

Availability, safety and quality of blood products

Report by the Director-General

1. This report is submitted in response to decisions EB148(9) (2021) and WHA74(17) (2021) in the context of the WHO governance reform process related to specifying end dates for reporting on governing bodies mandates with unspecified reporting requirements and providing the governing bodies with an opportunity to decide on future reporting requirements.

OVERVIEW OF THE IMPLEMENTATION OF RESOLUTION WHA63.12 (2010)

2. Since resolution WHA63.12 on availability, safety and quality of blood products was adopted, WHO has undertaken numerous initiatives and implemented many support activities.

Activities and achievements

3. **Self-sufficiency in blood and blood products and voluntary non-remunerated donation.** In 2011, WHO issued an expert consensus statement on national self-sufficiency in blood and blood products based on voluntary non-remunerated blood donation. The statement provided a global definition of self-sufficiency, together with strategies and mechanisms for achieving it. Having published a global framework for action on voluntary blood donation in 2010, the Secretariat published guidelines on blood donor selection in 2012 and on blood donor counselling in 2014. In addition, the Secretariat prepared training materials on blood donor management to guide the development of voluntary non-remunerated blood donor programmes worldwide. World Blood Donor Day is celebrated in a growing number of countries in all regions, which has provided a focus for campaigns on voluntary non-remunerated blood donation. The WHO Regional Office for the Eastern Mediterranean has conducted regional and national training workshops on blood donor management. The WHO Regional Office for Africa has provided support to Member States to celebrate World Blood Donor Day in 12 countries and to strengthen the national blood donor recruitment programme in 14 countries.

4. **Blood supply systems.** In 2011, the Secretariat published policy guidance in an aide-mémoire for health ministries on developing a national blood system and has provided technical assistance and capacity-building to strengthen national blood policies and related governance, including leadership and management through regional and national workshops. At the regional level, in 2014 the Regional Committee for the Americas approved the Plan of Action for Universal Access to Safe Blood (2014–2019) and in 2016 the Regional Committee for the Eastern Mediterranean endorsed the regional strategic framework for blood safety and availability (2016–2025), providing strategic guidance and reflecting political commitment.¹ The Regional Office for the Americas provided technical support to Member States on cost-effectiveness analysis to optimize the organization of blood services. In order to strengthen emergency preparedness and response capacity, assessments were conducted in a number of

¹ See resolutions CD53.R6 and EM/RC63/R.5.

countries in the Eastern Mediterranean Region in 2018 subsequent to a regional consultation, held in 2016, on the availability and safety of blood transfusion during humanitarian emergencies. In 2019, national workshops were also organized for Iraq and Yemen to support blood systems during humanitarian emergencies. In the South-East Asia Region, WHO has undertaken capacity-building activities with national blood programme managers. The activities are designed to enable managers to review the existing blood transfusion services in order to identify challenges and develop action plans, leveraging information contained in the 2021 regional desk review of haemoglobinopathies with an emphasis on thalassemia. Furthermore, a workplan to accelerate progress towards universal access to safe blood products in the African Region has been developed and integrated in country support plans for the Programme budget 2022–2023.

5. WHO has developed a number of tools to guide national and international efforts to ensure access to a safe and adequate blood supply in emergency situations, including during pandemic influenza and Zika virus and infectious disease outbreaks and on estimation of residual risk of infections via blood components and plasma. Most recently, in 2020, it developed guidance on maintaining a safe and adequate blood supply during the pandemic of coronavirus disease 2019 (COVID-19) and on the collection of COVID-19 convalescent plasma. More comprehensive guidance is being developed to address blood shortages and blood service disruptions in the context of natural disasters and humanitarian crises. Assessments of the impact of the COVID-19 pandemic on blood supplies and transfusion services were conducted in the African, South-East Asia and Eastern Mediterranean regions.

6. **Quality systems and haemovigilance.** In 2012, WHO and international partners organized a global consultation on haemovigilance in collaboration with the International Haemovigilance Network and the International Society of Blood Transfusion to provide guidance on establishing national haemovigilance systems. In 2016, WHO published guidance on establishing national haemovigilance systems and on establishing external quality assessment programmes for screening donated blood for transfusion-transmissible infections. This guidance was disseminated in the Region of the Americas and the South-East Asia and Eastern Mediterranean regions by means of discussion seminars, regional consultations and web courses.

7. At the regional level, the Pan American Health Organization, with support from its collaborators in the Region of the Americas, developed and published the *Manual Iberoamericano de Hemovigilancia* (Ibero-American haemovigilance manual) in 2015; in 2017, it translated the WHO publication *A guide to establishing a national haemovigilance system*, into Spanish. Technical guidance on stepwise implementation of the haemovigilance system is being developed for publication in 2022, to provide guidance on the practical implementation of haemovigilance systems at the country level. In addition, the Regional Office for South-East Asia conducted a web series on quality assurance in transfusion-transmissible infections testing and immunohaematology in 2021. At the country level, the three levels of WHO have supported Algeria, Bhutan, Burundi, Eswatini, Mauritius, Pakistan and Zambia in the development and implementation of haemovigilance systems.

8. **Safe and rational use of blood and blood products and patient blood management.** In 2010, WHO issued policy guidance in an aide-mémoire on clinical transfusion process and patient safety. It has conducted several multicountry consultations and workshops on appropriate use of blood, safe transfusion practices and patient safety, including an interregional consultation on strengthening the role of nurses and midwives in ensuring safe clinical transfusion and patient safety. In 2021, the Secretariat published educational modules on clinical use of blood and a policy brief on the urgent need to implement patient blood management. Technical guidance on the implementation of patient blood management is being prepared, which will guide countries implementing such programmes.

9. **National blood regulatory systems.** In 2011, the Secretariat published guidelines on good manufacturing practices for blood establishments and organized regional workshops bringing together national regulatory authorities and national blood services. In 2012, it published a technical report on assessment criteria for national blood regulatory systems representing the collective view of the WHO Blood Regulators Network and the WHO Expert Committee on Biological Standardization.

10. In October 2013, WHO published the addition of blood and blood components as essential medicines on the WHO Model List of Essential Medicines. The Organization has provided support for the assessment of regulatory systems in three countries and for building the capacity of authorities and transfusion services in 18 countries in the African Region. In 2019, it reviewed existing legislative instruments for blood systems of countries in the Eastern Mediterranean Region and developed a template of legislation by country across the Region. In 2021, the Regional Office for South-East Asia conducted a desk review of regulatory systems for blood and blood products.

11. WHO has developed a Global Benchmarking Tool (GBT) for evaluation of national regulatory systems. Assessment criteria for blood regulation have now been integrated into GBT Revision VI, which will be called GBT + blood. Capacity-building webinars on global benchmarking tools for blood were conducted in 2020 for priority countries.

12. Since 2018, WHO has supported the development of the African Blood Regulators Forum – which provides advocacy and communications targeted to policy-makers and the general public to enhance understanding of and support for blood regulation – and will strengthen the capacity of national blood regulators.

13. WHO has provided support to eight West African Economic and Monetary Union countries in the African Region to develop a joint directive on the regulation of blood and blood products and to revise the procedure for the registration of plasma-derived medicinal products. Furthermore, the Organization has provided support to the United Republic of Tanzania to review the Tanzania Food, Drugs and Cosmetics (Control of Blood and Blood Products) Regulations. A report on the regulation of blood services in Africa was published in 2021.

14. **WHO international biological reference preparations.** Since the adoption of resolution WHA63.12, 34 WHO biological reference preparations have been produced in order to reinforce quality control in the areas of blood products and blood safety-related in vitro diagnostic devices. WHO reference standards for blood products and related in vitro diagnostic devices are promoted through the WHO online catalogue of international biological reference preparations held and distributed by the WHO international laboratories for biological standards, as well as through workshops and international professional organizations. The WHO Expert Committee on Biological Standardization established guidelines on management of blood and blood components as essential medicines and on the estimation of residual risk in blood components for transmissible viruses, as well as international reference preparations for blood products and in vitro diagnostics, including those needed for detection of pathogens in disease outbreaks. The WHO guidelines for the production, control and regulation of snake antivenom immunoglobulins were revised.

15. **Increasing supply of plasma-derived medicinal products through fractionation of domestic plasma.** WHO is currently working with regulatory authorities and national blood services in priority countries in the Region of the Americas and in the African, South-East Asia and Eastern Mediterranean regions to ensure the implementation of blood regulatory systems as a strategy to strengthen quality systems in blood establishments, thus enhancing local production of good-quality plasma from whole blood donations in low- and middle-income countries.

16. In 2021, the Secretariat published guidance on increasing supplies of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma in order to provide a strategic framework to support Member States in increasing their volume of quality plasma for fractionation. In addition, it published guidance on centralization of blood donation testing and processing in order to support Member States in deciding whether to consolidate donation testing and processing.

17. **WHO Action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023.** The launch of the WHO Action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023 (Action Framework) in February 2020 and its subsequent implementation is a major milestone in the implementation of resolution WHA63.12. The Action Framework aligns with the WHO Thirteenth General Programme of Work, 2019–2023, highlighting universal health coverage and appropriate access to affordable and quality-assured medicines, vaccines and health products, including blood products. Since the launch of the Action Framework, the WHO Blood and other Products of Human Origin Team have worked with WHO regional offices to carry out the planned activities listed in the Action Framework. These activities include the development of a number of guidance documents and implementation tools, described in this document. In addition, a series of relevant capacity-building webinars and online trainings were organized in 2020 and 2021.

CHALLENGES

18. Despite the progress achieved since the adoption of resolution WHA63.12 in 2010, progress in establishing and strengthening national blood systems has been slow in many parts of the world. It is clear from regional reviews conducted in recent years that the goal of universal access to safe blood and blood products remains to be achieved in many countries. WHO monitoring data point to a number of inadequacies in blood supply and safety, particularly in relation to: gaps in policy and the regulation, governance and financing of national blood systems; insufficient collection and availability of blood for transfusion; low levels of voluntary non-remunerated donations; deficiencies in control measures to ensure blood safety, effectiveness and quality; suboptimal clinical practices; and the absence of effective haemovigilance and pharmacovigilance systems.

WAY FORWARD

19. It is proposed that the Health Assembly should continue to provide guidance and scrutiny in respect of the implementation of resolution WHA63.12 on availability, safety and quality of blood products. It is further proposed that the Secretariat should continue to report on the implementation of resolution WHA63.12, on a biennial basis until 2030.

ACTION BY THE HEALTH ASSEMBLY

20. The Health Assembly is invited to note the report and to consider the following draft decision:

The Seventy-fifth World Health Assembly, having considered the report by the Director-General,

Decided to request the Director-General to continue to report to the Health Assembly every two years until 2030 on progress made in the implementation of resolution WHA63.12 (2010).

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