World Health Organization

Safe Blood Components

AIDE-MÉMOIRE

for National Health Authorities

Safe blood may be used most effectively if it is divided into components prepared from whole blood donations or obtained by apheresis procedures. One unit of whole blood can be used to meet the needs of more than one patient and provide only that component that is required. In addition, the availability of blood components enables the provision of therapeutic support for patients with conditions such as disorders of haemoglobin, coagulation and bone marrow.

An effective blood component programme requires a sustainable national blood programme, including a well-organized, nationally coordinated blood transfusion service (BTS), a stable base of suitable, voluntary non-remunerated blood donors, accurate testing systems, quality systems and a suitable regulatory mechanism. For this, the commitment and support of national health authorities and additional human, financial and technological resources are needed.

Requirements for a blood component programme include:

- Effective strategies for the recruitment and retention of voluntary non-remunerated blood donors, including apheresis donors, where applicable, to ensure a safe, adequate and reliable source of blood for component preparation
- Centralization or regionalization of blood processing and testing to permit economies of scale and uniform standards of performance
- Systems and standardized procedures for donor selection, blood collection, processing, testing, storage and transportation to ensure the consistent quality, safety and efficacy of blood components
- Training of BTS staff in all activities related to the provision of safe blood components
- Training in appropriate blood component therapy for staff involved in the clinical transfusion process.

Consideration should be given to the use of surplus plasma for the production of plasma-derived medicinal products through fractionation, utilizing facilities either within or outside the country.

Words of advice

- **Assess the clinical demand for blood components and the feasibility of a component preparation programme**
- **Develop a programme that complies with regulatory requirements and is appropriate to the level of the health care system, including the diagnostic and medical services available**
- **Allocate adequate human and financial resources to ensure the sustainability of the programme**
- **Build a stable base of regular, voluntary non-remunerated blood donors to meet collection targets for blood components**
- **Consolidate blood processing and testing within major centres**
- **Strengthen the interaction between the BTS and hospitals and promote appropriate blood component therapy**

Checklist

Organizational requirements

- ❑ Nationally-coordinated BTS with centralized/regionalized processing and testing
- ❑ Assessment of clinical demand and feasibility of blood component programme
- ❑ Adequate, sustainable finances
- ❑ Suitable premises, working environment and waste management system
- ❑ Appropriate infrastructure
- ❑ Suitable regulatory mechanism
- ❑ Sufficient number of trained staff
- ❑ Appropriate technology, equipment and materials for blood collection, testing and processing
- ❑ Effective quality systems, including standardized procedures and good manufacturing practices
- ❑ Documentation of all processes and accurate labelling

Blood donors and blood collection

- ❑ Panel of regular voluntary blood donors
- ❑ National criteria for donor selection and deferral
- ❑ Donor call-up and blood collection planned to meet component preparation targets
- ❑ Suitable blood collection bag systems

Component preparation, testing and distribution

- ❑ Specifications for blood components, equipment and materials
- ❑ System for quarantine, release and recall, including labelling
- ❑ Quality monitoring of blood components

Storage and transportation

- ❑ Correct storage and transportation of blood bags, donor specimens, collected units, blood components, reagents and materials
- ❑ Separate storage areas for untested, quarantined and available units
- ❑ Suitable temperature-monitored equipment

Blood component stock management

- ❑ Agreements between the BTS and hospitals on stocks, order and supply
- ❑ Monitoring and evaluation of availability, utilization and outdating of components

Blood component therapy

- ❑ Guidelines on use of blood and blood products
- ❑ Hospital transfusion committees
- ❑ Training of clinical staff involved in transfusion
- ❑ Accurate transfusion records
- ❑ Haemovigilance system
- ❑ Ongoing assessment of need for components

Key elements

Organizational requirements for an effective blood component programme

Before a blood component programme is established, a systematic assessment of its feasibility and scope is required. The scale and level of development of the programme should be determined by the clinical demand for components, including the availability of medical and diagnostic services, and the capacity of the BTS.

If the clinical demand for component therapy cannot fully be met from components prepared from whole blood, consideration might be given to developing an apheresis programme.

A blood component programme should be accessible and sustainable. The BTS should be allocated adequate financial resources to meet the additional costs of component preparation, including:

- Suitable premises that comply with good manufacturing practices
- Sufficient number of trained staff
- Specialized equipment for blood collection, processing, testing, storage and transportation and a preventive maintenance system
- Reliable supply of blood collection bags and reagents.

BTS infrastructural requirements include:

- Suitable working environment for donor selection, blood collection, processing, testing and storage
- Reliable water and power supplies with back-up systems
- Waste management system
- Reliable transportation systems
- Effective communication systems.

An effective planning and communication system should be established to set and evaluate targets for donor recruitment, blood collection and component preparation.

A quality system should be in place in all areas to ensure good manufacturing and laboratory practices. This should include:

- Specifications for blood components, equipment and materials
- Validation of processes, procedures, equipment and materials
- Regular maintenance and calibration of equipment to ensure quality and minimize down-time
- Standardized procedures
- Hygiene and safety of environment, equipment, blood donors and staff
- Documentation of all processes and accurate labelling to ensure traceability
- Ongoing training of staff
- Monitoring of all activities to ensure continuous quality improvement.

Blood donors and blood collection

A reliable base of regular voluntary non-remunerated blood donors is a prerequisite for a safe and effective blood component programme that can meet the transfusion requirements of all patients. Effective donor recruitment, call-up and retention strategies are needed to promote regular donation by suitable donors. This requires:

- National donor selection and deferral criteria, including criteria specific to component preparation
- Mechanism for setting blood collection targets to meet component preparation targets and clinical demand.

Effective blood collection requires:

- Systematic planning and preparation for fixed and mobile sessions
- Planning of number and type of collections per session from whole blood/apheresis donors
- Appropriate staffing, equipment and materials, including blood bags.

Component preparation, testing and distribution

The centralization or regionalization of blood processing and testing in major centres permits more efficient, cost-effective use of technology and resources. It also facilitates uniform standards of performance, resulting in improved quality and safety.

Safe component preparation requires:

- Preparation of components only from whole blood or apheresis donors who meet standard selection criteria
- Testing of all donated units and discard of all blood and components that test positive for any transfusion-transmissible infection
- Quality system and good manufacturing practices for all aspects of component preparation and distribution
- Compliance with specifications for components, equipment and materials
- Labelling system for untested, quarantined and available stock
- Mechanisms for quarantine and release
- System for recall of defective components
- Cleaning and maintenance of all areas and equipment to minimize the risk of contamination of components
- Quality monitoring of components, including statistical process control.

Storage and transportation

Correct storage and transportation conditions are required at all times for blood donations and specimens, blood bags, reagents and other materials, especially in extremes of temperature. This entails:

- Storage and transportation of collected units and specimens to processing centres and testing laboratories within prescribed temperature and time limits
- Separate storage areas for untested, quarantined and available units
- Suitable areas and equipment for storage and transportation that meet specifications for time and temperature
- Monitoring and recording of temperatures in all blood cold chain equipment
- Corrective and preventive action in cases of deviation from specified temperature ranges and time limits.

Blood component stock management

Efficient stock management systems are needed in the BTS and hospitals, including:

- Formal agreement and ongoing communication between the BTS and hospitals on optimum stocks, order and supply
- Monitoring and evaluation of component availability and utilization, including shortfalls and outdating.

Blood component therapy

The optimum use of blood as a scarce national resource requires:

- National and hospital guidelines on the use of blood and blood products and alternatives to blood transfusion
- Hospital transfusion committees to develop local policies and guidelines, and monitor component utilization
- Training of clinical staff involved in the prescription and administration of components
- Accurate transfusion records to ensure the traceability of component usage
- Haemovigilance system for monitoring, investigation and reporting of adverse transfusion events
- Ongoing assessment of current and future clinical needs for components.

Blood Transfusion Safety, Department of Essential Health Technologies
World Health Organization
1211 Geneva 27, Switzerland
Fax: +41 22 791 4836 E-mail: bloodsafety@who.int www.who.int/bloodsafety

00079256

我们的产品

大数据平台

国内宏观经济数据库

国际经济合作数据库

行业分析数据库

条约法规平台

国际条约数据库

国外法规数据库

即时信息平台

新闻媒体即时分析

社交媒体即时分析

云报告平台

国内研究报告

国际研究报告