



AIDE-MÉMOIRE

for Ministries of Health

Blood transfusion contributes to saving millions of lives every year, improves life expectancy and the quality of life of patients suffering from life-threatening conditions, and supports complex medical and surgical procedures. Every country should put in place policies, systems and structures to ensure the safety, quality, accessibility and timely availability of blood and blood products to meet the needs of all patients who require transfusion.

The ministry of health (MoH) should provide effective leadership and governance in developing a national blood system that is fully integrated into the health-care system. Essential functions of a national blood system include policy formulation and standard setting, strategic and operational planning, provision of resources and national coordination and management to ensure an adequate supply of blood and blood products and safe clinical transfusion.

The structure of the national blood system will depend on the organization and level of development of the health-care system. However, all critical activities within a national blood system should be coordinated at national level to promote uniform standards, economies of scale, consistency in the quality and safety of blood and blood products and best transfusion practices.

Core components of a national blood system include:

- Specific unit within the ministry of health for coordination, programme management and monitoring of the blood system throughout the country
- Advisory body which brings together the major stakeholders to assist the ministry of health in formulating policy and plans, setting standards and advising on key issues
- Blood transfusion service/s (BTS) involved in donor recruitment, blood and plasma collection, and the testing, processing, storage and distribution of blood and blood products. Common service delivery models include:
 - A single service provider, either governmental or delegated to a not-for-profit, nongovernmental organization
 - Multiple service providers, including governmental and nongovernmental organizations, and private institutions
- Hospital blood banks, clinical transfusion services and transfusion committees for the timely provision of compatible blood and its safe and appropriate use.

An effective national blood system requires coordination and collaboration with relevant government ministries, national reference laboratory and agencies and institutions for public health, surveillance, regulation, accreditation and plasma fractionation.

Words of advice

- Provide effective leadership and governance for the development of a sustainable national blood system
- Develop an effective programme for the achievement of 100 per cent voluntary non-remunerated blood donation
- Establish a mechanism for the coordination of all public, private and voluntary sector institutions, organizations and agencies involved in the national blood system
- Establish an efficient, cost-effective organizational structure for blood transfusion services with an optimal level of consolidation of critical activities
- Create an effective mechanism for regulatory oversight of the blood system



Checklist

Leadership and governance

- National blood policy and strategic plan
- Legislative framework
- Standards
- Financial sustainability
- Risk assessment and management
- Expertise on medical, scientific, financial and ethical issues
- Regulatory mechanism

Coordination and collaboration

- Efficient organizational structure
- Consolidation of critical activities
- Coordination of institutions and organizations involved in:
 - Voluntary blood donation
 - Provision of blood and blood products, including plasma derivatives
- Coordination with hospitals and facilities involved in blood transfusion
- Human resource management, including education, training and career development
- Surveillance and haemovigilance
- Procurement and supply systems
- Data collection and reporting
- Collaboration and partnerships
- Monitoring and evaluation

Provision of safe blood and blood products

- Adequate qualified, trained staff
- Suitable infrastructure and facilities
- Quality system
- Donor education, recruitment and retention
- Donor selection, blood collection and donor management
- Donor counselling and referral
- Blood processing and testing
- Waste management
- Blood storage and inventory management
- Blood cold chain and distribution
- Liaison with hospital transfusion services

Clinical transfusion in patient management

- Hospital standards and guidelines
- Education and training
- Estimation of blood requirements
- Blood storage and handling
- Blood stock management
- Patient's involvement in treatment
- Patient and product identification
- Quality systems
- Hospital transfusion committees
- Haemovigilance

Key elements

Leadership and governance

The MoH has ultimate responsibility for ensuring an adequate supply of safe blood and blood products and their safe and rational use. The MoH should establish a sustainable national blood system which is recognized through a national blood policy, strategic plan and appropriate legal instruments.

The MoH should demonstrate its commitment, leadership and governance through the establishment of systems and structures, including a specific unit or department with overall responsibility for the national blood system. Key functions include:

- Formulate and oversee the implementation of the national blood policy and strategic plan
- Define the roles, responsibilities and accountability of institutions and

organizations that comprise the national blood system

- Set national standards for blood and blood products, services, processes and systems
- Establish regulatory mechanisms for the registration, licensing, operation and inspection of blood transfusion services.

Where blood transfusion services are fully or partially delegated to not-for-profit, nongovernmental organizations, legal agreements are required to define roles, responsibilities and accountability.

The MoH should also establish a national blood commission or council, with representation of key stakeholders, that provides expert on measures for the safety and sufficiency of the national blood supply,

risk management and safe clinical transfusion. The establishment of a national blood authority with executive functions may be more appropriate in countries with complex blood systems, such as those involving multiple institutions and agencies.

The MoH should ensure that adequate, sustainable financing for the national blood system is integrated within the financial structure of the health system, through mechanisms such as a specific budget, cost-recovery and health insurance or a combination of these.

Regulatory mechanisms should be established for the control, inspection and licensing of blood transfusion services to enforce blood product standards and monitor product safety.

Coordination and collaboration

The national blood system should be organized and coordinated by the MoH in a manner that ensures the most efficient and cost-effective use of all resources. Blood transfusion services may operate either under a single service provider, such as a national blood transfusion service (NBTS), or through multiple organizations and institutions. Whichever service delivery model is in place, blood transfusion services should be coordinated at national, regional and provincial levels, with critical activities such as blood screening and processing consolidated in strategic locations.

In countries with a single service provider, the coordination role of the MoH may be undertaken by the NBTS. Requirements include:

- Coordination of all organizations and institutions providing blood transfusion services to harmonize approaches, foster joint planning and collaboration, optimize use of resources, avoid duplication and wastage
- Mechanism to ensure the uniform implementation of national standards
- Efficient procurement and supply chain systems to ensure the continuity of supplies in all blood centres and hospital blood banks
- National system for standardized data collection and reporting
- Systems for traceability, surveillance and haemovigilance
- Policies, standards and systems in blood transfusion services and hospitals for the management of waste from transfusion-related activities
- Monitoring and evaluation of the national blood system
- Strategic partnerships with organizations involved in voluntary NR blood donation
- Collaboration with academic and research institutions, scientific and professional societies, blood donor and patient associations, and industry
- Linkages with health programmes such as maternal and child health, HIV/AIDS and hepatitis, infection control and patient safety.

Provision of safe blood and blood products

Blood transfusion services should comply with national policies and strategies to ensure they implement standards and meet targets for the provision of safe blood and blood products. To perform their functions efficiently, BTS should have:

- Adequate number of qualified, skilled and experienced personnel in human resource management, finance and administration, quality systems, transfusion medicine, blood donor programme and laboratory testing and blood processing
- Suitable infrastructure and facilities in all centres in which blood collection, testing, processing and storage of blood and blood products take place.

Requirements include:

- Effective quality system within which all activities are performed in a quality-focused way and are continuously monitored
- Sustainable donor education, motivation, voluntary NR blood donor recruitment and retention programme
- Safe blood collection process, including donor selection and deferral, donor care, notification, counselling and referral, and confidentiality
- Testing and processing using the most appropriate and effective methodologies and best laboratory practices
- Efficient inventory management system for optimum blood stocks and minimal wastage
- Effective blood cold chain for safe storage and distribution of blood and blood products
- Information management system encompassing all activities from blood donors to distribution of blood and blood products to hospitals, and issue and transfusion of blood and blood products to patients
- Liaison with hospitals in the implementation of transfusion guidelines and staff training
- Participation in national haemovigilance system.

Clinical transfusion in patient management

Hospitals and other health facilities that perform transfusion are an integral part of the national blood system. National and hospital authorities should allocate sufficient resources to optimize blood transfusion for patient health. Requirements include:

- National guidelines on the clinical use of blood and blood products
- Quality systems for the clinical transfusion process, including standardized procedures, blood request forms, labels and records
- Training for clinicians, nurses, midwives and laboratory technical staff
- Systems, processes and procedures for:
 - Compatibility testing and issue of blood
 - Rational use of blood and blood products
 - Safe transfusion practice at the bedside
 - Patient monitoring and follow-up
- Process to assess current and future blood needs
- Availability of critical supplies for alternatives to transfusion, compatibility testing and blood administration
- Systems for correct storage and handling of blood units in hospital blood banks and clinical areas
- Efficient blood stock management for the timely availability of compatible blood and reduced wastage
- Patient involvement in blood management through information and consent
- System for patient and product identification
- Hospital transfusion committees with responsibility for implementing transfusion guidelines and monitoring transfusion practices
- Indicators for assessing trends and improving transfusion practice through clinical audit
- System for monitoring and investigation of adverse transfusion events to feed into the national haemovigilance system.