WHO-EM/LAB/389/E

Strategic framework for blood safety and availability

2016–2025

World Health Organization
Regional Office for the Eastern Mediterranean

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1. Introduction

Blood transfusion is an essential component of health care that contributes to saving lives and improving the quality of life for millions of people worldwide. Blood transfusion is most commonly used in caring for women suffering from bleeding associated with pregnancy and childbirth, children suffering from severe anaemia due to malaria and malnutrition, and victims of trauma, emergencies, disasters and accidents. It is also used to support advanced medical and surgical procedures, including cardiovascular surgery and transplantation in countries with advanced health care systems. Blood and blood products[1] are essential in the treatment of blood and bone marrow disorders, as well as immune deficiency conditions. Universal and timely access to safe blood and blood products, and their appropriate use, are essential components of good health care provision.

The demand for blood and blood products continues to grow as a result of several factors, including the growth and aging of the population, and the availability of, and access to, increasingly sophisticated medical and surgical procedures. Ministries of health are responsible for meeting the increasing clinical needs of patients for safe blood and blood products and for ensuring the quality, safety, availability and equitable distribution of these products through the establishment of an effective national blood supply and transfusion service that is integrated into the national health system.

However, despite the availability of effective measures to ensure the quality and safety of blood and blood products, there is still significant risk associated with their clinical use, including adverse reactions and transmission of transfusion-transmitted infection (TTI).

The safety and availability of blood transfusion depends on the:

- availability of a well-organized and adequately funded nationally coordinated blood transfusion service, with an effective blood component programme under well-defined regulatory oversight;
- collection of blood and blood components from voluntary, non-remunerated and regular blood donors from low risk populations;

[1] The term "blood products" is defined by the Expert Committee on Biological Standardization as follows: "any therapeutic substances derived from human blood, including whole blood, labile blood components and plasma-derived medicinal products" (WHA63.12 Availability, safety and quality of blood products).

- quality-assured testing of all donated blood, including screening for TTIs, ABO and Rhesus D grouping, and compatibility testing;
- reduction in unnecessary transfusions through appropriate clinical use and safe administration of blood and blood products; and
- implementation of effective quality systems in all areas, including quality management, development and implementation of quality standards, effective documentation systems, training of all staff and regular quality assessment, including haemovigilance, based on a national quality policy and strategy.

WHO has been at the forefront of the movement to improve blood and blood product safety and availability as mandated by successive World Health Assembly resolutions, the earliest dating from 1975 (see WHA28.72 Utilization and supply of human blood and blood products, WHA58.13 Blood safety: proposal to establish World Blood Donor Day, WHA63.12 Availability, safety and quality of blood products). In 1987, at its 34th session, the WHO Regional Committee for the Eastern Mediterranean endorsed resolution EM/RC34/R.9 on the development of national blood transfusion services in the countries of the Eastern Mediterranean Region. However, significant challenges remain in providing access to sufficient, affordable and sustainable supplies of blood and blood products, while ensuring the quality and safety of these products in the presence of known and emerging threats to public health.

In response to this situation, the strategic framework for blood safety and availability (2016–2025) was endorsed by the 63rd Session of the Regional Committee in 2016 in resolution EM/RC63/R.6 (see Annex 1). The strategic framework is intended to guide countries in developing and strengthening national blood systems to ensure the continuity, sufficiency, sustainability and security of national supplies of safe and efficacious blood and blood components to meet national needs. It was developed through broad consultation with national blood transfusion service providers, regional and international organizations, and experts working in the field. The strategic framework, with its accompanying framework for action and priority interventions (see Annex 2), will guide countries in developing and strengthening national blood systems to meet national needs.

2. Situation in the Region

2.1 Situation analysis

WHO undertook a comprehensive situation analysis of blood transfusion services in the Eastern Mediterranean Region using data collected from 18 countries and verified by the directors of the national services. The findings, as described below, indicate gaps in all areas of the key elements of a national blood system (summarized in Annex 3), including leadership and governance, coordination and collaboration, provision of safe blood and blood products, clinical transfusion in patient management, and quality system management throughout the blood transfusion chain. About a third of the countries have insufficient national blood supplies to meet the needs of patients for transfusion and the vast majority of people with bleeding disorders and immune deficiencies still have no, or very limited, access to plasma-derived medicinal products.

2.2 Leadership and governance

Of the 18 countries that responded, 14 have a national blood policy, 13 have a national strategic plan and 12 have constituted a national advisory committee (or equivalent) for blood transfusion services. Where there are national advisory bodies established, they are not empowered to take key technical decisions. A regulatory mechanism for the registration, licensing, operation and inspection of the blood transfusion service exists in nine countries and nine have legislation that covers the safety and quality of blood and blood products.

Financing of blood transfusion services is often given low priority and many countries report a lack of adequate, sustainable and specific funding by governments. A dedicated budget for national blood donor and national blood services is only provided for in eight countries. Nine countries report receiving extra budgetary funding from bilateral or multilateral cooperation agencies and development partners. Only seven countries have put in place a cost-recovery system through health insurance schemes or direct payments, such as user fees, to improve available funding.

2.3 Coordination and collaboration

Countries in the Region are at varying stages of development with respect to their blood transfusion service. While some countries have established well-funded and

well-developed services, in many countries services are still developing and fragmented, with challenges of coordination and collaboration among different stakeholders. In 12 countries, a specific unit or department responsible for blood transfusion services exists within the ministry of health. In some countries, blood transfusion services continue to be under the umbrella of laboratory services, which are often not nationally coordinated. In countries that have blood banks in the private sector, these work in isolation from public sector blood services and are mostly unregulated.

In many countries there is a centralized system of evaluation and validation of test kits and reagents. Stock management, as an integral part of the quality system and its management, is ineffective, inadequate or even absent. Five countries report interruption in the regular supply of test kits, reagents and consumables, often due to insufficient budgetary allocation or to trade embargo. Interruption of this kind is a major obstacle for the collection, screening and processing of blood donations.

National systems for standardized data collection and reporting encompassing all activities from blood donation to distribution to hospitals, issuing to patients and the recording of transfusions of blood and blood components to patients, are absent in most countries. These are necessary to facilitate monitoring and evaluation of the vein-to-vein transfusion chain, including traceability and surveillance (haemovigilance). The current information management systems are not well developed and are mainly laboratory-oriented and paper-based.

National policies, standards, regulations, guidelines and standard operating procedures for biomedical waste management are inadequate and insufficient. Not all blood services have access to personal protective equipment and not all countries have a recognized immunization strategy for conventionally recognized infectious agents, especially hepatitis B virus (HBV) and influenza, for all staff.

Strategic partnerships and collaborations with blood donor organizations, patient associations, academic and research institutions, scientific and professional societies, and industry, are not strong. In addition, there is an absence of linkages with key health programmes, such as those for maternal and child health, HIV/AIDS and hepatitis, infection control and patient safety.

2.4 Provision of safe blood and blood products

Many blood services in the Region are not provided with facilities and infrastructure that have been adequately planned and constructed with respect to requirements for space, design, utilities and waste disposal in line with good manufacturing practice

(GMP) requirements. Adequacy of equipment is also not universal and is reported as available in only half the countries.

There is a general shortage of trained specialized staff in blood transfusions services, together with a lack of opportunities for professional development and inadequate staff retention strategies and remuneration, which are not at the same level as other health care workers. Trained biomedical engineers for maintenance and repair of laboratory equipment and facilities are not available in many countries. Coordination in the teaching curricula between the ministry of health and ministry of education requires significant improvement. Only six countries have undergraduate and postgraduate educational and training programmes in transfusion medicine in place, and only 12 countries have opportunities for continuing medical education and training.

Only 6% of the global blood supply is collected in the Region, while it has 9% of the world's population. The blood donation rates in the Region range from 0.42 to 26 per 1000 population. Eight countries reported collecting less than 10 whole blood donations per 1000 population.

Sixteen countries in the Region have implemented strategies for donor motivation and retention and have developed national donor selection criteria. The number of voluntary non-remunerated whole blood donations increased by 28% from 2.52 million in 2004 to 3.24 million in 2011. The mean proportion of voluntary non-remunerated whole blood donations is 59.2%; only two countries reported 100% donation from voluntary non-remunerated donors, with some countries reporting below 10%. Close to 40% of the blood collected is still from family replacement donors, and also from (hidden) paid professional donors.

In all 18 countries, 100% of transfused units screen for HIV 1 and 2 (antigen/antibody), HBV (HBsAg), hepatitis C virus (HCV) and syphilis, using enzyme-linked immuno assay (EIA), and eight countries use nucleic acid amplification test (NAAT), in addition to conventional EIA testing. In five countries, NAAT is carried out routinely in addition to EIA on all samples; while in three countries, NAAT is used selectively, as and when considered necessary. One country screens for syphilis using rapid plasma reagin. Screening for malaria is carried out in four countries. Sixteen countries report collaboration with a national reference laboratory for confirmation of HIV reactive samples.

Overall, 75% of whole blood collected is processed into components, with rates varying among countries from 2% to 84%. There is a lack of capacity, expertise and resources to produce components. Moreover, quality control procedures are not consistently practised during component production. Prescribing clinicians are often reluctant to utilize components because of a misguided preference for whole blood.

Large volumes of plasma recovered from whole-blood donations are currently discarded because of concerns that quality, logistical and budgetary requirements are not being met for contract plasma fractionation due to inadequate GMP. Out of a total of approximately 28.7 million litres of plasma sent for fractionation globally in 2011, only 144 722 litres of recovered plasma from whole blood (0.5% of the global plasma sent for fractionation) was from countries in the Region. Most countries import plasma-derived medicinal products from international sources to meet the needs of patients.

Current estimates suggest that there are 26 524 patients with bleeding disorders in the Region, contributing 9% of the global reported disease burden. Among these, 17 430 have haemophilia (14 027 with haemophilia A, 3128 with haemophilia B and 209 with unknown type), 3605 have von Willebrand disease and 5489 have other bleeding disorders.2 These figures underestimate the real magnitude of the problem.

Haemoglobin disorders, mainly comprising different types of haemoglobinopathies (thalassaemia and sickle cell disorders), present a significant problem worldwide. Around 7% of the global population has an abnormal haemoglobin gene and more than half a million affected children are born each year. The countries of the Region are almost all in the "thalassaemia belt", which accounts for 35% of the global estimate of children born with transfusion-dependent beta (β)-thalassemia. Sickle cell disorders are also a problem in the Region and affect 0.84 per 1000 of births.[3]

In many countries, the blood cold chain system is not effective or is inadequate and has no maintenance programme. The median percentage of total donations (whole blood/red blood cells) discarded in 2011 was 6.5%. This is largely due to donations with a reactive or positive TTI test. Incomplete collections and problems in processing, storage, transportation and dates of expiry also contribute to the discard and wastage of blood and blood components. Data is not available on donor exclusions due to anaemia, underweight or other reason.

The safety and availability of blood and blood components is of great concern in the Region, particularly for populations in humanitarian emergencies, where health systems have been weakened or destroyed as a result of armed conflict, displacement of populations and other complex emergencies. Nearly three quarters of countries, and more than 76 million people in the Region, are currently affected by humanitarian emergencies, including almost 16 million refugees or internally displaced people.

[2] World Federation of Hemophilia report on the annual global survey 2014. Montreal; World Federation of Hemophilia: 2015 (http://www1.wfh.org/publications/files/pdf-1627.pdf accessed 15 September 2016).

[3] Modell B, Darlison M. Global epidemiology of haemoglobin disorders and derived service indicators. Bull World Health Organ. 2008;86(6):417–496 (http://www.who.int/bulletin/volumes/86/6/06-036673/en/, accessed 15 September 2016).

2.5 Clinical transfusion in patient management

Complete and accurate data on clinical transfusions and utilization of blood and blood products are limited. However, information collected from some countries suggests that transfusions are often given unnecessarily, with a preference to transfuse whole blood rather than blood components. National guidelines on the clinical use of blood are available in 13 countries. However, the guidelines are often not adhered to by clinicians or may not be effectively distributed and updated. Quality systems for clinical transfusion processes are not in place.

Only 11 countries have established hospital transfusion committees, which are variably active and suffer from lack of support from hospital management and clinical staff. In general, communication is weak between the blood services, hospital blood banks and hospitals/clinicians (clinical interface), and there are shortcomings in compatibility testing and issue of blood, appropriate clinical use of blood and blood products, safe transfusion practice at the bedside, and patient monitoring and follow-up. Training of clinicians, nurses, midwives and laboratory technical staff on clinical transfusion has only been carried out in six countries.

2.6 Quality system management throughout the blood transfusion chain

Quality management programmes have been initiated in the blood transfusion systems in many countries, but have not been subsequently followed up. Standards and standard operating procedures have been developed, but are not applied uniformly within countries. There are challenges in the development of complete and accurate records and systems for controlling documents. Training of blood transfusion service and clinical staff on quality and quality systems has been conducted. Thirteen countries participate in a national external quality assessment scheme for TTI testing and 11 for blood group serology and compatibility testing, while only five countries report participation in an international external quality assessment scheme and only 10 have protocols for reporting adverse transfusion events and for post-transfusion management of patients.

3. Strategic framework for blood safety and availability 2016–2025

3.1 Background and rationale

Despite the recognition that universal and timely access to safe blood and blood products is essential for good health care provision and the progress made in developing blood transfusion services in many countries in the Region, significant challenges remain that affect the availability, safety, quality, affordability and clinical efficacy of blood and blood products. Approximately 30% of countries in the Region have insufficient or unsustainable national blood supplies, with a median blood donation rate of less than 10 per 1000 population. Moreover, although plasma-derived medicinal products for the treatment of coagulation factor deficiencies and immune deficiency diseases were added to the WHO Model List of Essential Medicines in 1979, the vast majority of people with bleeding disorders and immune deficiencies in the Region still have very limited or no access to these products.

The safety and availability of blood and blood products has a vital role in the implementation of essential interventions for reproductive, maternal, newborn and child health, the delivery of universal health coverage, and the achievement of the strategic priorities for public health in the Region. It is also a critical element in achieving Sustainable Development Goal 3 targets to reduce maternal deaths, end preventable deaths of newborns and children under 5 years of age, end the AIDS epidemic, combat hepatitis, reduce the number of deaths and injuries from road traffic accidents and achieve universal health coverage by 2030.

The strategic framework for blood safety and availability 2016–2025 has been developed to address the challenges identified in the regional situation analysis and to improve the health of the nearly 583 million people in the 22 countries of the Region. The strategic framework will guide countries over the next 10 years (2016–2025) in developing and strengthening national blood transfusion systems, which will ensure the continuity, sufficiency, sustainability and security of national supplies of safe and efficacious blood and blood products to meet the needs of their populations.

The strategic framework will also play an important role in integrating blood transfusion services into health care systems as a cross-cutting service and in support of the implementation of: World Health Assembly resolutions WHA28.72, WHA58.13 and WHA63.12, and Regional Committee resolution EM/RC34/R.9, on

the safety, quality and availability of blood and blood products; Executive Board decision EB136(2) on principles for global consensus on the donation and management of blood, blood components and medical products of human origin; World Health Assembly resolutions WHA63.18 and WHA67.6 on hepatitis; WHA59.20 on sickle-cell anaemia; and Executive Board decision EB118.R1 on thalassemia and other haemoglobinopathies.

3.2 Purpose and scope

The goal of the strategic framework is to improve the availability, safety, affordability and accessibility of blood and blood products in the Eastern Mediterranean Region in order to reduce mortality and morbidity in countries.

The objectives of the strategic framework are to support countries in:

- ensuring access to a safe and sufficient supply of blood and blood products;
- achieving complete reliance on regular voluntary non-remunerated donors for blood and blood components;
- preventing transfusion transmitted infections (TTIs) through quality-assured screening of all donated blood and blood components, and ensuring quality-assured testing for blood grouping and compatibility (immunohaematology);
- developing quality and quality management systems throughout the blood transfusion chain; and
- promoting appropriate clinical use of blood and blood products.

A framework for action (Annex 1) outlines the priority interventions and actions needed from countries to achieve the following targets by 2025.

- All countries will have developed or reviewed and implemented a national blood policy and strategic plan for a nationally coordinated blood transfusion service;
- All countries will have developed and implemented an appropriate framework for regulatory mechanisms for the registration, licensing, operation and inspection of blood transfusion services;
- All countries will have achieved 100% voluntary non-remunerated donations from low risk populations;
- All countries will have achieved or maintained 100% quality-assured testing of donated blood for TTIs;
- All countries will have processed at least 75% of whole blood collected into components within a quality system;
- All countries will have developed and implemented national guidelines on the clinical use of blood;
- All countries will have a functioning and sustainable hospital transfusion committee in at least 80% of hospitals;

- All countries will have implemented national quality management systems at all levels of the blood services; and
- All countries will have established a national haemovigilance system.

3.3 Priority interventions of the strategic framework

Strengthen leadership and governance of the national blood transfusion service

This will be achieved through:

- establishing or strengthening a specific organization, unit or department with overall responsibility for the national blood transfusion service, as appointed and approved by the ministry of health/national health authority;
- appointment of a competent leader or strengthening of the existing leadership;
- the development, or updating, and implementation of a national blood policy and strategic plan;
- the development, or updating, and implementation of an appropriate framework for a regulatory mechanism for the registration, licensing, operation and inspection of the national blood transfusion service;
- establishing and strengthening a national blood advisory body for advising the ministry of health/national health authority on the safety and adequacy of the national blood supply, and appropriate clinical use;
- setting national standards for quality blood and blood products, services, processes and systems; and
- ensuring adequate and sustainable financing for the national blood transfusion service through mechanisms such as a specific fiscal budget, cost-recovery through health insurance, economies of scale and cost-effectiveness, or a combination of these based on the necessary integration of blood supply and consumption in the health care system, in both the private and public sector.

Support coordination and collaboration

This will be achieved through:

- improving national coordination of the blood transfusion service to promote uniform standards, appropriate economies of scale, consistency in the quality and safety of blood and blood products, and best transfusion practices;
- developing effective mechanisms to assist in the selection, procurement and maintenance of equipment, devices and consumables;
- strengthening coordination and collaboration with blood donor and patient associations, academic and research institutions, scientific and professional

societies, and industry (public and private), and establishing links with other health programmes (national, regional and international);
- improving biomedical waste management and occupational safety as part of a comprehensive health and safety policy in blood transfusion services;
- developing an effective national system for the collection and management of data, monitoring and evaluation, and research and development; and
- strengthening blood supply contingency planning for preparedness and response to emergencies, threats and natural disasters.

Strengthen provision of safe blood and blood products to meet patients' needs

This will be achieved through:

- establishing a sustainable voluntary (non-remunerated and regular) blood donor panel from low risk populations through effective public education and donor motivation, recruitment/mobilization and retention programmes, including converting family replacement donors to regular voluntary non-remunerated blood donors;
- ensuring safe blood collection processes, including donor selection and deferral, donor care, notification, counselling, referral and confidentiality;
- strengthening quality-assured testing of blood using the most appropriate and effective methodologies for mandatory screening for HIV 1 and 2, HBV, HCV and syphilis;
- where appropriate and cost-effective, considering other health care priorities, implementing screening strategies using NAAT and other risk-reduction technologies such as pathogen inactivation;
- promoting quality blood component production;
- establishing a mechanism for the coordination and integration of blood and plasma collection programmes aimed at optimizing the use of recovered and source plasma for contract fractionation and minimizing wastage;
- establishing or strengthening an information management system to collect, monitor and ensure the accuracy, transparency and traceability of all data on blood and blood products; and
- developing mechanisms for human resource development through education and training of staff working throughout the transfusion chain.

Promote appropriate clinical use of blood and blood products

This will be achieved through:

- the development, or updating, and implementation of national guidelines on the clinical use of blood and blood products;
- the establishment of mechanisms, such as hospital transfusion committees, to assess current and future needs, monitor trends and improve clinical practice through clinical audits;

- setting up systems, processes and procedures for compatibility testing and issue of blood, safe transfusion practice at the bedside, and patient monitoring and follow-up;
- ensuring availability of critical supplies for alternatives to transfusion, compatibility testing and blood administration; and
- training for clinicians, nurses, midwives and laboratory scientists/technical staff on safe transfusion practice.

Strengthen quality system management throughout the blood transfusion chain

This will be achieved through:

- ensuring management commitment to establishing appropriate quality systems and standardized procedures in the national transfusion service for the collection, testing, processing, storage, distribution and use of blood and blood products;
- developing, or strengthening, and implementing a quality policy, appointing a national quality manager, and appropriate national quality and technical standards;
- developing, or strengthening, an appropriate and comprehensive documentation system captured in a quality manual including process descriptions, standard operating procedures, equipment operating procedures, complete and accurate records, and a system for document control to manage the quality system;
- capacity-building (education, teaching and training) of blood transfusion service staff and other health care professionals involved in blood transfusion medicine and quality management;
- participating in assessment programmes and accreditation; and
- establishing and strengthening national haemovigilance systems for monitoring all aspects of clinical transfusion practices, including adverse events occurring in the vein-to-vein transfusion chain.

See Annex 2 for more detailed actions and targets.

3.4 Implementation of the strategic framework

The implementation of the strategic framework at country level is a collective endeavour that will require concerted and coordinated actions by all stakeholders, national and international, under the leadership of the Ministry of Health. These actions should be adapted to and aligned with each country's specific context, political and socioeconomic environment, available resources and capacities, and overarching health and development strategies, laws and regulations.

The following actions will have a critical role for implementation and are common for most countries regardless of national context.

- Conduct a thorough assessment of the current blood transfusion service.
- Use the results of the assessment to mobilize high-level political commitment and cross-sectoral support for the strengthening of the blood transfusion service.
- Develop a national blood policy and strategic plan through an inclusive consultative process and consensus-building with relevant stakeholders, and officially endorse/enact the policy and plan through appropriate country mechanisms and channels.
- Mobilize the necessary resources, including human, technical and financial resources.
- Establish a national mechanism for monitoring and evaluation of the performance of the blood transfusion service and the implementation of the national blood policy and strategic plan.

The monitoring of the strategic framework should be undertaken annually, by each country, to enable necessary adjustments to be made on time. At the regional level, progress reports will be developed and disseminated every two years. A mid-term review will be conducted after five years of implementation of the strategic framework (2020) and reports on the status of blood safety availability in the Eastern Mediterranean Region will be developed and published.

Data on blood safety and availability indicators will be collated annually for the WHO Global Database on Blood Safety, and each country will in addition define monitoring indicators based on its specific situation that will be used to assess its own progress.

4. The way forward

Universal and timely access to safe blood and blood products and their appropriate use are essential components of good health care provision. With the goal of ensuring universal access to safe blood and blood products, WHO has been at the forefront of the movement to improve safety and availability as mandated by successive World Health Assembly and Regional Committee resolutions. However, countries in the Region still face major challenges in providing access to sufficient, affordable and sustainable supplies of blood and blood products, while also ensuring the quality and safety of these products in the presence of known and emerging threats to public health.

The strategic framework has been developed to address the challenges identified in the situation analysis and to guide countries over the 10 year period 2016–2025 in developing and strengthening national systems. This will ensure the continuity, sufficiency, sustainability and security of national supplies of safe and efficacious blood and blood products to meet the needs of patient populations.

The following recommendations are proposed for Member States.

- Implement the proposed actions as outlined in the strategic framework, adapted to national priorities, regulations and specific context through a broad-based partnership with national and international partners and stakeholders
- Use the strategic framework to guide the development/review of national blood policies and strategic plans, based on the findings of a sound situation analysis and inclusive priority-setting, aligned with the overarching national health plan and national development strategy, and synchronized with national financial policy cycles.
- Ensure provision of adequate financial, human, infrastructural and technical resources for implementation of national blood policies and strategic plans through sound resource planning and programme budgeting, leveraging the support available from domestic and international sources.
- Build and expand the mechanisms and institutional base for monitoring and evaluation of blood transfusion services and of the progress towards implementation of national blood policies and strategic plans.

Countries should carry out a review of their blood transfusion services regularly and develop their own strategic and operational plans, guided by the strategic framework, to address country-specific needs in accordance with their existing resources.

A framework for action (see Annex 2) has been developed to summarize priority interventions and actions by countries with support from WHO, along with indicators and a baseline (2015), including targets for 2020 and 2025, and to assist monitoring of implementation.

WHO will continue to provide support to Member States at regional and country level in their efforts to improve their health blood transfusion services in a cross-cutting and comprehensive manner.

The safety, quality, availability, affordability and clinical efficacy of blood transfusion remain a serious challenge for countries in the Eastern Mediterranean Region. This strategic framework examines the weaknesses of the blood transfusion services in the Region and proposes a framework for action in order to foster timely progress in this vital sector.

Annex 1. Resolution EM/RC63/R.5

REGIONAL COMMITTEE FOR THE EASTERN MEDITERRANEAN | **EM/RC63/R.5 October 2016**

Sixty-third Session

Strategic framework for blood safety and availability 2016–2025

The Regional Committee,

Having considered the technical paper on the strategic framework for blood safety and availability 2016–2025[4];

Recalling resolutions WHA 28.72 on utilization and supply of human blood and blood products, WHA58.13 on blood safety: proposal to establish World Blood Donor Day, WHA63.12 on availability, safety and quality of blood products and EM/RC34/R.9 on the development of national blood transfusion services in the countries of the Eastern Mediterranean Region;

Acknowledging blood transfusion as an essential component of health care;

Noting the status of blood transfusion services in Member States of the Region and the progress made so far, and the continuing gaps in providing access to sufficient, affordable and sustainable supplies of safe and quality blood and blood products;

1. **ENDORSES** the strategic framework for blood safety and availability 2016–2025 and its framework for action (annexed to this resolution);

2. **URGES** Member States to:

    2.1 Take the necessary steps to establish effective and sustainable blood transfusion services, with appropriate legislation and regulatory mechanisms and dedicated budget lines, and to develop national strategic and operational plans based on the strategic framework;

[4] EM/RC63/6 Rev.1.

2.2 Establish effective coordination and collaboration mechanisms among all relevant stakeholders in the public and private sectors;

2.3 Establish, implement and support a national quality management system throughout the blood transfusion chain;

2.4 Take the necessary steps to ensure regular voluntary non-remunerated donation of blood and blood components, and to improve public education, donor motivation, mobilization and retention and all other elements to ensure a safe and sustainable donor programme;

2.5 Develop competent human resource capacity through the provision of initial and continuing education and training of all staff involved in the vein-to-vein chain;

2.6 Establish a mechanism for the integration of blood and plasma programmes, aimed at optimizing the use of recovered and source plasma for fractionation;

3. REQUESTS the Regional Director to:

3.1 Provide support to Member States to develop national strategic and operational plans based on the strategic framework;

3.2 Foster coordination and collaboration with all relevant stakeholders and partners;

3.3 Report to the Regional Committee every two years, starting from 2018, on the progress in implementation of the regional strategic framework for blood safety and availability 2016–2025.

Annex to Resolution EM/RC63/R.5

Framework for action for blood safety and availability 2016–2025

Priority interventions	Action by countries	Progress indicator
Strengthen leadership and governance of the national blood transfusion service	Establish a specific organization, unit or department with overall responsibility for the national blood transfusion service Develop or update and implement a national blood policy and strategic plan Develop or update and implement an appropriate framework for a regulatory mechanism for the registration, licensing, operation and inspection of the national blood transfusion service Establish and strengthen the national blood advisory body to advise the Ministry of Health on the safety and adequacy of the national blood supply and appropriate clinical use Set national standards for quality blood and blood products, services, processes and systems Ensure adequate and sustainable financing for the national blood transfusion service	Country has: implemented a national blood policy and strategic plan for a nationally coordinated blood transfusion service implemented an appropriate framework for a regulatory mechanism for the national blood transfusion service
Support coordination and collaboration	Improve national coordination of the blood transfusion service to promote uniform standards, appropriate economies of scale, consistency in the quality and safety of blood and blood products and best transfusion practices Develop effective mechanisms to assist in the selection, procurement and maintenance of equipment, devices and consumables Strengthen coordination and collaboration with blood donor and patient associations, academic and research institutions, scientific and professional societies, and industry (public and private) and establish links with other health programmes Develop an effective national system for the collection and management of data, monitoring and evaluation, research and development Strengthen blood supply contingency planning for preparedness and response to emergencies, threats and natural disasters	Country has: established a centralized national blood information management system a blood supply contingency plan included in the national emergency preparedness and response plan
Strengthen provision of safe blood and blood products to meet patients' needs	Establish a sustainable voluntary (non-remunerated and regular) blood donor panel from low risk populations Ensure safe blood collection processes, including donor selection and deferral, donor care, notification, counselling and referral and confidentiality Strengthen quality assured testing of blood using the most appropriate and effective methodologies for mandatory screening for HIV 1 and 2, HBV, HCV and syphilis and implement other risk-reduction technologies where appropriate and cost-effective Promote quality blood component production Establish a mechanism for the coordination and integration of blood and plasma collection programmes Establish or strengthen an information management system to collect, monitor and ensure the accuracy, transparency and traceability of all data on blood and blood products Develop mechanisms for human resource development through education and training of staff	Country has: achieved 100% voluntary non- remunerated donations from low risk populations processed at least 75% of whole blood collected into components within a quality system started using plasma for fractionation

Promote appropriate clinical use of blood and blood products	Develop, or update, and implement national guidelines on the clinical use of blood and blood products Establish mechanisms, such as HTCs, to assess current and future needs, monitor trends and improve clinical practice through clinical audits Set up systems, processes and procedures for compatibility testing and issue of blood, safe transfusion practice at the bedside and patient monitoring and follow up Ensure availability of critical supplies for alternatives to transfusion, compatibility testing and blood administration Train clinicians, nurses, midwives and laboratory scientists/technical staff on safe transfusion practice	Country has: developed and implemented national guidelines on the clinical use of blood a functioning and sustainable hospital transfusion committee in at least 80% of hospitals
Strengthen quality system management throughout the blood transfusion chain	Ensure management commitment to establish appropriate quality systems and standardized procedures in the national transfusion service for the collection, testing, processing, storage, distribution and use of blood and blood products Develop or strengthen implementation of quality policy, appointing a national quality manager, and appropriate national quality and technical standards Develop or strengthen an appropriate and comprehensive documentation system captured in a quality manual including processes descriptions, standard operating procedures (SOPs), equipment operating procedures (EOPs), complete and accurate records and a system for document control to manage the quality system Build capacity of blood transfusion service staff and other health care professionals involved in blood transfusion medicine and quality management Participate in assessment programmes and accreditation Establish and strengthen national haemovigilance systems for monitoring all aspects of clinical transfusion practices, including adverse events occurring in the vein-to-vein transfusion chain	Country has: implemented national quality management systems at all levels of the blood services established a national haemovigilance system (in all areas of transfusion medicine, including donor and patient adverse events)

Annex 2. Priority interventions

1. Strengthen leadership and governance of the national blood transfusion service

Intervention components	Action by countries	Action by WHO	Progress indicator	Baseline 2015	Target 2020	Target 2025
1.1 Organizational structure	Establish a clearly defined organizational structure and management for the national blood transfusion service Establish a specific organization, unit or department with the necessary authority from ministry of health/national health authority with overall responsibility for the national blood transfusion service, separate from laboratory services	Disseminate aide-memoire on developing a national blood system (Arabic, English, French) Provide assistance when and where requested	Number of countries with a specific organization, unit or department for national blood transfusion service	12	21	22
1.2. National blood policy	Develop or update and implement a national blood policy through active participation of all stakeholders	Support countries in developing, updating and implementing national blood policy	Number of countries with endorsed (updated) national blood policy	14	22	22
1.3. National strategic plan	Conduct situation and SWOT analysis Develop or update a realistic and practical national strategic plan with defined targets and timelines Implement national strategic plan in a stepwise approach	Support countries in developing, updating and implementing national strategic plan	Number of countries with endorsed (updated) national strategic plan	13	22	22
1.4. Regulatory mechanism	Develop legislation for the national blood transfusion service where it does not exist and ensure it covers all activities Develop an independent, effective and appropriate regulatory body or strengthen the existing regulatory mechanism for the registration, licensing, operation and inspection of blood transfusion service in public, nongovernmental and private health sectors Identify and define the roles of regulators and inspectors/auditors Assess and develop the competency of regulators, inspectors/auditors and operators	Technical support for countries in developing, updating and implementing a regulatory mechanism for national blood transfusion service Advocate, promote and support countries to develop competent regulatory body Identify a suitable collaborating centre in the Region for training of regulators and inspectors/auditors	Number of countries with an established and operational regulatory body	9	18	22

Intervention components	Action by countries	Action by WHO	Progress indicator	Baseline 2015	Target 2020	Target 2025
1.5. National blood transfusion service executive board	Establish and/or strengthen a national blood services executive management board, which provides information and advice to the ministry of health on policies and strategies for key national issues, with representation of the ministry of health/national health authority and all other major stakeholders Countries are advised and urged to review the membership of existing national advisory committees to select suitable members from these bodies and society who can contribute to the establishment of a sustainable and effective functioning executive management board	Support countries in establishing and/or strengthening a functional national blood services executive management board Establish WHO regional expert advisory panel for blood and transfusion safety	Number of countries with national blood transfusion service executive board (or equivalent)	12	20	22
1.6. Financial resources	Allocate a specific budget based on a cost analysis for a sustainable national blood transfusion service linked to the national health financing plan Introduce strategies and mechanisms for sustainable financing of the national blood transfusion service (e.g. cost-recovery, health insurance, efforts to introduce economies of scale and cost-effectiveness)	Respond to request for assistance in developing a costing tool for national blood transfusion service financial management Assist in mobilization of funds and supplies from international partners, bilateral and/or donor agencies	Number of countries with a specific and sustainable budget allocation for blood transfusion service	8	14	22
1.7. Human resources	Develop a national human resources and development plan to include number of staff, deployment, training needs, continuing professional development, remuneration, incentives, retention mechanisms and career development options Develop curriculum for induction and orientation of new staff, and pre-service training of staff categories working throughout the transfusion chain Advocate and develop academic degrees and scientific diplomas for staff working in blood transfusion either at university level or postgraduate level for medical, nursing and technical staff, to create career prospects and recruit more human resources to work in this field	Respond to requests to support countries in the development of national human resource and development plan for blood transfusion service Support countries in integrating hospital blood banking and transfusion medicine in pre-service curriculum	Number of countries with human resources plan for blood transfusion service	10	18	22

2. Support coordination and collaboration

Intervention components	Action by countries	Action by WHO	Progress indicator	Baseline 2015	Target 2020	Target 2025
2.1. National coordination	Establish national coordination of the blood transfusion service with partners and other blood providers at various levels to promote uniform standards, economies of scale, consistency in the quality and safety of blood and blood products and best transfusion practices Calculate the national needs of plasma-derived medicinal products and the estimated plasma targets required Address availability and safety of plasma and plasma-derived medicinal products in the national blood policy, national strategic plan, regulatory mechanisms and implementation of the national blood transfusion service	Support countries in coordinating with partners Organize regional consultations on optimization of recovered plasma collection and integration of plasma collection targets in overall blood programmes Support countries in addressing plasma and plasma-derived medicinal products requirements in their national blood policy, national strategic plan and regulatory mechanisms	Number of countries that meet plasma quality requirements	3	14	22
2.2. Procurement and supply management	Establish and promote centralized bulk procurement of equipment, test kits, reagents, consumables based on pre-validation (sensitivity, specificity), expiry dates, shelf-life and cost Improve stock management and cold chain control measures for transportation, and traceability Improve planned preventive maintenance and repair of equipment, facilities, and vehicles Develop approved suppliers list	Support countries in the development of national procurement and supply management system Support countries in developing a system for planned preventive maintenance, repair and replacement of equipment, facilities and vehicles	Number of countries reporting stock out of reagents and supplies	5	0	0

Intervention components	Action by countries	Action by WHO	Progress indicator	Baseline 2015	Target 2020	Target 2025
2.3. Partnerships	Develop and implement stakeholder's analysis Support blood donor organizations, patient associations and develop mechanisms to improve partnership with the community Establish working relationships with academic and research institutions, scientific and professional societies and industry Establish links with health programmes such as maternal and child health, HIV, hepatitis, surgery, trauma care, centres for accident, emergency and road traffic injuries, haemophilia, thalassemia and sickle cell disease Celebrate World Blood Donor Day and/or national blood donor days	Establish a regional network of blood donor organizations Strengthen patient associations in the region	Number of countries with functional national blood donor organizations	11	20	22
2.4. Occupational safety and biomedical waste management	Develop a national biomedical waste management policy for blood transfusion service Provide appropriate infrastructure, facilities, environment and equipment for biomedical waste management Develop and implement standard operating procedures for biomedical waste management Procure and distribute equipment and commodities for biomedical waste management Improve access to personnel protective equipment and immunization for pre- and post-exposure prophylaxis Train staff on biomedical waste management and health and safety at work in blood transfusion service Establish policies and procedures for reporting and management of sharp and needle-stick injuries	Support countries in developing and implementing national strategies and guidelines on biosafety, waste management and infection control Organize regional training for blood transfusion service staff on biosafety, waste management and infection control	Number countries with appropriate physical structure and equipment for biomedical waste management	13	20	22

Intervention components	Action by countries	Action by WHO	Progress indicator	Baseline 2015	Target 2020	Target 2025
2.5. Information management system	Develop a national centralized blood information management system to collect, monitor and ensure the accuracy, transparency, traceability and confidentiality of all data on blood and blood products from the donor to the recipient with data backup system Develop national guidelines on archiving that specify legal requirements and the length of time that reports, records and data are to be maintained	Adaptation and translation of blood information management system guidelines Technical support in setting up national blood information management system	Number of countries with centralized national blood information management system	8	19	22
2.6. Research and development	Review existing information (including WHO Global Database on Blood Safety) and identify priority research topics Collaborate with academic and research institutions, scientific and professional societies and industry to conduct operational and basic research	Strengthen and support WHO collaborating centres to conduct operational research Prepare biennial regional progress reports on blood safety and availability	Number of countries submitted complete data to WHO Global Database on Blood Safety	16	22	22
2.7. Contingency planning	Create awareness of the need for ensuring adequate blood supply during humanitarian emergencies and outbreaks of emerging infections Include blood supply contingency plan in the national emergency preparedness and response plan to provide a framework for a rapid and coordinated response to emergencies Review the supply of blood and blood products during emergencies and outbreaks of emerging infections (when applicable)	Organize regional consultations on blood transfusion during humanitarian emergency situations Technical support in developing guidelines for rapid response for emerging infections, surveillance and reporting system Technical support in developing national/regional guidelines for rapid response during humanitarian emergencies, disasters and regional/global threats	Number of countries with blood supply contingency plan included in national emergency preparedness and response plan	15	22	22

3. Strengthen provision of safe blood and blood products to meet patients' needs

Intervention components	Action by countries	Action by WHO	Indicator	Baseline 2015	Target 2020	Target 2025
3.1. Blood donor programme	Establish voluntary non-remunerated and regular blood and blood component donor education, motivation, mobilization and retention programme Designate a public education, blood donor motivation and retention unit within blood transfusion services Develop national guidelines and perform quality assurance for donor selection, deferral, safe blood collection process, donor care (including donor vigilance), notification, counselling and referral Collaborate with the media, blood donor organizations and other community organizations to promote the culture of voluntary non-remunerated and regular (repeat) donation Convert family replacement donors to voluntary non-remunerated donors Educate and train blood bank staff on public education, motivation, recruitment, retention and safe blood collection procedures Translate documents in local languages	Translate to Arabic and distribute WHO guidelines for donor selection and donor counselling Organize World Blood Donor Day as a regional event Provide technical support in developing relevant information, education and communication materials Provide technical support in translation of documents and information, education and communication material	Number of countries collecting 100% of their blood supply from voluntary non-remunerated donors	2	17	22
3.2. Quality assured testing	Develop strategies for screening for transfusion-transmitted infections (TTIs) based on epidemiology, capacity of laboratories and a cost-benefit analysis Convert step-wise from rapid test to enzyme-linked immunoassay and consider appropriateness of introduction of screening strategies using nucleic acid amplification test and other risk-reduction technologies such as pathogen inactivation as appropriate Collaborate with national, regional or global reference laboratories for evaluation of assays, investigation of infection transmission cases and confirmation of test results Provide required infrastructure, equipment and maintenance, financial resources, and competent staff	Translate to Arabic and disseminate WHO guidelines on screening donated blood for TTIs Facilitate regional EQAS Organize regional training on testing and selection of appropriate screening and testing algorithms	Number of countries with 100% quality-assured and uninterrupted testing of donated blood for TTIs	18	22	22

Intervention components	Action by countries	Action by WHO	Indicator	Baseline 2015	Target 2020	Target 2025
	Ensure availability of quality control material, procedures and participation in External Quality Control System (EQAS)					
3.3. Component production	Implement a step-wise component production programme based on needs and feasibility Procure equipment and supplies required for component production, storage and distribution (cold chain) Train staff on component production, cold chain management and component therapy	Disseminate aide-memoire on safe blood components Support countries in strengthening quality blood component collection and production	Number of countries processing at least 75% of whole blood collected into components	12	18	22
3.4. Fractionation	Integrate plasma programmes in the national blood transfusion service to optimize the use of recovered plasma and minimize wastage Introduce and implement the necessary operational and quality systems to produce adequate volumes of qualified plasma for fractionation Include plasma-derived medicinal products in national list of essential medicines	Explore feasibility of fractionation programmes on a regional or national level (including contract or loan fractionation)	Number of countries using plasma for fractionation	3	3	5

4. Promote appropriate clinical use of blood and blood products

Intervention components	Action by countries	Action by WHO	Indicator	Baseline 2015	Target 2020	Target 2025
4.1. National guidelines on appropriate clinical use of blood and blood products	Develop and implement guidelines on appropriate clinical use of blood and blood products by consensus with clinicians and the blood transfusion service Procure and distribute critical supplies for alternatives to transfusion, compatibility testing and blood administration	Provide technical support for the development and implementation of guidelines on appropriate clinical use of blood and blood products	Number of countries with endorsed national guidelines on the appropriate clinical use of blood and blood products	13	20	22
4.2. Hospital transfusion committees	Establish and support hospital transfusion committees in all hospitals with clearly defined terms of reference Conduct annual review of the activities of hospital transfusion committees	Provide technical support in establishing hospital transfusion committees	Number of countries with at least 80% of hospitals having functional hospital transfusion committees	11	18	22
4.3. Clinical transfusion	Establish systems, processes and procedures for compatibility testing and issue of blood, safe transfusion practice at the bedside and patient monitoring and follow-.up Assign transfusion officers and train staff to monitor patient transfusions and report any adverse reactions	Develop or adapt tools for estimating blood needs Provide technical support for implementation of the guidelines on appropriate clinical use of blood and blood products	Number of countries implemented the national guidelines on appropriate clinical use of blood and blood products	8	12	22
4.4. Education and training	Conduct education and training for clinicians, nurses, midwives, pharmacists and laboratory technical staff on appropriate clinical use of blood and blood products and safe transfusion practice Conduct regular clinical audits to monitor and train clinical staff including clinicians, nurses, laboratory staff and any other staff involved in the transfusion chain	Support countries in planning and implementing training activities on appropriate clinical use of blood and blood products and patient blood management	Number of countries conducted national training on appropriate clinical use of blood and blood products	10	21	22

5. Strengthen quality system management throughout the blood transfusion chain

Intervention components	Action by countries	Action by WHO	Indicator	Baseline 2015	Target 2020	Target 2025
5.1. Organizational management	Develop national quality policy and plan Assign quality managers at national and facility levels Designate a quality section/team in each blood bank and hospital	Provide technical support for developing national quality policy and plan	Number of countries with quality policy and plan	14	18	22
5.2. Standards	Develop or update quality and technical standards on the management and operational processes for blood transfusion service and clinical transfusion, supported and based on legislation Include quality and quality management in the regulatory mechanism for registration, licensing, operation and inspection of blood transfusion service Ensure standards cover all critical processes and products vein-to-vein, are agreed by all stakeholders and followed by all facilities Review and revise standards at regular intervals	Provide technical countries in developing and updating standards Develop an electronic resource including all national standards	Number of countries with blood transfusion service standards	14	18	22
5.3. Documentation	Develop a quality manual including the quality policy, standards and procedures Produce and use appropriate, comprehensive documents for all activities, including standard operating and equipment procedures, forms, labels and any other documents required Develop a system for document control and records for storage and traceability	Provide technical support for developing a national quality manual	Number of countries with quality manual	11	18	22
5.4. Education (teaching and training)	Conduct competency-based training for blood transfusion service and clinical staff in general principles of quality, the quality system, documentation and use of quality monitoring tools Assess competency of staff regularly Advocate and contribute in updating or developing curricula for undergraduate and postgraduate education in blood banking and transfusion medicine	Provide technical support for quality management training Identify and support regional centre that can provide exchange visits to promote quality models for best practice	Number of countries with undergraduate and postgraduate training programmes in blood banking and transfusion medicine	6	15	22

Intervention components	Action by countries	Action by WHO	Indicator	Baseline 2015	Target 2020	Target 2025
5.5. Assessment	Conduct validation of all processes, procedures, equipment and reagents Conduct regular internal and external audits of operational and quality systems Develop a system for reporting and analysis of errors and non-conformities with corrective and preventive action Participate in external quality assessment schemes Participate in accreditation programmes (national, regional or international) Develop a risk assessment system	Provide technical support for validation, audits, assessment and accreditation schemes	Number of countries participating in EQAS for TTI screening and immunohaematology	11	18	22
5.6. Haemovigilance	Assign a national haemovigilance focal person Develop a system for monitoring and investigating adverse events in clinical transfusion Develop systems of surveillance on the incidence and prevalence of TTIs in blood donors and general population and for follow-up investigation of infection transmission cases Develop a system to monitor incidence, prevalence, follow-up and look-back investigation of TTIs Collaborate with public health agencies in surveillance of diseases that have impact on blood safety and supplies Encourage hospitals to enrol in a regional or international voluntary haemovigilance initiatives (e.g. the Arab Haemovigilance Network of the Arab Transfusion Medicine Forum)	Establish regional programmes for vigilance, rapid alert and information sharing for emerging infections Translate to Arabic and disseminate aide-memoire and the guide on establishing a national haemovigilance system Organize regional consultation on haemovigilance Provide training on haemovigilance	Number of countries with a national haemovigilance system for donor and patient adverse events	10	19	22

Annex 3. Summary of the key elements of a national blood system

Leadership and governance

The ministry of health/national health authority has ultimate responsibility for ensuring an adequate national supply of safe blood and blood products and their safe and appropriate clinical use. The ministry of health/national health authority should establish a sustainable national blood transfusion service that is authorized and recognized through the formulation and implementation of a national blood policy and strategic plan, defining the roles, responsibilities and accountability of institutions and organizations, which comprise a coordinated national blood service, setting national standards for blood and blood products, services, processes and systems, and establishing appropriate regulatory mechanisms for the registration, licensing, operation and inspection of blood transfusion services. It should also demonstrate its commitment through the establishment of systems and structures, including a specific organisation, unit or department with overall responsibility for the national blood service. Furthermore, the ministry of health/national health authority should provide a mechanism for the appointment of a national blood advisory committee to provide expert guidance on areas of improvement in the blood service and clinical transfusion practice, as and when necessary. It should also provide adequate, sustainable financing for the national blood service, which is integrated within the financial structure of the national health care system.

Coordination and collaboration

The national blood transfusion service should be organized and coordinated by the body approved by ministry of health/national health authority in a manner that ensures the most efficient and cost-effective use of all resources. Blood transfusion services may operate, in a coordinated manner, either under a single service provider 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 cost-effective and strategic locations.

Source: Adapted from Developing a national blood system: aide mémoire for ministries of health [website]. Geneva: World Health Organization; 2016 (http://www.who.int/bloodsafety/publications/am_developing_a_national_blood_system.pdf, accessed 15 September 2016).

Provision of safe blood and blood products

Blood transfusion services should comply with national policies, strategies and plans to ensure the implementation of standards to meet targets for the provision of safe blood and blood products. In order to perform their functions efficiently, blood transfusion services should have an adequate number of qualified, skilled and experienced personnel in human resource management, finance and administration, quality systems, transfusion medicine, blood donor programmes, laboratory testing and blood processing, and suitable infrastructure and facilities in all centres in which blood collection, testing, processing and storage of blood and blood products take place.

The most robust and safe national blood services that ensure the continuity, sufficiency, sustainability and security of national supplies are based on the principle of voluntary non-remunerated donations of blood and blood components donated by regular blood donors from low-risk populations. Sustainable public education, donor motivation, recruitment, mobilization and retention programmes, and a safe blood collection process, including donor selection and deferral, and donor care, notification, counselling, referral and confidentiality, are the foundations of an effective blood donor programme.

Testing and processing using the most appropriate and effective methodologies and best laboratory practices, efficient inventory management system for optimum blood stocks, and effective blood cold chain for safe storage and distribution of blood and blood products are key requirements to ensure the safety and availability of blood and blood products and to reduce wastage.

Clinical transfusion in patient management

Hospitals and other health facilities that perform transfusion should liaise and work closely with the national blood transfusion service. National and hospital authorities should allocate sufficient resources to optimize blood transfusion for patient health. Cooperation of national blood transfusion services with hospitals in the implementation of transfusion guidelines, staff training and participation in national haemovigilance are of paramount importance to improve clinical transfusion. Hospital transfusion committees with clear terms of reference and responsibility for implementing transfusion guidelines and monitoring transfusion practices are key institutional mechanisms to improve clinical transfusion.

Quality system management throughout the blood transfusion chain

A quality system addressing organizational management, standards for quality systems, documentation, training and assessment is a key requirement for provision of safe blood and blood products in patient management. In an effective quality system all activities are performed in a quality-focused way and are continuously monitored.

The strategic framework for blood safety and availability (2016–2025), with its accompanying framework for action and priority interventions, is intended to guide countries in developing and strengthening national blood systems to ensure the continuity, sufficiency, sustainability and security of national supplies of safe and efficacious blood and blood components to meet national needs. It was developed through broad consultation with national blood transfusion service providers, regional and international organizations, and experts working in the field.