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# **Regional Committee for Africa**

<u>Seventy-fifth session</u> <u>Lusaka, Republic of Zambia, 25–27 August 2025</u>

Agenda item 10

Framework to advance universal access to safe, effective and quality-assured blood products in the WHO African Region: 2026–2030

## Report of the Secretariat

#### **Executive summary**

- 1. Blood transfusion plays a critical role in life-saving health care, particularly for vulnerable populations. However, countries in the WHO African Region face persistent challenges in ensuring adequate and equitable access to safe and quality-assured blood and blood products. More than 50% of blood needs remain unmet in the Region, leading to severe health consequences. This framework aims to support Member States in strengthening blood transfusion systems through improved governance, enhanced infrastructure, available funding, workforce development and awareness initiatives.
- 2. Countries in the African Region are facing a high demand for blood and blood products, mostly due to a high prevalence of life-threatening conditions, such as postpartum haemorrhage, sickle-cell and other chronic diseases. WHO recommends a minimum of 10 blood donations per 1000 population. It further advises that at least 80.0% of these donations should be from voluntary non-remunerated blood donors (VNRBDs). Furthermore, all collected blood must be screened for the four mandatory transfusion-transmitted infections (TTIs) prior to transfusion. While there have been improvements in access to safe, effective and quality-assured blood products, most countries are still unable to meet their needs. Africa remains the WHO region with the most severe blood shortages. In 2022, the total number of blood units collected was 5 926 276, with a mean proportion of voluntary non-remunerated blood donations of 68.4%; and an annual average blood donation rate per 1000 population of 5.2. Eighteen countries have reached the regional target of collecting at least 80.0% of their blood donations from VNRBDs, while 98.5% of donations were screened for the four mandatory TTIs before being used for transfusions.
- 3. The main challenges in scaling up access to quality-assured blood and blood products in the Region include: limited policies, leadership and governance; insufficient skilled workforce and funding; inadequate blood regulatory oversight; limited availability of blood and blood products; deficiencies in safety and quality assurance; inappropriate clinical transfusion practices; and inefficient data collection and information management systems on blood safety.
- 4. Since 1975, WHO has adopted numerous resolutions through the World Health Assembly and the Regional Committee pertaining to blood safety. In 2019, the Global action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023 was

developed, contributing to the triple billion targets as defined in the WHO Thirteenth General Programme of Work. Access to blood and blood products is essential to achieving the first of the three targets. The framework focuses on six strategic objectives, with related activities, outputs and outcomes.

- 5. The regional framework aims to provide strategic guidance for Member States to: (i) strengthen governance and stewardship, including regulatory frameworks; (ii) ensure sustainable financing and increased domestic and external investments in blood transfusion services; (iii) upgrade infrastructure and equipment, thereby enhancing blood collection and processing capacities; (iv) develop human resources by building the capacity of both blood service personnel and clinicians prescribing blood products; (v) improve data collection and monitoring for evidence-based decision-making; and (vi) promote blood donation awareness and education, ensuring adequate and timely availability of blood supplies.
- 6. To address existing gaps and ensure sustainable progress, Member States should adopt and implement these priority interventions based on their national contexts. Strengthening governance, securing funding, enhancing infrastructure and promoting voluntary blood donation, are key actions required to improve access to safe and effective blood transfusion services.
- 7. The Regional Committee examined and adopted the actions proposed.

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#### **Abbreviations**

BTS blood transfusion service

EQAS external quality assessment scheme FRD family replacement donors/donations

GBT Global Benchmarking Tool

GDBS Global Database on Blood Safety

HBV hepatitis B virus HCV hepatitis C virus

HIV human immunodeficiency virus
HTC Hospital Transfusion Committee

IVD in vitro diagnostic

MPHO medical products of human origin
NBTS national blood transfusion service
NRA national regulatory authority

PDMP plasma-derived medicinal products

QMS quality management system

RC Regional Committee

SDG Sustainable Development Goal
TTI transfusion-transmitted infection

UHC universal health coverage

VNRBD voluntary non-remunerated blood donation

WHO World Health Organization

WHO AFRO World Health Organization, African Region

#### Introduction

- 1. Blood transfusion plays an essential role in the provision of medical care against diverse health conditions, particularly among vulnerable people such as women suffering from postpartum haemorrhage, undernourished and malaria-affected children, victims of trauma and accidents and patients suffering from sickle-cell and other chronic diseases. Blood transfusion also supports complex medical and surgical procedures in health care. The availability, safety, quality, timely access to, and appropriate use of, blood and blood products are essential components of health systems strengthening and good health-care provision. When these products are not available and readily accessible, conditions can become life-threatening and result in death. Currently, African countries collect only 5.2 units of blood for every 1000 people, below the 10 donations or more per 1000 people recommended by WHO. Yet, the demand for blood remains constant, while the supply often falls short.<sup>1</sup>
- 2. The World Health Assembly and the Regional Committee have adopted several resolutions, such as WHA28.72 and WHA58.13, and urged Member States to implement policies and promote the development of systems for voluntary non-remunerated blood donation, and strengthen capacities to provide oversight, organize and coordinate blood donation and transfusion activities, in order to improve their availability, quality, safety, accessibility and efficacy. 1,2,3,4,5,6,7,8,9
- 3. This regional framework draws inspiration from the outcomes of the implementation of the global Action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023, <sup>10</sup> and is aligned with the WHO Fourteenth General Programme of Work, 2025–2028 (GPW 14). It highlights universal health care (UHC) and supports increased access to medical products of human origin (MPHO), essential medicines and health products, <sup>11</sup> and aims to guide Member States in planning and implementing priority interventions to advance universal access to safe, effective and quality-assured blood products.

World Health Organization. WHO African Region status report on blood availability, safety, and quality. Brazzaville, Republic of Congo: World Health Organization; 2022. (<a href="https://apps.who.int/iris/handle/10665/363421">https://iris.who.int/handle/10665/379310</a>)

World Health Organization. Utilization and supply of human blood and blood products. In: Twenty-eighth World Health Assembly 1975. Geneva, Switzerland: WHO; 1975 [Resolution WHA28.72] (https://www.who.int/bloodsafety/en/WHA28.72.pdf).

World Health Organization. Blood safety: proposal to establish World Blood Donor Day. In: Fifty-eighth World Health Assembly 2005. Geneva, Switzerland: WHO; 2005 [Resolution WHA58.13] (<a href="https://www.who.int/bloodsafety/WHA5813-en.pdf">https://www.who.int/bloodsafety/WHA5813-en.pdf</a>).

World Health Organization. Availability, safety and quality of blood products. In: Sixty-third World Health Assembly. Geneva, Switzerland: WHO; 2010 [Resolution WHA63.12] (<a href="http://apps.who.int/medicinedocs/documents/s19998en.pdf">http://apps.who.int/medicinedocs/documents/s19998en.pdf</a>).

World Health Organization. Regulatory system strengthening for medical products. In: Sixty-seventh World Health Assembly. Geneva, Switzerland: WHO; 2014 [Resolution WHA67.20] (https://apps.who.int/medicinedocs/documents/s21456en/s21456en.pdf).

World Health Organization. AIDS control: current status of AIDS control activities in the African Region. In: Forty-fourth Regional Committee for Africa;1994 [Resolution AFR/RC44/R12]. WHO Regional Office for Africa, Brazzaville, Congo; 1994.(https://apps.who.int/iris/bitstream/handle/10665/99667/AFR RC44 R12 eng.pdf?sequence=1).

World Health Organization. Blood safety: a strategy for the African Region. In: Fifty-first Regional Committee for Africa. Brazzaville, Congo; 2001 [Resolution AFR/RC51/R2] WHO Regional Office for Africa, Brazzaville, Congo; 2001. (https://www.afro.who.int/sites/default/files/sessions/resolutions/AFR-RC51-R2%20Blood%20safety.pdf).

World Health Organization. Regional strategy on the regulation of medical products in the African Region, 2016-2025. In: Sixty-sixth Regional Committee for Africa. Addis Ababa, Ethiopia; 2016 [Resolution AFR/RC66/R2]. WHO Regional Office for Africa, Brazzaville, Congo; 2016. (https://www.afro.who.int/sites/default/files/sessions/resolutions/afr-rc66-r2-en-2109.pdf).

World Health Organization. Framework for health systems development towards UHC in the context of the SDGs in the African Region. In: Sixty-seventh Regional Committee for Africa. Victoria Falls, Zimbabwe; 2017 [Resolution AFR/RC67/10]. WHO Regional Office for Africa, Brazzaville, Congo; 2017. (https://iris.who.int/handle/10665/260237)

#### **Current situation**

- 4. Data from a 2022 survey highlight progress in key blood safety indicators across most countries. However, significant gaps remain, necessitating further action to ensure universal access to safe, quality-assured blood and blood products.<sup>9</sup>
- 5. The 2022 survey on blood availability, safety and quality revealed that the WHO African Region, which accounts for 13.8% of the global population, has made progress in the development of policies and strategies. Among 45 responding countries, 41 (91%) have a national blood policy, 34 (75.5%) have an operational strategic plan, 24 (53.3%) have blood transfusion legislation, which is a key component for governance, 35 (77.7%) provide government funding, while 21 (46.7%) have a cost recovery system in place. Meanwhile, 41 countries (91.0%) have national standards for blood and blood components, and 36 (80.0%) have guidelines for clinical use of blood. Only 14 countries (31.0%) have a national haemovigilance system to monitor and enhance blood transfusion safety.
- 6. In 2022, total blood donations amounted to 5 926 276 units, with 68.4% from voluntary non-remunerated blood donations. However, the annual blood donation rate remains low at 5.2 per 1000 population, covering 52.0% of estimated blood needs. Six countries have reached the WHO-recommended 10 donations per 1000 population. Eighteen countries have met the regional target of at least 80% of blood supply from VNRBD, including 13 countries that have achieved f100% VNRBD collection. 11,12
- 7. Blood safety remains a concern. In 2022, blood donations were screened for HIV and hepatitis B (99.9%), hepatitis C (97.3%), and syphilis (97.1%), falling short of WHO's 100% screening target. Only 62.2% of countries participated in an external quality assessment scheme for transfusion-transmissible infections (TTIs), and only 59.7% of whole blood donations were processed into blood components, limiting optimal utilization.
- 8. Blood components were distributed and transfused as follows: whole blood, 23.5%; red cell concentrates, 48.7%; platelet concentrates, 13.0%; and fresh frozen plasma, 13.7%. <sup>11</sup>
- 9. To enhance access to plasma-derived medicinal products (PDMPs), 23 countries (51%) have included them in their Essential Medicines List, but all rely on imports. South Africa remains the only country producing PDMPs through locally collected plasma fractionation.
- 10. The COVID-19 pandemic significantly disrupted blood transfusion services. In 2020, blood donation rates dropped by 17% and the frequency of blood drives declined by 25%. Concurrently, demand for blood decreased by 13% due to the suspension of routine surgeries and fewer people seeking care.
- 11. Despite progress, blood transfusion services remain fragmented and underfunded in many African countries. The low blood donation rate, limited screening compliance, and lack of haemovigilance systems, hinder efforts to ensure universal access to safe blood and blood products. Moreover, while many countries have policies in place, functional blood transfusion services remain weak, with challenges related to governance, infrastructure and human resources. Persistent

Congo, Gabon, Mauritius, Namibia, Seychelles, South Africa.

Benin, Botswana, Burkina Faso, Burundi, Central African Republic, Côte d'Ivoire, Eritrea, Ethiopia, Kenya, Malawi, Mauritius, Namibia, Senegal, South Africa, Togo, Uganda, Zambia, Zimbabwe.

Botswana, Burundi, Central African Republic, Côte d'Ivoire, Eritrea, Ethiopia, Malawi, Namibia, South Africa, Togo, Uganda, Zambia, Zimbabwe.

gaps in blood availability and safety threaten progress towards achieving the SDGs, the WHO Thirteenth General Programme of Work (GPW 13), and universal health coverage.

#### Issues and challenges

- 12. **Deficiencies in national legislation, policy, governance and financing:** A number of barriers to the effective implementation of World Health Assembly and Regional Committee resolutions exist in most countries of the Region. They include: lack of political commitment and awareness of the essential role of national blood transfusion services (NBTS) in the national health system; lack of, or weak legal and regulatory frameworks; and insufficient resources in terms of infrastructure, funding and qualified personnel. In addition, most regulatory authorities in the Region focus more attention on medicines and are often unable to ensure the effective oversight needed for the implementation of quality and safety standards for blood safety due to overlapping missions between them and the NBTS.
- 13. **Insufficient supply of safe blood and blood products for transfusion:** The African Region makes up 13.8% of the global population but has access to only 5.2% of the globally collected blood. <sup>13</sup> In most countries in the Region, blood shortages are often common. These countries generally do not have national blood donor programmes and cannot attract enough donors to meet the need for blood. Additionally, costs of donor recruitment, cultural resistance, insufficient public education and outreach to promote awareness of blood donation are the other major issues affecting blood donation.
- 14. **Deficiencies in blood product safety, effectiveness, and quality:** Weak quality management systems for blood collection, testing and preparation of blood components, as well as deficiencies in the quality of laboratory testing, can result in failures in terms of the availability of safe blood and blood products. Barriers to quality-assured TTI testing of blood grouping and compatibility testing of blood donations include unreliable supply management of test kits for donation screening and blood grouping reagents and weak control of reagents and assays, and related laboratory practices.
- 15. **Suboptimal clinical practices in transfusion of blood components:** Barriers to appropriate clinical use of blood transfusions in the Region include limited training and knowledge of medical, nursing, scientific and technical staff in transfusion medicine; poor practices in blood component storage and handling; insufficient national evidence-based guidelines for appropriate clinical use of blood; and absence of effective hospital transfusion committees (HTC).
- 16. Weak data collection and information management systems in blood services: Most countries in the Region do not include blood in their national health information system performance indicators. The lack of efficient information management systems impedes decision-making that informs policies and stewardship interventions.
- 17. Due to these challenges, the importance of ensuring access to safe, effective and quality-assured blood and blood products cannot be overemphasized. It is crucial for the attainment of UHC and other health-related SDGs.

## Vision, goal, objectives, targets and milestones

18. **Vision**: Universal access to safe, effective and quality-assured blood and blood products contributing to the attainment of UHC in the WHO African Region.

World Health Organization (2020). Action framework to advance universal access to safe, effective, and quality-assured blood products 2020–2023. (https://apps.who.int/iris/handle/10665/331002)

19. **Goal**: All the people that require blood transfusion in the African Region have access to safe, effective and quality-assured blood and blood products.

# 20. Objectives

- (a) Establish a well-coordinated, sustainably resourced national blood system in countries, with strong governance, leadership, and management.
- (b) Strengthen regulatory frameworks, national standards, and quality assessment programmes to ensure safety and compliance.
- (c) Improve access to safe and effective blood and blood products by enhancing their collection, screening, processing, and distribution.
- (d) Increase VNRBD through sustainable donor recruitment and retention strategies.
- (e) Enhance surveillance, haemovigilance, and pharmacovigilance systems to ensure patient safety and monitor transfusion risks.
- (f) Optimize clinical transfusion practices by implementing patient blood management and promoting appropriate use of blood products.
- (g) Foster partnerships and collaboration at all levels to address challenges and enhance blood safety systems.

## 21. Targets and milestones

- (a) Targets by 2030
- (i) Reach seven donations per 1000 population in the Region.
- (ii) Achieve 80% rate of blood donations from VNRBD in the Region.
- (iii) Achieve 100% rate of screening for the four mandatory TTIs in the Region.
- (iv) 100% (47/47) of countries will have implemented national guidelines on the clinical use of blood.
- (v) 50% (24/47) of countries will have established national haemovigilance and pharmacovigilance systems, ensuring full monitoring of transfusion-related risks.
- (vi) 20% (10/47) of countries will have established a national blood regulatory system.

## (b) Milestones by 2027

- (i) Reach six donations per 1000 population.
- (ii) Achieve 70% rate of blood donations from VNRBD in the Region.
- (iii) Achieve 99% rate of screening for the four mandatory TTIs in the Region.
- (iv) 90% (42/47) of countries will have implemented national guidelines on the clinical use of blood.
- (v) 40% (19/47) of countries will have established national haemovigilance and pharmacovigilance systems, ensuring full monitoring of transfusion-related risks.
- (vi) 10% (5/47) of countries will have established a national blood regulatory system.

## **Guiding principles**

22. **Equity and human rights:** All patients have a right to equitable access to safe blood, when needed, without distinction of race, religion, political belief, economic and social status, geographical location, or clinical condition.

- 23. Country leadership and ownership: Governments are responsible for coordinating and ensuring that all interventions are in line with country priorities and enable involvement of all relevant stakeholders at all stages from policy, planning and investment-making through implementation to monitoring and evaluation.
- 24. **Transparency and accountability:** The provision of an adequate supply of safe blood depends on the efficient, cost-effective organization and management of transparent blood transfusion services (BTS) that optimize the use of resources and maintain uniform standards of compliance.
- 25. Community participation and cultural sensitivity: There should be an emphasis on engaging with communities and civil society, including blood donor organizations and patient associations, to enable them to play their roles in scaling up interventions at all levels. Interventions must respect and integrate local cultural and religious values to foster trust and participation in blood donation programmes. This includes engaging traditional and religious leaders, using local languages and adapting messages to community norms.
- 26. **Integrated partnerships and approach:** A holistic, integrated approach is key to strengthening partnerships across sectors, ensuring resilient blood transfusion systems through harmonized support and sustainable collaboration.

#### **Priority interventions and actions**

- 27. Developing and implementing evidence-based policies, plans and regulatory frameworks: To improve access to safe blood, countries must develop, update and implement national blood policies, strategic plans and legislation that integrate findings from localized research, including sociocultural studies on donor behaviour, barriers to voluntary donation and community perceptions of transfusion services. Establishing and strengthening national blood regulatory systems will ensure effective oversight of blood establishments, blood products and associated medical devices. National regulatory authorities (NRAs) should be supported in implementing WHO's Global Benchmarking Tool Plus Blood (GBT+ Blood) to ensure regulatory compliance and quality assurance. Regulatory oversight should cover screening, processing and distribution of blood and blood products, while national policies, guidelines and standards for blood transfusion services must be developed and enforced.
- 28. **Improving management of blood services**: Establishing a well-structured, well-coordinated, and integrated national blood transfusion service (NBTS) will be necessary. Efforts should focus on strengthening the efficient and cost-effective management of blood services, building the capacity of NBTS managers in planning, organization and management, and improving blood facility infrastructure, equipment procurement, and supply chain management. Additionally, coordination and collaboration with blood donor organizations, research institutions, and patient associations must be enhanced, alongside developing preparedness and response plans to ensure safe blood supply during health emergencies.
- 29. **Building human resource capacity**: Strengthening leadership and management training for NBTS managers is critical. Countries should develop education and training programmes for NBTS staff and health care professionals, while advocating for the integration of blood safety into national health school curricula to ensure sustainable human resource development in the blood sector.
- 30. **Ensuring adequate and sustainable funding**: A sustainable blood supply requires adequate and sustainable funding. Countries must integrate blood supply and consumption into national health financing mechanisms, allocate specific government budgets to national blood services, and

develop cost-recovery strategies, including health insurance mechanisms and private sector engagement. Governments and partners should also be engaged in advocacy for increased investments in blood safety.

- 31. Developing and implementing strategies for blood donor education, recruitment and motivation: Culturally tailored public education and awareness programmes should be strengthened to promote voluntary non-remunerated blood donation. Countries must establish sustainable donor panels from low-risk populations, develop youth and school-based education programmes on blood donation, and support World Blood Donor Day celebrations annually. Blood collection processes should be safe, confidential, and ensure proper donor care, counselling, and referral mechanisms.
- 32. **Testing all donated blood in a quality-assured manner and increasing availability of quality-assured blood components**: Ensuring quality-assured testing, processing, storage, and compatibility testing of donated blood is critical. Countries should strengthen national capacity for quality systems in blood transfusion services, establish national external quality assessment schemes, and support external quality assessment for transfusion-transmissible infections and blood group serology. Blood cold chain management must be reinforced to ensure safe storage and transport, while plasma-derived medicinal product manufacturing initiatives should be encouraged.
- 33. Developing documents for quality management systems and applying quality management in blood transfusion services: A robust quality management system is essential to improving blood safety. Countries must implement a national quality policy and technical standards, establish comprehensive documentation systems, and strengthen national capacity for quality assessment through external quality control mechanisms. New technologies, such as artificial intelligence, may be leveraged to improve documentation and quality monitoring. Additionally, technologies such as the use of drones have proven effective in improving access to blood in rural areas, as seen in Rwanda and Ghana. These innovations should be explored to enhance efficiency and equity in blood supply chains.
- 34. **Promoting appropriate clinical use of blood**: Countries should develop and implement national guidelines for the clinical use of blood and blood products, while ensuring the availability of critical supplies for transfusion alternatives and compatibility testing. Establishing hospital transfusion committees will help monitor transfusion trends and the conduct of clinical audits. Health care professionals, including clinicians, nurses and midwives, must receive training in safe transfusion practices. An effective national haemovigilance system should also be set up to track transfusion safety.
- 35. Strengthening monitoring and evaluation systems: National data collection and management systems for blood services must be developed to incorporate indicators for donor and recipient satisfaction, as well as the effectiveness of outreach interventions. This will ensure effective tracking of blood availability, safety and quality. Countries should produce and disseminate annual reports on blood transfusion services. To ensure accountability, progress reports on the implementation of this framework will be presented to the Regional Committee every two years for review.
- 36. **Providing policy guidance, technical support, capacity-building and advocacy support**: WHO will continue to assist Member States by developing and disseminating standards and guidelines to ensure safe blood collection, testing, storage and transfusion. Additionally, WHO will play a pivotal role in helping countries establish national regulatory frameworks and strengthen blood transfusion services through training programmes, quality assurance systems and laboratory capacity-building. WHO's advocacy and resource mobilization efforts will be enhanced to engage

global partners and donors, with the aim of increasing funding and technical assistance for sustainable blood safety programmes. By promoting regional collaboration and research, WHO will enable countries to adopt innovative solutions to improve blood supply and reduce transfusion-related risks, ultimately enhancing health outcomes across the Region.

- 37. **Strengthening partnerships and collaboration**: Partners play a vital role by providing funding and technical assistance to support infrastructure development, ensuring the availability of critical screening reagents and equipment to improve blood collection, screening, and storage. They should assist in public awareness campaigns to promote voluntary blood donation, support the implementation of modern blood information systems, and promote research and innovation for safer and more efficient blood transfusion services. Through public-private partnerships (PPPs), they will enhance supply chain management and access to essential blood products.
- 38. The implementation of these priority interventions and actions will be assessed through periodic evaluations by Member States, WHO and partners, with progress reports presented to the Regional Committee.

## **Actions proposed**

39. The Regional Committee examined and adopted the actions proposed.