



WORLD HEALTH ORGANIZATION

# Quality Systems for Blood Safety

## AIDE-MEMOIRE for National Blood Programmes

Blood transfusion is a key part of modern health care. It is the responsibility of the national blood programme to provide an adequate supply of blood for all patients requiring transfusion and to ensure the quality of blood and blood products for clinical use. All products must be safe, clinically effective and of appropriate and consistent quality.

The strategies for achieving this are:

- A well-organized, nationally-coordinated blood transfusion service (BTS)
- Blood collected from regular, voluntary non-remunerated blood donors from low-risk populations
- Testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing
- Appropriate clinical use of blood.

Every blood transfusion service should develop an effective quality system to ensure the implementation of these strategies. The quality system should cover all aspects of its activities and ensure traceability, from the recruitment and selection of blood donors to the transfusion of blood and blood products to patients. It should also reflect the structure, needs and capabilities of the BTS, as well as the needs of the hospitals and patients that it serves.

Key elements of quality systems include:

- Organizational management
- Standards
- Documentation
- Training
- Assessment.

Management commitment and support are essential for the development, implementation and monitoring of a national quality system in order to ensure continuous quality improvement. All staff should understand the importance of quality and the consequences of failure in the quality system.

### Words of advice

- Secure the commitment and support of management at all levels
- Identify the need for quality in the national blood policy
- Develop a national quality policy and plan
- Secure adequate resources
- Designate a national quality manager with overall responsibility for the implementation of quality systems in BTSs at all levels
- Develop a quality section, with appropriate staffing and expertise, in each blood centre and hospital blood bank
- Provide training in quality for all BTS staff and other health care professionals involved in blood transfusion
- Assess the effectiveness of the quality system continually



### Checklist

#### Prerequisites

- ☐ Nationally-coordinated BTS
- ☐ Management commitment and support
- ☐ Integration of quality in the national blood policy
- ☐ National quality policy and plan
- ☐ National quality manager
- ☐ Adequate resources

#### Organizational management

- ☐ Clearly defined organizational structure
- ☐ Quality manager in each blood centre and hospital blood bank
- ☐ Quality section in each blood centre and hospital blood bank
- ☐ Culture of quality
- ☐ Commitment and support of all staff
- ☐ Identification of processes and procedures and their critical control points

#### Standards for quality systems

- ☐ Regulatory or legislative framework
- ☐ Appropriate national or international standards
- ☐ Standards relevant to BTSs

#### Documentation

- ☐ Appropriate, comprehensive documents, including a quality manual and standard operating procedures (SOPs)
- ☐ Complete, accurate records
- ☐ System for controlling documents

#### Training

- ☐ Training policy and plan
- ☐ Training of all BTS staff in quality and quality systems
- ☐ Training of other health care professionals involved in blood transfusion
- ☐ Evaluation of training and its impact

#### Assessment

- ☐ Validation
- ☐ Ongoing data collection and analysis
- ☐ Haemovigilance
- ☐ Regular review of all activities
- ☐ Internal and external audits
- ☐ Error management, corrective and preventive action
- ☐ External quality assessment schemes

# Key elements

## Requirements for quality systems in blood transfusion

It is the responsibility of governments to ensure that the blood and blood products provided for clinical use by the national blood programme are safe, adequate to meet demand, effective and produced consistently to the appropriate standards.

To achieve this, the blood transfusion service must develop an effective quality system. This should provide a framework within which BTS activities are established, performed in a quality-focused way and continuously monitored to improve outcomes.

The establishment of a quality system will ensure the collection of adequate supplies of blood from regular, voluntary non-remunerated donors, the testing of all blood before use and the appropriate clinical use of blood.

Prerequisites for developing a quality system within the national blood programme include:

- Nationally-coordinated blood transfusion service
- Commitment and support of management at all levels
- Recognition of the importance of quality in the national blood policy

- National quality policy and quality plan detailing the strategy, mechanism and resources for their implementation
- Designation of a national quality manager with the necessary responsibility and authority for the development, implementation and monitoring of the quality system
- Provision of appropriate, adequate and sustainable resources to support the development and maintenance of the quality system.

### Organizational management

Central to an effective quality system is commitment and support from management at all levels, including:

- Clearly defined organizational structure that defines accountability, authority and responsibility
- Designation of a quality manager, with the necessary skills and expertise, in each blood centre and hospital blood bank
- Formation of a quality section or identified work area in each blood centre and hospital blood bank from which quality activities can be coordinated
- Development of a culture of quality through a management focus on building quality into all activities
- Motivation of staff to ensure their commitment and support for the quality system
- Identification of specific processes and procedures and their critical control points.

### Standards for quality systems

Relevant and appropriate standards are required to provide the framework for the development of the quality system:

- The existence of any relevant national legislation or regulations must be acknowledged and incorporated into the framework for quality
- Standards may be national or international: e.g. International Organization for Standardization (ISO) and Good Manufacturing Practice (GMP)

- The standards adopted must be relevant to the BTS and its activities.

### Documentation

An effective and accurate documentation system that ensures traceability of all BTS activities is the foundation of good quality management.

Important activities include:

- Development of a quality manual: a document describing the quality system, including the organization's quality policy, standards and procedures
- Production and use of appropriate, comprehensive documents for all activities, including standard operating procedures, forms, labels and any other documents required
- Generation and maintenance of complete and accurate records
- Development of a system to manage the issue, use and retrieval of documents.

### Training

Comprehensive, appropriate and effective training is required for all BTS staff and other health care professionals involved in blood transfusion.

Important activities include:

- Training policy and plan
- Training for all BTS staff in general principles of quality, the quality system, documentation and the use of quality monitoring tools

- Training programmes for other health care professionals involved in blood transfusion
- Clear understanding of the role of the individual in the quality system and the consequences of quality failures
- Ongoing monitoring and evaluation of training and its impact.

### Assessment

Ensuring quality is a continual process. Ongoing assessment of the effectiveness of the quality system is essential through:

- Validation of all processes, procedures, equipment and reagents
- Ongoing collection and analysis of data generated from key activities and their use in quality improvement
- Establishment of haemovigilance through a system of monitoring, reporting and investigation of adverse incidents related to all blood transfusion activities
- Regular review of all activities to assess the overall effectiveness of the quality system and ensure continuous improvement
- Programme of regular internal and external audits of the quality system
- Reporting and analysis of errors with effective corrective and preventive action
- Active participation in appropriate external quality assessment schemes to improve laboratory performance.



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