

## **Progress report on implementation of the regional strategic framework for blood safety and availability 2016–2025**

### **Introduction**

1. In October 2016, the Sixty-third session of the Regional Committee for the Eastern Mediterranean adopted resolution EM/RC63/R.5 endorsing the regional strategic framework for blood safety and availability 2016–2025 and its framework for action.
2. In the resolution, the Committee urged Member States to: (a) 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; (b) establish effective coordination and collaboration mechanisms among all relevant stakeholders in the public and private sectors; (c) establish, implement and support a national quality management system throughout the blood transfusion chain; (d) 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; (e) 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; and (f) establish a mechanism for the integration of blood and plasma programmes, aimed at optimizing the use of recovered and source plasma for fractionation.
3. The Committee also requested WHO to: (a) provide support to Member States to develop national strategic and operational plans based on the strategic framework; (b) foster coordination and collaboration with all relevant stakeholders and partners; and (c) monitor the progress achieved in implementing the strategic framework and report on it to the Regional Committee on a biennial basis.
4. The regional strategic framework identified a set of strategic interventions to improve blood safety and availability in five priority areas: leadership and governance; coordination and collaboration; provision of safe blood and blood products to meet patients' needs all the time, including during humanitarian emergencies; appropriate clinical use of blood and blood products; and quality system management throughout the blood transfusion chain.
5. This report provides a progress update on implementation of the regional strategic framework by Member States and WHO during the first two years of the ten-year framework.

### **Progress update**

6. Recognizing the many challenges in ensuring blood safety and availability, implementation has focused on priority interventions. These include generating information for evidence-based planning and monitoring, fostering coordination and collaboration among relevant partners, strengthening leadership and governance of the blood system and improving access to quality-assured blood and blood products at all times, including during humanitarian emergencies.

### **Strengthening leadership and governance of national blood systems**

7. Strengthening blood regulatory systems was one of the priority interventions. Currently, nine countries reported having in place blood legislation and a regulatory mechanism for the registration, licensing, operation and inspection of blood supply and transfusion systems. WHO has reviewed existing blood legislation in these countries and developed template legislation that countries can adapt to foster adherence to good manufacturing principles and harmonization across the Region. Two national consultations were

conducted in Pakistan to review, update and strengthen blood regulatory systems. In line with the regional strategic framework, WHO supported Sudan to develop a national blood policy and a strategic plan for strengthening its national blood system.

## **Supporting coordination and collaboration**

8. Progress has been made in strengthening coordination and collaboration with relevant units and departments within WHO and WHO Collaborating Centers. In addition, several collaborative activities were conducted with the Arab Authority for Blood Transfusion Services, the International Federation of Red Cross and Red Crescent Societies, professional societies such as the Arab Transfusion Medicine Forum, national professional societies, the Asian Association of Transfusion Medicine, the International Society of Blood Transfusion, the American Association of Blood Banks, the International Haemovigilance Network, blood donor organizations such as the International Federation of Blood Donor Organizations and its national chapters, patient organizations such as the World Federation of Haemophilia, the Haemophilia Eastern Mediterranean Network and the Thalassemia International Federation, and the International Plasma Fractionation Association.

## **Strengthening the provision of safe blood and blood products to meet patients' needs**

9. In order to improve access to a safe and sufficient supply of blood and blood products through regular voluntary non-remunerated blood donations, WHO initiated and promoted the establishment of blood donor management programmes. Regional and national workshops on blood donor management were conducted in Egypt, Jordan and Pakistan to address gaps in relevant knowledge and skills identified through a comprehensive assessment.

10. Recognizing the gaps in quality-assured testing and processing of blood donations, regional workshops on good manufacturing practices and immunohaematology were conducted in the Islamic Republic of Iran with participants from countries in the Region.<sup>1</sup>

11. The availability and safety of blood transfusion during humanitarian emergencies remains a major concern in the Region. Assessment conducted in affected countries<sup>2</sup> showed an increase in the demand for blood transfusion and identified challenges in providing transfusion services. The need to build stronger and more resilient national blood systems that can meet the increased demand for blood during emergencies was one of the recommendations of the regional consultation on the availability and safety of blood transfusion during humanitarian emergencies held in 2016.<sup>3</sup> In this regard, WHO has provided technical assistance to affected countries to implement the recommendations of the consultation.

12. A workshop on plasma fractionation was organized in 2018 with the aim of optimizing the use of plasma for fractionation, reducing its wastage and facilitating the integration of blood and plasma programmes.<sup>4</sup>

## **Promoting appropriate clinical use of blood and blood products**

13. Inappropriate use of blood, unsafe transfusion practices and a lack of effective patient blood management programmes continue to be major concerns in the Region. WHO and the International Society of Blood Transfusion are updating the guidelines on the clinical use of blood to meet the need for appropriate guidance. Efforts are ongoing to establish a mechanism for clinical governance of the blood transfusion service at hospital level through the establishment of hospital transfusion committees.

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<sup>1</sup> Participants from Afghanistan, Islamic Republic of Iran, Iraq, Morocco, Oman and Sudan.

<sup>2</sup> Participants from Afghanistan, Iraq, Libya, Pakistan, Palestine, Somalia, Sudan, Syrian Arab Republic and Yemen.

<sup>3</sup> Summary report on the Regional consultation on the availability and safety of blood transfusion during humanitarian emergencies, Tunis, Tunisia, 15–16 May 2016.

([http://apps.who.int/iris/bitstream/handle/10665/249542/IC\\_Meet\\_Rep\\_2016\\_EN\\_18967.pdf?sequence=1&isAllowed=y](http://apps.who.int/iris/bitstream/handle/10665/249542/IC_Meet_Rep_2016_EN_18967.pdf?sequence=1&isAllowed=y)).

<sup>4</sup> Participants from Algeria, Libya, Mauritania, Morocco and Tunisia.

## **Strengthening quality system management throughout the blood transfusion chain**

14. Ensuring the commitment of management to establishing appropriate quality systems and standardized procedures in the blood supply and transfusion systems, including participation in assessment programmes and accreditation, was given due attention in the reporting period. Regional external quality assessment (EQA) programmes for testing of transfusion-transmitted infections and blood group serology were initiated in collaboration with WHO Collaborating Centers in the Islamic Republic of Iran and Tunisia, respectively. The number of participating countries is growing steadily.

15. As part of work on quality systems, establishing and strengthening haemovigilance systems for monitoring all aspects of clinical transfusion practice was prioritized in the reporting period. WHO convened a regional consultation on haemovigilance to launch the WHO guidance document on establishing national haemovigilance systems and to identify the way forward in implementing the guidance.<sup>5</sup> Subsequently, six countries have designated national focal persons for haemovigilance and initiated implementation of recommendations from the consultation.<sup>6</sup> In addition, technical support was provided to Oman to strengthen its haemovigilance system.

## **Challenges**

16. The current status of blood safety and availability, including the challenges that need to be addressed, have been documented in the regional status report on blood safety and availability, published in 2017.<sup>7</sup>

17. One major challenge is the low priority given to establishing effective and sustainable blood supply and transfusion systems, with appropriate regulatory mechanisms and proper organization, at the national level.

18. Furthermore, inadequate attention is being given to the role of access to affordable and quality-assured blood and blood products at all times, including during humanitarian emergencies, for achieving universal health coverage.

19. Insufficient efforts are being made to ensure regular voluntary non-remunerated donation of blood and blood components, and to establish effective and sustainable blood donor management programmes.

20. In addition, there is continued wastage of recovered plasma due to a lack of integration of blood and plasma programmes and absence of national or regional mechanisms for plasma fractionation in most countries.

## **The way forward**

21. Member States are urged to continue taking action to accelerate implementation of the regional strategic framework with a focus on updating the organization of the blood system and establishing appropriate regulatory systems for the management of blood and blood products. These are essential medicines and an integral part of efforts toward universal health coverage.

22. Member States should continue promoting and supporting the establishment of effective blood donor management programmes and promoting regular voluntary non-remunerated donations, including converting family replacement donors to regular voluntary non-remunerated donors.

23. In collaboration with WHO and partners, Member States should facilitate the development of national and regional capacity for plasma fractionation to optimize the use of plasma and reduce its wastage.

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<sup>5</sup> Summary report on the Regional consultation on haemovigilance, Amman, Jordan, 4–5 December 2016. ([http://apps.who.int/iris/bitstream/handle/10665/254703/IC\\_Meet\\_Rep\\_2017\\_EN\\_19555.pdf?sequence=1&isAllowed=y](http://apps.who.int/iris/bitstream/handle/10665/254703/IC_Meet_Rep_2017_EN_19555.pdf?sequence=1&isAllowed=y)).

<sup>6</sup> The six countries are Afghanistan, Bahrain, Morocco, Oman, Qatar and Saudi Arabia.

<sup>7</sup> Regional status report on blood safety and availability 2016. ([http://apps.who.int/iris/bitstream/handle/10665/258923/EMROPub\\_2017\\_EN\\_18907.pdf?sequence=1&isAllowed=y](http://apps.who.int/iris/bitstream/handle/10665/258923/EMROPub_2017_EN_18907.pdf?sequence=1&isAllowed=y)).

24. WHO will continue to provide Member States with guidance and technical support to scale up implementation of the regional strategic framework, and will provide the next progress report during the Sixty-seventh session of the Regional Committee.