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A Study on Implementation of Quality Control Measures for Blood Bank Services in Super Specialty Hospital

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Abstract
Context: - *Quality is defined as degree of excellence. The standard operating procedures (SOP) are vital documents which are essential components of quality system in any organization. SOP use is mandatory, as well as records in a prescribed format by all the staff members of the blood bank every time they perform an activity.The accreditation and licensing procedures also demand compulsory use of SOP*
Aims and Objectives:- *To study existing physical facilities, staff pattern, equipment, policies, procedures and implementation of quality control measures in the blood bank services.*
Study design:-*prospective observational study, in blood bank,Department of Hospital Administration from September 2010 to August 2011in Narayana Medical Hospital(NMCH), Nellore.*
Analysis:-*Quality control checks were compared with standards*
Conclusion:-*Location,Layout of blood bank was satisfactory, away from emergency usage. Physical facilities,hygiene were adequate. Qualified,experiencedpersonnel present howeverinadequate number. Equipment adequacy, maintenance, calibration was good. Quality measures of reagents, procedures, storage, issues and record maintenance were adequate. Satisfactory Bio safety waste disposal Insufficient blood donation camps, lacking Computerization of records, noblood policy andquality audit in blood bank,.SOP's maintained as per standards.*
Recommendations:-*Enhancement of staff strength, Central monitoring system,formation of appropriate committee preparation of policy, conveyance of quality audit and Conduction of Voluntary blood donation camps are recommended*
Key words:-*quality control, procedures, standards*

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I. Introduction

Blood is circulating fluid of the body circulated through the heart, arteries, capillaries, and veins[1].Blood transport oxygen and nutritive materials to the tissues, carbon dioxide and various metabolic products removed for excretion. Blood consists of plasma,erythrocytes, leukocytes, and platelets[1].

Blood loss may result from injury, major surgery, or diseases that destroy red blood cells or platelets. Excess of blood loss leads to low blood volume results in shock[1].

Haemotherapy denotes transfusion of whole blood, blood components, fractions or artificial blood, whole blood replacement is the treatment for blood loss[1].

Blood Bank is a transfusion service facility that performs or responsible for the collection, processing, storage, and distribution of human blood and/or blood components intended for transfusion[2].

The goal of transfusion services are to provide blood and its components(red cells, platelets, fresh frozen plasma, granulocytes,etc.)for safe transfusion and that pose minimal risk of transfusion transmissible infections.

Risk of transfusion transmitted diseases tothe recipientareimmune deficiency virus,HBS Ag, HCV, Syphilis, VDRL, Malaria Human T cell leukemia virus(HTLV-I & HTLV-II) etc[3].

To minimize transfusion of diseases three levels of safety strategies include pre donation screening,screening of the donor unit, and using blood only when truly needed.

Greater risk associated with blood transfusion is transfusion reaction - administration of wrong blood to the wrong patient-leads to fatal haemolytic reaction including death may occur [4].

Quality simply means the fitness for use or conformity to requirements. Quality Control is defined as operational techniques and activities used to fulfil the requirements for quality[5]

Quality Management System includes Equipment management, Process management, Documents and records, etc5Quality Management Principles are Organization and leadership, customer focus, facilities, work environment, and safety, human resources, suppliers and materials management, equipment management, process management[5].

The standard operating procedures (SOP) are vital documents which are essential components of quality system in any organization.Written Standard Operating Procedures shall be maintained and include from collection to issue is necessary [6]

This study was taken to know about the quality control was really implemented in the blood bank for the safe transfusion to the persons in need

II. Aim And Objectives

1. To study the existing location, layout, physical facilities, staff and staffing pattern in blood bank
2. To know the existingblood bank equipment maintenance, calibration in NMCH.
3. To assess the implementation of quality control measures in the blood bank services at NMCH.
4. To compare the existing procedures with the prescribed standard of policies and procedures at NMCH

III. Subjects and Methods

3.1 Study design*:* - Prospective observational study undertaken in the blood bank by the Department of Hospital Administration from September 2010 to August 2011in Narayana Medical College, Nellore.

3.2 Study Method:-Direct Observational Study of blood bank regarding the location, layout, physical facilities, equipment, and staff working, the quality of services providedin the blood bankwere noted. Presence of policies, procedures and quality control measures followed in the collection, processing, compatibility testing, storage and sale or distribution of blood and/or preparation of blood components for transfusion were assessed

3.3Analysis:-quality control checks were compared with standards

IV. Observations and Discussion

Present study was under taken inthe department of transfusion medicine at super specialty hospital in Narayana Medical College, Nellore,

Physical Facilities of Blood Bank

Location of the blood bank*:*-Blood bank in the ground floor near hospital entrance,outpatient (OP) registration counter, opposite to Administrative block and away from open sewage, drain, public lavatory or unhygienic conditions.Blood bank was far away from Emergency Medicine Department(EMD), IntensiveCare Unit(ICU) and Operation Theater(OT) complex.

Quality control:- location in ground floor,near to entranceand hygienic conditions was good but far away from emergency block[6].

***Layoutand Infrastructure*:-**The total plinth area was 3021.33 square feet (280.79 square meters), ordinary ceiling height 10 feet, bleeding room has roofed with plaster of Paris,flooring marble stones.

The blood bank had Reception area, Medical Examination room,Refreshment room,Bleeding room, Toilet room, Wide corridor, Spare roomwith sink, Quality roomfor quality check, Store room.

The laboratory 1 with sink for cross matching, Blood storage room with refrigerators, Spare room, Lab 2 with sink used for Elisa room,Washing room with sink to wash the instruments and hands.

Components preparation room, components storage room and two toilets situated outside for staff.All rooms were fully furnished with required equipment

Quality control*:* -The blood bank lay out, accommodation, facilities for each purpose were as per standards [6]

Air conditioning (AC) system*:* - Split Air Conditions present- three AC's in bleeding room, one Ac in each cross matching room, refreshment room, store room, Elisa room,storage and preparation room.

Quality control: - Air conditioning was as per requirementstandards[6]

Overall hygiene,atmosphere in the blood bank was good.The blood bank well covered, preventing insects, mites.Ventilation, lighting system, drainage system were good, water supply and tapping system remained adequate[6].

Staff and Staffing Pattern of Blood Bank

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Table-1: Staff Pattern in Blood Bank

Designation	Personnel
Professor / Reader (MD) Pathology(path)	1
Associate Professor(MD) (path)	2
Assistant Professor (MD) (path)	3
Medical officer- Tutor (MBBS)	1
Technicians (DMLT)	6
Technical In charge (BSc, MLT)	1
Staff Nurse (GNM)	1
unskilled worker	1

Work Pattern: - The Blood bank in NMCH functions 365 days and 24 hours in a day.All the staff attends immediately on call day and night .The duty hours were two shifts day and night duties. The Medical Officer, Assistant Professor was on call duty on turn beyond the office hours.

In the blood bank qualified staff with good experience of more than 6 months upto 10 years was working with satisfactory income.All employees free from contagious or infectious diseases and were provided with clean overalls, headgears, foot wears and gloves. Adequate, clean and convenient hand washing and toilet facilitieswere available.Regular Training, Research programmes were conducted to M.D. Pathology students, MBBS Students, Nurses, Technicians (MLT), and DMLT students

Quality Assurance of Personnel (Man Power): - all persons working in the blood bank were qualified,experienced from Professor to technicians. Competent hierarchy supervise all the staff in all aspects and academically active. Health status, hygiene, sanitation of staff was good. During the study period the staff was not followed dress code.

Table-2: Staff Pattern requirement in Blood Bank

Staffing pattern for whole blood					
Staff required	**Annual blood collection (units)**				
	Up to 5,000	**Up to 10,000**	**Up to 20,000**	**>20,000**	**>50,000**
Medical Director / Incharge	1	1	1	1	1
Medical personnel	1	2	4	6	10
Counselor	1	2	2	2	3
Nurse	1	2	3	4	8
Senior Technical Assistant	1	1	1	1	2
Lab. Technologist	3	6	10	12	20
Lab. Attendant	1	3	4	4	8
Staffing pattern for components					
Staff required	**Annual blood collection (units)**				
	Up to 5,000	**Up to 10,000**	**Up to 20,000**	**>20,000**	
Doctor	Nil	1	2	2	
Technologist	1	2	3	3	
Staffing pattern for Apheresis					
Staff required	**Annual blood collection (units)**				
	Up to 5,000	**Up to 10,000**	**Up to 20,000**	**>20,000**	**>50,000**
Doctor	1	1	1	1	2
Nurse / Technologist	1	1	1	1	2
Total strength of staff in the blood bank					
Total Staff	**Up to 5,000**	Up to 10,000	**Up to 20,000**	**>20,000**	**>50,000**
A+B+C+D	12	22	32	37	64

(Drugs and cosmetics (Amendment) Rules, 1999, Compendium of Transfusion Medicine, Dr.R.N.Makro-2009.)

Personnel required for blood donation camp are one Medical Officer and two nurses or phlebotomists for managing 6-8 donor tables; two medico social workers; three blood bank technicians; two attendants[6].

Increased workloadexperiencedfrom 2000 – 3000 units of collections to 6000 - 7ooo unitsin NMCH a twofold of utilizations per annum. As per Drugs and Cosmetic rules the laid down standard in (1945 amended in 1999- in 122.G) the staff pattern was 12 persons for 5000 units /annum and 22 persons in 10,000 units[7].
In NMCH 16 persons were working, in the night duties only one technician present.. Compared to the work load total staff strength is not sufficient especially during night times.

Quality Assurance of Personnel (Man Power):-qualified, trained experienced persons available for proper functioning of blood bank and for conduction of outdoor blood collection camps but staff strength insufficient and number of camps not adequate for increased demand[6]

Equipment in the Blood Bank
Equipment used for collection, processing, testing, storage and sale/ distribution of blood and its components were maintained in a clean and proper manner. The equipment were observed, standardized and calibrated on a regularly scheduled basis as described in the Standard operating procedures Manual and operated accordingly [6]

Table – 3: Equipment in NMCH Blood Bank

S. No	Name of Equipment	Quantity	S. No	Name of Equipment	Quantity
1.	Blood Bag storage Refrigerators	4	22.	Domestic Freezers	3
2.	Donor Couches	6	23.	Blood Bag squeezer	1
3.	Blood collection monitor	5	24.	Needle Destroyer	2
4.	Tube sealer (Blood Bag)	1	25.	Incubators	2
5.	Cryo bath	1	26.	View box	1
6.	Platelet Incubator	2	27.	Hand grips	6
7.	Platelet Agitator	1	28.	Almaras	3
8.	Terumo Sterile connecting Device TSCD	1	29.	Emergency Kits	1
9.	Plasma Bath	1	30.	Stethoscopes	2
10.	Hot air Oven	1	31.	Weighing machines	2
11.	Auto Clave	1	32.	B.P. Apparatus	6
12.	VRDC Rotator shaker	1	33.	Haemoglobinometer	4
13.	ELISA Washer	1	34.	Urinometer	1
14.	ELISA Reader	1	35.	Blood cell Separator	1
15.	Plasma Expressers	1	36.	Deep Freezer	2
16.	Sterile tubing welder	1	37.	Micro pipette	4
17.	Opti press	1	38.	Computer	2
18.	Digital colorimeter	1	39.	Cell counter	4
19.	Centrifuge	1			
20.	Water bath	1			
21.	Binocular microscope	1			

Table – 4: Equipment's that are observed, Standardized and calibrated

S.No	Equipments	Location	Incharge	Material required	Performance	Frequency	Frequency of Calibration
1.	Refrigerated Centrifuge	Quality Control room	Technician	Thermometer Tachometer	Check the temp shown in display and on the thermometer check speed with Tachometer	Each day	As often as necessary
2.	Blood collection	Quality Control room	Technician	Calibrated weights	Check the volume and monitor with calibrated weights	Each day	As often as necessary
3.	Temperature Recorder	Quality Control room	Technician	Thermometer	Check the temp in recorder and on the thermometer	Daily	As often as necessary
4.	General Lab Centrifuge	Quality Control room	Technician	Tachometer	Check the speed on display and Tachometer	As often as necessary	Every 6 months
5.	Haemoglobinometer	Quality Control room	Technician	Cyanmethemoglobin	Check the temp as recorder and an thermometer	Each day of use	-
6.	Urinometer	Quality Control room	Technician	Distilled water	Standardized against distilled water	Each day of use	-
7.	Water bath	Quality Control room	Technician	Thermometer	Check temp on the water bath and an thermometer	Daily	As often as necessary

8.	Auto clave	Quality Control room	Technician	Thermometer	Check the temperature	Daily	As often as necessary
9.	Serologic Rotator	Quality Control room	Technician	Tachometer	Check the R.P.M. with the Tachometer	Daily	As often as necessary
10.	Laboratory Thermometer	Quality Control room	Technician	Pre – calibrated Thermometer	Check the temperature in thermometer	-	Before Initial use
11.	Electronic Thermometer	Quality Control room	Technician	Pre – calibrated Thermometer	Check the temperature in thermometer	Monthly	As often as necessary
12.	Hot air oven	Quality Control room	Technician	Thermometer	Check the temp on the thermometer fixed as H.A.O. and an thermometer used for caliberation	-	As often as necessary
13	Incubator	Quality Control room	Technician	Thermometer	Check the temperature an recorder and an thermometer	Daily	As often as necessary

General Equipment's and Instruments -Blood collection needdonor beds, chairs and tables, Sphygmomanometer, stethoscope,recovery beds for donors. Refrigerators, for storing separately tested and untested blood, with provision for continuous power supply. Weighing devices present for donor and blood containers.

Hemoglobin determination*:* Copper sulphate solution (specific gravity 1.053), sterile lancet and impregnated alcohol swabs. Capillary tube (1.3 x 1.4 x 96 mm for Pasteur pipettes), Rubber bulbs for capillary tubing's.Sahli'shaemoglobinometer / Colorimetric method.

Temperature and pulse determination: Clinical thermometers, Watch and a stop-watch.

Blood containers:-Only disposable PVC blood bags shall be used (closed system) as per specifications of IP/USP/BP

Anticoagulant solution:-present insterile, pyrogen-free status .Citrate-Phosphate-Dextrose (CPD) Solution. Citrate-Phosphate-Dextrose-Adenine (CPDA-1) each solution 14 ml solution was required for 100 ml of blood, 100 ml SAG-M/ADSOL or any approved additive solution containing saline adenine and glucose (or with Mannitol) was added to packed cells after separation of plasma for storage.Add additive solutions such as SAGM, ADSOL, NUTRICEL may be used for and retaining Red Blood Corpuscles up to 42 days.

Emergency equipment's:- Oxygen cylinder with mask, gauge and pressure regulator, 5 per cent Glucose or Normal Saline Disposable sterile syringes and needles of various sizes, Disposable sterile I.V. infusion sets, Ampoules of Adrenaline, Noradrenalin, Mephentin, Betamethasone or Dexamethasone, Metoclopramide injections, Aspirin were available in blood bank

Accessories;-Such as blankets, emesis basins, hemostats, set clamps, sponge forceps, gauze, dressing jars, solution jars, waste cans, Medium cotton balls, 1.25 cm adhesive tapes, Denatured spirit, Tincture Iodine, green soap or liquid soap, Paper napkins or towels, Incinerator, Stand-by generator were available.

Laboratory, Special equipment was observed, standardized and calibrated as noted in "Table-3,4 "

Quality Assurance of Equipment*:-* The equipment that are observed in NMCH Blood Bank are - General equipment instruments used for blood collection, hemoglobin determination, temperature and pulse determination, blood containers, emergency equipment /item, accessories and laboratory equipment were adequate. The existing special equipment the functioning, standardization and calibration were well maintained according to the standards[6]

Reagents

Table – 5: Quality Control check of reagents and solutions

Reagents and solutions	Frequency of testing along with control
Anti-human serum	Each day of use
Blood	Each day of use

Lectin	Each day of use
Antibody screening and reverse grouping cells	Each day of use
Hepatitis test reagent	Each run
Syphilis serology reagent	Each run
Enzymes	Each day of use
HIV I and II reagents	Each run
Normal saline (LISS & PBS)	Each day of use
Bovine Albumin	Each day of use

All reagents were clearly labeled with batch number (no), expiry date, storage temperature and instructions, and used accordingly to manufacturer instructions and listed in registers. Use of positive and negative controls was performed with each batch, recommended temperature were maintained to prevent freezing.All reagents and kits were high quality with shelf life of at least one year. Supply, storage and transportation of kits and reagents follow standard protocol. The feedback was given to in charge about the quality and supply. Low potency, contaminated, defective reagents were discarded. Visual inspections was carried out carefully on each vial for precipitation, gel formation, turbidity or change in color as part of quality assurance,

Quality Control: - In the blood bank of NMCH all the reagents were checked regularly, according to the standards[6]

Preparation AndUtilization Of Blood And Its Components

Collection of Blood**: -**Blood collection from the donor was from 8.00 am to 5.00pm on regular basis for 6 days a week and in emergencies round the clock.

Selection of Donor: - Donor allowed todonate blood were voluntary donors, replacement donors, paid and professional donors are not entertained.Thorough enquiries about health, behavior, past history of any diseases,vaccinations, drug intake, any surgeries significant were noted. Detailed physical examination, systemic examinations and Hb% estimation was done to all donors. Those having habit of voluntary donation, time interval between donations were enquired and strict gap was maintained.Later the "Donor card was issued to fill up" their names, address and bio data with informed consent taken.

Quality Measure**: -** The procedure followed in the blood bank for the selection of donor is as perstandards[6]

Selection of Bag: - Bags were selected according to the components to be prepared and weight of the donor. Before the bag usage checked visually for any discoloration, breaks, leaks, presence of sufficient quantity of the anticoagulant, clarity of anticoagulant, checking the expiry date of the bag. After checking the bag the details like type of bag, manufacturer's name, Batch No, expiry date are entered.

Quality measure: **-** The selection of bag is done as per WHO standard operating procedures[8].

Collection of blood from donor**:** - Throughout the process staff nurse and technicians present by the side of patient, and supervised by Medical Officer. If any problem arises during bleeding time proper attention was given by the M.O and staff immediately, the time taken for bleeding was not more than 5-8 minutes. Volume of blood collection was not exceeding 10ml/ kg body weight. Amount of blood drawn =. $\frac{Donor\ Wt \times 450ml}{55kg}$ measured with a balance (while collection of blood.)[6]. Post donation care given, immediately after donation the donor was observed in bleeding room for any adverse reaction like giddiness, syncope attack, bleeding from wound site. Later the donor was sent to the refreshment room for relaxation and refreshments. Until the donor leaves the blood bank donor should be under observation of the staff nurse and Medical Officer.

Donor cards were issued with colour code –

O – Blue, A -Yellow, B – Pink, AB – White

Quality Control**:** The anticoagulant solution, volume of blood collection, time taken for blood collection, aseptic precautions for collection of blood by venipuncture, and post donation care the above mentioned are taken according to WHO SOPs[8].

Investigations in blood bank

ABO grouping and Rh typing was done by Slide method, Tube method,Micro plate method, I.D. micro typingMethod,Automated / semiautomatic instrumentation. Results were entered in concerned register

Weak variant of D testing (DU) was done later results were entered in DU register

Cross matching was used to detect the unexpected antibodies in patient's serum against donor cells. Before cross matching the name, registered number on requisition form, over the bottle were checked and Blood grouping Rhtyping once again checked. Methods used for cross matching - saline technique,coombs' cross matching, Lisscoomb's cross matching, Bovine Albumin cross matching. Results were entered in cross matching and compactable register.

Anti-GlobulinTest was done for unexpected antibody/ies with pooled O Rh (D) positive cells or preferably screening cell panel using albumin/enzyme/indirect. It was done by Direct anti globulin test,Indirect anti globulin test.

Screening for Infectious Diseases**: -**All Blood units are screened for HBS Ag, HCV, HIV, Syphilis, VDRL, Malariaby using kits later entered in screening register. Test positive blood was discarded without usage and entered in discard register. The test results will be informed to donor about his/ her status and for any treatment necessary

***Quality Control*: -**ABO reagents, ABO groupingandCross matching was done with Bovine Albumin method the quality of all checked every day,Indirect and direct tests for anti-globulin test were done.Screening tests performed in blood bank of NMCH were done as regularly to each denoted blood. Quality controls regarding investigations in blood bank were as per SOP's of WHO[8].

Blood Components Preparation

Table-6 blood components collection - storage

Donor		Components	Bags	
Weight	Aspirin intake required	Required	Type	Qty. (ml) Of Blood
>55 Kg	NO	PC+FFP+PLT	Triple or Quadruple	450ML
>55 Kg	YES	PC+FFP PC+FVIID+CRYO	Double	350/450ML
45-55 Kg	NO	PC+FFP PC+FVIID+CRYO PC-PLT	Double	350ML
45-55 Kg	YES	PC+FFP PC+FVIID PC+FVIID+CRYO	Double	Double

Blood Collection for component Preparation,Packed RBC,Platelet Concentrate were according to above "table- 6"The components preparation was under strict sterile conditions in closed system. Preparations of components were taken in separate components preparation room with AC. Labeled according to group,colour code after preparation and stored as per standards. Each blood component pilot tube was identified by numeric or alpha numeric at the time of collection, the unit number was unique to identify the donor. The quality controls of all components were doing except cryo precipitate (which is sent out side lab.) The components details were entered in concerned register, at the time of issue each bag was checked about the details, bag condition and the details entered issue register.

Quality Control: - Preparation, storage, distribution of components were done as per the standard guidelines of SOPs of WHO[8].

Labelling of bags

It includes proper name of product, name,address of blood bank, License number, serial Number, date of drawn blood, date of expiry, colors code to each group. After the investigations blood grouping, Rh typing, screening status, volume of blood, anti-coagulant types, and also either voluntary or replacement donor were maintained.

***Quality Control*: -** The labeling of blood bags after bleeding was done as per recommendation of WHO SOP guidelines[8].

Blood Storage

Table-7 Blood and Blood Components Storage

Shelf Life of Blood and Blood Products		
Component	**Storage Temperature**	**Shelf Life**
Whole Blood	2-6^{0}C	35 days
Packed RBC	2-6^{0}C	35 Days
Red cell concentrates with additives – SAGM &Adsol	2-6^{0}C	42 days
Washed red cells	2-6^{0}C	24- Hours
Platelets	22- 24^{0}C in an agitation	3-5 days
FFP/ CRYO	<30^{0}C to – 80^{0}C	1 Year

Once blood was collected it was kept in quarantine storage after screeningstored in refrigerators as shown in "Table-7". Temperature in Blood storage equipment has uniform temperature distribution with an alarm system to detect irregularities in temperature with a temperature chart recorder. A daily temperature recording register was maintained and 4 hourly temperature recording was done by duty technician.

The refrigerators, storage system are working, maintaining in good condition. Temperature checking was done regularly by technicians, good supervision on storage system. Written display of instructions to maintain the blood and blood components at the event of power failure or failure of equipment were present. If there was power failure alternate generator facility available.

Quality Control: **-**Quality maintenance of storage system expiry and transportation of blood and components was good as per standards of drug and cosmetics rules of central Government[6].

Blood Issue

It was observed that the blood issued to the required patient after getting requisition form. The cross matching form and their details were checked thoroughly. The blood group, Rh typing, number, expiry date, collection date was checked. The recipient name, IP No, age, indication, and blood group was checked in detail. Blood bag once again checked for leakage, change in color, unusual turbidity and hemolysis. Before issuing the blood to the concerned health person, details of issue were noted in the issue register. Once the blood issuedlater it was not allowed into the blood bank due to breakage of cold chain system. The concerned signature of the doctor was taken before the issue of blood.

Quality Control: **-**. Quality control of blood issue is as per the standards of WHO SOPs[8].

Transfusion Reactions:- Transfusion reactions are recorded, interpreted and evaluated as per the standards of WHO SOPs[9].

Infections Transmissible by Transfusion: - Infections transmissible by transfusion if any were recorded

Bio safety and Waste Disposal

***Protection of blood bank personnel against laboratory infection*:–** It was observed that all the staff members in blood bank were aware of hazards happen in blood bank. The staff members were following the universal precautions. Incidental exposure to infected samples like bag breakage, splash, and needle stick injury the staff immediately report to the concerned authorities, post exposure prophylaxis was taken as per guidelines under State AIDS Control Programme.

Disposal of blood and laboratory material: **-** It was observed that all reusable glassware were disinfected by treating with hypochlorite ,detergent before cleaning and subsequently glassware can go to hot air oven. Needles were burnt using electric needle destroyers or soaked in hypochlorite solution or discarded in a puncture proof container of a non-chlorinated plastic. These were sent for deep burial or incineration. Spills on the table tops/ sink the spill were covered with filter papers or plain cloth and soaked with 1% hypochlorite solution for at least 30 minutes and later swabbed. Broken glass wears were handled carefully while disposing. All the discarded bags due to infections and expiry of time were disposed in a secured bio hazard bag and disposed safely. The chemical hazards were avoided by careful handling by wearing gloves, masks while dealing with chemical reagents. There were good measures for fire or electrical accidents.

Quality Control: **-** All the measures are taken in disposing of bio medical waste as per standards of Blood Banks and the Blood Transfusion services[9].

Documentation of Transfusion Service

Records: **-** The following records were maintained in the blood bank as per the guide lines of Drugs and Cosmetics rule, NACO standards.Master register, patient sample register, donor register, single donor platelet

record, donor deferral register, blood grouping register, cross matching register, DU register, blood bank daily stock register, stock register for blood bag, stock register for diagnostic kits and reagents, stock register kits and reagents, whole blood issue register, components issue register, discarded Blood bag register: Record of transfusion adverse reaction register , records of ACD/ CPD/ CPD-A/ SAGM bags, single, double, Triple bags register, components separate registers, transmissible diseases register were maintained.

Quality Control: -. All the records were maintained as per standards of Blood Banks and the Blood Transfusion services[9].

STANDARD POLICY AND PROCEDURES

Standard policy:- In NMCH there was no policy document as per Standards for blood banks and blood transfusion services, NACO, 2007[10,11].

***Standard procedures*:-** In NMCH blood bank the Standard Operating Procedures were prepared as per the Model WHO SOPs as follows[8]

Quality control:-In NMCH blood bank the Standard Operating Procedures were following as per the Model WHO SOPs. In addition to WHO SOPs, NMCH BB was implementing more number of SOPs for the proper function of blood bank as for the need[8].

Administrative Protocols and Procedures

Hospital transfusion committee present will look after the proper functioning, quality maintenance of blood bank and if any issues will be sorted out.

Computerization of data and records are not adequate as per the standards

Quality audit :- No quality audit for the blood bank

IV. Conclusion

Present Location of blood bank was satisfactory but separate building block is necessary near to ICU,EMD,and OT. Layout, Infrastructureavailability of rooms was adequate for different purposes. Physical facilities like Flooring, Ceiling, walls, ventilation, lighting, drainage system, tapping, water supply, washing system were adequate andA.C facility was sufficient.

Qualification, experience of staff was adequate but number of staff not adequate especially during night duties. Hygiene, health personal sanitation, clothing, hand washing were satisfactory. Preventive measure of wearing gloves and dress code coats was mandatory but a small percentage of staff was not following standard protocol.Adequacy, maintenance, and calibration of equipment were good. Procedures for collection, investigation,labelling,components preparation, storage, issues of blood, record maintenance and quality control checks of reagents and procedures wereadequate as per the standards.Bio safety waste disposal is maintained satisfactorily

Blood donation camps were inadequate to the present demand. There was no blood policy, no quality audit,Computerization of data and records were not adequate as per the standardsin the blood bank. All the SOPS are maintained adequate and satisfactorily as per WHO Sops for guidelines.

V. Recommendations

Increase staff strength, Central monitoring system for monitoring the temperature of various equipment's are necessary.Appropriate committee for blood bank is needed for policy,quality audit and procedures in addition to adequate administrative mechanisms. Conduction of Voluntary blood donation camps regularly in hospital and serving community needed.

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