Action framework to advance universal access to safe, effective and quality-assured blood products

2026–2030

World Health Organization

Action framework to advance universal access to safe, effective and quality-assured blood products

2026–2030

World Health Organization

Action framework to advance universal access to safe, effective and quality-assured blood products 2026–2030

ISBN 978-92-4-012290-1 (electronic version)
ISBN 978-92-4-012291-8 (print version)

Suggested citation. Action framework to advance universal access to safe, effective and quality-assured blood products 2026-2030. Geneva: World Health Organization; 2026. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at https://iris.who.int/.

Design and layout by L'IV Com Sàrl.

Contents

Preface

Access to safe, effective and quality-assured health products, including blood, is fundamental to achieving global health goals. WHO's work on access to health products contributes to the goals of the World Health Organization (WHO) General Programme of Work, in particular to the strategic objective of advancing the primary health care approach and essential health systems capacities. The 2025 WHO report *Access to safe, effective and quality-assured health products and technologies: roadmap for WHO action 2025–2030* further elaborates the WHO role as a leader, developer and provider of norms and standards, policy guidance and technical support more broadly.

The 2010 World Health Assembly (WHA) resolution 63.12 *Availability, safety and quality of blood products* requests the Director-General to guide Member States in aligning their legislation, national standards and regulations with internationally recognized benchmarks to ensure effective control of the quality and safety of blood products. The resolution further calls upon the Director-General to provide advice and build capacity in Member States in the leadership and management of blood and plasma programmes to ensure the provision of WHO international biological reference preparations for use in quality control and regulation of blood products; to develop, disseminate and provide guidance and technical support to strengthen nationally coordinated blood and plasma programmes; and to promote the safe and rational use of blood products and effective patient blood management. In addition, the Director-General is requested to report regularly – at least every 4 years – to the WHA, through the Executive Board, on actions taken by Member States and other partners to implement this resolution, up to the year 2030.

The WHO *Action framework to advance universal access to safe, effective and quality-assured blood products 2026–2030* (Action Framework) is an updated version of the 2020–2023 Action Framework. It aims to provide strategic direction for global efforts to overcome existing barriers to the safety and availability of blood products. The 2020–2023 Action Framework primarily focused on developing norms and standards for blood products and providing technical assistance to Member States. Under that framework, 13 new guidelines related to blood products were developed, published and disseminated; 57 WHO international biological reference preparations were established; and technical support was provided to several countries to strengthen their national blood systems. Building on these achievements, the updated framework for 2026–2030 places greater emphasis on providing strategic guidance across all three levels of WHO to support Member States in enhancing their blood systems through the effective implementation of existing WHO guidelines.

I am deeply grateful for the support of the WHO Expert Panel on Transfusion Medicine, WHO Advisory Group on Blood Regulation, Availability and Safety, WHO collaborating centres, WHO Blood Track of the Expert Committee on Biological Standardization and the International Society of Blood Transfusion – a non-state actor in official relations with WHO – for their invaluable efforts and significant contributions to the development of this framework. This collaborative effort highlights the importance of strong partnerships and coordinated collaboration between WHO, at all levels, and its stakeholders in supporting Member States to strengthen and improve their national blood systems.

Dr Deusdedit Mubangizi
Director for Medicines and Health Products Policies and Standards
World Health Organization

Acknowledgements

The development and publication of the *Action framework to advance universal access to safe, effective and quality-assured blood products 2026–2030* was coordinated by Yuyun Maryuningsih (Team Lead, Blood and Other Products of Human Origin, Health Products Policy and Standards Department, WHO headquarters), and led and co-led by Peter Flanagan (WHO Expert Advisory Panel on Blood Transfusion Medicine) and Christian Schaerer (Chair of the WHO Advisory Group on Blood Regulation, Availability and Safety [AG-BRAS]).

The contributions of the following individuals and technical groups are gratefully acknowledged.

WHO gratefully acknowledges the working group members who contributed to drafting the chapters.

Arwa Zakariya Al-Riyami (Department of Hematology, Sultan Qaboos University Hospital, University Medical City and College of Medicine and Health Sciences, Sultan Qaboos University, Oman; AG-BRAS).
Justina Kordai Ansah (National Blood Service, Ghana; AG-BRAS).
Mauricio Beltrán Durán (WHO Regional Office for the Americas, United States of America).
Thierry Burnouf (Graduate Institute of Biomedical Materials and Tissue Engineering, Taipei Medical University, Taiwan, China; Working Party for Global Blood Safety, International Society of Blood Transfusion [ISBT], France).
Jay Epstein (Working Party for Global Blood Safety, ISBT, United States of America).
Peter Flanagan (Expert, New Zealand; WHO Expert Advisory Panel on Blood Transfusion Medicine).
Salwa Ibrahim Hindawi (King Abdulaziz University, Saudi Arabia; AG-BRAS).
Cheuk Kwong Lee (Hong Kong Red Cross Blood Transfusion Service, Hong Kong SAR, China; AG-BRAS).
Roland Willy Niyibizi (WHO Regional Office for Africa, Republic of the Congo).
Jens Reinhardt (Paul Ehrlich Institute, Germany).
Christian Schaerer (Swissmedic, Swiss Agency for Therapeutic Products, Switzerland; AG-BRAS Chair).
Aparna Singh Shah (WHO Regional Office for South-East Asia, India).
Sitalakshmi Subramanian (St John's Laboratory Services, Department of Transfusion Medicine and Immunohaematology, St John's Medical College Hospital, India; AG-BRAS).
Diana Teo (Expert, Singapore; WHO Expert Advisory Panel on Blood Transfusion Medicine).
Elizabeth Vinelli (Honduras Red Cross Blood Program, Honduras; AG-BRAS).
Silvano Wendel (Hospital Sirio-Libanés Blood Bank, Brazil; AG-BRAS).
Erica Wood (Transfusion Research Unit, Monash University, Australia; AG-BRAS).
Junping Yu (Blood and Other Products of Human Origin, Health Products Policy and Standards Department, WHO headquarters).
Yong Ming Zhu (Shanghai Blood Centre, China; AG-BRAS).

WHO extends thanks to the individuals and organizations for their review and comments during the development of the document.

Ai Leen Ang (Blood Services Group, Health Sciences Authority, Singapore).
MK Boukef (Expert, Tunisia; WHO Expert Advisory Panel on Blood Transfusion Medicine).
Nabajyoti Choudhury (Asian Association of Transfusion Medicine, India).
Mohammed Farouk (African Society for Blood Transfusion, South Africa).
Mahrukh Getshen (National Blood Bank, JDW, National Referral Hospital, Bhutan).
Mahtab Maghsudlu (Iranian High Institute for Research and Education in Transfusion Medicine, Islamic Republic of Iran).
Liyana Rakinaturia (WHO Indonesia Country Office, Indonesia).
Jens Reinhardt (Paul Ehrlich Institute, Germany).

Eric Salenga (WHO Indonesia Country Office, Indonesia).
Shanti Sibuea (Indonesian Food and Drugs Authority, Indonesia).
W Martin Smid (Academic Institute IDTM, the Kingdom of the Netherlands).
Marion Vermeulen (ISBT African Region, South Africa).
Xi Zhang (Shanghai Blood Centre, China).

Development of the guidance

This action framework was developed following an initial virtual meeting involving a selected group of experts in transfusion medicine, WHO Regional Advisers for Blood and Transplantation, and WHO headquarters staff working on Blood and other Products of Human Origin. During this meeting, participants discussed the need to update the *WHO Action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023*. The group identified key areas requiring revision, and a series of online working group meetings was subsequently held to prepare the draft.

An editorial group was then formed from within the working group, and the final guidance was developed through an iterative process by the initial expert group. The resulting document was then reviewed by a number of WHO-identified external experts.

Declarations of interest by external contributors

Declarations of interest by external contributors acting in their capacity were collected, assessed and managed, as per WHO policy. The standard WHO form for declaration of interests was completed and signed by each expert. The WHO Blood and other Products of Human Origin Team reviewed all the forms before finalizing the experts' invitations to participate. No competing interests were declared, and therefore no further action was taken.

Abbreviations and acronyms

ABRF	African Blood Regulators Forum
ABR-TC	African Blood Regulators Technical Committee
AG-BRAS	WHO Advisory Group on Blood Regulation, Availability and Safety
BSS	blood system self-assessment tool
CP	convalescent plasma
cryo-PR	pathogen-reduced cryoprecipitate
ECBS	WHO Expert Committee on Biological Standardization
EML	WHO Model List of Essential Medicines
EMLc	WHO Model List of Essential Medicines for Children
FENSA	Framework for Engagement with Non-State Actors
GBT	WHO Global Benchmarking Tool (also, GBT+Blood) (for the assessment of the blood regulatory authority)
GDBS	Global Database on Blood Safety (WHO)
GMP	good manufacturing practices
GPW 14	Fourteenth General Programme of Work, 2025–2028
HBV	hepatitis B virus
HCV	hepatitis C virus
HICs	high-income countries
HTC	hospital transfusion committee
ICDRA	International Conference of Drug Regulatory Authorities
IHN	International Haemovigilance Network
ISBT	International Society of Blood Transfusion
IVD	in vitro diagnostic
LICs	low-income countries
LMICs	lower middle-income countries
NRA	national regulatory authority
NSA	non-state actor
PBM	patient blood management
PDMP	plasma-derived medicinal product

SDG	Sustainable Development Goal
TTIs	transfusion-transmissible infections
UMICs	upper middle-income countries
VNRD	voluntary non-remunerated donation
WB	World Bank
WFH	World Federation of Hemophilia
WHA	World Health Assembly
WHO	World Health Organization

Executive summary

Blood transfusion is an essential component of health care. An insufficient or unsafe blood supply for transfusion has a negative impact on the effectiveness of key health services and programmes for patient care in numerous acute and chronic conditions. To ensure lifesaving blood transfusion, access to whole blood and blood components is vital. Other types of blood products, plasma-derived medicinal products (PDMPs) in particular, are critical for the prevention and treatment of major morbidities associated with a wide range of inherited and acquired medical conditions and diseases. For these compelling reasons, it is important to ensure access to safe, effective and quality-assured blood products in all countries.

The need for a nationally coordinated and well managed blood system to ensure the safety, effectiveness and quality of blood products has been recognized in numerous World Health Assembly (WHA) resolutions since 1975. In response to the recommendations of these resolutions and calls for action from Member States, WHO has developed important guidelines, aides-mémoire and other tools to underpin advancements in safety, effectiveness and quality of blood products, and has provided guidance and technical assistance to countries in building and strengthening their national blood systems. Moreover, between 2020 and 2025, 57 WHO international biological reference preparations, comprising 13 for blood products and 44 in vitro diagnostics, have been produced to reinforce quality control in the areas of blood products and blood safety-related in vitro diagnostic devices. Since 1998, through the Global Database on Blood Safety (GDBS), WHO has collected and analysed data essential to adequately understand the status worldwide of blood availability and safety.

In 2020, WHO published the *Action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023* based on interim analysis of the 2018 GDBS. Under this framework, WHO published a series of high-level guidelines, policy and guidance documents and self-assessment tools designed to assist Member States in assessing the status of their blood systems (including regulatory frameworks, blood supply and transfusion services). The goal is to identify strengths and weaknesses and to enable Member States to take actionable steps towards building a robust, safe and effective blood system. Additionally, global forums for blood were organized which successfully convened relevant international stakeholders to discuss challenges and develop solutions related to blood safety and availability. Furthermore, intrinsic threats to the safety of blood products have arisen repeatedly from new and emerging pathogens, highlighting the importance of WHO actions to promote effective surveillance and vigilance systems for blood and transfusion safety at national, regional and global levels. Increasingly, WHO has been supporting Member States to ensure the availability of safe, effective and quality-assured blood products during epidemics and other types of emergencies, such as natural disasters and conflict situations.

Despite these actions, progress in establishing and strengthening national blood systems has been slow in many parts of the world. Data from the 2023 WHO GDBS continue to point to a number of inadequacies in the supply and safety of blood, particularly related to gaps in policy, regulations, governance and sustainable financing of national blood systems; insufficient collection and availability of blood to meet patient needs; low levels of voluntary non-remunerated donations; deficiencies in control measures to ensure blood safety, effectiveness and quality; suboptimal clinical practices; and absence of effective quality management, haemovigilance and pharmacovigilance systems.

The WHO *Action framework to advance universal access to safe, effective and quality-assured blood products 2026–2030* (Action Framework) aims to provide updated strategic direction to global efforts to address present barriers to the safety and availability of blood products. This aligns with the WHO Fourteenth General Programme of Work, 2025–2028 (GPW 14) and the Global Health Strategy for 2025–2028 and advocates the implementation of a series of national, regional and international resolutions, goals and strategies to ensure safe blood products, which are integral to the achievement of the health-related Sustainable Development Goals (SDGs) by 2030 while future-proofing health and care systems.

The updated WHO Action Framework focuses on seven strategic objectives, defined as desired outcomes, including outputs and related activities to guide the development and implementation of context-specific actions to address the needs of regions and countries. Efforts to achieve these objectives are supported by relevant WHO guidance documents and self-assessment tools. Reaching the overall goal of universal access to safe, effective and quality-assured blood products can best be achieved through effective collaboration between WHO, its Member States and relevant organizations. WHO will be drawing on new and existing partners globally in its efforts to coordinate the implementation of this global framework to improve access to safe blood products worldwide.

The seven strategic objectives are:

1. Member States have implemented the essential steps for establishing and implementing a continuously operating, appropriately structured, well-coordinated, well-governed and sustainably resourced national blood system.

2. An appropriate national regulatory framework is in place in Member States to ensure fully operational mechanisms of the necessary regulatory functions in order to enable an adequate supply of blood products, including PDMPs, that are safe, effective and meet quality standards.

3. Affordability, availability and accessibility of safe, effective and quality-assured blood products in Member States assures timely patient access to needed blood and blood products.

4. Effective implementation of patient blood management to optimize clinical practice of transfusion.

5. Effective surveillance, haemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection, evaluation, risk reduction and communication are implemented.

6. Mechanisms are implemented for jointly addressing challenges and emerging threats to national blood systems at global, regional and national levels.

7. WHO leadership, partnerships, collaboration and information exchange to achieve key priorities and jointly address challenges and emerging threats at global, regional and national levels.

World Blood Donor Day 2025
© WHO/Loan Tran

1 Context

Blood transfusions can have a critical impact on patient outcomes. Medical therapeutic products derived from human donations of blood and plasma play an essential role in health care and are fundamental for achieving universal health coverage. When used correctly, safe, effective and quality-assured blood products contribute to improving and saving millions of lives every year. This includes a reduction in child mortality, improved maternal health, improved life expectancy and quality of life in serious and life-threatening disorders, and supporting complex medical and surgical procedures. However, blood transfusion also carries potential risks of complications including haemolytic transfusion reactions, as transfusion-related acute lung injury and transfusion-associated circulatory overload, as well as transfusion-related infections such as HIV, hepatitis viruses, malaria parasites and other bloodborne pathogens. Such risks, which may result in major morbidity or even be fatal, can be minimized through safety measures in blood collection, processing and testing. Ensuring access to safe, effective and quality-assured blood products is imperative to safeguard public health. The COVID-19 pandemic highlighted vulnerabilities of blood systems including lack of emergency preparedness and continuity planning; widening of equity gaps between mature and fragile blood systems, and between urban and rural areas; absence of digital readiness for donor mobilization and stock management; fragility of financing systems reliant on ad hoc or external sources; and over-dependence on global plasma and plasma-derived medicinal product (PDMP) supply chains.

A blood product is any therapeutic substance derived from human blood, including whole blood and blood components for transfusion, plasma for fractionation (either separated from whole blood or prepared by apheresis) and PDMPs *(1)*. In high-income countries (HICs), blood products are most commonly used to support advanced

medical and surgical procedures, including treatment of cancer and haematological diseases, trauma resuscitation, cardiovascular surgery and transplantation. Although recent advances in patient blood management (PBM) have decreased the demand for blood transfusions, this has been partially offset in some instances by increased need resulting from changing population demographics and more advanced surgical and medical procedures. In lower income countries where diagnosis and treatment options are limited, whole blood is mainly used to treat women with obstetric emergencies, children suffering from severe anaemia often resulting from malaria, haemoglobinopathies and malnutrition, and trauma victims sustaining massive injuries.

The importance of blood products is emphasized by the inclusion of whole blood, red blood cells, platelets, fresh frozen plasma and pathogen-reduced cryoprecipitate (cryo-PR) in the WHO Model List of Essential Medicines (EML), as well as PDMPs such as normal immunoglobulin, anti-D immunoglobulin, anti-rabies immunoglobulin, anti-tetanus immunoglobulin, coagulation Factor VIII and coagulation Factor IX *(2, 3)*. However, blood donations in many countries are insufficient to meet even basic requirements for blood and safety measures to minimize complications are still inadequate in some countries *(4)*. At the same time, because of barriers in production, a large percentage of human plasma separated from whole blood is not used and is often categorized as waste material and destroyed instead of being used to produce essential PDMPs *(5)*. An imbalance exists between higher income and lower income countries in access to safe, effective and quality-assured blood products, and under-transfusion remains a problem in many countries. Conversely, inappropriate transfusion occurs frequently in many health care systems, compromising patient outcomes and increasing health care costs.

A functioning national blood system[1] is required to ensure access to safe, effective and quality-assured blood products, and should support equitable availability and affordability. National blood systems must be developed as an integral part of the health care system based on the principles of primary health care, in line with the WHO comprehensive approach to strengthening health systems. The development and strengthening of national blood systems are essential for overall health system strengthening and key to building and strengthening national and regional capacities to respond to emergency situations, including natural disasters, humanitarian crises and emerging infectious threats. The WHA adopted its first resolution addressing the issue of blood safety in 1975, namely resolution WHA28.72 on the utilization and supply of human blood and blood products *(6)*. This was followed by a series of WHA and WHO regional resolutions, including resolution WHA63.12 which requests WHO and its Member States to improve the availability, safety and quality of blood products *(7)*. Despite this, progress in blood regulation, availability and safety has been slow in many parts of the world.

The WHO *Action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023* was developed in a renewed effort to scale up programme implementation and improve access to blood products *(8)*. It provided an overview of the main challenges faced and established six strategic objectives to guide the efforts of WHO, in collaboration with its partners. This included a programme of work comprising related activities, outputs and outcomes, to guide the development and implementation of context-specific actions to address the needs of regions and countries. Based on this programme, a range of high-level guidance documents was developed, as well as a self-assessment tool to assist Member States, blood regulatory bodies and blood establishments in understanding the strengths and challenges in their blood systems and to determine how to prioritize investments and interventions.

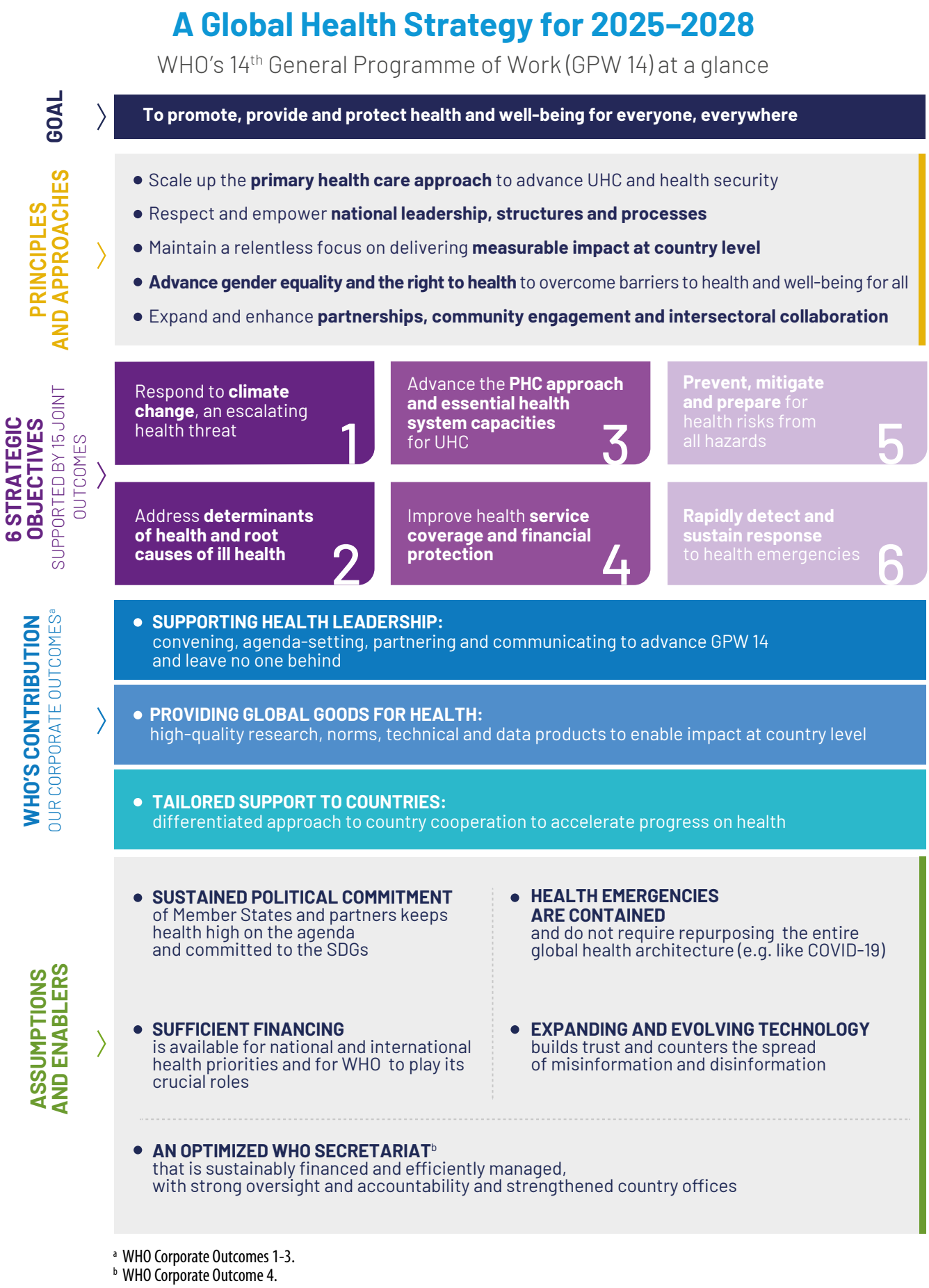
With completion of the programme for 2020–2023, the Action Framework has been revised and updated for 2026–2030. This includes a review of activities that have been completed and an

[1] A blood system encompasses blood regulatory systems; blood supply systems or "services"; blood transfusion systems, including hospital blood banks and clinical transfusion services; related laboratories; and allied industries, including providers of related substances, reagents and medical devices.

assessment of the progress in achieving the six strategic objectives using relevant data obtained from the Global Database on Blood Safety (GDBS), primarily the 2023 GDBS. Moving forward, the focus for 2026–2030 will shift to implementation at country level. In the face of unprecedented changes globally, this will require new levels of cooperation among the different stakeholders at country, regional and global levels, with alignment on shared goals, agenda, priorities and commitments. To achieve this, the roles and responsibilities of WHO headquarters, regional and country offices, WHO partners and other stakeholders including academic organizations must be reconsidered and clarified, and ways to improve communication and coordination in implementing change at a country level identified. The Action Framework for 2026–2030 reflects these new challenges and strategies.

The Action Framework aligns with WHO's Fourteenth General Programme of Work (GPW 14) (Fig. 1), which maps out the Global Health Strategy for 2025–2028 and aims to get the health-related SDGs back on track for 2030 while future-proofing health and care systems *(9)*. Medicinal products derived from human donation of blood and plasma play a critical role in health care and therefore in the realization of the SDGs, in particular SDG target 3.8 (achieve universal health coverage). The Action Framework supports GPW 14 strategic objective 3 to advance the primary health care approach and essential health system capacities for universal health coverage. It also contributes to the other GPW 14 strategic objectives, such as 4 and 6, that address equitable coverage and financial protection, risk mitigation and rapid response to emergencies. The focus on achieving measurable impact at country level follows the principles and approaches enunciated in GPW 14. The increased attention on expansion and enhancement of partnerships and collaborations adopted in this Action Framework is also aligned with the GPW 14 Global Health Strategy, which prioritizes joint action and partnership for impact, with greater elaboration of the role of WHO and its partners guided by the three corporate outcomes developed in GPW 14 – supporting health leadership, providing global goods for health, and tailored support to countries.

Fig. 1. **WHO Global Health Strategy for 2025–2028**



[a] WHO Corporate Outcomes 1-3.
[b] WHO Corporate Outcome 4.

Department of Immunology, Rigshospitalet in Copenhagen
© WHO/Uka Borregaard

2 Current challenges and WHO response

WHO's current work on blood safety emerged in 1975 when the 28th WHA adopted regulation WHA28.72 *Utilization and supply of human blood and blood products (6)*, calling on Member States to promote the development of national blood services based on voluntary non-remunerated donation (VNRD). This initiative was supported by the WHO Global Programme on AIDS and the Global Blood Safety Initiative in the late 1980s. In 2000, WHO declared safe blood as an organization-wide priority and blood safety was designated the theme of World Health Day. Following resolution WHA58.13 of 2005, the WHA designated 14 June as World Blood Donor Day, serving to thank blood donors for their voluntary, lifesaving gift of blood; to raise community awareness of the need for safe blood for transfusion; and to emphasize the importance for each country to establish nationally coordinated, well-organized blood services based on VNRD *(10)*.

The International Conference of Drug Regulatory Authorities (ICDRA) is instrumental in guiding WHO and national regulatory authorities (NRAs) in the regulation of blood and associated substances and medical devices, including in vitro diagnostic (IVD) devices. The need for haemovigilance systems to monitor the safety of blood donation and blood transfusion was highlighted in the recommendations of the ICDRA meeting held in 2018 *(11)*. In 2006, the WHO Blood Regulators Network was established in response to a request by the WHO Expert Committee on Biological Standardization (ECBS) for a global network of blood regulatory authorities. In 2020 the Blood Regulators Network was replaced and expanded with the creation of the WHO AG-BRAS.

The importance of blood components and PDMPs as medical products for the global population was underscored in 2013 by the inclusion of whole blood, red blood cells, platelets and fresh

frozen plasma in the 18th edition of the EML for adults and EMLc for children, in addition to the previously listed PDMPs. In 2023, pathogen-reduced cryoprecipitate (cryo-PR) was included in the EML *(12)* and EMLc *(13)*, with non-pathogen-reduced cryoprecipitate listed as a therapeutic alternative. These products are retained in the 2025 edition of the EML *(2)* and EMLc *(3)*.

Since 1998, WHO has collected and analysed data on blood and blood product safety and availability from Member States through the GDBS data collection tool *(14)*, which provides global status updates and evidence-based data to formulate actions to improve blood systems globally. The present document cites information from interim analysis of the 2023 GDBS *(14)* or from previous GDBS surveys *(15)*, when data were not available from the 2023 GDBS survey. Whilst the GDBS has a number of acknowledged limitations,[2] the 2023 survey benefited from an 85.6% response rate[3] and provides high-level insights and guidance to global efforts to ensure access to safe blood products, identifying a series of current challenges:

1. deficiencies in national policy, governance, financing and regulation of the blood system;
2. insufficient supply of safe, effective and quality-assured blood products for transfusion;
3. insufficient availability of safe and effective PDMPs;
4. deficiencies in blood product safety, effectiveness and quality;
5. need to improve clinical use of blood and blood products;
6. insufficient emergency preparedness and responsiveness of the blood system including access to blood products;
7. insufficient access to appropriate funding and resources including for WHO regional and country offices.

These challenges, and the actions taken to address them to date, are presented below.

Challenge 1

Deficiencies in national policy, governance, financing and regulation

A national blood system is a prerequisite for safe, effective and quality-assured blood products in a country. Barriers to a well-functioning national blood system include:

- lack of sustained political commitment and awareness of the essential role of a national blood system in the larger health system;
- lack of national health policy to facilitate supply with safe PDMPs to cover the needs of patients;
- failure to appreciate the impact of an inadequate supply of safe blood products on the national health system and the society;
- fragmented service provision and unclear financing mechanisms that weaken national coordination and hamper consistent standards of safety and quality;
- inadequate legal and regulatory frameworks for a national blood regulatory system; and
- resource limitations, including in the areas of financing and infrastructure, and insufficient numbers of qualified and

[2] Acknowledged limitations of the data and survey included in the WHO *Global status report on blood safety and availability 2021* include inherent dependence on reporting by national health authorities without the ability to obtain independent verification; differences in scope and effectiveness of country-level data collection systems; national reporting in some countries versus reporting based on a subset of blood centres in other countries; and incomplete responses to the survey constraining the analysis.

[3] In total, 153 of 194 WHO Member States responded in 2023 *(14)*. If no data were available for 2023, data from 2020 (two countries) and 2018 (13 countries) were included. The analysis is therefore based on data from 168 (86.6%) countries, with a coverage of 96.3% of the global population.

Table 1. Percentage of countries by WHO region with a national blood policy and specific legislation related to the safety, effectiveness and quality of blood transfusion (2023)

	African		Americas		South-East Asia[a]		European		Eastern Mediterranean		Western Pacific	
Year:	2023	2018	2023	2018	2023	2018	2023	2018	2023	2018	2023	2018
% with national blood policy	87	91	71	58	82	80	81	71	82	78	68	60
% with specific legislation	53	51	68	52	73	70	100	95	71	72	59	56

Note: A few countries reporting "Yes" to the question on existence of national blood policy in the 2018 GDBS survey reported "No" in the 2023 survey.
[a] In accordance with resolution WHA78.25 (2025), Indonesia was reassigned to the WHO Western Pacific Region as of 27 May 2025. In this instance, data analysis had already been completed with data pertaining to Indonesia included in the South-East Asia regional aggregates. WHO regional comparisons must be done with caution. This note applies to all tables in this document that present regional data.

trained personnel functioning as health workers and as national experts for policy, planning and oversight in blood product safety and transfusion practice.

Several key observations support the concept of a national blood service based predominantly on collections at community blood centres and mobile units they control rather than at hospitals. Blood establishments that are centralized under the health ministry (or a designated authority) have a clearer focus with fewer competing priorities and contribute to better coordination of the overall blood system. When the blood service sits mainly inside hospitals, its strategy, staffing and budgetary needs compete with everyday clinical pressures. Furthermore, this unclear position within the health system can obscure accountability and prevent adequate budgeting. A stand-alone, community-based blood collection service avoids these constraints and focuses attention on the national mission of a quality safe and sufficient blood supply.

Central coordination also enables uniform standards, economies of scale, and consistent quality and safety across the country. Direct national oversight promotes regulatory readiness and assures implementation of quality systems. Additionally, centralized leadership promotes emergency preparedness by enabling a comprehensive view of the blood inventory, an integrated approach to donor mobilization and more coherent responses.

In the 2023 survey, 133 (79%) of 168 countries reported the existence of a national blood policy compared with 73% in 2018, with notable regional variation (Table 1). 80% of countries reported having a government unit with responsibility for overseeing blood products. Furthermore, 71% of Member States reported having specific legislation related to the safety, effectiveness and quality of blood transfusion compared with 66% in 2018, again with regional variation.

A challenge to the establishment of a fully functional blood system may arise from lack of integration of a blood policy within the national health programme. In WHO Member States, health authorities may have provision for a safe blood product supply as a priority strategy in their national health plans, but this is not universal nor always comprehensive. These plans should cover the whole chain from recruitment and management of blood donors and the collection of blood in blood establishments to ensure a sufficient supply of safe blood components for transfusion, but also the provision of quality plasma for further manufacturing and supply of the PDMPs needed by the patients.

However, blood establishments may not be able to collect or review information relating to capital and recurrent costs. This can arise when the blood establishment funding is managed centrally by the ministry of health or when it is funded indirectly within a hospital. Therefore, an adequate budget cannot be provided, whether through budgetary allocation, a cost recovery system or a combination of the two. There is often also an incorrect perception that, since blood is donated voluntarily without reimbursement, costs are minimal. These perceptions need to be corrected and targeted public education programmes developed to clarify the distinction

Table 2. Funding available per blood collection for countries by World Bank income group

Country income group	Funding per collection and median (interquartile range) in US$
High income (21 countries reported)	323 (157–565)
Upper middle income (17 countries reported)	126 (50–239)
Lower middle income (21 countries reported)	53 (27–77)
Low income (14 countries reported)	40 (21–94)

between processing fees and payment for donated blood. Transparency regarding the costs of blood is essential for growing and sustaining a robust voluntary donor base.

The GDBS shows that total funding available per blood collection is directly related to the income status of Member States (Table 2). Sources of funding varied greatly.

The 2023 GDBS survey indicated that 62% of countries in the European Region financed the blood system partially or entirely through cost recovery. On the other hand, 49% of countries in the African Region financed the blood system solely through government budget allocations. In 36 countries, additional financial support was received from international or other external sources. While this reflects the many models by which national blood systems are financed, what is most important is establishing a system that can ensure sustainable, adequate and consistent budgets for the blood programme aligned with the wider national health financing system.

Overall, 62% (104 of 168) of countries reported systems of licensing for blood establishments as compared with 2018 where 59% (101 of 171) countries reported systems of licensing for blood establishments. 64% (101 of 168 countries) reported systems of regular inspections of blood establishments by a national regulatory authority (NRA) or other entity compared with 59% (101 of 171) in 2018. The percentage varies between regions (Table 3).

WHO response to date

Supporting implementation of policy guidance on national or regional level

In resolution WHA63.12, the WHA expressed concern about the unequal access to blood products worldwide, which deprives many patients with serious congenital or acquired conditions of adequate treatment. In response to this concern, it urged WHO Member States to take all necessary measures to update their national regulations concerning the preparation[4]/manufacture of blood, blood components and PDMPs, as well as the functioning of regulatory authorities, to ensure that regulatory control over the quality and safety of blood products throughout the transfusion chain meets internationally recognized standards *(7)*.

In order to further support Member States in ensuring a sufficient supply of PDMPs, the

[4] Preparation refers to the preparation of blood or a blood component, including all blood collection, processing, testing, release and storage steps *(1)*.

Table 3. Percentage of countries in WHO regions with systems for licensing and regular inspections of blood establishments (2023)

	African	Americas	South-East Asia	European	Eastern Mediterranean	Western Pacific
% with licensing systems	38	61	64	86	88	45
% with regulatory inspection systems	36	61	73	93	65	68

policy guidance on increasing supply of PDMPs in low- and middle-income countries through fractionation of domestic plasma was published in 2021 *(16)*. The establishment of national or regional plasma fractionation programmes to increase the availability of PDMPs was further facilitated by the policy guidance on implementing cross-border transfer of domestic plasma to obtain PDMPs which was published in 2024 *(17)*.

In accordance with resolution WHA63.12 and recognizing that achieving national self-sufficiency in the supply of safe blood is an essential element in preventing blood shortages, WHO added whole blood and major blood components to the primary list of the EML in 2013 *(18)*. In 2023, the inclusion of cryo-PR in the list of EML was approved, with non-pathogen-reduced (native) cryoprecipitate listed as a therapeutic alternative for use in emergency situations when pathogen-reduced cryoprecipitate was not available *(12, 13)*. This was retained in the 2025 EML and EMLc *(2, 3)* with the recognition that widespread global access to cryo-PR is still limited *(19)*. Including blood and blood components on the EML highlighted the role of Member States in providing the organizational support needed to establish and maintain safety and quality standards and good practices in the preparation of products intended for transfusion *(2)*.

WHO has provided policy guidance on good policy processes for blood safety and availability *(20)* and organized a global consultation on universal access to safe blood transfusion *(21)*. WHO has also provided policy guidance on voluntary blood donation *(22)* and developing a national blood system *(23)*.

While national haemovigilance systems are well established in some countries, there is a lack of effective blood safety surveillance in many settings, as outlined in the WHO fact sheet on blood safety and availability *(24)*. The absence of effective haemovigilance and external quality assessment systems prevents "closing the quality loop" on blood collection, testing, processing, storage and distribution of blood and blood products, and in transfusion decision-making, administration and monitoring of blood transfusions. These limitations hinder the ability to objectively identify, learn from, and take action to improve sub-optimal practice(s).

Recognizing that all countries can take steps, both small and large, to improve blood safety, and to assist countries as they develop and evolve their haemovigilance systems, WHO has developed tools for stepwise implementation of haemovigilance systems *(25)*, working with experts from the International Haemovigilance Network (IHN), the International Society of Blood Transfusion (ISBT), from WHO-related units, and others in haemovigilance systems worldwide.

Strengthening national blood regulatory systems

A competent blood products regulatory authority ensures that appropriate standards are met for production of blood products and monitoring of blood safety *(26)*. WHA resolution WHA63.12 paved the way for major blood system reforms by committing governments to the strengthening of leadership and management to improve national blood systems and relevant blood products regulation *(7)*.

Blood product regulation is an essential element of a national blood system that helps to optimize the safety, effectiveness and quality of blood products. Effective regulation functions to ensure the health and safety of blood donors and patients, address the national need for blood, promote efficiency of the blood service, enable the use of quality-assured plasma to produce PDMPs and ensure that plasma derivatives are safe and effective. Additionally, effective blood product regulation monitors the status of the blood system, including collection of data from blood donors and blood product recipients, through haemovigilance and pharmacovigilance, and permits timely and effective responses to emerging blood safety threats.

In line with its renewed focus on strengthening regulatory systems, WHO has supported countries in developing regulatory frameworks, including implementation and enforcement of

good manufacturing practices (GMP) in blood establishments that collect, process, store and distribute blood products, and regulation of blood safety-related IVD devices.

Mandated by resolution WHA67.20 on regulatory system strengthening *(27)*, WHO developed the Global Benchmarking Tool (GBT) for evaluation of national regulatory systems for vaccines and medicinal products *(26)*, which was later extended with relevant criteria for blood regulation. This new tool was published in 2023 and is called the Global Benchmarking Tool Plus Blood (GBT+Blood), which includes the earlier published assessment criteria for blood regulation *(28, 29)*.

A prototype version of the GBT+Blood tool was pilot tested in 10 African countries, confirming its utility for identifying gaps in blood regulation *(30)*. Under the GBT+Blood tool, indicators are provided for assessing the maturity of the blood regulator in establishing and implementing relevant functions (for example, approval of blood components and plasma for fractionation). An overall maturity level of 3 on a scale of 1–4 would indicate the presence of a fully competent national blood regulator.[5] Based on an external, officially assessed maturity level of 3 or greater, WHO will list authorities on which less developed regulators can rely in making their own product evaluations. At country level, WHO has reviewed existing blood legislation within countries in the WHO Eastern Mediterranean Region and a template for legislation that was developed for use by countries to ensure and promote adherence to GMP and harmonization across countries.

Continued technical assistance and support for capacity building to strengthen national blood policies and related governance, including leadership and management *(31)*, was provided by WHO. These trainings focused on the main regulatory functions as defined in the GBT+Blood tool. Webinars on strengthening blood system through effective blood regulation in all official languages took place in 2020, 2023 and 2024.

A special focus on capacity building for national blood regulatory authorities and national blood services was also assigned to the implementation of GMP in blood establishments and the regulatory oversight of its implementation by NRAs. WHO guidelines on GMP for blood establishments were published in 2011 *(32)* and have been completely revised in 2025 to fully align with other international guidance documents and renamed as *WHO good practices for blood establishments (33)*. Several virtual trainings took place in 2023 and 2024 to strengthen the understanding of the elements of GMP in order to facilitate their implementation in blood establishments and the building of capacity for inspections by NRAs.

WHO also recognizes the importance of haemovigilance to identify and prevent occurrence or recurrence of donation and transfusion-related adverse events, and to increase the safety, efficacy and efficiency of blood transfusion. In 2020, WHO reaffirmed the importance of haemovigilance as one of the strategic objectives of global efforts to improve capacity to monitor, investigate and assess adverse events in blood donors and transfusion recipients. A webinar on haemovigilance was conducted in 2020 in French, to support Francophone countries in Africa to develop their haemovigilance systems. A user guide for navigating resources on stepwise implementation of haemovigilance systems was published in 2022 *(25)*.

Since 2018, WHO has supported development of the African Blood Regulators Forum (ABRF). The aim of this forum, which was established officially in October 2019, was to facilitate access to quality, safe and affordable blood products for all people of Africa through information sharing and reliance for strengthening and harmonizing regulatory systems for blood products. The forum has provided advocacy and communications

[5] Consistent with ISO 9004 guidance, WHO characterizes maturity level 3 under the GBT as a systematic approach for regulatory oversight of medical products in which regulatory processes and procedures are well established and documented for all essential functions. At maturity level 4, the regulatory system operates at an advanced level of performance that includes use of electronic databases, stakeholder and public transparency, risk-based management, outcome monitoring and continuous improvement.

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 through external assessment against the GBT+Blood tool along with cooperation in addressing identified gaps and deficiencies. Between 2018 to 2021, the ABRF drafted several documents: a guidance document on collection and use of COVID-19 convalescent plasma; a stepwise framework for blood regulation in Africa; and GMP guidelines for blood establishments in Africa. Unfortunately, starting in 2021, the activity of ABRF was interrupted by the COVID-19 pandemic, and its activity was completely stopped in 2022. However, it was revitalized in 2025 as the African Blood Regulators Technical Committee (ABR-TC) of the African Union Development Agency. The committee decided on a workplan for 2025 to finalize and publish the guideline *Stepwise framework for blood regulation in Africa and the Good practice guidelines for blood establishments in Africa*. It is envisaged going forward that the ABR-TC will support the work of the African Medicines Agency.

Costing of blood services

In 1998, in response to the challenge of financing blood services, WHO published the document *Safe blood and blood products: costing blood transfusion services*. This has been revised and updated in 2025, including the provision of an Excel tool, as the *WHO model for costing of blood products* *(34)* to assist blood establishments in performing a cost analysis on which to base cost collection for their services. Broadly, the cost of blood components for transfusion includes both the direct product acquisition costs and the additional cost of activities associated with the provision of transfusions.

WHO has conducted pilots in several countries using the new version of the costing model. Cost collection and cost analysis will provide governments and funding agencies with the information needed to develop and maintain sustainable national blood systems.

Challenge 2

Insufficient supply of safe, effective and quality-assured blood products for transfusion

Countries with well-structured health systems and blood transfusion services based on VNRD are generally able to meet the demand for blood products. In contrast, countries with less-developed health systems and blood programmes, including many low- and middle-income countries, rely on family or replacement donation and, to a lesser extent, paid donations and often struggle to maintain a stable blood supply leading to chronic blood shortages. These countries often lack structured blood donor programmes, making it difficult to recruit enough donors to meet the demand for blood in emergencies, planned surgery and routine transfusion. There are also major inequalities in availability and access to safe blood products between central and urban areas and peripheral, remote areas.

Paradoxically, despite severe blood shortages in many countries, unnecessary blood transfusions are often administered when safer, less expensive treatments could offer equal or better patient outcomes. This not only exposes patients unnecessarily to the risk of potentially fatal transfusion reactions, but also exacerbates the imbalance between supply and demand, further contributing to shortages of blood and blood products for patients in critical need.

WHO estimates that over 1 million people contract sexually transmitted diseases every day worldwide, some of which are transfusion transmissible. 4.5 million new cases of HIV, hepatitis B (HBV) or hepatitis C (HCV) occur annually *(35)*. These infections not only increase the global burden on disease control and health systems but also pose additional challenges to maintaining an adequate and safe blood supply.

Moreover, in many countries, ageing populations and increasingly stringent donor selection criteria have reduced the pool of eligible donors.

Furthermore, the volume of blood collection is often not well matched with the estimated population-based transfusion requirements, and inadequate to support health care needs.

Several barriers that contribute to the inability to collect sufficient blood to meet population need, include:

- ineffective donor recruitment strategies, leading to low rates of VNRDs;
- reliance on family, replacement and, to a lesser extent, paid donations, rather than establishing a community-based system to ensure availability of a stable inventory of blood and blood components;
- challenges in reaching non-urban populations, particularly in low- and middle-income countries, due to logistical and infrastructure constraints;
- lack of government commitment to a nationally coordinated blood service, which is critical for optimizing resources and reduces inefficiencies caused by competition among multiple service providers;
- lack of resources, including competent staff and reliable supplies of consumables for blood collection;
- cultural and behavioural barriers and lack of awareness, which affect individuals' willingness to donate blood;
- reliance on monetary compensation or monetary value incentives for donors, especially in private plasma collection centres, which endanger the principles of VNRD and result in negative consequences to sustaining a stable and safe blood supply both in the short and long term; and
- increasing deferral criteria for infectious diseases, resulting from increased international travel (e.g. dengue, chikungunya, malaria) and changes in lifestyle, which reduce the available donor pool.

Globally, 168 Member States responded to the 2023 GDBS survey, of which 23 were from low-income countries (LICs), 51 from lower middle-income countries (LMICs), 45 from upper middle-income countries (UMICs) and 49 from high-income countries (HICs) *(14)*. The survey results indicate that whole blood collection is disproportionately concentrated in HICs, which account for 36% of global blood donations despite comprising only 15% of the world's global population (Table 4). In contrast, LICs represent 8% of the global population, but collect only 2% of the world's blood supply. LMICs and UMICs, home to 77% of the global population, collect 62% of the total blood supply.

Table 4. Percentage of global population and whole blood donations for countries by World Bank (WB) income group (2023)

	LICs	LMICs	UMICs	HICs
Member States responding to the survey	23	51	45	49
% of global population	8	41	36	15
% of global donations	2	25	37	36
Median annual WB donation in units/1000 populations (range among countries)	4.5 (0.4–10.7)	8.5 (1.7–25.6)	18.2 (5.0–48.8)	28.9 (9.8–53.8)

Note: Percentages may not sum to exactly 100% due to rounding of numbers.

Table 5. Percentage of global population and whole blood donation for countries in WHO regions (2023)

	African	Americas	South-East Asia	European	Eastern Mediterranean	Western Pacific
% of global population	16	13	27	10	9	25
% of global donations	6	20	20	22	8	25
Mean annual WB donation in units/1000 populations (range among countries)	6.0 (0.6–41.1)	15.2 (1.7–39.6)	9.7 (3.7–43.1)	30.9 (5.0–53.8)	14.2 (0.4–48.8)	16.9 (5.6–45.5)

Note: Percentages may not sum to exactly 100% due to rounding of numbers.

Comparing GDBS 2023 data across WHO regions, the greatest disparities between whole blood collection and population are observed in the African and European regions. The African Region, with 16% of the world's population, has access to only 6% of globally collected blood, while the European Region, which accounts for 10% of the world population, has access to 22% of globally collected blood (Table 5). The mean annual blood donation, measured in units per 1000 population, is five times higher in the European Region compared with the African Region.

WHO historically has recommended a minimum of 10 whole blood donations per 1000 populations per year to meet a nation's basic blood supply needs *(24, 36)*. This index was first mentioned in 1971 in a WHO document entitled *Blood transfusion: a guide to the formation and operation of a transfusion service*, which was published on behalf of WHO, the ISBT and the League of Red Cross Societies *(37)*. While not a direct target and recognizing that more accurate estimates could be achieved through appropriate modelling that considers geographic variability in disease burden, health care infrastructure and transfusion practices *(38)*, this index remains useful for comparison of blood use in different countries and may also serve as a simple and practical benchmark when localized data are unavailable. Of the 168 countries responding to the 2023 GDBS survey, a total of 55 countries reported less than 10 units of whole blood donation per 1000 population. This includes three countries in the European, Eastern Mediterranean and Western Pacific regions each, six in the Region of the Americas, six in the South-East Asia Region and 36 in the African Region. Based on World Bank (WB) income categories, 22 countries in LICs reported collections of less than 10 units of whole blood donation per 1000 population, 30 countries in LMICs, two in UMICs and one in HICs.

WHO response to date

In May 1975, the 28th WHA adopted regulation WHA28.72 *Utilization and supply of human blood and blood products (6)*, calling on Member States to promote the development of national blood services based on VNRD. To assist Member States in achieving self-sufficiency in blood products, WHO issued policies, guidance, aides-mémoire and other documents, and organized workshops, webinars and hosted various events. In implementing regulation WHA58.13: *Blood safety: proposal to establish World Blood Donor Day (10)*, adopted by the WHA in May 2005, WHO requested Member States to organize and support the annual celebrations of World Blood Donor Day – established to raise global awareness of the need for safe blood and blood products and to highlight the critical contribution VNRDs – on 14 June each year. The theme for celebrating 2025 World Blood Donor Day was "Give blood, give hope: together we save lives".

In May 2010, the WHA adopted WHA63.12: *Availability, safety and quality of blood products (7)*. WHO has been providing technical assistance and capacity-building support to countries to strengthen their blood programmes through 100% VNRD and careful selection of healthy donors at low risk of infection with a transfusion-transmissible infections (TTIs). In 2021 WHO published *Guidance on centralization of blood*

donation testing and processing (1) and *Guidance on increasing supplies of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma (16)*. Webinars were organized to promote these two documents in May 2021. In 2022, WHO released the results of the new GDBS data survey, *Global status report on blood safety and availability 2021 (15)*, as well as the *Guidance to identify barriers in blood services using the blood system self-assessment (BSS) tool (39)*, and its web annex *(40)*. Since 2024, WHO has issued and updated four documents. Three have already being published – *Guidance on implementation of a quality system in blood establishments (41)*, *Implementing cross-border transfer of domestic plasma to obtain plasma-derived medicinal products: policy guidance (17)* and the *WHO model for costing of blood products (34)*. The revised *Guidance on blood donor selection* is scheduled for publication in 2026.

WHO assists Member States to improve their blood regulatory framework and blood infrastructure system by organizing various workshops and webinars. Two webinars on strengthening blood systems through effective blood regulation were organized in 2020 and 2024. A webinar on building effective national blood donor programmes to ensure safe and secure blood supplies was held in 2022. In 2021 WHO held a special webinar to introduce the Global Benchmarking Tool (GBT+Blood) *(29)*. This tool was designed for NRAs to evaluate performance on 10 functions, with an outcome of at least maturity level 3 indicating that the regulatory framework is both functioning and stable.

In response to the potential impact of the COVID-19 pandemic on blood sufficiency and safety, WHO promptly issued an interim guidance in July 2020, *Guidance on maintaining a safe and adequate blood supply during coronavirus disease 2019 (COVID-19) pandemic and on the collection of COVID-19 convalescent plasma (42)*. In February 2021, WHO updated the guidance as *Maintaining a safe and adequate blood supply and collecting convalescent plasma in the context of the COVID-19 pandemic (43)* and webinars were organized for this guidance. In 2023, WHO released the *Guidance on ensuring a sufficient supply of safe blood and blood components during emergencies (44)* to address a wider range of scenarios. A webinar was organized in December 2024 to present this guidance and two other recent publications.

In 2021, WHO established the AG-BRAS to advise on and support the development of WHO norms, standards and technical guidelines, as well as to provide strategic recommendations to ensure the safety, quality and availability of blood products while promoting their appropriate use and equitable access. The Advisory Group also guides implementation of existing WHO policies and strategies, including innovative and tailored approaches to strengthen national blood supply and regulation systems, with the ultimate goal of achieving universal access to safe and quality-assured blood products *(45)*. It also provides scientific assessments of current and emerging threats to blood safety and availability and advises WHO on recommended actions for Member States to enhance preparedness and response to public health threats *(44)*. Since its establishment, the Advisory Group has been involved in several projects, including harmonization of terminologies on blood-related terminologies, design of a disaster reporting toolkit, providing recommendations on the disseminations of WHO publications, and participating in the revision of WHO guidance documents.

Challenge 3

Insufficient availability of plasma-derived medicinal products

The availability of an adequate supply of essential PDMPs is critical to meeting a population's health needs. This includes normal (i.e. polyvalent) and hyper-immune immunoglobulins and replacement products for specific congenital and acquired plasma protein deficiencies including fibrinogen (in massive haemorrhage, including traumatic and peripartum), clotting factors such as coagulation Factor VIII, Factor IX and von Willebrand Factor, and other plasma proteins such as C1-esterase inhibitor and alpha-1 antitrypsin. However, availability of these medicinal products

is insufficient in numerous low- and middle-income countries and shortages still occur in HICs.

Reports from 2016 suggest that over 9 million litres of plasma collected in low- and middle-income countries are either not produced from whole blood donations or discarded for lack of acceptability for fractionation *(5)*. This wastage has likely increased in parallel with the overall rise in whole blood collections in low- and middle-income countries to meet clinical needs for red blood cells, particularly in situations where whole blood is not clinically suitable. In many countries, blood establishments focus only on the delivery of transfusion services. As a result, recovered plasma is often discarded despite its potential as a valuable resource for plasma fractionation. To ensure that plasma meets the stringent requirements for fractionation, the establishment of dedicated facilities with specialized infrastructure, quality systems and regulatory oversight is essential.

Production of plasma for fractionation into PDMPs faces numerous challenges related to non-compliance with traceability of donors, testing, regulatory controls, quality systems, GMP, and required freezing and cold chain conditions. Consequently, in low- and middle-income countries a large percentage of human plasma, separated from whole blood, if not utilized for clinical purposes, is categorized as waste material and destroyed *(5, 46)*. Collaboration between countries, through appropriate regulatory standards and transfer of technology, will be required to build local capacity for production of recovered and apheresis plasma suitable as a source material for manufacture of PDMPs through small-scale local processing and industrial contract or domestic fractionation. Stepwise pathways, such as strengthening plasma quality and traceability and piloting contract fractionation abroad, can be considered where domestic fractionation is not yet feasible. Co-operation might include the transfer of raw materials, intermediates or finished products between countries and through the joint provision of quantities of plasma suitable for processing and production of PDMPs.

Barriers to the provision of plasma for fractionation include:

- limited use of component preparation, resulting in low availability of recovered plasma;
- absence of a robust quality management system with limited availability of testing equipment and quality control systems that affect the ability to monitor plasma safety and quality, and resulting in poor compliance with required standards;
- failure to meet internationally recognized GMP and standards for blood collection, donation testing, blood component preparation, quality control testing and other requirements (e.g. nucleic acid testing of donations, suitable conditions of plasma freezing) necessary to ensure quality of recovered plasma acceptable to a contract fractionator;
- poor cold chain and supply chain logistics;
- high cost and complexity of apheresis needed to generate sufficient volumes of plasma;
- high cost, technical complexity and volume requirements of fractionation facilities that prevent development of domestic fractionation;
- absence of regulatory oversight precluding assurance that appropriate standards in plasma production are met;
- blood establishments primarily focused on provision of transfusion services rather than on supplying plasma for fractionation;
- inappropriate overuse of plasma in clinical practice, leading to lower volumes available for fractionation; and
- lack of designated funding for a national or regional plasma programme.

Providing quality domestic plasma for fractionation (in addition to or as an alternative to external procurement) can be part of a strategy to secure a national supply of PDMPs. The feasibility of this strategy depends on the determination by a fractionator and relevant regulatory authorities that plasma collected in a country[6] meets quality standards for use in fractionation, as well as the willingness of the national authority to invest in appropriate testing and quality control systems. Concurrently, this determination is an indicator of optimization of blood collection by avoiding wastage of surplus plasma collected in excess of clinical need, and additional specific collection of plasma for fractionation by apheresis. However, the 2023 GDBS survey indicated that only 49 countries used domestically collected plasma for fractionation providing variable proportions of supply of essential medicines including albumin, normal immune globulin and coagulation Factor VIII. Worldwide experience also indicates that global sufficiency of PDMPs cannot be achieved without large-scale programmes of plasmapheresis. The current and ongoing escalation of demand for PDMPs (particularly immunoglobulin products) also highlights the need for effective management and use of PDMPs through appropriate clinical guidelines.

Normal and hyperimmune globulins can be obtained only by fractionation of plasma. Despite the availability of recombinant Factor VIII, Factor IX and von Willebrand Factor products in HICs, cryoprecipitate and plasma-derived coagulation factors remain the only treatment options in many low-resource settings. WHO and patient organizations have reaffirmed the urgency of improving equitable access to these essential therapies. The World Federation of Hemophilia (WFH) has indicated for years that 70–75% of patients with haemophilia globally do not receive any form of appropriate treatment *(47–49)*. A recent survey conducted by WHO showed that many countries, of all income levels, continue to produce non-pathogen-reduced cryoprecipitates, which are used to treat inherited bleeding disorders (i.e. haemophilia A and Von Willebrand disease) and other bleeding conditions *(50)*. Production of pathogen-reduced cryoprecipitates was reported by six countries including three HICs and three middle-income countries. Recognizing the continued importance of access to cryoprecipitates, the 2025 version of the WHO EML lists pathogen-reduced cryoprecipitate (cryo-PR) under blood and blood components *(2)*. Cryo-PR is included as a core-listed product for the replacement of coagulation factors in cases of life-threatening haemorrhage. The revised listings permit use of cryo-PR for the treatment of von Willebrand disease and Factor XIII deficiency, and as an alternative to Factor VIII concentrate in haemophilia A in situations of acute bleeding when concentrates are unavailable or unaffordable. The EML specifies minimum content requirements per unit (> 50 IU FVIII, > 100 IU vWF and > 140 mg clottable fibrinogen). Native (non-pathogen-reduced) cryoprecipitate is retained only as a therapeutic alternative, and its use is restricted to life-threatening haemorrhage when cryo-PR is not available.

The 2025 EML update also moved plasma-derived and recombinant Factor VIII and Factor IX concentrates, as well as emicizumab for prophylaxis in haemophilia A, to the core list. Factor IX complex was removed because of its associated risk of thrombosis.[7] These changes reflect stakeholder input and consensus. The WFH advocated for the upgrade of Factor VIII and Factor IX concentrates (plasma-derived and recombinant) to the core list and supported removal of Factor IX complex. The ISBT supported the continued inclusion of cryoprecipitate, particularly cryo-PR, as a necessary blood component, consistent with the listing of other non-pathogen-reduced blood components such as whole blood, red blood cells, fresh-frozen plasma and platelets.

The 25th WHO Expert Committee on Selection and Use of Essential Medicines emphasized that while cryo-PR remains important as a bridging therapy in settings where access to factor concentrates is limited, plasma-derived and recombinant clotting factor concentrates

[6] Either by separation from whole blood or by apheresis.

[7] Factor IX complex is also known as prothrombin complex.

remain the preferred treatment for haemophilia A and von Willebrand disease wherever they are available and affordable. The COVID-19 pandemic demonstrated the importance of maintaining accessible plasma stocks and responsive donor mobilization systems, which are also essential for strategies to assure availability and access to PDMPs as well as potential future needs for hyperimmune globulins or convalescent plasma.

WHO response to date

Preventing wastage of domestic plasma is a key opportunity to improve access to essential medicines in resource-constrained settings. WHO will continue to urge countries to reduce the discard of plasma through national policies that promote component separation, meet quality standards for recovered plasma, establish supply chain and cold chain systems for plasma suitable for fractionation, and support the progressive implementation of stepwise plasma processing for fractionation.

In 2021, WHO published the *Guidance on increasing supplies of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma*, which promotes a stepwise approach *(16)*. To improve access to safe blood products through local production and technology transfer in blood establishments *(5, 45)*, and consistent with this guidance, WHO is supporting countries in exploring collaborative models to increase access to virus-inactivated locally produced plasma proteins and PDMPs through contract fractionation arrangements to improve cost-effectiveness and supply security.

Production of PDMPs requires plasma as a starting material that must consistently and sustainably fulfil requirements for minimum batch volume, safety and quality. Implementation of GMP in blood establishments and regulatory oversight of blood establishments is necessary to ensure the safety, effectiveness and quality of plasma suitable for fractionation. In 2002–2005 WHO implemented the Achilles project *(51)*, which aimed to assist countries in improving access to safe blood products through local production and technology transfer in blood establishments. The Achilles project was revitalized in 2022. WHO continues working with regulatory authorities and national blood services in multiple geographic regions to ensure 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. Worldwide experience also indicates that global sufficiency of PDMPs cannot be achieved without large-scale programmes of plasmapheresis. WHO advocates for all plasma donation to be non-remunerated due to the risks for exploitation of donors and the potential disruptions to non-remunerated donations for transfusion that may arise with commercialization of plasma donation by plasmapheresis *(21)*. Related efforts are continuing to promote establishment of centres that carry out consolidated blood donation testing and component preparation and to promote regional self-sufficiency in production of PDMPs.

WHO international biological reference preparations are the basis of a uniform system to ensure the quality of biological products, including PDMPs. Reference preparations are established by the ECBS and designed, prepared and validated by a responsible WHO collaborating centre. They serve as a comparator against results from laboratories, regardless of location or methods employed, and are an important tool in quality testing. These biological reference preparations are generally in limited supply and are only distributed to qualified laboratories, namely national control laboratories and manufacturers of biological medicinal products. Since 2020, 57 WHO biological reference preparations have been produced to reinforce quality control in the areas of blood products and blood safety-related IVD devices. WHO promotes reference standards for blood products and related IVD devices through an online catalogue *(52)*, as well as through workshops and interactions with international professional organizations. Moreover, the ECBS has established guidelines on management of blood products as essential medicines *(53)*.

Challenge 4
Deficiencies in blood product safety, effectiveness and quality

Selection of donors at lower risk and laboratory testing of donations for evidence of TTIs are fundamental strategies to ensure blood safety, effectiveness and quality. Dependence on first-time donations, practices of family or replacement donation and paid blood donation contribute to risks of TTIs compared with repeated collections from VNRD. As noted above, among countries, the proportion of blood donations by VNRD generally varies with income level.

Barriers to ensuring that blood is collected from low-risk donors include:

- insufficient budget and other resources allocated for donor recruitment and retention of low-risk donors, leading to a reliance on first-time and infrequent donors;
- insufficient public education and outreach to promote awareness and to overcome fears and cultural biases;
- inadequate donor selection due to lack of clear donor selection criteria during pre-donation screening;
- inadequate staff training and poor staff retention leading to inconsistent and unsuitable donor screening and selection practices;
- inadequate and inconsistent infectious disease marker testing, including reliance on less sensitive tests (e.g. rapid tests);
- lack of or inadequate implementation of GMP from lack of awareness and insufficient knowledge;
- absence of epidemiological monitoring for TTIs in the general population and in the blood donor population, hindering public health efforts to identify and recruit low-risk donors;
- high prevalence of TTIs in the population, particularly those for which sensitive tests for donor screening are not available; and
- absence of national blood donor deferral registers and the ability to identify donors who have been deferred for high-risk activities.

Voluntary blood donation plays a critical role in ensuring the availability of safe and adequate blood supplies around the world. Each year, approximately 120 million blood donations are collected globally. The 2023 GDBS reported that in 80 countries, over 90% of the blood supply comes from voluntary, unpaid donors, but 59 countries rely on family or replacement donation and paid donation to cover more than 50% of their population's blood needs. There is a general trend indicating a higher proportion of repeat VNRD amongst donors in higher income countries. The GDBS data report a rate of 98% in HICs, 87% in UMICs, 68% in LMICs and 63% in LICs *(14)*. The proportion of whole blood collected from VNRD was 69% in the African Region, 78% in the Region of the Americas, 75% in the South-East Asia Region and 61% in the Eastern Mediterranean Region compared with 98% in the European Region and 99% in the Western Pacific Region. Encouragingly, low- and middle-income countries have made significant progress over the past decade. For example, between 2008 and 2018, voluntary blood donations in 119 countries, for which data for both years are available, increased by 127% in the South-East Asia Region and by 81% in both the Africa and Americas regions *(15, 54)*. Furthermore, the 2023 GDBS reported that in 168 countries, 80% of countries report having national selection criteria for assessing donor suitability for blood donation *(14)*.

As discussed in Challenge 1, insufficient regulatory and professional oversight and absence of or poorly implemented regulatory frameworks compromise all aspects of blood safety. Among the impacts, deficiencies in the quality of laboratory testing and blood screening reagents can result in failures to detect TTIs in donors, and infectious transmissions from transfusions may go unrecognized.

Barriers to quality-assured infectious disease, blood grouping and compatibility testing of blood donations include:

- unreliable supply management of reagents and assays (for example, test kits for donation screening and blood grouping reagents);
- lack of properly functioning laboratory testing systems and equipment, or which have not been properly evaluated and qualified for the purpose for which they are used;
- use of commercial blood screening reagents that have not been properly evaluated and qualified or inhouse screening reagents that have not been validated;
- use of tests and testing algorithms with lesser sensitivity or unsuitable for blood donor screening, weak or absent controls of reagents and assays and related laboratory practices;
- lack of confirmatory testing for positive results in screening tests conducted, including that performed in hospital laboratories;
- insufficient training and lack of competence in the proper use of available laboratory systems;
- weak or absent quality management systems in blood collection and preparation of blood components; and
- lack of external quality assurance and haemovigilance monitoring to identify safety issues and drive improvements.

Constraints in resources, infrastructure and trained personnel further complicate these issues in low- and middle-income countries.

The 2023 GDBS survey indicated that some countries reported not being able to test 100% of the blood collected for one or more of the four TTIs – HIV, HBV, HCV and syphilis – as required by the national testing policy (Table 6). In addition, in some countries not all quality-assured testing procedures were followed. An example is that 68% of LICs, 48% of LMICs, 68% UMICs and 92% of HICs reported the blood screening laboratories participated in external quality assurance schemes.

Table 6. Number of countries by WHO region reporting less than 100% donation testing for a major transfusion-transmissible infection (2023)

	Region (number of countries reporting)					
Infection	African (45)	Americas (31)	South-East Asia (11)	European (42)	Eastern Mediterranean (16)	Western Pacific (21)
HIV-1/2	0	0	0	1	0	0
HBV	2	0	0	1	0	0
HCV	4	2	0	1	0	2
Syphilis	3	0	0	3[a]	2[b]	1[c]

Notes:
[a] One country reported implementing a policy of not routinely performing syphilis testing for blood donations. Another country reported implementing a policy of syphilis testing for selective donations.
[b] One country reported implementing a policy of not routinely performing syphilis testing for blood donations.
[c] One country reported implementing a policy of syphilis testing for selective donations.

Table 7. Median prevalence of transfusion-transmissible infection markers in blood donations by World Bank income group (2023)

Country income group	HIV	HBV	HCV	Syphilis
High income	0.004	0.01	0.007	0.03
Upper middle income	0.08	0.17	0.16	0.45
Lower middle income	0.25	1.34	0.29	0.79
Low income	0.81	1.92	0.66	0.91

Note: Marker rates are elevated over true positive rates due to reporting by some countries of reactive screening test results without additional confirmation of positivity. Conversely rates may be lowered in other countries due to insensitivity of testing.

The prevalence of markers of TTIs in blood donations varies inversely by the income status of Member States (Table 7). WHO recommends that 100% of blood donated by donors should be screened for infections with HIV, HBV, HCV and syphilis to avoid the transmission of such infections from blood donors to patients through transfusion *(55)*.

The use of rapid tests for all or part of the blood donations was reported in 33 of 139 countries[8] (14 in the African Region, seven in South-East Asia Region, three in the Eastern Mediterranean Region and nine in the Western Pacific Region). Most of these countries are LICs (seven countries) and LMICs (22 countries). Widespread use of less sensitive rapid diagnostic tests in many low- and middle-income countries contributes to the risk of TTIs.

Blood safety, quality and efficacy depend critically on preparation practices and procedures that meet WHO or other internationally recognized standards applicable to the entire blood transfusion chain (from recruitment of donors to clinical administration of the blood) *(33, 55, 56)*.[9] The assurance that blood for transfusion meets standards for safety and quality depends on the existence of national standards and systems of monitoring and assessment, including integrity of the cold chain during storage and transportation of blood products. Globally, 84% of countries reported existence of standards for preparation of blood products; 79% reported existence of national external quality assessment schemes for TTI testing; 66% external quality assessment schemes for blood group serology and compatibility; 62% systems of licensing for blood establishments; and 64% reported systems of regular inspection of blood establishments by an NRA or other entity. Across the WHO regions, 39% of countries in the African Region, 38% in the Region of the Americas, 64% in the South-East Asia Region, 86% in the European Region, 88% in the Eastern Mediterranean Region and 45% in the Western Pacific Region reported the existence of a system of licensing and 36% of countries in the African Region, 61% in the Region of the Americas, 73% in the South-East Asia Region, 93% in the European Region, 65% in the Eastern Mediterranean Region and 68% in the Western Pacific Region reported the existence of a system of regular inspection. Only 40% reported that national blood transfusion services were accredited. Among reporting countries, 69% reported programmes of continuing education for personnel involved in blood collection, testing and processing and 67% in blood transfusion. WHO regions vary in the extent to which these elements of quality assurance and monitoring are in place (Table 8).

[8] The 2023 GDBS survey on the use of rapid tests does not include countries in the WHO Region of Americas, except Canada and the United States of America.

[9] Standards can relate to ethical aspects of blood donation, donor suitability assessment, collection and component preparation, donation testing, labelling, storage, distribution and shipping (including an assured cold chain), appropriate clinical use, haemovigilance reporting and investigation of adverse reactions in donors and recipients and look-back and trace-back procedures "from vein to vein".

Table 8. Number (and %) of countries by WHO region reporting existence of quality assurance standards and monitoring activities for blood (2023)

	African	Americas	South-East Asia	European	Eastern Mediterranean	Western Pacific
Implementation of GMP	26 (58)	ND	9 (82)	30 (71)	13 (76)	10 (45)
National standards	33 (73)	23 (74)	9 (82)	39 (93)	16 (94)	21 (95)
Licensing	17 (38)	19 (61)	7 (64)	36 (86)	15 (88)	10 (45)
Regular inspection	16 (36)	19 (61)	8 (73)	39 (93)	11 (65)	15 (68)
Accreditation	12 (27)	7 (23)	5 (45)	27 (64)	7 (41)	10 (45)

WHO response to date

In addition to GMP for blood establishments *(32)*, WHO has issued specific recommendations on screening of donated blood for TTIs *(55)*, maintenance of the blood cold chain *(57)* and strategies to protect the blood supply during infectious disease outbreaks *(58)*.

WHO tools and training materials *(40, 59, 60)* to enhance the quality of blood transfusion service management are used in the development of national standards and quality management systems in many countries. Furthermore, to increase awareness of the importance of safety of blood products, the ECBS has established guidelines on estimation of residual risk in blood components for transfusion-transmissible viruses *(61)*, as well as several international biological reference preparations (see Annex 2) for benchmarking of blood products and IVD assays, including those needed for detection of pathogens in disease outbreaks.

WHO has also worked to strengthen national blood transfusion services in countries affected by the Ebola virus disease and provided emergency guidance during the outbreak of Zika virus disease *(62)*. At regional level, the Plan of Action for Universal Access to Safe Blood 2014–2019 for the Region of the Americas, and the Regional Strategic Framework for Blood Safety and Availability 2016–2025 for the Eastern Mediterranean Region, provide strategic guidance and reflect government commitment. Likewise, in the South-East Asia Region, WHO has strengthened capacities among national blood programme managers to review the existing capacities of blood transfusion services to identify challenges and develop action plans.

WHO considers convalescent plasma[10] (CP) a short-term, emergency-use option when no vaccines or specific therapies are available. It has emphasized the need for well-designed studies and the availability of standardized antibody testing (e.g. neutralizing antibody titres) to facilitate this, while recognizing that high cost, logistical complexity and quality control issues limit its long-term applicability. During the 2014–2016 West Africa Ebola Outbreak WHO supported use of CP as an experimental treatment under the MEURI protocol (Monitored Emergency Use of Unregistered and Investigational Interventions). WHO coordinated clinical trials in Guinea and Liberia which confirmed its safety although efficacy was inconclusive due to non-randomized design and limited sample size. During the COVID-19 pandemic WHO provided guidance to enable blood products to be collected safely from donors.

Ethical guidance for emergency use of CP, including informed consent, patient safety and oversight structures was also provided. In 2022 WHO issued a recommendation against using COVID-19 CP in both non-severe and severe COVID-19 patients. This was based on systematic

[10] Convalescent plasma (CP) is plasma collected from individuals who have recovered from an infectious disease and developed antibodies. It can be transfused into patients with active infection to provide passive immunity.

reviews of 16 randomized controlled trials involving over 16 000 patients, showing little or no benefit in reducing mortality or disease progression. The recommendation was published in WHO's *Therapeutics and COVID-19: living guideline (63)*. This recommendation has, however, since been superseded by new evidence showing potential benefit in some clinical settings *(64)*.

Challenge 5

Need to improve clinical use of blood and blood products

Blood transfusions are essential to many aspects of patient care and are often lifesaving. For patients receiving transfusion, suboptimal clinical practices compromise patient safety and lead to inappropriate use of the already limited supply of blood products. Furthermore, many health care systems are over-reliant on the use of transfusions, whereas a more holistic approach to patient care should be considered, including the use of alternatives to transfusion wherever possible. Endorsed in 2010 by the WHA in resolution WHA63.12 *(7)*, PBM is defined as a set of evidence-based practices to optimize medical and surgical patient outcomes through preservation of the patient's own blood *(65)*.

Implementation of robust PBM strategies can lead to improvements in patient outcomes and a reduction in health care costs while ensuring that blood is available for the people who need it most. In many countries, professional societies have already developed comprehensive clinical guidelines for PBM. The principles of PBM *(66)* highlight a patient-centred approach aimed at improving patient outcomes by managing and preserving the patient's own blood through:

- detection and management of anaemia and iron deficiency;
- minimization of blood loss and optimization of coagulation; and
- leveraging and optimizing the patient specific physiological tolerance of anaemia.

These practices enable avoidance of unnecessary transfusions. PBM is increasingly recognized as a fundamental element of good clinical practice in transfusion. Furthermore, it plays a key role in primary health care, given its importance for the treatment of anaemia (for example, identification and treatment of anaemia in patients planned for surgery, and other at-risk groups including older adults, pregnant women and children). This approach can optimize patient outcomes and minimize inappropriate transfusion and health care costs.

Barriers to appropriate clinical use of blood and blood products include:

- lack of awareness, and appropriate knowledge and training in PBM among clinicians as this is not included in undergraduate and postgraduate medical curricula;
- absence of, or lack of implementation of national evidence-based guidelines for transfusion;
- weak compliance with established national or institutional transfusion guidelines;
- absence or limited effectiveness of hospital transfusion committees (HTCs);
- poor practices in blood component preparation, storage and handling, including maintenance of the cold chain;
- inadequate infrastructure and resources to facilitate safe transfusion practices;
- lack of knowledge and limitations in access for adequate diagnosis and treatment of disorders manageable with PDMPs;
- overuse of whole blood transfusions from lack of knowledge about its appropriate use or insufficient availability of blood components;

- poor communication between laboratory and clinical areas; and
- lack of haemovigilance systems.

Education and training

The role-specific education and training needs of medical, nursing, scientific and technical staff in the availability of safe blood for transfusion need to be recognized and addressed. While degree-level courses do not indicate all opportunities for transfusion-specific training, in the 2018 GDBS, existence of degree programmes in blood banking and transfusion medicine was reported by only 40% of countries *(15)*.

Additionally, promoting education and targeted training in transfusion medicine across all levels of health care can bridge existing gaps in knowledge and practice.

Clinical guidelines

In 2023, globally, 77% of countries reported existence of national guidelines on clinical use of blood, including 76% of countries in the African Region, 65% in the Region of the Americas, 82% in the South-East Asia Region, 81% in the European Region, 88% in the Eastern Mediterranean Region and 77% in the Western Pacific Region.

Oversight and monitoring of transfusion practice

The availability, use and ability to monitor evidence-based practices for transfusion is reflected in the existence of national transfusion standards and guidelines and the presence of HTCs. The 2023 survey indicated that only 30% (median) of hospitals globally reported having a HTC, more specifically, 9% in LICs, 25% in LMICs, 28% in UMICs, and 85% in HICs.

However, it remains difficult to compare reports between countries and regions, A gap exists between national and international guidelines and their application in daily clinical practice, and the activity and effectiveness of HTCs remain largely unknown. In many cases even established HTCs do not meet regularly and/or have limited functionality. More work is needed to support these committees, including clarity on their function, membership and range of activities, such as promoting the importance of haemovigilance and clinical audit programmes.

In the absence of national requirements for HTCs, cooperation and collaboration between local institutions can still provide important support for both developing HTCs and established committees.

Availability and clinical use of blood components

Component therapy is generally considered preferable in most situations, to specifically meet the patient's clinical need, and to make best use of donated blood. For example, use of concentrated red cells in additive solutions (rather than whole blood) is considered as a best transfusion practice for the optimal use of collected blood in most conditions where increase in red cell mass for improved oxygen-carrying capacity is required *(67)*. In a patient with thrombocytopenia and bleeding, transfusion of a platelet concentrate may be required, without the need for red cells or plasma. Cryoprecipitate may be used as a source of fibrinogen concentrate in bleeding patients with inherited or acquired fibrinogen deficiency. In countries where clotting factor concentrates are unavailable or unaffordable, locally prepared cryoprecipitate also offers an alternative for patients with haemophilia A or von Willebrand disease, albeit with increased infectious disease risk unless treated to inactivate transfusion-transmissible agents.

Processing of whole blood into components in countries varied in 2023 by WHO region (66% in the African Region, 92% in the Region of the Americas, 81% in the South-East Asia Region, 98% in the European Region, 94% in the Eastern Mediterranean Region and 91% in the Western Pacific Region). The proportion of whole blood use correlates inversely with country income group (Table 9).

Table 9. Proportion of whole blood transfusion by countries by World Bank income group (2023)

Income group (no. of countries reporting)	Proportion of whole blood transfusions
Low-income countries (10)	40.5%
Lower middle-income countries (30)	16.7%
Upper middle-income countries) (29)	1.5%
High-income countries (40)	0.01%

In LICs and LMICs, the use of whole blood likely reflects ongoing inability to process whole blood donations into components for clinical use. For example, whole blood may be being used instead of red cells for treatment of anaemia, where red cell concentrates are not available. In HICs, where components are routinely available, there is increasing clinical interest in, and demand for, use of whole blood for resuscitation purposes in major haemorrhage – especially in trauma settings, both military and civilian. Therefore, even though only a small proportion of trauma patients require massive transfusion and only a small minority of the total number of red cells transfused in HICs are used in trauma resuscitation, it might be anticipated that the use of whole blood will increase in the coming years, driven by this change in clinical practice.

Haemovigilance

Surveillance procedures for blood transfusion, also called haemovigilance, are an important part of a national blood system, and should cover the entire blood transfusion chain. A national haemovigilance system promotes optimal clinical practices through monitoring of blood use and safety outcomes of blood donation and transfusion. Data collection and aggregated reporting enable countries to monitor and improve their clinical use of blood, their haemovigilance and overall blood systems. A functioning haemovigilance system provides surveillance on blood collections, marker rates of TTIs in blood donors, and adverse reactions in blood donors and transfusion recipients. It also enables the identification of epidemiological trends and benchmarking of performance across countries, as well as providing evidence for any need for a change in practice.

A significant proportion of Member States have no comprehensive haemovigilance system, reflecting the absence of national commitment, funding and infrastructure for reporting, as well as a lack of awareness on the importance of haemovigilance. Globally, the 2023 GDBS survey showed that only 52% of countries had a national haemovigilance system, including 36% in the African Region, 26% of countries in the Region of the Americas (nine of 31 responding countries, excluding four reported as "partial"), 82% in the South-East Asia Region, 81% in the European Region, 53% in the Eastern Mediterranean Region and 55% in the Western Pacific Region.

WHO response to date

WHO has provided policy guidance on the appropriate clinical use of blood components for transfusion and PBM *(68)*; convened a global forum on PBM; provided technical assistance and capacity building to countries for safe transfusion practice and patient safety; and supported the development of systems and capacities for the appropriate use of blood. WHO has updated the WHO *Educational modules on clinical use of blood (67)* in collaboration with the ISBT. Data point to a recent increase in countries with national transfusion guidelines, as well as hospitals with transfusion committees. The important role of nurses was highlighted in the WHO 2010 interregional consultation on strengthening the role of nurses and midwives in ensuring safe clinical transfusion and patient safety *(69)*. A key point is that there should be training for designated national transfusion nurses and safety officers in addition to medical specialists in transfusion medicine. This will help ensure that PBM strategies are effectively implemented and sustained in clinical practice.

In 2012, WHO and key international partners organized a global consultation on haemovigilance in collaboration with the IHN and the ISBT to provide guidance on establishing national haemovigilance systems. In 2016, WHO published guidance on establishing national haemovigilance systems and on implementing external quality assessment programmes for screening donated blood for TTIs *(70, 71)*, and a consultation was held to promote their use in the Eastern Mediterranean Region. Several countries have received technical assistance to develop and work towards implementation of haemovigilance systems. WHO partnered with ISBT to develop a library of references for haemovigilance, freely available to all, with ongoing curation by ISBT *(72)*. Consistent with such investments, data indicate an increase in the number of countries with national haemovigilance systems (from 80 countries in 2018 to 89 countries in 2023).

WHO has taken steps to increase awareness of PBM as a central concept and strategy in clinical use of blood and will expand its efforts in this area *(65)*. WHO developed a policy brief on the urgent need of PBM implementation and published the *Guidance on implementing patient blood management to improve global blood health status* to support countries in establishing and implementing PBM *(73)*. In many countries, professional societies or local institutes have already developed comprehensive policy and clinical guidelines for PBM *(74, 75)*.

Challenge 6

Insufficient access to blood during emergency situations

With increasing incidences of emergency situations arising from natural and civil disasters, emergency situations, infectious disease outbreaks, extreme weather conditions and humanitarian crises, the number of patients being affected by insufficient access to blood during emergency situations is of growing concern. In some situations, there may be a surge in need for blood and components with many injured; in other cases, there may be reduction of blood supply due to disruption of the blood service infrastructures or inaccessibility to the donation facilities. In the worst scenarios both circumstances happen concurrently. In addition, there may be displacement and death of health workers, disruption and interruption of power supplies, shortage of supplies and transport capacity, and cold chain deficits. Depending on the specific context and the type of emergency, such factors as economic and political instability, or even blockades and sanctions, may result in other barriers to access. Emergency situations can impact the availability and safety of blood more indirectly as well – for example, during population displacements, hygiene is often compromised, increasing the risk of infectious disease outbreaks. Difficulties may also arise with maintaining environmental cleanliness and asepsis in blood collection and processing, thereby increasing the risk of blood product contamination. Considering these and other challenges, it is crucial that Member States enhance their preparedness and take adequate measures to ensure a safe blood supply during emergency situations through practices that assure resilience of the blood systems and its supply chains *(76)*.

As such, emergency situations often present a dual challenge namely to provide sufficient supplies of safe blood and blood components to support those directly affected by these situations, while also maintaining sufficient blood supplies to meet the obligatory baseline demand from patients requiring blood transfusion for their treatment, surgeries or even in other situations related to pregnancy and childbirth. Safe and timely access to quality blood products is therefore of lifesaving importance *(44, 77–80)*. In those Member States where the blood service is less robust, maintaining access to and delivery of safe and sufficient supplies of blood and blood products, as well as PDMPs may be especially difficult. Factors affecting the scope and severity of an emergency affecting the blood system may include some or all of the following:

- the emergency may have damaged the available civil and health care infrastructure, disrupting mobility, transportation and service provision that

affect the accessibility of staff and donors and transportation of blood and blood products for testing and processing, and distribution to hospitals;

- members of the population may not come forward to donate blood, for example, due to fear, accessibility and illness (e.g. from infectious diseases);
- the overall health care system may become overburdened;
- the channels of communication may no longer be reliable; and
- blood services may be overwhelmed with a massive influx of donors causing disruptions to operations.

The role of the national blood system during emergencies must therefore be clearly defined; it needs to be an integral part of national emergency preparedness and response planning. In this way, availability of safe blood in emergencies, such as natural and civic disasters (e.g. earthquake), infectious disease outbreaks (e.g. the COVID-19 pandemic), extreme weather conditions (e.g. flooding and landslides) and humanitarian emergencies may be secured.

A key element in enabling a country to sustain a sufficient supply of safe blood and components during any emergency is a properly structured, coordinated and funded blood service. Ideally, this is a centralized national service within the national health care system, directly responsible to and funded by the government. It not only also simplifies coordination within the national response by reducing the number of individual entities involved but also helps to maximize the ability to respond to the situation swiftly.

As well as affecting the sufficiency and safety of blood supply, major incidents in countries undertaking transplantation could also threaten the safety and sufficiency of the supply of other products of human origin, such as cells, tissues and organs.

WHO response to date

In response to the increasing incidences of emergency situations and blood service disruptions, WHO has developed several tools to guide national and international efforts to ensure access to and supply of safe blood in emergency situations. *Maintaining a safe and adequate blood supply during Zika virus outbreaks: interim guidance (62)*; *Protecting the blood supply during infectious disease outbreaks: guidance for national blood services (58)*; *Guidelines on estimation of residual risk of HIV, HBV or HCV infection via cellular blood components and plasma (61)*; *Laboratory biosafety manual (81)*; *Maintaining a safe and adequate blood supply and collecting convalescent plasma in the context of COVID-19: interim guidance (43)*; and *Guidance on ensuring a sufficient supply of safe blood and blood components during emergencies (44)*. Once published, WHO organized webinars to disseminate the new guidance documents.

Whilst these guidelines focus on protecting the blood supply from infectious diseases, more comprehensive guidance will be required to address blood shortages and blood service disruptions at baseline and in the context of natural disasters and humanitarian crises and to ensure the safety of blood products throughout the transportation network, including an intact cold chain, mobilization of donors and communications, staff access and communication, etc.

Challenge 7

Insufficient access to appropriate funding and resources for WHO headquarters, regional and country offices

The WHO headquarters, in close collaboration with WHO regional and country offices, plays a critical role in providing technical guidance and support to countries in ensuring the safety, quality and accessibility of blood products. Since 2019, with the support of global stakeholders, WHO has successfully developed, updated and disseminated a wide range of guidance documents. This includes resources on blood donation during disease

pandemics and emergencies, quality systems, plasma fractionation, clinical use of blood, haemovigilance and good practice for blood establishments, as well as policy guidance on PBM.

In parallel, WHO has supported improvements in national blood systems through targeted initiatives such as the Achilles project and the implementation of GBT+Blood tool, which aims to strengthen national blood regulatory frameworks.

The success of these initiatives is highly dependent on the sustained support of diverse stakeholders – ranging from financial contributions by donors to the technical expertise of international experts. For example, the development of WHO guidance documents requires not only subject-matter input but also financial support for tasks such as editing, design and dissemination. Likewise, implementation activities – including training, capacity building and distribution of materials – rely heavily on engagement from WHO regional and country offices. All these efforts demand consistent access to financial, human resources, logistics and infrastructure resources.

Chronic underfunding of blood programmes

Despite these efforts, funding constraints remain a long-standing challenge – both within WHO and across many low- and middle-income countries. Blood services are frequently undervalued within health systems, despite their critical role in maternal and child health, chronic disease management, surgical care and emergency care. A persistent misconception is that blood services are "free" because donations are voluntary. However, the entire vein-to-vein process of the blood transfusion process – from donor recruitment to post-transfusion surveillance – requires significant investments in infrastructure, supplies and trained personnel that meet specific quality and safety standards.

Unfortunately, governments, especially in low- and middle-income countries, do not allocate sufficient budgetary resources to sustain their national blood services. Compounding the issue, many development partners regard blood programmes as long-term, routine public health services that should be financed domestically, limiting external funding.

As a result, chronic underinvestment has become the norm in many low- and middle-income countries. This has led to inadequate infrastructure, limited availability of safe blood products and insufficient training for health care personnel. These funding gaps constrain the development of effective blood donation programmes, quality assurance systems, and the development of strategic reserves to respond to emergencies.

Regional disparities and structural challenges

According to the 2022 WHO survey report on blood availability, safety and quality in the African Region, only 35 of the 47 countries in the region indicated having a dedicated budget line for blood services, while 28 countries reported receiving financial or technical support from development partners *(82)*. Furthermore, just 21 countries had established a cost recovery system for blood services, leaving the majority at risk of chronic underfunding and heavy reliance on donor support, thereby compromising financial sustainability and long-term continuity of services. In addition to financial constraints, many national blood services also face significant workforce shortages, with an insufficient number of trained personnel to ensure the safety, quality and efficiency of blood collection, testing and transfusion. These systemic gaps contribute to the ongoing struggle to meet the growing demand for safe blood, particularly for maternal care, trauma and treatment of conditions such as sickle cell disease. Addressing these funding and workforce deficits is vital to ensuring equitable access to lifesaving transfusion services across the continent.

Similar challenges exist across other WHO regions. All regions report challenges in implementing WHO tools such as the GBT for blood regulation and BSS, and guidelines like

GMP for blood establishments. Within the African Region, Ethiopia was the only country to fully implement the BSS tool in 2025 while no country has yet reached maturity level 3 for the GBT+Blood tool. Progress in developing haemovigilance systems and broader health surveillance programmes has also been hampered by a lack of resources and technical capacity. According to the aforementioned report, 14 countries in the African Region reported having a haemovigilance system in place.

Declining and unpredictable donor support

In recent years, WHO's work on blood safety has benefited from the support of key international partners – including government agencies and philanthropic organizations. This support has enabled the development of technical guidance and facilitated direct assistance to countries. However, most of this funding has been project based and time limited. In today's evolving global funding landscape, several key partners have significantly reduced or discontinued their support. For example, the Pan American Health Organization, as the WHO Regional Office for the Americas, has faced persistent difficulties in mobilizing donor support, partly due to the limited presence of donor organizations in the region. In the African Region, although many donors actively support health programmes aimed at reducing maternal deaths from postpartum haemorrhage and child mortality from anaemia, primarily due to malaria, most do not provide dedicated support for blood services – despite these programmes being the largest consumers of safe blood products. A similar situation exists for HIV and hepatitis prevention programmes, even though blood services play a critical role in minimizing TTIs through effective pre-transfusion testing reflecting the weak integration of blood services into existing health financing systems.

This situation underscores the urgent need for more predictable, sustainable and coordinated financing – from both WHO and its Member States – to ensure the continuity and scaling-up of blood safety efforts aligned with WHO's mandate.

Workforce capacity gaps

An equally pressing challenge is the shortage of skilled personnel at international, regional and national levels. WHO must ensure that all three levels of the organization are adequately staffed with trained and experienced experts in blood safety to organize, lead and deliver technical support and developmental programmes. While WHO has made commendable efforts to disseminate its guidance through webinars, knowledge-sharing platforms and direct outreach, country-level implementation often remains limited. In many cases, the guidance materials are not fully utilized due to a lack of awareness, inadequate local capacity or insufficient follow-up support.

Moreover, staffing and funding limitations at WHO further restrict the organization's ability to offer in-person training, technical assistance missions or strategic planning support to countries. Without additional investments in human resources and operational capacity, these limitations are expected to persist.

WHO response to date

Collaboration with a wider platform of stakeholders has been fostered. For example, many experts assisted WHO in developing the guidance on maintaining blood supplies during the COVID-19 pandemic, with ISBT providing support in managing COVID-19-related information and educational activities and other organizations supporting this activity at the regional level. Other collaborations also included those with the International Plasma and Fractionation Association and the Plasma Protein Therapeutic Association in developing policy and implementation guidance related to plasma fractionation; with the International Society on Thrombosis and Haemostasis in reviewing proposals to establish the international measurement standard of blood products; with the International Foundation for Patient Blood Management in developing a policy brief and guidance on PBM; and with blood establishments, regional and national societies for transfusion medicine in reviewing draft documents related

to blood. In the Region of the Americas, the Government of Canada is supporting the development of a short course on PBM, and in cooperation with the Brazilian Government (Ministry of Health and ANVISA), a course on GMP for blood services was developed. Moreover, WHO headquarters was able to establish a funding agreement with the ISBT for 2022–2027 to support blood-related activities under certain projects of the ISBT in countries that join the Achilles project.

In the past biennium, WHO headquarters and regional offices have also received expressions of interest from private sector organizations willing to support activities, particularly from companies that manufacture equipment and supplies used in blood services and transfusions. These offers typically come through their charitable funding channels. Such engagements are covered under the context of WHO's engagement with non-state actors (NSAs) *(83)*, including nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions. A set of rules and procedures to facilitate WHO's engagement with NSAs is available. In order to ensure a smooth interaction, WHO has established guidance and a handbook *(84)* to guide WHO staff on engagement with NSAs and guide NSAs engaging with the WHO through the principles and processes of the Framework of Engagement with Non-State Actors (FENSA) to ensure smooth interaction with WHO.

The path forward: a call for collaboration

To address these multifaceted challenges, stronger and more coordinated collaboration is urgently needed between the WHO, Member States, donor partners and technical stakeholders at all levels. Sustainable investments in both funding and workforce capacity are essential to building resilient, equitable and effective national blood systems. Only through joint commitment and action can WHO's global vision for blood safety be fully realized.

Blood transfusion, South Sudan, February 2019
© WHO/A. Câmpeanu

3 Proposed actions

Establishment and maintenance of a national blood system requires a broad range of societal, scientific and medical competencies which must operate under local conditions and constraints. In an increasingly complex world, strengthened capacities in science, innovation, data, digital transformation and health emergency preparedness and response are also needed. Given the breadth and scope of the issues and challenges, an interactive set of strategies is essential.

The *overall goal* of this WHO Action Framework is to advance universal access to safe, effective and quality-assured blood products, contributing to the goal to "promote, provide and protect health and well-being for everyone, everywhere" as defined in the WHO GPW 14 *(9)*. The high-level challenges and strategic objectives identified in the previous Action Framework for 2020–2023 *(8)* remain relevant but have been reorganized to address the current context and re-prioritized focus areas, with greater emphasis on self-assessment and implementation based on available guidance documents and self-assessment tools developed by WHO. The Action Framework for 2026–2030 will focus on *seven strategic objectives* that are intended to guide the development and implementation of context-specific actions to address the needs of regions and countries. These seven strategic objectives are presented below. The Action Framework includes a logframe with details on the strategic objectives and related activities, outputs, intermediate outcomes and high-level outcomes (Annex 1). Each strategic objective includes mechanisms that will allow countries to conduct their own risk assessment and develop implementation and plans to address their individual needs as well as to evaluate and monitor progress.

Strategic objective 1

Member States have implemented the essential steps for establishing and operationalizing a continuously operating, appropriately structured, well-coordinated, well-governed and sustainably resourced national blood system

An appropriately structured, well-coordinated and sustainably resourced national blood system ensures access to safe, effective and quality-assured blood products to support the national health system. Member States can establish or transition to a centralized, autonomous national blood establishment directly accountable to and financed by the national health authority, with a clear mandate for donor recruitment, blood collection, testing, processing, distribution, haemovigilance and regulatory compliance in conjunction with PBM at the clinical interface. This structure operationalizes the call for an appropriately structured, well-coordinated and sustainably resourced national system and strengthens uniform standards, appropriate financing and performance management. Strong leadership, political will and governance at the national level are essential to guide the establishment, coordination and management of the national blood system.

First, the national blood system must be appropriately structured and integrated into the national health system, with clearly defined roles and accountabilities for all its key functions, institutions and organizations. These requirements are outlined in the WHO BSS tool *(39)*. Effective coordination at the national level promotes uniform standards, economies of scale, consistency in quality and safety of blood products and best transfusion practices.

Second, appropriate frameworks for financing blood products and services that are integrated within the financial structure of the health system, supported by sound costing and budgeting practices, are critical in ensuring that the national blood system is adequately and sustainably resourced to cover all the costs for performing its functions.

Third, national blood policies, legislation, regulation, risk management, decision-making and governance frameworks should be in place and integrated into the wider strategic health system planning to ensure good stewardship, systematic assessment of national blood needs, uniform standards, performance management and appropriate allocation of resources. The governance structure is strengthened by local stewardship and performance management systems that include HTCs, community and stakeholder engagement, quality improvement, blood utilization evaluations and organizational blood drive participation.

WHO will, with partners, provide tools, resources, technical assistance and capacity building on how to establish and develop an appropriately structured and well-coordinated national blood service that is sustainably resourced and has adequate governance and oversight, including adequate costing, budgeting, and financing of the national blood service. The WHO guidelines on costing of blood services (1998) have been revised and updated and made available to Member States and relevant stakeholders *(34)*.

To achieve strategic objective 1, the following high-level outcomes have been identified:

1.1 The national blood system is appropriately structured, well-coordinated, well-governed and integrated into the national health system.

1.2 Blood and transfusion services are adequately and sustainably costed, financed and budgeted while avoiding costs to patients.

1.3 Member States have strengthened their regulatory frameworks and implemented international standards for blood systems.

The logframe in Annex 1 provides a more detailed overview of the outcomes, outputs and activities related to strategic objective 1. Annex 3 provides a list of relevant WHO guidance documents.

Strategic objective 2

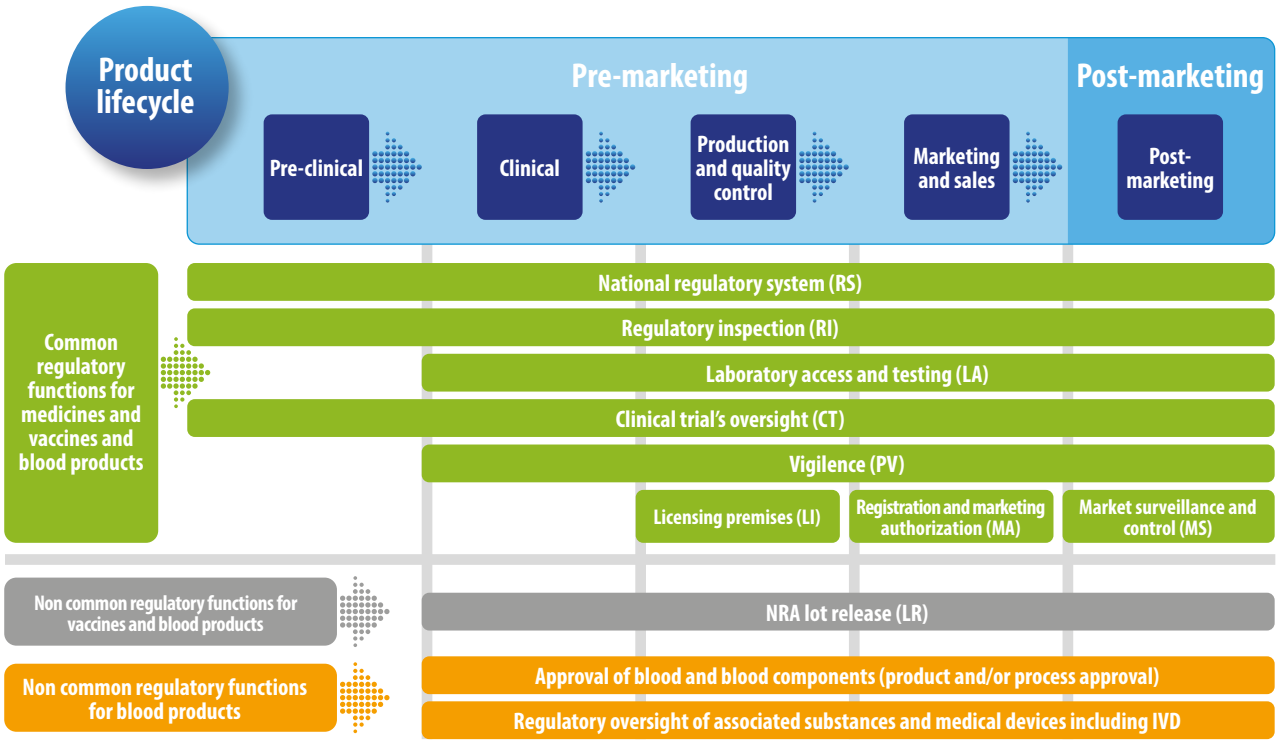
An appropriate national regulatory framework is in place in Member States to ensure fully operational mechanisms of the necessary regulatory functions in order to enable an adequate supply of blood products, including PDMPs, that are safe, effective and meet quality standards

An appropriate national framework of regulatory controls, national standards and quality assessment programmes is crucial in ensuring the safety and quality of blood products, associated medical devices and testing reagents. To this end, each Member State should have a functioning NRA established in law, which has the authority and capability to set and enforce blood standards and monitor donor and product safety effectively. In national systems, where oversight responsibilities for blood products and transfusion practices are divided among governmental and/or nongovernmental bodies, effective coordination of functions and responsibilities is essential.

Moreover, regulatory mechanisms should be established where necessary to undertake the essential regulatory functions as defined in the GBT+Blood tool. These functions are listed below and Fig. 2 shows the alignment in relation to the blood product lifecycle and indicates overlaps with benchmarking criteria for vaccines and medicines:

- national regulatory system
- registration and marketing authorization
- vigilance
- market surveillance and control
- licensing establishments
- regulatory inspection
- laboratory testing
- clinical trials oversight

Fig. 2. Essential functions of national blood regulatory systems identified in the GBT+Blood tool



- NRA lot release
- approval of blood and blood components, including plasma for fractionation (product and/or process approval)
- regulatory oversight of associated substances and medical devices including IVD devices. This function includes implementation of regulatory control systems on associated substances such as reagents, tests kits and medical devices used in the collection, processing, testing, storage and administration of blood products.

As shown in Fig. 2, within the GBT+Blood tool, eight of the regulatory functions for blood products are integrated with the common functions for other medicinal products (coloured green). Some regulatory functions may be separate from the common functions, e.g. the regulatory function for NRA lot release (coloured grey) is integrated with that of vaccines only, while two other regulatory functions (coloured orange) are specific to blood products only.

In addition to the legal provisions to ensure key regulatory functions, it is essential to develop and maintain national standards and minimum product and performance specifications, also taking into consideration the available internationally harmonized guidelines. Compliance with legal provisions and standards should be enforced through regulatory inspections of blood establishments and blood products' manufacturing facilities, participation in external quality assessment schemes and proficiency testing programmes, where appropriate.

Policies and decisions affecting quality, safety, efficacy, availability and accessibility of blood products should be made in the interests of public health through a structured policy process of risk-based decision-making that is in accordance with national health system policies, level of development of the national blood programmes, and optimal use of available resources. As it may already have been quite challenging for many countries to achieve GBT+Blood tool maturity level 2, dedicated regional networks to provide technical and scientific capacity to the Member States are necessary to facilitate the establishment and implementation of the regulatory structures. Such networks should be strengthened through capacity building and by starting to apply existing international standards as a common basis for early interactions among the main stakeholders, thus facilitating a stepwise implementation of regulatory systems for blood and blood products.

In recent years WHO has provided a substantial number of comprehensive guidance documents and standards; however, their effect to accelerate the implementation of the blood regulatory functions has been low. WHO will, with partners, continue to provide tools, resources and technical assistance to Member States, but will focus more on promoting the implementation of the guidance documents and on building blood regulatory capacities at national and regional level.

The global use of the GBT+Blood tool is of paramount importance in the process of initiating the implementation of regulatory functions. WHO will therefore support additional pilot programmes and roll them out stepwise on a global level.

WHO will continue to support the establishment of regional regulatory forums, such as the ABR-TC, and to raise governmental commitment and awareness of the essential role of a national blood regulatory system in the wider health system.

To achieve strategic objective 2, the following high-level outcomes have been identified:

2.1 WHO has raised the global awareness for the need to implement a national blood regulatory system and the use of relevant existing WHO guidance documents.

2.2 Member States have initiated the process to perform self-assessments of existing national regulatory

authorities using the GBT+Blood tool, increasing the political commitment and awareness of the essential role of a national blood regulatory system.

2.3 Member States are supported in developing a road map and legal frameworks to establish and formally implement regulatory mechanisms for comprehensive oversight of blood products, associated substances and medical devices, including IVD devices.

2.4 Member States have authorized and empowered their national medical product regulatory authorities to establish and strengthen the relevant blood regulatory functions.

2.5 Each region has established an informal blood regulatory network that is used to facilitate implementation of the relevant structures and functions within the regions, e.g. by organizing workshops, congresses and exchange programmes.

The logframe in Annex 1 provides a more detailed overview of the outcomes, outputs and activities related to strategic objective 2. Annex 3 provides a list of relevant WHO guidance documents.

Strategic objective 3

Affordability, availability and accessibility of safe, effective and quality-assured blood products in Member States assures timely patient access to needed blood and blood products

A well-functioning and efficiently managed blood service ensures the timely and adequate availability of safe and effective quality-assured blood products for clinical use. Blood services should be efficiently and cost-effectively managed, with suitable infrastructure and adequate qualified and trained staff.

First, a safe and stable blood supply depends on blood collected from voluntary and non-remunerated blood donors from low-risk populations. Where this has not yet been achieved, strategies should be developed to convert family or replacement donors to voluntary donors and eliminate paid donation. Countries should also work on incorporating the concept of VNRD as an integral part of their own culture; this takes time and effort to identify which elements should be addressed to ensure adequate education and motivation. Programmes to protect the health and safety of blood donors and to promote repeat blood donation from VNRD include donor education and motivation, donor selection and deferral, donor care before, during and after donation to avoid adverse complications of donation, notification of abnormal test results including medical counselling and referral, and confidentiality. These programmes should also be accompanied by public health measures on surveillance of iron deficiency and anaemia and preventive care, and to minimize adverse events.

Second, efficient donation, processing, inventory and distribution systems should also be in place to ensure continuity of supplies. Furthermore, reference centres must be available at national level to provide specialized testing, including confirmatory testing, for infectious disease screening. One essential strategy to optimize resources and promote quality is to consolidate blood processing and testing in facilities that have achieved effective implementation of quality systems. Centres that carry out consolidated blood donation testing and processing should also be established to promote achievement of quality in blood donation testing and blood component processing. On the clinical side, avoiding overuse of transfusions can help to optimize the use of the available blood inventory. Patient-centred medical practices that include use of appropriate transfusion alternatives can help to assure that blood will be available to patients when transfusion is indicated.

Third, a needs assessment of blood and blood products is a critical foundation for planning an effective and sustainable blood service. It helps determine the actual demand for blood and blood products across different regions, health facilities and patient groups. By identifying usage patterns, seasonal variations and clinical needs,

health authorities can allocate resources more efficiently, reduce waste and avoid shortages. It also supports evidence-based decision-making for donor recruitment, stock management and infrastructure development. Ultimately, a well-executed needs assessment ensures that the blood supply system is responsive, equitable and aligned with national health priorities.

Blood should be processed into blood components based on the clinical needs of the health care system, appropriately processed and tested to ensure patient safety, and stored and distributed efficiently to maximize accessibility and minimize wastage. Efficient inventory management ensures optimum blood stocks and minimizes wastage, and an effective and reliable blood cold chain maintains safe storage and transportation of blood components. Functioning liaison and collaboration with hospitals and clinical users, including appropriate ordering mechanisms, will ensure appropriate clinical transfusion and patient management practices, including quality-assured compatibility testing and evidence-based practices of transfusion. Quality systems should be in place across the entire blood transfusion chain and all activities performed in a quality-focused way and continuously monitored. These include compliance with GMP; maintenance of a cold chain in handling and transportation; and haemovigilance and pharmacovigilance. Systems and standardized procedures should be established for donor selection, blood collection, processing, testing, storage and transportation to ensure consistent quality, safety and efficacy of blood components.

To ensure sufficient access to and availability of PDMPs, strategies must be planned and coordinated at national level, which may involve a combination of strategies to strengthen domestic plasma production capacity, prevent or reduce plasma wastage and organize procurement of commercially available PDMPs. Measures to strengthen domestic plasma production capacity include enhancing the volume and quality of recovered plasma suitable for manufacture and suitable arrangements for fractionation of surplus plasma recovered from whole blood. Where PDMPs are unavailable or not affordable, interim solutions such as local production of cryo-PR and immune globulins from small plasma pools may be considered to provide therapies in some conditions. Coordinated efforts are therefore necessary at global and regional levels, between countries and with fractionation organizations, to improve the volume of plasma suitable for manufacture of PDMPs and facilitate access to fractionation facilities through appropriate regulatory standards, contract manufacturing and technology transfer.

In summary a cost-efficient blood service should be supported by a centralized structure with a clear national blood policy and legal framework. It should be coordinated by a national blood authority and implemented through a national blood transfusion service or programme that manages all aspects of blood collection, testing, processing and distribution. The system must be non-profit, sustainably financed through national budgets and alternative sources, and promote VNRD. A well-defined costing structure is essential to ensure transparency, sustainability and efficient resource allocation. It allows for accurate budgeting, supports cost recovery mechanisms and helps identify areas where savings can be achieved without compromising safety or quality. Standardized quality systems, trained personnel and national coordination are also critical to ensure safety, efficiency and equitable access across each country.

WHO will, with partners, provide tools, resources, technical assistance and capacity building on how to increase safe blood donations and establish and manage a quality blood management system. This will be supported by implementation of the WHO and International Federation of Red Cross and Red Crescent Societies global framework for action towards 100% voluntary and repeat blood donation *(22)*, the WHO guidelines on assessing donor suitability for blood donation *(56)*, and the WHO guidelines on GMP for blood establishments *(33)*. Furthermore, WHO will develop and disseminate guidelines and other relevant knowledge and build capacities to enhance countries' preparedness for safe blood supplies during emergency situations.

To achieve strategic objective 3, the following high-level outcomes have been identified:

3.1 Blood establishments meet WHO or other internationally recognized standards for preparation and quality assurance of all distributed blood products and blood-derived raw materials used for further processing.

3.2 Member States ensure the quality and sufficiency of blood products and starting blood-derived raw materials used for further processing through the recruitment and retention of voluntary non-remunerated blood donors and laboratory testing of all donations.

3.3 Strategies to strengthen the domestic production of quality plasma for fractionation and the procurement of commercially available PDMPs to ensure sufficient access to and availability of PDMPs.

The logframe in Annex 1 provides a more detailed overview of the outcomes, outputs and activities related to strategic objective 3. Annex 3 provides a list of relevant WHO guidance documents.

Strategic objective 4

Effective implementation of patient blood management to optimize clinical practice of transfusion

Anaemia, blood loss and coagulopathy represent some of the world's biggest, largely preventable, yet greatly underestimated public health and health-economic burdens. PBM is a patient-centred, systematic, evidence-based approach to improve patient outcomes by managing and preserving a patient's own blood, while promoting patient safety and empowerment *(65)*. PBM can greatly improve individual and public blood health by ensuring patient safety and quality of care related to blood transfusion and clinical use of PDMPs thereby improving patient outcomes. Therefore, efforts should be made to implement PBM effectively in all health care systems.

WHO has developed guidance on implementation of PBM *(73)*. The drivers of the PBM implementation process focus on evidence-based clinical transfusion practices by minimizing unnecessary transfusions and its associated risks. Two essential aids provided by the guidance document for implementation of PBM are an eight-model pathway that engages all relevant stakeholders and six PBM toolkits which includes resources, strategies and tools designed for specific patient populations and diverse levels of medical resources.

For the smooth implementation of PBM at the clinical level, it is necessary to make appropriate structural changes to anchor PBM within each country's WHO-aligned quality and safety framework, ensuring the provision of professional PBM education, empowering patients and their advocates regarding blood health, and its implications for outcomes and safety. Essential sequential steps in PBM implementation include the following actions:

- Conducting PBM pilot projects at local health care organizational level to develop PBM data systems and to conduct PBM training.
- Benchmarking and reporting at national level to monitor progress. Crucial outcome data that determine blood health should be monitored.
- Developing and establishing clinical PBM standards, followed by certification of health care professionals, and certification, accreditation and auditing of health care organizations.
- Collaboration, sharing of experience, and coordination of efforts at local, national and international levels should be encouraged and facilitated.

To achieve strategic objective 4, the following high-level outcomes have been identified:

4.1 Patient blood management is nationally prioritized, promoted as part of

quality assurance in medical practice, embedded in medical education, and practised based on national clinical guidelines and practice standards.

4.2 A quality system is in place in hospitals for all pre-transfusion testing and clinical transfusion processes, and in hospital blood bank laboratories.

The logframe in Annex 1 provides a more detailed overview of the outcomes, outputs and activities related to strategic objective 4. Annex 3 provides a list of relevant WHO guidance documents.

Strategic objective 5

Effective surveillance, haemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection systems, evaluation, risk reduction and communication are implemented

Effective systems are needed to facilitate monitoring and evaluation of the blood system, including donor safety, blood product quality and safety and transfusion safety. Accurate vein-to-vein data collection and monitoring are crucial in order to understand the current status of and trends in access to quality blood products at national, regional and global levels. Availability of good data is also essential for understanding the status of clinical practices, such as pre-operative anaemia and transfusion rates, and assessing the effectiveness of PBM programmes.

The existence of a data collection and reporting system is an important element of a well-managed, nationally coordinated blood transfusion programme. Adequate national data on blood availability and safety allow countries to set priorities and to further strengthen the national blood system. There is a need to establish systems of surveillance on the incidence and prevalence of HIV, HBV, HCV and other TTIs in blood donors and vigilance on the transfusion outcomes of recipients, including post-transfusion risk of infection. Information on clinical transfusion forms the basis for the monitoring of clinical transfusion practice and provides critical performance measures to influence desirable changes in prescribing and administration of blood and reduce undesirable variations in transfusion practice. There is a need for national blood transfusion services to provide greater structure and support for the information management system, promote the use (where feasible) of digital solutions to optimize bidirectional traceability of products and recipients, and for facilitating haemovigilance data collection, aggregation and analysis. Hospitals will also need to establish mechanisms for improving data collection, donor tracking, traceability and overall haemovigilance.

Adverse events and reactions in blood donors and patients should also be monitored to ensure adequate action is taken to address these issues and to protect the health of future blood donors and patients. Systems for haemovigilance and pharmacovigilance should be established at organizational and national levels to monitor adverse events, adverse reactions and known threats to blood availability and safety, and to enable informed decisions. The ability to effect end-to-end traceability from collection to use, and to carry out surveillance, are important prerequisites to such systems. To support this, blood collection centres and hospitals must also have systems to monitor, investigate and assess adverse events, and to educate and train all staff involved in transfusion chain in the recognition, management, investigation and reporting of adverse events and adverse reactions in blood donors and in recipients of blood products. Public campaigns to promote awareness of haemovigilance and pharmacovigilance as well as targeted provision of educational materials to donors and patients can enhance the effectiveness of safety reporting.

The GDBS is an important tool for data collection and analysis, and depends on the collection, analysis and reporting of data at the national level. There should, therefore, be a national system for standardized data collection and reporting, and mechanisms to ensure uniform implementation. Robust and secure data management and information reporting systems on availability, utilization, safety and quality

of blood products should be implemented in blood services and hospitals to facilitate this. To enable more consistency and comparability of reported information, data definitions need to be improved, through common good practices and greater collaborative efforts to develop more standardized and harmonized terminology.

WHO will, with partners, provide tools, resources, technical assistance and capacity building to establish and strengthen systems for routine, standardized data collection and accurate national reporting, national data management, haemovigilance and pharmacovigilance. WHO will also continue to coordinate the collection of data from national blood establishments into the WHO GDBS and provide an analysis and summary in the periodic *Global status report on blood safety and availability*.

To achieve strategic objective 5, the following high-level outcomes have been identified:

5.1 There is a fully integrated national system for standardized haemovigilance and pharmacovigilance data collection and reporting, and mechanisms to ensure uniform implementation.

5.2 There are policies and systems for traceability, surveillance, haemovigilance and pharmacovigilance at national and organizational levels.

5.3 There are education and training mechanisms in place to continuously support haemovigilance and pharmacovigilance awareness and education of health care staff.

5.4 The WHO GDBS provides comprehensive and accurate data on the global status of blood product availability, safety and quality.

The logframe in Annex 1 provides a more detailed overview of the outcomes, outputs and activities related to strategic objective 5. Annex 3 provides a list of relevant WHO guidance documents.

Strategic objective 6

Mechanisms are implemented for jointly addressing challenges and emerging threats to national blood systems at global, regional and national levels

The role of the national blood system during emergencies must be clearly defined as part of national emergency preparedness and response planning, thus ensuring timely availability of safe blood and blood products, as well as PDMPs in situations such as natural and civil disasters, infectious disease outbreaks, extreme weather conditions and humanitarian crises including disputes and wars. Moreover, depending on the specific context of the country and the type of emergency, such factors as economic and political instability, or even blockades and sanctions, could also result in other barriers to access.

Considering these and other challenges such as damage and disruption of infrastructure preventing access by donors and staff, displacement and death of workers (staff), shortage of supplies, transport and cold chain deficits and disruption and interruption of power supplies, and massive IT failure, it is crucial that Member States develop and enhance their preparedness and take adequate measures to ensure timely availability of safe blood supply during emergency situations, in addition to that for the baseline demand.

WHO will draw on its network of experts and partners to provide guidance and technical assistance on the development of disaster preparedness and contingency planning, identification of key processes involved, responses to ongoing threats from emergencies and recovery of blood system from emergencies. At the same time, WHO advises Member States to conduct ongoing review and drills on their preparedness and planning.

To achieve strategic objective 6, the following high-level outcomes have been identified:

6.1 WHO has raised global awareness on the key functions of a national blood

system and its importance in the context of a national health system.

6.2 WHO headquarters, regional offices and Member States should have mechanisms for monitoring and evaluating the implications for the blood system during emergency situations at global, regional and national levels.

6.3 Member States have developed an emergency preparedness and contingency plan with coordination of major and relevant stakeholders to ensure an adequate and safe supply of blood, blood components and PDMPs during emergency situations such as disasters, humanitarian crises and emerging threats.

6.4 Member States have developed mechanisms for ongoing review, assessment and update of their emergency preparedness and contingency plan.

6.5 There is a joint and coordinated response to emerging health threats associated with blood and blood products.

The logframe in Annex 1 provides a more detailed overview of the outcomes, outputs and activities related to strategic objective 6. Annex 3 provides a list of relevant WHO guidance documents.

Strategic objective 7

WHO leadership, partnerships, collaboration and information exchange to achieve key priorities and jointly address challenges and emerging threats at global, regional and national levels

The WHO GPW 14 for 2025–2028 underscores the urgent need for a new level of international cooperation among health actors in response to a rapidly changing global landscape. Climate change, demographic shifts, unprecedented migration, evolving geopolitical dynamics, the increasing frequency of "spill-over events" and rapid advances in science and technology are occurring alongside growing humanitarian needs. Addressing these complex challenges requires not only stronger collaboration within the health sector but also enhanced engagement with health-contributing sectors, sustained political commitment and strong national leadership.

In alignment with this strategic direction, since 2019 WHO has developed a range of guidance documents on blood to assist Member States in strengthening their national blood systems. In the upcoming biennium, and in response to Member State requests, the Blood and Other Products of Human Origin Team expects that supporting the implementation of existing guidance will take precedence over developing new guidance. Experience from the Achilles project in Ethiopia, Indonesia and Senegal has demonstrated that the most effective support includes onsite assessments, hands-on technical guidance and face-to-face training. Delivering these activities at scale will require increased investment in both human resources and financial support.

To meet this growing demand, all levels of WHO must actively pursue diverse and sustainable funding sources. Yet, in an increasingly volatile global environment – marked by climate change, economic uncertainty, overlapping crises and shifting demographics – mobilizing adequate resources remains a significant challenge. These global pressures are likely to exacerbate disease outbreaks, increase the frequency of natural disasters, raise operational costs and reduce available international aid. In this context, forging strong partnerships is more critical than ever – not only within WHO, but also with a wide range of external stakeholders.

To achieve strategic objective 7, the following high-level outcomes have been identified in consideration of the challenges, and in alignment with the WHO change pathways described in GPW 14:

7.1 Strengthening WHO leadership and coordination in global, regional and national contexts.

7.2 Strengthening strategic alliances for collective action.

7.3 Effective mechanisms for information exchange and knowledge management.

7.4 National capacities are strengthened through coordinated technical cooperation.

The logframe in Annex 1 provides a more detailed overview of the outcomes, outputs and activities related to strategic objective 7. Annex 3 provides a list of relevant WHO guidance documents.

© Indonesian Ministry of Health/Robby Nur Aditya

4 WHO management of the Action Framework

WHO has served as the directing and coordinating authority for health within the United Nations system since its establishment in 1948, providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends. WHO, governed by 194 Member States, has a unique decentralized structure comprising six regional offices and presence in 150 countries, territories and areas. WHO believes in strong collaboration between all three levels of the organization in order to deliver strong results. WHO draws on an extensive network of technical expertise through its ECBS, Expert Advisory Panel on Blood Transfusion Medicine and AG-BRAS. It also works in close collaboration with national and international organizations with expertise in the field, WHO collaborating centres worldwide, and a network of NSAs which include nongovernmental organizations in official WHO relations. With ministries of health as national counterparts and the political support expressed through a series of WHA resolutions, WHO is best placed to coordinate global action towards universal access to quality and safe blood products.

The overall implementation of this updated WHO Action Framework will mirror the mechanisms used for the original 2020–2023 Action Framework. This will be accomplished under the responsibility of the WHO Secretariat, in close collaboration with specialized staff in WHO regional offices and country offices, and relevant external partners. However, Member States hold the primary public health responsibility for establishing national systems to ensure universal access to safe and quality-assured blood products for their populations. As key stakeholders and implementation partners in this Action Framework, they are expected to provide the necessary investments to support its execution. WHO is responsible for advocating

with ministries of health in Member States and for providing and coordinating support for the implementation of the Action Framework at the national level.

A WHO programme management group will be established with operational responsibility, including technical and financial planning, implementation, monitoring, evaluation and benefactor reporting. Financial management in WHO adheres to the International Public Sector Accounting Standards, representing leading international accounting practices for the public sector and United Nations specialized agencies. WHO technical and managerial expertise will address a spectrum of knowledge and capacities required to guide global action on blood availability and safety. These areas include blood donor recruitment, retention and counselling; risk-based blood donor selection and laboratory testing; blood component preparation and banking; prequalification of IVD devices and oversight of laboratory quality; clinical practice of transfusion medicines; PBM and patient safety; and production, control and regulation of human plasma for fractionation. Underlying knowledge and capacity include information technology; behavioural science; regulatory systems strengthening, including GMP; development of norms and standards; and programme management and coordination.

References[11]

1. Guidance on centralization of blood donation testing and processing. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/340182). Licence: CC BY-NC-SA 3.0 IGO.
2. WHO Model List of Essential Medicines, 24th list. Geneva: World Health Organization; 2025 (https://iris.who.int/handle/10665/382243). Licence: CC BY-NC-SA 3.0 IGO.
3. WHO Model List of Essential Medicines for Children, 10th list. Geneva: World Health Organization; 2025 (https://iris.who.int/handle/10665/382242). Licence: CC BY-NC-SA 3.0 IGO.
4. Jacobs JW, Bates I, M'baya B, Eichbaum Q, Louw VJ, Al-Riyami AZ et al. Ensuring a safe and sufficient global blood supply. N Engl J Med. 2024;391(12):1079-1081 (https://www.nejm.org/doi/10.1056/NEJMp2403596).
5. Improving access to safe blood products through local production and technology transfer in blood establishments. Geneva: World Health Organization; 2015 (https://iris.who.int/handle/10665/336863).
6. Utilization and supply of human blood and blood products (WHA28.72). Geneva: World Health Organization; 1975 (https://iris.who.int/handle/10665/93010).
7. Availability, safety and quality of blood products (WHA63.12). Geneva: World Health Organization; 2010 (https://iris.who.int/handle/10665/3086).
8. Action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023. Geneva: World Health Organization; 2020 (https://iris.who.int/handle/10665/331002). Licence: CC BY-NC-SA 3.0 IGO.
9. Global Health Strategy and Fourteenth General Programme of Work 2025–2028 [website]. Geneva: World Health Organization; 2025 (https://www.who.int/about/general-programme-of-work/fourteenth).
10. Blood safety: proposal to establish World Blood Donor Day (WHA58.13). Geneva: World Health Organization; 2005 (https://iris.who.int/handle/10665/20363).
11. 18th International Conference of Drug Regulatory Authorities (ICDRA) recommendations. WHO Drug Information. 2018;32(4) (https://iris.who.int/handle/10665/330900). Licence: CC BY-NC-SA 3.0 IGO.
12. WHO Model List of Essential Medicines, 23rd list. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/376570). Licence: CC BY-NC-SA 3.0 IGO.
13. WHO Model List of Essential Medicines for Children - 9th list, 2023. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/371091). Licence: CC BY-NC-SA 3.0 IGO.
14. Global Database on Blood Safety 2023 [website]. Geneva: World Health Organization; 2025 (https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/blood-and-products-of-human-origin/quality-and-safety/global-database-on-blood-safety).
15. Global status report on blood safety and availability 2021. Geneva: World Health Organization; 2022 (https://iris.who.int/handle/10665/356165). Licence: CC BY-NC-SA 3.0 IGO.

[11] All references were accessed on 5 April 2026.

16. Guidance on increasing supplies of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/340171). Licence: CC BY-NC-SA 3.0 IGO.

17. Implementing cross-border transfer of domestic plasma to obtain plasma-derived medicinal products: policy guidance. Geneva: World Health Organization; 2024 (https://iris.who.int/handle/10665/380192). Licence: CC BY-NC-SA 3.0 IGO.

18. The selection and use of essential medicines (2013), TRS No. 985. Geneva: World Health Organization; 2014 (https://iris.who.int/handle/10665/112729).

19. The selection and use of essential medicines, 2025: report of the 25th WHO Expert Committee on Selection and Use of Essential Medicines, executive summary. Geneva: World Health Organization; 2025 (https://iris.who.int/handle/10665/382350). Licence: CC BY-NC-SA 3.0 IGO.

20. Aide-mémoire for national health policy makers: good policy process for blood safety and availability. Geneva: World Health Organization; 2008 (https://iris.who.int/handle/10665/340542).

21. Universal access to safe blood transfusion. Geneva: World Health Organization; 2008 (https://apps.who.int/iris/handle/10665/69747).

22. Towards 100% voluntary blood donation: a global framework for action. Geneva: World Health Organization; 2010 (https://iris.who.int/handle/10665/44359).

23. Aide-mémoire for ministries of health: developing a national blood system. Geneva: World Health Organization; 2011 (https://iris.who.int/handle/10665/330045).

24. Blood safety and availability – WHO fact sheet [website]. Geneva: World Health Organization; 2025 (https://www.who.int/news-room/fact-sheets/detail/blood-safety-and-availability).

25. User guide for navigating resources on stepwise implementation of haemovigilance systems. Geneva: World Health Organization; 2022 (https://iris.who.int/handle/10665/360060). Licence: CC BY-NC-SA 3.0 IGO.

26. WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory system of medical products - Revision VI. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/341243). Licence: CC BY-NC-SA 3.0 IGO.

27. Regulatory system strengthening for medical products (EB134.R17). Geneva: World Health Organization; 2014 (https://iris.who.int/handle/10665/173022).

28. Assessment criteria for national blood regulatory systems. Geneva: World Health Organization; 2012 (https://iris.who.int/handle/10665/346361).

29. WHO Global Benchmarking Tool + Blood (GBT+ Blood) for evaluation of national regulatory systems [website]. Geneva: World Health Organization; 2025 (https://www.who.int/tools/global-benchmarking-tools).

30. Samukange WT, Kafere C, Heinrich K, Sabblah GT, Siame MM, Chirinda L et al. Strengthening blood regulatory systems to tackle Africa's unmet needs for blood and blood products. Transfus Med Hemother. 2022;50(2):123-128 (doi: 10.1159/000528077).

31. Management of national blood programmes: proceeding of three WHO workshops (2007–2009). Manila: WHO Regional Office for the Western Pacific; 2010 (https://iris.who.int/handle/10665/207609).

32. WHO guidelines on good manufacturing practices for blood establishments in: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-fifth report. Annex 4 (WHO Technical Report Series) TRS No. 961. Geneva: World Health Organization; 2011 (https://iris.who.int/handle/10665/44079).

33. TRS No. 1060 - Annex 4: WHO good practices for blood establishments. In WHO Expert Committee on Specifications for Pharmaceutical Preparations, fifty-eight report. Annex 4 (WHO Technical Report Series) TRS No. 1060. Geneva: World Health Organization; 2025 (https://iris.who.int/handle/10665/381072). Licence: CC BY-NC-SA 3.0 IGO.

34. WHO model for costing of blood products. Geneva: World Health Organization; 2025 (https://iris.who.int/handle/10665/383247). Licence: CC BY-NC-SA 3.0 IGO.

35. Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022–2030. Geneva: World Health Organization; 2022 (https://iris.who.int/handle/10665/360348). Licence: CC BY-NC-SA 3.0 IGO.

36. Global database on blood safety: summary report. Geneva: World Health Organization; 2009 (https://www.who.int/publications/m/item/gdbs-summary-report-2009).

37. Blood transfusion: a guide to the formation and operation of a transfusion service. WHO, International Society of Blood Transfusion, League of Red Cross Societies. Geneva: World Health Organization; 1971. A 1978 updated version of this document can be accessed on the WHO website (https://iris.who.int/handle/10665/37999).

38. Jacobs JW, Bates I, Cohn CS, Choudhury N, Owusu-Ofori S, Vrielink H et al. The global blood donation index: an imperfect measure of transfusion needs. Lancet. 2024;404:988-990 (doi: 10.1016/s0140-6736(24)01550-2).

39. Guidance to identify barriers in blood services using the blood system self-assessment (BSS) tool. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/374355). Licence: CC BY-NC-SA 3.0 IGO.

40. Guidance to identify barriers in blood services using the blood system self-assessment (BSS) tool. Web annex: Blood system self-assessment. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/374183). Licence: CC BY-NC-SA 3.0 IGO.

41. Guidance on implementation of a quality system in blood establishments. Geneva: World Health Organization; 2024 (https://iris.who.int/handle/10665/376096). Licence: CC BY-NC-SA 3.0 IGO.

42. Guidance on maintaining a safe and adequate blood supply during the coronavirus disease 2019 (COVID-19) pandemic and on the collection of COVID-19 convalescent plasma: interim guidance, 10 July 2020. Geneva: World Health Organization; 2020 (https://iris.who.int/handle/10665/333182). Licence: CC BY-NC-SA 3.0 IGO.

43. Maintaining a safe and adequate blood supply and collecting convalescent plasma in the context of the COVID-19 pandemic: interim guidance, 17 February 2021. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/339793). Licence: CC BY-NC-SA 3.0 IGO.

44. Guidance on ensuring a sufficient supply of safe blood and blood components during emergencies. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/366870). Licence: CC BY-NC-SA 3.0 IGO.

45. The Advisory Group on Blood Regulation, Availability and Safety [website]. Geneva: World Health Organization; 2024 (https://www.who.int/news-room/articles-detail/the-advisory-group-on-blood-regulation--availability-and-safety).

46. Improving access to safe blood products through local production and technology transfer in blood establishments, phase II. Geneva: World Health Organization; 2016 (https://iris.who.int/handle/10665/336753).

47. WFH statement on recent developments related to hemophilia therapies, 26 March 2025. Montréal: World Federation of Hemophilia; 2025 (https://wfh.org/article/wfh-statement-on-recent-developments-related-to-hemophilia-therapies/).

48. Srivastava A. The case for equitable haemophilia care. Lancet Haematology. 2021;8(9):e626 (doi: 10.1016/S2352-3026(21)00132-0).

49. Lewandowska M, Nasr S, Shapiro AD. Emerging therapies in hemophilia: improving equitable access to care. J Blood Med. 2025;16:95-115 (doi: 10.2147/JBM.S490588).

50. Availability and clinical use of cryoprecipitate: report on the international survey. Geneva: World Health Organization; 2025 (https://iris.who.int/handle/10665/382033). Licence: CC BY-NC-SA 3.0 IGO.

51. Achilles Project for Improving Quality of Blood for Transfusion and Plasma for Fractionation [website]. Geneva: World Health Organization; 2025 (https://www.who.int/initiatives/achilles-project).

52. Catalogue of WHO international reference standards for biological products [website]. Geneva: World Health Organization; 2025 (https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards/catalogue).

53. Guidelines on management of blood and blood components as essential medicines. In: WHO Expert Committee on Biological Standardization: sixty-seventh report. WHO Technical Report Series, Annex 3: TRS No. 1004. Geneva: World Health Organization; 2017 (https://iris.who.int/handle/10665/255657). Licence: CC BY-NC-SA 3.0 IGO.

54. Supply of blood for transfusion in Latin America and Caribbean countries 2016-2017. Washington, DC: Pan American Health Organization; 2020 (https://iris.paho.org/handle/10665.2/52966). Licence: CC BY-NC-SA 3.0 IGO.

55. Screening donated blood for transfusion-transmissible infections: recommendations. Geneva: World Health Organization; 2009 (https://apps.who.int/iris/handle/10665/44202).

56. Blood donor selection: guidelines on assessing donor suitability for blood donation. Geneva: World Health Organization; 2012 (https://apps.who.int/iris/handle/10665/76724).

57. Aide-mémoire for national blood programmes: the blood cold chain. Geneva: World Health Organization; 2011 (https://iris.who.int/handle/10665/330065).

58. Protecting the blood supply during infectious disease outbreaks: guidance for national blood services. Geneva: World Health Organization; 2019 (https://iris.who.int/handle/10665/311443). Licence: CC BY-NC-SA 3.0 IGO.

59. Safe blood and blood products. Establishing a distance learning programme in blood safety: a guide for programme coordinators. Geneva: World Health Organization; 1998 (https://iris.who.int/handle/10665/66372).

60. Quality management training for blood transfusion services: facilitator's toolkit guide. Geneva: World Health Organization; 2005 (https://iris.who.int/handle/10665/341004).

61. Guidelines on estimation of residual risk of HIV, HBV or HCV infections via cellular blood components and plasma. In: WHO Expert Committee on Biological Standardization, sixty-seventh report, Annex 4. WHO TRS No. 1004. Geneva: World Health Organization and WHO Expert Committee on Biological Standardization; 2017 (https://iris.who.int/handle/10665/255657). Licence: CC BY-NC-SA 3.0 IGO.

62. Maintaining a safe and adequate blood supply during Zika virus outbreaks: interim guidance. Geneva: World Health Organization; 2016 (https://iris.who.int/handle/10665/204436).

63. Therapeutics and COVID-19 living guideline. Geneva: World Health Organization; 2025 (https://iris.who.int/handle/10665/382888). Licence: CC BY-NC-SA 3.0 IGO.

64. Hoffmann S, Schrezenmeier E, Desmarets M, Halleck F, Durrbach A, Peters L et al. Early, very high-titre convalescent plasma therapy in clinically vulnerable individuals with mild COVID-19: an international, randomised, open-label trial. eBioMedicine. 2025;113:105613.

65. Global Forum for Blood Safety: patient blood management. Concept paper. Geneva: World Health Organization; 2011 (https://cdn.who.int/media/docs/default-source/biologicals/blood-products/document-migration/gfbs_01_pbm_concept_paper.pdf?sfvrsn=f189661_3).

66. The urgent need to implement patient blood management: policy brief. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/346655). Licence: CC BY-NC-SA 3.0 IGO.

67. Educational modules on clinical use of blood. Geneva: World Health Organization 2021 (https://iris.who.int/handle/10665/350246). Licence: CC BY-NC-SA 3.0 IGO.

68. Aide-mémoire for national health authorities and hospital management: clinical transfusion process and patient safety. Geneva: World Health Organization; 2010 (https://iris.who.int/handle/10665/330063).

69. Strategic directions for strengthening nursing and midwifery services 2011–2015. Geneva: World Health Organization; 2010 (https://iris.who.int/handle/10665/70526).

70. A guide to establishing a national haemovigilance system. Geneva: World Health Organization; 2016 (https://apps.who.int/iris/handle/10665/250233). Licence: CC BY-NC-SA 3.0 IGO.

71. Establishing external quality assessment programmes for screening of donated blood for transfusion-transmissible infections: implementation guide. Geneva: World Health Organization; 2016 (https://apps.who.int/iris/handle/10665/246169).

72. Haemovigilance tools and resources [website]. International Society of Blood Transfusion; 2025 (https://www.isbtweb.org/resources/hv-tools.html).

73. Guidance on implementing patient blood management to improve global blood health status. Geneva: World Health Organization; 2024 (https://iris.who.int/handle/10665/380784). Licence: CC BY-NC-SA 3.0 IGO.

74. Patient blood management guidelines [website]. National Blood Authority Australia; 2016 (https://www.blood.gov.au/patient-blood-management-guidelines).

75. Patient blood management guidelines [website]. Association for the Advancement of Blood and Biotherapies; 2025 (https://www.aabb.org/blood-biotherapies/blood/transfusion-medicine/patient-blood-management).

76. Torrado A, Barbosa-Povoa A. Towards an optimized and sustainable blood supply chain network under uncertainty: a literature review. Cleaner Logistics and Supply Chain. 2022;3:100028 (https://doi.org/10.1016/j.clscn.2022.100028).

77. AABB Disaster operation handbook v2.0. Association for the Advancement of Blood & Biotherapies; 2008 (https://www.aabb.org/about-aabb/organization/disaster-response).

78. Doughty H. Disaster planning in blood banking (presentation). International Society of Blood transfusion; 2023 (https://www.isbtweb.org/resource/disaster-planning-in-blood-banking.html).

79. Manual for the development of safe and sustainable national blood programs 2021. Global Advisory Panel on Corporate Governance and Risk Management of Blood Services in Red Cross and Red Crescent Societies; 2021 (https://globaladvisorypanel.org/wp-content/uploads/2022/10/GAP-Blood-Program-Manual-2021_final.pdf).

80. Blood supply contingency and emergency plan (B-SCEP) [website]. European Directorate for the Quality of Medicines & HealthCare; 2022 (https://www.edqm.eu/en/blood-supply-contingency-and-emergency-plan-b-scep-).

81. Laboratory biosafety manual, 4th edition. Geneva: World Health Organization; 2020 (https://iris.who.int/handle/10665/337956). Licence: CC BY-NC-SA 3.0 IGO.

82. Status of blood availability, safety and quality in the WHO African Region: 2022 survey report. Brazzaville: WHO Regional Office for Africa; 2024 (https://iris.who.int/handle/10665/379310).

83. Guide for staff on engagement with non-state actors, second edition. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/366748).

84. Handbook for non-state actors on engagement with the World Health Organization, second edition. Geneva: World Health Organization; 2024 (https://iris.who.int/handle/10665/376253). Licence: CC BY-NC-SA 3.0 IGO.

Annex 1

Logframe for action framework to advance universal access to safe, effective and quality-assured blood products 2026–2030

Strategic objective 1: Member States have implemented the essential steps for establishing and operationalizing a continuously operating, appropriately structured, well-coordinated, well-governed and sustainably resourced national blood system			
High-level outcome	**Intermediate outcome**	**Output**	**Activities**
1.1 The national blood system is appropriately structured, well coordinated, well governed and integrated into the national health system.	Member States have the knowledge and capacity to establish and sustain a national blood system that is appropriately structured, well coordinated and integrated into the national health system, with clearly defined roles and accountabilities, and regulatory decision-making and governance frameworks.	Awareness and commitment of the ministry of health exist to develop a national blood policy and implementation plan.	The ministry of health establishes a national blood policy under which the blood system is an essential part of the health system. See: *Aide-mémoire for national health policy makers: good policy process for blood safety and availability*. WHO; 2008 (https://iris.who.int/handle/10665/340542).
		A national blood policy, plan and standards are established and implemented, incorporating existing WHO guidelines and other relevant knowledge products in the development of national blood policies, legislation and regulation.	Roles and responsibilities of the national blood organization and the national blood regulatory authority are defined to set and enforce blood standards. See: *Guidelines on management of blood and blood components as essential medicines, Annex 3*, TRS No. 1004. WHO; 2017 (https://iris.who.int/handle/10665/255657). WHO regional and country offices to support Member States in applying WHO guidelines and other relevant knowledge products through training, workshops and webinars, with the aim of achieving a national blood system that is appropriately structured, well coordinated, and integrated into the national health system. This includes: • *WHO aide-mémoire for ministries of health: developing a national blood system;* • *WHO aide-mémoire for national health policy makers: good policy process for blood safety and availability;* • *WHO aide-mémoire for national blood programmes: blood safety* (https://iris.who.int/handle/10665/66698).

Strategic objective 1. *continued*

High-level outcome	Intermediate outcome	Output	Activities
	The blood system operates under a national blood policy and plan including oversight by a national blood regulatory authority and timely provision of products to meet patient needs.	The blood services operate under common standards in an efficiently organized network under the oversight of a competent national blood regulatory authority.	The national blood system engages in a self-assessment using the WHO Blood System Self-Assessment (BSS) tool to identify opportunities to streamline blood service operations.
		Key functions of the blood establishment are consolidated to improve efficiencies.	WHO regional and country offices perform a gap analysis of the status of national blood processing and testing in Member States. WHO regional and country offices to assess the degree of adherence of Member States to WHO guidelines and other relevant knowledge products on national blood processing and testing.
		A comprehensive information system is in place incorporating all functions of the blood establishments and hospital blood banks.	Blood establishment functions of donation testing and processing are centralized as feasible to promote standardization of practices, operational efficiency and economies of scale. See: *Guidance on centralization of blood donation testing and processing*. WHO; 2021 (https://iris.who.int/handle/10665/340182).
1.2 The national blood service and transfusion system are adequately and sustainably costed, financed and budgeted while avoiding costs to patients.	Member States have the knowledge and capacity to establish a sustainable financing framework and mechanisms, and to carry out the adequate costing, financing and budgeting of the national blood system.	The necessary costs to sustainably operate the national blood service and transfusion system are known.	Member States engage in costing of the national blood service and transfusion system including use of the *WHO model for costing of blood products*.
	Member States have developed mechanisms to maintain the knowledge and capacity to establish a sustainable financing framework, and to carry out adequate costing, financing and budgeting of the national blood system.	Mechanisms are established to finance sustainable operations of the national blood and transfusion system through available sources.	Member States engage in costing of the national blood service and transfusion system. Funding sources are identified to finance the costing requirements of a sustainable national blood service and transfusion system.
	The national blood service and the transfusion system are adequately and sustainably funded.	The national network of blood establishments responsible for blood products manufacturing is well defined and organized to promote efficiencies including economies of scale and timely provision of products to meet patient needs.	Budgets are established on a routine basis to assure stable financing of the national blood service. Budgets are established on a routine basis to assure stable financing of the national transfusion system.
		Stable financing of the national blood services and transfusion system is achieved for timely allocations of funds or other remuneration mechanisms.	

Strategic objective 1. *continued*

High-level outcome	Intermediate outcome	Output	Activities
1.3 Member States have strengthened their regulatory frameworks and implemented international standards for blood systems.	Regulatory capacity is strengthened through collaborative capacity-building and harmonization initiatives, including the use of reliance.	Harmonized international standards for the regulation, licensing, oversight and operation of blood establishments have been adopted and implemented in at least 20 countries, with technical support from WHO.	Establish and implement a regional regulatory strengthening programme to support Member States in adopting WHO international standards and implementing effective mechanisms for the oversight and licensing of blood establishments.
	Training programmes for key functions of the national blood system are established and operational.	The essential functions of national competent authorities have been strengthened, including inspection, surveillance, traceability and risk management, in accordance with the indicators of the Global Benchmarking Tool +Blood (GBT+Blood) and WHO technical guidelines.	Disseminate the GBT+Blood tool to the national regulatory authorities, assisted by the three levels of WHO.
	The capacity to carry out external assessment and certification for GMP of blood establishments is in place.	All levels of the WHO are actively engaged with national regulatory authorities and external assessors in order to obtain support for assessment and certification for GMP of the blood establishments.	WHO regional and country offices identify one or two pilot countries per region for joining certification programmes for blood establishments.

Strategic objective 2: An appropriate national regulatory framework is in place in Member States to ensure fully operational mechanisms of the necessary regulatory functions in order to enable an adequate supply of blood products, including PDMPs, that are safe and meet quality standards			
High-level outcome	**Intermediate outcome**	**Output**	**Activities**
2.1 WHO has raised the global awareness for the need to implement a national blood regulatory system and the use of relevant existing WHO guidance documents.	Member States have the knowledge and capacity to develop the national blood regulatory system.	All regions provided at least one training every 2–5 years using existing WHO webinars on the implementation of national blood regulatory systems.	WHO to share the existing webinar materials with WHO regional offices. Necessary translations of the webinar materials for each region are made available by WHO regional offices.
	Member States have the knowledge and capacity on the objectives and mechanisms of using the GBT+Blood assessment tool.	All regions provided at least one training every 2–5 years using existing WHO webinars on the objectives and mechanisms of using the GBT+Blood assessment tool.	WHO promotes the performance of the self-assessments in the regions.
	Member States have the knowledge on the stepwise implementation of regulatory mechanisms for pre-market review, registration, licensing, certification and compliance measures applicable to blood establishments and blood products.	Relevant national decision-makers understand the important need to implement national blood regulatory systems based on existing WHO guidelines applicable to blood product regulation and are committed to take action.	
	Member States have the knowledge on existing WHO guidelines applicable for blood and blood products.	Information on relevant existing WHO guidelines is actively promoted and implemented within the regions.	WHO to share the relevant existing WHO guidelines with WHO regional offices. WHO regional offices to assess degree of implementation of existing WHO guidelines in Member States.
2.2 Member States have initiated the process to perform self-assessments of existing national regulatory authorities using the GBT+Blood tool, increasing the political commitment and awareness of the essential role of a national blood regulatory system.	WHO regional offices have developed a regional self-assessment plan with the objective that all Member States in the region will have performed a self-assessment within 5 years.	Self-assessments of all Member States are performed within 2–5 years.	WHO to provide support to Member States and WHO regional offices in preparing a self-assessment using the GBT+Blood tool. WHO to offer training of national and/or regional experts in the use of GBT+Blood as a self-assessment tool.
	Member States initiate the necessary steps to establish an adequate legal framework that defines the minimal regulatory functions and formally designates national competent authorities responsible for the oversight of blood and blood products.	Political committment for defining objectives, scope and timelines for a stepwise implementation of the regulatory functions exists for each Member State.	Member States conduct a structured review of existing national laws and regulations to identify gaps in the legal oversight of blood and blood products.

Strategic objective 2. *continued*

High-level outcome	Intermediate outcome	Output	Activities
	Member States develop gap analysis to inform the definition of objectives, scope and timelines for a stepwise implementation of the regulatory functions, tailored to national needs and context and aligned with the development of the legal framework.	A pool of trained experts for supporting self-assessment within the regions is available.	Member States to submit a 2–5 year action plan to the WHO regional office based on gaps identified in the self-assessment using a prioritized, time-bound and resource-based strategy.
2.3 Member States are supported in developing a road map and legal frameworks to establish and formally implement regulatory mechanisms for comprehensive oversight of blood products, associated substances and medical devices, including IVD devices.	Member States have developed road maps defining the processes and timelines for establishing the necessary legal framework governing blood and blood products.	Reporting on identified gaps using the existing GDBS data collection mechanisms provides a means to demonstrate progress achieved.	WHO to modify the GDBS data collection tool to include additional questions on the implementation status of blood regulation for each Member State.
	At least one initial or additional Member State in each region has in place the necessary legal framework to establish the regulatory functions, including the designation of a national regulatory authority for blood and blood products.	Templates for legal frameworks covering the relevant regulatory functions are available to support Member States in implementing national legal frameworks.	WHO to support implementation of regulatory functions by providing trainings and piloting activities for implementation.
	Establishment of twinning projects within regions to foster institutional cooperation and capacity building among the national regulatory authorities, including peer-to-peer exchange on strengthening regulatory functions.	The national regulatory authorities exist and are establishing the necessary regulatory functions.	WHO to support twinning programmes by facilitating the establishment of contacts between regulatory authorities.
2.4 Member States have authorized and empowered their national medical products regulatory authorities to establish and strengthen the relevant blood regulatory functions.	Relevant authorities have established appropriate capacity and regulatory mechanisms for pre-market review, registration, licensing, certification and compliance measures applicable to blood establishments and blood products according a maturity level 3 or 4.	Relevant authorities have established regulatory oversight and operational relevant regulatory functions.	Continuous capacity building to improve and maintain the established regulatory functions.
		Relevant authorities have regulatory oversight for plasma as a raw material for fractionation.	National blood policies, legislation and regulation are in place and are maintained.
2.5 Each region has established an informal blood regulatory network that is used to facilitate implementation of the relevant structures and functions within the regions, e.g. by organizing workshops, congresses and exchange programmes.	Each region has defined Members States' roles, responsibilities and functions toward their regional blood regulatory network.	Informal blood regulatory networks are established in all regions.	WHO facilitates the establishment of informal blood regulatory networks. Regular status updates from the regions are presented to WHO/Advisory Group for Blood Regulation, Availability and Safety.
	Regional road maps for a stepwise implementation of the blood regulatory networks within 5 years are defined and agreed.	WHO regional offices organize an annual meeting of the regional blood regulatory networks.	WHO to support exchange between the informal blood regulatory networks of different regions, e.g. by organizing workshops, congresses, exchange programmes. Annual reports on activities and workplan of informal regional blood regulatory network are made available by WHO regional offices.

Strategic objective 3: Affordability, availability and accessibility of safe, effective and quality-assured blood products in Member States assures timely patient access to needed blood and blood products			
High-level outcome	**Intermediate outcome**	**Output**	**Activities**
3.1 Blood establishments meet WHO or other internationally recognized standards for preparation and quality assurance of all distributed blood products and blood-derived raw materials used for further processing.	Member States assure the performance of blood products and associated substances and medical devices, including IVD devices, through use of reference biological standards and external quality assessment schemes.	Member States have the knowledge and capability to establish a national blood regulatory authority responsible for setting standards for preparation and quality assurance of blood products and starting blood-derived raw materials used for further processing, in alignment with WHO or other internationally recognized standards.	WHO promotes universal adoption of a quality culture in all blood systems and shares existing guidance and guidelines respectively on a) good manufacturing practices (GMPs) for blood establishments; b) criteria for assessing the maturity level of a national blood authority; and c) developing a quality system in blood establishments. WHO provides support as needed for interpretation and implementation of these documents.
	Blood establishments are mandated to operate in compliance with WHO or other internationally recognized standards for preparation and quality assurance of all distributed blood products and blood-derived raw materials used for further processing and meet all national licensing requirements.	The blood system has the knowledge and capability to engage in self-assessments using the 2023 WHO guidance on the Blood System Self-Assessment (BSS) tool to identify deficiencies in quality management and quality assurance in preparation of distributed blood products and starting blood-derived raw materials used for further processing.	WHO shares existing guidance on the WHO Blood System Self-Assessment (BSS) tool and provides support for its use in Member States through training, workshops or webinars. See: *Guidance to identify barriers in blood services using the blood system self-assessment (BSS) tool*. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/374355).
	Blood establishment deficiencies in quality management and quality assurance are identified and corrected in a timely manner consistent with a comprehensive quality culture and framework of quality management.	Blood establishments have the knowledge and capability to develop corrective action plans that address identified deficiencies in quality management and quality assurance related to the preparation and distribution of blood and blood products and starting blood-derived raw materials used for further processing.	
	Blood establishments are accredited externally by the national blood regulatory authority or by recognized international organizations.	Periodic and for-cause audits of blood establishments are conducted by the national blood regulatory authority and/or authorized organizations to assure compliance with established standards for preparation and quality assurance of blood products and starting blood-derived raw materials used for further processing as a basis for accreditation.	WHO distributes relevant knowledge products and provides technical assistance to promote use of external audits to determine blood establishment compliance with GMPs.

Strategic objective 3. *continued*

High-level outcome	Intermediate outcome	Output	Activities
3.2 Member States ensure the quality and sufficiency of blood products and starting blood-derived raw materials used for further processing through the recruitment and retention of voluntary non-remunerated blood donors and laboratory testing of all donations.	Member States to have the knowledge and capacity to establish and sustain a donor recruitment and retention programme, including a donor counselling programme that is appropriately structured, well coordinated and integrated into the national health system, with clearly defined roles and accountabilities, and regulatory and governance frameworks. Criteria for blood and plasma donation that minimize the risks of collection from persons who may have a relevant transfusion-transmissible infection are available. Member States have the knowledge and capacity to increase the awareness of public and youth on voluntary blood donation.	Legal and regulatory policies mandate that blood components for transfusion are obtained from voluntary non-remunerated blood donors as much as possible. Promotional activities on blood donation are frequently held in the Member States, and donor appreciation and recognition events are regularly organized. World Blood Donor Day is celebrated annually in the Member States. 100% voluntary blood donation to be achieved in all Member States by 2030. Blood systems have the knowledge and capability to establish donor selection criteria to avoid collections from donors at higher risk of having relevant transfusion-transmissible infections.	WHO shares existing guidance on blood donor selection and donor counselling including recommendations for voluntary non-remunerated donation. WHO to update existing guidances on donor recruitment, including the documents: *Towards 100% voluntary blood donation: a global framework for action and Blood donor counselling*. Member States ensure the presence of qualified and trained personnel to provide counselling, ensure donor safety and support the appropriate selection of blood donors. WHO regional and country offices to support Member States in applying WHO guidelines and other relevant knowledge products through training, workshops and webinars, with the aim of increasing voluntary non-remunerated blood donation by 2030. WHO provides training on risk management for transfusion-transmissible infections to prevent blood collection from high-risk donors. WHO leads coordinated global efforts for World Blood Donor Day by setting annual themes, providing multilingual campaign toolkits and organizing high-impact events that mobilize Member States and amplify public engagement worldwide. WHO establishes a global dashboard to monitor voluntary donation rates by country and publish progress reports highlighting successes and gaps.
	Member States have the knowledge to minimize the risk of transfusion-transmitted infections.	Blood services have knowledge and ability to identify and assess technology options to minimize the risk of transfusion-transmitted infections, e.g. use of pathogen-reduction methods for blood components.	WHO facilitate regional workshops to share best practices and innovations.
	Quality-assured laboratory testing of all blood and plasma donations is in place.	Blood services have the knowledge and capability to implement appropriately sensitive laboratory testing of all blood and plasma donations for relevant transfusion-transmissible infectious agents. Member States ensure that external quality schemes for transfusion-transmissible infections and blood grouping and antibody screening are made available to all blood centres which test blood donations.	WHO shares existing guidance on implementation of laboratory testing of blood and plasma donations to detect infections by relevant transfusion-transmissible infectious agents. WHO shares existing guidance on the development and implementation of external quality assessment schemes for transfusion-transmissible infections and blood grouping and antibody screening of blood donations.

Strategic objective 3. *continued*

High-level outcome	Intermediate outcome	Output	Activities
3.3 Strategies to strengthen the domestic production of quality plasma for fractionation and the procurement of commercially available PDMPs to ensure sufficient access to and availability of PDMPs.	Developing national policies to increase component use, reduce plasma wastage and improve its quality for fractionation or domestic processing.	National policies to increase component use and reduce plasma wastage to support PDMP production. Blood establishments have the knowledge, motivation, resources and means to separate collected whole blood into components.	WHO shares guidance on GMP in blood establishments regarding preparation of blood components, provides relevant knowledge products on evidence-based utilization practices of blood components, and encourages national funding to support the implementation of blood component separation in countries in need.
		Member States have the knowledge and capability to ensure that recovered plasma, whether obtained from whole blood or by apheresis, and produced in excess of transfusion needs meets the required criteria for use in fractionation.	WHO shares guidance on increasing supplies of PDMPs through fractionation of domestic plasma and provides support for interpretation and implementation of the guidance. See: *Guidance on increasing supplies of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma*. WHO; 2021 (https://iris.who.int/handle/10665/340171). WHO shares policy guidance on implementing cross-border transfer of domestic plasma to obtain PDMPs. See: *Implementing cross-border transfer of domestic plasma to obtain plasma-derived medicinal products: policy guidance*. WHO; 2024 (https://iris.who.int/handle/10665/380192).
	Supporting domestic initiatives towards contract fractionation based on adoption of established contract fractionation models.	Member States have the knowledge and capability to establish and implement a national plasma policy and programme including regulatory oversight to assure that recovered plasma produced from whole blood or by apheresis, generated in excess of needs for transfusion is made available for fractionation.	WHO shares guidance on increasing supplies of PDMPs through fractionation of domestic plasma and provides support for interpretation and implementation of the guidance. See: *Guidance on increasing supplies of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma*. WHO; 2021 (https://iris.who.int/handle/10665/340171). WHO shares policy guidance on implementing cross-border transfer of domestic plasma to obtain PDMPs. See: *Implementing cross-border transfer of domestic plasma to obtain plasma-derived medicinal products: policy guidance*. WHO; 2024 (https://iris.who.int/handle/10665/380192). WHO regional and country offices to support Member States in applying WHO guidelines and to develop national policies to increase component use and reduce wastage of plasma that could be used for PDMP production through training/workshops/webinars. WHO regional and country offices to mobilize, convene and provide technical assistance to Member States to build capacity on the initiation of contract fractionation for PDMP production based on adoption of established contract fractionation models.

Strategic objective 3. *continued*

High-level outcome	Intermediate outcome	Output	Activities
			WHO regional and country offices to facilitate twinning programme between Member States on the establishment of fractionation contracts based on adoption of established contract fractionation models. WHO regional and country offices to mobilize, convene and provide technical assistance to Member States to provide quality recovered and apheresis plasma to manufacture PDMPs. This includes support to in-country initiatives of PDMP manufacturing, as well as contracting of manufacturers in other countries (e.g. under the Achilles project).
	Knowledge exchange between Member States on the establishment of fractionation contracts based on adoption of established contract fractionation models.	Contract fractionation for PDMP production based on adoption of established contract fractionation models.	WHO regional and country offices to disseminate knowledge products relevant to increasing the volume and quality of recovered plasma for fractionation to manufacture PDMPs to Member States and other relevant stakeholders through training/workshops/webinars. This includes: • WHO recommendations for the production, control and regulation of human plasma for fractionation; • WHO report on improving access to safe blood products through local production and technology transfer in blood establishments; • WHO information sheet on the plasma contract fractionation programme; • WHO information sheet on ensuring the quality and safety of PDMPs.
		Ministries of health have the knowledge and capability to negotiate contract agreements with an established international fractionator for the export of domestic plasma for fractionation, with the provision for importation of PDMPs to meet domestic needs.	WHO regional and country offices to support Member States on initiating contract fractionation for PDMP production based on adoption of established contract fractionation models through training/workshops/webinars.
	Coordinated efforts are necessary at global and regional levels between countries and with fractionation organizations to improve the volume of plasma suitable for manufacture of PDMPs and facilitate access to fractionation facilities through appropriate regulatory standards, contract manufacturing and technology transfer.	Ministries of health have the knowledge and capability to achieve volumes of plasma suitable for fractionation through regulatory agreements that permit a foreign fractionator to pool domestic and foreign plasma demonstrated to meet the same quality and safety standards for fractionation.	WHO to support stakeholders to achieve volumes of plasma suitable for fractionation through training/workshops/webinars.
		National blood regulatory authorities have the knowledge and capability to establish legal frameworks whereby PDMPs prepared from pools of domestic and foreign plasma can be accepted for importation.	WHO to put forward recommendations for the production, control and regulation of human plasma for fractionation.

Strategic objective 3. *continued*

High-level outcome	Intermediate outcome	Output	Activities
		Ministries of health have the knowledge and capability to negotiate a contract under which domestic and foreign plasma can be pooled for fractionation abroad in return for acquisition of PDMPs.	WHO regional and country offices to report on improving access to safe blood products through local production and technology transfer in blood establishments.
		The volume of domestic plasma suitable for foreign fractionation under a contract can be optimized through technology transfer by the fractionator.	
	Expanding WHO technical assistance for national and regional plasma programme development.	Additional countries will benefit from technical assistance for national and regional plasma programme development through the Achilles project.	WHO information sheet on the plasma contract fractionation programme.
	Promoting innovation in pathogen reduction and domestically implementable safe plasma protein preparation technologies.	An increased number of Member States will have the knowledge and capability to implement validated pathogen reduction in preparation of blood components.	WHO information sheet on ensuring the quality and safety of PDMPs.
		An increased number of Member States will have the knowledge and capability to implement validated pathogen reduction and protein purification technologies in local preparation of plasma protein products.	WHO will disseminate knowledge products on research and regulatory authorization of pathogen reduction and protein purification technologies designed for use in local preparation of plasma protein products.

Strategic objective 4: Effective implementation of patient blood management to optimize clinical practice of transfusion			
High-level outcome	**Intermediate outcome**	**Output**	**Activities**
4.1 Patient blood management is nationally prioritized, promoted as part of quality assurance in medical practice, embedded in medical education, and practised based on national clinical guidelines and practice standards.	Member States have the knowledge and capacity to implement evidence-based international guidelines through effective hospital transfusion committees and develop national guidelines and practice standards as needed.	Continuous improvement in the efficiency of hospital transfusion committees reflected by the key performance indicators.	WHO regional offices to provide support through webinars, workshops and training programmes of stakeholders for capacity building at regional and national level. WHO to develop and use key performance indicators to assess the functions of hospital transfusion committees.
	Member States have the knowledge and capacity to establish supply systems to support good transfusion practice and use of appropriate transfusion alternatives.	Member States develop expertise and infrastructure in patient blood management at regional and national levels to optimize the clinical use of blood components and blood products.	WHO regional offices provide support through webinars, workshops and training programmes of stakeholders on principles of patient blood management. WHO country offices monitor the implementation and effectiveness of patient blood management programmes in hospitals. Member States implement patient blood management protocols in hospitals with clear documentation and audit mechanisms. Member States promote appropriate blood use and alternatives to transfusion.
	Clinicians and other relevant health care providers have the knowledge and capacity to practice good patient blood management.	Increase in the number of health professionals at national and regional levels who have awareness and expertise in patient blood management.	WHO provides support to Member States on enhancing the practice of patient blood management among clinicians by incorporating the *Patient blood management* module in undergraduate and postgraduate medical curricula, and by supporting ongoing postgraduate continuing education programmes to ensure clinicians remain updated with best practices in patient blood management.
	Hospitals have the knowledge and capacity to carry out key functions of the quality system for all pre-transfusion testing and clinical transfusion processes, including in hospital blood bank laboratories.	Member States ensure that all pre-transfusion testing and clinical transfusion processes are performed as per the guidelines and mandatory requirements, e.g. by conducting regular third party audits. All hospitals have access to adequate pretransfusion testing laboratories.	WHO provides knowledge products relevant to pre-transfusion testing and guidelines on clinical transfusion practices to underpin external audits of hospital laboratories and clinical practices.
4.2 A quality system is in place in hospitals for all pre-transfusion testing and clinical transfusion processes, including hospital blood bank laboratories.	Member States have the knowledge and capacity to establish supply systems to support good transfusion practice and use of appropriate transfusion alternatives.	Member States to develop and implement national training programmes and technical guidelines on blood supply management and transfusion alternatives.	WHO country offices monitor the implementation and effectiveness of patient blood management programmes in hospitals.

Strategic objective 5: Effective surveillance, haemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection systems, evaluation, risk reduction and communication are implemented			
High-level outcome	**Intermediate outcome**	**Output**	**Activities**
5.1 There is a fully integrated national system for standardized haemovigilance and pharmacovigilance data collection and reporting, and mechanisms to ensure uniform implementation.	Member States have the knowledge and capacity to establish and maintain a legal framework for haemovigilance and pharmacovigilance systems at national level.	Ministries of health of Member States define legal framework covering the relevant vigilance aspects and traceability requirements.	WHO provides and shares guidances on establishment of national haemovigilance systems and their implementation.
		Member States identified gaps using the WHO GBT+Blood tool for self-assessment.	WHO and WHO regional offices provide regular training on implementation of haemovigilance systems including self-assessments using the GBT+Blood tool.
	National regulatory authorities, blood establishments and manufacturers of PDMPs have the knowledge and capacity to establish and maintain a national system for standardized data collection and reporting, and mechanisms to ensure uniform implementation management systems for traceability and surveillance.	Member States have an efficient national system for traceability, surveillance, haemovigilance and pharmacovigilance in place.	WHO provides support in defining coding and traceability requirements.
	Blood establishments, hospitals and health professionals have the knowledge and capacity to monitor and assess adverse events and adverse reactions in blood donors and blood product recipients and to report this to national vigilance systems.	Haemovigilance and pharmacovigilance systems are operational and relevant data are collected and assessed on a national level.	WHO provides guidance on assessing haemovigilance data using WHO training material for additional support of national regulatory authorities, blood establishments and health care professionals.
5.2 There are policies and systems for traceability, surveillance, haemovigilance and pharmacovigilance at national and organizational levels.	Member States have the knowledge and capacity to establish and maintain a national policy for traceability, haemovigilance and pharmacovigilance at national and organization levels.	Traceability requirements are defined taking into consideration international coding systems.	WHO provides support in defining coding and traceability requirements.
	National regulatory authorities develop a national policy and system for collecting and assessing haemovigilance and pharmacovigilance data on a national level.	National policies are in place and implemented.	WHO and WHO regional offices perform regular survey to assess progress in stepwise implementation of national haemovigilance and pharmacovigilance systems.
		Reporting mechanisms are in place and relevant data are collected and regularly assessed.	WHO provides regular training on assessing haemovigilance data using WHO training materials for additional support of national regulatory authorities, blood establishments and health care professionals. WHO shares guidelines on hemovigilance and assists Member States to establish stepwise, reliable and effective hemovigilance systems at national and organizational levels.

Strategic objective 5. *continued*

High-level outcome	Intermediate outcome	Output	Activities
	Data definitions are standardized and harmonized to improve the consistency and comparability of reported information, including harmonization of data elements with other international systems.	Harmonized vigilance data are available on a national level and are sufficiently accurate to be fed into international databases (e.g. WHO GDBS). Understanding of GDBS definitions is available, and GDBS participation and data quality is improved.	WHO will promote use of consistent terminology and measurements in the field of transfusion medicine, used as a basis for clear, comparable and sustainable information and data for the GDBS. WHO publishes comparable vigilance data providing benchmarking and feedback to those countries which provide the data.
5.3 There are education and training mechanisms in place to continuously support haemovigilance and pharmacovigilance awareness and education of health care staff.	Member States have the knowledge and capacity to establish mechanisms for haemovigilance awareness and education of healthcare staff at organization level and nationally.	National blood establishments and clinical provider organizations have trained and knowledgeable health care staff.	WHO shares knowledge products and provides support for awareness and implementation training of health care staff on haemovigilance and traceability.
	National regulatory authorities develop mechanisms for haemovigilance awareness and education of health care staff.	National regulatory authorities conduct workshops and courses for awareness and training of health care staff on haemovigilance and traceability.	
5.4 The WHO GDBS provides comprehensive and accurate data on the global status of blood product availability, safety and quality.	Member States have the knowledge and capacity to be able to provide accurate data on the status of blood product availability, safety and quality to WHO.	Up-to-date information on the status of blood products availability and safety is available.	WHO provides training on collection, analysis and dissemination of vigilance data. WHO regional and country offices provide technical support to priority Member States on establishing/improving national data reporting system. WHO may consider drafting guidance for use, where feasible, of digital solutions to optimize bidirectional traceability of donations, products and recipients and for gathering a hemovigilance data collection, aggregation and analysis.
		National regulatory authorities can continuously improve quality and safety of blood products and avoid risks along the transfusion chain from donor to patient through collection and dissemination of vigilance data.	Member States may consider to incorporate blood service data into national health information systems to strengthen coordination, surveillance and evidence-based decision-making.
	WHO amends the GBDS survey to include appropriate vigilance data.	WHO can provide global data on the status of implementation of haemovigilance and pharmacovigilance systems.	WHO performs a regular GDBS survey and publishes a report.

Strategic objective 6: Mechanisms are implemented for jointly addressing challenges and emerging threats to national blood systems at global, regional and national levels			
High-level outcome	**Intermediate outcome**	**Output**	**Activities**
6.1 WHO has raised global awareness on the key functions of the national blood system and its importance in the context of the national health system.	Member States have the knowledge and political support to sustain a national blood system and PDMP supply during disasters, humanitarian crises and emerging threats.	Ministries of health are aware and committed to develop national emergency and contingency plans to maintain the blood system and PDMPs supply during disasters, humanitarian crises and emerging threats.	WHO headquarters and WHO regional offices establish training, workshops and webinars on the role of the blood systems within the national health system disaster and emergency response plan for senior decision-makers within both national health systems and blood services. WHO regional and country offices assess status of development and update of national emergency and contingency plans to maintain the blood system and PDMPs supply during disasters, humanitarian crises and emerging threats.
	Member States have the knowledge of mechanisms to prevent blood and PDMPs shortages and blood service disruptions in the context of disasters, humanitarian crises and emerging threats.	WHO guidelines to address blood and PDMPs shortages and blood service disruptions in the context of disasters, humanitarian crises and emerging threats.	WHO may offer support through training, workshops or webinars of relevant existing or new guidelines, e.g. WHO guidance on preparing for national response to health emergencies and disasters. Member States perform a gap analysis of the national disaster response plan against existing WHO recommendations on yearly basis.
		WHO self-assessment tool for identifying risk in the supply chain of blood services during disasters, humanitarian crises and emerging threats is available.	WHO to draft a new guideline.
	Member States have the knowledge of relevant WHO recommendations regarding the maintenance of a safe and adequate blood and PDMPs supply in the context of disasters, humanitarian crises and emerging threats.	Information on relevant existing WHO guidelines is actively promoted within the regions.	WHO to share the relevant existing WHO guidelines with WHO regional offices. This includes: • WHO guidance on preparing for national response to health emergencies and disasters; • Maintaining a safe and adequate blood supply during pandemic influenza: guidelines for blood transfusion services; • Maintaining blood supply during COVID-19 pandemic; • Collection of COVID-19 convalescent plasma-WHO: interim guidance and Guidance on ensuring a sufficient supply of safe blood and blood components during emergencies; • Maintaining a safe and adequate blood supply during Zika; • Protecting the blood supply during infectious disease outbreaks: guidance for national blood services; • Maintaining a safe and adequate blood supply and collecting convalescent plasma in the context of COVID-19: interim guidance 2020-2021; • Guidance on ensuring a sufficient supply of safe blood and blood components during emergencies, WHO 2023.

Strategic objective 6. *continued*

High-level outcome	Intermediate outcome	Output	Activities
6.2 WHO headquarters, regional offices and Member States should have mechanisms for monitoring and evaluating the implications for the blood system during emergency situations at global, regional and national levels.	WHO develops tools to support monitoring and evaluation of emergency situations and preparedness at global, regional and national levels.	Data on global, regional and national emergency situations and preparedness are regularly available.	WHO publishes the *WHO disaster self-assessment toolkit* and encourages Member States to use this to report on their preparedness. WHO gathers information in the GDBS and periodically publishes reports on countries' emergency preparedness.
		WHO GDBS data assessment provides necessary information on national and regional disaster management plans for blood establishments, and on availability of special legal instruments and mechanisms covering mutual supply of blood and blood products across different countries.	WHO to include in the next edition of GDBS the following questions: 1. Is there a national disaster management plan for blood establishments? 2. Is there specific legislation or legal instrument covering receiving and supplying blood and blood products from and to other countries?
	Member States have assessed the situation and needs in the countries regarding PDMPs availability, particularly albumin, for use in disasters such as earthquakes.	Assessment tool is available for Member States.	WHO to develop and dissemination an assessment tool for PDMPs availability in countries, particularly albumin, for use in disasters such as earthquakes.
6.3 Member States have developed an emergency preparedness and contingency plan with coordination of major and relevant stakeholders to ensure an adequate and safe supply of blood, blood components and PDMPs during emergency situations such as disasters, humanitarian crises and emerging threats.	Member States ensure the development of their emergency and contingency plans to enhance preparedness for disasters, humanitarian crises and emerging threats.	Member States have emergency and contingency plans in place.	WHO may offer support through training, workshops or webinars of relevant guidelines. See: *WHO guidance on preparing for national response to health emergencies and disasters*. WHO; 2021 (https://iris.who.int/handle/10665/350838).
6.4 Member States have developed mechanisms of ongoing review, assessment and update of their emergency preparedness and contingency plan.	Member States follow existing WHO guidelines and recommendations in reviewing their emergency preparedness and contingency plans.	Member States have updated documents with latest development, practices and recommendations with regards to their emergency preparedness and contingency plans.	WHO is updating relevant reference documents if necessary, such as: *Maintaining a safe and adequate blood supply during pandemic influenza: guidelines for blood transfusion services*; *Maintaining a safe and adequate blood supply during Zika virus outbreaks: interim guidance*; *Protecting the blood supply during infectious disease outbreaks: guidance for national blood services*; *Use of convalescent plasma for emerging infectious diseases*.
	Member States ensure access and use of the WHO disaster assessment toolkit as part of the drills in assessing their disaster response plan.	Wider availability of the WHO disaster assessment toolkit.	WHO to finalize and disseminate the *WHO disaster assessment toolkit* so that blood establishments in countries can use it to report to WHO during active disasters. WHO regional offices may offer support through training, workshops or webinars on the use of the *WHO disaster assessment toolkit*. WHO country offices incooperate use of the *WHO disaster assessment toolkit* in the regular national disaster response drills.

Strategic objective 6. *continued*

High-level outcome	Intermediate outcome	Output	Activities
	Member States regularly update their disaster plans and emergency procedures.	WHO establishes regular survey for Member States to report on frequency and outcomes of disaster drills and updates made in their emergency plan.	WHO may offer support through training, workshops or webinars of relevant guidelines. See: *WHO guidance on preparing for national response to health emergencies and disasters*. WHO; 2021 (https://iris.who.int/handle/10665/350838). WHO country offices to monitor country application of disaster drills and updates made in their disaster plans and emergency procedures.
6.5 There is a joint and coordinated response to emerging health threats associated with blood and blood products.	The ability to evaluate relevant new technologies and innovations is integrated into the national blood system to overcome local challenges and address urgent situations.	Blood services are integrated into national preparedness and response plans for health emergencies (e.g. pandemics, epidemic outbreaks, conflicts).	WHO country offices assist Member States to implement the WHO guidelines on blood-related threats at the national level.
		Emerging risks have been identified, assessed and mitigated through collaboration and preparedness mechanisms led by WHO.	WHO documents emergencies affecting blood services, followed by a thorough assessment of the implementation and impact of mitigation measures.

Strategic objective 7: WHO leadership, partnerships, collaboration and information exchange to achieve key priorities and jointly address challenges and emerging threats at global, regional and national levels			
High-level outcome	**Intermediate outcome**	**Output**	**Activities**
7.1 Strengthening WHO leadership and coordination in global, regional and national contexts.	The blood programme at all WHO levels is organized within a clear structure and is properly managed.	WHO is recognized as the technical and coordinating authority for responding to health priorities and emerging threats related to blood and blood products.	The Global Database on Blood Safety (GDBS) is effectively collected, utilized and regularly monitored. WHO strengthens the use of existing global mechanisms within WHO for the timely issuing of guidance in responding to emerging threats to blood safety and availability. WHO leads the organization of the annual celebration of World Blood Donor Day, and calls on developing national blood programmes based on 100% voluntary blood donation.
		Functional inter-agency and intersectoral coordination mechanisms, led or facilitated by WHO, have been established at all levels.	WHO facilitates inter-agency and intersectoral coordination and plays a leading role in mobilizing and coordinating WHO advisory groups, collaborating centres, nongovernmental organizations in official relation with WHO, other institutions of excellence and experts to implement the Action Framework.
	The blood programme at all WHO levels is adequately funded by the WHO assessment contribution and voluntary contribution funds.	Blood services functions at all WHO levels can be run according to plan.	Fundraising through voluntary contributions is actively pursued at all levels of WHO. WHO regional and country offices identify and establish communication with blood-related funding agencies at both regional and country levels.
	WHO collaborating centres and non-state actors in official relations with WHO are well-managed, with their activities directed, and closely monitored.	WHO collaborating centres and non-state actors activities are directed to support the implementation of blood services functions at all WHO levels.	Regular meetings are held between WHO, WHO collaborating centres and non-state actors at all levels to discuss and align their respective blood service programmes, using existing WHO guidance, to identify and prioritize countries that require support in strengthening their blood systems.
7.2 Strengthening strategic alliances for collective action.	Political commitment from all stakeholders regarding the blood products programme at all levels of WHO is evident and actively implemented.	WHO partnerships, collaboration and information exchange with stakeholders at all levels are strong and effective.	Engage regional networks, cooperation agencies and reference centres to create shared road maps and coordinate actions.

Strategic objective 7. *continued*

High-level outcome	Intermediate outcome	Output	Activities
		WHO stakeholders at all levels are clearly identified.	WHO identifies and engages stakeholders involved in blood services at all levels, blood-related regional organizations, ministries of health, national regulatory authorities, national control laboratories, national societies of transfusion medicine, and providers of medical devices and in vitro diagnostics (IVDs) used in blood and transfusion services.
	Clear and effective partnerships, collaboration and information exchange exist between WHO and its stakeholders.	Multisectoral alliances have been consolidated with key actors (international cooperation, governments, scientific societies, the private sector, academia) in at least two regions.	WHO actively disseminates blood service programmes at each level to gain stakeholder support, e.g. by having regular meetings with stakeholders.
		Technical and financial resources have been mobilized at the global, regional or national levels to implement priority interventions of the global blood framework.	WHO actively disseminates proposals for blood service activities to stakeholders to obtain technical and financial support.
7.3 Effective mechanisms for information exchange and knowledge management.	The existence and interoperability of national and regional information systems and their coordination with the GDBS is promoted.	The global and regional platform for the timely exchange of information on blood and blood products has been strengthened (sustained increase in reporting to the GDBS).	Meetings every 6 months between WHO headquarters and WHO regional offices, and between WHO regional offices and WHO country offices to discuss and analyse blood services data at regional and national levels.
		Joint analyses have been prepared and disseminated in technical reports that guide policy decisions on blood (globally and by region).	Develop a regional and national work plan on blood services based on the analysed data.
7.4 National capacities are strengthened through coordinated technical cooperation.	International standards are in place for regulatory oversight.	National plans aligned with the global framework, international standards and national priorities, including regulatory and emergency components, have been develop and adopted.	Technical assistance to develop and update evidence- and risk-based national blood policies and national blood plans.
	International standards have been established to strengthen operational and organizational capacity.	Member States have strengthened national networks and institutional and technical capacities for the provision, distribution and rational use of blood through cooperation led by WHO and partners.	Support the design and strengthening of logistics networks for the equitable distribution of blood products.
			Train national, regional and local officials in planning and managing blood access.

Annex 2

WHO international biological reference preparations for blood products and in vitro diagnostics

Source of information	Name of biological reference preparation for blood products	Name of BRP for in vitro diagnostic
2025, TRS 1063, 80th report	None	• Epidermal growth factor receptor variant T790M (c.2369C>T) genomic DNA • Epidermal growth factor receptor variant L858R (c.2573T>G) genomic DNA • Epidermal growth factor receptor variant p.E746_A750del (c.2235_2249del) genomic DNA • Serum amyloid A • Thyroglobulin antibodies (human serum) • Tissue transglutaminase antibodies (human serum)
2024, TRS 1059, 79th report		• HIV-1 p24 antigen • Lassa virus RNA for NAT-based assays Lineages II, III, V and VII
2024, TRS 1054, 78th report	• Thrombin activatable fibrinolysis inhibitor (plasma)	• Protein S (plasma) • Q fever (*Coxiella burnetii*) antibodies (human, plasma)
2023, TRS 1048, 77th report	• Blood coagulation factor VIII concentrate	• Antibodies to human leukocyte antigen (negative plasma) • Antibodies to human leukocyte antigen (negative serum) • Antibodies to human leukocyte antigen (strong positive plasma) • Antibodies to human leukocyte antigen (weak positive plasma) • Antibodies to citrullinated peptide/ protein • Hepatitis B virus DNA for NAT-based assays
2023, TRS 1045, 76th report	• Blood coagulation factor XIII (plasma)	• Antibodies to chikungunya virus
2022, TRS 1043, 75th report		• Anti-human neutrophil antigen-3a immunoglobulin G • Lassa virus RNA for NAT-based assays • Anti-β2GPI immunoglobulin G
2022, TRS 1039, 74th report	• von Willebrand factor (concentrate) • Ferritin (human, recombinant)	• Mycobacterium tuberculosis (H37Rv) DNA for NAT-based assays • Varicella zoster virus DNA for NAT-based assays • Anti-Lassa virus immunoglobulin G • Anti-Lassa virus immunoglobulin G (no unitage assigned) • Anti-thyroid peroxidase antibodies
2021, TRS 1028, 72nd and 73rd reports	• Anti-human platelet antigen-15b immunoglobulin G (human)	• Insulin-like growth factor 1 (recombinant, human) • Herpes simplex virus type 1 DNA for NAT-based assays • Herpes simplex virus type 2 DNA for NAT-based assays • West Nile virus lineage 1 RNA for NAT-based assays • West Nile virus lineage 2 RNA for NAT-based assays
2021, TRS 1028, 71st report	• Thrombin	• Plasmodium vivax antigen

Source of information	Name of biological reference preparation for blood products	Name of BRP for in vitro diagnostic
2020, TRS 1024, 70th report	• Prekallikrein activator • Streptokinase • Anti-tetanus immunoglobulin (human) • Assignment of additional analyte for blood coagulation factor XIII-B subunit antigen (total) to the current First WHO International Standard for blood coagulation factor XIII • Establishment of RBC13–30 blood group genotyping alleles (lyophilized) as a companion set to the WHO international reference reagent collection for blood group genotyping • Red blood cell transfusion relevant bacterial reference strains	• Hepatitis C virus RNA for NAT-based assays • Human papillomavirus type 6 DNA for NAT-based assays • Human papillomavirus type 11 DNA for NAT-based assays • Human papillomavirus type 31 DNA for NAT-based assays • Human papillomavirus type 33 DNA for NAT-based assays • Human papillomavirus type 45 DNA for NAT-based assays • Human papillomavirus type 52 DNA for NAT-based assays • Human papillomavirus type 58 DNA for NAT-based assays • Anti-Müllerian hormone (human, recombinant) • Insulin (human) • HCT 15 cancer genome • MOLT-4 cancer genome • ATDB102 reference genome
Total	**13 biological reference preparations**	**44 biological reference preparations**

Note: TRS – Technical Report Series.

Annex 3

WHO guidance documents

Strategic objective of the Action Framework 2026–2030	WHO related guidance	Link (all accessed on 28 October 2025)
Strategic objective 1 Member States have implemented essential steps for establishing and operationalizing a continuously operating, appropriately structured, well-coordinated, well-governed and sustainably resourced national blood service and transfusion system	Aide-mémoire for national health policy makers: good policy processes for blood safety and availability	https://www.who.int/publications/i/item/WHO-EHT-08.02
	Blood safety and availability: WHO fact sheet	https://www.who.int/news-room/fact-sheets/detail/blood-safety-and-availability
	Aide-mémoire for ministries of health: developing a national blood system	https://www.who.int/publications/i/item/aide-mémoire-developing-a-national-blood-system
	Aide-mémoire for National Blood Programmes: Blood safety	https://www.who.int/publications/i/item/WHO-BCT-02.03
	Global Benchmarking Tool plus Blood (GBT+Blood)	https://www.who.int/tools/global-benchmarking-tools/VI
	Good practices for blood establishments	https://iris.who.int/handle/10665/382401
	WHO model for costing of blood products, 2025	https://iris.who.int/handle/10665/383247
	User guide for navigating resources on stepwise implementation of haemovigilance systems	English: https://www.who.int/publications/i/item/9789240047860 Chinese: https://iris.who.int/handle/10665/378432 French: https://iris.who.int/handle/10665/360060 Spanish https://iris.who.int/handle/10665/378434
	Guidance on increasing supply of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma	English: https://iris.who.int/handle/10665/340171 Spanish: https://iris.paho.org/handle/10665.2/56233
	Implementing cross-border transfer of domestic plasma to obtain plasma-derived medicinal products: policy guidance	https://iris.who.int/handle/10665/380192
	EML 2025	https://www.who.int/publications/i/item/B09474 https://www.who.int/news/item/05-09-2025-who-updates-list-of-essential-medicines-to-include-key-cancer--diabetes-treatments

Strategic objective of the Action Framework 2026–2030	WHO related guidance	Link (all accessed on 28 October 2025)
Strategic objective 2 An appropriate national regulatory framework is in place in Member States to ensure fully operational mechanisms of the necessary regulatory functions in order to enable an adequate supply of blood products, including PDMPs, that are safe, effective and meet quality standards	Guidance on centralization of blood donation testing and processing	English: https://iris.who.int/handle/10665/340182 Spanish: https://iris.paho.org/handle/10665.2/57421
	Guidance on increasing supply of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic	English: https://iris.who.int/handle/10665/340171 Spanish: https://iris.paho.org/handle/10665.2/56233
	Guidance to identify barriers in blood services using the blood system self-assessment (BSS) tool	English: https://iris.who.int/handle/10665/374355 The tool (English): https://www.who.int/publications/i/item/9789240082267 The tool (French): https://iris.who.int/handle/10665/378161 The Tool (Chinese): https://iris.who.int/handle/10665/378011
	Guidance on implementation of a quality system in blood establishments	English: https://iris.who.int/handle/10665/376096 French https://iris.who.int/handle/10665/376877 Spanish https://iris.who.int/handle/10665/376924 Chinese https://iris.who.int/handle/10665/376963
	Implementing cross-border transfer of domestic plasma to obtain plasma-derived medicinal products: policy guidance	https://iris.who.int/handle/10665/380192
	WHO model for costing of blood products, 2025	https://iris.who.int/handle/10665/383247
	Maintaining a safe and adequate blood supply and collecting convalescent plasma in the context of the COVID-19 pandemic: interim guidance, 17 February 2021	https://apps.who.int/iris/handle/10665/339793
	Guidance on ensuring a sufficient supply of safe blood and blood components during emergencies	English: https://iris.who.int/handle/10665/366870 Spanish: https://iris.who.int/handle/10665/378092 French: https://iris.who.int/handle/10665/378093 Chinese: https://iris.who.int/handle/10665/375165
Strategic objective 3 Affordability, availability, and accessibility of safe, effective and quality-assured blood products in Member States and acceptability of safe, effective and high-quality blood products assures timely patient access to needed blood and blood products	Guidance on increasing supplies of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma	English: https://iris.who.int/handle/10665/340171 Spanish: https://iris.paho.org/handle/10665.2/56233
	Improving access to safe blood products through local production and technology transfer in blood establishments, Phase II	https://iris.who.int/handle/10665/336863 https://iris.who.int/handle/10665/336753

Strategic objective of the Action Framework 2026–2030	WHO related guidance	Link (all accessed on 28 October 2025)
Strategic objective 4 Effective implementation of patient blood management to optimize clinical practice of transfusion	Screening donated blood for transfusion-transmissible infections: recommendations	https://apps.who.int/iris/handle/10665/44202
	Aide-mémoire for national blood programmes: the blood cold chain	https://www.who.int/publications/i/item/WHO-EHT-11.04#
	Protecting the blood supply during infectious disease outbreaks: guidance for national blood services	https://www.who.int/publications/i/item/9789241515214
	Therapeutics and COVID-19: living guideline	https://www.who.int/publications/i/item/B09540
Strategic objective 5 Effective surveillance, haemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection systems, evaluation, risk reduction and communication are implemented	WHO Educational modules on clinical use of blood	https://iris.who.int/handle/10665/350246
	A guide to establishing a national haemovigilance system	https://apps.who.int/iris/handle/10665/250233
	Establishing external quality assessment programmes for screening of donated blood for transfusion-transmissible infections: implementation guide	https://apps.who.int/iris/handle/10665/246169
	The urgent need to implement patient blood management: policy brief	English: https://iris.who.int/handle/10665/346655 Spanish: https://iris.who.int/handle/10665/361481 Chinese: https://iris.who.int/handle/10665/373154 French https://iris.who.int/handle/10665/380758 Portuguese: https://www.afro.who.int/pt/publications/necessidade-urgente-de-implementar-o-programa-de-gestao-do-sangue-do-paciente
	Guidance on implementing patient blood management to improve global blood health status	https://iris.who.int/handle/10665/380784
Strategic objective 6 Mechanisms for jointly addressing challenges and emerging threats to national blood systems at global, regional and national levels	Maintaining a safe and adequate blood supply during Zika virus outbreaks: interim guidance	https://apps.who.int/iris/handle/10665/204436
	Protecting the blood supply during infectious disease outbreaks: guidance for national blood services	https://apps.who.int/iris/handle/10665/311443
	Guidelines on estimation of residual risk of HIV, HBV or HCV infection via cellular blood components and plasma	https://apps.who.int/iris/handle/10665/255657
	Laboratory biosafety manual, 4th edition	https://www.who.int/publications/i/item/9789240011311
	Maintaining a safe and adequate blood supply and collecting convalescent plasma in the context of the COVID-19 pandemic: interim guidance	https://apps.who.int/iris/handle/10665/339793
	Guidance on ensuring a sufficient supply of safe blood and blood components during emergencies	English: https://iris.who.int/handle/10665/366870 Spanish: https://iris.who.int/handle/10665/378092 French: https://iris.who.int/handle/10665/378093 Chinese: https://iris.who.int/handle/10665/375165

Strategic objective of the Action Framework 2026–2030	WHO related guidance	Link (all accessed on 28 October 2025)
Strategic objective 7 WHO leadership, partnerships, collaboration, and information exchange to achieve key priorities and jointly address challenges and emerging threats at global, regional, and national levels.	Guide for staff on engagement with non-state actors, second edition	WHO-CRE-DAN-2023.2-eng.pdf
	Handbook for non-state actors on engagement with the World Health Organization, second edition	https://www.who.int/publications/i/item/9789240089303

World Health Organization
Department of Health Products Policy and Standards
20 avenue Appia
CH-1211 Geneva 27
Switzerland
bloodproducts@who.int
https://www.who.int/bloodproducts