Guidelines For Setting Up Blood Storage Centres At First Referral Units

Maternal Health Division
Department of Family Welfare
Government of India
2003

Guidelines for Setting up Blood Storage Centres at First Referral Units

Foreword

It is estimated that for every 100,000 live births, 407 pregnant women die every year in India due to causes related to pregnancy and childbirth. The major causes of these deaths have been identified as anaemia, hemorrhage (both ante and post partum), toxemia (Hypertension during pregnancy), obstructed labour, puerperal sepsis (infections after delivery) and unsafe abortions. Over the years, efforts to reduce maternal mortality and morbidity have included providing family planning services, improving essential obstetric care including antenatal care, safe/institutional deliveries, prophylaxis and treatment of anaemia and postnatal care and **emergency obstetric care.**

Complications associated with pregnancies are not always predictable. Therefore, provision of emergency obstetric care as close to the community as possible was envisaged under the CSSM Programme by setting up First Referral Units at the community health centres/sub-district level hospitals. However, most of the identified FRUs could not become fully operational due to lack of skilled manpower, particularly anesthetists and gynecologists, adequate infrastructure, medicines and **blood banking facilities**. Non-availability of blood storage/transfusion facilities at the first referral units has thus been a major constraint in provision of emergency obstetric care services. However, now that the Drug and Cosmetics Rules have been amended, it would be possible to set up blood storage centres at the sub-district level health facilities without going through the elaborate exercise of setting up Blood Banks in all these places.

A core group of experts with Dr (Mrs.) Ira Ray, former Additional Director General of Health Services, Government of India, as the Chairperson and Dr. V. K. Manchanda, Deputy Director General (Maternal Health/Training), as Convener, was constituted to finalise the Guidelines for setting up of blood storage centres at first referral level units.

I am happy to note that the group has not only been able to put together the guidelines for setting up the blood storage facilities but also drawn up the **Standard Operating Protocol** and **the Clinician's Guidelines for Appropriate use of blood and blood products**. For the benefit of administrators, clinicians and other health functionaries, the three documents are being put together in one volume.

I would like to acknowledge here the efforts put in by the members of the core group. I am sure this effort will go a long way not only in planning and setting up of the services, but also in ensuring uniform and good quality service at these blood storage centres.

(J. V. R. Prasada Rao)
Secretary
Department of Family Welfare
Ministry of Health & Family Welfare
Government of India

10th June, 2003

Preface

The National Blood Policy has been adopted. A well organised Blood Transfusion Service (BTS), which is a vital component of the Health care delivery system of the country and expected to ensure accessible and adequate supply of safe and quality blood and blood component, is being implemented.

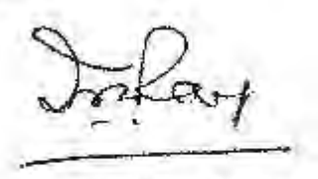
So far, the services have been made available only through established blood banks extending up to district level. These blood banks have the responsibility for collection of blood through proper donor selection, screening these units of blood, storage and preventing unnecessary transfusions and establishing an effective quality assurance system.

However, the large number of maternal mortality in India is caused by lack of timely availability of safe blood to women during or after childbirth. The Drugs and Cosmetics Rules so far did not permit the establishment of Blood Storage Centres (BSCs), which has only recently been amended. The BSC must obtain approval from the Drug Controller General of India to initiate their activity and provide for infrastructure and equipment.

Hence, a provision is being made by the Family Welfare Department of the Government of India, to extend services for providing safe blood at sub-district levels, i.e. First Referral Units (FRUs) through Blood Storage Units. These units would be named Blood Storage Centres (BSCs). These centres would procure required units of safe blood from specified Mother Blood Banks, already established at the district hospitals or Regional Blood Transfusion Centres. They would have the responsibility of procuring units of blood from Mother Blood banks, proper storage, cross matching, transfusion and all other associated activities. As the BSC will have limited activities, the doctors and technicians already in position could be trained for the job of blood transfusion.

A group of technical experts have prepared a manual for the setting of Blood Storage Centres at First Referral Units (FRUs). The first part, i.e. the guidelines indicates the requirements and responsibilities of BSCs, which may be used by Policy makers, and Programme Officers. The second part is Standard Operating Procedures detailing the procedures to be followed by the laboratory personnel in conducting the actual tests of cross matching and transfusion. The third part of the document is a guide to rational use of blood, blood products and substitutes by clinicians.

It is earnestly hoped that this effort of establishing Blood Storage Units at sub-district levels would ensure availability of adequate quantity of safe blood to a large population and especially to women during childbirth.



Dr. (Mrs.) Ira Ray
National Consultant, WHO
& Former Additional Director General
Ministry of Health and Family Welfare

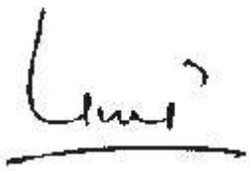
Acknowledgements

The publication of guidelines for setting-up the Blood Storage Centres, the Standard Operating Procedures and the Clinician's Guide to appropriate use of blood and its substitutes, fulfills a long-standing need in the efforts of Department of Family Welfare towards strengthening Emergency Obstetric Care at the First Referral facilities. I gratefully acknowledge the encouragement, guidance and help provided by Shri J. V. R. Prasada Rao, ex-Secretary in Department of Family Welfare. It was due to his initiative that the expert group for working on these guidelines was constituted and has been able to complete the task within a short period. I am also thankful to Shri S. S. Brar, Joint Secretary (RCH), for his guidance and help during the preparation of these guidelines.

I would specifically like to express my gratitude to Dr. Ira Ray, National Consultant-WHO and Chairperson of the expert group, for her contribution and guidance. The time, effort and sharing of thoughts and experiences by the members of the expert group, Dr. R. N. Makroo, Director, Department of Transfusion Medicine, Indraprastha Apollo Hospital, New Delhi, Dr. Veena Doda, Head, Blood Bank, RML Hospital, New Delhi, and Dr. P. Salil, Joint Director, NACO, New Delhi, has been extremely valuable in putting together the guidelines and I express my sincere appreciation for their contribution.

I owe special thanks to Dr. V. N. Sardana, Consultant, NACO, and my colleagues Dr. Narika Namshum, Dr. Himanshu Bhushan and Dr. D. C. Jain, for their help during the preparation of these guidelines.

I acknowledge the help provided by Mrs. Reeta Madan and Shri Shailendra Kumar Singh for their secretarial help in putting together of the document.



(Dr. V. K. Manchanda)
Deputy Director General
Maternal Health & Training Division
Department of Family Welfare
Ministry of Health & Family Welfare
Government of India.

List of Members of the Expert Group

1. Dr. (Mrs.) Ira Ray, National Consultant - WHO — Chairperson
   B-265, Greater Kailash - I
   New Delhi - 110 048

2. Dr. R. N. Makroo — Member
   Director, Department of Transfusion Medicine
   Indraprastha Apollo Hospital
   New Delhi - 110 044

3. Dr. P. Salil, Joint Director (BS) — Member
   NACO, Chanderlok Building, 36, Janpath
   New Delhi - 110 001

4. Dr. Veena Doda, Head, Blood Bank — Member
   RML Hospital, New Delhi - 110 001

5. Dr. V. K. Manchanda, DDG (MH/Trg) — Convener
   Nirman Bhawan, New Delhi - 110 011

Special Invitees :

1. Dr. V. N. Sardana
   Consultant (BS)
   NACO
   Chanderlok Building
   36, Janpath
   New Delhi - 110 001

2. Dr. Narika Namshum
   AC (MH-I)
   Nirman Bhawan
   New Delhi - 110 011

3. Dr. Himanshu Bhushan
   AC (MH-II)
   Nirman Bhawan
   New Delhi - 110 011

4. Dr. D. C. Jain
   AC (Trg)
   Nirman Bhawan
   New Delhi - 110 011

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GUIDELINES

INTRODUCTION

There has been a significant improvement in the health status of the Indian population; however, maternal mortality due to causes related to pregnancy and childbirth continues to be high. According to the estimates of the Registrar General of India, the Maternal Mortality Ratio in 1998 was 407 per 100,000 population. The National Population Policy-2000, has charged us with the responsibility of bringing it down to 100 by the year 2010.

The major causes of maternal mortality are ante partum haemorrhage, post partum haemorrhage, anaemia, Obstructed labour, hypertensive disorders, post partum sepsis and unsafe abortions. While deaths due to anaemia, Obstructed labour, hypertensive disorders and sepsis are preventable with provision of adequate antenatal care, referral and timely treatment of complications of pregnancy, promoting institutional and safe delivery practices and postnatal care, haemorrhage during pregnancy is generally not predictable. These cases and those developing complications during deliveries conducted at homes and in PHCs require provision of adequate emergency obstetric care services and timely referrals to facilities capable of handling such cases.

Provision of emergency obstetric care as close to the community as possible was envisaged under the CSSM Programme (1992-97) by setting up First Referral Units at the Community Health Centre (CHC)/sub district hospital Level. 1724 First Referral Units were identified by the states and provided with 12 types of equipment kits, which were considered necessary for carrying out laparotomies, caesarian sections, other necessary surgical interventions and newborn care. However, most of the identified FRUs could not become fully operational due to a variety of reasons, including lack of blood transfusion facilities. Non-availability of blood storage/ transfusion facilities at the first referral units has been a major constraint in provision of emergency obstetric care services.

The Drug and Cosmetics Act, has recently been amended with the objective of setting up blood storage facilities at the FRUs / CHCs / PHCs. 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 centres, which are transfusing blood and/or its components less than 2000 units per annum. In order to ensure the safety and quality of blood and/or its components to be stored in such blood storage centres, the notification lays down some conditions which have to be met before getting exemption from the purview of taking of a license from the respective State Drugs Controllers. The details of the notification and guidelines issued in this regard by the Ministry of Health and Family Welfare are at ***Annexure I.***

It would now be possible to set up blood storage facilities within the existing FRUs without putting up any additional infrastructure or engaging any additional staff. Training of the existing staff and additional equipment if not already available, would, however, be required. The National AIDS Control Organisation has already supplied blood bag refrigerators of different types to a number of States. Department of Family welfare, Government of India, will take up the provision of equipment and training of staff for blood storage and transfusion in health facilities at identified FRUs, where emergency obstetric care services/ institutional deliveries are being conducted or are proposed to be conducted but the facility has not been covered by NACO.

The detailed guidelines as given in the following pages have been formulated by an expert Group for setting up a blood storage facility at identified FRUs with up to 50 beds. For setting up similar units at hospitals with more beds, the same guidelines would apply except that the requirement of equipment and consumables may increase. The district and State level officers responsible for setting up the blood storage facilities may follow these guidelines for planning their requirements. Care has, however, to be taken to ensure that this is done in a phased manner and only such FRUs are taken up in the first phase, which would become fully operational once the blood storage facilities are in place.

APPROVAL OF THE BLOOD STORAGE FACILITY

First referral Units, Community Health Centres, Primary Health Centres or any other hospitals are required to obtain approval from the State/Union Territory licensing authority. For this, an application has to be made as per the guidelines enclosed at Annexure I. The State Licensing Authority shall approve the blood storage unit after satisfying the conditions and facilities through inspection. The approval shall be valid up to a period of two years from the date of issue unless sooner suspended or cancelled. An application for renewal will have to be made three months prior to the date of expiry of the approval.

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

1. REQUIREMENTS

(i) ***Space :***

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

(ii) ***Manpower :***

In the present phase no additional staff is required. One of the existing doctors and technicians should be designated for this purpose. They should be trained in the operation of blood storage centres and other basic procedures like storage, grouping, cross- matching and release of blood.

The medical officer designated for this purpose will be responsible for overall working of the storage centre.

(iii) ***Electricity :***

Regular 24 hours supply is essential. Provision of backup Generator is required.

(iv) ***Equipment :***

Each FRU should have the following :

1. Blood Bag Refrigerators having a storage capacity of 50 units of Blood.
2. Deep Freezers for freezing ice packs required for transportation. The deep freezers available in the FRUs under the Immunisation Programme can be utilised for this purpose.
3. Insulated Carrier boxes with ice packs for maintaining the cold chain during transportation of blood bags.
4. Microscope and centrifuge: Since these are an integral part of any existing laboratory, these would already be available at the FRUs. These should be supplied only if they are not already available.

(v) ***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″ x 2″ 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 500 pairs per year
Blotting / tissue paper	As required
Marker Pen (Alcohol Based)	As required
Tooth Picks	As required

(*vi*) ***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 (Polyclonal – IgG & Compliment)	1 vial per month

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.

(vii) ***Disinfectants***

Bleach & Hypochlorite Solution	As required.

2. SUGGESTED QUANTITIES OF WHOLE BLOOD UNITS TO BE AVAILABLE AT A BLOOD STORAGE UNITS

5 units each of	A, B, O (Positive)
2 units of	AB (Positive)
1 units each of	A, B & O (Negative)

This can be modified according to the actual requirement.

3. STORAGE & TRANSPORTATION

Cold Chain :

It is necessary to maintain the cold chain at all levels i.e. from the mother centre to the blood storage centre to the issue of blood. This can be achieved by using insulated carrier boxes.

During transportation, the blood should be properly packed into cold boxes surrounded by the ice packs. Ice, if used should be clean and should not come in direct contact with the blood bags.

The blood should be kept in blood bank refrigerator at 4-6°C ± 2°C. The temperature of the blood should be monitored continuously.

Storage :

The storage centre should check the condition of blood on receipt from the mother centre and also during the period of storage. The responsibility of any problem arising from storage, cross matching, issue and transfusion will be of the storage centre. Any unit of blood showing hemolysis, turbidity or change in colour should not be taken on stock for transfusion.

Due care should be taken to maintain sterility of blood by keeping all storage areas clean.

The expiry of the blood is normally 35/42 days, depending on the type of blood bags used. The Medical officer in-charge should ensure that unused blood bags should be returned to the Mother Centre at least 10 days before the expiry of the blood and fresh blood obtained in its place.

The blood storage centres are designed to ensure rapid and safe delivery of whole blood in an emergency. The detail of storage of packed cells, fresh frozen plasma and platelets concentrate, are therefore not given in these guidelines. In case, however, these are required to be stored, the storage procedures of the mother blood bank should be followed.

4. ISSUE OF BLOOD

Patients' blood grouping and cross matching should invariably be carried out before issue of blood. A proper record of this should be kept.

First In and First Out (FIFO) policy, whereby blood closer to expiry date is used first, should be followed.

5. DISPOSAL

Since all the blood bags will already be tested by the Mother Centre, disposal of empty blood bags should be done by landfill. Gloves should be cut and put in bleach for at least one hour and then disposed as normal waste.

6. *DOCUMENTATION & RECORDS*

The Centre should maintain proper records for procurement, cross-matching and issue of blood and blood components. These records should be kept for at least 5 years.

7. *TRAINING*

Training of doctors and technicians, who will be responsible for the Blood Storage Centre, should be carried out for 3 days in an identified centre as per the guidelines. Training will include :

- Pre transfusion checking, i.e. patient identity and grouping
- Cross- matching
- Compatibility
- Problems in grouping and cross-matching
- Troubleshooting
- Issue of blood
- Transfusion Reactions and its management
- Disposal of Blood Bags

The states will have to identify the institutions where training of the staff responsible for running the blood bank is to be held. These could be the blood banks at Medical Colleges, Regional Blood Banks, Indian Red Cross Blood Banks, or any other well setup, licensed Blood Bank, provided they have the necessary infrastructure for undertaking training.

The training will be for three-days duration during which the Medical Officer and the technician from the identified FRUs will be posted at the training institution.

A "Standard Operating Procedures Manual" (SOPM) has been developed and is part of these guidelines. This SOPM will be used as the training material. A copy of this SOPM will be made available to the Medical Officer for use in his Blood Storage Centre for undertaking storage, grouping, cross-matching and transfusion.

In addition to the training of the above Medical Staff, it is considered necessary that the clinicians who will be responsible for prescribing the use of blood are also sensitised on the various parameters of blood transfusion. For this the "Clinician's Guide To Appropriate Use Of Blood" has been developed. It is suggested that one-day sensitisation programme for the clinicians may be organised at the District Hospital/Medical College.

Government of India will make the expenditure for the above-mentioned trainings, available as per the norms of training under the RCH Programme. This training will, however, be coordinated by the Training Division of Department of Family Welfare. The states are required to include training as part of the overall State Action Plan for establishing Blood Storage Centres.

ANNEXURE I

GUIDELINES FOR APPROVAL OF BLOOD AND/OR ITS COMPONENTS TO STORAGE CENTRES AND FIRST REFERRAL UNIT, COMMUNITY HEALTH CENTRE, PRIMARY HEALTH CENTRE OR ANY HOSPITAL

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 Centres which are transfusing blood and/or its components less than 2000 units per annum.

In order to ensure the safety and quality of blood and/or its components to be stored in such blood storage Centres, the following conditions are applicable before getting exemption from the purview of taking of a license from the respective State Drugs Controllers:-

(Extract from notification No x-11014/3/2001-DMS&PFA)

The provisions of Chapter IV of the Act and the rules made there under which require obtaining of a license for operation of a blood bank or processing Whole Human Blood and / or its components, subject to the following conditions, namely:-

(1) 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.

(2) The captive consumption or Whole Human Blood I.P. or its components in the First Referral Unit, Community Health Centre, Primary Health Centre and/or any Hospital shall not be more than 2000 units annually.

(3) The Whole Human Blood and/or its components shall be procured only from Government Blood Bank and/or Indian Red Cross Society Blood Bank and/or Regional Blood Transfusion Centre duly licensed.

(4) 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.

(5) The First Referral Unit, Community Health Centre, Primary Health Centre and/or any Hospital shall have the following technical staff for storage of blood or its components:-

(a) A trained Medical Officer for proper procurement, storage and cross matching of blood and/or its components. He/she shall also be responsible for identifying haemolysed blood and ensure non-supply of date expired blood or its components.

(b) A blood bank Technician with the qualification and experience as specified in Part XII B of Schedule F or an experienced laboratory technician trained in blood grouping and cross matching.

(6) The First Referral Unit, Community Health Centre, Primary Health Centre and Hospital shall have an area of 10 square metres. It shall be well lighted, clean and preferably air-conditioned. Blood bank refrigerator of appropriate capacity fitted with alarm device and temperature indicator with regular temperature monitoring shall be provided to store blood units between 2°C to 8°C and if the components are proposed to be stored, specified equipments as specified in Part XII B of Schedule F shall also be provided.

(7) 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.

(8) 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."

[No. X – 11014/3/2001-DMS & PFA]

(DEEPAK GUPTA)
JOINT SECRETARY TO GOVT. OF INDIA

Source : Internet Site : ***www.cdsco.nic.in***

ANNEXURE I *(Contd.)*

GUIDELINES BEFORE GRANT OF APPROVAL FOR OPERATION OF WHOLE HUMAN BLOOD AND/OR ITS COMPONENTS STORAGE CENTRES RUN BY FIRST REFERRAL UNIT, COMMUNITY HEALTH CENTRE, PRIMARY HEALTH CENTRE OR ANY HOSPITAL

The following guidelines may be followed before exempting the said institutions for obtaining of a license for operation of a Blood Bank or processing Whole Human Blood / or its components :

1. The applicant shall be First Referral Unit, Community Health Centre, Primary Health Centre or any Hospital.
2. 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.
3. The applicant shall enclose list of equipment needed for storage viz blood bank refrigerator with alarm system & temperature indicator. A separate list of equipments for blood components would be enclosed if proposed to be stored.
4. The applicant shall furnish the following :
   (a) Name of the medical officer responsible for conducting operation of blood storage centre
   (b) Attested certified copies of MBBS or MD qualification
   (c) Name, certified copies of qualification and experience of the blood bank technician
   (d) Name, attested certified copies of qualification and experience of the blood bank technician having non-DMLT qualification
5. The applicant shall furnish the source of procurement of Whole Human Blood / Blood Components namely the name and address of the Blood Banks.
   (a) The source of procurement of blood / components shall be from licensed Blood Banks run by Govt. Hospitals / Indian Red Cross Society / Regional Blood Transfusion Centres only
   (b) A letter of consent from the above Blood Banks who intend to supply Whole Human Blood / Blood Components to the Blood Storage Centres shall be furnished along with the application
6. The applicant shall submit the plan of the premises. A minimum area of 10 sq. metres is essential for the Blood Storage Centre.
7. 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.
8. 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.

9. The Blood Banks who intend to supply the blood units / components shall test the following mandatory tests before supplying to Blood Storage Centres.

   (a) Blood Grouping

   (b) Anti Body Testing

   (c) Haemoglobin Content

   (d) HIV I & II Anti Bodies

   (e) Hepatitis B Surface antigen

   (f) Hepatitis C Anti Body

   (g) Malarial Parasite

   (h) Syphillis or VDRL

   The label of the tested blood unit shall contain the above particulars with date of testing before supplying to Blood Storage Centres.

   The Blood Bank shall maintain a separate register for supply of blood units / components to Blood Storage Centres with all necessary details.

10. The validity of approval shall be for a period of 2 years from the date of issue of the approval.

11. The State Licensing Authority shall forward the approved Blood Storage Centres to the concerned Zonal Officer immediately.

12. A format of the approval proforma is enclosed.

ANNEXURE I *(Contd.)*

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 :
5. Bank from whom the blood units would be procured :
6. The approval shall be inforce from to :

Dated

Signature
Designation
Licensing Authority

CONDITIONS

The Blood Storage Centre shall comply with the conditions as stipulated under item 5B of Schedule K of the Drugs and Cosmetics Rules which also includes as under :-

1. The captive conception of Whole Human Blood or its components in the above said centre shall not be more than 2000 units annually.
2. In the event of any change in the technical staff shall be forthwith reported to the licensing authority.
3. In the event of any change in the name of the licensed blood bank from whom the blood units are procured, the same shall be intimated to the licensing authority for approval.
4. The centre shall apply for renewal of the approval to the licensing authority three months prior to the date of expiry of the approval.
5. The centre shall maintain records and registers including the details of procurement of blood* / its components.
6. The centre shall store samples of donors' blood as well as patients' sera for a period of 7 days after transfusion.

** Delete whichever is not applicable.*

ANNEXURE -II

SPECIFICATIONS

BLOOD BANK REFRIGERATOR CAPACITY - 50-60 STANDARD BLOOD BAGS

1. Capacity : It should be able to accommodate 50-60 standard blood bags of each 450 ml capacity.
2. Temperature ratings : 2°C to 6°C with setting accuracy ± 1°C.
3. Should have provision for air circulation.
4. Digital temperature display and audio visual alarm system.
5. Technical data : Input voltage 220/240 volts, 50 cycles, single phase, AC.
6. Weight : To be indicated by the bidder.
7. Construction : Outside C. R. Sheet at least 1 mm thick and inside stainless steel of at least 22 G. It should have 2-3 rolled out type drawers of stainless steel of 22 G.
8. A line voltage corrector of appropriate rating will form part of standard configuration.
9. Warranty : The warranty for 2 years from date of installation followed by comprehensive annual maintenance contract including spare parts for subsequent four years.

BINOCULAR MICROSCOPE

The microscope should have a sturdy base and be fitted with standard outfit as below :

1. Objective - Achromatic, spring loaded - 4x (NA 01); 10x (NA 0.25); 40x (NA 0.35); 100x(NA 1.25)(Oil immersion)-one pair each.
2. Eye pieces - 5 x, 10 x- one pair each.
3. Inbuilt arrangement of illumination halogen lamps fitted directly under field lenses (Koehler's system).
4. Transformer and other electricals fitted inside the base with extra mirror attachment.
5. Condenser - Bright field Abbe's NA 1.25 and dark field NA 1.25.
6. Nosepiece - quadruple, revolving on smooth ball bearing.
7. Power supply - 220/240 volts, 50 cycles, single phase.
8. Inclination angle - to be declared by the bidder.
9. Spare Halogen Lamps - 6 Nos. to be supplied with each microscope.
10. Technical Literature - The firm shall positively submit printed illustrated technical literature/leaflet indicating the model quoted by them. If quoted model is a modified version of their any standard product that also be indicated in the offer.

ANNEXURE II *(Contd.)*

11. Warranty	:	The warranty and maintenance contract should be for a period of at least 3 years along with spare parts.
COLD CHAIN BOXES (INSULATED)	-	***AS PER UIP SPECIFICATIONS.***
(8-15 Bags for FRUs)		
Size	:	To take 8-15 blood bags.

BENCH TOP CENTRIFUGE

1. Capacity	:	16-24 up to 15 ml.
2. Built in time	:	(1 minute ± 5 seconds) and speed regulator, ± 20 rpm with suitable speed indication and lid lock system.
3. RPM	:	500 to 5000 rpm.

4. Power supply – 220/240 volts, single phase, 50 cycles plus minus 12 AC.
5. A line voltage corrector of suitable rating should form part of the configuration as per IS:9815/89 or latest amended.
6. Installation, commissioning and trail run will be the responsibility of the supplier.
7. Technical literature - The firm shall positively submit printed illustrated technical literature/leaflet indicating the model quoted by them. If quoted model is a modified version of their any standard product that also be indicated in the offer.

8. Warranty	:	The warranty for 2 years from date of installation followed by comprehensive annual maintenance contract including spare parts for subsequent four years.

STANDARD OPERATING PROCEDURES

INTRODUCTION

The Department of Family Welfare is now initiating the setting up of a Blood Storage Centres at the First Referral Units (FRUs) to make blood readily available especially at time of emergency. This service would be available to the women during and after childbirth and is expected to bring down Maternal Mortality.

To establish the Blood Storage Centres, it is essential to train the medical officers and technicians working in these FRUs in the various methods of handling blood including storage, blood grouping, cross-matching, transfusion and adverse reactions.

A ***Standard Operating Procedure Manual (SOPM)*** has been developed as a part of the guidelines to facilitate the training of medical officers and technicians from identified FRUs, which would act as Blood Storage Centres (BSCs).

It is suggested that three-days training for the medical officers and technicians in identified institutions should be undertaken for the medical officers and laboratory technicians who will be responsible for the running of the blood storage centres.

BLOOD GROUPING

ABO GROUPING

INTRODUCTION :-

There are four basic blood groups i.e. A, B, AB & O, depending upon the presence of antigens on red cells and reciprocal presence or absence of antibodies in the serum.

SLIDE METHOD

Slide grouping should be done only in emergencies. This is not a very sensitive method for detecting weak antigens &low titer antibodies.

ALL SLIDE TESTS MUST BE CONFIRMED BY TUBE TECHNIQUE.

MATERIALS & METHODS FOR SLIDE GROUPING

Glass Slide/Tile

Glass Marking Pencil/Permanent marker pen

Reagent antisera (anti-A, anti-B, anti-AB, anti-A1 lectin)

Reagent Red Cells (Pooled A, Pooled B, Pooled O cells)

Test samples of Donors/Patients (red cells 30-40% suspension & serum)

Pasteur Pipette

Applicator sticks

METHOD (Preliminary Cell or Forward Grouping)

1. Label the slide/tile for identification
2. Add one drop of 30-40% test red cells suspension to one drop of test serum i.e. anti A, anti B, anti AB.
3. Mix the cells and reagent antisera with clean applicator stick.
4. Gently rotate the slide with your hands to observe for the reaction.
5. Record the results within two minutes.

METHOD (Preliminary Serum or Reverse Grouping)

1. Label the slides for identification
2. Add one drop 30-40% suspension of pooled A cells, B cells, O cells and auto control cells to two drops of serum to be tested (refer preparation of pooled cells).
3. Mix the cells & serum with clean applicator stick.
4. Record the results within two minutes.

INTERPRETATION

The agglutination can be recorded as: -

1) ++++Complete agglutination of all cells.
2) +++Majority of cells agglutinate but few cells are free also.
3) ++Many fairly large clumps and many free cells seen.
4) +Fine granular appearance is seen visually and definite small clumps are seen in low power field only.
5) (-) No agglutination.

PREPARATION OF POOLED A,B, & O CELLS FOR SERUM GROUPING

1. Label test tubes as 'A' cells, 'B' cells & 'O' cells
2. Select 2-3 blood bags of known 'A' group, 'B' group & 'O' group.
3. Break away one segment from the tag of each bag.
4. Add 3-4 drops of red cells from each tag into the group specific labeled tubes.
5. Wash all the cells with normal saline five times using at least 10 ml of saline for each wash.
6. Remove the saline carefully. Remove the supernatant saline of last wash carefully.
7. Re-suspend the cell button with 5-7 ml of normal saline.
8. Store these in the refrigerator for use in serum grouping.
9. Prepare a 5-10% cell suspension with normal saline before use in serum grouping.

TUBE METHOD FOR ABO GROUPNIG

The tube technique has the advantages as it allows for long incubation without any drying. The tubes can be centrifuged to enhance antigen antibody reaction. The tube testing can be done either by:

- Immediate Spin Technique / Sedimentation Technique.

IMMEDIATE SPIN TECHNIQUE / SEDIMENTATION TECHNIQUE

This is good for ABO grouping than slide technique.

MATERIALS

75 x 10 mm tubes or 75 x 12 mm tubes.

Reagent test serum (anti A, anti B, anti AB)

Test samples (3-4% red cells suspension of Donor/Patient & serum of Donor/ Patient).

3-4% Pooled cell suspension of group A, group B and group O cells.

METHOD (Cell or Forward Grouping)

1. Set up three rows of clean test tubes & label them.
2. Add 2 drops of anti-sera i.e. anti A, anti B, anti AB in pre-labeled tubes.
3. Add one drop of 3-4% cell suspension in each tube.
4. Centrifuge for 15-20seconds after 5 minutes (immediate spin technique) /leave for half an hour (sedimentation technique).
5. Look for haemolysis or agglutination against well-lighted background.
6. Record the results as ++++ or +++ or ++, etc. (see interpretation).

SERUM GROUPING OR REVERSE TYPING

In this use a similar tube technique to test donors/patients serum with 3-4% pooled cell suspension of group A cells, B cells and O cells.

METHOD (Serum or Reverse Grouping)

1. Set three rows of clean test tubes and label them.
2. Add one drop of 3-4% pooled cells i.e. A cells, B cells and O cells in pre-labeled tubes.
3. Add two drops of test serum in each tube.
4. Mix the contents of each tube gently. Centrifuge for 15-20 sec. after 5 minutes or leave for 1/2 hour at room temperature.

5. Look for agglutination
6. Record the results as discussed under interpretation.

NOTE:

- All the blood-grouping reports are to be entered in the appropriate registers.
- The results of cell & serum grouping should tally. Any discrepancy must be solved before interpreting the true group of an individual. (No over writing - should be made in register). In case of a discrepancy the previous report should be cut meticulously and signed and the entry correction countersigned by the Sr. Technician on duty / doctor.

PRECAUTIONS TO BE TAKEN FOR BLOOD GROUPING OF NEWBORN INFANT

1. Reaction with anti sera may be weak & should be checked carefully because of weak expression to antigens on red cells.
2. Serum grouping is not recommended till 4 months, as the corresponding ABO antibodies are usually absent in newborn.

Rh GROUPING

Introduction:

Routine Rh grouping of Red Cells involves testing for D antigens in patients and D and Du antigens in donors. It is important to test for D-antigen on red cells using anti - D from two sources i.e., IgM - anti D and (IgM + IgG blend) or polyclonal anti -D.

Material for Rh Grouping :

1. Anti -D (IgM) - (Monoclonal)
2. Anti -D (IgM+IgG) Blend
3. Test red cells
4. Test tubes
5. Test tube racks

Method for Rh Grouping

1. Add one drop of anti - D into prelabeled test tubes.
2. Add to one drop of 3-5 % of red cell suspension.
3. Mix the contents & leave for 15-30 minutes at room temperature.
4. Look for agglutination & record the results.
5. All Rh negative results should be checked under microscope.

PRECAUTIONS

1. Ratio of antisera & cell suspension should be proper.
2. Glassware should be clean.
3. Sample should not be heamolysed.
4. Incubation time should be proper.
5. All negative results must be checked under microscope.

COMPATIBILITY TESTING

INTRODUCTION:

The term compatibility testing or pre-transfusion testing, refers to set of procedures required before blood is issued as being compatible. The purpose of pre-transfusion testing is to select blood and it's components that will have:

- Acceptable survival when transfused.
- Cause no destruction of recipient's red cells.

COMPATIBILITY TESTING PROCEDURE INVOLVES

- Proper identification of recipient (patient) i.e. blood sample and request form.
- Checking the patient's previous records.
- ABO & Rh groupings of recipient.
- Screening for irregular antibodies with identification (if possible).
- Selection of ABO & Rh compatible donor blood free blood transmissible diseases & irregular antibodies.

- Cross matching.
- Proper labeling of donor blood before use.

IDENTIFICATION OF RECIPIENT (PATIENT) BLOOD SAMPLE

The sample of blood should be collected after proper identification of recipient by the patient's physician (Doctor in-charge of the patient) in a clean dry screw cap test tube/vial, Pre-labeled (undetectable) giving relevant details of patient (recipients) i.e. Name, Age, I.P. No., Ward/Bed & Date and signature of the person who has drawn the sample.

REQUEST FORM FOR BLOOD/BLOOD COMPONENTS

All recipient blood samples must be accompanied with request form, which must be complete in all aspects like name, age, sex, ID No., and should match with the details on the sample container. Besides this the request form should contain address, clinical diagnosis, blood group (if known), indication of blood transfusion, No. of units required, date and time when required, etc., duly signed by the attending physician.

CHECKING THE PATIENT'S PREVIOUS RECORD

If the patient has history of transfusion, his/her previous records must be checked (if possible) for: -

- ABO & Rh blood group.
- Presence of unexpected antibodies.
- Any problem in compatibility testing.
- Any transfusion reaction.

ABO & Rh GROUPING

ABO & Rh grouping of patient's samples must be performed by using recommended techniques.

SELECTION OF BLOOD

Blood must be selected to suit the need of each individual patient. Following points to be kept in mind, while selecting blood for transfusion.

1. It is preferable to use ABO group specific blood/component for the recipient.
2. When group specific blood is not available, use alternate ABO compatible blood, only after seeking prior permission in writing from the doctor in charge of the patient.
3. Select the blood of same Rh (D) type as that of patient, particularly in female patients who are of childbearing age.
4. In emergency situation, if Rh (D) negative blood is not available, Rh (D) positive blood can be given in male patients & in female patients after menopause provided no preformed anti-D is demonstrable in their sera. Doctor in charge of the patient should give in writing for use alternative blood.
5. If patient has unexpected antibody, identify the antibody if possible and then select the corresponding antigen negative blood for cross-match.
6. In general oldest units should be used first but there are following exceptions.
   (A) Patients receiving massive blood transfusion (i.e. transfusion of blood equal to or more than patients blood volume within 24 hours) should be given fresher blood available.
   (B) Exchange transfusion in neonates should also be performed by fresh blood <5 days old.
   (C) Patients of thalassemia & sickle cell anaemia should also receive relatively fresh blood.

(D) In Rh hemolytic disease of new born Rh (D) Negative blood of the same ABO group as that of the baby is used if it is same as that of the mother or if it is compatible with mother's blood. Once the baby's ABO group is not compatible with mothers ABO Group, then O Rh (D) negative blood is selected and matched with the mother's serum.

TABLE 1a : CHOICE OF ALTERNATIVE BLOOD

Patient Blood Group	Alternative Blood Group First Choice (Given as Packed Cells)	Second Choice (Given as Packed Cells)
O	None	None
A	O	None
A_2 with anti A_1	O	None
B	O	None
A_1B	A or B	O
A_2B	A or B	O
A_2 with anti A_1	A_2 or B	O

In group AB, patients A group Blood as an alternate source is preferred over B group blood, as anti B in Group A is weaker than anti A in B group. It is advisable not to change form group A to group B blood or vice versa, when more than one unit is given in a continuous transfusion.

The decision to change back to group specific blood, would be based on the presence or absence of anti A/ anti B in subsequent sample of patient.

CROSS-MATCHING

The terms compatibility test and cross-matching are sometimes used interchangeably, however they should be clearly differentiated. A cross-match is only part of compatibility test & its functions are:

- It is the final check of ABO compatibility between the donor and patents.
- It may detect the presence of an antibody in the patient's serum that will react with an antigen on donor red cells, which was not detected in antibody screening because of the absence of corresponding antigens in screening cells.

CROSS-MATCH TECHNIQUES

- Immediate spin technique
- Saline room temperature technique
- Indirect anti-globulin technique

IMMEDIATE SPIN TECHNIQUE/SALINE ROOM TEMPERATURE TECHNIQUE

Immediate spin technique or saline room temperature techniques are enough to rule out any ABO grouping error but are inadequate for detection of clinically significant IgG type of antibodies.

CROSS-MATCHING METHOD

1. Set up a row of two test tubes in test tube rack & label them 1 & 2.
2. Put two drops of patient's serum in test tube no. 1 & 2.
3. Add 1 drop of 2-4% donor red cell suspension in tube no. 1 & 2.

4. Mix the contents of the tubes and incubate tube no. 1 at room temperature for 5-10 minutes (immediate spin method) or for 45-60 minutes for saline room temperature technique.
5. Incubate tube no. 2 at 37ºC for 45 minutes (indirect antiglobulin technique).
6. Centrifuge the tube no. 1 at 1000 rpm for 1 minute (immediate spin technique) while in saline room temperature technique centrifugation is optional.
7. Examine the tube no. 1 for haemolysis or agglutination. If haemolysis or agglutination is present, cross-match is incompatible. If no haemolysis or agglutination is seen, wait till the incubation of tube no. 2 is complete.
8. Examine the tube no. 2 for any haemolysis or agglutination; if negative wash the contents of the tube no. 2 three times with saline and decant the last wash completely.
9. Add 1 drop of anti-human globulin (AHG) reagent and centrifuge at 1000 rpm for 1 minute and look for haemolysis or aggluatination macroscopically & microscopically.
10. Record the results.

NOTE : Run Auto Control i.e., patient's serum & patient's washed red cells (3-4%).

INTERPRETATION :

No haemolysis or agglutination indicates compatible cross-match, while haemolysis or agglutination indicates incompatible cross-match.

LABELING & ISSUE OF BLOOD

Before issuing a unit of blood for any patient for transfusion, it should be properly labeled. The label should have the following information.

- Name of the patient
- Hospital Registration No. (I.D. No.)
- Ward No.
- Bed No.
- ABO & Rh Blood Group

DONOR UNIT NUMBER

- Donor ABO & Rh Blood Group
- Expiry Date
- Date of Cross-match
- Initials of the Technician cross matching the blood.

The satellite blood centre should maintain the record of each unit of blood issued in a proper Register.

- Name of Patients
- Hospital registration No.
- Ward
- Bed
- Blood Group
- Donor unit No. Issued
- Blood group of donor unit / component
- Date & time of issue
- Name & Signature of person who has issued the blood
- Name & signature of person who has collected the blood from the blood bank.

It is advisable to check each & every unit before issue for any change in colour or haemolysis, leaks, etc., & also issue a cross-match report along with the blood unit.

The clinician in charge of the patient should be advised to send the reaction form completely filled, in case of any reaction for evaluation.

INVESTIGATION OF A TRANSFUSION REACTION

In case of a suspected transfusion reaction the following things are to be done :

Things to be done in the ward by the sister immediately.

- Stop the transfusion

- Keep IV line open
- Notify the physician
- Antihistaminics and steroids to be administered
- Keep monitoring the vitals of the patient

The following samples are to be sent to the Blood Bank along with the reaction report:

- EDTA
- Plain Vial
- First Urine sample after the transfusion reaction
- The blood bag along with the transfusion set

Whenever a transfusion reaction occurs, the Doctor Incharge should enter the following records in the patient's file.

- Date & Time of Reaction
- Bag No. / Unit No.
- Patient's ID No.
- Blood group as entered in the file

The following things have to be done in the Blood Bank

- Check all the labels & records for any clerical error & also record the volume of the blood that has been transfused and that remaining in the bag.
- Check the blood group of the patient and the donor (blood group on the bag issued)
- Check the colour of the plasma / serum sample of the patient
- Perform the cross-match again with both the pre & post transfusion sample – ICT (Refer to Coomb's testing)
- Perform DCT (Refer to Coomb's testing)
- The urine should be examined for haemoglobinurea and dismorphic RBCs
- Gram Stain
- Then report the type of transfusion reaction.

COOMB'S TEST

INDIRECT ANTIGLOBULIN / COOMB'S TEST

Principle:- Red cell which is sensitised coated with incomplete antibody and complement binding antibodies in vivo will be agglutinated by the antihuman globulin(AHG) / coomb's reagent.

USED IN

Compatibility testing.

Screening and identification of unexpected antibody in serum.

MATERIAL

Test tube

Test serum

Washed pooled O positive red cell

AHG reagent

Control

Positive: Tested IgG + IgM against sensitised cell

Negative: Bovine Albumin

METHOD

1. Label one test tube for donor sample. Setup a row of 2 test tubes in test tube rack.
2. Put two drops of patient's serum in setup prelabeled test tubes.
3. Add one drop of 2-4% of donor's red cells in each.
4. Incubate for 15 minutes for immediate spin saline technique.
5. Centrifuge at 1000 rpm for 1 minute (spin method). Record the results.
6. Incubate the 2nd tube at 37°C for 45 minutes.
7. Wash the tubes 3 times with saline & decant the last wash carefully.
8. Add one drop of anti human globulin serum (poly specific) & centrifuge at 1000 rpm & record the results.

INTERPRETATION :

Harmolysis or agglutination indicate incompatibility.

Positive: - If agglutination appears after adding AHG in positive control test tube.

Negative: - If there is no agglutination after adding AHG in Negative control test tube.

Valid: - If agglutination occurs in Negative test or control after adding sensitised cell.

Invalid: - If agglutination doesn't occur in Negative test or control after adding sensitised cell.

PRECAUTIONS

Cell and serum ratio should be proper (1:2)

Incubation time (1hr) and temperature (37°C) should be proper.

Decant last washing properly.

DIRECT ANTIGLOBULIN / COOMB'S TEST

Principle :- Red cell which is sensitised coated with incomplete antibody and complement binding antibodies in vivo will be agglutinated by the antihuman globulin(AHG) / coomb's reagent.

USED IN

Diagnosis of Hemolytic disease of newborn (HDN)

Diagnosis of autoimmune hemolytic anaemia AIHA

Investigation of drug induced red cell sensitised

Investigation of hemolytic transfusion reaction.

MATERIAL

Test Tube

Test red cell

AHG reagent

Sensitised red cell (O Pos)

METHOD :

1. Wash test red cells 3 times with saline & final wash properly.
2. Take 2 drops of 3-4% washed test red cell in a clean pre-labeled glass tube.
3. Add 1-2 drops of AHG or coomb's reagent.
4. Mix & centrifuge at 1000 rpm for imitate.
5. Gently shake the tube and read result.
6. If the test result is negative, add 1 drop of control cell.
7. Mix and centrifuge at 1000 rpm for one minute and look for agglutination.

INTERPRETATION : -

The test is called positive if agglutination appears after adding AHG reagent.

The test is called Negative if there is no agglutination after adding AHG reagent.

The test is called valid if agglutination occurs in Negative test after adding sensitised cells.

The test is called invalid if no agglutination occurs in Negative test after adding sensitised cells.

CLINICIAN'S GUIDELINES

INTRODUCTION

The Department of Family Welfare is now initiating the setting up of a Blood Storage Centres at the First Referral Units (FRUs) to make blood readily available, especially at times of emergency. This service would be available to the women during and after childbirth and is expected to bring down Maternal Mortality.

To establish the Blood Storage Centres, it is essential to train the medical officers and technicians working in these FRUs in the various methods of handling blood, including storage, blood grouping, cross-matching, transfusion and adverse reactions. A formal training programme of 3 days duration is envisaged for one medical officer and one laboratory technician from each of the identified FRUs where blood storage centres are to be set up. It is however considered essential, that the medical officers and also the clinicians who handle obstetric emergencies are sensitised on the important issues related to various aspects of transfusion of blood and blood products.

While a Standard Operating Procedure Manual (SOPM) has been prepared for the training of medical officers and technicians, The "Clinicians Guide to Appropriate Use of Blood" has been prepared keeping in mind the needs of the clinicians who will be responsible for prescribing and transfusing blood and blood products. For this purpose, it is suggested that a one day sensitisation workshop may be undertaken in each district for the medical officers/specialists posted at FRUs. The workshop may be held at the medical colleges or in district hospitals where a pathologist/ trained blood bank officer is in position.

OBSTETRIC CONDITION WHERE WHOLE BLOOD IS NEEDED

- Anaemia
- Haemorrhage
  - Antepartum
  - Postpartum

It is estimated that about one third of all maternal deaths are due to haemorrhage, both ante partum and postpartum (SRS-1998). The National Family Health Survey 1998-99 has brought out that almost half of the pregnant women are moderately to severely anaemic. Presence of anaemia in a pregnant woman who develops haemorrhage, increases the chances of her dying, manifold. Timely transfusion of blood is thus an important intervention which can save the lives of many such women, if adequate supply of blood is available at the first referral unit level. If it is used appropriately, many women who would otherwise die, can be saved.

Blood is the main oxygen carrier in the body yet it cannot be used as a tonic. The use of blood should be judicious. The benefits attached to blood transfusion should be weighed against the risks involved with transfusion of blood. Since blood cannot be sterilised, there is possibility of transmitting any agent present in red cells or plasma which has not been detected by routine screening tests for transfusion-transmissible infections, including HIV, Hepatitis B, C, other Hepatitis viruses, Syphilis and Malaria, etc.

Administration of red blood cells

- Check the identity of patient properly before transfusion
- Must be ABO & Rh D compatible with patients
- Alternative blood group can be given at times, if group specific blood is not available

TABLE 1b : CHOICE OF ALTERNATIVE BLOOD

Patient Blood Group	Alternative Blood Group First Choice (Given as Packed Cells)	Second Choice (Given as Packed Cells)
O	None	None
A	O	None
A2 with anti A1	O	None
B	O	None
A_1B	A or B	O
A_2B	A or B	O
A_2 with anti A_1	A_2 or B	O

- Transfuse within 4 hrs.
- Transfuse blood within ½ hr of issue from blood storage centre.
- Complete the transfusion within 4 hrs.
- Blood once issued will not be received back in the storage centre.

RESPONSIBILITIES OF CLINICIAN IN CASE THE PATIENT NEEDS TRANSFUSION

Inform and explain to the patient or relatives about the proposed transfusion of blood/blood products ***(Benefits & Risks)*** and record the same in the patient's file. Ensure proper identity of the patient & correctly complete a blood request form. Collect the blood sample from the right patient in the right sample tube & correctly label the sample tube. Order blood in advance, whenever possible.

Provide the blood storage centre with clean information on:

- The number of units required
- The reason for transfusion
- The urgency of the patient's requirement for the transfusion
- When and where the blood is required.

Ensure the correct storage of blood and blood products in the clinical area before transfusion.

Formally check the identity of the patients, the product and the documentation at the patient's bedside before transfusion.

Correctly record transfusion in the patient's notes:

- Reason for transfusion
- No. of units transfused
- Time of transfusion
- Monitoring of the patient before, during and after transfusion
- Any adverse events.

Collecting Blood/Blood Components prior to Transfusion

A common cause of transfusion reaction is the transfusion of an incorrect unit of blood that was intended for a different patient. This is often due to mistakes while collecting blood from the blood storage centre. It is important to follow these instructions.

1. Ensure proper identification of patient prior to transfusion.
2. Check that the following details on the compatibility label attached to the blood pack, exactly match the details on the patients documentation:
   - Patient's family name and given name
   - Patient's hospital reference number (I.P.NO)
   - Patient's ward, operating room or clinic
   - Patient's ABO and Rh (D) group.

Whole Blood

Should be issued from the blood storage centre in a cold box or insulated carrier (brought from the ward) which will keep the temperature between 2 – 6°C if the ambient (room) temperature is greater than 25°C or there is a possibility that the blood will not be transfused immediately.

Should be stored in the ward refrigerator at 2 – 6°C until required for transfusion.

1. The upper limit of 6°C is essential to minimise the growth of any bacterial contamination in the unit of blood.
2. The lower limit of 2°C is essential to prevent haemolysis, which can cause fatal bleeding problems or renal failure.

Storing blood products prior to transfusion

Once issued by the blood storage centre, the transfusion of whole blood, frozen plasma should be commenced within 30 minutes.

If the transfusion cannot be started within this period, they must be stored in an approved blood refrigerator at a temperature of 2° to 6°C, preferably in the centre shelf.

The temperature inside every refrigerator used for blood storage in wards and operating rooms should be monitored and recorded daily, to ensure that the temperature remains between 2° to 6°C.

If the ward or operating room does not have a refrigerator that is appropriate for storing blood, the blood should not be released from the blood storage centre until immediately before transfusion.

ADMINISTERING BLOOD

Staff involved in the administration of blood / blood components should ensure the FINAL IDENTITY check of the patient, the blood pack, the compatibility label and the documentation**.**

For each unit of blood supplied, the blood storage centre should provide documentation stating:

1. Patient's name on the requisition and that given on the sample
2. Patient's ABO and Rh-D group
3. Unique donation number of the blood pack
4. Blood group of the blood pack
5 Compatibility label

   A compatibility label is attached firmly to each unit of blood, showing the following information. This information should be checked before administering blood.

Blood Pack NO._____

1. Patient's Name :
2. Patient's hospital reference number (I.P.NO)
3. Patient's ward
4. Patient's ABO and Rh (D) group
5. Expiry date of blood
6. Date of compatibility test with the signature of the technician
7. Blood group of blood pack

Checking the blood pack

The blood pack should always be inspected for signs of deterioration on arrival in the ward. However the staff taking the blood from blood storage centre should check for any leakage before signing the issue register.

Discolouration or signs of any leakage may be the only warning that the blood has been contaminated by bacteria and could cause a severe or fatal reaction when transfused.

The final identity check should be undertaken at the patient's bedside immediately before commencing the administration of the blood product. It should be under taken by two persons, at least one of whom should be a registered nurse or doctor.

The Final Patient Identity Check

- Ask the patient to identify himself / herself by family name, given name date of birth and any other appropriate information
- If the patient is unconscious, ask a relative or a member of staff to state the patient's identity. Check the patient's identity and gender.
- Patient's identity wristband or label
- Patient's medical notes
- Check the following details on the compatibility label attached to the blood pack, exactly matching the details on the patient's documentation and identity wristband:
  1. Patient's family name and given name
  2. Patient's hospital reference number
  3. Patient's ward or operating room
  4. Patient's blood group
- Check that there are no discrepancies between the ABO & Rh (D) group on the Blood pack compatibility label
- Check there are no discrepancies between the unique donation number on the Blood pack compatibility label
- Check that the expiry date on the blood pack has not been passed

The final check at the patient's bedside is the last opportunity to detect an identification error and prevent a potentially incompatible transfusion, which may be fatal.

TIME LIMITS FOR INFUSION

	Start Infusion	***Complete Infusion***
Whole blood or red cells	Within 30 minutes of removing pack from refrigerator	Within 4 hrs (or less in high ambient temperatures)

DISPOSABLE EQUIPMENT

For blood administration

Cannulas for infusing blood products

1. Must be sterile and must ***never*** be reused
2. Use flexible plastic cannulas if possible as they are safer and preserve the veins

For Whole blood / Red cells

1. Use a new sterile blood administration set containing an integral 170-200 micron filter
2. Change the set at least 12 hourly during blood component infusion
3. In a very warm climate change the set more frequently and usually after every four units of blood, if given within a 12 hour period.

For Paediatric patients

Use a special paediatric set for paediatric patients.

These allow the blood or other infusion fluid to flow into a graduated container built into the infusion set. This permits the volume given and the rate of infusion to be controlled simply and accurately.

Warming blood

There is no evidence that warming blood is beneficial to the patient when infusion is slow

At infusion rates greater than100 ml/minute, cold blood may be contributing factor in cardiac arrest. However, keeping the patient warm is probably more important than warming the infused blood.

Warmed blood is commonly required in;

Large volume rapid transfusion:

Adults : greater that 50 ml /kg/hour

Children : greater that 15 ml/kg/hour

Exchange transfusion in infants

Patients with clinically significant cold agglutinins

Blood should only be warmed in a blood warmer.

Blood should never be warmed in a bowl /oven as this can result in haemolysis of red cells which can prove fatal.

RECORDING THE TRANSFUSION

Before administering blood products, it is important to write the reason for transfusion in the patient's case-notes. If the patient later has a problem that could be related to the transfusion, the records should show who ordered the blood and why. This information is also important in conducting the audit of transfusion services.

The following information should be recorded in the patient's notes:

- Whether the patient and or relatives have been informed about the proposed transfusion treatment
- The reason for transfusion
- Signature of the prescribing clinician

PRE-TRANSFUSION CHECK ON

1. Patient's identity
2. Blood pack
3. Compatibility label
4. Signature of the person performing the pre-transfusion identity check the transfusion
5. Volume of blood transfused
6. Unique donation number of each unit transfused
7. Blood group of each unit transfused
8. Time at which the transfusion of each unit commenced
9. Signature of the person administering the blood
10. Monitoring of the patient before, during and after the transfusion.

TRANSFUSION REACTIONS, if any

Severe reaction mostly occurs within the first 15 minutes of the start of transfusion. So all patients should be monitored carefully during this period. This should be followed for every subsequent unit of blood to be transfused.

Things to be done in the ward by the medical officer in case of a reaction

In case of a suspected transfusion reaction the following things are to be done :

- Stop the transfusion
- Keep IV line open
- Notify the physician
- Antihistaminic and steroids to be administered
- Constant monitoring the vitals of the patient

INVESTIGATION OF A TRANSFUSION REACTION

The following samples are to be sent to the Blood Storage Centre along with the reaction report:

- EDTA
- Plain Vial
- First Urine sample after the transfusion reaction
- The blood bag along with the transfusion set

Whenever a transfusion reaction occurs, the doctor In charge should enter the following records in the patient's file.

- Date & Time of Reaction
- Bag No. / Unit No.
- Patient's ID No.
- Blood group as entered in the file, patient file and the donor (blood group on the bag issued).
- Check all the labels & records for any clerical error & also record the volume of the blood that has been transfused, and that remaining in the bag.

APPROPRIATE USE OF BLOOD COMPONENTS

Unlike earlier times, whole blood is now considered as raw material rather than transfusion medium. The only one indication for whole blood transfusion is exchange transfusion. The use of whole blood is obsolete and is now completely replaced by various blood components like:

- Packed Red Cell
- Platelet Concentrate
- Fresh Frozen Plasma

PACKED CELLS

Indications

- Severe chronic anaemia to reduce chances of overload
- Hypoplastic anaemia
- Hemolytic anaemia especially in aplastic crisis

Advantages

Less blood group antibodies so "O" Negative blood (group-non- specific) can be given to patients with other groups.

Less Plasma proteins with packed cells so there are minimum anaphylactic reactions.

Storage : 2-6°C

Expiry : 35-42 days depending upon blood collection bag. Day of blood collection is taken as Zero Day.

TRANSFUSION TRIGGER

Transfusion requirement of each patient should be based on clinical status, rather than Hb value on Haematocrit. However, patients with haemoglobin levels less than 7.5 gms/dl (transfusion trigger) undergoing surgery, should be considered for transfusion.

ADMINISTRATION OF PACKED RED CELLS

- Check the identity of patient properly before transfusion.
- Must be ABO & Rh D compatible with patients.

- Alternative blood group can be given at times if group specific blood is not available e.g.
  - ❏ For AB the alternative blood in order of preference should be A, B & O
  - ❏ For A group ———— O group
  - ❏ For B group ———— O group
- No alternative blood for O group
- Transfuse within 4 hrs.
- Transfuse blood within ½ hr of issue from Blood Bank.
- Complete the transfusion within 4 hrs. Blood once issued will not be received back.

Infection risks are same as for whole blood.

PLATELET CONCENTRATE (To be procured from Mother Blood Bank)

Description

Derived from single blood donation

Volume 65 – 80 ml

Should not have any visible RBC contamination red cells (1.2 x 10° red cells)

Storage 5 days at 22°C ±2. Day of collection is taken zero day.

Indication

- Thrombocytopenia of any cause except ITP unless life saving.
- Platelet functional defects of any cause

Dosage

1 unit of platelet concentrate / 10 kg body weight e.g. for 60 kg man 6 units of random donor platelets concentrate.

Administration

1. No special transfusion sets required
2. No cross-matching required, however if contaminated with red cells, cross-match is indicated.
3. Use group specific platelets, however group non-specific platelets can be used if group specific platelets not available.
4. Platelets don't carry Rh antigen however in young ladies of child bearing age, don't give Rh Positive platelets, in case there is any RBC contamination.

Complications :

Allergic & febrile transfusion reaction are not uncommon, especially in patients receiving multiple transfusions.

Infection risks are same as for whole blood.

FRESH FROZEN PLASMA (To be procured from Mother Blood Bank)

Description

- Volume 180 – 220 ml
- Contains stable coagulation factors albumin & immunoglobulin
- Factor VIII (20% of normal)
- Fibrinogen 150-230

Dosage 12-15ml/ kg body wt.

Indications

Replacement of multiple coagulation factor deficiencies e.g.

- Liver disease
- Massive blood loss
- Over dose of anticoagulants e.g. (Warfarin & Dicumerol)
- DIC
- TTP

Storage

Stored at -20°C & below. Before use FFP should be thawed at 37°C & once thawed should be stored at 4 - 6°C & used within 6 – 8 hrs.

Complications

- Allergic & febrile transfusion reaction
- Transmission of infections same as for whole blood

CRYOPRECIPITATE

Description:

Prepared from FFP by thawing it under controlled conditions at 4°C. It contains approximately 80-100 IU of factor VIII & 150-300mg of fibrinogen per pack.

Storage At - 30°C & below for 1 year.

Indications

As an alternative factor VIII concentrate in the treatment of: -

- Vonwilliebrand disease
- Hemophilia A
- Factor XIII deficiency
- Fibrinogen deficiency e.g. DIC

Infection risks are same as for whole blood.

Dosage

Depends upon severity of the factor deficiency normally 4-6 packs to be repeated 12 hourly.

Administration

- To be given immediately within 6 hrs after thawing
- Use standard blood administration set
- No compatibility testing required

CRYO POOR PLASMA

Description:

Plasma which is deficient in factor VIII& fibrinogen but contains all other plasma constituents

Indication

- For volume replacement
- As replacement fluid in exchange transfusion
- As a source of plasma proteins.

Infection risks are same as for whole blood.

FRESH BLOOD

There is no indication of fresh blood today when the blood components are available, as the fresh whole blood is not going to meet the requirements of the patients.

APHAERESIS BLOOD COMPONENTS (To be procured from Mother Blood Bank)

Aphaeresis blood components are gaining importance because they;

1. Provide adequate adult dose from a single donor.
2. Reduce donor exposure to the patient, thus improving blood safety.
3. Reduce bacterial contamination, especially in platelets.
4. Lower chances of refractoriness to blood components.
5. One donor can donate platelets twice a week, provided platelets counts are adequate.

IRRADIATED BLOOD COMPONENTS

Indications

- Severe immuno-suppresed patients to prevent graft versus host disease (GVHD)
- Bone marrow transplant patients
- Peripheral blood progenitor cell transplant patients
- Pre-mature new born
- Patients with hematological malignancies
- Intrauterine transfusion

Before sending the request for irradiated blood components, the consultant in charge of the patient should discuss with the consultant of the transfusion medicine department.

TIME LIMITS FOR INFUSION

Blood Component	***Start Infusion***	***Complete Infusion***
• ***Whole blood or red cells***	Within 30 minutes of removing pack from refrigerator	Within 4 hrs (or less in high) ambient temperatures
• ***Platelet concentrates***	Immediately	Within 20 minutes
• ***Fresh Frozen plasma & Cryoprecipitate***	As soon as possible	Within 20 minutes

DISPOSABLE EQUIPMENT FOR BLOOD ADMINISTRATION

Cannulas for infusing blood products; Must be sterile and must ***never*** be reused.

Use flexible plastic cannulas if possible as they are safer and preserve the veins.

Whole blood, red cells & plasma

Use a new sterile blood administration set containing an integral 170-200 micron filter. Change the set at least 12 hourly during blood component infusion. In a very warm climate change the set more frequently and usually after every four units of blood, if given within a 12 hour period.

BLOOD SUBSTITUTES

There is no substitute as yet developed which has all the properties of blood. However replacement fluids, plasma protein solutions and hemoglobin substitutes are being used in place of blood components in special conditions.

Plasma Protein Solutions (PPS)

Plasma protein solution is prepared from pooled plasma after removal of factor VIII concentrate, fibrinogen and immunoglobulins either by Cohn ethanol extraction method or by chromatographic method.

Preparations

- Albumin 5% contains 50 mg/ml of albumin
- Albumin 20% contains 200 mg/ml of albumin
- Albumin 25% contains 96% albumin and 4% globulin. It contains 250 mg/ml of albumin. It is diluted to 5% solution in electrolyte before infusion. Mostly available in 100ml vial
- Plasma protein fraction (PPF) It is available as 5% solution in electrolyte and contains 83% albumin and 17% alpha and beta globulins

All albumin preparations including PPF are heated to 60°C for 10 hrs to inactivate viruses like HIV.

Shelf life of albumin on the storage temperature

Temperature	***Shelf-Life***
Room temp (20-25°C)	3 years
(2-8°C)	5 years
After opening vial	4 hours

Uses

Albumin is responsible for 80% colloid osmotic pressure.

Indications for 5% albumin and PPF

- Hypoproteinemia following burns and extensive surgery. Albumin is administered to maintain the albumin level of 5.2 g/dl.
- Replacement fluid in therapeutic plasma exchange.
- Haemorrhagic shock
- For priming the pump in cardio-pulmonary by-pass.

Indications for 25% albumin

- Severe Hypoproteinemia in acute nephritic syndrome & acute liver disease

  Dosage : Adults 100-400 ml daily

  : Children 1.5-6 ml/kg body weight in 24 hrs
- Hyperbilirubinemia in newborn: 5-10 ml of salt poor albumin is given along with blood for exchange transfusion. It binds to excessive bilirubin and reduce incidence of kernicterus.
- Toxemia of pregnancy: 50 ml of salt poor albumin given daily.

Contraindications

- Hypoproteinemia in malnutrition.
- Chronic nephritic syndrome.
- Cirrhosis.

Infection risk

No risk of transmission of viral infections if correctly manufactured

Administration

No compatibility testing required.

No filter required.

Adverse Effects

- Urticaria and Anaphylactic reaction.
- Circulatory overload.
- Febrile reaction.
- Hypotension due to vasoactive substances from plasma.

PLASMA SUBSTITUTES

Those designed to provide colloid osmotic pressure or expand volume i.e. crystalloid and colloid.

Those able to transport oxygen i.e. perflouro - compounds and encapsulated hemoglobin.

Colloid Solutions (Table 2.)

1. Dextrans: They are mixtures of polysaccharide molecules of different molecular weights i.e. Dextran 40 and Dextran 70.
2. Hydroxyethyl starch 450.
3. Gelatin.

TABLE 2 : COLLOID SOLUTIONS

Genetic Name	*Contents*	*Intravascular Half Life*
Dextran 40	10% polysaccharide (MW 40,000) with normal saline	4-6 hrs
Dextran 60-70	6-7% polysaccharide (MW 70,000) with normal saline	6-8 hrs
Hydroxyethyl starch	6% solution in 0.9% saline (MW 45000)	24 hrs
Gelatin (haemacel)	3.5% gelatin polypeptide (MW 35,000) with Ringer's solution	3-5 hrs

DEXTRAN 60 & DEXTRAN 70

Indication

- Replacement of blood volume.
- Prophylaxis of postoperative venous thrombosis.

Dosage

Dextran 60 should not exceed 50 ml/kg body weight in 24 hours.

Dextran 70 should not exceed 25 ml/kg body weight in 24 hours.

Side Effects

- Minor allergic reactions.
- Transient increase in bleeding time may occur.
- Hypersensitivity reaction may occur, rarely, severe anaphylactic reactions. Can be prevented with injection of 20 ml of Dextran 1 immediately before infusion, where available.

HYDROXYETHYL STARCH (HETASTARCH OR HES)

Indications

- Replacement of blood volume.
- HES is used as an additive to increase granulocyte yields in leucopheresis by cell separator.

Dosage

Should not exceed 20 ml/kg body weight in 24 hours.

Side Effects

- Minor allergic reactions due to histamine release.
- Transient increase in bleeding time may occur.
- Hypersensitivity reaction may occur, rarely, severe anaphylactic reactions.
- Serum amylase level may rise (not significant).
- HES is retained in cells of reticuloendothelial system.

GELATINS

Succinyl gelatin and partially degraded gelatin have molecular weight of 35,000. They are available as 3.5-4.0% solutions in 500 ml bottles ***(haemacel).***

Indications

Replacement of blood volume.

Dosage

The dose is 500-1000 ml. No known dose limits.

Side Effects

- Minor allergic reactions due to histamine release.
- Show no interference with hemostasis in volumes up to 1000-1500 ml in 24 hours.
- Acute circulatory overload.

FACTOR VIII CONCENTRATE

Partially purified Factor VIII is prepared from large pools of donor plasma Factor VIII ranges from 0.5-20 iu/mg of protein.

The products are heated &/or chemically treated to reduce the risk of transmission.

Vials of freeze-dried protein labeled with content, usually about 250 iu of Factor VIII.

Indications

- Treatment of Haemophilia A.
- Treatment of von Willebrand's disease. Preparation containing von Willebrand's factor are used.

Dosage

Depending on the severity of the disease.

Factor VIII dose (iu)= body weight (kg) x [desired increase in factor level (as % of normal)] x 0.5 iu/kg.

Storage

2-6°C up to the stated date of expiry.

FACTOR IX CONCENTRATE

Different preparations available

- Factor II, IX and X.
- Factor IX only.
- Some preparations also contain factor VII.

Available as freeze-dried protein labeled with 350-600 iu of Factor IX.

Indications

- Treatment of Hemophilia B.
- Immediate correction of prolonged prothrombin time.

Dosage

Depending on the severity of the disease.

Factor IX dose (iu)= estimated plasma volume(ml) x 1.0 iu/ml

$$X \left[\frac{\text{target factor IX} - \text{starting factor IX (in \% or normal)}}{100\%}\right] \times 2$$

IMMUNOGLOBULIN

Concentrated solutions of IgG antibody component of plasma.

Standard or normal immunoglobulins: Prepared from large pools of donations and contains antibodies against infectious agents to which donor population has been exposed.

Indications

Hyperimmune or specific immunoglobulins from patients with high levels of specific antibodies to infectious agents

Prevention of specific infections.

RECOMBINANT HUMAN ERYTHROPOIETIN

EPO is a glycoprotein (hormone) produced by the kidney.

Indications

- Anaemia of chronic disorders.
- Anaemia of chronic renal failure.
- Anaemia secondary to zidovidine therapy in HIV patients.
- To facilitate autologous blood collection within predeposit programme.

Dosage

50-100 IU/kg bodyweight three times a week either intravenously or subcutaneously.

Contraindications

Uncontrolled hypertension

RED CELL SUBSTITUTES

Red cell substitutes having oxygen carrying capacity have been developed but their clinical applications are limited.

- Unmodified and modified haemoglobin solutions.
- Perfluorochemical compounds.

UNMODIFIED AND MODIFIED HAEMOGLOBIN SOLUTIONS

- Stroma free haemoglobin and cross-linked.
- Microencapsulated haemoglobin.

Stroma free haemoglobin and cross linked

Stroma free haemoglobin is prepared from outdated red blood cells. Hb exists as a tetramer of two alpha and two beta red blood cells. But in solutions it tends to dissociate into dimmers and then monomers.

Microencapsulated Haemoglobin

Stroma free Hb can be encapsulated in artificial membrane made of phospholipids.

Perflourocarbons

PFCs or perflourocarbons are large organic compounds in which all hydrogen atoms have been replaced by fluorine atoms.

compounds in which all hydrogen atoms have been replaced by fluorine atoms.

- They are chemically inert.
- Resistant to thermal and radiation damage.
- Can be solid, liquid and gases.
- High solubility of gases is a major reason for their current biological use.
- For use as blood substitute preparation, PFCs that are liquid are preferred.
- PFC solution can dissolve 40% to 70% oxygen per unit volume, almost three times the oxygen carrying capacity of blood.
- They do not carry carbon monoxide and can be given to patients of CO poisoning till abnormal red cells are replaced.
- Another potential use related to PFCs small size, which enables the suspension to penetrate occluded vessels in situations such as cerebral ischemia or myocardial infarction.

Disadvantages

- PFCs do not preferentially extract oxygen from air as haemoglobin does, so oxygen level in a perflourocarbon solution equilibrates with oxygen level in the atmosphere. Thus concurrent administration of 60-100% oxygen is a must with PFC administration.
- They are instable in emulsified state and hence need to be frozen.
- Its third and serious disadvantage is that it is retained in the liver and spleen.

Maternal Health Division
Ministry of Health & Family Welfare
(Department of Family Welfare)
Government of India
Nirman Bhavan, New Delhi - 110 011