REMI GROUP

# Blood Bank Chronicles

The Transfusion Medicine Update

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## Index



*'Blood Bags – Life Saving Medical Device'*

## Editorial

### Quality of Blood Bags & its Impact on Components

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Quality management is an integrated system of quality assurance covering all matters which individually or collectively influence the components in order to guarantee their quality. Quality of blood bags used for blood collection and component preparation is an important component in determining the overall quality of the component.

Maintenance of the highest standards of quality during manufacture of blood bags is imperative as blood bags are not mere plastic bags but life saving medical devices. There are stringent licensing requirements and guidelines given by the International organization for standardization (ISO). The ISO guidelines for Blood bags come under- ISO 3826-1:2003 - Specifies requirements, including performance requirements, for plastic collapsible, non-vented, sterile containers complete with collecting tube outlet port(s), integral needle and with optional transfer tube(s), for the collection, storage, processing, transport, separation and administration of blood and blood components. The plastic containers may contain anticoagulant and/or preservative solutions, depending on the application envisaged. It includes double, triple, quadruple or multiple units.

ISO 3826-3:2006 specifies requirements, including performance requirements, for integrated features on plastic, collapsible, non-vented, sterile containers (blood bag systems).`The integrated features refer to leucocyte filter, pre-donation sampling device, top and bottom bag, platelet storage bag and needle stick protection device.

The ISO standards cover all aspects of quality requirements for the plastic blood bag. These include dimensions, design, physical properties, chemical requirements, requirements for plastic material, biological requirements and anticoagulant solutions.

In spite of the various safeguards some defects may creep in during manufacturing. Sometimes these defects are not detected by the manufacturers during routine quality control measures and these defective blood bags are released for use leading to various problems at the user end. Inspecting blood bags prior to use is an important part of quality assurance in blood collection. The complexity of blood bags increases as they are designed for preparation of specialized components such as buffy coat platelets, leucodepleted components increasing the scope for error. The defects in blood bags may be classified as critical and non-critical, critical referring to defects which compromise the integrity of the blood bag and may lead to bacterial contamination. These includes

- Contaminated or soiled Blood bag
- Hole in Bag or tube
- Joint failure
- Tear in pack

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# Expert Speaks

## Recent Advances in Blood Bag Technology

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### Introduction:

Blood bag is a disposable biomedical device used for collection, manipulation, storage and transportation of human blood and blood components. Blood bags are one of the single most critical consumable items used by any blood transfusion service globally and they have an ardent effect both on the quality as well as the safety of the final product. It generally consists of a single or multiple bags connected with tubings, needle, needle cover, sample pouch, and clamp. The bag is made up of plastic material which is biocompatible with the blood and its components. In the present article, we have reviewed some of the recent advances that have taken place with respect to the design and the material used in blood bag technology.

### Advances in the plastic materials used for blood bag:

The combination of polyvinyl chloride (PVC) copolymer (55%) plasticized with di-2-ethylhexyl phthalate (40% w/w of DEHP) as a material has all the desired properties required in the blood bag, i.e. flexibility, temperature resistance, strength, safety, compatibility, and production feasibility. However DEHP leaches into the blood during storage and has been shown in animal studies to be a toxic compound. Patients requiring large transfusions and multiply transfused adult patients are at risk of high exposure to DEHP and thus to the toxic effects of DEHP. The knowledge on the toxic effects of DEHP has provoked the search for alternatives that would provide the technical characteristics of PVC-DEHP blood bags without the leaching of the plasticizer.(1) Recently, n-butyryl-tri(n-hexyl)-citrate (BTHC) has been developed for use in red cell storage containers and studies have shown that the in-vivo recovery of red cells was comparable to that of DEHP. Another alternative is di-isononyl cyclohexane- 1,2-dicarboxylic acid (DINCH) for red cell storage, and there was no difference with respect to ATP , haemolysis by week 6, provided the units held in DINCH-plasticizer containers were mixed weekly.(2) Tris-octyl tri-mellitate (TOTM)-PVC, polyolefin and di n-decyl phthalate (DnDP) PVC are the material options for the platelet storage. (3)

### Thickness of the container:

The thickness of the material used influences the permeability, flexibility and the tensile strength. The larger surface area and thickness of approximately 0.28 mm allow higher gas permeability and are specifically designed for 7-day platelet storage.

### Blood bag texture:

Hadjesfandiari et al have studied the topography of two different platelet storage bag surfaces, textured (rough) and smooth surfaces. They found that the bacterial adhesion and biofilm formation were significantly higher on the rough surfaces of A15 bags compared to the smooth surfaces. Rough surfaces of platelet bags can contribute to missed detection of bacterial strains and the poor quality of platelets due to the higher bacterial adhesion and biofilm formation. (4)

### Blood Bags and Accessories:

Several technological advances have taken place to ensure the safety of blood components as well as the health care workers. Some of those accessories integrated to the blood bag system are mentioned below:

**a. Modified phlebotomy needles**

- Reduces the tissue damage, offers smooth venipuncture and superior flow. Ensures minimal activation of blood components. The line is also provided with the needle injury protector. (5)
- Lateral striations on needle hub to provide a better grip and control of the needle during collection. One way permanent water tight clamp option avoids the bacterial contamination of the blood. (6)

**b. Pre-attached luer adapter and tube holder**

Helps to collect the sample from the donor

**c. Diversion Blood sampling arm**

Studies have shown that integration of diversion pouch into blood bags to divert the first 30 mL blood during blood collection on top of the current skin disinfection protocol can significantly reduce the risk of bacterial contamination. (7)

**d. Inline filter system**

Blood component preparation with leukocyte reduction is possible with the in-line filter system. Different kinds of blood components such as leukodepletd Red Cell Concentrates (RCC), RCC + plasma, RCC + Platelets preparation is possible with this system.

### Containers compatible with pathogen inactivation system:

Particular plastics can be selected for its permeability to the wavelength of the UV light used to perform the pathogen reduction. In THERAFLEX UV technology, to ensure optimal illumination, the platelets are transferred to a large illumination bag that allows for the homogeneous 'penetration' of thin platelet suspensions under frequent agitation.(8)

### Tracking and Traceability:

Barcoding and handheld scanners are used to capture the data on the blood bag. However, the blood bags equipped with RFID technology could allow for significant improvements in tracking and traceability of the blood bags.

Innovation in the blood bag systems is towards the enhanced safety of blood components, donors, and the healthcare workers. However, it is important to consider the cost-effectiveness analysis of newly added features to the blood bag systems.

*For References : Contact the author on Email Id: shameegirish@gmail.com

# Transfusion Medicine Chronicles

**1950 : Carl Walter and W.P. Murphy Jr. develop the plastic bag for blood collection.**

# Best Practices

## Ensuring Quality of Blood Bags at User End

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Blood bags are life saving medical devices intended to collect a unit of blood from a blood donor. It is essential to ensure that critical supplies like blood bags conform to the quality parameters as this is not only important for the health of the patient to which this blood unit would be transfused, but also equally important in order to safe guard the health of the donor donating blood.

The quality practices for blood bags at the user end must start right from the moment the blood bags consignment is received at the blood bank premise and extends to all the stages of blood collection and blood administration. Blood bags should be evaluated for quality parameters at the time of receiving, during storage at the blood bank, just before blood collection, during usage for blood collection, during component preparation, storage and issue. In addition final feedback from the clinical users about any issues related to blood bags during the process of blood transfusion should also be assessed.

Information on the topic is sparse in literature; however there is a generic protocol for blood bag evaluation detailed by the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee wherein they have described the outline of the assessment plan of evaluation of blood bags, detailing the objective, phases of trial, confidentiality and quality monitoring. [1]

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**1. At receipt stores of the blood bank:** The inspection points worth noting during the goods inward receipt would comprise of

- Check whether the packaged material is as per the supply order in quality and quantity.
- Whether the label on the carton details all important details like manufacturer, type of blood bag, number of packaged blood bags, lot number, date of manufacture and expiry.
- Check of the packaging of cartons of blood bags on receipt for compliance to the packaging guidelines of the ISO.
- Examination and documentation of relevant details like damage to cartons in form of physical damage, soiling or fungal growth and the extent of damage if any.

**2. Prior to usage in blood donation:** The blood collection team record

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Non-critical faults include those that do not compromise the integrity of the blood bag but may cause donor discomfort, cosmetic disfigurement, convey wrong information. These include-

- Label Adhesion problems
- Burred or blunt needle
- Filter failure
- Missing part
- Printing error
- Broken or damaged parts
- Cosmetic fault
- Kinked or bent needle
- Moulding error
- Wrong size

In addition to good quality blood bags, the quality of components is also improved by the use of additive solutions, leucodepletion and by use of buffy coat preparations

Additive Solutions are preservative solution specifically tailored to the needs of RBCs and thereby improve the shelf life of RBCs and removal of excess plasma to allows collection of higher volumes of FFP. Whenever possible blood bags with additive solutions should be used for component preparation. Leucodepletion improves the quality of blood components by reducing the incidence of transfusion reactions, decreasing alloimmunization and making blood CMV safe. In addition leucodepletion has also been shown to improve RBC quality by causing a reduction in hemolysis during storage to the extent of 50%. Another process-Buffy coat preparation of platelets leads to an increase in the yield of platelets and also decreases platelet activation during preparation. These newer advances have added immensely to the quality of blood components.

Newer technologies have lead to improvement in the quality of components, but as the complexity of blood bags is increasing day by day with the increasing number of additional devices such as leucodepletion filters, additive solutions , pre-donation sampling devices, needle protection devices there is a greater scope for errors to occur and defects to creep in. Rigorous monitoring of blood bags, documentation of defects in blood bags and regular feedback to the manufacturers is essential in improving and maintaining the quality of blood bags. Co-operation and interaction with the manufacturers is the need of the hour.

**Future Directions:** There is great interest among researchers to improve the quality of blood components and the fields in which active research is going on are-

- Improved Blood bags with better biocompatibility
- Lyophilization of RBCs, Platelets
- Use of intracellular sugars to stabilize RBCs during freezing and thawing
- Extending period of liquid preservation of RBCs ( Experimental Additive Solutions-EAS-61,EAS-64, EAS-67, EAS-76)
- Extended Storage of Platelets
- Cryopreservation of Platelets

Some of these issues are being discussed in this edition of Blood Chronicles.

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**1958 : Jean Dausset & Rose Payne discovers blood compatibility due to HLA on the blood cell.**

# Cryopreservation of Red cells & Platelets

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## 1. Introduction

Optimal long term storage of cellular blood products with preservation of their biological competency has been a challenge for researchers in the field of transfusion medicine. Cryopreservation offers a potential to store these cells for a longer period at sub-zero temperatures. Other methods of long term bio-preservation besides cryopreservation include **vitrification** (by ultra-fast cooling rates, to avoiding ice formation, with high solute concentration to achieve amorphous glass state); **lyophilization** (a "freeze dried" state to sublimate water and allow stability) and **vacuum drying**. Among these available methods, cryopreservation with controlled rate freezing is still the standard method for freezing human cells for long term storage.

Polge and colleagues reported one of the first practical attempt of cryopreserving a cell (fowl spermatozoa) and a year later Smith published first attempt to cryopreserve RBCs using glycerol as cryoprotective agent (CPA).[1,2] Blood components such as red blood cells (RBCs), platelets, lymphocytes (for donor lymphocyte infusions) and peripheral blood stem cells (PBSC) since then have been successfully cryopreserved in recent time with acceptable results. This review will cover the cellular injury with hypothermic temperatures and fundamentals of cryopreservation along with basic updates of the process of cryopreserving RBCs and Platelets.

## 2. Cellular injury at low temperatures and fundamentals of Cryo-Biology

An attempt to store the human cell for long term is most efficiently achieved by storing it at ultra-low temperatures (as low as -190°C). At low temperatures cell is able to achieve a cessation of most of its cellular metabolism. However, cells undergoes two major damages with decrease of temperature one by the cooling rate of the cell (cold shock) and other by low temperature exposure to the cell per se (chilling injury).

- **Cold Shock:** Hypothermic range induces a state of shock for the cell. Reduction in the surrounding temperature decreases the intracellular metabolic rate and creates a biochemical imbalance. Slow cooling results in cell death from cellular dehydration and rapid cooling results in cell death due to intracellular ice formation.

- **Chilling Injury:** This is induced by the exposure of long period of low temperature to the cell. This causes the lipid membrane to convert to solid-gel phase and result in lateral separation of proteins. This transition changes the function of the cell with changes in the transmembrane ionic homeostatic balance. Subsequently there is increased production of reactive oxygen species further increasing transmembrane damage, inhibiting protein synthesis and release of free fatty acids. All these changes induce cellular stress and may result in death via apoptosis or secondary necrosis.

**Table 1** *Describes the variety of cellular response to hypothermic state. The ability to with stand low temperatures and degree of cessation of metabolic activity varies with different type of cells in human body.*

| - Table 1 - | |
|---|---|
| **Type of Response by a Cell at Low Temperatures** | |
| 1. Disassembly of cell cytoskeleton | 5. Reduction in metabolism |
| 2. Reduced protease activity | 6. Osmotic stress |
| 3. Reduced ATP expenditure | 7. Oxidative stress |
| 4. Attenuation of transcription and translation | 8. Delayed apoptosis |

Low temperatures also convert intracellular & extracellular water into ice. Formation of ice within the cell with reduction of temperature is referred as nucleation. It may be of two types; Heterogeneous (initiated by an array of intracellular hydrophilic site mimicking water molecule) and Homogeneous (merging of random groups of water molecules and spontaneous ice formation). Intracellular ice is formed when the super-cooled cytoplasm reaches its homogeneous nucleation temperature and freezes or when membrane defects allows growing of the ice crystals.

Extracellular ice is formed initially around the cell further concentrating the extracellular solutions and increasing the osmotic pressure resulting in efflux of water from the cell (dehydrating injury). On increasing the concentration of extracellular solute (by adding extracellular cryoprotective agents) there is increased viscosity and lowering the diffusion of water into ice. With increasing the concentration of the solute and decreasing temperature, the solution vitrifies (glass like state) preventing further movement of water and inhibits further ice crystal formation. RBCs can expand to twice of their volume in a ½ isotonic solution before hemolysing[3] but the great osmotic stress leads to membrane injury and rupture. This rupture can be avoided by freezing the cells rapidly so that the water does not have time to enter the cell. Controlled rate freezers (CRF) are recommended for a rapid and uniform rate of temperature reduction. Mechanical deep freezers (-80°C) have also been used at some centres with impressive results.

Cryoprotective Agents (CPA) inhibits and reduces the damage from the ice crystals, as they are able to increase the viscosity around or inside the cells hence reducing further ice formation. CPA also stabilize the lipid membranes as it bonds with the polar heads of the membrane lipids. The effectiveness of CPA depends on cell for which it is applied as the degree of permeability and toxicity of CPA for each cell varies. Cryoprotectants are primarily of two types:

- **Extracellular Cryoprotectants** (Non Permeating; eg. Dextrose, Lactose, Sucrose, Albumin, Hydroxyethyl starch (HES), Polyvinyl

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## Transfusion Medicine Chronicles

**1960 : Alan Solomon & John L. Fahey develop plasmapheresis, for separating plasma and RBC**

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pyrolidone (PVP) & Dextran) are of high molecular weight. They do not penetrate the cell but increase extracellular viscosity thereby reducing cooling velocity[4] and forming a glassy shell around the cell.

and forming a glassy shell around the cell.

- **Intracellular Cryoprotectants** (permeating; eg. Glycerol, DMSO) are of low molecular weight which dilute the total cellular water content, limiting the influx of water hence prevents the rupture of the cell.

CPA also requires a base media to prepare the final suspension. The media is usually isotonic electrolyte solutions (eg. Isolyte or PlasmaLyte). These base media's are devoid of proteins, fats and cholesterol, which is required to reduce the cryo-injury within the cell. In order to prevent these injuries fetal bovine serum was used to supplement the base media but due to the safety issues with the bovine serum, presently human albumin or autologous plasma is preferred.

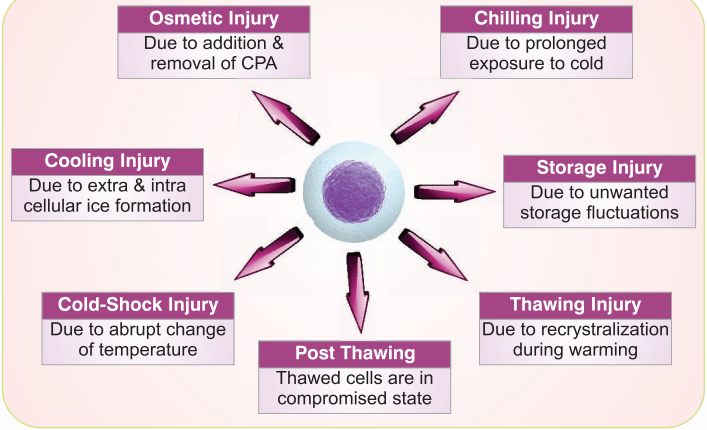
The cell damage by cryopreservation is thus multifactorial involving toxicities of CPAs, cellular injury with hypothermic range of temperatures and formation of ice. **Figure-1** summarizes the mechanism and factors determining the process of cryopreservation and the outcome. Other factors which also influence the final outcome of cryopreservation are type of cell stored, concentration of CPA used and the container used for cryo-storage.

### 3. Red Blood Cell Cryopreservation

The first successful cryopreservation of erythrocytes was reported in 1953.[5] Since that time many protocols and CPA were studied to freeze RBCs, out of all of them Glycerol was most extensively studied CPA[6]. Glycerol is non-toxic intracellular CPA which can achieve high intracellular concentration on administration and also offers a very slow rate of osmosis with RBCs.

Presently there many published protocols for cryopreserving RBCs among them the two most frequently used protocols are 'Low Glycerol' and 'High Glycerol'. The "low" glycerol protocol used a concentration of about 20% with rapid cooling by liquid nitrogen; the "high" glycerol protocol uses a concentration of about 40% with slow cooling in -80°C

**Figure 1 : Mechanism & Factors Determining the Cryopreservation Process**




freezers. The low glycerol frozen RBCs must be maintained in the vapour phase of liquid nitrogen, whereas the high-glycerol frozen RBCs are stable at temperatures below - 65°C. The high cost of maintaining a liquid nitrogen freezer along with the difficulty in transporting the frozen products, both limit the utility of the low-glycerol system. High-glycerol frozen RBCs can be transported on dry ice.

Glycerol is relatively non toxic even if administered IV however RBCs treated with glycerol should have the final concentration reduced to 1-2% otherwise it will result in swelling of the cell and will cause hemolysis on contact with plasma (water will enter the cell more rapidly, than glycerol can exit it)[7]. When the RBCs are thawed, the glycerol must be removed promptly to prevent it from poisoning the red cell metabolism.

Since the initials attempt there have been numerous studies to validate a protocol for freezing red cell. These protocols can be validated with their "therapeutic effectiveness", which account for red cell losses by cryo-injury, by both in vitro and in vivo analysis. Index of therapeutic effectiveness (ITE) is the in-vitro recovery of the cells i.e. the number of cells available for transfusion as a percentage of the number of cells in original unit. This Index emphasizes that post transfusion survival alone hence gives an over optimistic picture of freezing as a means of preservation. Valeri et al showed that survival in vivo after storage of RBCs up to 21 yrs was 80-85% but the ITE was only 70-75%[8].

### Automation in RBCs Cryopreservation

A closed blood processor (Haemonetics ACP 2115, Haemonetics Corp. Braintree MA) for glycerolization and deglycerolization of red cells is also available[9-11]. It contains 0.22 $\mu$m bacteria barrier filter, disposable polycarbonate bowl with an external seal allowing sequential processing of 2 RBC units as well as permitting post thaw extended storage up to 14 days in AS-3 solution. The validation study showed in-vitro recovery of 87 ± 5 % with mean a hemolysis of 0.6 ± 0.2% after 4°C in AS-3 for 15 days.

### Indication and applications of RBC Cryopreservation:

One of the published reports showed transfusion of over 100 units of frozen RBCs, with rare phenotype, stored for over 10 years without any transfusion reactions[12]. Frozen RBCs have now been keenly considered for variety applications. Few of them are:

1. Cryopreserved red cells offers the possibility of long term storage of rare red cell phenotypes (eg. e-, U-, Fy(a-b-) & Bombay phenotypes) for transfusions.

2. Cryopreservation of autologous blood units has also been done but analysis showed that it often remained unused and resulted in wastage. .

3. Cryopreserved RBCs provide a ready source of blood in the battle field as well as in cases of bioterrorism which has the potential to endanger the suitability of the donors at the time of the disaster.

Quality assurance of each unit post cryopreservation is challenging

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**1964 : Judith Pool discovered a method of concentrating clotting factors from FFP for hemophilia patient.**

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though they have been shown to be biochemically similar to liquid stored RBCs. Cryopreservation offers a promising option for RBC storage in some scenarios, but there are financial and logistical issues of controlled rate freezers and equipments for deglyceralization.

### 4. Platelets Cryopreservation

The concept of cryopreservation of platelets first came into existence in 1970s with the US department of Defence showing interest in the idea.

By the mid 70s, Dr Robert Valeri, with the support of the US office of Naval Research began the work on developing protocols for cryopreserving platelets. His original protocol included freezing the platelets using 6% DMSO at -80°C; on thawing DMSO was removed by washing using centrifugation and further re-suspension in plasma13. Centrifugation was one of the major hurdles in adopting it for the battle field therefore a second method was developed where DMSO was removed from the platelets before freezing[14].

Initial applications of cryopreserved platelets were primarily for managing HLA alloimmunized platelet refractory haematology/oncology patients requiring platelets to treat chemotherapy or bone marrow transplant induced thrombocytopenia. Presently frozen platelets are also being studied in patients requiring cardiopulmonary bypass and trauma patients. The US FDA's criteria for accepting any protocol for cryopreserved autologous platelets requires recoveries ≥ 67% of the autologous fresh recoveries and survival ≥58% of fresh survivals[15].

In general cryopreserved platelets show approximately 50% less platelets recoveries (corrective count increment; CCI) than fresh platelets stored at 22°C. The mean loss of platelets during the process of cryofreezing is 28% ± 12%. However the haemostasis has been found to be adequate with minor adverse events (abnormal odours or metallic taste). DMSO used for platelet cryopreservation is safe and well tolerated even in patients who have received multiple transfusions.

In a recent study published in Transfusion[16], nine patients were enrolled in a study to assess the safety and feasibility of using autologous cryopreserved platelets. In this retrospective analysis, a total of 40 autologous platelets units with a median of 32 days (range, 9-994) of cryopreserved storage were thawed at the patient's bedside and transfused. Non-plasma reduced irradiated (50 Gy) apheresis platelets were cryopreserved with a cryprotective freezing medium consisting 10% DMSO, 10 U/mL Heparin and RPMI 1640-wp (without phenol red) with 1 x 1011 platelets in each bag. Freezing was done using controlled rate freezing with storage in liquid nitrogen. The median platelet count increments did not differ at 1 and 24 hours post transfusion. No major bleeding or reaction to DMSO was reported. The study concluded that cryopreserved autologous platelet transfusions are feasible and safe option and there is partial maintenance of platelet function.

Recently interest has been revived in cryopreserving platelets with a view of its application at battle fronts. With the recent protocol by Dr Valeri, two main critical requirements were met for cryopreserved platelets to be used at battle front. One of them was elimination of centrifugation step to remove DMSO and the other was the small volume of each frozen platelet allowing smaller freezer space as both the issues lead to qualitative and quantitative loss of platelets. Irradiation of platelets was done to reduce the chances of administering leukemic stem cells as reported from the TRAP study. The cost and logistics of cryopreseving platelets are high and the cost of arranging one frozen unit can be as high as three times the cost of liquid preservation, hence there is a growing interest in finding more cost effective protocols to cryopreserve these cells.

### Application of Cryopreservation in India and Strategy for application

In India, one of the initial projects of cryopreservation of RBCs was headed by Dr Nanu[17], which reported improvement in utilization of RBCs with reduction in wastage as well as supplementation of liquid stock of Rh (D) negative blood with cryopreservation. Another recent study by Dr Sen[11] & Dr Khetrapal, analysed the automated equipment (Haemonetics ACP 2115) for cryopreservation of 100 red cells units. The study showed mean red cell recovery of 86.12% on day 0 & 84% on day 14 post thawing. The residual glycerol, pH, percentage haemolysis and mean supernatant potassium in all the bags were in acceptable limits up to 14 days post thawing.

With growing awareness and educated manpower in the field of transfusion medicine in India, it is just a matter of time that we will be able to develop our own protocols for cellular cryopreservation. We need to work on a protocol which is simpler, less expensive and practical. The support of the Government and Armed Forces can facilitate multi-centric trials to make these protocols viable and readily available for any emergencies, rare phenotype transfusions and research applications.

*For References : Contact the author on Email Id: satyamarora83@gmail.com

## Blood Bank Chronicles Important Links

| Website | Particular |
|---|---|
| http://www.who.int | Blood Bank GMP Guideline |
| http://www.transfusionguidelines.org | UK BT Guidelines |
| https://blood.ca/ | Canadian Blood Services |
| onlinelibrary.wiley.com › Hematology › Blood Transfusion › Vox Sanguinis | Vox Sanguinis - Wiley Online Library |

## Transfusion Medicine Chronicles

**1968 : Rh Immune Globulin, discovered to address the differences between -ve & +ve blood types**

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any fault in the insulated packaging and the individual transparent packaging with special emphasis on the following points

- The integrity and ease of opening the overwrap
- The presence of leakage, seepage, soiling, discolouration of anticoagulant solution, further any particulate matter or jellification observed.
- Whether the label on the blood bag details all important details like manufacturer, type of blood bag, number of packaged blood bags, lot number, date of manufacture and expiry.
- The integrity of label, any peeling or any suspected fungal growth around the glue used to paste the label.
- The conformity of tubing (length and flexibility)
- The conformity of needle capping.

**3. During blood collection:** The phlebotomist must carefully report any noncompliance with special focus on the following points

- Ease of uncapping the needle
- Any blunting of needle or any rusting observed

The perceived ease of phlebotomy puncture by the phlebotomist and the perceived pain reported by the donor.

- Any issues with the blood bag like leakage delayed filling time of any unusual stickiness of the inner layers of blood bags.
- Any issues with the clamp.
- Any issues with the stripping and sealing of the tube segment.

**4. During blood processing:** The medical technologist should bring forth any of his/her observations during component preparation

- Any leakage, spill or tear or problem with the seal between primary and satellite bags.
- Problem encountered during sealing.
- Length, flexibility and readability of tube segment number of tube segment.
- Compatibility with docking device.
- The stability of label with markings and breakage rates following freezing.

**5. User end feedback from the clinical counterparts:** Liaison between the blood bank and clinical blood users in order to obtain factual details on

- The acceptability to end users in terms of ease of puncture of ports to establish the blood transfusion set any leakage from primary bag or ports.
- The stability of label during transfusion
- The faults observed in blood bags have been divided into critical and non-critical in the article entitled "Blood pack fault monitoring from the National Health Services, UK" in detail.[2] They have categorised faults such as contamination or soiling, hole in pack or tube, joint failure and tear in pack as critical faults. Whereas label adhesion problems, broken or damaged parts, burred or blunt needle, cosmetic faults, filter failure, kinked or bent needle, missing part, moulding error, printing error, wrong size as non-critical faults. This can be adapted for usage in blood bank standard operating procedure for training and ensuring compliance from staff members. This will help in generating data on these events, which can be used to take corrective actions and preventive actions which in turn will raise awareness among the blood bank staff and facilitate steps towards decreasing undesirable events in both recipients of blood and blood donors.

In a published study from the Department of Transfusion Medicine, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India 5 events of blood collection timing more than prescribed 8 minutes were observed, despite a single venipuncture, wherein the root cause analysis pointed out that a kink in inflow tubing at the point of contact with Robert clamp was the cause. Further the authors of the study reported 7 events of non filling of primary blood bag due to sticky inner surface of the blood bag and 4 events of breakage in tubing during stripping over a period of 6 months.[3]

Another unpublished report from PGIMER Chandigarh (By Bajpai M. & Marwaha M.) shows defects found at inspection prior to use. This study was done on 57,827 blood bags from 3 manufacturers. The types of blood bags used were Triple bags, Double bags, Single bags and Quadruple bags (SAGM). The results are tabulated below:

**Table 1: Defects in Blood Bags inspected prior to use**

| Defects / Firm | A | | B | | C | | Total |
|---|---|---|---|---|---|---|---|
| Type of blood bags | S-350 | SAGM | T-450 | D-450 | S-350 | D-350 | S-350 |
| No. of bags | 14095 | 1961 | 25089 | 16155 | 300 | 227 | 57827 |
| CPDA1 leakage | 2 | 0 | 33 | 26 | 1 | 0 | 62 (46.6%) |
| Needle bent/broken | 7 | 0 | 16 | 10 | 2 | 0 | 35 (26.3%) |
| Leakage of CPDA1 from primary to satellite bag | 0 | 0 | 22 | 0 | 0 | 0 | 22 (16.5%) |
| Discoloration of anticoagulant preservative solution | 0 | 1 | 2 | 3 | 0 | 0 | 6(4.5%) |
| Discoloration of label | 0 | 0 | 0 | 0 | 0 | 6 | 6 (4.5%)) |
| Short tubing (needle to b.bag) | 0 | 0 | 0 | 0 | 1 | 0 | 1(0.75%) |
| Wrong label | 0 | 0 | 1 | 0 | 0 | 0 | 1 (0.75%) |
| **Total** | 9 (6.7%) | 1 (0.85%) | 74 (55.6% | 39 (29.3%) | 4 (3%) | 6 (4.5%) | 133 |

Aside from the above mentioned points it would be pertinent to have a bacterial and fungal culture report prior to the implementation of a new lot, batch, even though the certification to this effect is provided by the manufacturer and is primarily a liability of the manufacturer. Similarly the chemical composition analysis report and endotoxin assay are must for record purposes.

*For References : Contact the author on Email Id: suchet.sachdev@gmail.com

**1969 : Scott Murphy and Frank Gardner develop a method for storing platelets at room temperature.**

# Facts Compendium

## Transfusion Ten Commandments

1. Transfusion should only be used when the benefits outweigh the risks and there are no appropriate alternatives.

2. Results of laboratory tests are not the sole deciding factor for transfusion.

3. Transfusion decisions should be based on clinical assessment underpinned by evidence-based clinical guidelines.

4. Not all anaemic patients need transfusion (there is no universal 'transfusion trigger').

5. Discuss the risks, benefits and alternatives to transfusion with the patient and gain their consent.

6. The reason for transfusion should be documented in the patient's clinical record.

7. Timely provision of blood component support in major haemorrhage can improve outcome – good communication and team work are essential.

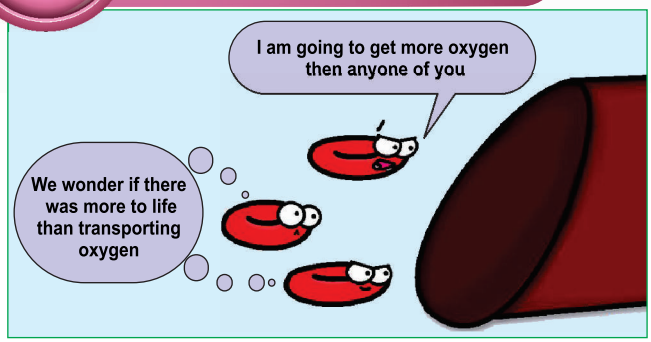
8. Failure to check patient identity can be fatal. Patients must wear an ID band (or equivalent) with name, date of birth and unique ID number. Confirm identity at every stage of the transfusion process. Patient identifiers on the ID band and blood pack must be identical. Any discrepancy, DO NOT TRANSFUSE.

9. The patient must be monitored during the transfusion.

10. Education and training underpin safe transfusion practice.

***Reference :*** *http://www.transfusionguidelines.org/transfusion-handbook/1-transfusion-ten-commandments*

# Humor




# Quiz

**Q. Select the standard method for long term storage of blood cells?**

*a) Vitrification* *b) Lyophilization*

*c) Vacuum Drying* *d) Cryopreservation with controlled freezing*

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