



AIDE-MÉMOIRE

for national blood programmes

Blood transfusion is an essential part of modern health care, and it helps to save millions of lives every year. National health authorities have a responsibility to ensure adequate blood supplies in a timely manner, to meet the needs of all patients requiring transfusion. The conditions under which blood and blood products are stored and transported have a direct effect on their safety, efficacy and availability. The blood cold chain is a system for storing and transporting blood and blood products, within the correct temperature range and conditions, from the point of collection from blood donors to the point of transfusion to the patient.

Deviations from specified temperature ranges and conditions during storage and transportation of blood and blood products can seriously affect the viability of the constituents of blood, thus leading to reduced clinical benefits. It can also increase the risk of bacterial proliferation in blood components during storage and may cause potentially life-threatening transfusion reactions, such as septic shock and even death. A break in the blood cold chain leads to wastage and discard of unsuitable blood units, which may adversely affect the supply of blood and blood products for transfusion.

Implementation of WHO blood safety strategy in many countries has led to the consolidation of key operations (e.g. testing and processing) in selected, strategically located sites as well as the expansion of safe blood transfusion services to cover wider geographic areas. This situation requires frequent movement of blood, blood products and blood samples across different blood centres and hospitals. An effective blood cold chain is thus an important part of the strategy to promote universal access to safe blood transfusion.

The establishment of a reliable system for blood cold chain requires commitment and support of national health authorities and sustainable funding. This is best achieved in a blood transfusion service that is coordinated at different levels within the national health care system. Quality principles should apply to all aspects of the blood cold chain, in blood centres, in hospital blood banks and in all institutions handling blood, blood products and blood samples. Quality system should be established and implemented for effective management of blood cold chain, including equipment, personnel and procedures.

Words of advice

- Secure government commitment and support for the development and management of blood cold chain
- Develop national guidelines on the storage and transportation of blood and blood products
- Establish systems for the procurement, management and maintenance of blood cold chain equipment
- Train all personnel involved in the blood cold chain, and maintain a culture of adherence to the relevant standard operating procedures
- Establish systems for monitoring and evaluation of the blood cold chain.



Checklist

Situation analysis and needs assessment

- ☐ Review of the blood supply structure
- ☐ Mapping of processes involved in the blood cold chain
- ☐ Identification of gaps and needs
- ☐ Establishment of action plans, based on the needs assessment
- ☐ Assessment of resources needed
- ☐ Adequate and sustainable finances

Equipment management

- ☐ Minimum performance specifications
- ☐ Selection and procurement in accordance with standard procedures
- ☐ Inventory of blood cold chain equipment
- ☐ Installation in accordance with manufacturers' instructions
- ☐ Validation and calibration of equipment and devices
- ☐ Preventive maintenance programmes

Quality system

- ☐ National guidelines on the storage and transportation of blood and blood products
- ☐ Standardized procedures for operation of blood cold chain
- ☐ Validation of blood cold chain processes and procedures
- ☐ Documentation of validation, calibration, maintenance and repair

Human resources

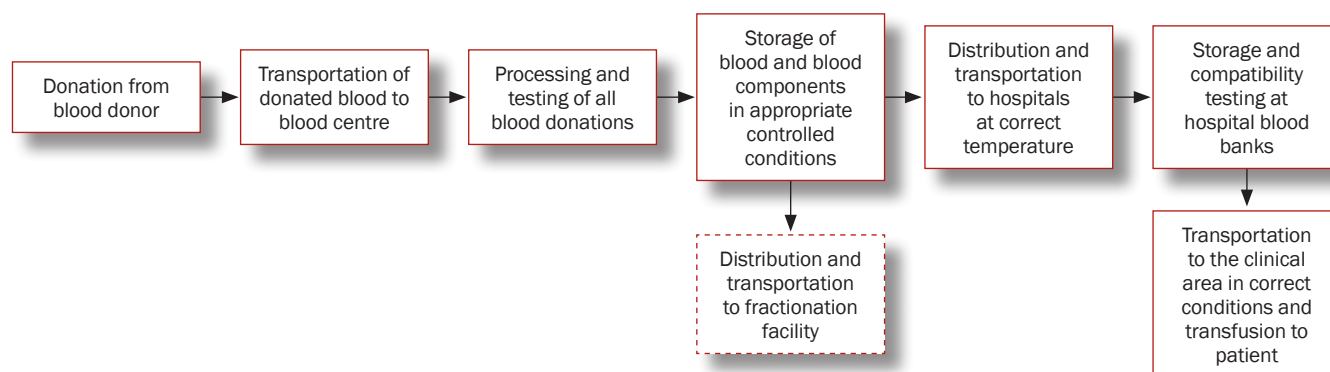
- ☐ Education and training of all staff involved in blood cold chain operation
- ☐ Training of blood centre and hospital staff in basic preventive maintenance

Monitoring and evaluation

- ☐ Monitoring and evaluation of critical control points in the blood cold chain
- ☐ Inclusion of the blood cold chain in inspections, audits and regular evaluation programmes
- ☐ Cycle of remedial, corrective and preventive actions to lead to continuous improvement

Key elements

Blood cold chain



Quality system embraces all aspects

Situation analysis and needs assessment

A detailed situation analysis and a needs assessment are required to identify the gaps and weaknesses in the blood cold chain, to provide a safe and timely blood supply. This entails:

- Review of the blood supply structure within the health delivery system
- Mapping of processes involving the blood cold chain, from collection to clinical use
- Review of back-up capability in the event of power or equipment failure
- Identification of gaps and needs for strengthening the blood cold chain
- Assessment of equipment, human resources and training requirements
- Development of action plan to remove gaps and correct weaknesses within the blood cold chain.
- Adequate and sustainable finances for procurement of equipment and management of the blood cold chain

Equipment management

An effective blood cold chain requires a mechanism for the selection, procurement, installation, commission, maintenance and correct use of blood cold chain equipment. This also helps to maximize the working life of the equipment. Key requirements include:

- Specifications based on internationally recognized standards, including WHO recommended minimum specifications, for essential blood cold chain equipment, devices and accessories
- Selection of equipment and devices according to agreed specifications
- Sufficient stocks of spare parts and consumables procured at the time of purchase of equipment
- System and procedures for the standardized procurement of equipment and accessories, including reliable

servicing, availability of additional spare parts and adequate and reliable technical support

- Installation and commissioning of equipment in compliance with the manufacturer's guidelines
- Inventory register to manage equipment, devices, accessories and spare parts
- Preventive maintenance programme, including maintenance and servicing contracts with manufacturers
- Mechanism for ongoing maintenance and repair with relevant partners or companies
- System to ensure regular calibration of equipment and devices and checking of audiovisual alarm systems, with timely correction or repair of identified problems
- Mechanism to ensure that all donated equipment meets defined specifications.

Quality system

As a quality requirement, processes and procedures in all areas of the blood cold chain should be identified, validated and documented. Key requirements include:

- National guidelines on storage and transportation of blood and blood products, implemented in blood centres and hospitals
- Availability of user and service manuals for equipment, in user-requested official languages
- Identification of critical control points in the blood cold chain
- Validation of the blood cold chain processes
- Standard operating procedures for transportation and storage of blood and blood products, from collection to clinical use
- Use of appropriate coolants and cold boxes for transportation of blood and blood products at the correct temperature

- Storage of blood donations, blood samples, stock of test kits and reagents, empty blood collection bags and apheresis kits, within correct temperature range and conditions
- Documentation of validation, calibration, maintenance and repairs of blood cold chain equipment.

Human resources

Personnel who manage, maintain and use the blood cold chain are the most important component of the system. Key requirements include:

- Education of all involved personnel to ensure they understand the importance of the blood cold chain
- Training for all involved personnel in the operation and management of the blood cold chain
- Training of staff working in blood centres and hospital blood banks in basic preventive maintenance of equipment
- Documentation of training provision and staff competency assessment.

Monitoring and evaluation

A well-designed system of monitoring and evaluation contributes to continuous improvement, and is essential for a blood cold chain that meets quality standards. Key activities include:

- Monitoring of critical control points and indicators in the blood cold chain, such as discard rates of blood and blood products due to failure of specified conditions and temperature control
- Evaluation of the improvements in the blood cold chain system
- Inclusion of the blood cold chain in inspections, audits and regular assessment of blood centres and hospital blood banks
- Remedial, corrective and preventive actions that lead to continuous improvement of the blood cold chain.

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