

WHO Action Framework to Advance Universal Access to Safe, Effective and Quality-Assured Blood Products

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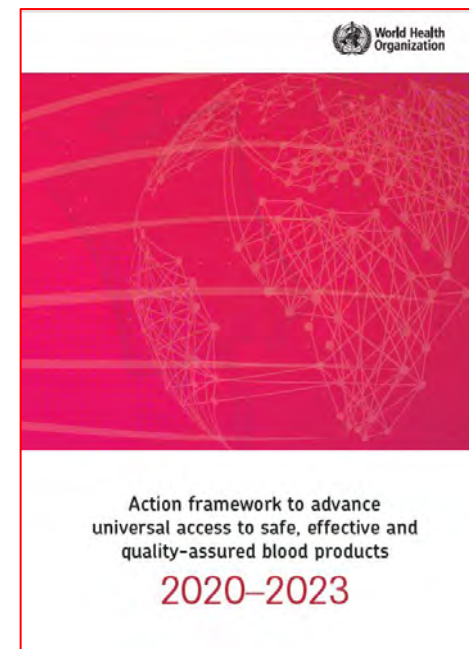
30 November 2024

OUTLINE

1. Introduction
2. Action Framework to Advance Universal Access to safe, effective and Quality Assured Blood Product 2020-2023
3. Implementation of the Action Framework
4. Global Benchmarking Tool for Blood
5. 2024-2025 Workplan
6. Closing

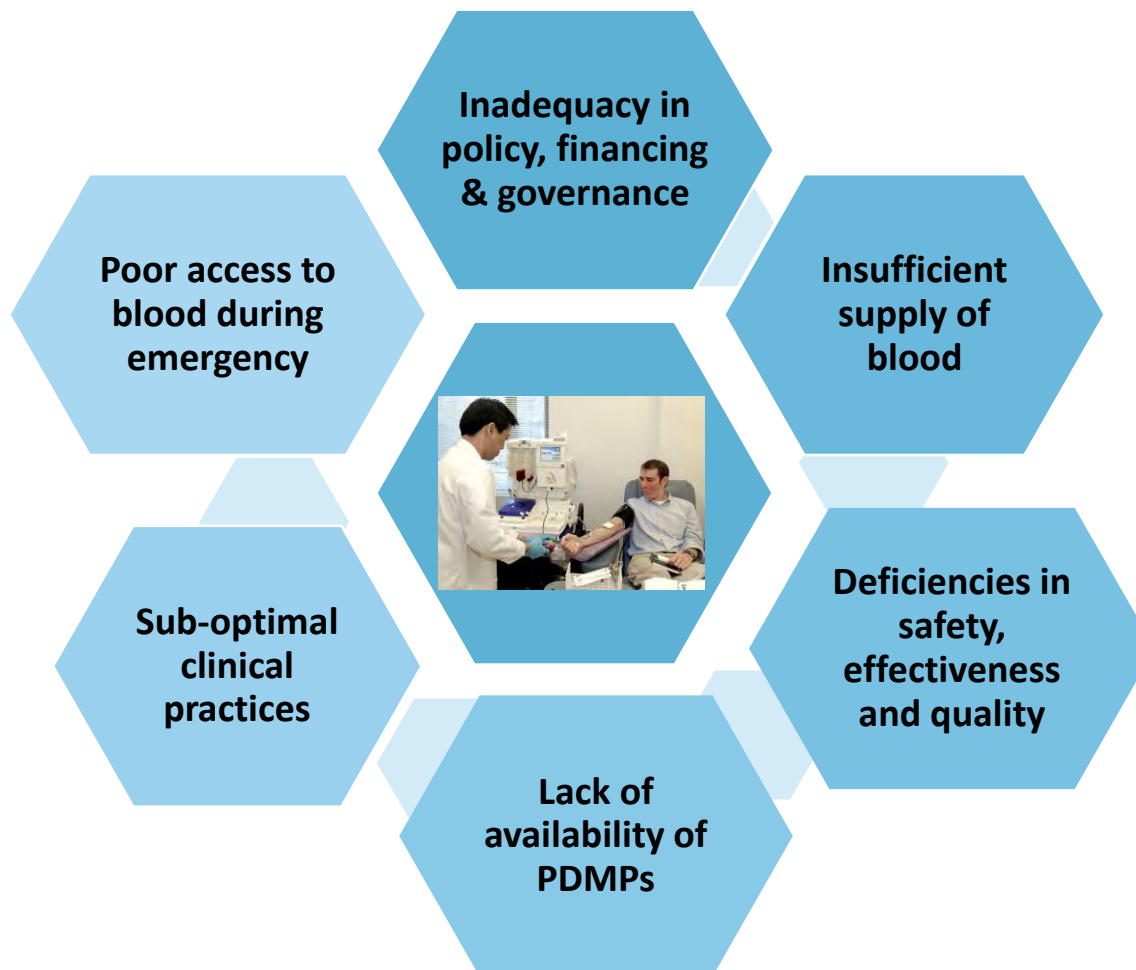
INTRODUCTION

- ❑ The Action Framework was launched on 27 February 2020
- ❑ **Strategic direction** to global efforts to address present barriers to safe blood
- ❑ Responds to **WHA 63.12 (2010)** on Availability, safety and quality of blood products that emphasized:
 - Achievement of 100% VNRD
 - Self-sufficiency of blood products
 - Implementation of good manufacturing practice
 - Put in practice clinical use of blood, patient blood management and hemovigilance
- ❑ There are six challenges on blood system faced by LMICs, identified through Global Database on Blood Safety (GDBS)



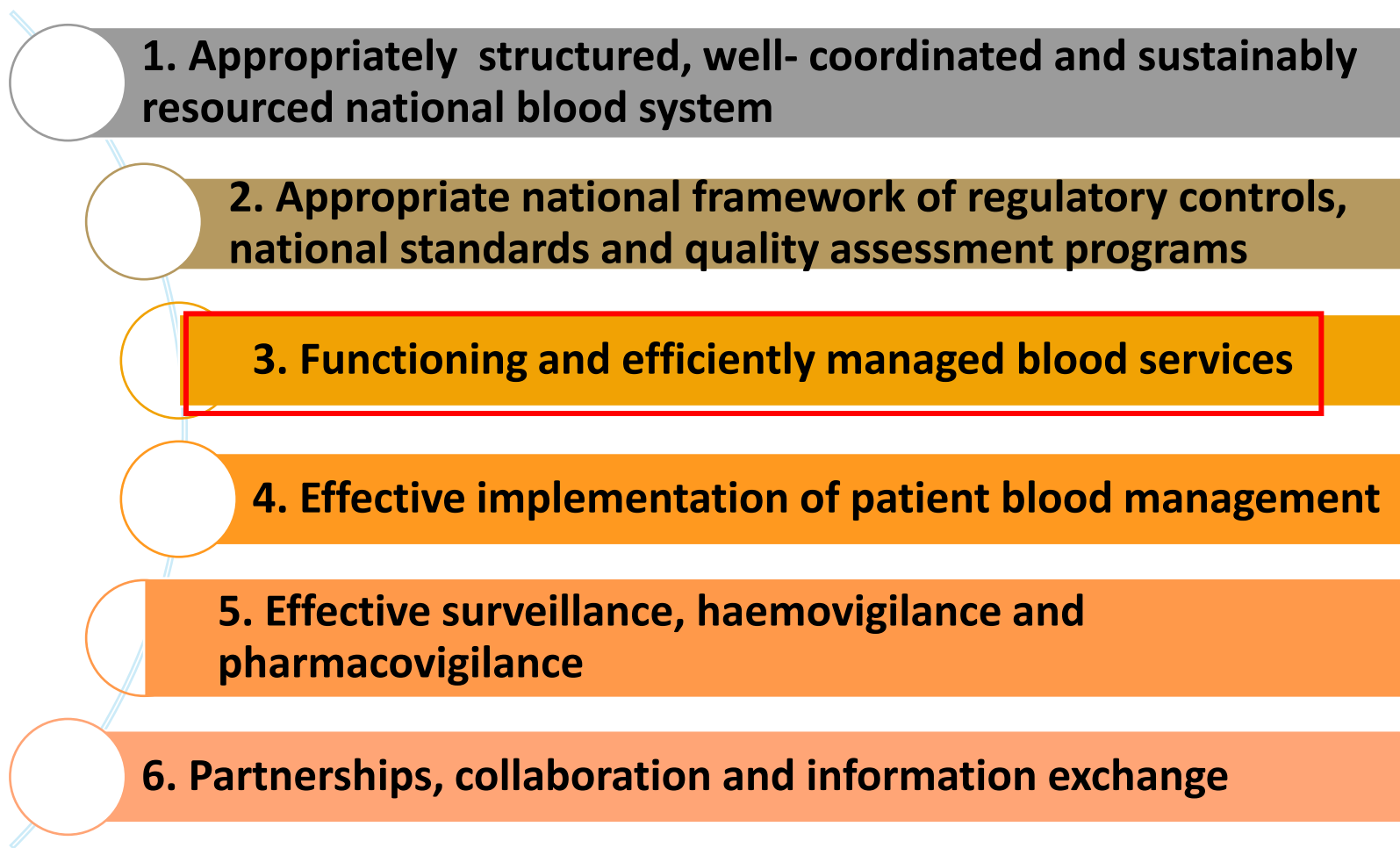
INTRODUCTION

GLOBAL CHALLENGES IN BLOOD SAFETY AND QUALITY



Source: Global Report on Blood Safety 2021, <https://apps.who.int/iris/handle/10665/356165>

Proposed Actions : 6 Strategic Objectives of the Action Framework



1. Appropriately structured, well- coordinated and sustainably resourced national blood system

2. Appropriate national framework of regulatory controls, national standards and quality assessment programs

3. Functioning and efficiently managed blood services

4. Effective implementation of patient blood management

5. Effective surveillance, haemovigilance and pharmacovigilance

6. Partnerships, collaboration and information exchange

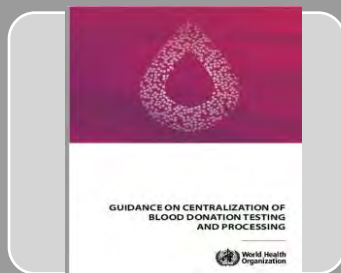
IMPLEMENTATION OF THE ACTION FRAMEWORK

- ❑ Development of WHO Guidance,
 - Inline with the function of the Blood and Other Products of Human Origin (BTT) Team, which is under the Health Products Policy and Standards (HPS) Department
 - Requested by the member states
 - In response to raised issues that require guidance
- ❑ Country Assistance
 - Information and Education Activities: Webinars, Workshops, Trainings
 - Onsite assessment
- ❑ Other achievements

Development of WHO Guidance

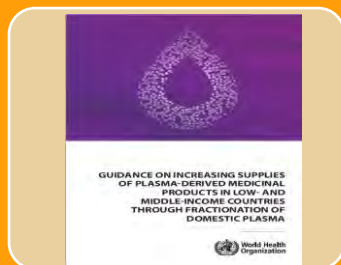
STRATEGIC OBJECTIVE	No	GUIDANCE NAME	IMPLEMENTATION			
			2020	2021	2022	2023-2024
Strategic Objective 1 Structured, well coordinated and sustainably resourced NBS	1	Guidance on costing of blood services New Costing Tool is ready, writing the manual is ongoing				X
	2	Guidance on ensuring safe blood supply during emergency situations			X	
Strategic Objective 2 Appropriate national framework of regulatory controls	3	Guidance on quality system for blood establishment				X
Strategic Objective 3 Functioning and efficiently managed blood services	4	Guidance on Centralization of blood donation testing and processing.	X			
	5	Guidance on increasing supply of plasma-derived medicinal products (PDMPs) in LMICs through fractionation of domestic plasma	X			
	6	Guidance to identified barriers in blood services using self-assessment tool				X
Strategic objective 4 Effective implementation of patient blood management to optimized clinical practice of transfusion	7	Education Module on Update clinical use of blood		X		
	8	Policy Brief: the urgent need to implement Patient Blood Management		X		
	9	Guidance to implement PBM The draft document is on WHO formatting			X	X
Strategic objective 5 Effective surveillance, HV, and pharmacovigilance	10	User Guide for navigating resources on Stepwise implementation of Haemovigilance Systems		X	X	

LINK TO PUBLICATIONS



Guidance on Centralization of blood donation testing and processing, 2021

- English: <https://iris.who.int/handle/10665/340182>
- Spanish: <https://iris.paho.org/handle/10665.2/57421>
- Chinese: Published by Shanghai Blood Centre



Guidance on increasing supply of plasma-derived medicinal products (PDMPs) in LMICs through fractionation of domestic plasma, 2021

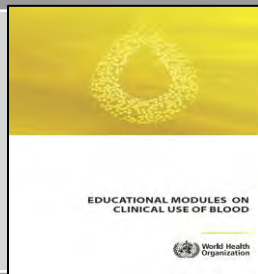
- English: <https://iris.who.int/handle/10665/340171>
- Spanish : <https://iris.paho.org/handle/10665.2/56233>
- Chinese: Published by Shanghai Blood Centre



Policy Brief: The Urgent Need to Implement Patient Blood Management (2021)

- English:: <https://iris.who.int/handle/10665/346655>
- Spanish:: <https://iris.who.int/handle/10665/361481>
- Chinese: <https://iris.who.int/handle/10665/373154>

LINK TO PUBLICATIONS



Educational modules on the clinical use of blood, 2021

- English: <https://iris.who.int/handle/10665/350246>



User Guide for navigating resources on Stepwise implementation of Hemovigilance Systems, 2022

- English:: <https://iris.who.int/handle/10665/360060>
- 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 ensuring a sufficient supply of safe blood and blood components during emergencies, 2023

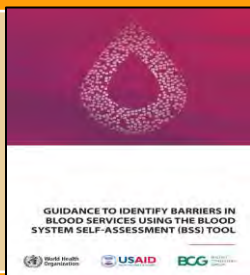
- English:: <https://iris.who.int/handle/10665/366870>
- Spanish:: <https://iris.who.int/handle/10665/378092>
- French: <https://iris.who.int/handle/10665/378093>
- Chinese: <https://iris.who.int/handle/10665/375165>

LINK TO PUBLICATIONS



Guidance on the implementation of a quality system in blood establishments, 2023

- 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>



Guidance to identify barriers in blood services using the blood system self-assessment (BSS) Tool and the BSS Tool, 2023

- English: <https://iris.who.int/handle/10665/374355>

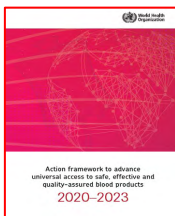


The Blood System Self-Assessment (BSS) Tool, 2023

- English: <https://iris.who.int/handle/10665/374183>
- French: <https://iris.who.int/handle/10665/378161>
- Chinese: <https://iris.who.int/handle/10665/378011>

Implementation of the Action Framework for blood products

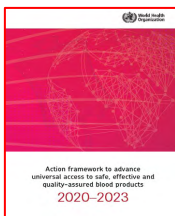
Dissemination of Guidance 2020-2024



STRATEGIC OBJECTIVE	No	WEBNARS/WORKSHOPS	Conducted in				2024
			2020	2021	2022	2023	
Strategic Objective 2 Appropriate national framework of regulatory controls	1	Webinar on “Strengthening Blood Systems Through Effective Blood Regulation”	Aug				Nov
	2	Webinar on Introduction to the Global Benchmarking Tool (GBT) + blood		Apr			
	3	WHO GBT Plus Blood Regional Self-benchmarking Workshop		Jul			
Strategic Objective 3 Functioning and efficiently managed blood services	4	Webinar on Maintaining blood supply during the COVID-19 pandemic:	May				
	5	Webinar on The collection of COVID-19 convalescent plasma: WHO Interim Guidance	Jul				
	6	Webinar on Use of WHO IRR for IVDs and production of secondary standards		Feb			
	7	Webinar on Guidance on Centralization of Blood testing and Processing; and on Increasing access to PDMPs in LMICs through fractionation domestic plasma		May			
	8	Webinar on Building Effective National Blood Donor Program to Ensure Safe and Secure Blood Supplies			Jun		
	9	Workshop on GMP for Blood Establishment in French				Jun	

Implementation of the Action Framework for blood products

Dissemination of Guidance 2020-2024



STRATEGIC OBJECTIVE	No	WEBINARS/WORKSHOPS	Conducted in				2024
			2020	2021	2022	2023	
Strategic Objective 3 Functioning and efficiently managed blood services	10	Webinar on Blood System Self-Assessment (BSS) Tool					X
	11	Webinar to introduce recent guidance					X
Strategic objective 4 Effective implementation of patient blood management to optimized clinical practice of transfusion	12	Webinar on Educational Module on CUB; and Policy Brief on Patient Blood Management (PBM)			Jul		
Strategic objective 5 Effective surveillance, HV, and pharmacovigilance	13	Webinar on Haemovigilance (Zambia and Burundi)	Oct				
	14	Webinar on Haemovigilance (Eswatini and Mauritius)		Nov			
	15	Webinar on Strengthening Data and Information Management for Blood and Capacity to Report to GDBS in Member States			Aug		

Note: The WHO also actively disseminated the guidance during the webinar, workshop, and congress organized by stakeholders

IMPLEMENTATION OF THE ACTION FRAMEWORK FOR BLOOD PRODUCTS

COUNTRY ASSISTANCE

Revived Achilles Project

- Aims to assist country in improving safety and quality of blood and plasma, in an effort to increase access to blood products
- Activities: Situational assessment, assisting on improving blood regulatory framework through implementation of GBT Plus Blood; and technical aspect, through implementation of GMP for Blood Establishment
- Stepwise access to plasma-derived medicinal products through local production of Pathogen-Reduced blood products, contract fractionation and local fractionation

Implementation of the Action Framework for blood products

Country Assistance 2020-2024



STRATEGIC OBJECTIVE	No	WEBNARS/WORKSHOPS	Conducted in				
			2020	2021	2022	2023	2024
Strategic Objective 2 Appropriate national framework of regulatory controls	1	WHO Assisted Self-Benchmarking for Blood Regulatory System using GBT Plus Blood for Serbia					X
Strategic Objective 3 Functioning and efficiently managed blood services	2	Pathogen-Reduced (PR) Cryoprecipitate production in Dakar NBC-Senegal (Situational analysis, training on Blood Regulation and GMP, and training on using VIPS in Egypt)			X	X	X
	3	Contract Plasma Fractionation (CPF) in Indonesia (Workshops on Centralization of blood donation testing and processing (January 2022); and QC on PDMPs (June 2022); and workshop on Plasma Master File			X	X	X
	4	PR Immunoglobulin production in Ethiopia NBC (Situational analysis Workshop on GMP, Self-Assessment using Blood System Self-Assessment (BSS) Tool and Webinar on Blood Regulation					X

GLOBAL BENCHMARKING TOOL (GBT) FOR BLOOD



<https://www.who.int/tools/global-benchmarking-tools/VI-plus-blood>

❑ It is a tool for National Regulatory Authority to evaluate 10 functions:

- | | |
|-------------------------------------|---|
| 1. National Regulatory System, | 6. Regulatory Inspection, |
| 2. Marketing Authorization, | 7 Laboratory Testing, |
| 3. Vigilance, | 8. Clinical Trials Oversight, |
| 4. Market Surveillance and Control, | 9. Lot Release, and |
| 5. Licensing Establishment, | 10. Approval of blood and blood components including plasma for fractionation |

❑ Expectation: at least Maturity Level 3 – Regulatory framework is functioning and stable

OTHER ACHIEVEMENT

Develop the Advisory Group for Blood Regulation, Availability, and Safety (AG BRAS) in 2022, which has proposed:

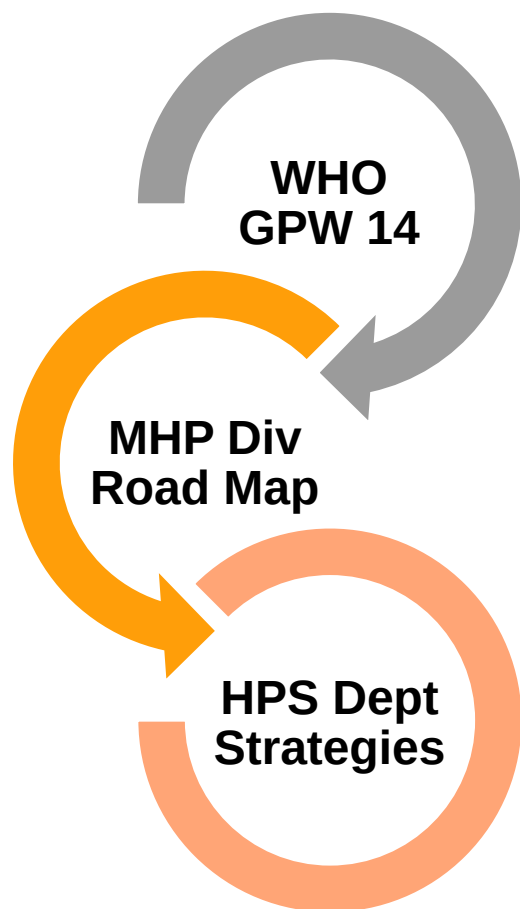
- Harmonization of terminology on blood donor and donation
- WHO Disaster Assessment Kit
- Strategies to disseminate WHO Publications
- Updating WHO Guidance on GMP

As member of the Steering Committee of the International Coalition for Safe Plasma Protein Products (ICSPP) led by ISBT Working Party on Global Blood Safety

WHO Assisted Self-Benchmarking for Blood Regulatory System using GBT Plus Blood for Serbia

WAY FORWARDWAY FORWARD

To update the Action Framework on Blood Product 2020-2023, align it with



- SO: Provide advance PHC approach and essential health system capacities for UHC
- Outcome: Access to quality assured health products substantially improved

- Ensure safe, effective and quality-assured health products and technologies
- Improve affordability, availability, accessibility and acceptability for health products and technologies

- Improve access to safe, effective, quality health products;
- Provides authoritative guidance and standards on quality, safety, and efficacy of health products; and
- Supports countries to formulate evidence-based policies and ensure good practice throughout the value chain

WAY FORWARD

ACTIVITIES

1. Development of Global Norms and Standards on Blood
2. Country supports in implementing the guidance
3. Strengthening partnership and collaboration:
 - Strengthening collaboration within WHO on assisting MS to improve their blood regulation and local production; and on procurement of blood during emergency
 - Strengthening collaboration with Stakeholders to disseminate and assist MSs to utilize the Guidance (e.g. under the Achilles Project)

EXPECTATION FROM THE COUNTRY



- ❑ Increase awareness among governments and blood establishments (BEs) to enhance the quality and safety of blood products by:
 - Includes blood products in the national formulary of essential medicines
 - Strengthening the regulatory framework
 - Providing resources to improve technical capabilities
- ❑ Establish a strategy to implement the WHO Guidance
- ❑ Utilize plasma for manufacturing PDMPs

CLOSING

The WHO Action Framework for Blood Products, a strategic guide to global efforts to address barriers to safe blood – now need to be updated to align it with the GPW 14, MHP Roadmap and HPS Strategies

Continue to develop norms and standards for blood

Assist Member States in the improvement of the blood regulatory framework through GBT Plus Blood

Assis Member States in the improvement of technical aspects of blood services through implementation of GMP standards under the Achilles Project



THANK YOU