

SAFE BLOOD

AND BLOOD

PRODUCTS

Manual on the management, maintenance and use of blood cold chain equipment



World Health Organization
Geneva

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Mrs Beryl Armstrong, South African National Blood Service, Pinetown, South Africa
Dr Neelam Dhingra, World Health Organization Headquarters, Geneva, Switzerland
Dr Jean Emmanuel, National Blood Transfusion Service, Malawi
Ms Jan Fordham, World Health Organization Headquarters, Geneva, Switzerland

Reviewers included:

Dr Noryati Abu Amin, World Health Organization Headquarters, Geneva, Switzerland
Dr Rama Bhasin, All India Institute of Medical Sciences, New Delhi, India
Professor Kamel Boukef, National Blood Transfusion Centre, Tunis, Tunisia
Dr Jose Cruz, World Health Organization Regional Office for the Americas/Pan American Health Organization, Washington, D.C., United States of America
Dr Graham Harrison, World Health Organization Regional Office for the Western Pacific, Manila, Philippines
Mrs Shân Lloyd, World Health Organization Headquarters, Geneva, Switzerland
Dr Nishi Madan, University College of Medical Sciences, New Delhi, India
Dr Ana del Pozo, Argentine Association of Hemotherapy and Immunohematology, Buenos Aires, Argentina

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Preface

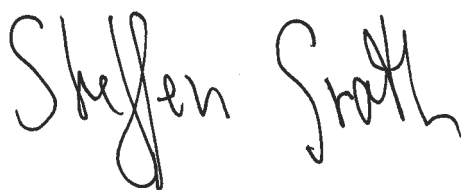
The critical contribution that effective management and use of medical equipment brings to health service delivery is only recently gaining recognition. Managing medical equipment has often been misunderstood as the mere procurement of accessible products within a given budget. However, this narrow perspective has proven neither effective, nor cost-effective in the running of health services. The World Health Organization (WHO) promotes the adoption in countries of a comprehensive life cycle approach that falls largely into the following stages: (i) planning and decision-making (e.g. policy, needs assessment and budgeting); (ii) acquisition (including selection, procurement and donation guidelines); (iii) installation (inspection, testing, acceptance, inventories and documentation); (iv) monitoring of performance and use, including preventive maintenance, care and repair; and (v) decommissioning.

The first two stages have been covered extensively in the publication *The Blood Cold Chain: Guide to the Selection and Procurement of Equipment and Accessories*.¹ In that Guide, WHO provided blood bank managers, procurement agencies and manufacturers with a description of, and minimum performance specifications for all the essential equipment needed for the efficient storage and transportation of blood and blood components. WHO plans to update this Guide in line with the improved pre-qualification process for immunization cold chain equipment.²

This new, complementary publication concentrates on the later stages of the life span. Detailed explanations, illustrations and standard operating procedures provide hospital administrators, managers, technicians and all users of blood cold chain equipment with information on how to receive, install, operate, maintain and monitor the equipment. Inspired by the WHO distance learning materials on Safe Blood and Blood Products,³ activities and exercises are offered to make the information as relevant as possible for the reader. Blood cold chain managers are also encouraged to adapt the information in this Manual to personalize training materials for their staff. Finally, a set of forms for selected blood cold chain procedures are provided in Sections 5 to 8 which we hope will prove useful.

The development of this publication – and all our materials – is carried out in close partnership with our technical colleagues in countries and with the WHO regional offices. I look forward to receiving any comments you may like to provide on the usefulness of these materials to ad-

dress your needs. This is an important means to evaluate the progress we hope we can make towards our common goals: providing cost-effective solutions to health problems through safe and reliable health technologies.

A handwritten signature in black ink, reading 'Steffen Groth'. The signature is written in a cursive, flowing style.

Dr Steffen Groth

Director

Department of Essential Health Technologies

Useful abbreviations

AC	Alternate current	Hz	hertz (cycles per second)
cc	cubic centimetre	IEC	International Electrotechnical Commission
CIF	Cost of item, insurance and freight to nearest port of destination, excluding customs clearance charges to be borne by buyer	ISO	International Organization for Standardization
CFC	Chlorofluorocarbon, found in some types of refrigerant gases	kg(s)	kilogramme(s)
CR	Corrosion Resistance	kV(A)	kilovolt-ampere
dB(A)	decibels	Kwh	Kilowatt-hours
DC	Direct current	LED	Light-emitting diode
DIN	Deutsche-Industrie-Norm, any of a series of technical standards	l or lts	litre(s)
dxl	diameter by length	m	metre
EHT	WHO Department of Essential Health Technologies	max.	maximum
EN	European Norms	min.	minimum
EXW	Ex Works: factory price; everything else to be paid and organized by the buyer	mm	millimetre
FOB	Free on Board. Cost of item and delivery cost cleared for export to the seller's freight agent. All other expenses are for the buyer	NT	not tested
FOT	Free on Truck	PC	Personal Computer
HCFC	Hydrochlorofluorocarbon	pk	pack
hr(s)	hour(s)	PVC	Polyvinyl chloride plastic
		RH	Relative humidity
		RPM	Revolutions per minute
		SOP	Standard Operating Procedure
		TTM	Time temperature monitor
		v	volt
		VAC	voltage alternating current
		VDC	voltage direct current

Glossary*

“30 minute rule”: A general rule in the blood bank stating that a maximum time of 30 minutes is allowed for a blood component issued from the blood bank to a ward to be returned.

Ambient temperature: atmospheric temperature of the immediate surroundings.

Amplitude of the agitation: The side-to-side movement of the trays in a platelet agitator. The amplitude is expected to be within the range of 3.6 to 4.0 cm.

Available stock: Blood components that have been released from quarantine by the quality officer as they have passed all the essential tests. The components are available for transfusion.

Blood cold chain: The maintained storage and transportation of blood and blood components at the appropriate storage temperature and conditions from the point of collection to the point of use.

Blood: whole blood. In this Manual, the generic term “blood” is used to mean whole blood, red cells, blood components and blood products.

Blood component: A separable part of whole blood obtained using centrifugation, e.g. red cells, platelet concentrates or fresh frozen plasma.

Blood products: Blood components obtained from plasma using pharmaceutical processes. These are generally referred to as plasma derivatives. Examples of blood products are albumin and immunoglobulins.

CFC (Chlorofluorocarbon): Refrigerant gas component that contributes to the depletion of the ozone layer of the atmosphere (see Annex 1).

Crossmatched blood: Donor whole blood or red cell components matched with the blood of the recipient.

Defrost cycle: Occasionally frost or ice builds up in plasma freezer cabinets. This ice should be removed as it results in excessive running of the compressor. Modern freezers have an automatic defrost cycle. The temperature of the cabinet should not rise during the defrost cycle.

De-rating: The altitude and ambient temperature of the environment affects the performance of an electricity generator. The following is the formula used for adjusting the estimated performance rating of the generator accordingly: Reduce estimated performance by 1% of its capacity for

* See also Section 3.1.

every 100 m above sea level and further adjust by 1% for every 5.5 °C above +20 °C. This process is referred to as “de-rating” of the generator and enables the supplier to provide a generator with the correct estimated performance for the locality in which it is to be installed.

Door-opening test: This is used to assess the effect of continual opening of the door of the refrigerator or freezer on the stable running temperature during an evaluation.

Down time: The length of time between breakdown of equipment and its use after repair.

Electrical safety rating: This is used to assess the safety of the equipment according to internationally accepted standards, for example in the prevention of electric shock.

Energy consumption: It is important to know the amount of electrical energy consumed by equipment as this affects its running costs. Unless otherwise stated, this is measured at full load.

Essential tests: Every donation received must pass all the essential tests determined by the transfusion service or blood bank before the component is released for transfusion.

Evaluation: The specific selection process to determine the suitability of a procedure or material (e.g. reagent, blood pack and equipment).

Gasket: Rubber lining between two metal surfaces that provides an air tight seal.

Hermetic seal: The seal on the blood pack. This is only broken when a transfusion set is inserted in the pack.

National Blood Transfusion Service (NBTS): the organization with statutory national responsibility for the provision of blood for transfusion, and liaison with clinical services. The NBTS coordinates all activities concerned with blood donor recruitment and the collection, testing, processing, storage and distribution of blood and blood products, the clinical use of blood and surveillance of adverse transfusion events. The activities are carried out within a network of national/regional/provincial blood centres and hospital blood banks.

National/Regional/Provincial Blood Centre: a centre which carries out donor recruitment, blood collection (whole blood and, in some cases, apheresis), testing for transfusion-transmissible infections and blood groups, processing into blood components, storage, distribution to other blood centres and hospital blood banks within a defined region, and liaison with clinical services. Blood centres usually operate at national and regional/provincial level as part of the National Blood Transfusion Service.

Blood transfusion services: a term that describes a series of independent facilities involved in the provision of blood in countries where there is no coordinated National Blood Transfusion Service.

Hospital Blood Centre: a centre, usually based within a hospital, which combines the functions of a larger blood centre and a hospital blood bank. The hospital blood centre is responsible for the collection of blood (often from family/replacement blood donors), testing for transfusion-transmissible infections and blood group, processing into blood components and storage. It also performs compatibility testing and

issues blood and blood components for clinical use within the hospital or to nearby health facilities. The centre may or may not have a voluntary blood donor programme.

Hospital Blood Bank: a laboratory, or part of a laboratory within a hospital which receives and stores supplies of tested whole blood and blood components from a blood centre. The hospital blood bank performs compatibility testing and issues blood and blood components for clinical use within the hospital.

Blood Donation Centre: a centre with responsibility only for blood collection and associated activities for donor recruitment and recall, assessment of donor suitability and donor care. Following collection, blood units are stored for the shortest possible period of time before transportation to a blood centre for testing and processing.

Processed blood: Blood that has been processed into components. Generally refers to the red cell component. The essential tests may or may not have been done.

Quality assurance: As part of the overall quality management programme, the range of activities and systems that provide confidence within the organization and for the authorities that all quality requirements are met.

Quality control: Also a component of quality management, these are tests put in place to ensure that processes, procedures and products meet the quality requirements.

Quality department: The identified and authorized department within an organization responsible for the overall development, organization and management of quality and quality systems.

Quality officer: An individual who works within the quality department of an organization and who is primarily concerned with the day-to-day operation and maintenance of the quality system.

Quarantine: To place in isolation. For example, unprocessed blood is kept in isolation (not accessible for use) until all essential tests are completed.

Stable running temperature: The stability of the temperature of the equipment within set limits and test conditions.

Standard Operating Procedure (SOP): Written instructions for the performance of a specific procedure.

Stroke: The number of times the tray of the platelet agitator moves from side to side per minute; 65 to 75 strokes per minute is considered adequate.

Tagging units: the matching of blood packs with a detachable card that, when removed, attests that the pack has been tampered with.

Unprocessed (pre-processed) blood: Donated blood that has not been processed into components, i.e., whole blood received from a donor. The essential tests have not yet been carried out.

Validation: Confirmation and provision of objective evidence that the requirements for a specific intended use or application have been fulfilled. That part of a quality assurance system that evaluates in advance the steps involved in operational procedures or product preparation to ensure quality, effectiveness and reliability.

Voltage fluctuation test: To assess the stability of the electronic temperature control devices when exposed to voltage fluctuations.

1

Introduction

1.1 Blood: the raw material

Blood transfusion is an essential therapeutic intervention. We all may need blood in an emergency, and some of us need regular transfusions. The purpose of a transfusion is to provide the blood component(s) that will improve the physiological status of the patient. Various blood components can be harvested from a single donation of whole blood. Most blood banks are able to separate red cells and plasma components. Others are able to prepare components such as platelet concentrates and cryoprecipitate. All these components, prepared by centrifugation, are often referred to as 'wet or labile products'. Other plasma products, generally referred to as plasma derivatives, can be harvested from plasma by a pharmaceutical process called plasma fractionation, which renders their properties stable.

The collection of blood from donors may take place within the blood transfusion centre or hospital blood bank. It is also often collected from donors during mobile blood collection sessions. The blood is then taken to a laboratory for testing and processing into components and for storage and distribution as the need arises.

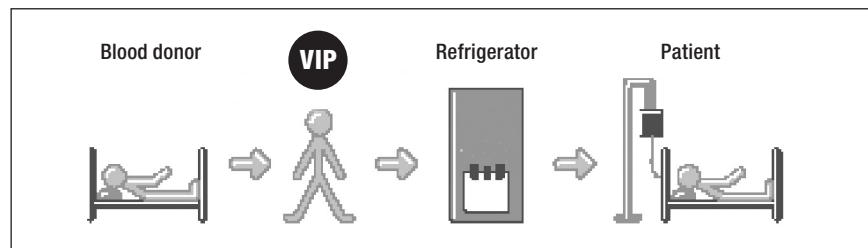
Blood is collected at body temperature, i.e. +37 °C. But in order to maintain its vital properties, it must be cooled to below +10 °C to be transported, and stored at refrigeration temperatures of around +4 °C until use. Hence the term, *blood cold chain*, which begins the moment the blood is collected and continues until it is transfused. If blood is stored or transported outside of these temperatures for long, it loses its ability to transport oxygen or carbon dioxide to and from tissues respectively upon transfusion. Other factors of serious concern are the risk of bacterial contamination if blood is exposed to warm temperatures. Conversely, blood exposed to temperatures below freezing may be damaged, and the transfusion of such blood can be fatal.

1.2 Links in the cold chain

The blood cold chain is a series of interconnected activities involving equipment, personnel and processes that are critical for the safe storage and transportation of blood from collection to transfusion. Like any process, the chain is only as strong as its weakest link, and a failure of a link will result in the collapse of the chain. This has potentially fatal

Figure 1. A simple blood cold chain

The chain may simply consist of one refrigerator and one Very Important Person (VIP) responsible for blood storage.



consequences for the recipient of the blood, and is why each link must be carefully maintained.

Breaks in the cold chain happen for many reasons. Far too often, the equipment does not meet standards of quality and safety, is unsuitable for blood storage – common examples are domestic refrigerators and picnic boxes, both in wide use in developing countries – or is not properly maintained or repaired. Preventive maintenance and rational use prolongs the life of the equipment, significantly decreases safety risks and reduces replacement costs by 50%. Yet many countries still do not have a cost-effective equipment maintenance programme.

The major items of blood cold chain equipment for whole blood are refrigerators and transport boxes. Freezers are also essential for transfusion centres that store plasma. Other vital devices and accessories include standby generators and temperature monitors that can be fitted in refrigerators to warn health personnel as soon as the blood stock approaches unacceptable temperatures.

1.3 Target audience for this Manual

There are many health workers involved in the establishment and maintenance of the blood cold chain, each playing a vital role to protect the safety and efficacy of the blood. They include the managers responsible for procuring the equipment, implementing quality control systems and the training of all staff. They also include the many users of the blood cold chain. Among these are blood collection staff, clerks packing the blood units, drivers transporting the batches, laboratory technical staff assuring quality control of the product, engineers and technicians maintaining the equipment, staff trainers, and hospital clinic staff operating blood warmers and ensuring safe blood transfusion to the patient.

Notwithstanding, this Manual has been especially produced for laboratory technical staff in blood transfusion centres, public health laboratories and hospital blood banks who are responsible for the installation, monitoring and routine maintenance of blood cold chain equipment. It focuses particularly on the training needs of staff in small blood banks where responsibility for the monitoring and maintenance of blood cold chain equipment rests with employees who are unlikely to have been trained in basic refrigeration mechanics. The Manual may also serve colleges that train technical staff who will work in blood banks. The materials can help other personnel, such as managers of blood banks or hospitals who procure blood bank equipment, and can act as a resource to familiarize refrigeration engineers with the special requirements for the blood cold chain in a hospital setting.

1.4 Using the Manual

This Manual describes in detail each process involved in the blood cold chain and the correct management and use of all items of blood cold chain equipment, that will ensure the viability of blood and blood components, and their safety when transfused. It is expected that the information provided will enable the technical staff to:

- Safely handle, transport and store blood.
- Correctly use and care for the equipment and understand its technology.
- Use Standard Operating Procedures (SOPs) to:
 - Install blood cold chain equipment
 - Ensure correct usage of the equipment
 - Train staff
 - Carry out care and preventive maintenance
 - Ensure orderly disposal of discarded equipment.
- Maintain an inventory of all blood cold chain equipment, accessories and spare parts.
- Systematically identify and handle minor technical faults and refer to a service engineer when necessary.

This will ensure the optimal performance of the equipment and the viability of blood components and plasma derivatives.

The reader will benefit from using this Manual in conjunction with the WHO *Blood Cold Chain: Selection and Procurement of Equipment and Accessories*.¹

1.5 Limitations of this Manual

This Manual does not discuss the following specific topics:

- Domestic (kitchen) type refrigerators or freezers. WHO does not encourage the use of this equipment for the storage of blood and blood components because the design of the equipment does not guarantee the safe storage of blood components. As the compressor is not mechanically isolated from the body of the refrigerator, vibration from the compressor adversely affects red blood cells. In addition, there is no internal cooling fan in the cabinet, which means that the uneven temperature distribution may affect the components. More importantly, temperature-monitoring devices such as alarms are not routinely fitted to such equipment.
- Absorption types of cold chain equipment such as Kerosene powered refrigerators or freezers, which are not considered reliable to maintain temperatures for the safe storage of blood components. Only 'compression type' refrigerators and freezers are discussed in this Manual.
- Red cell freezers or rapid plasma freezers (blast freezers) since WHO has not evaluated them for the purposes of the blood cold chain.
- Picnic type transport boxes, as they do not provide adequate insulation during the transportation of blood. WHO recommends the use of blood transport boxes that meet its minimum performance specifications (see Annex 2).

- The use of bottles for the collection and storage of blood. There is little evidence of the use of bottles in countries, since plastic blood bags are readily accessible, affordable and very much safer for the collection, preparation, storage and handling of blood and blood components.
- Other special blood components such as granulocytes. Further information on the storage and handling of such products may be available from the publications listed in the references.
- The management of devices and equipment in ambient temperatures below 0 °C.

2

Storage and transportation of blood and blood components

The purpose of this section is to describe the simple procedures for the safe storage and transportation of blood and blood components that have been collected or prepared in plastic blood collection bags containing anticoagulant/preservative. These procedures should be followed in every blood bank or transfusion service, whatever its size.

LEARNING OBJECTIVES

When you have completed this Section, you should be able to:

- Appreciate the importance of the correct storage of blood.
- Describe the correct temperature ranges for the storage of whole blood, red cells, platelets, fresh frozen plasma and plasma derivatives.
- State the correct procedures for the storage, packing and transportation of blood.
- Review these procedures in your blood bank and take appropriate corrective action required to ensure the safety and efficacy of the blood.

2.1 Safe storage of blood

2.1.1 Whole blood

Whole blood and red cells must always be stored at a temperature between +2 °C and +6 °C.

The main reasons for giving a blood transfusion are to restore or help to maintain the body's oxygen-carrying capacity and the volume of blood circulating around the body. If blood is not stored at between +2 °C and +6 °C, its oxygen-carrying ability is greatly reduced.

The anticoagulant/preservative solution in the blood bag contains nutrients for the blood during storage and stops the blood from clotting. The red cells can only carry and deliver oxygen if they remain viable: that is, if they retain the same properties as they have during their normal circulation in the body.

The most important substances in maintaining the viability of red cells are glucose and adenosine triphosphate (ATP). It is essential to maintain an equilibrium between ATP, 2,3 Diphosphoglycerate (2,3 DPG), glucose



Visual check of a unit of red cell concentrate

and pH. One of the anticoagulant/preservatives most commonly used is citrate phosphate dextrose with adenine (CPDA-1). The dextrose and adenine help the red cells to maintain ATP during storage, and the citrate is the anticoagulant which stops the blood from clotting.

Another important reason for storing blood between +2 °C and +6 °C is to keep the growth of any bacterial contamination in the unit of blood to a minimum. If blood is stored above +6 °C, bacteria that may have inadvertently entered the unit during collection may grow to such an extent that transfusion of the contaminated blood could be fatal.

The lower limit of +2 °C is also very important. This is because red cells are very sensitive to

freezing. If they are allowed to freeze, the red cell membranes rupture and the haemoglobin is released; that is, the cells are haemolysed. The transfusion of haemolysed blood can also be fatal.

The following table summarizes the essential storage conditions for whole blood and packed red cells (red cell concentrates).

Table 1. Storage and transport conditions for whole blood and red cells

Condition	Temperature range	Storage Time
Transport of pre-processed blood	+20 °C to +24 °C	Less than 6 hours
Storage of pre-processed or processed blood	+2 °C to +6 °C	Approx. 35 days
Transport of processed blood	+2 °C to +10 °C	Less than 24 hours

2.1.2 Fresh frozen plasma

Fresh frozen plasma (FFP) is plasma that has been separated from a unit of whole blood within 6 to 8 hours of collection, and has been rapidly frozen and maintained at all times at a temperature of –20 °C or lower. There is no lower temperature limit for the storage of FFP, although the optimal temperature is –30 °C or lower (see Table 2 below).

Plasma contains water, electrolytes, clotting factors and other proteins (mostly albumin), most of which are stable at refrigerator temperature, i.e. +2 °C to +6 °C. Factor V and Factor VIII, however, which are essential in the clotting mechanism, will deteriorate and diminish in quantity if they are not stored at –20 °C or lower and greatly reduce the clotting activity of the plasma. FFP may be given to a patient to restore or help to maintain coagulation factors such as Factor V or Factor VIII.

Plasma should not be used as a volume expander unless crystalloids and colloids are unavailable.

2.1.3 Cryoprecipitate

Cryoprecipitate is the cold insoluble portion of plasma remaining after FFP has been thawed between +1 °C and +6 °C and is useful for correct-

ing certain coagulation defects. It contains approximately 50% of Factor VIII and von Willebrand Factor, 20–40% of fibrinogen and some of the Factor XIII originally present in the fresh plasma.

Plasma is separated from red cells within 6 to 8 hours of collecting blood. The plasma is frozen solid rapidly, certainly within 30 minutes of separation from the cells. The plasma is then thawed slowly at below +4 °C. In order to get the maximum yield of Factor VIII in the cryoprecipitate from a blood unit it is important to adhere strictly to the standard procedures for the collection, storage and processing of the component. The stability on storage is dependent on the storage temperature available. The optimal storage temperature is below –30 °C. Table 2 shows the permitted storage times and temperatures for both FFP and cryoprecipitate.

Table 2. Permitted storage time according to temperature used to store fresh frozen plasma and cryoprecipitate

Product	Storage temperature	Maximum storage time
FFP	–65 °C or below	7 years
FFP or Cryoprecipitate	–40 °C to –64 °C	24 months
FFP or Cryoprecipitate	–30 °C to –39 °C	12 months
FFP or Cryoprecipitate	–25 °C to –29 °C	6 months
FFP or Cryoprecipitate	–20 °C to –24 °C	3 months

2.1.4 Platelet concentrates

Platelet transfusions are used to prevent spontaneous bleeding or to stop bleeding in patients with established thrombocytopenia or platelet dysfunction – e.g. hypoplastic anaemia or bone marrow failure – due to replacement with malignant cells or to the effects of chemotherapy.

Both manual and automated methods can be used in the preparation of platelet concentrates. Lower temperatures adversely affect platelet function and viability. For this reason, whole blood should be kept at between +20 °C and +24 °C until it is processed into platelet concentrates and other blood components.

Platelet agitator with technician inspecting one of the platelet pools



Platelet-rich plasma must be separated from whole blood by centrifugation within 8 hours of phlebotomy. Additional centrifugation and removal of most of the supernatant plasma may then concentrate the platelets.

Platelet concentrates should be stored at a temperature of between +20 °C and +24 °C with continuous agitation. This is essential to prevent platelet aggregation which results in loss of viability. The shelf life and transport conditions differ according to the type of plastic bag used to store the component. Platelet concentrates stored at between +20 °C and +24 °C maintain their function and viability better than refrigerated platelet concentrates. Current plasticizers used in the manufacture of plastic bags

allow for storage of up to five days, because gaseous exchange takes place between the container and the environment and this results in the maintenance of pH in the component, which is critical for platelet storage.

If no platelet agitator or rotator is available, it is not possible to store platelets. Once prepared, they must be transfused immediately unless the blood bank is equipped with:

- an air-conditioned facility with a temperature monitoring system that will maintain an ambient temperature of between +20 °C and +24 °C or
- a platelet incubator that will keep the platelet concentrates at a temperature of between +20 °C and +24 °C.

Since platelet concentrates are stored at room temperature, they pose a greater risk for bacterial proliferation. SOPs on the cleaning of the venepuncture site prior to donation must be strictly followed, and the disinfectant in use must undergo regular quality control checks. Storage conditions and expiry dates should also be strictly adhered to in order to prevent septic shock for the recipient.

After the hermetic seal is broken, platelet concentrates should be transfused as soon as possible, but definitely within a maximum of 4 hours of storage at between +20 °C and +24 °C.

Table 3. Length of time permitted for the storage and transportation of platelet concentrates within the temperature range +20 °C to +24 °C

Process	Maximum Storage Time
Storage	5 days
Transport	24 hours
After issue, before transfusion	30 minutes
Open system and/or pooled	4 hours

ACTIVITY

Find out how platelets are stored in your facility. Is there a platelet agitator?

At what temperature are platelets stored? If they are kept at room temperature, attach a sheet of paper and a thermometer as close to the agitator as possible. Record the temperature at least four times a day, and check whether it is maintained within the acceptable range. Assess whether an air-conditioning unit is needed to maintain the ambient temperature between +20 °C and +24 °C.

2.1.5 Plasma derivatives

Unlike blood components, plasma derivatives such as albumin or immunoglobulin are concentrated, sterile specific proteins, obtained from large pools of donor plasma through a complex pharmaceutical process called plasma fractionation. They are used to treat patients with specific protein deficiencies or requirements for passive immunity.

In some countries, plasma derivatives fall under the responsibility of the pharmacy unit of the Ministry of Health. This unit orders, stores and distributes the products according to need. However, in other countries the

Table 4. Storage of plasma derivatives

Products	Storage	Shelf Life*	Other
Albumin and plasma protein fractions (liquid)	< +25 °C	3 years	Do not freeze
	+2 °C to +8 °C	5 years	
Immune serum (liquid)	+2 °C to +8 °C	3 years	Do not freeze globulin. Use promptly
Freeze Dried Factor VIII	+2 °C to +8 °C	2 years	Do not freeze
	< +25 °C	up to 2 years	Use promptly after reconstitution
Freeze Dried Factor IX	+2 °C to +8 °C	1 year	Do not freeze
	Room temperature	1 month	Use promptly after reconstitution

* The shelf life durations in this Table are indicative. Always follow the expiry date recommended by the manufacturer.

control of plasma derivatives falls under the blood transfusion service. It is, therefore, essential to store all plasma derivatives according to the manufacturer's instructions. Table 4 above gives a general guide for the storage of these products.

2.1.6 Cold chain samples and reagents

The storage and transportation of reagents or blood samples is as critical as that for blood. Manufacturers of laboratory reagents recommend methods for their safe storage and transportation. The recommendations in the package inserts must be followed to avoid deterioration of the reagents and subsequent poor performance in use. Testing of the blood samples should be carried out rapidly after collection. The longer that testing is delayed, the poorer the results. The method of collection, storage and transportation of blood samples will depend on the type of laboratory test to be carried out.

2.2 Packing and transportation of blood and blood components

An efficient system must be in place to ensure that all blood and blood components shipped by or received into a blood bank or blood transfusion service have been maintained within the correct temperature ranges. Red blood cell components must be kept at a temperature of +2 °C to +10 °C during transportation. All components routinely stored at +20 °C to +24 °C should be kept at these temperatures during shipment. All frozen components should be transported in a manner to maintain their frozen state. The transit time for blood and blood components should not normally exceed 24 hours.

2.2.1 Transportation of whole blood from the collection site to the laboratory

Blood and blood components collected at donor sessions should be transported to the blood centre in appropriate conditions of temperature, security and hygiene in accordance with standard operating procedures.

After collection, blood should be cooled to between +2 °C and +10 °C. An exception to this rule is if the blood is to be used for the preparation of platelet concentrates, in which case it should not be cooled to below

PACKING BLOOD COMPONENTS FOR TRANSPORTATION

The following general observations must be kept in mind:

- Label the container THIS WAY UP with an arrow.
- Ice should be placed above the blood because cool air moves downwards. Cubed wet ice may be better than chipped or broken ice for long distance shipments of blood because it melts more slowly. Ice packs can be used at -5°C or below.
- The recommended storage conditions must be maintained when blood is moved from one location to another, including:
 - from a mobile or satellite collection site to the laboratory
 - from the blood bank to a different facility (to a hospital or clinic or another blood bank)
 - from the blood bank to hospital wards or operating rooms

Red cell components: at no point should ice be allowed to come into direct contact with the blood as the red cells nearest to the ice may freeze and haemolyse. Appropriate materials and packing arrangements are therefore necessary. In boxes shipped long distances or at high environmental temperatures, the volume of ice should at least equal that of the blood. In an insulated container, the temperature can be considered to be in the $+2^{\circ}\text{C}$ to $+10^{\circ}\text{C}$ range as long as unmelted ice is still present on arrival at destination.

Plasma: there should be at least as much wet ice in the cold box as there is plasma. It is important to protect the frozen plasma units during transportation. If possible, they should have been placed in cardboard boxes before freezing to protect the bags from developing small cracks. A simple method to determine if plasma units have thawed and refrozen is to place a rubber band around the unit at the time of preparation. Once the unit freezes it leaves an indentation at the sides. If the unit has thawed, or thawed and refrozen, the indentation will not be there.

Platelets: containers for transporting platelets should be equilibrated at a temperature of $+20^{\circ}\text{C}$ to $+24^{\circ}\text{C}$ before use. If outdoor temperatures are extremely high, special chemical, coolant pouches are available that may be shipped with platelets and will maintain temperatures of approximately $+20^{\circ}\text{C}$ to $+24^{\circ}\text{C}$ for up to 12 hours. Also available are containers with a power source that maintains temperatures between $+20^{\circ}\text{C}$ and $+24^{\circ}\text{C}$. Platelets should reach their destination within 24 hours, which is the maximum time allowed without agitation

$+20^{\circ}\text{C}$ or it will lose its viability. Blood packs should be transported from the collection site to the component preparation laboratory as soon as possible, but elapsed time between their collection and centrifugation for component preparation should not exceed 6 hours. Depending on the distance and on the ambient temperature, special gel pouches are now available to keep the blood units intended for the preparation of platelet concentrates at between $+20^{\circ}\text{C}$ and $+24^{\circ}\text{C}$ during transportation. If special gel pouches are not available, the blood packs should be transported as quickly as possible at a temperature of $+2^{\circ}\text{C}$ to $+10^{\circ}\text{C}$, but cannot then be used for the preparation of platelet concentrates.

It is mandatory to record the maximum and minimum temperature achieved since the box was sealed of each batch of blood packs when it arrives in the laboratory from mobile collections. A max/min thermometer should be placed between a sandwich of two packs that have been rubber-banded together during packing of the box at the mobile session. The maximum or minimum temperature readings attained during transportation are noted when the box is opened in the blood bank.

ACTIVITY

Review the procedures in your blood bank for the transportation of whole blood from the collection site back to the processing laboratory and answer the following questions:

- What type of container is used to transport whole blood from the collection site to the processing laboratory?
- At what temperature is whole blood received in the processing laboratory, and how long after collection?
- Is a form kept to record this temperature?
- How long does it take to process the components and store them at the correct temperatures?

Identify any possible problems and propose solutions. Design a form to record temperatures of blood packs arriving in the bank if this is not available.

2.2.2 Transportation of blood components from one blood bank to another

Whole blood and packed red cells

The temperature of whole blood and red cell components must be kept at +2 °C to +10 °C during transport. Specially designed blood transport boxes should be used, wherever possible. If these are not available, sturdy, well-insulated containers may be used only after they have been evaluated and validated to ensure that they can reliably maintain temperatures at +2 °C to +10 °C for the planned journey, using appropriate coolants or ice packs.

The refrigerant recommended for most shipments is wet ice in leak-proof containers, such as plastic bags. Wet ice from commercial ice-making machines is satisfactory. Super-cooled cubed ice, canned ice or dry ice should **not** be used for shipping or storing whole blood or red cells, because they can create very low local temperatures which may cause red cells in their immediate vicinity to freeze and undergo haemolysis. Blood shipped by air may freeze if transported in an unpressurized storage compartment.

Frozen plasma and cryoprecipitate

During transport, frozen components must be maintained at or below the required storage temperature. This can be achieved with a suitable quantity of dry or wet ice in well-insulated containers or standard shipping cartons lined with insulating material such as plastic air bubble packaging or dry packaging fragments.

Platelet concentrates

Every effort must be made to ensure that platelets are maintained at temperatures between +20 °C and +24 °C during shipment. A well-insulated container without added ice is often sufficient.

2.2.3 Issuing blood components to clinical areas

When blood is issued from the blood bank, the time of issue must always be recorded. Blood should be issued in a cold box or insulated carrier which will keep the temperature under +10 °C. To avoid wastage, only one unit of red cells should be removed from the blood bank refrigerator at a time unless the rapid transfusion of large quantities of blood is required. It is also recommended that the blood packs are tagged or sealed into the box. A tag that has to be broken by the ward staff before the blood can be taken from the box for use assists the blood bank in deciding whether blood that has been returned by ward staff can be placed in available stock.

Platelet concentrates should be issued from the blood bank in a carrier that will keep the temperature at between +20 °C and +24 °C. Platelets should be transfused as soon as possible. If unused, they should **never** be placed in a refrigerator, but returned immediately to the blood bank.

FFP and cryoprecipitate are thawed at between +30 °C and +37 °C in the blood bank before issue and transported to the ward at ambient temperature. They must be used immediately and should **never** be refrozen.

The hospital ward refrigerator

The blood bank personnel are responsible for the issue of blood to the respective hospital ward on the understanding that the blood will be transfused within 30 minutes. If the transfusion cannot be commenced within 30 minutes, the blood may be stored in an approved and monitored blood storage refrigerator in the hospital ward until required for transfusion. The refrigerator must maintain a temperature of between +2° C and +6° C and be fitted with an appropriate temperature alarm. In busy facilities such as the operating theatre or the intensive care unit, it is commonplace to have a blood bank refrigerator that stores blood components for immediate use. This may be crossmatched blood or Group O RhD negative blood.

Blood bank staff should have access to the refrigerator for the purposes of monitoring the temperature and retrieving unused blood.

If no approved blood refrigerator is available and the red cells cannot be administered within 30 minutes, the blood should be returned to the hospital transfusion laboratory or blood bank for storage until required.

Ward staff must be trained in the procedures for use of the hospital ward blood refrigerator or freezer. A general notice should state, for example, that the refrigerator should only be used for the storage of blood components, and no other consumables of the ward, even for brief periods, in order to reduce door openings which affect temperature maintenance.

If the alarm on a blood refrigerator is activated, it is the responsibility of the staff in the ward or theatre to notify the hospital transfusion laboratory to allow it to take action to safeguard the contents of the refrigerator. Some hospitals may have an alarm system that automatically notifies the transfusion laboratory.

Returned and reissued blood

If a unit of blood is returned to the blood bank, the following checklist should be used to decide whether it should be put back into stock or discarded.

- Check that the unit has been returned to the blood bank within 30 minutes of issue.
- If the “tagging” system was used, check the seal.
- Verify that the unit has not been opened, by squeezing it gently and looking for blood at the entry port.
- Check the temperature by hand or by folding the unit around a thermometer.
- After mixing the unit gently, keep it in the upright position while it ‘settles out’ in the refrigerator and look for signs of haemolysis or other signs of deterioration in the plasma and red cells.

THE UNIT MUST BE DISCARDED IF:

- it has been out of the refrigerator for longer than 30 minutes, OR
- if the seal is broken, OR
- there is any sign that the pack has been opened, OR
- there is any sign of haemolysis, OR
- if the temperature is over +10 °C.

ACTIVITY

The next time a unit of blood is returned from one of the wards, check the following:

- Was the transport box properly insulated or sealed or should it be replaced by another box?
- Were there enough ice-packs?
- Were the ice packs completely frozen (if not, the freezer may need to be checked).
- Was the temperature of the incoming unit out of range? If so, request authorization to dispose of it and try to determine the causes of the problem.

The decision to discard or to re-use a unit of blood should only be taken after consulting with senior colleagues at your hospital or blood bank.

Summary

- Whole blood and packed red cells must always be stored at +2 °C to +6 °C and transported between +2 °C and +10 °C.
- Blood components and plasma derivatives should never be stored in unmonitored equipment.
- Red cells, platelets or whole blood must never be allowed to freeze.
- The optimal storage temperature for conditions for fresh frozen plasma and cryoprecipitate is –30 °C, and they must always be frozen solid.

They can be stored at lower temperatures, but must never be warmer than -20°C .

- Platelets must be stored at $+20^{\circ}\text{C}$ to $+24^{\circ}\text{C}$ with constant agitation and transported at temperatures within this range.
- During transportation, frozen components must be maintained at a temperature that ensures they will remain frozen.
- It is important to use a temperature monitor during transportation in order to check temperature ranges on receipt of the shipment.
- To assist the maintenance of temperatures for blood components, it is often useful for hospital wards to possess a refrigerator for short-term storage of issued blood from the blood bank.

3

Blood storage equipment

Refrigerators, plasma freezers and platelet agitators

Blood refrigerators, plasma freezers and platelet agitators are the blood cold chain equipment used for the storage of blood components. Blood refrigerators and plasma freezers rely on refrigeration systems. Refrigeration (and air-conditioning) is the process of removing heat from a confined environment until the desired temperature is attained, and then maintaining the air at this temperature range. Whatever the design, size or purpose of the elements of a refrigeration system, the principles of operation remain the same.

This section aims to provide you with an understanding of the equipment used to store blood components and the key elements of the refrigeration or temperature maintenance systems.

The WHO recommended performance specifications of these items are published in *The Blood Cold Chain: Guide to the Selection and Procurement of Equipment and Accessories*.¹

LEARNING OBJECTIVES

When you have completed this Section, you should be able to:

- Explain the technical terms used to describe the performance of blood cold chain equipment.
- Understand and cite the different designs and types of blood refrigerators, plasma freezers and platelet agitators.
- Describe the elements of a refrigerator and freezer and their use.
- Relate the knowledge gained to the safe use and care of cold chain equipment.

3.1 Technical terms for specifications of blood cold chain equipment

WHO uses specific technical terms in determining the minimum performance specifications for blood cold chain equipment. Manufacturers also use these terms to describe the performance of their equipment. It is important, therefore, for users of blood cold chain equipment to understand terms in common use in defining the specifications and performance of refrigerators, freezers and platelet agitators.

Amplitude of the agitation

The side-to-side movement of the tray of the platelet agitator is expected to be within the range of 3.6 to 4.0 cm.

Cooling down time

This is the length of time it takes the cold chain equipment to reduce the temperature of a quantity of blood components from a defined temperature to the storage temperature for that component. A rapid cooling down time maximizes the quality of product stored.

Defrost cycle

Occasionally frost or ice builds up in plasma freezer cabinets. This ice should be removed as it affects the accessibility of products, and results in excessive running of the compressor. Modern freezers have an automatic defrost cycle, during which time the temperature of the cabinet does not rise.

Fan air cooling

Blood bank refrigerators and plasma freezers have a fan for circulating air in the cabinet. This enables a uniform temperature throughout the cabinet and reduces the cooling down time. The fan is activated by a thermostat and stops when the door is opened.

Forced air cooling

Cold air is directed to the contents of the cabinet in order to achieve low temperatures rapidly. This is usually applied in plasma – or blast – freezers. Forced air cooling technology is efficient but expensive.

Hold-over time

This is the length of time that the temperature remains within the acceptable range when there is a loss of power. The hold-over time depends on the ambient temperature and the insulation provided on the equipment. It is also affected by the frequency of door openings. The longer the hold-over time the better because this provides the user with more time to find alternative storage. Nonetheless, there is a limit to the quantity of insulation that can be used in the design of the equipment as it makes the equipment expensive and bulky. Hold-over time is particularly critical in countries where the ambient temperature is high and the energy supply may be unreliable.

Stroke

The number of times the tray of the platelet agitator moves from side to side in a given time, usually per minute.

3.2 Design features common to refrigerators and freezers

In addition to the ideal design features listed specifically under Blood Refrigerators or Plasma Freezers (see 3.3 and 3.4 below), the following are ideal features common to both:

- Audiovisual alarms: temperature out of range, door ajar and power failure (warning) with battery back-up.
- Temperature Display Unit at 0.1 °C graduation.
- Continuous Temperature Recorder: seven-day chart with battery back-up.
- Roll-out type of drawers or trays.
- Interface for Remote Temperature Monitoring.
- Casters for easy movement of the equipment.
- Stainless steel construction.

3.2.1 The cabinet

The cabinet of the refrigerator or freezer stores the blood packs or plasma packs respectively. Key factors in the design of the cabinet are:

- A. Structure
- B. Insulation
- C. Interior lining
- D. Doors and lighting
- E. Shelving

A. Structure of the cabinet

Upright refrigerator

Blood bank refrigerators are usually of the “upright type” with glass doors. This is because they are frequently opened to place or retrieve blood packs. It is useful to have the blood packs displayed so that the blood group and date of expiry can be identified without opening the door. Blood bank refrigerators generally have a cooling fan to ensure air circulation within the cabinet.

Chest refrigerators

Ice-lined and solar powered refrigerators are of the chest type and have a cooling fan to ensure air circulation within the cabinet. Ice-lined refrigerators are designed to achieve a relatively longer hold-over temperature because they are used in locations that experience frequent and lengthy power cuts. Solar powered equipment needs heavier insulation because the energy source may be unreliable. Furthermore, the chest type refrigerator is not ideal for the placing or retrieving of blood packs because the baskets have to be lifted out completely.

Upright freezers

The general construction of an upright freezer is very similar to the blood bank refrigerator. The insulation is heavier so that temperatures of -35°C or colder can be maintained. An upright freezer takes up less space but is not as efficient as the chest type, because every time the door is opened, air inside escapes at the bottom of the opening, and moisture enters with the air. This can be minimized by having solid shelves to hold the components and fan air cooling which automatically stops when the door is opened, thus reducing air exchange with that from the outside.

Chest freezers

The most common and efficient design of freezers is the chest type, for the following reasons. Firstly, since chest freezers are opened less frequently than the upright version, they maintain desired temperatures better. They also stop a considerable amount of moisture from entering the cabinet, since cold air does not spill out when the lid is opened as it is heavier than warm air (the door is referred to as the lid). However, it is sometimes difficult to gain access to frozen products near the bottom of the chest freezer, despite the assistance of fitted baskets that can be lifted out.

B. Insulation

In order to reduce heat transfer from the room to the contents of the cabinet, good insulation using CFC-free material is necessary. In the case of freezers, a thicker insulation material is used. Good insulation reduces the workload on the compressor, which in turn adds to the life span of the equipment.

C. Interior lining

The internal cabinet lining of refrigerators and freezers is made of corrosion resistant materials. WHO recommends stainless steel for this purpose, which is easy to clean, stain and scratch resistant, gives a longer life to the equipment and looks good.

Drops of blood can cause bacteria and other pathogens to grow. This may contaminate the surfaces of blood bags and can be dangerous for staff handling the blood and for the patient. It is therefore important that the equipment is cleaned with a mild detergent whenever spillage happens (see Section 7 on care and maintenance of cold chain equipment). A hypochlorite solution (bleach) should **not** be used to clean metallic surfaces.

D. Doors and lighting

Blood refrigerator doors are designed to minimize the need for door openings. There may be a glass door or solid (opaque) door covering an internal see-through glass or epoxy door. This design enables the user to view the contents with minimal effect on the internal temperature of the refrigerator. Freezers do not have glass front doors because of the need for higher insulation. Equipment with a large capacity usually has two doors in order to minimize heat transfer.

Door seals (gaskets) are crucial for maintaining temperatures. Any leakage in the seal will raise the temperature of the cabinet, and door seals therefore need to be checked regularly. Similarly, the door hinges may affect the door seals and may need adjusting to correct the problem.

Fluorescent lighting is now a standard feature of most blood bank refrigerators. In refrigerators with glass doors, the fluorescent lighting remains on permanently to assist the user in viewing the contents. In refrigerators with solid doors, the lighting is automatically turned off when the door is closed.

E. Shelving

Different types of shelving are available for refrigerators and plasma freezers to cater for the variety of pack sizes available. The important factor is that the packs are accessible and, in the case of refrigerators, that the packs are visible without opening the doors of the cabinet. Shelving may be on rollers, which can be partly pulled out to load or retrieve blood packs. The shelving must be strong and well spaced to allow for the effective circulation of cold air.

ACTIVITY

Identify the blood refrigerators and plasma freezers in the blood bank where you work and classify them into upright and chest type. Against each type, list the type of door, the number of shelves, whether they are the roll-out type or fixed, and what type of door lighting is available. How are you able to view the contents of each piece of equipment?

3.3 Ideal design features specific to blood bank refrigerators*



Two standard electric blood refrigerators, one with glass doors showing the digital temperature logger

- Preset alarm points at +1.5 °C and +5.5 °C.
- Thermal glass door to view contents from the outside.

The purpose of a blood refrigerator is to store whole blood and red cells at between +2 °C and +6 °C. There are various compression type blood refrigerators using CFC-free refrigerant gas for use in different environments. They are generally frost and condensation free. An electric fan forces air circulation to ensure a uniform temperature throughout the cabinet. The following paragraphs describe the different types available.

A. Standard electric (WHO Specification BTS/RF.1)

Standard electric blood refrigerators operate from an AC voltage of 110V/60Hz or 220V/50Hz mains supply.

* See Annex 2 for WHO minimum performance specifications for blood refrigerators.

B. Ice-lined (WHO Specification BTS/RF.2)

Ice-lined compression type refrigerators are designed for environments where the national grid electricity power supply is unreliable. Ice-lined refrigerators are usually of the “chest type” (see 3.2.1 A above) and are especially designed to have a long hold-over time. This means that, unlike standard electric refrigerators, they may hold the temperature below +10 °C for up to 17 hours following a power cut. The ice lining consists of plastic tubes or other containers filled with water that is frozen during operation. They may also have a freezer section for the storage of ice packs. During periods of power failure and load shedding, the ice packs act as cold storage to protect the units of blood in the refrigerator. The freezer section is approved for the freezing of ice packs, but **not** for the storage of plasma products.

C. Solar or ‘photovoltaic’ (WHO Specification BTS/RF.3)

Solar or photovoltaic powered compression refrigerators convert solar energy into Direct Current (DC), as an alternative source of electricity to the mains supply. The major difference from standard electric refrigerators is that the insulation of the cabinet is higher so that the hold-over time is at least 24 hours. Batteries store the electrical energy during daylight. In the event of disconnection from solar panels or poor sunlight, the batteries continue to provide electricity, thus adding to the hold-over time. Only WHO approved companies should provide the solar panels and related accessories. This ensures that the design of the panels suits the energy needs of the blood refrigerator and its general use. The installation of solar powered refrigerators is expensive because it requires skilled manpower. However, once correctly installed, solar powered blood refrigerators are relatively cheap to maintain. They may also have a freezer section for storing ice packs, but **not** for the storage of plasma products.

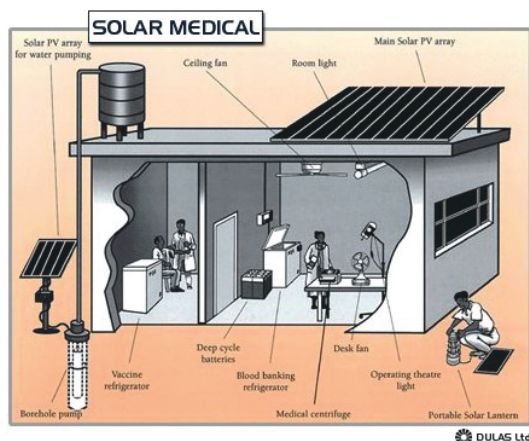


Figure 2.
Solar power for blood
and vaccine storage in
a remote health centre

Solar powered equipment is useful, but its hold-over time is dependent on the quality of the insulation and, except in areas with plenty of sunshine, its efficiency is limited. Nonetheless, despite their limitations, solar powered refrigerators are storing blood in remote, rural communities with no access to the national electricity grid. Moreover, improvements in solar technology design are on the horizon, and may well be the technology of the future.

Table 5. Classification of blood refrigerators by capacity (WHO Specification BTS/RF.1)

	BR1	BR2	BR3	BR4	BR5
Approx. number of 450 ml blood units	<50	51–150	151–25	251–500	501–1000
Approx. internal capacity of equipment (litres)	<130	131–390	391–650	651–1350	1351–2700

3.4 Ideal design features specific to plasma (and cryoprecipitate) freezers*



Upright plasma freezer with in-built temperature alarms
PHOTO FROM DOMETIC

- Preset alarm point at -25°C .
- Chest design.

“Compression type” plasma freezers are suitable for the storage of plasma (FFP) and cryoprecipitate. The main difference between a blood refrigerator and a plasma freezer is in the temperatures that they are capable of maintaining. A plasma freezer is expected to operate at a temperature of below -30°C . The equipment should use CFC-free refrigerant gas and electricity supply from the national grid. The freezer has an internal fan cooling mechanism to ensure the even distribution of air in the cabinet.

The general construction of a plasma freezer is similar to that of a blood refrigerator, except that there is more insulation in the cabinet of a freezer, allowing the maintenance of the lower temperatures necessary. There is a difference in the evaporator arrangement that results in the lower temperatures being attained. The equipment also has a temperature monitoring device similar to that of the refrigerator. The hold-over time is at least 24 hours unless the freezer door is opened frequently.

Table 6. Classification of plasma freezers by capacity (WHO Specification BTS/FR.1)

	PF1	PF2	PF3	PF4	PF5
Approx. number of 300 ml plasma packs	<50	51–150	151–250	251–500	501–1000
Approx. internal capacity of equipment (litres)	<75	76–200	201–300	301–625	626–1300

3.5 Walk-in cold rooms and freezer rooms

Although there are currently no WHO minimum performance specifications for cold or freezer rooms, the information below is provided for users of this equipment.



Access to cold room through the blood stock management area. Crates contain blood of the same type, stored in expiry date order, ready for despatch to a hospital blood bank.

Walk-in cold and freezer rooms are storage fixtures that are available in a wide variety of sizes to suit every need. They are either permanently erected or of the knockdown type that can be moved. Very large installations are permanent and cannot be moved. Cold and freezer rooms are best constructed at the same time as the blood transfusion centre, since they are expensive items whose positioning needs careful planning. The cooling mechanism of the equipment also uses CFC-free refrigerant gas. Cold rooms operate at between $+2^{\circ}\text{C}$ and $+6^{\circ}\text{C}$, are ideal for the bulk storage of blood components and are therefore usually found at central blood banks or major regional centres.

Freezer rooms are generally constructed as cold rooms except they have much thicker insulation and the cooling mechanism provides for temperatures below -30°C . Ideally a freezer room is accessed through the cold room in order to minimize temperature change in the freezer. If the door of the freezer room opens directly to “open air” temperatures,

* See Annex 2 for WHO minimum performance specifications for plasma freezers (WHO Specification BTS/FR.1).

there is a risk of a rapid temperature rise in the freezer room, resulting in the temperature alarm being triggered. It is equally important to ensure that the door mechanism on the freezer is secured to prevent it opening into the cold room and freezing the blood. Ideally cold and freezer rooms have plastic sheeting against the inside of the door to assist with trapping cold air inside and preventing warm air entering the room.

A dual cold and freezer room exists that is constructed in the same way as a freezer room, except that the thermostat of the refrigeration plant is adjustable to meet freezer or cold room purposes.

The exterior of the cabinet is made of galvanized metal or aluminium. The recommended internal lining is stainless steel. The doors of the cabinet are usually of the same construction as the box. Instead of insulation, the doors may have two or three dead air spaces arranged in such a way that they are airtight. Since a power failure will cut off the electricity supply, measures should be taken to ensure emergency lighting and alternative current to activate the panic button.

Ideal design features of cold rooms and freezer rooms

- Pre-set alarm at +1.5 °C and +5.5 °C (cold room) and at –25 °C (freezer room).
- Temperature Display Unit at 0.1 °C graduation.
- Audiovisual alarms: temperature out of range and power failure warning with battery back-up.
- Continuous Temperature Recorder: seven day chart with battery back-up.
- Shelving: to hold trays of blood packs (cold room) or plasma and cryo-precipitate packs (freezer room).
- Doors: door open lighting system and door open alarm system.
- Temperature Monitoring: Interface for Remote Temperature Monitoring.
- Alternate refrigeration or freezer plant with emergency automatic or programmed switchover of refrigeration systems.
- Safety latch on the inside of door to allow anyone trapped inside to get out and/or an alarm (panic button).

3.6 Platelet agitators*

Platelet concentrates are harvested from whole blood by centrifugation or during platelet apheresis. Platelet concentrates are suspended in about 60 ml of plasma. The packs are continually agitated in a platelet agitator in a room with an ambient temperature of between +20 °C and +24 °C. This generally requires that the laboratory is air-conditioned in order that the temperatures are maintained within the desired range. The recommended type of agitator is a flatbed agitator with horizontal or vertical agitation as this ensures no platelet clumps are formed. The key operational factors of the agitator are the number of strokes per minute (ideally 65 to 75) and the amplitude of each stroke (ideally 3.6 to 4.0

* See Annex 2 for WHO minimum performance specifications for platelet agitators



Platelet agitator with wall-mounted maximum-minimum thermometer to monitor ambient temperature.

cm). Platelet agitators are essential in the blood bank as they ensure proper storage of the platelets for transfusion.

Platelet agitators that are integrated into an incubator are also available (WHO Specification BTS/PAC/IN/1). The incubator maintains temperature at between $+20^{\circ}\text{C}$ and $+24^{\circ}\text{C}$, and is fitted with temperature monitoring devices to ensure that the temperature is maintained within this range. These devices comprise alarm systems for motion failure, and temperature display and recording devices for a permanent record of the temperatures reached. Platelet incubators are ideal where there is no air-conditioning in the laboratory. There are different sizes of agitators on the market to cater for all types of need.

Ideal design features of platelet agitator in an incubator

- Preset alarm points at $+20^{\circ}\text{C}$ and $+24^{\circ}\text{C}$.
- Amplitude 3.6 to 4.0 cm; 65 to 75 strokes/minute.
- Temperature Display Unit at 0.1°C graduation.
- Audiovisual alarms: temperature out of range and power failure warning with battery back-up.
- Continuous Temperature Recorder: seven-day chart with battery back-up.
- Glass door to allow inspection of products.
- Roll-out type of trays.
- Casters for easy movement if floor standing equipment is procured.

3.7 The cooling mechanism and its maintenance (the refrigeration cycle)

The primary components of the refrigeration cycle are the compressor, the condenser, the evaporator or cooling unit, and the thermostat that controls the cycle.

Key to the entire process of refrigeration is the refrigerant gas, which

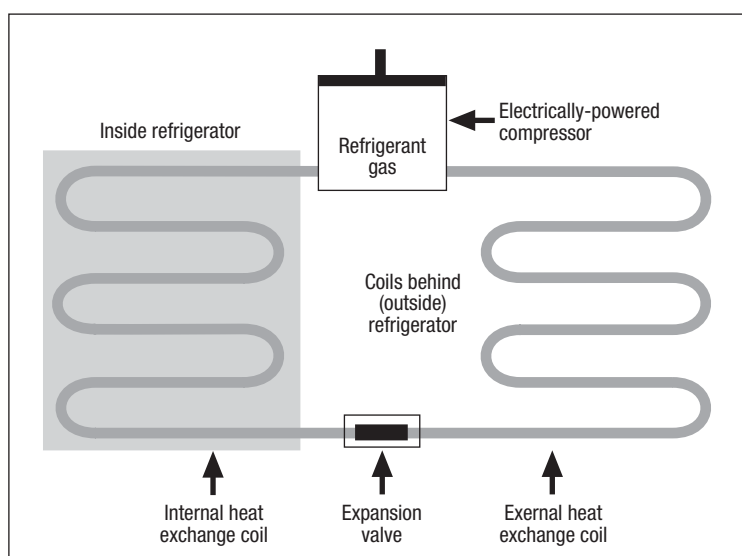


Figure 3.
The refrigeration cycle

starts in a gaseous state, passing through a number of changes before it returns to a gaseous state. This series of processes is referred to as the “refrigeration cycle”, and it is this cycle that enables the cooling of the cabinet and maintenance of the desired temperatures. This technology applies equally to refrigerators and freezers. A basic knowledge of the cooling mechanism will allow you to communicate effectively with the maintenance engineers and understand the maintenance requirements of the different components. The refrigerant gas will be discussed first.

3.7.1 Refrigerant gas

This is the fluid in a refrigeration system that changes from a liquid to a vapour, and back to liquid, as it moves from one component of the cycle to the other. The most important aspect of the refrigerant gas is that it **must be CFC-free** as chlorofluorocarbons (CFCs) contribute to the depletion of the ozone layer in the earth's atmosphere. All managers and users **must** ensure that they buy equipment with CFC-free refrigerant gas, and that existing CFC gas equipment is replaced according to the requirements of the Montreal Protocol (see Annex 1).

Refrigerant gases rarely need replacing if the equipment has been handled well in transit. However, it may happen that the gas escapes or becomes depleted. It is therefore important to identify a local source of the gas since, without it, the refrigerator or freezer ceases to cool the cabinet down.

Extreme care is needed to prevent refrigerant from coming into contact with your eyes, face or skin. **Never let refrigerant spray on to your skin** as frost bite or cold burn will result. Replacing the refrigerant gas requires a trained refrigeration expert.

3.7.2 The compressor

The compressor is the heart of the refrigeration system. It compresses the refrigerant vapour and pumps the heat-laden refrigerant gas to the condenser. The compressor rarely breaks down, but if it does, the only solution is to replace it with a new compressor or reconditioned unit. The major causes of failure of compressors are fluctuation in the voltage supply that affects the compressor motor, particularly at starting, when a considerable load of power is consumed. Replacement of the compressor should only be carried out by a refrigeration expert. The compressor is the most expensive part of the equipment.



Technician checking on a blood bank refrigerator. Back view, showing compressor, condenser and the rear of the temperature monitor/alarm.

3.7.3 The condenser

The condenser releases heat from the refrigerant gas to the surrounding air. The condenser is easy to identify as it is usually made of steel or copper and is normally painted black. Condenser pipes are kept together by wire fins, which also help to increase the cooling surface area of the condenser. The condenser rarely fails. However, because of its crucial role in heat transfer, it needs to be kept clean and free of dust.

3.7.4 The evaporator

The evaporator is the area that absorbs heat from the cabinet and its contents. The refrigerant gas enters the evaporator as a liquid and absorbs heat and flows out the other end as a vapour. The vapour flows into the condenser under a high pressure from the compressor as the cycle begins again. The evaporator rarely requires repair but needs to be kept clean.

The cycle continues until the desired temperature of the cabinet is attained. However, the temperature may rise again due to the limited capacity of the insulation and/or door opening effect. A thermostat re-starts or cuts the cycle.

3.7.5 The thermostat

The thermostat is a device that senses temperature changes, and at a predetermined temperature activates or deactivates a mechanical or electric activity. Thermostats thus have “cut in” and “cut out” set temperatures. These predetermined temperatures may be permanently set in the factory, or may be adjustable by the user. The thermostat starts the compressor when the temperature inside the cabinet rises to a predetermined level, e.g. +5.0 °C, and stops it when the temperature inside the cabinet is reduced to a predetermined minimum, e.g. +2.5 °C. Blood bank refrigerators and plasma freezers have their thermostats set in the factory. Only a qualified refrigeration technician should carry out any adjustment to the thermostat.

ACTIVITY

Study the refrigerator and freezer technical manuals supplied with your equipment. Identify:

- the compressor
- the condenser
- the evaporator

Check the type of refrigerant gas in use. Check if it is CFC-free and that a local source for replacing the gas has been identified should it be necessary.

3.8 Ensuring electrical safety of the equipment

Exposed electrical wires present the most serious danger to users of refrigeration equipment, particularly when the equipment is ageing, and/or has been moved to a different location.

There is also a danger after equipment has been repaired if the electrician has not ensured adequate insulation of the cables, including earth connections. The safety of personnel using the equipment and the equipment itself cannot be guaranteed unless the ground wire (green/yellow) of the power cord is earthed correctly.

Electric shocks can be fatal. It is therefore essential the equipment be checked periodically for exposed wires, and that any problems are corrected by a qualified refrigeration engineer.

3.9 Care of refrigeration equipment

The safety of blood cold chain equipment depends on its location and the care it receives, especially during transportation and installation. Always ensure that the equipment is safely handled. The heat loss from refrigeration equipment affects the ambient temperature of the room. This in turn means greater activity of the compressors to keep the temperature

of the cabinets within acceptable limits. It is therefore important to ensure a reasonable quantity and spacing of the equipment and to avoid the equipment being in sunlight or near heat-generating equipment. See Section 7 for more details.

Summary

- There are important common and specific design features of blood refrigerators, plasma freezers and platelet agitators.
- Managers and users of blood cold chain equipment need to understand the principal technical terms used to describe the specifications and performance of these pieces of equipment so that selection and procurement decisions are based on current and future needs.
- Each component of the refrigeration cycle has a critical role in the refrigeration cycle.
- Users must be trained in the safety elements of cold chain equipment and its individual components.

4

Other blood cold chain devices

In addition to blood storage equipment (see Section 3), other devices, such as transport boxes for the movement of blood, are essential components of the blood cold chain.

LEARNING OBJECTIVES

When you have completed this Section, you should be able to:

- Describe the different supplementary devices available for use in the blood cold chain.
- Define the technical specifications used in describing the performance characteristics of these devices.
- Demonstrate understanding of the key features of the devices and their relevance and use in the blood cold chain.

The following essential blood cold chain devices and equipment are described in detail in this Section.

- Plasma thawing equipment
- Equipment for the transportation of blood
- Temperature monitoring devices
- Blood cold chain accessories

4.1 Plasma thawing equipment*

This is a specially designed waterbath able to maintain constant temperature at around +37 °C. The unit is designed to agitate frozen products in order to enhance thawing. Some equipment does this by directing a stream of warm water onto the frozen product. Defrosting the maximum packs of plasma from –30 °C to 0 °C in this way is achieved within approximately 20 minutes. At the end of the thawing procedure, the component retains its original volume, biological content and expected activity.

An ordinary waterbath at +37 °C may also be used as it can retain the constant temperature desired. However, it will take longer for plasma to

* See Annex 2 for WHO minimum performance specifications for plasma thawing equipment (WHO Specification BTS/PT/IN.1)



Plasma thawer with three isolated sections and digital temperature control.

thaw because there is no mechanism for agitating the plasma, and there remains the risk that the water may be contaminated by chemicals or bacteria, making it unsafe for thawing plasma. It is therefore important to put the plasma in a sealed plastic bag while it is being thawed.

The plasma thawer achieves a uniform and quality standard of defrosted plasma for transfusion. Plasma packs may be thawed in batches or at random according to the manufacturer's instructions.

There are two main types of plasma thawer: the "wet" and the "dry" type. In the "wet" type of thawer the plasma packs are suspended from clamps and packed to be in direct contact with the water. Note that detergent should never be added to the water. In the "dry" type of thawer the plasma packs are protected from direct contact with the water by leak proof containers (bladders) that come as part of the equipment. The warm water is circulated around the bags. The "dry" type of thawer is ideal because the operator's hands and the plasma packs remain dry.

The water in plasma thawers should be regularly tested for the presence of micro-organisms. Plasma thawers should also be subjected to a rigorous schedule of cleaning and decontamination, including changing of the water (see Section 7.2.4).

Ideal design features of plasma thawing equipment

- Able to handle all types of plasma packs, such as apheresis packs.
- Audiovisual alarms: temperature out of range and low water level.
- An efficient water drainage system for ease of cleaning the bath.
- Rocking of units in dry waterbath or stirring of water in wet water-bath.

4.2 Equipment for the transportation of blood

4.2.1 Technical terms used

Robustness: this is a term used to describe the resistance of the blood transport box when dropped from a certain height a number of times. It is an important specification as boxes are usually handled roughly.

Cold life of a box: cold life is based on the time period between loading a box with frozen ice packs and blood packs at +4 °C and the warmest internal temperature to reach +10 °C when the external temperature is held constant at +43 °C.

4.2.2 Blood transport boxes*

The inability to maintain the correct temperature for blood in transit from one blood bank to another has been identified as a major cause of unsafe blood transfusion. WHO therefore supports the need to develop a

* See Annex 2 for WHO minimum performance specifications for blood transport boxes (WHO Specification B4/BC1)

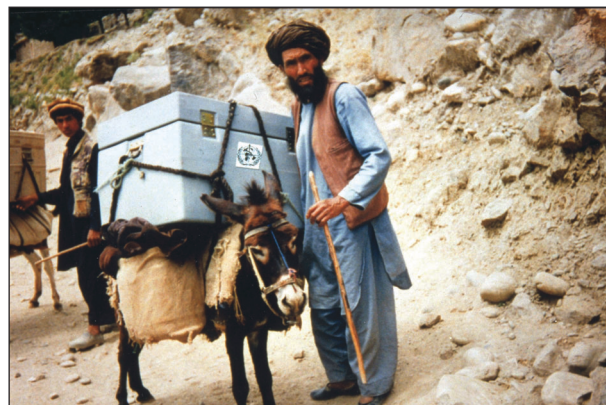


Blood transport box

transport box specific for blood that is affordable to all. Blood transport boxes must be specially designed to maintain the internal temperature between $+2^{\circ}\text{C}$ and $+10^{\circ}\text{C}$ for at least 24 hours using appropriate ice packing, i.e. to have a cold life of at least 24 hours. Transport boxes are manufactured in different sizes to suit different needs. The manufacturer of the transport box defines the number of ice packs required to keep blood within a temperature range of $+2^{\circ}\text{C}$ to $+10^{\circ}\text{C}$. However, the quantity and type of coolants to be used will depend on the blood components or products to be transported and the distance. It is recommended that a blood bank carry out on-site evaluations to ensure the cold life is maintained as part of the validation of the Standard Operating Procedures covering this activity.

It is important to highlight a major difference between the use of blood transport boxes and that of vaccine cold chain transport boxes that affects the design of the boxes. Although vaccine transport boxes are often used to transport blood, vaccine cold boxes are designed to be able to transport products over a period of up to five days, especially to reach remote villages. Blood transportation is limited to fairly short periods, generally below 24 hours. If it were necessary to transport blood for more than 24 hours to a remote location, it would be preferable to collect the blood locally. The level of insulation of the blood transport box can therefore be lower than that of a vaccine cold box, which will make it cheaper and thereby more accessible.

Some transport boxes are designed to operate from the direct current of a motor vehicle battery. There are now transport boxes that only require a rechargeable battery to maintain the cold life for over 24 hours. These are not cheap, but they enable the use of cold boxes over a long period without the need for coolants. Blood transport boxes may also be used for the temporary storage of blood components in the event of a breakdown of the blood refrigerator.



Donkeys assuring the cold chain through rugged mountain terrain

Ideal design features of a blood transport box

- Lightweight
- Robust
- Secure and lockable
- Cold life of at least 30 hours at +43 °C.

4.2.3 Ice packs, cooling plates and cooling pouches (WHO Specification WHO/EPI:E5/IP.1 and E5/IP.2)⁵

Purpose: To be used in combination with transport boxes for the safe movement of blood.

Description

Ice Packs: those used for transporting vaccines are safe to use for the transport of blood and blood products, with the precaution that they should not come into direct contact with the unit of whole blood or packed red cells. Prefilled ice packs (blue ones) are not recommended for transporting liquid products because they have a lower freezing point than water, which may lower the temperature of the box too much and freeze the product. Pre-filled ice packs can be used for transporting plasma products. Two standard sizes exist for ice packs: 0.4 litre and 0.6 litre.

Cooling plates and cooling pouches: both plates and pouches allow the storage and transportation of unprocessed blood or platelets for up to 24 hours at between +20 °C and +24 °C. The aluminium plates contain nylon-laminated polyethylene bags filled with 200 ml of a gelatinous substance called Butane-1,4-diol. The pillow-like pouches, filled with the same substance, are stored at between +2 °C and +10 °C for 3 hours or until completely solidified before use.

As cooling plates and pouches have not been very long on the market, they may not be readily available.

4.3 Temperature monitoring devices

Table 7 summarizes the different devices available to monitor temperatures in blood cold chain equipment.

Table 7. Different types of devices available to monitor temperatures

Device	Remarks
Portable thermometers	Graduated small bore mercury or alcohol thermometers (–10 °C to +110 °C). Can also be maximum/minimum version. Fragile.
Digital electronic probes (usually connected to an electronic device)	Either portable with temperature probes and LED temperature display when requested; or fixed onto equipment with LED temperature display and visual/audible alarm systems included. Fixed version needs battery back up but no consumables.
Temperature recorders/thermographs	
Electronic data loggers	Accurate, reusable battery-powered data loggers to monitor equipment and shipments. Require a computer to download data.
Chart recorders	May monitor one piece of equipment, or version exists to monitor multiple devices with the same or different temperature requirements. Battery back up required. Ink, pen and 7-day recorder charts are major consumables.

4.3.1 Portable thermometers

Thermometers have been used in the monitoring of cold chain equipment for many years. The advantages of thermometers are:

- Ease of use.
- Transferability from one piece of equipment to another.
- The units can be calibrated and offer accurate results when used correctly.

The major disadvantages of portable thermometers are that:

- It is not possible to have an electronic memory of the temperatures measured.
- They can easily break or be misplaced.
- It is sometimes difficult to get an accurate reading, since the temperature may change during the transfer of the thermometer from refrigeration to the ambient environment where it will be interpreted.
- You need to open the door of the refrigerator to read them, affecting the temperature in the cabinet.



Maximum/minimum Celsius thermometer, here showing ambient temperature

Nonetheless, thermometers remain a very basic and important tool for taking readings of the temperature inside cold chain equipment.

Maximum/minimum thermometers

Maximum/minimum thermometers are designed to record permanently the maximum and minimum temperature attained since the thermometer was set. Maximum/minimum thermometers are therefore very useful and can be used in blood transport boxes, in refrigerators and freezers. The data, however, has to be captured manually.

Built-in temperature display units



Close-up of an inbuilt digital temperature display

A light-emitting diode (LED) displays the temperature of the equipment which means that there is no need to open the cabinet to measure the temperature reading on a thermometer. The display may also show the maximum/minimum temperatures achieved since the thermometer was set. The electronic temperature display unit is therefore a major improvement on the maximum/minimum thermometer for monitoring the temperature of equipment.

4.3.2 Temperature recorders/thermographs

Temperature recording devices provide a permanent record of the temperatures achieved at any time in cold chain equipment. They may be available as optional extras when purchasing cold chain equipment. A temperature recorder comes with a chart with paper on which changes in the temperature inside the equipment are recorded over a given period, usually 24 hours or seven days.



Seven-day constantly recording thermograph

The advantage of temperature recording devices is that the charts can be kept as a permanent record of the temperatures inside the equipment, which is a requirement of the quality system.

The disadvantage is that they are dependent on accessories such as chart paper and ink for the pen that records the temperature. Manufacturers normally supply sufficient materials for one year of use. Users then have to order further supplies of the charts and ink. These accessories are often unavailable for various reasons, mainly logistical and financial, and the devices cannot be used if supplies run out. Therefore, when purchasing any equipment that is designed to include a temperature recording device, accessories for up to five years should be acquired at the time of purchase.

Devices for the simultaneous monitoring of different cold chain equipment

Devices are now available that can simultaneously record the temperature of different cold chain equipment, although they are relatively expensive. Thermographs are linked to temperature probes inserted in several items of cold chain equipment. The temperature of each of these items of equipment is simultaneously recorded and displayed at a central location selected by the user. The data captured may be displayed in two ways:

i) Computer-linked software

The cold chain manager monitors the temperature of the various pieces of equipment on a computer. A record of the temperature for each piece of equipment and any “events” are automatically displayed, recorded or recalled. This is a very convenient method of temperature monitoring for blood banks with different types of cold chain equipment. Instead of checking the temperature of each item of equipment separately, it is possible to check them simultaneously at a site that is convenient to all users. The software also allows the manager to print the data at any time and for any defined period. This option may not be suitable for environments without a continuous electric supply



Computer-linked temperature logger

ii) Temperature recorders or thermographs

The temperature readings from the different pieces of equipment are simultaneously recorded by different pens and are displayed on a temperature chart recorder. Each piece of equipment is defined by the colour of the ink used in the pen. However, thermographs must be carefully maintained and checked for accuracy using other temperature monitoring devices such as data loggers.

Temperature data loggers

Temperature data loggers are now available that use computer software to record the temperature. A cassette similar to a photographic film spool is used to record the temperature of any equipment over a period of time selected by the user. When the user wants to access the record, the cassette is put into a computer and, using appropriate software, the temperatures attained will be displayed and, if desired, printed.



Example of a temperature data logger used during the transport of blood

This is a significant improvement on temperature display units and temperature recording charts. At present, however, the disadvantages of these devices are their cost and the need for a computer and appropriate software.

4.4 Manual recording of temperatures

It may be necessary to measure temperature manually. If your blood bank refrigerator/freezer is not equipped with a continuous recording thermograph, the temperature must be recorded, preferably on a chart or in a record book, along with the date and time it was taken and the position of the thermometer. If the temperature is not between +2 °C and +6 °C, the possible cause and any action taken should also be recorded and reported. It is a good idea to stick a temperature chart on the front of the refrigerator to remind you that the temperature must be taken regularly. Temperature records are retained as part of the blood bank records.

Table 8. Example of a temperature record form for a blood bank refrigerator

Date	Time	Shelf	Temperature	Action
06.01.05	09:00	Low	+4 °C	None
06.01.05	16:00	High	+10 °C	Check in 1 hour
06.01.05	17:00	High	+6 °C	None

Blood bank refrigerators have a cooling fan that ensures even distribution of cold air in the cabinet. Therefore, there should be no differences in temperature at any position in the cabinet.

ACTIVITY

Measure the temperature in different parts of a domestic type refrigerator and a blood bank refrigerator which has a fan, as follows. Wrap a blood pack around a thermometer in order to accurately measure the temperature of the blood. Put one such thermometer on every shelf in both refrigerators and surround it completely with other blood packs. Take the temperature on at least five different days so that you can calculate the average temperature for each part. Always take the temperature at the same time of the day. Compare the temperature readings of the blood at the different shelves of the two types of equipment.

If blood is stored in a different part of the hospital, make sure that someone is responsible for monitoring and recording the temperature as has been described. If it is not being checked at least twice a day, you should speak to your supervisor with a view to identifying someone who works there to take responsibility for monitoring and recording the temperature. Explain the procedure carefully, and check periodically whether it is being carried out correctly. Alternatively, make yourself responsible for checking that refrigerator because it contains blood that has been issued by the blood bank, which must be kept safe for patients.

4.5 Alarm systems

Safe blood storage requires that blood components are kept at the appropriate temperature continuously. To achieve this, modern blood bank refrigerators are fitted with different types of alarms, e.g. for temperature, power failure or door-ajar alarms.

In the event of power failure, a warning light as well as a continuous sound is generated to alert the user. The warning light ceases when the power supply returns.

Even if the blood storage equipment works efficiently, the temperature may often be higher than +6 °C if the door is opened too often. The door-open alarm can activate at a preset time (e.g. if the door is left open for more than one minute), or may continue to sound as long as the door is open.

Temperatures exceeding the set thermostat values, i.e. the permissible maximum and minimum temperatures, trigger temperature alarms. The alarm signal shall be set to activate at a temperature that will allow proper action to be taken before the stored blood or blood products reach undesirable temperatures. In the case of refrigerators the set temperatures are +1.5 °C and +5.5 °C. For freezers, the alarm is triggered when the freezer cabinet temperature rises above –20 °C. The significant point with alarm systems for refrigerators is that they are set to measure the temperature of a liquid with the same viscosity as blood, e.g. 10% glycerol, while 100% glycerol is used for monitoring the temperature probes for freezers. The glycerol level must be checked regularly and must always be maintained full. The manufacturer of the blood storage equipment installs the probes at the ideal position in both the lower and upper half of the cabinet. This is because the bottom half of the cabinet usually has a lower temperature than that in the upper part in cabinets without fan cooling. However, readings from the two probes are synchronised and displayed as one reading or for triggering the alarm.

Alarm systems are now generally incorporated into the temperature display units of cold chain equipment. It is most important that temperature alarms are checked regularly for any defects, especially the battery which is invariably the energy source for the alarm.

A rechargeable battery, or an independent electrical circuit served by an emergency generator, is essential as a back-up energy supply. Alarm signals (visual or audible) should be placed in an area that has adequate personnel coverage 24 hours a day, to ensure that immediate corrective action can be taken.

ACTIVITY

Check in the user's manual of your blood bank refrigerator where the temperature probe is located (they are usually located near the door). Note its position in the cabinet wall if it is not readily visible. Place the probe in cold water and ice and record the temperature at which the alarm is triggered. Do this exercise again by placing a water bottle with warm water against the probe and check the temperature when the alarm goes off. Most modern blood bank refrigerators and freezers have automatic alarm checks.

Alarm probes should be checked at least every three months: make up a chart for each piece of equipment in order to check the alarms regularly.

4.6 Blood warmers

The blood bank has no responsibility to warm blood, which it delivers to the hospital ward at a temperature of between +2 °C and +10 °C. On average, it takes 10 minutes for a unit of blood to reach +10 °C at an ambient temperature of between +20 °C and +30 °C. Cold blood can be administered at a slow rate without ill effects. However, in cases where rapid transfusion is clinically indicated, e.g. if the patient requires the rapid transfusion of a large volume of blood, complications such as cardiac arrhythmia can be avoided if blood is warmed to +37 °C.

Blood should never be warmed in a bowl of hot water, in hot towels or close to a heating device as this could lead to extensive haemolysis and serious transfusion reactions. Specifically designed blood warmers are available that warm blood safely and this should be part of the essential equipment of a hospital ward, especially in the intensive care unit or operating theatre. The apparatus should be equipped with a visible temperature monitoring device and an audible alarm, which should be checked regularly.

4.7 Essential accessories for all refrigeration equipment

4.7.1 Voltage regulators (stabilisers)

Severe voltage fluctuations in the mains power supply occur in some countries. Voltage fluctuations greater than 15% may damage the electronic components of cold chain equipment, notably the compressors and motors. The local electrical engineer should advise if the fluctuation exceeds 15%, thus requiring a voltage regulator.



Voltage regulator, fitted with circuit breaker

A voltage regulator or stabiliser eliminates the effects of voltage fluctuation on the power line feeding the cold chain equipment, i.e. the cold chain equipment draws power through the voltage regulator, which is normally fitted between the power source and the cold chain equipment in order to ensure a consistent power supply

to the compressor. In so doing, any power fluctuations are neutralised by the regulator and a constant power supply reaches the cold chain equipment. Voltage regulators are therefore necessary to protect sensitive electronic and electrical equipment such as the compressor from the effects of power fluctuations.

4.7.2 Stand-by generators

All blood bank refrigerators, freezers, cold rooms and freezer rooms should be connected to a stand-by electricity generator.

Stand-by generators are designed to generate electricity using petrol or diesel fuel. They are connected to the main electricity supply unit, may be manually started or automatically switched on when there is a power failure. Ideally, stand-by generators should have an automatic transfer switch, which turns on the generator when a power failure occurs, which can be at any time.



Very small stand-by generator

Generator location and security: A generator should be sited so that it does not create a fire hazard. Typically, it should be located in a separate building or weatherproof enclosure. The fuel tank should be isolated and should be surrounded by a low wall or an earth bank to prevent fuel spills from spreading.

Both the generator and the fuel tank should be located in a secure compound to prevent theft. The fuel filler cap should be locked and the fuel line protected so that it cannot be tampered with. Fire extinguishers capable of extinguishing fuel oil, engine and electrical fires should be fitted close to the generator fuel tank.

The type and size of the generator to select and purchase is a very important issue. The following points need to be taken into account:

- The number of items of equipment to be serviced by the generator.
- The starting and running currents of each piece of cold chain equipment.
- The altitude and ambient temperature where the equipment is to be located.
- If the generator is to run continuously on full power, a generator with a higher energy output will be required.
- The type of fuel used: diesel fuelled machines are more robust than petrol.
- The type of cooling for the generator: air-cooled is better than water cooled.

Emergency power supply

Hospital blood banks are generally on the same emergency stand-by generator as the other critical departments of the hospital such as operating rooms and intensive care. It is necessary to ensure that most, if not all of the cold chain equipment is wired to the stand-by emergency generator power source.

Stand-alone blood banks require their own stand-by generators. In some situations, a generator is the only source of power for blood bank equipment. However, in this section we are assuming that the energy source for the blood bank equipment is the main national grid and, therefore, the alternative energy source is a generator or an alternative site to store blood in an emergency.

Alternative site: It may be necessary to identify other storage sites for blood in an emergency, i.e. in the event of a long power failure. Depending on the cause or location of the power failure, it may be necessary to move the equipment to another location within the hospital where power is available. It may even be necessary to find a hospital department or site which already has a stand-by generator as an alternative storage area, such as the Intensive Care Unit.

Two options for alternative storage location are:

1. Space in an existing government or private hospital which could be adapted to suit the needs of the blood cold chain.
2. Commercial storage which could be purchased or rented.

ACTIVITY

List the types of blood cold chain equipment in your establishment.

What temperature monitoring devices does your laboratory have for the following pieces of equipment?

- blood transport boxes
- blood bank refrigerators
- plasma freezers
- platelet agitators
- plasma thawers

Is there a stand-by generator or other emergency power source for cold chain equipment in the blood bank? If so, where is it located? How is it switched on, and when and how is it tested?

Summary

In this Section, we have :

- Reviewed additional blood cold chain devices and equipment, i.e.
 - boxes for the transportation of blood components: boxes must meet WHO defined specifications to ensure the blood is safe.
 - temperature monitoring devices: there are many different types now on the market. Devices that enable the recall of data are critical in the quality monitoring of the temperature of blood components in blood cold chain equipment.
 - plasma thawers: a plasma thawer achieves a uniform and quality standard of defrosted plasma for transfusion.
 - accessories such as standby generators: these are important in the event of power failure.
- Noted that blood cold chain equipment should be fitted with appropriate alarm systems, and must have a back up energy source.

5

Installing blood refrigerators and plasma freezers

The installation of a refrigerator or freezer is fairly straightforward as is evidenced by the fact that domestic equipment is invariably installed without the help of a refrigeration expert. In some countries, maintenance technicians from the ministry of health or an autonomous blood transfusion service carry out the installation. In others, the manufacturer's representative performs this task. A new refrigerator or freezer is an important part of the blood cold chain and you should be familiar with their components and make sure that they have been installed correctly so that blood is stored safely.

This section focuses specifically on blood refrigerators and plasma freezers since other blood bank equipment and devices do not need the same level of attention. The reception of equipment, as well as issues such as documentation and training, are valid for all cold chain items.

LEARNING OBJECTIVES

When you have completed this Section, you should be able to:

- Identify the factors that are critical to the safe installation of refrigeration equipment.
- Correctly install or supervise the installation of blood cold chain equipment.

5.1 Action on reception of equipment

Use the following checklist when any new refrigeration equipment is delivered.

- i) Check that the voltage shown on the packing list (or on the packing case) is correct for your power supply.
- ii) Check the packing case for damage. If you see or suspect any damage, take a photograph of it and **notify the supplier before unpacking it**.
- iii) Remove the equipment from the manufacturer's pallet. Unpack the equipment carefully and remove all packing pieces.
- iv) Double-check the equipment serial plate to determine whether the voltage is correct. If it is not the correct voltage, inform the supplier immediately. **Connecting the equipment to the wrong voltage supply may damage it.**

- v) Locate and note the serial number.
- vi) Check the compressor, condensing units and fans for hold-down bolts and loosen them.
- vii) Check the equipment for any damage or loose component. If it is damaged, **notify the supplier and shipper immediately.**
- viii) Check that the guarantee card, the operating manual and other supplies, such as spare parts, temperature charts, pens, batteries and keys have been included. They should be inside the packing case or the equipment itself. Most manufacturers include a list of contents.
- ix) Read the instructions and follow them exactly; for example:
 - Remove any documentation or other items from inside the equipment.
 - Complete the guarantee card according to the manufacturer's instructions, and ensure that it is kept safely in line with the Standard Operating Procedures.
 - Fit shelves, temperature monitor recorder or alarm.
 - Connect sensors.
 - Connect batteries and check the connections.
 - Fill solution bottles.

5.2 Siting of refrigerators and plasma freezers

All refrigeration equipment must be correctly sited or it may not work efficiently. The critical factors in siting refrigeration equipment are to:

- Avoid heat and direct sunlight.
- Ensure air circulation around the equipment.
- Check the equipment is level.
- Ensure there is an adequate distance between it and other equipment.
- Verify no external pipes or fittings are in contact with other metallic surfaces or walls.
- Make sure it is out of reach of water supply such as taps, to prevent electric shock.

Some of these critical factors are further elaborated below.

5.2.1 Heat and light

Refrigeration equipment should be placed in the coolest part of the building. **Never** place it in direct sunlight or near any other source of heat. Laboratory equipment generates heat depending on the size of the equipment and energy output. There is, thus, reduced heat loss if equipment is placed too close to another piece of equipment generating heat. If several cabinets are installed together, make sure that hot air from one cannot pass over the condenser of another and in so doing, impair efficiency.

5.2.2 Air circulation

Always place refrigeration equipment in a well-ventilated room. Position it so that there is good air circulation around all sides and the top of the cabinet. Make sure there is at least 30 cm between the equipment and the wall, and 40 cm to the ceiling.



Ensuring adequate distance between two pieces of refrigeration equipment

It is recommended that, in very hot climates, a fan is used to blow air between the wall and refrigerator or freezer. In the case of solar operated equipment, make particularly sure there is good air circulation in front of the ventilation grill. **Never** cover or put anything on top of the openings.

5.2.3 Levelling

Refrigeration equipment must be level for proper operation and to avoid unnecessary noise and vibration. To ensure this:

- i) Install the cabinet on a level floor.
- ii) Adjust the legs or wheels in accordance with the manufacturer's instructions.

If the cabinet does not have wheels, raise it off the floor by placing it on wooden blocks or a wooden platform at least 25–50 mm thick (1–2 inches). In this position, you can easily clean around it, and it will not be damaged by water and dirt when the floor is washed.

- iii) Use a spirit level on the top and against the side of the equipment to check whether it is standing firm and level on these blocks.
- iv) If the equipment is not level, use an extra wooden wedge to level it or adjust the legs. Do **not** use cardboard or paper wedges as their thickness will fluctuate.



Using a spirit level to check that the refrigerator is level

5.3 Door seals

Check whether the door or lid seals properly, using the method shown below.

- i) Open the door and place a thin strip of paper against the front of the cabinet.



Testing efficiency of refrigerator door seal.

- ii) Close the door.
- iii) Pull the strip of paper: if it moves easily or falls by itself, adjust the door sealing according to the manufacturer's instructions.
- iv) Check **all the way** around the door. Pay particular attention to the corners.

5.4 Cleaning

Clean the equipment before first use, using only warm, soapy water. Never use abrasive detergents, steel wool, abrasive sponges or chemical solvents. After cleaning, dry all parts carefully.

5.5 Energy supply

For refrigerators and freezers: Having double-checked the serial plate or the compressor label at the back of the equipment to ensure the voltage is correct for the local energy supply, place the equipment close to a power supply socket. Use the recommended power source and follow the manufacturer's instructions for switching the machine on.

For solar (photovoltaic) powered equipment and solar energy, it is important to use a WHO approved supplier, who will determine the correct number and size of panels and related accessories.

- Photovoltaic voltage is normally 12V or 24V direct current (DC).
- Refrigerant type, e.g. R134A-95G.

5.6 Starting the equipment

Before switching on the equipment, carefully read the operating instructions supplied by the manufacturer.

- i) Check that batteries for the alarm are connected and the temperature charts have been inserted.
- ii) Check that solution bottles are full, in accordance with the manufacturer's instructions.
- iii) Close the door. Make sure the electric socket is dry before connecting the power supply cable. Turn the power supply on.
- iv) When initially turned on, the cabinet will not be at the correct operating temperature. Follow the manufacturer's instructions to silence the alarm until the cabinet reaches the correct operating temperature.
- v) Let the equipment operate for 24 hours without opening the door, then check the temperature display or measure the temperature inside the cabinet manually. It must be between +2 °C and +6 °C. If it is not, refer to the manufacturer's instructions or if necessary, notify the supplier.

If a technician of the supplier has installed the equipment, he/she should demonstrate the operation of the equipment, its care and maintenance and the safety system (alarm). The following form should also be com-

pleted before the technician leaves and should be affixed to the piece of equipment.

Equipment installation record

- 1 Address of the blood bank (incl. tel, fax, e-mail)
- 2 Location of the equipment
- 3 Date of installation
- 4 Period of guarantee
- 5 Make and model of equipment installed
- 6 Serial number of equipment installed
- 7 Name, address and telephone number of technician responsible for servicing and repair of refrigerator
- 8 Verified by
 - Responsible officer at the blood bank
 - Chief installation technician
- 9 Date
- 10 Names of blood bank staff trained to use the equipment, and those able to carry out routine preventive maintenance

Each piece of equipment needs to have a retrievable and permanent record of its history, from acquisition to the date it is relocated or disposed of. In order to do this effectively, use the standard operating procedures for the record keeping of the equipment installed and include the following data in the **inventory register** of your laboratory:

- Location of equipment (Town and health facility where equipment is to be used)
- Equipment code (a set of numbers, letters or both issued by the blood bank (often at central level) that identifies the equipment)
- Manufacturer's details
- Price of equipment
- Type of equipment (e.g. refrigerator, freezer)
- Make and model of the equipment (from the manual or plate affixed to the back of the equipment)
- Power rating (Voltage/Hz/Watts)
- Temperature range
- Capacity of the equipment (e.g. 240L)
- Serial number of the equipment (from the manual or plate affixed to the back of the equipment)
- When the equipment was delivered, installed and passed for routine use
- When the equipment guarantee expires
- List of items supplied with the equipment and their location (give full description and quantity supplied), e.g.
 - Instruction manual

Table 9. Equipment Inventory: Blood Bank Refrigerators

Institution:										Responsible Officer:									
Address:										Position:									
Town:										Tel/Fax:									
Province/Region:										E-mail:									
Cost of equipment :										Period of guarantee:									
List of accessories supplied :																			
No.	Internal ID	Manufacturer & country of origin	Model	Serial No.	Blood Bank or Domestic	CFC-free?	Date first used	Internal capacity	Max. blood packs	Temp. monitors*	Location								
1																			
2																			
3																			
4																			
5																			

* TC = Temperature chart; A = Audio temperature alarm; V = Visual temperature alarm; D = Door ajar alarm; and/or TD = Temperature display

— Spare parts

— Pens and ink for the chart recorder

— Tools, e.g. screwdrivers

— Temperature recorder charts

- Name, address and telephone number of the supplier and the maintenance technician (if different from supplier)
- Date equipment relocated to another blood bank or department or for permanent disposal (this record moves with the equipment except when equipment is disposed of permanently)

In practice, the user may wish to merge some of the information from the Inventory Register with that of the Installation Record. See also Section 7 for Preventive Maintenance and Repair Records that will monitor how the equipment is performing over time.

If appropriate, an inventory of spare parts and accessories should also be maintained along the lines of the following model:

Table 10. Inventory of spare parts/accessories

Institution:			Responsible Officer:			
Address:			Position:			
Town:			Tel/Fax:			
Province/Region			E-mail:			
Description of spare part:			Part Number:			

Stock levels			Description of equipment to be repaired		Issuing Officer	
Opening stock	Quantity issued	Closing stock	Type and model	Serial No.	Location	Signature and date

5.7 Verifying installations and operational performance

Once the installation is complete, it is essential to check whether the equipment has been acceptably installed and is operating correctly before it is used for the storage of blood and blood products. Follow the Standard Operating Procedures for the validation and use of the equipment installed.

ACTIVITY

Use the following checklist to make sure the equipment in your institution has been installed correctly and is operating as it should:

- 1 Is the equipment placed so that it is never in direct sunlight or near other sources of heat?
- 2 Is there good air circulation between the equipment and the walls and ceiling?
- 3 Is the cabinet raised off the floor to protect it from damp and dirt?
- 4 Is the equipment level? How has this been checked?
- 5 Is the voltage correct for the local power supply? How do you know?
- 6 Is the supply cable plugged in?
- 7 If there is an On/Off switch, is the refrigerator switched on?
- 8 Are the materials used to clean the equipment suitable? Describe them.
- 9 Has the alarm system been checked?
- 10 Does the indicator light show that the equipment is connected to the power supply?
- 11 Does the cabinet door or lid seal properly? How has this been checked?
- 12 Does the temperature record for the refrigerator cabinet indicate a temperature of more than +2 °C and less than +6 °C?

If the answer to all questions is yes, the equipment has been properly installed and is operating correctly.

Summary

In this Section, you have learnt that:

- A procedure for the receipt of cold chain equipment is essential.
- Factors relating to where to site the equipment in the laboratory and what to do before switching on the machine need to be carefully reviewed.
- Records must be kept relating to installation and care of the equipment.
- The equipment must be validated thoroughly before blood is stored in the equipment.

6

Organizing the blood cold chain

Blood is donated in order that lives may be saved. It is extremely precious. It is the responsibility of everyone in the blood bank to make sure that the red cells and plasma are kept in such a way that their life-saving properties are preserved.

Donated blood passes through various stages from collection to transfusion. In order to manage the blood inventory efficiently and safely, it is necessary to have different types of cold chain equipment and a system in place for organizing the movement of blood. The purpose of this section is to explain how the successful organization of the blood cold chain programme depends on the availability of adequate cold chain equipment, its care and appropriate use, as well as a system for coordinating the series of processes.

LEARNING OBJECTIVES

When you have completed this Section you should be able to:

- Describe the stages and procedures involved in the movement of blood from donation to transfusion.
- Describe the cold chain and equipment required at each organizational stage.
- Describe the procedures necessary to ensure a safe blood cold chain.
- Identify a system for managing the inventory of blood.

6.1 The structure of a national blood transfusion service

If the national blood transfusion service (BTS) is hospital-based, the hospital blood bank is usually responsible for blood collection, testing, processing and distribution within that hospital. Blood banks may also crossmatch and issue blood to the hospital ward according to the agreement in place.

If the national BTS is organized with central and regional services, then the central BTS usually collects, processes and distributes blood for the populations in the main urban centres. Similarly, regional (and sometimes provincial) BTS will perform these functions for the populations at those levels.

A safe and effective blood cold chain is therefore more important in the second scenario because of the need to distribute blood outside the centre and for a longer time span.

ACTIVITY

Draw the structure of the national blood transfusion service in your country. Identify:

- the route of movement of blood from collection to transfusion;
- the cold chain equipment that would be required.

6.2 Activities of the blood bank

In order to manage the inventory in the blood bank, a management system needs to be in place that covers all the activities of the blood bank, which may include the following: blood collection, testing and processing, storage, and distribution of the blood and blood products. Some blood banks simply receive processed and tested blood and blood products for local use or further distribution to smaller blood banks or clinics. In the text below it is assumed that the blood bank does all the activities.

The **Donor Clinic** maintains a record of all donors and donations, assigns a number and the expiry date of the donation, and collects laboratory samples at the time of the donation. The **Component Production Section** of the laboratory receives a list of all donations, the blood packs and the donor samples from the donor clinic. After processing to obtain components, the blood is held in quarantine here until laboratory tests have been completed by the Laboratory Testing Section.

The **Laboratory Testing Section** receives a list of the samples as well as the samples themselves in sequence from the component production section. The donor clinic's records, registers and enrolment forms are invariably then returned to the donor clinic since it is the clinic that will inform the donor of the test results.

The **Blood Storage Section** receives the blood released from quarantine that has been approved for use by the quality assurance officer, based on the laboratory test results and quality of the blood components. This blood is kept as available stock in the appropriate cold chain equipment.

Plasma derivatives may be locally produced or imported, and these can only be made available after the quality assurance officer has accepted them for routine use.

Finally, the blood bank may produce some of the reagents needed for testing, or may purchase these externally.

The storage and handling of plasma derivatives and reagents is an important activity of the blood bank, for which dedicated cold chain equipment is required.

The **Compatibility Laboratory** is responsible for crossmatching and the issuing of compatible blood to hospital patients.

ACTIVITY

List the different Sections in your blood bank, and which activities fall under each Section.

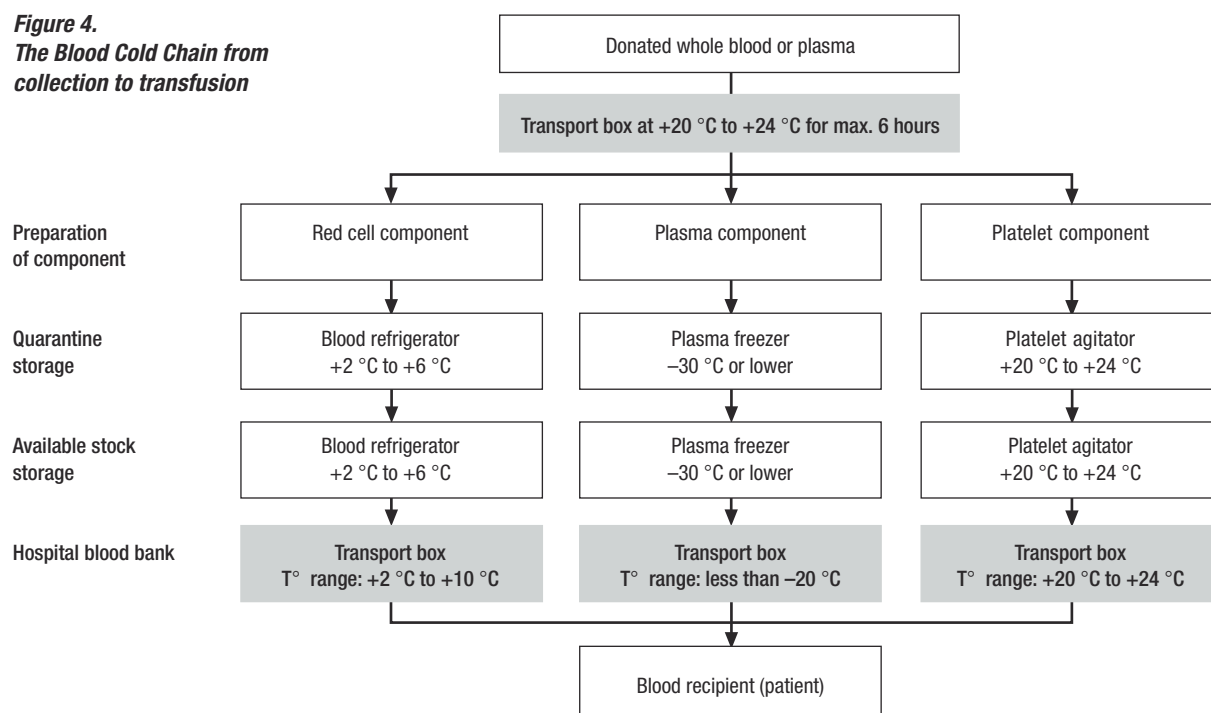
6.3 Critical stages in the movement of blood from collection to transfusion

The following steps are recognized as essential in the movement of blood from collection to transfusion:

- Packing and transportation.
- Receipt and handling of incoming, unprocessed blood and plasma derivatives.
- Receipt and handling of processed blood.
- Quarantine policies and procedures.
- Labelling of products.
- Method of storage of blood components in available stock.
- Release of blood components for use.
- Procedures for thawing of frozen plasma or cryoprecipitate.
- Procedures for the release of platelet concentrates.
- Discarded blood and its safe disposal.
- Monitoring the blood inventory.

Figure 4 below shows the movement of blood from collection to transfusion. If a blood bank has the capacity to prepare components, then it is important to ensure that the blood is kept between +20 °C and +24 °C.

Figure 4.
The Blood Cold Chain from collection to transfusion



Otherwise, it is recommended that the blood is transported in cold transport boxes, especially in countries with high ambient temperatures and humidity, as is often the case in tropical countries. Blood or blood components are stored in quarantine and moved into available stock refrigerators or freezers after the quality assurance officer has released them. Blood leaving the blood bank storage, e.g. for use at another hospital or for a patient within the hospital, must be moved using appropriate blood transport boxes.

6.3.1 Packing procedures for transportation

All biological products need to be appropriately labelled to facilitate the intended mode of transport, including their packing requirements (e.g. International Air Traffic Association (IATA) regulations must be followed for air freighting of blood). Coolants for cold transport boxes may be purchased from manufacturers, or made locally from plastic containers such as unused transfer or satellite packs filled with water and frozen, **provided they are well sealed**. They may, thus, be reused many times, as they can be refrozen. However, platelet coolants are different in that they are expected to maintain a temperature of approximately +20 °C to +24 °C as is required for platelet storage. Platelet coolants have to be maintained according to the manufacturer's instructions.

The quantity of coolants, usually ice packs, used to maintain an acceptable temperature in transit is determined by the quantity of blood to be placed in the cold transport box, the time to destination and ambient temperatures. Usually, the quantity required is determined experimentally by each blood bank.

It is important to ensure that the transport box is at the desired temperature prior to loading the blood components.

Ice packs for frozen plasma packs are usually used to assist in the maintenance of the temperature in transit, because they are more likely to melt first before plasma because of the nature of water compared to plasma. As stated above, the actual quantity required per transport box has to be determined. In countries where dry ice is available this is usually the product of choice for maintaining the plasma packs at the desired temperature. However, note that for air transportation this may **only** be done with the consent of the airline.

A temperature monitoring device such as an electronic temperature data logger or maximum/minimum thermometer should be placed in the transport box.

The consignment requires two persons to cross check the paper work in order to ensure that possible clerical errors are avoided, as they can be expensive to correct after the blood has been despatched. Errors impact negatively on the quality system and every effort – such as double-checking – must be made to prevent them from occurring.

Finally, when withdrawing blood from the blood bank, the supervisor is responsible for a visual check of the blood component for acceptable appearance, expiry dating, blood group labels and possible leakage from the pilot tube or other. The supervisor is also responsible for ensuring a

reasonable mix of blood with short, medium and long expiry dates in the transport box as part of good stock management.

ACTIVITY

Using the maximum quantity of specially-labelled expired blood* per box and a temperature-monitoring device (e.g. a maximum/minimum thermometer), estimate the appropriate quantity of ice packs necessary to maintain the correct temperature of the blood units to their destination by available transport. The exercise requires the cooperation of the laboratory receiving the consignment to check the max/min temperatures attained. The acceptable temperature throughout shipment is **between +2 °C and +10 °C**. This exercise may be repeated with the main blood bank receiving the shipment from an outstation blood bank.

As a general guide, assuming an insulation thickness of about 8 cm all round, six ice packs are adequate to maintain a temperature below +10 °C of 40 blood packs for up to 20 hours, *provided that* the transport box and contents are already at +4 °C at the time of packing, the ice packs are frozen solid, and the ambient temperature is between +20 °C and +30 °C.

* N.B. In an ideal situation, there should be no expired blood

6.3.2 Receipt and handling of incoming, unprocessed blood and plasma derivatives

Blood is a highly perishable product and a good medium for the growth of bacteria. Blood is collected in sterile containers after disinfection of the venepuncture site to minimize bacterial infection. To eliminate, or reduce this risk and/or haemolysis of the donated blood pack, it is important that **all** blood received in the blood bank is handled with extreme care and attention.

Blood is received in the blood bank in two main ways: from a mobile donor clinic session or from donor visits to the blood bank clinic.

Blood received from donors visiting the blood bank clinic is generally kept at room temperature until there is enough quantity to process, which largely depends on the centrifuge space. The decision on when to process the blood also depends on whether it is intended to make components, or if the rate of blood collection at the centre is sufficient.

Here, we will concentrate on issues related to the arrival of blood from mobile units, since bulk quantities are more likely to cause problems.

The following steps have to be carried out and certified as having been verified:

- Compare the time the blood was received in the blood bank with the time of the first donation at the clinic. The time interval should **not** exceed 8 hours if the blood is to be used to make labile components such as fresh frozen plasma.
- Check the actual blood packs received against the donor clinic records, i.e. the donor clinic register and the donor enrolment forms received.
- Check that the donation number on the sample attached to the unit matches that of the blood pack.
- Check the temperature of the blood packs on receipt, e.g. from maximum/minimum thermometers placed in the transport boxes.

- Check the plasma derivatives and reagents against the delivery order and store at the recommended temperature.

The samples are separated from the blood packs and put in sequence in a tray, and the laboratory lists of samples to be tested are packed together with the samples, and sent to the laboratory for tests to be carried out. The blood packs are then processed according to standard operating procedures in force in the blood bank.

A component production list is generated based on the blood packs received and all components produced.

Finally, all units are stored in quarantine until released by the quality assurance officer.

6.3.3 Receipt and handling of processed blood and blood components

Upon receipt of processed blood and blood components, the temperature of the contents should be verified immediately upon opening the box. The container should be inspected to ensure that it is intact and that the label is complete, securely fixed and legible.

A description of the component, source, date and time received and expiration date should be recorded, as well as any abnormalities detected. Processed blood components may be provided to hospital blood banks from the main central blood bank. BTS regional blood banks may also send processed blood to the main central blood bank. If the consignment is acceptable, the blood packs should be included in the inventory of blood at the centre.

6.3.4 Quarantine policies and procedures

As part of quality management of the blood bank, the quality policies form the basis for the various procedures undertaken. Placing blood packs that are undergoing processing and testing in quarantine is fundamental to good management of the inventory. The basic policy on management of a quarantine facility is to identify who has the responsibility to accept and/or release the products from quarantine. Furthermore, in order to ensure space for incoming blood products and the demands of the blood issue department, the time limit that blood can stay in quarantine needs to be clearly defined so that components are released regularly for use.

The quarantine refrigerator is normally kept locked. Officers who have authorized access to the quarantine refrigerator must record their name, the date and time of access and what action was taken. In particular a record of the units received or released from quarantine must be recorded.

Before blood or blood components are released from quarantine into available stock, they should always be inspected for any signs of deterioration, including:

- any sign of haemolysis, indicating that the blood has been contaminated, allowed to freeze or become too warm.
- any other sign of bacterial contamination, such as a change of colour in the red cells, which may look darker or purple/black when contaminated.

- any clots, which may mean that the blood was not mixed properly with the anticoagulant when it was collected.
- any signs that there is a leak in the pack or that it has already been opened.
- air in the pack.

In the case of frozen plasma, it is important to inspect for the following:



Blood pack showing signs of haemolysis

- Cracks in the plasma packs.
- Any evidence of the plasma thawing.

Platelet swirling phenomenon, due to the light scattering effect of normal platelets in movement, can be used as a quality control procedure, or as a routine check before issue.

If any of the above problems are identified, the supervisor or quality officer should be informed immediately.

Look at the image on the left in which the unit appears haemolysed. This shows the importance of always carrying out a visual inspection of the pack so that unsuitable units are not processed or used.

ACTIVITY

Note how different blood components are stored in your blood bank.

Is there adequate separation of components in different phases of preparation? If yes, document how this is done, in your notes. If not, discuss this with your supervisor and propose labelling and the segregating of units within the existing storage areas.

6.3.5 Labelling of products

The important information displayed on a blood component label is as follows:

- Temperature of storage
- Date blood was collected
- Expiry date of the component prepared
- Blood group (ABO + Rh(D)) of the blood component
- Donation or pack number
- Name and volume of the anticoagulant solution
- Name of the blood bank producing the component.

This information is put on the label after the quarantine procedure. The batch number of the blood pack is already permanently affixed by the manufacturer.

6.3.6 Method of storage of blood components in available stock

Blood components should be stored in date order according to the date of expiry, when they are in quarantine as well as when they are in the available stock section. The blood is stored in an orderly way in the re-

frigerator or freezer for ease of access, and also to ensure that blood and blood products with an earlier date of expiry are used first. This principle equally applies to the storage of plasma derivatives and laboratory reagents. It is also convenient to store blood components according to ABO blood group and Rh type when they are in the available stock refrigerator. A record of all the blood components in quarantine or available stock should be created and updated daily (see Figures 5 and 6).

6.3.7 Release of whole blood/red cells for use from available stock

Available blood stock is blood and blood products that have been processed, grouped and tested non-reactive for transfusion-transmissible infections (TTIs) and passed for use by the quality assurance officer. Blood is released upon a request from another blood bank or crossmatch laboratory. All issues from available stock are logged out. The cold chain equipment storing available stock is kept separate from equipment containing quarantine stock, and is under the Section head responsible for despatch, i.e. for releasing the blood components to other hospitals or directly to the compatibility laboratory section. The inventory of blood and blood products has to be maintained and checked frequently during a working day because blood is constantly being issued. It is from this list that it is possible to do an audit and calculate average and/or total blood use on a daily or monthly basis. Available plasma derivatives and laboratory reagents also fall under the control of the officer responsible for product issues.

The available stock list is thus an indispensable component of blood inventory control.

6.3.8 Procedures for thawing and releasing frozen plasma and cryoprecipitate

Frozen plasma or cryoprecipitate may be thawed only when transfusion is absolutely certain. This is because some clotting factors such as Factor VIII and Factor V are labile and may deteriorate rapidly if kept unfrozen for long, even in the refrigerator.

Blood group specific (if required) frozen plasma pack(s) or cryoprecipitate is retrieved from the plasma freezer. The pack number is recorded in the “blood issue register” and the date and time of thawing is recorded in the register and on the pack. The plasma pack is then put in a plastic overwrap made waterproof before immersion in a waterbath at maximum +37 °C dedicated for this purpose or in a plasma thawer. Observe any evidence of leakage as the plasma thaws, and if no leakage is detected, forward the pack to the ward.

Thawed plasma may be kept for a maximum of 6 hours at +4 °C before transfusion if it is intended to ameliorate a coagulopathy.

6.3.9 Procedures for the release of platelet concentrates

Platelets should be kept in a designated quarantine platelet agitator. Since platelet concentrates have a short shelf life (3–5 days), it is important to ensure that the inventory is regularly monitored to prevent wastage.

6.3.10 Discarded blood products and their safe disposal

Blood and blood products are generally discarded by personnel if they do not meet the specifications required during collection and preparation of a component, or as a result of laboratory testing. Laboratory personnel should also mark for disposal blood units that have been returned by the ward staff and does not meet the criteria for reuse. Blood held in stock that expires before use also has to be marked for disposal and accounted for. In summary, the following are examples of blood units that must be marked for disposal:

- Units which have tested positive for infectious agents.
- Unsuitable products, such as under- and overweight blood packs, or those where the temperature range has not been maintained.
- Discarded products: e.g. expired units.
- Blood returned unused but unsuitable for reissue.
- Blood packs in which leaks have been detected.

There should be a mechanism in place for reporting wastage of blood so that steps can be taken to prevent its recurrence.

Secure and exclusive quarantine storage must be available for blood units awaiting disposal. These units need to be recorded as blood products awaiting disposal as they form part of the managed inventory. In general, two persons must agree and ensure that the correct blood product marked for disposal has indeed been identified before being discarded. This is most important because every blood unit and any of its components or plasma-derived products must be fully accounted for. The final disposal of discarded blood products has to be authorized by the quality assurance officer.

Discarded blood components must not be left at room temperature, but should be stored in a designated refrigerator to minimize bacterial growth. It is also important to keep discarded products under a security lock to reduce the risk of abuse and prevent access by unauthorized persons.

Units discarded because of unsafe storage (see also 6.4.4)

When it is necessary to discard whole blood or red cells because they show signs of haemolysis or contamination, it is important to establish why this has happened. If the blood was sent to you from a blood transfusion centre or another hospital, you must inform them as soon as possible so that they can improve their system for issuing and transporting blood. Always remember to let them know the time the blood arrived and the temperature inside the container on arrival.

If the blood has been collected and stored in your blood bank, you must try to track the unit back to the point when it was collected to see if everything was done correctly, and identify the cause of the problem.

If you find that blood or plasma is not being kept at the correct temperatures during transportation, there are several things you could do to prevent this from happening in the future.

- Check that the transport box meets WHO minimum performance specifications.
- Check that the ice packs are completely frozen when the box is packed.
- Add more ice packs if the weather is very hot or the blood or plasma has to travel a long distance.
- Make sure that the transport box/container is securely sealed.

Blood products need to be safely treated and disposed of in an environmentally friendly way. Steam sterilization (autoclave) should be the preferred option (+121°C for 20 minutes). When incineration remains the only option, then high temperature pyrolytic incinerators (>1200°C) would be appropriate. Blood transfusion bags contain above 50% of polyvinyl chloride (PVC) and their incineration at low temperatures generates products of incomplete combustion such as dioxins or furans. The management of waste must be carried out professionally as part of the quality management of the blood transfusion programme.

Disposal via the laboratory sink or underground drains is strongly discouraged without prior disinfection with a chlorine-based solution and neutralization of potentially infected effluents into a buffer tank. In any case the blood establishment drainage system should be connected to the sewerage or to a soakaway pit, taking into consideration that a minimum distance of 30m must be respected with existing water sources.

6.4 Monitoring the blood inventory

6.4.1 Theoretical count

It is possible to calculate the stock on the basis of the available stock, receipts, and the delivery notes of blood issued for use. Similarly, it is possible to calculate the amount of blood accepted in quarantine on the basis of the receipts of donated blood, and that issued from quarantine to available stock. It is thus possible to calculate on a daily or monthly basis the theoretical stock level. However, as the method suggests, it can only be theoretical until a physical count is done of the actual stock. Ideally, the two figures should match, but they can differ for a variety of reasons, some of which are:

- Withdrawals are not carefully recorded by blood group or donation number.
- Blood released is not properly recorded.
- Blood returned to available stock has not been re-entered in the records.

Efficient management of the inventory improves blood safety because, for example, products not suitable for transfusion are accounted for and withdrawn from routine use. On the other hand, unsatisfactory management of the inventory can lead to the risk of an unsuitable blood product being transfused in error with disastrous consequences, especially if the reason for discard was an infected product.

6.4.2 Physical count

Taking a physical count of stock is a common procedure in any organization. Many of us hear of a shop or factory closed for stock taking for a day or longer. During this period the company is doing a physical count of all stock held. A factory has to check all raw materials, material still not passed for use and finished products at hand. This is the same for the inventory control of blood and blood products. If the physical count does not match the theoretical count, an investigation should be carried out to establish the reasons for the discrepancy.

6.4.3 Daily blood bank report

A daily blood inventory form gives the manager of the blood bank the overall picture of blood collection and how much has been released from quarantine to available stock. It also shows how much has been released for crossmatching and transfusion from the available stock. The daily blood bank sheet is usually completed at the beginning of the day so that staff know what is available for use. An example of an inventory form of available blood appears in Figure 5. Careful design of the form will enable a clerk to do an effective theoretical and physical count daily.

6.4.4 Unused blood components

Blood and blood products returned to the blood bank must be recorded in the “returned to stock” or “discard” register depending on whether the set criteria are met, or not, respectively. This enables the blood bank to trace any problems arising from transfusion of the product or follow up information from the ward about the blood product. The blood returned to stock thus affects the inventory. An unused component should therefore never be discarded at ward or theatre level, even if the patient has died or the pack has already been spiked, but no infusion has been commenced. A permanent record is created for every unit of blood that has been processed by the hospital transfusion laboratory and issued for transfusion. If the component is not returned to the laboratory, it will be assumed that it has been transfused to the patient for whom it was issued. It may be essential at a later date to identify all recipients of blood components from a particular blood donor, e.g. if the donor is subsequently diagnosed with an infectious disease that can be transmitted by transfusion, and this could have been undetected (in the window period) at the time of the previous donation.

Red cell packs

Red cell packs may be returned to the laboratory unused. However, whether to discard these packs or return them to available stock depends on the criteria for the acceptance of returned blood based on the quality policy. This policy is important and must be clear to all so that blood that has not been kept safely outside the blood bank – in terms of temperature and/or length of exposure to the temperature, or where the hermetic seal has been broken – cannot be reissued and cause harm to the recipient.

Fresh frozen plasma (FFP) and cryoprecipitate

FFP and cryoprecipitate that has been issued but not used must be returned to the hospital transfusion laboratory for disposal. These components cannot be refrozen or reissued to another patient.

Platelets

Platelets that have been issued but not transfused should be returned to the hospital transfusion laboratory. It is essential that platelets are not refrigerated during the period they are removed from the blood bank so that, if unused, it may be possible to reissue them to another patient.

Figure 5. Daily inventory of available blood stock

Date: Time: Signature:

		Analysis of stock				
		Rh POSITIVE		Rh NEGATIVE		
		WB	PC	WB	PC	TOTAL
	Previous day opening stock					
plus	Previous day stock received from quarantine					
plus	Blood units received from branches	0				
		A				
	<u>Total available stock</u>	B				
minus	Issues to hospitals	AB				
minus	Expired or other	TOTAL				
	<u>New available stock</u>					

A similar inventory can be established for blood in quarantine (Figure 6).

Figure 6. Daily inventory of blood stock in quarantine

	Previous day opening stock:	_____
plus	Previous day collections from:	_____
	HQ	_____
	Mobile 1	_____
	Mobile 2	_____
	Mobile 3	_____
	Mobile 4	_____
	<u>Subtotal previous day collections</u>	_____
minus	non-serological discards	_____
minus	serological discards (HIV, Hep B)	_____
minus	issues to available stock	_____
	<u>Closing stock in quarantine carried forward</u>	_____

ACTIVITY

If your blood bank uses similar forms to those above, make sure that they contain all the elements listed. If not, design a form for use in your blood bank.

Then, based on your form, establish the available stock in the blood bank for issue today.

Table 11. Standard operating procedures to manage all stages of the movement and storage of blood

The following are examples of standard operating procedures that should be available in your blood bank.*

Working process	Examples of standard operating procedures required
RECEPTION OF INCOMING STOCK	<ul style="list-style-type: none">• Reception of incoming unprocessed blood• Reception of processed blood components
STORAGE	<ul style="list-style-type: none">• Storage of blood prior to processing• Storage of blood in quarantine:<ul style="list-style-type: none">— Fresh frozen plasma— Cryoprecipitate— Platelets— Whole blood or red cells• Storage of blood in the wards• Storing ice packs and coolant pouches/plates
MANAGING THE BLOOD INVENTORY	<ul style="list-style-type: none">• Release of components<ul style="list-style-type: none">— from quarantine to available stock— from available stock to the hospital ward• Inspection of blood components prior to release• Handling of blood/blood components within hospital• Returning blood into stock• Preparing daily inventory of blood• Safe disposal of discarded blood
PACKING AND TRANSPORT	<ul style="list-style-type: none">• Packing/Transport of<ul style="list-style-type: none">— Whole blood or red cells— Platelets— Frozen plasma and cryoprecipitate
USING BCC EQUIPMENT	<ul style="list-style-type: none">• Installation of refrigerators and freezers• Temperature monitoring of equipment• Validation prior to use of<ul style="list-style-type: none">— Refrigerators and freezers— Cold rooms and freezer rooms— Platelet agitators• Appropriate use of<ul style="list-style-type: none">— Refrigerators and freezers— Platelet agitator— Cold/freezer room• Responding to power outages (cuts/failures)• Changing temperature charts• Checking and adjusting glycerol levels for blood bank refrigerators and freezers• Defrosting and cleaning a blood bank freezer• Preventive maintenance of BCC equipment• Disposal of equipment

* See also Section 7, Table 15

ACTIVITY

Make a list of all the standard operating procedures available for handling blood from collection to transfusion at your blood bank. If the list is different to that above, identify which additional documents you require.

6.5 Model list of essential blood cold chain equipment

The following cold chain equipment with appropriate temperature monitoring devices are classified according to their essential function. Note that the quantity and capacity of the cold chain equipment needs to meet the volume of blood components collected and processed at the blood bank (see Section 3, Tables 5 and 6 for how to assess your equipment needs).

Equipment for the movement of blood

- Blood transport boxes.
- Ice packs.
- Temperature monitoring devices.

Quarantine equipment

- Blood bank refrigerator(s) to hold blood undergoing processing before it is released for use.
- Blood plasma freezer(s) for storing plasma components, cryoprecipitate or serum.
- Platelet agitator(s).

N.B. It is necessary to lock the quarantine cold chain equipment. **Only** designated persons are given access/responsibility for these facilities.

Equipment for holding available blood stock

- Blood bank refrigerator(s) to hold blood available for issue.
- Blood plasma freezer(s) for storing plasma components, cryoprecipitate or serum.
- Platelet agitator(s) for storing platelet concentrates (+20 °C to +24 °C).
- Temperature recording devices/alarms.

Equipment for other activities

- Freezer and refrigerator for holding laboratory reagents.
- Facility for storing plasma derivatives. This may be a refrigerator or room with an acceptable ambient temperature depending on the recommended storage conditions.
- Plasma thawer.
- Refrigerator to hold units crossmatched for collection/delivery to the patient.
- Separate refrigerator, or locked compartment in a refrigerator for holding products unfit for use, i.e. products waiting to be discarded.
- Standby generator in case of power failure. The generator may be dedicated to the blood bank, or the blood bank equipment may be wired to the hospital emergency power supply.
- Voltage stabiliser or regulator, in areas where voltage fluctuations or power cuts are common.

- Finally, provision of back up cold chain equipment and a **contingency plan** to handle components if, for example, a quarantine refrigerator breaks down.

6.6 Ensuring the blood cold chain during the issuing of blood

Requests for blood components are received daily from the hospital wards and other hospital blood banks. Blood is released after receipt of a requisition detailing the quantity and type of product required, and is then issued if the available blood stock permits.

Ideally, the person responsible for inventory management prepares a list of components and other products that can be issued based on the **inventory** of available stock. A record is made of the units issued according to expiry dates and blood group. The blood is then immediately removed from available stock and put in the cold transport box ready for despatch. This is a much better system with regard to the integrity of the cold chain than opening the blood bank refrigerator to verify available stock and in so doing allowing cold air to escape and warm air to flow in. A computerized inventory management makes this task even simpler and more accurate.

It is discouraged to withdraw first the blood from the available stock refrigerator, lay it on the bench at room temperature and proceed to record the units to be issued. The cold chain is at risk of being broken because of the time taken to do the clerical work.

The removal of a blood unit from the refrigerator, or its return to the refrigerator can be documented electronically or manually. As a minimum, the following information should be recorded:

Table 12. Potential breaks in the blood cold chain (see also Table 17)

Reason for break	Cause
Inappropriate use of the equipment	<ul style="list-style-type: none"> i) Overloading of refrigerator causing a slow cooling down time ii) Excessive door opening of refrigerator or freezer iii) Inadequate ice packs in transport box for the distance travelled iv) Lid of transport box not well secured v) Time to destination of transport box excessive vi) Too many ice packs for few blood packs in a transport box, leading to freezing of components
Technical fault of the equipment	See Section 7.2.1, Table 17
Working environment not temperature controlled	<div> <div>Red cell units left exposed at high room temperature for too long</div> <ul style="list-style-type: none"> i) On the bench, during component preparation and crossmatching ii) During labelling of components iii) Equipment breakdown, e.g. refrigerated centrifuge, resulting in delays in processing blood iv) Delay in transfusion in the ward v) Failure to set up infusion set vi) Patient not available as expected vii) Slow rate of infusion if more than 1 unit collected from blood bank at a time </div> <div> <div>Red cell units left exposed to very cold temperatures</div> <ul style="list-style-type: none"> i) Technical fault of the equipment (thermostat) which allows freezing temperatures to be reached in refrigerators ii) In-built freezer room door connected to cold room left open </div>

- Donation number of the pack
- Blood group
- Expiry date
- Date and time of removal/return
- Signature.

This ensures that the ‘30-minute rule’ can be adhered to and monitored, i.e. where blood should not be outside its temperature range for more than 30 minutes.

6.7 Withdrawal of blood from the blood bank, transfusion service or a satellite refrigerator

The withdrawal of the wrong pack from its storage location is one of the major causes of transfusion of the incorrect blood component. The procedure for checking you have the right blood component is the same regardless of whether you are collecting blood from the hospital transfusion laboratory or from a satellite refrigerator in the clinical area.

The transfusion laboratory will only issue a blood component on receipt of information (on the collection slip, addressograph label, patient case notes or prescription form) bearing sufficient identification details about the patient that match the patient compatibility label on the component pack. Such details may include:

- Family name
- First name(s)
- Date of birth
- Hospital identity number
- Ward.

If there is any discrepancy between the patient details and the pack labeling, the blood should not be issued until the discrepancy is resolved.

Summary

In this Section, you have learnt the following:

- The different structures of the national blood cold chain.
- The sub-processes involved in the blood cold chain, e.g. handling unprocessed or processed blood.
- Awareness that the activities of the blood bank will contribute to an efficient system for managing the blood inventory.
- Items in quarantine should be placed in separate, locked equipment, only accessible to authorized personnel.
- How to establish a daily inventory of blood stocks.
- The documentation required to monitor the blood bank inventory.
- A list of the essential cold chain equipment required to manage blood stocks.

- Blood should always be checked for haemolysis, contamination or other signs of deterioration: before it is transported, on arrival in the blood bank, before it is issued and before it is transfused. If any signs of deterioration are present, the unit must be discarded.
- Fresh frozen plasma and cryoprecipitate should **never** be thawed in water above +37 °C. Once thawed, it should be transfused as promptly as possible. If a delay is anticipated, plasma must be stored at +2 °C to +6 °C and transfused within 24 hours (or within 4 hours in the case of cryoprecipitate).
- The blood cold chain can be broken at any point; thus it is important that all steps are monitored.

7

Preventive maintenance, care and repair of equipment

Blood cold chain equipment requires minimal maintenance if correctly installed and cared for. The routine preventive maintenance procedures recommended by the manufacturer must be observed in order to reduce the “down time” on the equipment. There is considerable variation in the level and complexity of equipment used in the blood bank. Although it is thought that more sophisticated equipment requires less attention, the opposite is often true. All equipment needs regular maintenance, if only once a year for certain items, to ensure that it is working as efficiently and reliably as possible.

This Section provides the reader with some basic information on the care of blood cold chain equipment, and how to organize effectively its preventive maintenance and repair.

LEARNING OBJECTIVES

When you have completed this Section, you should be able to:

- Organize an equipment maintenance system for blood cold chain equipment.
- Undertake the basic care and preventive maintenance of refrigerators and freezers.
- Describe the basic maintenance requirements of other blood cold chain equipment.

7.1 Organizing an equipment maintenance programme

Step 1: Create records

The **Care and Preventive Maintenance Form** should be completed for routine maintenance of the equipment carried out by the blood bank staff. All maintenance and calibration should be recorded, together with any follow-up action taken, since this is part of the quality system. A **Repair Record Form** should also be developed for whenever the equipment is sent for external maintenance or repair.

The forms are straightforward, but are very important tools in the blood cold chain and, indeed, in all laboratories.

Table 13. Routine Care and Preventive Maintenance Form

ROUTINE CARE AND PREVENTIVE MAINTENANCE LOG			
REFRIGERATOR MAKE AND MODEL:			
Location:	Equipment Code:	Manufacturer:	Serial No:
Date Installed:	Power Rating:	Gross Volume/Weight:	Signed:
Date (Day/Month/ Year) and Time (am/pm)	Maintenance Performed (Note SOP No.)	Comments	Operator initials

The Routine Care and Preventive Maintenance Log should be completed regularly following the Standard Operating Procedures set up by the Blood Bank, noting any further action needed to rectify problems identified.

Table 14. Repair Record Form

REPAIR RECORD			
FREEZER MODEL AND MAKE NO:			
Location:	Equipment Code:	Manufacturer (Make and Model):	Serial No:
Date Installed:	Power Rating:	Gross Volume/Weight:	Signed:
Date Fault Reported:	Description of malfunction:*	Date Referred:	Referred To (note supplier or other):
Reported by:	Complaint No:	If urgent , what action taken?	Under warranty?
Date repaired:	Description of service:	Cost of service and spare parts:	Name and contact details of repair engineer:
Date back in service:	Tested after repair?		Name and Signature of Responsible Officer

* Common examples of equipment malfunction include compressor fault, refrigerant gas leakage, corrosion of equipment, ice build-up, defective door sealing, faulty temperature monitors, faulty switches (e.g. circulating fan) or faulty thermostat. Note whether user-related malfunction or other (e.g. power surge or poor maintenance).



Laboratory technician completing the Routine Care and Preventive Maintenance Log

These meticulous records of the maintenance, servicing and repair of all cold chain equipment will be useful in identifying whether or not the equipment has consistently performed to expectations. The selection of equipment in the future may depend on this, and it is therefore important for senior staff to ensure that the users of each piece of equipment maintain such equipment records.

Step 2: Develop standard operating procedures (SOPs) for the preventive maintenance of blood cold chain equipment

The need for standardized procedures to ensure quality has been explained in Section 6.4, Table 11. The manufacturer should provide a manual with each piece of equipment in which a basic maintenance schedule is recommended. It is important that the senior laboratory officer in charge reads the manual and uses it to strengthen existing SOPs on routine care, maintenance and repair of the equipment, or develops new SOPs dedicated to that equipment.

Below is a list of SOPs that may be required, followed by an example.

Table 15. List of SOPs needed for preventive maintenance of blood cold chain equipment

- | |
|--|
| • Monthly alarm and battery checks |
| • Preventive maintenance of blood bank refrigerators |
| • Preventive maintenance of blood bank freezers |
| • Preventive maintenance of platelet agitators |
| • Preventive maintenance of plasma thawers |
| • Weekly maintenance of transport boxes |
| • Maintenance of generator |
| • Defrosting and cleaning a blood bank freezer |

Table 16. Example of a Standard Operating Procedure

Name of Facility: <i>Blood Centre XXX</i>	
SOP Number: ABC-1	
Title: Preventive Care and Maintenance of Blood Bank Refrigerator Model xxx	
Revision number: 2 ¹	
Written by	Edited by
Authorization signature	
Department (QA/QC)	Date
Effective date: 1 Jan 2005	Replaces Revision 1 dated: 2 Jan 2003
1. Purpose and scope	
This procedure explains the care and preventive maintenance needed for all refrigerators in the blood component laboratory	
2. Responsibility	
<ul style="list-style-type: none">• The blood component technologist is responsible for the correct operation, routine maintenance or setting, and cleaning and disinfecting of the refrigerator• The laboratory manager is responsible for ensuring that the corresponding report is completed according to the procedures.• The maintenance department is responsible for adjustments and repairs to the refrigerator; for performing the yearly calibrations; assessing the need for re-calibration after repairs; and for recording them in the Routine Care and Maintenance Log (or the Repair Record if the equipment has been sent for repair).	
3. Materials and Equipment	
<ul style="list-style-type: none">• Blood Bank Refrigerator• Cleaning solutions: AA, BB• Routine Care and Maintenance Log	
4. Procedure	
4.1 Weekly maintenance	
<ul style="list-style-type: none">• Wash interior surfaces and shelves using the cleaning solution prepared during the last month.• Check air circulation and door seals.• Check batteries and alarm systems.	
4.2 Monthly maintenance	
<ul style="list-style-type: none">• Prepare a fresh solution of the cleaning reagent each month.• Check the condenser and compressor are clean. Remove dirt or dust with a soft brush or cloth, or use a fine comb.• Check that the alarm goes off when the temperature is lower than +2 °C or higher than +6 °C:<ul style="list-style-type: none">a) put the thermocouple or temperature sensor into a bowl of ice and place it inside the refrigerator. A few spoonfuls of salt in the bowl will quickly lower the temperature to less than 0 °C. Close the door and note the time and temperature when the alarm is set off. Remove the bowl and note the temperature when the alarm stops.b) put the thermocouple or temperature sensor into a bowl of water between +12 °C and +15 °C using an ordinary thermometer. Place in the refrigerator, close the door and note the time and temperature when the alarm is triggered.• Check and adjust glycerol level.	
4.3 Quarterly maintenance	
<ul style="list-style-type: none">• Check door seal gasket.• Check door switches.	
5. Reporting	
<ul style="list-style-type: none">• Record information in the Routine Care and Maintenance Log (date, time, description of care and cleaning products used, and technician's initials).• Report all problems in the operation of the refrigerator immediately to the supervisor.	
6. Related Documents	
SOP No. on Preparation and Testing of Cleaning Solutions.	

¹ Must be reviewed at least once every two years.

ACTIVITY

Study the list of standard operating procedures for routine care and maintenance and the example above.

- (i) identify which SOPs exist in your Centre
- (ii) draft an SOP for the procedures that are lacking

7.2 Basic care and preventive maintenance of blood cold chain equipment and accessories

7.2.1 Blood bank refrigerators and freezers

Most faults on refrigerators and freezers are a result of poor care and maintenance by the user. We should take note of the following hints:

- i) Do not push your appliance against the wall where the condenser part touches the wall, thus preventing proper ventilation. It is recommended that you leave space behind your refrigerator/freezer to allow air to circulate freely and carry the heat away from the condenser.
- ii) When defrosting, switch the appliance off and remove the plug. **Never** use sharp objects such as a knife to poke or dig ice from the freezer compartment, which could lead to punctures whereupon refrigerant is released. Most evaporators are made of aluminium, which is very soft and punctures easily. Replacement of the gas is costly.
- iii) When transporting the equipment to another room or building, do not place the refrigerator on its back since oil from the compressor may be forced into the pipes. Stand it in an upright position to avoid disturbances of the gas circulation in the unit.
- iv) Do not fill the refrigerator or freezer too tightly as this limits internal air circulation, causing uneven cooling and excessive running of the compressor, which could lead to burn out.
- v) Ensure that the door seal gasket is sealed at all times, and do not adjust the thermostat or switch it off at night. It automatically regulates itself, switching itself on and off to keep internal temperatures constant within the preset range.
- vi) When closing refrigerator doors, do not bang them shut, because the door gaskets will lose their magnetism and fail to close the confined space tight, resulting in overworking of the compressor.
- vii) Doors should not be kept open for too long. Blood packs or plasma should be removed from or placed in the cabinet quickly.
- viii) Make sure that the door switch is in good operating order. It should switch off the cabinet light when the door is closed.
- ix) Only skilled personnel should undertake repairs, modifications or adjustments.
- x) Temperature chart recorders should be changed when due, e.g. 24-hour or 7-day records. It is important to ensure the chart is in motion and the pen is tracing. The date of change should be written on the chart.

Table 17. Common problems with refrigerators and freezers

Trouble	Common Cause	Remedy
General		
Equipment does not run	Not switched on Blown fuse Low voltage	Check power supply Check fuse Refer to electrician
Compressor runs continuously	Not enough circulation around unit Faulty thermostat Poor door seal Room temperature too warm Defective light switch Excessive door opening	Relocate cabinet or provide good clearance around it Call refrigeration expert Check door seals and adjust Ventilate the room Check if light goes out after door shut Restrict door opening
Noisy operation	Floor underneath not firm Cabinet not level Drip tray vibrating Cooling fan hitting cover Compressor loose	Move to sound flooring Adjust casters Move tray or cushion it Call refrigeration expert Call refrigeration expert
Temperature too warm	Repeated door openings Poor door seal Low refrigerant gas	Restrict door openings Level cabinet and adjust door seal or replace gasket Call refrigeration expert
Refrigerators		
Temperature too warm (see also General)	Overloading of shelves with warm blood: restricted air flow	Check packing and adjust
Temperature too cold	Faulty thermostat	Call refrigeration expert
Freezers build-up		
Freezer runs continuously (temperature too warm)	Ice build-up affecting insulation	Place contents in an alternative freezer, switch off unit until defrosted and dry. Call refrigeration expert if fault recurs
Rapid ice build-up on the evaporator	Leaking door gasket	Adjust door hinges; call refrigeration expert if problem continues
Door on freezer compartment freezes shut	Faulty door seal heater	Call refrigeration expert

Ice accumulation in cabinet insulation

Ice accumulation is one of the main problems encountered with poor quality blood storage equipment. A refrigerator or freezer may have an air leak in the outer casing (shell). This allows moisture from the atmosphere to enter and condense in the insulation. This condition will cause considerable problems in a freezer. Ice build-ups reduce the insulating ability of the cabinet, thus causing the compressor to run harder. A cold spot or condensation on the outside surface may indicate ice accumulation in a freezer. To eliminate the unwanted ice, place the contents in an alternative freezer, cut the power supply and allow it to warm up for a few days. Lightly packed fine fibreglass insulation is sometimes used to plug the leak. This should be considered a very temporary measure since the equipment is no longer suitable for freezing blood products, and should be condemned.

Cabinet gaskets

Most gaskets have magnets built into the vinyl to hold the door closed. If the door gasket does not provide an airtight seal, the compressor works harder. It must counteract the warm air leakage through the gasket,

resulting in higher operating costs. Always see to it that the door gasket closes tightly.

ACTIVITY

This activity determines whether the door gasket closes tightly. You need a thin piece of paper or a 0,008 mm thick plastic feeler gauge (available from car repair shops). See also Section 5.3.

- i) Open the refrigerator door about half way. Note carefully the pull required to open it. Allow the door to remain open for approximately 10 seconds.
- ii) Line the paper or feeler gauge on the door gasket.
- iii) Close the refrigerator door and allow it to remain closed for about 15 seconds.
- iv) Attempt to pull out the paper or feeler gauge. This should not be possible if the gasket closes tightly.
- v) Open the refrigerator door and note carefully the pull required. It should require more effort to open the door now than at the first opening.
- vi) If the paper or feeler gauge pulls out then the door gasket(s) need attention, or the door hinges need adjustment.

Explanation: Cold air comes out when the door is opened; warm air replaces it. When the door is closed, this warmer air is cooled and contracts. The result is that the pressure inside the cabinet is slightly less than the atmospheric pressure in the room. Timing is an important element in this test, as the pressures tend to balance quickly.

Table 18. Care and preventive maintenance schedule

	Blood Bank Refrigerators	Plasma Freezers	Walk-in Refrigerators and Freezers
Daily			Check temperature Listen to check cooling machinery runs smoothly Check for ice accumulation on the floor to prevent danger of slipping
End of each day			Switch off lights Check nobody inside Securely close door Test alarms Wipe plastic barrier strips in doorway if fitted
Weekly	Wash interior surfaces and shelves Check batteries and alarm systems	Check batteries and alarm systems	Check liquid sight glass is <i>completely</i> filled with liquid Check ice and frost formation on evaporator Check panic buttons are operational Check temperature of electric motor – if too hot, notify repair technician Replace lights not working Check standby generator (if specially fitted)
Monthly	Remove all dirt and dust from outside compressor, electric motor, condenser and fins Check and adjust glycerol level		Examine all connections and parts in refrigeration system for oil leakage Check compressor and electric motor belts have not become loose Check cold store door is sealing properly
Quarterly	Check door seal gasket Check door switches (light/cooling fan/door ajar)	Check and adjust glycerol level	
Periodically		Defrost and wash interior lining twice a year	

7.2.2 Blood transport boxes

Immediately	Disinfect thoroughly after spills
Weekly	Wash thoroughly with mild detergent and lukewarm water, dry the clean parts thoroughly For thermoelectric boxes, check if any ice has formed on the evaporator

7.2.3 Platelet agitators

Daily	Temperature checks (every 6 hours); if agitator is not equipped with an incubator, the temperature in the immediate vicinity should be monitored Validate strokes per minute Alarm checks
Weekly	Wash shelves or holders with mild detergent and lukewarm water, dry thoroughly

7.2.4 Plasma thawers

Daily	Temperature checks (every 6 hours) Check agitation Check status of the bags used to contain the plasma pack during thawing for leaks
Weekly	Depending on usage, change the water in the bath and clean the cabinet with mild detergent

7.2.5 Stand-by generators

All generators should be run at least once a week, and should be regularly serviced to ensure that they remain operational. The fuel tank should be kept full at all times, and it should be large enough to ensure 24 hours of continuous running. A meter to record the time the generator is in use should be purchased and fitted, in order to know when to service the equipment and also to monitor fuel consumption.



Technician with tool kit for basic preventive maintenance and repair

Maintenance procedures for each item of equipment should always conform to the guidelines provided by the manufacturer in the operating manual. A typical list of procedures to follow in order to ensure that generators are well maintained appears below. Blood bank staff, in accordance with a standard operating procedure and after suitable training, should undertake these procedures (or those recommended by the manufacturer). More advanced procedures should be undertaken by a maintenance engineer, for which a service contract should be set up when the generator is purchased and installed.

These procedures are recommended for average operating conditions. Under very dusty conditions, air cleaners, lubricating oil and fuel filters will require more frequent attention. Decarbonising

Table 19. A model maintenance schedule for a standby generator

Daily by blood bank staff	Check lubricating oil and top up if necessary Check that the cooling system is in order and free from obstruction Check fan belt tension Check the fuel level
By maintenance engineer	
• Every 50 hours' running:	Clean the air cleaner (oil bath type)
• Every 250 hours' running:	Clean the fuel filter. Check all nuts, bolts, etc. for tightness. The cylinder head nuts must not be tightened when the engine is hot Make sure the fuel tank filler cap vent hole is clear Clean the air cleaner (paper element type) Clean out deposit from exhaust system Clean the fuel feed pump strainer Grease the fan Drain the sump, flush out with flushing oil and refill with new oil. Clean the strainer. (Paraffin may be used if flushing oil is unobtainable, but the engine must not be run with paraffin in the sump) Test the fuel system for leaks Remove the fuel injectors and test spray. If in order, replace without further interference Check the valve clearance and adjust if necessary Fit new lubricating oil filter element and joint ring Lubricate the speed control linkage
Every 500 hours' running	Fit new fuel filter element Fit new air cleaner elements
Every 2000 hours' running	Decarbonise Clean out piston oil return holes; check cylinder bore wear Examine the crankshaft bearings and renew if clearance is excessive Clean out the fuel tank thoroughly Wash out lubricating oil system Fit new fan belt

may be required more often if engines are running on light load for long periods.

7.2.6 Basic preventive maintenance and repair tool kit

The tool kit proposed below should be an aid for the user of the blood cold chain equipment, i.e. the technical staff of the blood bank. The tool kit will enable the technicians to carry out minor on-site maintenance and repairs. This will reduce down time for equipment and ensure its safety and optimal function. If the technical staff can follow certain steps to identify a problem, this will assist the maintenance department to advise on how to resolve the problem, e.g. repair on site, send in a maintenance officer, or request the equipment be repaired externally. It is also practical and cost effective for the maintenance programme.

Examples of basic maintenance and repairs that can be done at the site are:

- Door adjustments if an air leak is identified
- Minor repairs to wiring, for example, if these are exposed by rodents
- Checking electrical faults using a voltmeter
- Door switch defects
- Repairs to temperature recorder charts

- Replacement of fuses and plugs
- Identifying refrigerant gas leakage
- Repairs to door locks on blood transport boxes

Proposed tool kit

- 1 Set of Hexagon socket spanners (Allen keys)
- 2 Adjustable spanner 150mm length
- 3 A standard set of screwdrivers
- 4 A standard set of “flat” screw drivers
- 5 A standard set of jewellery screwdrivers
- 6 Digital or analogue multimeter
- 7 Cutting pliers
- 8 Long-nosed pliers
- 9 Universal pliers
- 10 Scissors
- 11 Knife
- 12 Spirit level

7.2.7 Calibration of cold chain devices and equipment

Many items of equipment need regular calibration to ensure that they are accurate. It is important that incubators and waterbaths are regularly calibrated, as well as the more obvious items such as scales used to measure the volume of blood collected, pipettes and any automated sampling or dispensing equipment.

Calibration of refrigerators and freezers is only possible if a special device – such as a temperature data logger – and a qualified engineer are available to make any adjustments that may be required. If the device is available, temperatures recorded by the independent data logger and the in-built thermograph may be compared. Should there be a significant discrepancy, the in-built thermometer will need to be recalibrated by a qualified engineer.

7.3 Disposal or decommissioning of cold chain equipment

Cold chain equipment is removed from routine use permanently in the following situations:

1. The equipment fails to maintain desired temperatures.
2. The equipment’s technical features no longer meet new standards of safety or performance expected by the laboratory.
3. The equipment is beyond repair, i.e. there are no spare parts available or it is not cost-effective to repair.

Such equipment should be removed from the laboratory to a store room for final disposal. It should also be removed from the Equipment Inventory and listed for disposal according to the prevailing regulations.

ACTIVITY

Make a list of all the cold chain equipment in your donor clinic or laboratory. Find out when the last service was performed on each item and whether there is a maintenance contract on it.

Make an Action List of improvements that could be made in the monitoring of equipment and discuss them with your supervisor.

Summary

In this Section, you have learnt the following:

- A systematic programme for the maintenance, care and repair of blood cold chain equipment is critical if it is to give the best service. In order to effect this, quality policies are needed from which Standard Operating Procedures will be developed for training and routine use (see also Section 9).
- The manufacturer's instructions must be followed. Nevertheless, knowledge and skills to handle common maintenance problems within the blood bank or laboratory are very useful.
- Cold chain equipment that is no longer usable must be disposed of following a standard operating procedure and prevailing regulations.

8

Monitoring and evaluating the blood cold chain

This Section describes a systematic approach to monitoring and evaluation that will contribute to the continuous improvement of the blood cold chain programme.

LEARNING OBJECTIVES

When you have completed this Section, you should be able to:

- Develop a system for monitoring and evaluating the blood cold chain in your blood bank.
- Understand the key elements of the forms used to report the status of the blood cold chain.
- Monitor the important indicators that will ensure good quality management systems.

A well-designed system of monitoring and evaluation is essential for a safe and efficient blood cold chain. It is also likely to be a requirement by institutions such as the Ministry of Health, statutory authorities and funding agencies, as well as a part of keeping your working processes in control.

The responsibility for establishing a system for monitoring and evaluation should be shared by the national authorities, the blood transfusion service and the hospital blood banks. It is everybody's business to ensure that blood is stored safely, especially where there is a free exchange of products.

8.1 Definition of terms

Monitoring is a continuous process that takes place during the implementation of the programme in order to:

- Assess progress in achieving defined objectives
- Identify any problems
- Indicate any action needed to modify and improve the programme.

It typically aims to answer the questions 'How well are we doing?' and 'How can we do it better?' Regular collection and analysis of records and reports will generate most of the information required for programme monitoring.

Evaluation is defined here as the systematic analysis and interpretation of information at specific intervals, such as at the end of each year of operation of the programme, in order to judge its effectiveness. It typically aims to answer the questions ‘Were the objectives achieved?’ and ‘Is it worth continuing?’

8.2 Planning for monitoring and evaluation

An evaluation plan should be developed at the start of a given period so that it is undertaken in a systematic way. It will also make it easier to identify the baseline information needed, and design a record-keeping and reporting system which will generate much of the information required for routine monitoring.

Key questions to be addressed when developing an evaluation plan include:

- 1 Who needs information from evaluation and for what purpose?
- 2 What aspects of the programme should be evaluated?
- 3 How will the data be collected?
- 4 Who will analyse and interpret the data?
- 5 How much time and what skills will this require?
- 6 When should data collection and analysis take place?
- 7 In what form will the findings be presented?
- 8 How will the findings be used?

8.3 Quality indicators for evaluation

Since the purpose of evaluation is to assess the effectiveness of the programme, you need to specify measurable indicators of the extent to which its objectives are being achieved. These can be stated in terms of both ultimate and intermediate outcomes.

Table 20. Monitoring and evaluating the blood cold chain

Quality indicators and measurements	Frequency of recording	Responsible
STORAGE/TRANSPORT		
Temperature checks	Daily	BTS or hospital blood bank technicians
Average units stored	Daily	
Power failure events	Daily	
Relocated products events	Per occurrence	
Returned products as a result of unsuitable transport conditions	"	
Discarded products as a result of transport problems	"	
Discarded products as a result of storage problems	"	
Contaminated units	"	
Equipment accommodates stock	"	
Consolidated in "Blood Cold Chain Performance Report" (see 8.5.1)	Monthly	Head Technician
MAINTENANCE		
Equipment maintained correct temperature	Daily	BTS or hospital blood bank technicians
Preventive maintenance events	Weekly	
Repairs events	Per occurrence	
Cost of labour	"	
Consolidated in Blood Cold Chain Care and Preventive Maintenance Log and Repair Record (see 8.5.2)	Monthly	Head Technician

The ultimate objective of the programme, for example, may be to assure the safety, quality and adequacy of the supply of blood and blood products through:

- Correct storage and transportation.
- Preventive maintenance of blood cold chain equipment.

The intermediate outcomes relate to the operation, maintenance and repair of blood cold chain equipment; and the storage and transportation of blood and blood components by the various personnel in the blood transfusion service or hospital blood bank. The staff performing blood cold chain activities need to be appraised regularly through competency tests on their duties, which include:

- 1 Receipt and installation of equipment.
- 2 Operation.
- 3 Temperature monitoring.
- 4 Preventive maintenance and care.
- 5 Control of storage conditions.
- 6 Packing and transporting products.
- 7 Emergency response.

Table 21 offers some quality indicators/measurements that could be used to monitor and evaluate the safety and performance of the cold chain process.

8.4 Records

Since much of the data needed for monitoring and evaluation can be obtained from routine records, it is important that the documentation used in the programme should make it easy to collate and analyse the information required. Records should be simple, require as little time as possible to complete and present information in an easily accessible form. Although the requirements of a record-keeping system will differ in each country, a standardized recording system will need to be kept at each level of health care facility by:

- National Blood Programme Officer
- Blood Bank Head Technician
- Users at the Blood Transfusion Service or hospital level

8.5 Reports

Reports should provide a summary of the records held at each level of the programme. As with records, standardized report forms are easier and less time-consuming to complete, and are essential to ensure that comparable information is obtained from different parts of the country.

Programme personnel should be encouraged to report immediately on any problems encountered and to share information on how they tried to resolve them. Informal methods of reporting are likely to be more useful here.

Note that it is usual to supplement information obtained from records and reports with data from additional sources such as sample surveys by questionnaire.

8.5.1 Blood Cold Chain Performance Report

Purpose: To report on the status of equipment and blood products in a facility.

Responsible: The user. However, in a unit where different people are responsible for different equipment, the chief of the facility sends a copy of the form to the local manager.

Recipient: District manager, unless the user is located in a regional or central office, in which case the reports go to the National Officer.

When the report is prepared: At the end of every month.

How long to keep the report: At least 24 months after submission.

Table 21. Blood Cold Chain Performance Report

Name of facility:	
Address, Province:	
Period of report (month/year):	
Name and title of person filing the report:	
Equipment Type:	Refrigerator, freezer, platelet incubator, etc.
Equipment Code:	Number appointed by facility
Capacity:	Total number of units that can be stored in equipment, e.g. capacity of platelet incubator: 48 units
	Average units stored (add up all the units stored each day and divide by total days in period)
Power Failures:	State the dates and total number of minutes or hours affected
Efficiency (%)	Number of days units are at correct temperature divided by total number of days in period (count all days including weekends and holidays) multiplied by 100. For example, if the blood bank refrigerator broke down over a weekend in September, the efficiency calculation will be $28/30 \times 100 = 93.3\%$.
Product Viability	Number of units that had to be relocated because of storage problems
	Number of units that had to be discarded because of storage problems
	Number of units that had to be discarded because of unsuitable transport conditions after collection or after release

8.5.2 Blood Cold Chain Care and Preventive Maintenance Log and Repair Record

The purpose, responsible officer and timing of this report is essentially the same as that for the Blood Cold Chain Performance Report. Examples of the Care and Preventive Maintenance Log, as well as the Repair Record, can be found in Section 7, Tables 13 and 14.

ACTIVITY

Look at Tables 13, 14 and 21 and see how these forms can be adapted to fit your needs.

8.6 Analysis and interpretation of data

While much of the raw data required for evaluation may be readily available from records and reports, it then needs to be analysed or, at a minimum, collated, so that it can be interpreted and judgements made about the effectiveness of the programme and how it might be improved. The level of analysis required depends on the kind of data available and the needs of the users of the evaluation. Questionnaire responses will need to be tallied, and perhaps some simple statistics prepared, either manually or electronically.

If a large quantity of data has been collected from records and reports, it may be better to analyse it in segments, rather than attempting to handle an overwhelming volume of information that will take time to analyse and may not be absorbed by the evaluation users. It is important to schedule time for data analysis and interpretation, and to ensure that the findings can be fed into the cycle of programme planning and implementation.

8.7 Using the findings from the monitoring and evaluation exercise

Ensure that people sending in reports get feedback.

As the requirements of users of an evaluation will vary, it is important to identify the kind and amount of information they need, since this will determine the way in which it should be presented. The Ministry of Health and other relevant statutory authorities are likely to require a relatively brief report, which enables them to judge the efficiency and cost-effectiveness of the programme.

The information obtained from the different districts and regions should be reviewed monthly in order to take appropriate preventive and corrective actions, but it should also be reviewed annually, in order to incorporate the information into the decision-making process.

The information gathered from the different reports can be used, *inter alia*, for:

- 1 Policy formulation:
 - a. Standardization of equipment
 - b. Equipment distribution
- 2 Planning and budgeting for:
 - a. New equipment (capital needs)
 - b. Spare parts or supplies (recurrent needs)

3 Human resources

- a. Delegation of responsibilities
- b. Supervision
- c. Training.

Summary

In this Section you have learnt the following:

- The blood cold chain should be monitored and evaluated periodically so that preventive and corrective action can be taken in a timely fashion and improvements introduced.
- An evaluation plan should be developed at the start. Baseline information should be collected and a record-keeping and reporting system designed to generate the information required.
- Monitoring and evaluation require a systematic approach to data collection and analysis at all levels of the health system, and should be a shared responsibility.
- The standardization of reporting is essential to ensure that comparable information is obtained from different parts of the country.
- Evaluation findings should feed into the cycle of programme planning and implementation.
- Personnel performing blood cold chain activities also need to be monitored regularly through competency tests.

9

Guidelines for the development of a training programme

We have seen in this Manual that well-defined tasks and activities are required in order for processes to operate the correct way every time. In order for a Standard Operating Procedure (SOP) to be followed as expected, the staff performing the tasks should first be trained. This Section outlines for managers the objectives of a good training programme, and provides an example of a training guide and a training assessment tool that can be adapted to suit local needs.

9.1 Objectives

The overall objective is to ensure that the training requirements for staff are fulfilled in order to ensure the cold chain is well maintained.

9.2 Key points in the training programme

- Training provides the necessary knowledge and skills to perform a job correctly.
- Only trained staff should carry out activities.
- Students and volunteers should also be trained.
- SOPs are the best tools for training.
- An experienced instructor makes the training process effective.

9.3 Preparing a training programme

The following steps will guide you in preparing a training programme for your personnel:

- 1 Establish what it is you want your trainees or learners to know. Determine all the activities involved in each working process. For example, your staff need to learn how to monitor the temperature of blood and blood components; how to perform routine maintenance on blood bank refrigerators and freezers; and how to pack and transport blood products safely.
- 2 List all the SOPs that are involved in each activity.
- 3 Determine the resources and materials that are needed and how many individuals need to be trained; if large numbers of staff need to be trained it might be useful to host a one or two day workshop to get

their skills up to competence. The WHO publications listed in the References on page 84 can be useful in preparing lectures and demonstrations within a workshop.

- 4 Select appropriate training methods: some procedures might be easier to teach by simply observing it done a few times whilst more complex activities might involve interpretation of results and need written exercises in order to determine competence.
- 5 Decide what specific criteria need to be met to establish competence. This should include the estimated time the training will take and how well a task needs to be performed before an individual can carry it out independently. For example: if you are training a laboratory technician to perform an ABO typing, you would want to have 100% proficiency before this person can become responsible for typing a donor or patient's blood sample.
- 6 Document the training programme: keep folders for each of your staff. Include their previous and current training and competency records.

It may be your responsibility to ensure that only trained staff should perform critical activities. Staff should be trained when they come into the job, whenever procedures change or new ones are incorporated. Their skills should be assessed at least once a year to ensure that they maintain the level needed to perform their jobs proficiently.

Retraining National Blood Transfusion Service staff in quality management issues



9.4 Developing a training guide

Once SOPs have been developed they become the best tools for training. The SOP can be adapted into a training guide, which serves as a map for both the instructor and the learner.

The first step in developing a training guide is to decide upon a standard format that will be used consistently. The following example of a training guide was developed using the SOP which appears in Section 7, Table 16.

Table 22. Example of a training guide

Training Guide	
Task: Operate and maintain blood bank refrigerator according to the SOP	
Prepared by: BB Supervisor	Adopted: January 2005
Resources and materials: <ul style="list-style-type: none">1) SOP Maintenance for Blood Bank Refrigerators and Freezers2) User's Manual	
Training method: <ul style="list-style-type: none">1) Read SOP and references2) Observe demonstration on three occasions3) Practise under supervision on three occasions	
Competency evaluation: <ul style="list-style-type: none">1) Perform the skill under direct observation according to SOP2) Satisfactorily complete all items on the direct observation checklist	
Training checklist: <ul style="list-style-type: none">1) SOP for preparation of cleaning solution2) SOP for refrigerator maintenance	
Training record: <ul style="list-style-type: none">1) Initial training: 3 February 20052) Competency assessment: 10 February 2005	

Notes

Resources and materials: These can be: SOPs, references, package inserts, users manual, training notes inserted for use by the trainer during demonstrations and practice; direct observation checklist.

Training method: State the most appropriate method(s) to accomplish learning, e.g. reading the SOP, practise under supervision.

Competency evaluation: This should include measurable behaviour. For example: achieve 90% or above on the written test. It should include the evaluation method, i.e. written and/or oral examination. The direct observation checklist (see below) allows you to verify that all-important steps in an SOP are met.

Training checklist: Listing of all SOPs in which to be trained.

Training documentation records: Training guide, written examinations, competency records.

The following direct observation checklist can serve either to teach a new procedure, or as an assessment tool when validating competence. You can copy it and use it for many different procedures.

Table 23. Direct observation checklist

Facility identification:		
Direct observation checklist for [...] procedure		
Name of employee:	Name of observer:	
Date:		
Significant steps of procedure:		
Did the learner:		
1. validate the temperature at the established time?	Y	N
2. validate the temperature on the LED display of the equipment and that of the thermometer in the cabinet?	Y	N
3. record the temperature in the log-book?	Y	N
4. check for ice-formation on the evaporator?	Y	N
5. check that the condenser and compressor were both clean	Y	N
6. check the alarms:		
• Temperature	Y	N
• Door	Y	N
• Power failure	Y	N
Competent to perform (Yes/No)		
Re-training needed:		
Comments:		
Next competency assessment scheduled for:		
Signed by trainer:	Signed by employee :	

Summary

In this Section you have learnt the following:

- Standard Operating Procedures are one of the best tools for learning a task.
- Expectations from the training should be clear and the learning should be evaluated.
- Levels of competency should be re-evaluated and updated regularly.

References

- 1 *The Blood Cold Chain: Guide to the Selection and Procurement of Equipment and Accessories*. WHO, Marketing & Dissemination, 1211 Geneva 27, Switzerland. ISBN 92 4 154579 8. Order No. 1930202. 2002
- 2 See www.who.int/vaccines-access/vacman/pis/pqs.htm for full details of the WHO Performance Quality and Safety (PQS) project for devices used in immunization programmes.
- 3 *Safe Blood and Blood Products. Distance Learning Materials*. Revised Edition. WHO, Marketing & Dissemination, 1211 Geneva 27, Switzerland. ISBN 92 4 154546 1. Order No. 1150490. 2002
- 4 *American Association of Blood Banks (AABB) Technical Manual*, 13th Edition
- 5 WHO Product Information Sheets, 2000 edition, equipment for the Expanded Programme on Immunization, WHO/V&B/00.13

The use of CFC in blood cold chain equipment

Environmental and human health concerns about the depletion of the ozone layer in the earth's atmosphere have led to a global effort to phase out the production and consumption of CFCs. Until 1995, two major CFCs – R11 and R12 – were commonly used as refrigerants in compression refrigeration circuits, and as foaming agents for the insulation of refrigerators, freezers and insulated containers (cold boxes).

The Montreal Protocol¹

The international community has committed itself to the elimination of these refrigerants and foaming agents in an agreement called the Montreal Protocol. This Protocol calls for the cessation of CFC consumption, i.e. production, importation or exportation, as of 1 January 1996 in industrialized countries, and from 1 January 2010 in developing countries. Thereby:

1. R11 is no longer used as a foaming agent by any manufacturer listed in the WHO Product Information Sheets. It is now replaced by cyclopentane in European countries and by R141b in the USA (the use of R141b will eventually also be banned in 2030).
2. R12 is not used by the majority of the industrialized country manufacturers. It is commonly replaced with HFC 134a.
3. Although manufacturers in developing countries continue to produce equipment with CFCs, many have submitted CFC-free samples for testing.

WHO Policy

WHO fully supports the recommendations of the Montreal Protocol and draws attention to the following:

1. Countries should know that use of CFC equipment after 2010 is contrary to the Montreal Protocol, and are urged to stop purchasing equipment using CFCs forthwith.

¹ More detailed information on the Montreal Protocol and ozone layer depletion, replacements for ozone-depleting substances and supplies of alternative technologies can be obtained from: UNEP DTIE OzonAction Programme, Tor Mirabeau, 39–43, quai André Citroën, 75739 Paris Cedex 15, France. E-mail: ozonaction@unep.fr. Internet: www.uneptie.org/ozonaction.html

2. Manufacturers in developing countries should switch to CFC-free production as soon as possible.
3. A coordinated plan to replace CFC equipment within the national blood programme should attempt to phase in CFC-free equipment region by region in order to facilitate services and repairs.
4. The national equipment procurement plan should include provision for maintenance. This includes tools for the repair of CFC-free equipment and training of cold chain technicians.
5. Managers of national blood programmes are urged to purchase blood cold chain equipment that is CFC-free and meets WHO minimum performance specifications.
6. The opportunity should be taken to develop an equipment inventory and maintenance plan for all blood bank equipment, including where CFC-free equipment is installed.
7. Maintenance staff of the Ministry of Health may require retraining on CFC-free equipment.
8. When the equipment arrives in the country:
 - Check that the compressors are marked with a 100 mm blue disk that helps draw the attention of repair technicians.
 - Check that blood cold boxes are marked with the recommended WHO emblem.

WHO minimum performance specifications for blood cold chain equipment¹

Standard electric blood bank refrigerators

Specification Reference: BTS/RF.1

Purpose of Equipment: A refrigerator for storing whole blood or red cell packs in a blood bank

Type of Equipment: Compression type refrigerator that uses CFC-free refrigerant gas and electricity supply from the national grid

Laboratory Test Procedure: Standard Test Procedure: BTS/Proc/ 3

Construction: Internal: Stainless steel (min. 22g)
 External: Corrosion Resistant (CR at least 1mm thickness)
 CFC-free insulation
 Drawers: Roll out type
 Door: Glass or solid door

Electrical Characteristics: Input voltage: 220/240V 50Hz or 110V 60Hz single phase. Equipment meets electrical safety specifications such as that of IEC

Minimum Compressor Starting Voltage: 22% below nominal voltage

Internal Temperature Control: Electronic temperature control, range +2 °C to +6 °C with setting accuracy of ± 1 °C whatever the load
 Fan air cooling

External Ambient Temperature: Performs in an ambient temperature of +10 to +43 °C

Hold-Over Time*: A full load of blood packs at +4 °C (± 1 °C) takes at least 30 minutes to rise to above +6 °C

Cooling Down Time*: A full load of blood packs at +25 °C takes a maximum of 13 hrs for all the packs to reach below +6 °C

Temperature Monitoring: Digital temperature (LED) display with 0.1 °C graduation
 Temperature recording device
 Visual and audible alarm system indicating unsafe temperatures
 Battery back up for alarm and temperature recording device
 Facility for remote alarm contact

Solar powered blood bank refrigerators

Specification Reference: BTS/RFS.3

Purpose of Equipment: A refrigerator for the storage of whole blood/red cell packs in a blood bank

Type of Equipment: Compression refrigerator which uses CFC-free refrigerant gas and electricity from solar energy

Laboratory Test Procedure: Standard Test Procedure: BTS/Proc/ 5

* The hold-over time and cool down times were measured at +43 °C ambient at full load. This means that the lower the ambient temperature, the better the performance of the equipment.

Solar powered blood bank refrigerators (continued)

Construction: Chest type
Internal: Aluminium lining or similar
External: Corrosion Resistant (CR at least 1mm thickness)
CFC-free insulation
Blood pack racks for easy packing or retrieval of packs
Solid door

Electrical Characteristics: Input voltage: Direct Current to Required Voltage
Equipment meets electrical safety specifications such as that of IEC

Minimum Compressor Starting Voltage: 22% below nominal voltage

Internal Temperature Control: Electronic temperature control, range +2 °C to +6 °C with setting accuracy of ± 1 °C whatever the load

External Ambient Temperature: Performs in an ambient temperature of up to +43 °C and 60% humidity

Hold-Over Time*: A full load of blood packs at +4 °C (± 1 °C) takes at least 2 hrs to rise to above +6 °C

Cooling Down Time*: A full load of blood packs at +37 °C takes a maximum of 10 hrs for all the packs to reach below +6 °C

Temperature Monitoring: Digital temperature display with 0.1 °C graduation
Temperature recording device
Visual and audible alarm system indicating unsafe temperatures
Battery status visual display
Temperature recorder facility
Facility for remote alarm contact

Ice-lined blood bank refrigerators

Specification Reference: BTS/RF.2

Purpose of Equipment: A refrigerator for the storage of whole blood/red cell packs for use in blood banks with a limited electricity supply

Type of Equipment: Compression refrigerator that uses CFC-free gas and at least 8 hrs/day of electricity. The refrigerator compartment is lined with ice containers or has a freezer section with ice packs to enhance the temperature holding capacity of the refrigerator compartment during power failure

Laboratory Test Procedure: Standard Test Procedure: BTS/Proc/ 4

Construction: Internal: Stainless steel (min. 22kg)
External: Corrosion Resistant (CR at least 1mm thickness)
Chest type with CFC-free insulation
Upright trays
Solid door

Electrical Characteristics: Input voltage: 220/240V 50Hz or 110V 60Hz AC single phase
Equipment meets electrical safety specifications such as that of IEC

Minimum Compressor Starting Voltage: 22% below nominal voltage

Internal Temperature Control: Electronic temperature control, range +2 °C to +6 °C in refrigerator section with setting accuracy of \pm °C whatever the load. In freezer section, temperature range -20 °C to -40 °C
Fan air cooling

External Ambient Temperature: Performs in an ambient temperature of +10 °C to +43%

Hold-Over Time*: A full load of blood packs at +4 °C (± 1 °C) takes at least 1 hr to rise to above +6 °C
A full load of blood packs at +4 °C (± 1 °C) takes at least 2 hrs to rise to above +10 °C

Cooling Down Time*: A full load of blood packs at +37 °C takes a maximum of 8 hrs for all the packs to reach below +6 °C

Temperature Monitoring: Digital temperature (LED) display with 0.1 °C graduation
Temperature recording device
Visual and audible alarm system indicating unsafe temperatures
Battery back up for alarm and temperature recording device
Facility for remote alarm contact

* The hold-over time and cool down times were measured at +43 °C ambient at full load. This means that the lower the ambient temperature, the better the performance of the equipment.

Plasma freezers

Specification Reference: BTS/FR.1

Purpose of Equipment: To freeze and store plasma in a blood bank

Type of Equipment: Compression freezer with CFC-free refrigerant gas and electricity supply from the national grid

Laboratory Test Procedure: Standard Test Procedure: BTS/Proc/1

Construction: Internal: Stainless steel (min. 22g)
External: Corrosion Resistant (CR at least 1mm thickness)
CFC-free insulation
Design: Chest or Upright Type
Door: Solid door
Drawers: Roll out type

Electrical Characteristics: Input voltage: 220/240V 50HZ or 110V 60HZ AC single phase
Equipment meets electrical safety specifications such as that of IEC

Minimim Compressor Starting Voltage: 22% below nominal voltage

Internal Temperature Control: Electronic temperature control
Operating temperature, -35°C to -40°C with setting accuracy of $\pm 1^{\circ}\text{C}$ whatever the load
Fan air cooling
Automatic defrost within safe temperature range

External Ambient Temperature: Performs in an ambient temperature of $+10$ to $+43^{\circ}\text{C}$

Hold-Over Time*: A full load of plasma packs at -36°C takes at least 1 hr to rise to above -20°C
A full load of plasma packs at -36°C takes at least 32 hrs to rise to above -5°C

Cooling Down Time*: A full load of plasma packs at $+25^{\circ}\text{C}$ takes a maximum of 5 hrs for all the packs to reach below -5°C
A full load of plasma packs at $+25^{\circ}\text{C}$ takes a maximum of 30 hrs for all the packs to reach below -20°C

Temperature Monitoring: Digital temperature (LED) display with 0.1°C graduation
Temperature recording device
Visual and audible alarm system indicating unsafe temperatures
Battery back up for alarm and temperature recording device
Facility for remote alarm contact

Platelet agitators

Specification Reference: BTS/PAC/IN.1

Purpose of Equipment: To continuously agitate platelet concentrates in an incubator in an even suspension in a plasma bag

Type of Equipment: Flatbed agitator fitted inside a temperature-controlled incubator operating with CFC-free refrigerant gas and insulation material and electricity from the national grid

Laboratory Test Procedure: Standard Test Procedure: BTS/PAC/Proc. 1

Construction: Internal: Stainless steel (min. 304 grade)
External: Corrosion Resistant, at least 1mm thickness
Designed to hold a load of random platelet packs (300ml bag size) or apheresis platelet packs (500 x 1 litre) or a mixture of both types.
Doors enable inspection of contents without opening the door

Design of Shelves: Shelves are made of corrosion resistant material with sufficient clearance to minimize noise
Easy loading and withdrawal of platelet packs. Shelves cannot be pulled out in error
The agitator holding the shelves is suspended in such a way as to ensure minimum noise for the life of the agitator

Electrical Characteristics: Nominal input voltage: 220/240V 50Hz or 110V 60Hz
Equipment meets electrical safety specifications such as that of the IEC

Internal Temperature Control: Fan cooling. Electronic temperature control to maintain even temperature at $+22^{\circ}\text{C}$ ($\pm 0.5^{\circ}\text{C}$) at all shelves

External Ambient Temperature: Incubator performs in an ambient temperature range of up to $+43^{\circ}\text{C} \pm 1^{\circ}\text{C}$ and Relative Humidity of 60%

* The hold-over time and cool down times were measured at $+43^{\circ}\text{C}$ ambient at full load. This means that the lower the ambient temperature, the better the performance of the equipment.

Platelet agitators (continued)

Monitoring Motion of Agitator: A motion failure alarm

Temperature Monitoring: Digital temperature (LED) display with 0.1 °C graduation
Visual and audible alarm system indicating temperature and power failure. Door ajar alarm
Seven day chart recorder, or electronic record of maximum and minimum temperature attained

Performance: Agitation at 1.5 inch (3.6–4 cm) side to side stroke, 65–75 strokes/min.

Flatbed platelet agitators

Specification Reference: BTS/PA/IN.1

Purpose of Equipment: To continuously agitate platelet concentrates in a temperature controlled environment at +22 °C ± 5 °C in an even suspension in a plasma bag

Type of Equipment: Flatbed agitator which uses electricity from the national grid

Laboratory Test Procedure: Standard Test Procedure: BTS/PA.1/Proc. 1

Construction: Open system with no doors and a strong base with handles. Designed to hold a load of 300 ml random or apheresis type platelet packs of up to a litre, or a mixture of both

Design of Shelves: Shelves are made of corrosion resistant material.
Easy loading and withdrawal of platelet packs. Shelves cannot be pulled out in error
The agitator holding the shelves is suspended in such a way as to ensure minimum noise for the life of the agitator

Electrical Characteristics: Nominal input voltage: 220/240V 50Hz or 110V 60Hz
Equipment meets electrical safety specifications such as that of IEC

Internal Temperature Control: Not applicable

External Ambient Temperature: Performs in an ambient temperature of +22 °C ± 5 °C

Monitoring Motion of Agitator: A motion alarm and power failure alarm

Performance: Agitation at 1.5 inch (3.6–4 cm) side to side and 65–75 strokes/min.

Plasma thawers

Specification Reference: BTS/PT/IN.1

Purpose of Equipment: To thaw rapidly frozen plasma

Type of Equipment: At 37 °C water bath. Plasma packs held in special containers and constantly agitated uniformly in the bath until thawing is complete. Packs remain dry

Laboratory Test Procedure: Standard Test Procedure: BTS/PT.1/Proc. 1

Construction: Internal: Corrosion resistant material, easy to clean and no staining
External: Corrosion Resistant (CR at least 1mm thickness)
Design: Chest type, lid optional
Easy loading and removal of plasma packs
Easy to empty water when required

Electrical Characteristics: Nominal input voltage: 220/240V 50Hz or 110V 60Hz AC single phase
Equipment meets internationally accepted electrical safety specifications such as that of IEC

Internal Temperature Control: Tamper resistant temperature control set at 37 °C (± 1 °C)

External Ambient Temperature: Performs in an ambient temperature of 10 °C to 30 °C (± 5 °C)

Thawing Time: A full load of flat plasma packs (approx. 250ml volume) with a core temperature of –30 °C (± 1 °C) is thawed completely in less than 20 mins

Warning Systems: Digital temperature (LED) display with 0.1 °C graduation
Visual and audible alarm system indicating temperature outside range
Audio/visual alarm if water level drops
Audio/visual alarm if plasma pack leaks during thawing if pack is not in a leak proof container

* The hold-over time and cool down times were measured at +43 °C ambient at full load. This means that the lower the ambient temperature, the better the performance of the equipment.

Blood transport boxes (short cold life)

Specification Reference: B4/BC1

Purpose of Equipment: To carry whole blood from individual donors to blood bank or from blood bank to point of use

Laboratory Test Procedure: Standard Test Procedure: B4/PROC/4

Robustness: Fittings 2, casing 3 (see ratings in test procedure)

Net Capacity for Blood Bags: 1–4 litres (2 bags)

Maximum Weight Permitted: 6 kg

Cold Life: Maintenance of under +10 °C for minimum 30 hrs in ambient temperature of +43 °C

Maximum Ice Melting Rate: More than 15 hrs cold life per kg of ice melted at 43 °C

Cold Packs: To conform to specification E5/IP1 or IP2. Sufficient ice packs for freezing at –20 °C are provided to surround the sides

Means of Handling: To be suspended from the shoulder or held in one hand

Blood transport boxes (extended cold life)

Specification Reference: B4/BC2

Purpose of Equipment: To carry whole blood from individual donors to blood bank or from blood bank to point of use

Laboratory Test Procedure: Standard Test Procedure: B4/PROC/2

Robustness: Fittings 2, casing 2 (see ratings in test procedure)

Net Capacity for Blood Bags: 15 to 27 litres (approx. 20 bags)

Maximum Weight Permitted: 45 kg

Cold Life: Maintenance of under +10 °C for minimum 130 hrs in ambient temperature of +43 °C

Maximum Ice Melting Rate: More than 10 hrs per 1 kg ice melted during 43 °C cold life test

Cold Packs: To conform to specification E5/IP1 or IP2. Sufficient water filled ice packs for freezing at –20 °C are provided to surround the blood bags on all sides

Means of Handling: Carrying by vehicle. Two handles for easier lifting.

WHO basic operational framework for the blood cold chain

The WHO Department of Essential Health Technologies assists countries to achieve a safe and reliable level of health services in a variety of health technologies through its Basic Operational Frameworks. Below is a summary of the requirements for countries to attain this level of health service for the blood cold chain, and the products and services that WHO can make available to support this goal.

REQUIREMENTS AT COUNTRY LEVEL	IN PLACE			WHO PRODUCTS AND SERVICES
	YES	NO	PARTIAL	
POLICY				
National officer or authority responsible for the equipment				Guide to the Selection and Procurement of BCC equipment
Nationally coordinated procurement, including accessories and spare parts				Costing of Blood Transfusion Services
Budget available for procurement of equipment				Manual on Management, Maintenance and Use of the BCC equipment
Equipment inventory management system				Basic Operational Framework consultancy assessment
Needs assessment system				Medical Device Regulations: Global Overview and Guiding Principles
Licensing vendors: advertising, sale records back up support				WHO guidelines on equipment donation
Equipment disposal and replacement policy				
Acceptance of donated equipment				
QUALITY AND SAFETY				
Manufacturer follows GMP and quality control in production				Basic performance specifications if ISO standards not there
SOP Guide for installation and validation				Manual on Management, Maintenance and Use of the BCC equipment
Audit system on equipment performance				Aide Mémoire: Quality Systems for Blood Safety
National quality policy on equipment				Medical Device Regulations: Global Overview and Guiding Principles
Link to international vigilance on performance of equipment				
Safety requirements for equipment and staff				
Energy source and facilities for equipment				
ACCESS				
List of essential equipment				List of essential equipment and accessories
National procurement procedures				Guide to the Selection and Procurement of BCC equipment
Approved suppliers register of equipment				Data capture forms
Repair and maintenance facilities				Manual on Management, Maintenance and Use of the BCC equipment
Equipment inventory database				
USE				
Information materials on the equipment				Guide to the Selection and Procurement of BCC equipment
SOPs for use of equipment available				Manual on Management, Maintenance and Use of the BCC equipment
Guidelines and SOPs on preventive maintenance				Quality Management Programme
Training on blood cold chain management				

Following the success of *The blood cold chain: guide to the selection and procurement of equipment and accessories*, this new guide illustrates the importance of a systematic programme of maintenance, care and repair of the equipment. The correct storage and transportation of blood – and thereby safe and effective transfusion therapy for patients – depends on it.



Department of Essential Health Technologies
World Health Organization
1211 Geneva 27, Switzerland
E-mail: bloodsafety@who.int
www.who.int/bloodsafety/

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