

Service Contracts:

(b) Contracts need to be in place for all equipment items maintained by an external agent.

(c) Each service contract shall define exactly what is carried out/the frequency and by whom it is completed.

(d) At the completion of the service, a maintenance report is to be supplied, signed by the contractor and the officer in charge. The report shall detail the work carried out by the contractor.

Repair & beak down:

(a) Operating instructions for each item of equipment shall identify the steps required to be taken in the event of a fault or breakdown, and shall identify who is responsible for organising service or replacement.

(b) A log book of errors and corrective actions is to be maintained for all equipment items. In the event of equipment breakdown, it is essential that it be clearly labelled and identified as being "OUT OF SERVICE".

Maintenance Overdue:

The Quality Control Laboratory shall determine the suitability for ongoing use of any equipment that has passed it due date for routine maintenance (where this routine maintenance does not involve calibration). The laboratory must document their reasons for continuing to use an item of equipment that is overdue for maintenance. Where appropriate this should include explanation (and supportive evidence where available) that product quality has not been compromised by this delay in maintenance. Where possible documentary evidence from the manufacturer supporting this decision should be provided. Steps should be taken at the next instance of routine maintenance to evaluate whether any discernible damage has been caused to the equipment by the delay in maintenance.

30. Equipment Maintenance

Maintenance Overview:

(a) Identify each item of equipment in the unit that requires maintenance. Ensure all items have an Asset Number.

(b) Include clear outline of the relevant procedures, routine maintenance and preventive maintenance and cleaning of equipment. Write operator instructions for each item of equipment. Also include those responsible and names of service personnel. Maintain a documented log of servicing for all items.

Identify the relevant procedures for equipment maintenance determine the frequency of calibration and cleaning procedures clearly identifying the times eg., daily, monthly etc.

(c) Prepare a complete equipment and instrumentation list consisting of the following headings :

- **Equipment name/description.**
- **Asset Number.**
- **Serial Number.**
- **Model Number.**
- **Operation.**
  - Operating Range

(a) Calibration :

- Frequency.
- Referenced documents.
- Performed by

(b) Performance Check:

- Frequency.
- Referenced documents.

(c) Preventive maintenance :

- Frequency.
- Referenced documents.

- Performed by.

(d) Routine maintenance :

- Frequency.
- Referenced documents.

	Red Cells for Testing	
	Positive Reactors	**Negative Reactors**
Anti-A	Pooled A Cells	Pooled B,Pooled O Cells
Anti-B	Pooled B Cells	Pooled A, Pooled O Cells
Anti-AB	Pooled A, Pooled B Cells	Pooled O Cells
Anti-D Bioclone	RhD-positive cells (any ABO group)	RhD-negative cells (any ABO group)
Anti-D Monoclonal	RhD-positive (any ABO group)	RhD-negative (any ABO group)

Results:

A: Visual Inspection:

Record presence or absence of precipitate, gel formation, turbidity or colour change.

B: Reactivity and Specificity:

(a) Centrifuge the Tubes (as per manufacturer's instruction).

(b) Resuspend the red cell button and examine for agglutination/ haemolysis.

(c) Grade and record test results.

Interpretation:

A: Visual Inspection:

(a) The presence of precipitate, gel formation, turbidity, colour change indicates that the reagent is contaminated and should not be used.

(b) The absence of all the above indicates that the reagent is 'clear' and suitable for use.

B: Reactivity and Specificity:

(a) Agglutination of specific red cells in a positive reaction and indicates the reactivity of the corresponding antibody in the reagent. The expected agglutination reaction for positive test is +3 to +4.

(b) The absence of agglutination/haemolysis is considered to be a negative reaction and indicates the absence of the corresponding antibody specificity in the reagent.

(c) Clear cut negative reactions with the negative reactors rules out the presence of irregular agglutinins and haemolysis in the reagent.

31. Equipment Maintenance: Calibration

Calibration Schedules:

(e) Purchases each new piece of equipment or instrument according to specifications.

(f) Place new equipment on an asset register prior to use.

(g) Ask the supplier prior to delivery or after installation to calibrate new equipment and provide a certificate of calibration.

(h) Maintain Calibration/Maintenance schedules for all equipment.

The schedules of calibration or performance checks should be based on:

(a) Manufacturer's recommendations.

(b) The history of the item as per reliability.

(c) Reference standards.

(d) Recalibrate the measuring devices based on time intervals.

Reference standards, Traceability & Calibration Limits:

A. Reference Standards & Trace ability:

All measurement standards used to calibrate measuring devices should be traceable to a national standard of measurement either:

(a) Directly through purchase of pre-calibrated certified standards. These shall be supported by calibration documents or certificate from the supplier stating the date, accuracy (assigned value & units of measure), trace ability & conditions under which the results were obtained. These standards shall be re- calibrated at pre-determined intervals.

(b) Indirectly by preparation of an internal working standard calibrated against a certified standard. These shall be supported by internal test reports & any other supporting documentation.

(c) Where no recognised external standard exists an internal standard may be prepared and calibrated provided a written procedure is prepared and a rationale for assigning values, accuracy and units is established. These standards shall be supported by suitable records of calibration as above.

B. Calibration Limits:

Calibration is concerned with the measurement of values and their comparison with acceptable limits of standards resulting in adjustment or correction, if necessary. Compare calibration results with established limits for accuracy for the measuring device. If the device being calibrated does not fall within the limits then re-adjust and re-calibrate until it falls within pre-established limits. If not, remove from use.The establishment of limits should be based on a combination of:

(a) Those specified at the time of purchase.
(b) Recommendations from the manufacturer.
(c) Limits established in reference standards.

The acceptable limits required for satisfactory calibration of each instrument should be identified or referenced in the relevant procedure.

C. Calibration and Performance Check Procedures:

Prepare documented procedures based on the instrument manufacturer's written instructions and use for the calibration and performance checks for all measuring instruments and measurement standards.

Calibration procedure should include:

(a) A list of equipment to which the procedure is applicable.
(b) Calibration points, environmental requirements and special conditions.
(c) Limits for accuracy.
(d) List and identity of traceable standards.
(e) Sequence of calibration steps.
(f) Instructions for recording data with reference to the relevant standard form.
(g) Performance check procedures should follow a similar format.

D. Labeling:

Label all calibrated equipment with a label that has the following information :

(a) Date of last calibration.

(b) Signature of person who performed the calibration.

(c) Date next calibration due.

(d) Label the equipment that has passed its calibration due date until it is re- calibrated.

32. Incident Report

(a) Document all incidents on the standard form (Incident Report Form).

(b) Forward the incident summary report to the section supervisor for evaluation & completion.

(c) Initiate incident tracking.

(d) Develop corrective/preventive action in consultation with Section Supervisor, QA Manager & the Director.

(e) Forward original documents to the QA manager within 3 working days of the event.

(f) The QA manager reviews the report for completeness and appropriateness of corrective action.

(g) The status of an event remains active until effective action is taken and closed out. Record the details, date of action & close out and get the reports form signed by the Director.

(h) Notify the Director immediately in case of critical incidents such as those that could result in loss of life, product recall, failure to operate or adverse publicity.

(i) Provide monthly summary reports to the Director.