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# Progress report for blood safety and availability 2016–2025

### Introduction

1. In October 2016, the 63rd 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 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 the Regional Director 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) report on the progress achieved in implementation of the strategic framework to the Regional Committee on a biennial basis.

4. In line with WHO's vision of "health for all by all" in the Eastern Mediterranean Region and cognizant of the role of access to safe and quality-assured blood and blood products in benefiting 1 billion more people with universal health coverage and in protecting 1 billion more people from health emergencies, especially during the COVID-19 pandemic, implementation of the framework has focused on: leadership and governance of blood systems; coordination and collaboration; adequacy and safety of blood and blood products; appropriate clinical use; and quality management systems.

5. This report provides a progress update on implementation by Member States and WHO during the third two-year period of the 10-year framework, as well as challenges and the way forward.

# **Progress update**

#### Strengthening organization, leadership and governance of national blood systems

6. In line with the regional framework and WHO's guidance on the management of blood and blood components as essential medicines, WHO has been supporting countries to strengthen blood regulation: Egypt and the Islamic Republic of Iran conducted self-benchmarking of blood regulatory systems; Libya and Lebanon initiated blood system reform programmes; Iraq initiated developing a national blood policy; Pakistan has strengthened the blood system reform programme; and, Oman is establishing a national organ donation and transplantation programme. WHO also supported Somalia in the operationalization of the national blood centre and Egypt in implementing the national plasma fractionation project. In addition, the Regional Office for the Eastern Mediterranean, in collaboration with WHO headquarters and partners, organized and supported online workshops in 2020 and 2021 on:

blood regulation; benchmarking of blood regulatory systems; centralization of blood testing and processing; authorization and licensing of blood establishments; and, national strategies to ensure safe and adequate supply of blood, blood components and plasma derived medicinal products. The inclusion of blood, blood components and plasma-derived medicinal products in the national list of essential medicines was advocated and promoted in all countries.

#### Supporting coordination and collaboration

7. In line with *Vision 2023*, the Regional Office is working closely with WHO collaborating centres in the Islamic Republic of Iran (Iranian Blood Transfusion Organization), Tunisia (Tunisian National Blood Transfusion Centre) and Germany (Paul-Ehrlich-Institut) on blood regulation, blood donor management and quality management systems to support countries in the Region to build their capacity to improve the availability and safety of blood components.

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

8. The provision of safe blood and blood products remained a focus during the reporting period. With contributions from health ministries and other relevant stakeholders in the Region, WHO updated its recommendations on blood donor selection, established a WHO technical advisory group for blood regulation, availability and safety (with experts from Egypt, Oman, Pakistan and Saudi Arabia as members representing the Region), and initiated the development of guidance on ensuring sufficient supplies of safe blood and blood components during emergency situations. In addition, the Regional Office participated in the development of WHO's global action framework for tissue transplantation and of technical products, and supported a workshop on the development of international standards for organ donation and transplantation, convened by the Pontifical Academy of Sciences.

9. Maintaining a safe and adequate supply of blood and blood products during the COVID-19 pandemic was a major challenge during the reporting period. The Regional Office supported the development of WHO's interim guidance on maintaining a safe and adequate blood supply during the pandemic; assessed the impact of COVID-19 on blood supply and safety in 15 countries in the Region;<sup>1</sup> organized regional webinars and supported international webinars on blood supply and safety in the context of the COVID-19 pandemic; and provided support to all countries in implementing the WHO interim guidance on the experimental use of COVID-19 convalescent plasma in the treatment of patients, including focused in-country support to Pakistan.

10. The availability and safety of blood transfusion during humanitarian emergencies remains a major concern in the Region. In this regard, WHO provided technical assistance to affected countries (Libya, Iraq, Palestine, Somalia, Syrian Arab Republic and Yemen) to implement the recommendations of the regional consultation on the availability and safety of blood transfusion during humanitarian emergencies, held in 2016.<sup>2</sup>

11. To support countries to optimize the use of plasma for fractionation, reduce plasma wastage and facilitate integration of blood and plasma programmes, the Regional Office, in collaboration with WHO headquarters and partners, organized and supported workshops on: increasing supplies of plasmaderived medicinal products in low- and middle-income countries through fractionation of domestic plasma; enhancing access to medicines and other health technologies; and stepwise access to safe plasma proteins in resource-constrained countries.

<sup>&</sup>lt;sup>1</sup> Bahrain, Islamic Republic of Iran, Jordan, Lebanon, Libya, Morocco, Oman, Pakistan, Palestine, Qatar, Saudi Arabia, Sudan, Tunisia, United Arab Emirates and Yemen.

<sup>&</sup>lt;sup>2</sup> Summary report on the regional consultation on the availability and safety of blood transfusion during humanitarian emergencies. Cairo: WHO Regional Office for the Eastern Mediterranean; 2016

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

12. World Blood Donor Day was marked throughout the Eastern Mediterranean Region in 2020 and 2021. The Regional Office collaborated with WHO headquarters in the development of the theme, slogan and campaign materials for these global public health days.

#### 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 developed the *Educational modules on clinical use of blood*, in collaboration with the International Society of Blood Transfusion, and *The urgent need to implement patient blood management: policy brief.* Technical guidance on patient blood management is being prepared to guide countries in implementing their patient blood management programmes. Efforts are ongoing in countries to establish a mechanism for clinical governance of blood transfusion services at the hospital level through the establishment of hospital transfusion committees.

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

14. Quality system management and haemovigilance remain suboptimal in most countries of the Region. WHO is encouraging countries to establish appropriate quality management systems and standardized procedures for blood supply and transfusion systems through participation in assessment programmes, including regional external quality assessments for testing of transfusion-transmissible infections and blood group serology, and accreditation. Egypt reviewed national quality standards for blood; Morocco conducted ISO 9001:2015 certification audit of three regional blood centres; and Sudan is working on improving quality assurance. In addition, WHO conducted a webinar on quality management and inspection of blood establishments. Assessment of haemovigilance systems was conducted in 12 countries of the Region, as part of a global assessment.<sup>1</sup> WHO is also developing technical guidance on stepwise implementation of a haemovigilance system to provide support for the practical implementation of national haemovigilance systems.

15. The Regional Office supported data collection on blood safety and availability for the Global Database on Blood Safety and on donation and transplantation for the Global Observatory on Donation and Transplantation, and disseminated the global reports.

# Challenges

16. The low priority given to establishing effective, adequately funded and sustainable blood supply and transfusion systems at the national level, with appropriate regulatory mechanisms and proper organization, remains a major challenge to implementation of the strategic framework.

17. Similarly, inadequate attention is given to the role of access to affordable and quality-assured blood and blood products, including during emergencies, for achieving universal health coverage and protecting people in emergencies.

18. Inadequate efforts are being made to guarantee regular voluntary non-remunerated donation of blood and blood components, and to establish effective and sustainable blood donor management programmes.

19. Wastage of plasma due to a lack of integration of blood and plasma programmes and the absence of national or regional mechanisms for plasma fractionation remain a challenge in most countries.

<sup>&</sup>lt;sup>1</sup> Egypt, Iran (Islamic Republic of), Iraq, Jordan, Kuwait, Lebanon, Morocco, Pakistan, Qatar, Saudi Arabia, Tunisia and Yemen.

20. Overall, a lack of adequate resources at the three levels of WHO has affected the provision of sustained and coordinated technical support to Member States to implement the regional strategic framework for blood safety and availability.

### The way forward

21. Member States are urged to continue taking action to accelerate implementation of the strategic framework with a focus on updating the organization of their national blood systems, ensuring adequate and sustainable financing, 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 to promote and support the establishment of effective blood donor management programmes and to promote regular voluntary non-remunerated donations, including converting family/replacement donors to regular voluntary non-remunerated donors.

23. Member States should facilitate the development of national and regional capacities for plasma fractionation to optimize the use of plasma and reduce its wastage.

24. Expanding the scope of the blood programme to include other products of human origin, including organs, tissues and cells, will further facilitate alignment of regional work with global efforts in the management of donation and use of these products.

25. WHO will continue to provide Member States with sustained and coordinated guidance as well as technical support to scale up implementation of the regional strategic framework, and will provide the next progress report at the 71st session of the Regional Committee in 2024.