

REVIEW ARTICLE

ESTABLISHMENT OF BLOOD STORAGE FACILITY AT SECONDARY CARE HOSPITAL: ESIC EXPERIENCE AND REVIEW OF LITERATURE

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ABSTRACT: Background: National Blood Policy 2002, GOI states the objective to provide safe, adequate quantity of blood, blood components. Blood transfusion services may be broadly categorized as, either Hospital based/Stand-alone blood banks or Blood storage centres. Till 24-02-2014, I.G.E.S.I. Hospital, a secondary care, 300 bedded hospital had no facility of Blood transfusion Services. On my persuasion, the decision of starting Blood Storage facility was taken as the hospital was consuming less than 2000 units of blood & the components annually. The nearest R.B.T.C is G.T.B. H, Blood Bank, hence in charge G.T.B H. Blood Bank was contacted to be our Mother Blood Bank, MoU was signed between G.T.B H., Blood Bank and M.S, I.G.E.S.I. Hospital. As per," Guidelines for Setting up Blood Storage Centres "by NACO, all the Space, Human resource, material resources criteria were fulfilled, application for license was submitted to State Food Drug Controller Office. This study aims to provide essential background knowledge regarding establishment, day to day functioning of Blood Storage facility in India.

KEY WORDS: Blood Storage Facility, First Referral Unit, NACO Guidelines, National Blood Policy, Schedule K of Drugs & Cosmetics Act, State Licensing Authority.

INTRODUCTION:

Blood Transfusion Service is a vital part of the National Health Service and there is no substitute for Human Blood and its components. ⁽¹⁾ The provision of safe and adequate blood and blood products at national level is the responsibility of the government/national health authority of each country. ⁽²⁾ Blood safety is essential to ensure that

a patient who comes for treatment is not made sicker by another illness. ^(3,4) These products must be safe, clinically effective & of appropriate & consistent quality. ^(4,5) Also, increasing advancement in the field of Transfusion Technology has necessitated to enforce stricter control over the quality of Blood and its products. ⁽¹⁾

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National Blood Policy

Government of India published in the year 2002 the National Blood Policy. The objective of the policy is to provide safe, adequate quantity of blood, blood components and products. The policy also addresses various issues with regard to technical personnel, research, development and to eliminate profiteering by the blood banks by selling blood. ⁽¹⁾

Functionally, blood transfusion services may be broadly categorized as,

- Hospital based blood bank
- Stand-alone blood bank
- Blood storage centres. ⁽⁴⁾

The blood safety programme in India aims to make available safe and quality blood within one hour of requirement in a health facility. ⁽⁵⁾

In India, access to safe blood is mandated by law and it is the primary responsibility of the government (WHO, 2002). ^(4,5) The availability and accessibility of safe blood and blood products are vital for the prevention of HIV infection and to the achievement of the health-related Millennium Development Goals to reduce child mortality, improve maternal health, combat HIV and other infections. ⁽⁶⁾ However, access to safe and effective blood products is a major challenge in low and middle-income countries like India due to various reasons such as lack of basic facilities and systems, quality and safety standards need to be established, executed & strengthened, and insufficient supply.

Blood Storage Centres (BSC)

Ministry of Health & Family Welfare (Department of Health) vide Notification No. GSR 909(E) dated 20th December, 2001 exempted blood storage Centres run by FRU, Community Health Centre, PHC or any hospital from the purview of

obtaining license for operation. This notification has been inserted under Schedule K of Drugs & Cosmetics Rules, 1945 under serial no. 5B. The main aim of this notification is to make abundant availability of whole human blood or its components to the said hospitals without taking license. However, this exemption is applicable to those Centers which are transfusing blood and/or its components less than 2000 units per annum. ⁽⁷⁾

According to the FRU guidelines, blood-storage facility is one of the three critical determinants as First Referral Units (FRUs) have been identified to deliver EmOC services. ⁽⁸⁾

MATERIALS & METHODS:

Establishment of Blood Storage Facility: An ESIC Experience.

I.G.E.S.I. Hospital is a 300 bedded hospital and predominantly a secondary care hospital, with Oncology segment that is more developed. The hospital had fully functional obstetric Unit, Operation theatres working full throttle, Nursery and ICU. But till 24-02-2014, the hospital had no arrangement for blood transfusion services. This lacuna was recognised by administration and proactive decision followed by action was envisaged. It was decided by then Medical Superintendent, under the guidance of ESIC Headquarters to set up a Blood Storage Facility, as our hospital was transfusing less than 2000 blood units per annum. The Blood Storage facility was started under the department of Pathology with specialist initiating & overseeing the work. The nearest Regional Blood Transfusion Centre is G.T.B. Hospital Blood Bank, hence in charge G.T.B Hospital Blood Bank was contacted to be our Mother Blood Bank. MoU was signed between G.T.B Hospital Blood Bank and Medical Superintendent, I.G.E.S.I. Hospital, with G.T.B Hospital Blood Bank as a Mother Blood Bank for our blood storage facility. As per the document, Guidelines for Setting up Blood Storage Centres "by NACO, Ministry of Health and

Family Welfare Government of India, New Delhi ,2007, all the Space, Human resource, material resources criteria were fulfilled. As per **Annexure 1**, an application for approval of Blood Storage Facility was applied to State Drug Controller Authority, along with Site plan, List of staff with necessary certificates relating to education, experience and training in Blood Banking. The hospital had one Blood Bank Officer, was Post graduate medical officer working under the department of Pathology, one Blood Bank Technician with requisite experience and training. One more technician with DMLT was selected and trained in ESIC Hospital, Basaidarapur Blood Bank for Six months. As per ESIC context, in the present phase no additional staff was required, one of the existing doctors and technicians was designated for this purpose. Our designated staff fulfilled the criteria of education, experience and training as per the guidelines. After submission of application, the State Drug Controller inspectors inspected the proposed site and facilities for all the requirements. Few non-conformities were pointed out by Drug Controller team, within two months, corrections were made and repeat application was submitted. On repeat inspection by Drug Controller team, the approval was sent to Zonal Officer vide the format and directly the approval was received by post in our hospital.

RESULTS:

The resulting unit was equipped for issue of Whole blood, packed red cell concentrate. The equipment was installed within warranty, or AMC and CMC as mentioned in Guidelines for establishing Blood Storage Centres, NACO, MOHFW, 2007.

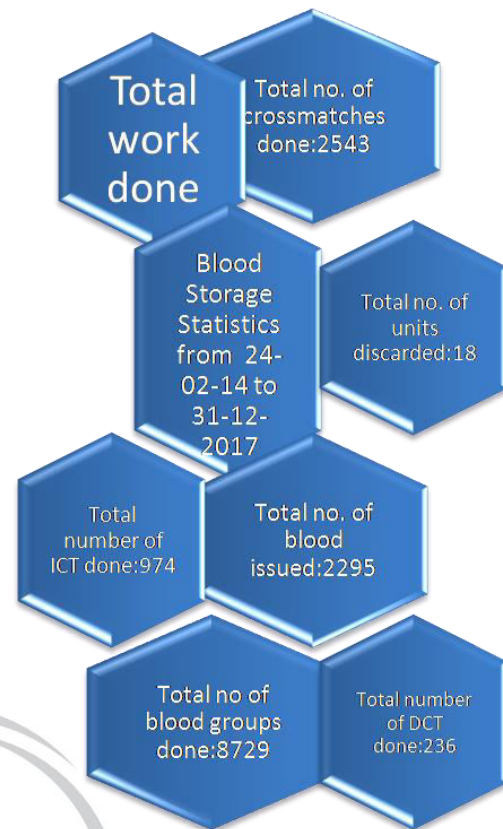


Fig. 1 Shows statistics of Blood Storage Facility from 24-02-2014 to 31-12-2017

DISCUSSION:

Licensing/Approval of blood storage and transfusion facilities

For the purpose of procuring licensing/ approval, an application has to be made as per the guidelines enclosed at Annexure I. The First Referral Unit, Community Health Centre, Primary Health Centre and / or any Hospital shall be approved by the State / Union Territory Licensing Authority after satisfying the conditions and facilities through inspection. The applicant shall furnish an undertaking to the licensing authority that the captive consumption of Whole Human Blood or Components shall not be more than 2000 units annually. (Extract from notification No x-11014/3/2001 DMS&PFA).⁽⁷⁾

The applicant shall furnish the, name of the medical officer responsible for conducting operation of blood storage centre with attested certified copies of MBBS or MD qualification, name, certified copies of qualification and experience of the blood bank technician. ⁽⁷⁾ The applicant shall enclose list of equipment needed for storage viz blood bank refrigerator etc and site plan. ⁽⁷⁾

The applicant shall furnish the source of procurement of Whole Human Blood / Blood Components namely the name and address of the Blood Banks. **These could be licensed blood banks run by Government Hospitals/Indian Red Cross/Regional Blood Transfusion Centres only.** ⁽⁷⁾ Even in case of FRUs/ CHCs/ PHCs before applying for the approval, the storage centre has to identify and obtain consent vide MOU from the blood bank, from where they will get the supply of blood/blood components. MOU of BSC with parent blood bank should clearly define the responsibility of mother blood bank and BSC.

The approval shall be valid for a period of two years from the date of issue unless sooner suspended or cancelled, and First Referral Unit, Community Health Centre, Primary Health Centre or the Hospital shall apply for renewal to the State Licensing Authority three months prior to the date of expiry of the approval. ⁽⁷⁾

In case the license of the parent blood bank/centre is cancelled, the license of the storage centre is also automatically cancelled.

The storage centers, can however, get affiliated to more than one blood bank/centre to ensure un-interrupted supplies, but a separate approval is required in each case, it can be up to three blood banks.⁽⁷⁾

CONCLUSION:

According to Facility Survey 2007-08, though 52% of Community Health Centres (CHC) were

designated as FRUs, only 9.1% had blood storage facilities (IIPS, 2010). ^(4,13) As per the Concurrent Evaluation of National Rural Health Mission (NRHM) in 2009, only 14% of the CHC were having blood storage facility, 74.1% of the District Hospitals have Blood Bank/ Blood storage unit (GOI, 2013). ^(4,14) which indicated the huge gap in making blood accessible to the rural population

As of March 2011, there were 2,891 FRUs (574 DH + 826 SDH+1491 CHCs) in the country (GOI, 2011) ⁽¹²⁾. The NACP phase III aimed to establish blood storage centres in 3222 CHCs with the equipment grant by RCH-II & annual recurrent grant by DAC and make available refrigerated vans in 500 districts for networking with blood storage centres (NACO, 2007g). ^(4,15) But, there are only 745 blood storage centres functioning across the country (NACO, 2013). ^(4,16)

Though the creation of blood storage centres in sub district level and first referral units have resulted in better access to blood than previously, these are still not available to all due to licensing and regulations as these blood storage centres are not authorized to supply blood to other facilities. ⁽⁴⁾

It is estimated that if FRUs were equipped with the proper blood supply, they could reduce maternal mortality by 30% (HINDU, 2007). ^(4,17)

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ANNEXURE - I

CERTIFICATE OF APPROVAL TO BLOOD STORAGE CENTRE FOR STORAGE OF WHOLE HUMAN BLOOD AND*/ OR ITS COMPONENTS

No. _____ Date of Issue _____

M/s _____ is hereby approved to store the following items on the premises situated at _____ under the supervision of the following technical staff:

1. Names of the approved medical officer :
2. Names of the items:
3. Name of the qualified Blood Bank Technician :
4. Name & address of the licensed Blood Bank from whom the blood units would be procured :
5. The approval shall be in force from to

Dated _____

The under mentioned requirements are as per the document "Guidelines for Setting up Blood Storage centres "by NACO, Ministry of Health and Family Welfare Government of India, New Delhi ,2007 as well as review of literature.

EQUIPMENT

- 1.) Blood Bank Refrigerator having a storage capacity of more than 50 units of Blood units. Annexure No. 2, fitted with alarm device and temperature indicator with regular temperature monitoring shall be provided to store blood units between 2°C to 8°C.
- 2.) Domestic refrigerator for storing reagents and as a backup.
- 3.) Dielectric cutter and tube sealer.
- 4.) Microscope. Annexure No. 2.
- 5.) Laboratory Centrifuge. Annexure No. 2.
- 6.) Rh View Box.
- 7.) Serological Water Bath.
- 8.) Hot Air Oven.
- 9.) Incubator.
- 10.) Blood Transportation Boxes or Insulated Carrier boxes with ice packs for maintaining

the cold chain during transportation of blood bags: Two. Annexure 2.

- 11.) Plasma Thawing bath.
- 12.) Deep Freezer -20 C
- 13.) Platelet Agitator and Incubator
- 14.) Gel Card Incubator & Centrifuge.⁽⁷⁾

These equipment schedules should be such to ensure that: • spaces are large enough to house the equipment; • the structure is adequate to support the equipment both in its installed location and along its movement path during installation or removal; • doorways including lift doors and corridors are large enough (measuring both height and width) to permit the movement of equipment during installation or relocation; • adequate power is available for the equipment in its installed location; • air conditioning is designed to cope with the heat generated by some pieces of equipment; the equipment budget is adequate.⁽⁹⁾

ELECTRICITY:

Regular 24 hours supply was available in the hospital along with provision of backup generator.⁽⁷⁾

DOCUMENTATION REQUISITES.

The First Referral Unit, Community Health Centre, Primary Health Centre and Hospital shall maintain records and registers including details of procurements of Whole Human Blood I.P. and/or blood components, as required under Part XII B of Schedule F.

The registers like Sample Receipt Register, Master Register, Blood Issue Register, Patient grouping register, Donor Grouping Register, Blood Stock Register, Register for DCT & ICT, Equipment Log Book are to be prepared as per SOPM. Other registers like Error reporting Register and Quality Control Register are to be made.^(7,10)

Blood Grouping Crossmatch Forms, Compatibility Report and Issue Tags with License Number of Mother Blood Bank, Blood release slips, Adverse transfusion reaction forms.^(7,10)

The First Referral Unit, Community Health Centre, Primary Health Centre and Hospital shall store samples of donors' blood as well as patients sera for a period of seven days after transfusion.⁽⁷⁾

SPACE

The area required for setting up the facility is only 10 square metres, well lighted, clean and preferably air-conditioned.⁽⁷⁾

Also, the layout is such that the real time control of all blood and blood sample movement into and out of the centre is required to ensure accurate documentation of all samples and products through processing, testing and storage and to ensure operational efficacy.⁽⁹⁾ The premises or layout should be such that to safe guard samples, information and resources from unauthorised access.⁽⁹⁾

MANPOWER

As per Report of Expert Working Group set up under Chairpersonship of Special Director General Health Services, Review and Recommendations; Manpower Norms for Blood Bank

Qualifications:

1. Medical Officer (Whole Blood)

- a) Degree in Medicine (MBBS) having experience of working in a licensed Blood Centre, not less than one year during regular service and also has adequate knowledge and experience in blood group serology, blood group methodology and medical principles involved in the procurement of blood and/ or preparation of its components, or
- b) Degree in Medicine (MBBS) with Diploma in Clinical Pathology or Diploma in Pathology and Bacteriology with six months experience in a licensed Blood Centre, or
- c) Degree in Medicine (MPBS) with Diploma in Transfusion Medicine or Diploma in Immunohematology and Blood Transfusion with three months experience in a licensed Blood Centre, or
- d) MD Pathology or DNB (Pathology) with three months experience in a licensed Blood Centre, or
- e) Post graduate degree in Transfusion Medicine- MD (Transfusion Medicine)/ MD (Immunohematology and Blood Transfusion) or DNB (Transfusion Medicine/ IHBT).

The degree or diploma shall be recognized by Medical Council of India or its equivalent.⁽¹¹⁾

Qualifications for Blood Bank Technician (Whole Blood)

- I. Diploma in Medical Laboratory Technology (DMLT) or Transfusion Medicine or Blood Bank Technology after 10+2 with one-year experience in the testing of blood and/ or its components in a licensed Blood Centre
- II. Degree in Medical Laboratory Technology (MLT) or Blood Bank Technology with six months experience in the testing of blood and/or its components in a licensed Blood Centre
- III. B.Sc. Haematology and Transfusion Medicine with six months' experience in the testing of blood or its components in a licensed Blood Centre
- IV. M.Sc. Transfusion Medicine with six month's experiences in the testing of blood or its components in a licensed Blood Centre v. PG DMLT/ PG DML-S with six months' experience in the testing of blood and/or its components in a licensed Blood Centre.⁽¹¹⁾

The degree or diploma shall be from a University / Institution recognized by the Central Government or State Government.

As per the document, they should be trained in the operation of blood storage centres and other basic procedures like storage, grouping, cross- matching and release of blood. Also, the medical officer designated for this purpose will be responsible for overall working of the storage centre.⁽⁷⁾

Blood Banks are not included within the scope of the Clinical Establishment Act and Rules thereof. However, as per IPHS Standards for District Hospitals (2012), the minimum manpower for blood bank is indicated as detailed below vide Table no. 1⁽¹⁰⁾

Table No.1.⁽¹⁰⁾ Minimum manpower for blood bank

SN o.	Cadre	100 Bedded	200 Bedded	300 Bedded	400 Bedded	500 Bedded
1.	Blood Bank In charge (Doctor/Pathologist)	-	-	1	1	1
2.	Male /Female Nursing Attendant	1	1	1	1	1
3.	Blood Bank Technician	1	1	1	2	2
4.	Sweeper	1	1	1	1	1

CONSUMABLES

There should be adequate provision for consumables and blood grouping reagents. The following quantities would suffice the annual requirement of an FRU with up to 50 beds.

Consumables Quantity

Pasteur Pipette 12 dozens/year
Glass tubes 7.5 to 10 mm -100 dozens/year
Glass Slides 1"x2" boxes of 20 or 25 each/year
Test Tube Racks 6 racks, each for 24 tubes
Rubber Teats 6 dozens / year
Gloves Disposable rubber gloves 500pairs per year
Blotting/tissue paper as required
Marker Pen (Alcohol Based) As required
Tooth Picks As required

Reagents

All the reagents should come from the Mother Blood Bank.

Anti-A 2-vials each per month
Anti-B 2-vials each per month
Anti-AB 2-vials each per month
Anti-D 2 vials each per month (Blend of IgM & IgG)
Antihuman Globulin 1 vial per month (Polyclonal - IgG & Complement)

Since quality of the reagents is an important issue, the supplies of these should be made from the same blood bank/centre from where blood is obtained. For this purpose, State Governments / Union Territories should provide the additional budgetary requirements to the mother blood bank/ centre.⁽⁷⁾

Disinfectants

Bleach & Hypochlorite Solution As required.

In order to satisfy the conditions and facilities, an inspection of the proposed Blood Storage Centre may be carried out by the respective State Drug Control Department.⁽⁷⁾ The Inspection team shall also inspect the Blood Banks who have given consent letters for supply of Whole Human Blood / Components. The inspection team may verify whether the Blood Banks have sufficient quantity of blood units to be supplied to the Blood Storage Centres and also verify the mode of shipper or containers used for supply of blood units / components to ensure that the proper storage condition is maintained as per the pharmacopeia. The Blood Bank shall label the blood units / components as per the Drugs & Cosmetics Rules, 1945. The State Licensing Authority shall forward the approved Blood Storage Centres to the concerned Zonal Officer immediately. ⁽⁷⁾

For this the "Clinician's Guide to Appropriate Use of Blood" has been developed. ^(4,12) It is suggested that one-day sensitisation programme for the clinicians may be organised at the District Hospital/Medical College. ⁽⁷⁾