



Strategic framework for blood safety and availability 2016–2025

Executive summary

1. With the goal of ensuring universal access to safe blood and blood products and their appropriate clinical use, WHO has been at the forefront of the movement to improve blood safety and availability as mandated by successive World Health Assembly and Regional Committee resolutions. However, countries in the Eastern Mediterranean Region still face major challenges in ensuring the availability, safety, quality, accessibility, affordability and clinical efficacy of blood and blood products.
2. WHO undertook a comprehensive situation analysis of national blood transfusion services, in the Region, using data collected from 18 countries which was verified by the directors of the national blood transfusion services. The findings showed gaps, in all areas, of the key elements of a national blood system, including leadership and governance, coordination and collaboration of national blood systems, provision of safe blood and blood components, patient blood management and clinical transfusion, and quality system and management.
3. The regional strategic framework for blood safety and availability (2016–2025) 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. The Regional Committee is invited to endorse the strategic framework with a view to mobilizing high-level political commitment and support and ensuring allocation of adequate resources by Member States.

Introduction

4. 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 are essential in the treatment of blood and bone marrow disorders, as well as immune deficiency conditions.
5. 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. The ministries of health are responsible for meeting the increasing clinical needs of patients for blood and blood products and for ensuring the quality and safety of these products. 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 transfusion transmitted infection (TTI).
6. WHO has been at the forefront of the movement to improve blood safety and availability as mandated by successive resolutions of the World Health Assembly (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 on Availability, safety and quality of blood products). In 1987, at its 34th session the Regional Committee endorsed resolution EM/RC34/R.9 on the development of national blood transfusion services in the countries of the Eastern Mediterranean Region. Since that time blood transfusion services in the Region have made progress towards ensuring universal access to safe blood and blood products. However, significant challenges remain 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.

7. The regional strategic framework for blood safety and availability (2016–2025) is intended to address the gaps in national blood transfusion services in the Region and improve the safety and availability of blood and blood products. The framework was developed through broad consultation with national blood transfusion service providers, regional and international organizations and experts working in the field. The strategic framework and accompanying framework for action will guide countries in developing and strengthening national blood systems to meet national needs.

Situation in the Region

8. 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, including leadership and governance, coordination and collaboration of national blood systems, provision of safe blood and blood components, patient blood management and clinical transfusion, and quality system and management. 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.

Leadership and governance

9. Of the 18 countries that responded, 14 (78%) have a national blood policy, 13 (72%) have a national strategic plan and 12 (67%) have constituted a national advisory committee (or equivalent) for blood transfusion services. A regulatory mechanism for the registration, licensing, operation and inspection of the blood transfusion service exists in nine (50%) countries and nine (50%) have legislation that covers the safety and quality of blood and blood products. A dedicated budget for the national blood donor and national blood services is only provided for in eight (44%) countries. Only seven (30%) countries have put in place a cost-recovery system through health insurance schemes or direct payments, such as user fees, to improve available funding.

Coordination and collaboration

10. In 12 (67%) countries a specific unit or department responsible for the blood transfusion service exists within the Ministry of Health. In some countries the blood transfusion service continues to be under the umbrella of the laboratory services. In countries which have blood banks in the private sector, these work in isolation from the public sector blood services and are mostly unregulated.

11. 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, in many cases due to insufficient budgetary allocation or trade embargo. Interruption of such supplies is a major obstacle for collection, screening and processing of blood donations.

12. National systems for standardized data collection and reporting 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.

13. 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 (HBV) and influenza, for all staff.

14. Strategic partnerships and collaborations with blood donor organizations and patient associations, academic and research institutions, scientific and professional societies and industry are not strong. In addition, there are no linkages with key health programmes, such as maternal and child health, HIV/AIDS and hepatitis, infection control and patient safety.

Provision of safe blood and blood products

15. Many blood services in the Region are not provided with facilities and infrastructures 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.

16. There is a general shortage of trained specialized staff in the blood transfusions services, together with a lack of opportunities for professional development and inadequate staff retention strategies and remuneration. 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 (38%), have undergraduate and post-graduate educational and training programmes in transfusion medicine in place, and in only 12 countries (70%) are there opportunities for continuing medical education/training.

17. Only 6% of the global blood supply is collected in the Eastern Mediterranean 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. 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.

18. In all 18 countries, 100% of transfused units were screened for HIV 1 and 2, HBV and hepatitis C (HCV) and syphilis using enzyme-linked immunoassay (EIA) and eight countries use nucleic acid amplification tests (NAT) in addition to conventional EIA testing. In five (29%) countries NAT is carried out routinely in addition to EIA on all samples, while in three (18%) countries NAT 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 (89%) countries report collaboration with a national reference laboratory for confirmation of HIV reactive samples.

19. Seventy-five per cent (75%) of whole blood collected is processed into components, which varies among countries ranging 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.

20. 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 Eastern Mediterranean Region. Most countries import plasma-derived medicinal products from international sources to meet the needs of patients.

21. 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.

22. 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. The safety and availability of blood and blood products is of great concern in the Region, particularly for populations in humanitarian emergencies.

Clinical transfusion in patient management

23. National guidelines on the clinical use of blood are available in 13 (72%) countries. However, the guidelines are often not adhered to by clinicians, or may not be effectively distributed to clinicians, and have not been updated. Quality systems for the clinical transfusion processes are not in place. Only 11 (61%) countries report having established hospital transfusion committees, which are variably active and suffer from lack of support from the hospital management and clinical staff. Training of clinicians, nurses, midwives and laboratory technical staff on clinical transfusion has only been carried out in six countries.

Quality system management throughout the blood transfusion chain

24. Quality management programmes have been initiated in the blood transfusion systems in many countries but have not subsequently been 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 staff of the blood transfusion system and of clinical staff on quality and quality systems has been conducted. Thirteen (72%) countries participate in a national external quality assessment scheme (EQAS) for TTI testing and 11 (61%) for blood group serology and compatibility testing. Only five countries report participation in an international external quality assessment scheme. Only 10 (56%) countries have protocols for reporting adverse transfusion events and for post-transfusion management of patients.

Purpose and scope of the regional strategic framework

25. The goal of the regional 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 the mortality and morbidity in the countries of the Region.

26. 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 of blood and blood components;
- preventing transfusion-transmitted infections 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.

27. The priority interventions are to:

- strengthen leadership and governance of the national blood transfusion service
- support coordination and collaboration

- strengthen provision of safe blood and blood products to meet patients' needs
- promote appropriate clinical use of blood and blood products, and
- strengthen quality system management throughout the blood transfusion chain.

28. A framework for action (Annex 1) outlines the 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 nationally coordinated blood transfusion services.
- All countries will have developed and implemented an appropriate framework for regulatory mechanisms for the registration, licensing, operation and inspection of the national blood transfusion service.
- 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 transfusion-transmitted infections.
- 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.
- All countries will have established a national haemovigilance system.

Key country actions

29. 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.

30. The following actions will have a critical role for implementation and are common for most of the countries regardless of the 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 of the implementation of the national blood policy and strategic plan.

Conclusions and recommendations

31. 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.

32. The Eastern Mediterranean regional 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.

33. 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.

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

35. The Regional Committee is invited to endorse the strategic framework for blood safety and availability.

Annex 1. 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	<p>Establish a specific organization, unit or department with overall responsibility for the national blood transfusion service</p> <p>Develop or update and implement a national blood policy and strategic plan</p> <p>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</p> <p>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</p> <p>Set national standards for quality blood and blood products, services, processes and systems</p> <p>Ensure adequate and sustainable financing for the national blood transfusion service</p>	<p>Country has:</p> <p>implemented a national blood policy and strategic plan for nationally coordinated blood transfusion service</p> <p>implemented an appropriate framework for a regulatory mechanism for the national blood transfusion service</p>
Support coordination and collaboration	<p>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</p> <p>Develop effective mechanisms to assist in the selection, procurement and maintenance of equipment, devices and consumables</p> <p>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</p> <p>Develop an effective national system for the collection and management of data, monitoring and evaluation, research and development</p> <p>Strengthen blood supply contingency planning for preparedness and response to emergencies, threats and natural disasters</p>	<p>Country has:</p> <p>established a centralized national blood information management system</p> <p>a blood supply contingency plan included in the national emergency preparedness and response plan</p>
Strengthen provision of safe blood and blood products to meet patients' needs	<p>Establish a sustainable voluntary (non-remunerated and regular) blood donor panel from low risk populations</p> <p>Ensure safe blood collection processes, including donor selection and deferral, donor care, notification, counselling and referral and confidentiality</p> <p>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</p> <p>Promote quality blood component production</p> <p>Establish a mechanism for the coordination and integration of blood and plasma collection programmes</p> <p>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</p> <p>Develop mechanisms for human resource development through education and training of staff</p>	<p>Country has:</p> <p>achieved 100% voluntary non-remunerated donations from low risk populations</p> <p>processed at least 75% of whole blood collected into components within a quality system</p> <p>started using plasma for fractionation</p>
Promote appropriate clinical use of blood and blood products	<p>Develop, or update, and implement national guidelines on the clinical use of blood and blood products</p> <p>Establish mechanisms, such as HTC, to assess current and future needs, monitor trends and improve clinical practice through clinical audits</p> <p>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</p> <p>Ensure availability of critical supplies for alternatives to transfusion, compatibility testing and blood administration</p> <p>Train clinicians, nurses, midwives and laboratory scientists/technical staff on safe transfusion practice</p>	<p>Country has:</p> <p>developed and implemented national guidelines on the clinical use of blood</p> <p>a functioning and sustainable hospital transfusion committee in at least 80% of hospitals</p>

Priority interventions	Action by countries	Progress indicator
Strengthen quality system management throughout the blood transfusion chain	<p>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</p> <p>Develop or strengthen implementation of quality policy, appointing a national quality manager, and appropriate national quality and technical standards</p> <p>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</p> <p>Build capacity of blood transfusion service staff and other health care professionals involved in blood transfusion medicine and quality management</p> <p>Participate in assessment programmes and accreditation</p> <p>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</p>	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)