

Augmentation of Blood Transfusion Services through Blood Component Therapy

Susan Cherian

Medical Division

Susan Cherian is th recipient of the DAE Scientific and Technical Excellence Award for the year 2014

Blood transfusion services are a vital part of modern health care system without which efficient medical care is impossible. BARC Hospital Blood bank had obtained license to prepare and store Whole Human blood IP in 1996. However to keep abreast with advances in transfusion medicine, component therapy was needed. This year BARC Hospital Blood bank obtained the license, to prepare and store all Blood Components namely: i) Concentrated Human Red blood Corpuscles IP ii) Fresh Frozen Plasma B.P iii) Platelet Concentrate IP iv) Cryoprecipitated Antihemophilic Factor IP. v) Cryo poor plasma (Factor deficient plasma) USP and vi) Single donor plasma USP. Presently all these components are prepared, stored and issued to patients as per the clinical requirement.

Humankind probably always has been interested in the blood because it is likely that even primitive peoples realized that loss of blood, if sufficiently great, was associated with death. The first transfusion of blood in humans occurred in 1667. Progress was slow thereafter because of the complexities of transfusion. The understanding of genetic differences and blood group between individuals, pioneered by Landsteiner in 1901 and technical progress shortly after World War I, permitted the rapid expansion of blood banking. This resulted in the use of blood transfusion as a therapeutic modality for maintenance of blood volume. The development of anticoagulants, blood preservatives, and sterile techniques allowed the collection and preservation of donor blood

for later use. More recently, component therapy has broadened the application of transfusion therapy from blood volume support to the specific replacement of most blood cells and many plasma proteins. This article outlines the rationale, requirements and procedures for blood component facility.

Rationale for Blood Component Therapy

Blood is a complex mixture of plasma (the liquid Component) in which red blood cells, white blood cells and platelets are suspended. Plasma consists mostly of water that contains dissolved salts (electrolytes), numerous metabolic substances and proteins. Proteins include albumin, immunoglobulins and clotting factors. Each of these components of blood has a specific function; also various diseases cause deficiency of different components.

A blood donor donates the product known as whole blood, from which components are prepared. The rationale to separate various components from whole blood is for the following reasons:

1. Separation of blood into components allows optimal survival of each constituents. For example after 24 hours storage of whole blood at 2-6°C, it has few viable platelets and levels of labile Factors V and VIII decrease, while after separation platelets can be stored for 5 days at 22°C and Factors V and VIII can be stored at FFP for 1 year at 30°C or below.

2. Component preparation allows transfusing only specific blood component that the patient requires. For example a patient suffering from complications of Dengue Hemorrhagic fever requires only platelet transfusion.
3. Transfusion of only the specific constituent of the blood needed avoids the use of unnecessary component, which could be contraindicated in a patient. For example, because of the risk of hypervolemia, an elderly anemic patient in congestive heart failure may not easily tolerate the transfusion of two units of whole blood, while the same patient can be transfused two units of red blood cells easily.
4. By using blood components, several patients can be treated with the blood from the donor, giving optimal use of every unit of donated blood.
5. Use of blood components, supplements blood supply – adds to blood inventory.

Statutory requirements of Blood Component Separation Facility

Blood and blood components are biological products and considered as Drugs under Section 2(b) of Drugs and Cosmetic Act. Hence Blood bank compliance with standards prescribed in the Drugs and Cosmetic Act is a mandatory requirement of the Drug Controller General of India (DCG-I) and FDA. All blood bank operations are regulated under this Act and a licence is granted/renewed for operating the blood bank by the State Licensing and Central Licence Approving Authorities after inspection. The requirements include conditions set out in Schedule F, Part XIIB and Part XIIC of the Act. These are requirements of accommodation, personnel, maintenance of premises, equipment, supplies/reagents, standard operating procedures (SOPs), Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Quality Control

and traceable documentation of every step. This is to ensure good manufacturing in blood bank in order to protect the health of both blood donors and recipients of blood and its products.

General Principles and steps of Component Preparation

Different blood components have different relative density, sediment rate and size they can be separated when centrifugal force is applied.

In increasing order, the specific gravity of blood components is plasma, platelets, leucocytes (Buffy Coat-BC) and packed red blood cells (PRBCs).

Blood component preparation to separate blood products from one unit whole blood is done by specialized equipment called as refrigerated centrifuge. Preparing only PRBC and fresh frozen plasma (FFP) is by single-step heavy spin centrifugation, however preparing platelet concentrate (PCs), PRBC concentrates and FFP is by two step centrifugation. The two main procedure of preparing PC are either by platelet-rich plasma (PRP) method or BC method.

The Whole blood is collected as 350 ml or 450 ml in double/triple/quadruple or penta bags with anti-coagulant CPDA-1 or additive solution (SAGM). After blood collection components should be separated within 5-8 hours. Component room should be a separate sanitized room. All precautions to avoid red cell contamination have to be taken such as tapping the segment ends, proper balancing of opposite bags, following standard programs and protocols described in the manual of refrigerated centrifuge manufacturer. The programme is run with mainly two spins-heavy (e.g. 5000 G for 10-15 min) and light spin (e.g. 1500 G for 5-7 min). The heavy and light spin configuration varies with manufacturer and model. Here *G* is relative centrifugal force calculated using revolutions per minute and rotor length. Whole blood is centrifuged to

sediment the red blood cells (RBCs). Most of the supernatant “platelet-rich plasma” is pushed off through integrally attached tubing into a sterile satellite bag. The bag containing platelet-rich plasma may be centrifuged at a higher rate to sediment the platelets. All but 40 to 70 ml of plasma is then removed into a third satellite bag. The platelet pellet is resuspended in the residual 40 to 70 ml of plasma, called a platelet concentrate. The plasma is frozen at –30 °C or lower. If it is frozen within 8 hours of collection, it is called fresh frozen plasma (FFP). FFP may be further processed into Cryoprecipitated AntiHemophilic Factor (AHF) (“cryo”) by subsequently thawing the FFP at 1 to 6°C in a refrigerated water bath, removing the supernatant, and refreezing the cold, insoluble cryoprecipitate within 1 hour of preparation. The supernatant from the

cryoprecipitate preparation, depleted in factor VIII and fibrinogen, may be labeled as Cryo poor plasma.

Functional efficiency of each component is dependent on appropriate processing and proper storage hence these are tightly regulated.

Storage of Blood Components Prior to Transfusion

The “Blood Cold Chain “is the system for storage and transportation of Blood and Blood Components so that they are kept at the correct temperature at all times from collection from the donor to administration to the patient. Different components need different storage conditions and temperature requirements for therapeutic efficacy as shown in Table 1.

Table 1: Storage requirements and shelf life of Blood Components

Sr No	Component	Storage Temperature	Shelf Life
1.	Concentrated Human Red blood Corpuscles IP	4 ± 2 ⁰ C	In CPDA-1 for 35 days In SAGM for 42 days
2.	Fresh Frozen Plasma B.P	• 30 ⁰ C	12 months
3.	Platelet Concentrate IP	20-24 ⁰ C with continuous gentle agitation in a Platelet Agitator	5 days
4.	Cryoprecipitated Antihemophilic Factor IP	• 30 ⁰ C	12 months
5.	Cryo poor plasma (Factor deficient plasma) USP	• 30 ⁰ C	12 months
6.	Single donor plasma USP	• 18 ⁰ C	12 months

Issuing Blood and Blood Components

In order to avoid outdating, First in First out (FIFO) policy is implemented in blood bank. The blood components are issued only as per written request for the same in the medical file of the patient by the treating medical officer. The following are checked before issue:

1. Ensure compatibility testing has been carried out.
2. Ensure that the compatible units are tested for Transfusion Transmitted Diseases (TTD) and found suitable for use.
3. Remove the correct unit from the blood bank refrigerator.
4. Keep it in the thermal box for transport.
5. Make entries in the issue register.
6. Instruct the individual to take the unit straight to the Operation theatre/Ward for transfusion.

Summary

Haemovigilance (making blood transfusion a safe practice) is achieved by ensuring quality assurance at every stage, well-trained technical personnel, proper collection and proper storage, use of quality products, properly calibrated equipment, quality reagents and

proper documentation. Safe and effective blood transfusion requires the combined efforts of blood transfusion services and clinicians, to ensure that the right patient receives the right blood component for the right reason. The role of blood donors is equally important as; the first line in defense in providing a safe blood supply and minimizing the risk of transfusion-transmissible infections, is to collect blood from well-selected, repeat voluntary non-remunerated blood donors. All this will help in achieving the goal to judiciously transfuse blood products that are safe, pure, potent and adequate to meet patient's need.

References:

1. Wintrobe MM. Blood, pure and eloquent: a story of discovery, of people and of ideas. New York: McGraw-Hill, 1980
2. Drugs and Cosmetics Act and rules 1940 (along with Amendments), Section XB and XIIB Ministry of Health and Family Welfare Govt. of India.
3. AABB technical Manual, 17th edition (2010), AABB Press USA.
4. Transfusion Medicine – Technical Manual. 2nd ED. New Delhi, India: Directorate General of Health Services (DGHS), Ministry of Health and Family Welfare, Government of India; 2003.



Centrifugation of whole blood in refrigerated centrifuge.



Separation of packed red cells and plasma in the laminar flow.



Separation of platelets from the plasma in the laminar flow.



Blood component storage room with Platelet agitator and deep freezers (-40&-80 degree Celsius).



Issue of the Concentrated Human Red blood Corpuscles IP.