

Implementation of WHA 63.12 on Availability, Safety and Quality of Blood Products



Member States Information Session

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AGENDA

INTRODUCTION

BLOOD RELATED RESOLUTIONS

CHRONIC CHALLENGES IN BLOOD SYSTEM

ACTIVITIES AND ACHIEVEMENTS IN IMPLEMENTING THE WHA 63.12

WAY FORWARD

Introduction

- Blood transfusion is a key part of modern health care
- Insufficient or unsafe blood supply impact on the effectiveness of key health services to provide appropriate patient care
- Similarly, Plasma Derived Medicinal Products (PDMs) are critical in the prevention and treatment of major morbidities associated with inherited and acquired medical disorders
- Assuring the quality and safety of blood and blood products has been recognized in three key World Health Assembly (WHA) resolutions

Blood Related Resolutions

**WHA
28.72
(1975)**

- **Utilization and supply of human blood and blood products**
- Noting the extensive and increasing activities of commercial blood collection and plasmapheresis projects → urges MS to implement well organized, coordinated and sustainable blood program

**WHA
58.13
(2005)**

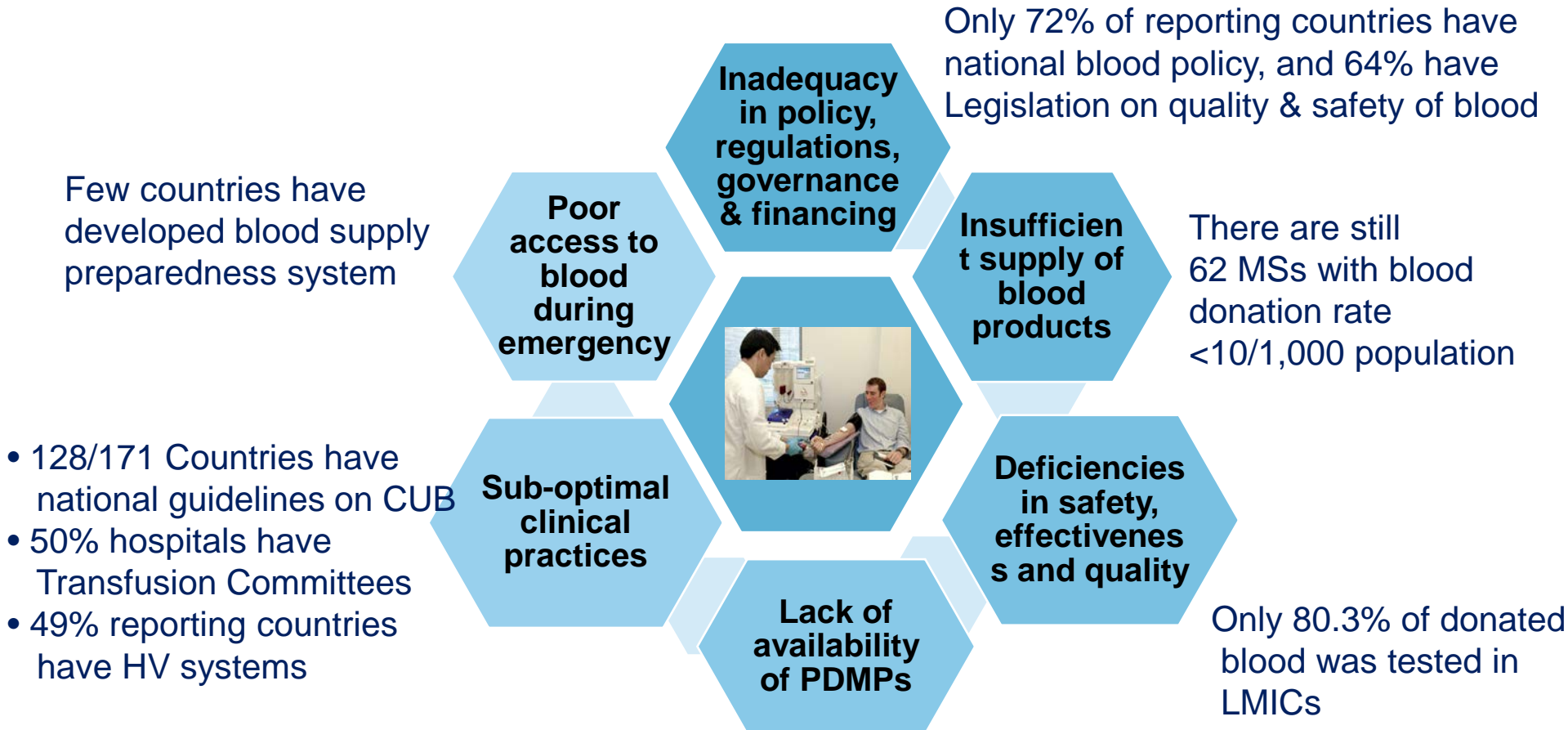
- **Blood safety: Proposal to establish World Blood Donor Day**
- Recognizing that voluntary, non-remunerated blood donation is the cornerstone of a safe and adequate national blood supply → Agree to establish WBDD on June 14

**WHA
63.12
(2010)**

- **Availability, safety and quality of blood products**
- Concerns on unequal access globally to blood products → urges MS to achieve self-sufficiency of safe blood, blood components and plasma-derived medicinal products

GDBS 2015-2018: Chronic challenges in Blood System

<https://www.who.int/news-room/fact-sheets/detail/blood-safety-and-availability>



Activities and Achievements in implementing the WHA 63.12 (through responding the challenges)

1. Responses to challenge in inadequacy in policy, regulations, governance & financing



Global Level

- 2011: Aide Mémoire for Ministry of Health on Development a National Blood System
- 2011: Guidelines on Good Manufacturing Practices for blood establishments
- 2012: A technical report on Assessment criteria for national blood regulatory systems
- 2013: Add blood and blood components into WHO Model List of Essential Medicines
- 2019: Support the development of African Blood Regulator Forum
- 2020: Global Benchmarking Tools Plus Blood
- Assessment of regulatory systems in three countries and building the capacity of authorities and transfusion services in 18 countries in the African Region

Regional/Country level

- Organized workshops bringing together national regulatory authorities and national blood services.
- Review the Tanzania Food, Drugs and Cosmetics (Control of Blood and Blood Products) Regulations
- WHO regional office for the Eastern Mediterranean (EMRO):
 - Reviewed existing legislative instruments for blood systems
 - Developed a template of legislation by country across the Region
- WHO regional office for South-East Asia (SEARO):
 - Conducted a desk review of regulatory systems for blood and blood products

2. Responses to challenge in insufficient supply of blood products

Global Level

- 2011: WHO issued an expert consensus statement on national self-sufficiency in blood and blood products based on voluntary non-remunerated blood donation
- 2012: Guideline on blood donor selection
- 2014: Guideline on blood donor counselling
- Training materials on blood donor management
- World Blood Donor Day is celebrated in a growing number of countries in all regions

Regional/Country level

- EMRO:
 - Regional and national training
 - Endorsed the regional strategic framework for blood safety and availability (2016–2025)
- The Regional Committee for the Americas approved the Plan of Action for Universal Access to Safe Blood (2014–2019)

3. Responses to challenge in deficiencies in safety, effectiveness and quality



Global Level

- 2009: Aide Memoire on Quality and safety on blood products and related substances
- 2016: Guidance on establishing external quality assessment programmes for screening donated blood for transfusion-transmissible infections
- Development and promotion of WHO reference standards for blood products and related in vitro diagnostic devices
- Guidance on the estimation of residual risk in blood components for transmissible viruses
- Conducted training on Quality Management System for all countries

Regional/Country level

- SEARO:
 - conducted a web series on quality assurance in transfusion-transmissible infections testing and immunohematology

4. Responses to challenge on Lack of availability of Plasma-Derived Medicinal Products



Global Level

- 2013: Achilles Project in South Africa and Indonesia: a Project to assist country in improving quality of plasma for fractionation

Regional/Country level

- WHO regional offices for Africa (AFRO), the Americas (AMRO), the Eastern Mediterranean (EMRO), South-East Asia (SEARO):
 - Enhancing local production of good-quality plasma from whole blood donations in low- and middle-income countries

5. Responses to challenge in sub-optimal clinical practices



Global Level

- 2010: aide-mémoire on clinical transfusion process and patient safety
- 2016: Guidance on establishing national haemovigilance systems
- 2021: Educational modules on clinical use of blood and a Policy Brief on the urgent need to implement patient blood management

Regional/Country level

- Conducted several multi-country consultations and workshops on appropriate use of blood
- Interregional consultation on strengthening the role of nurses and midwives in ensuring safe clinical transfusion and patient safety
- AMRO developed the Ibero-American haemovigilance manual
- Supporting the development and implementation of haemovigilance system in Algeria, Bhutan, Burundi, Eswatini, Mauritius, Pakistan and Zambia

5. Responses to challenge in poor access to blood during emergency



Global Level

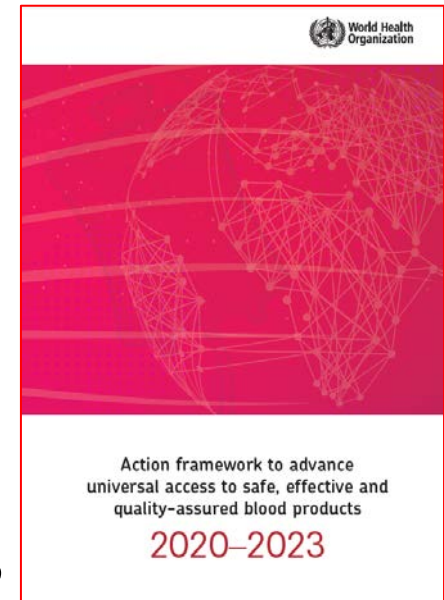
- Guidance to ensure adequate blood supply in emergency situations (pandemic of influenza and Zika)
- Interim Guidance in maintaining safe blood supply during COVID-19 pandemic

Regional/Country level

- AFRO, EMRO, SEARO: Assessments of impact of the COVID-19 pandemic on blood supplies and transfusion services

6. Development and implementation a comprehensive action framework, February 2020

- ✓ Part of WHO response to **WHA 63.12 (2010)** on Availability, safety and quality of blood products
- ✓ Aligns with **13th WHO GPW** and **Strategic Plan** for Regulatory Support Activities for Health Products 2019-2023
- ✓ Serves as **strategic direction** to global efforts to address present barriers to safe blood



<https://www.who.int/bloodproducts/en/>

Six Strategic Objectives



1. **Appropriately structured, well- coordinated and sustainably resourced national blood system (NBS)** through adequate leadership and governance of the NBS
2. **Appropriate national framework of regulatory controls** to regulate and assess blood products and associated medical devices, including IVDs
3. **Functioning and efficiently managed blood services** to ensure efficient safe and quality blood, blood components and plasma derived medicinal products
4. **Effective implementation of patient blood management to optimize clinical practice of transfusion** which improve patient outcomes and patient safety
5. **Effective surveillance, haemovigilance and pharmacovigilance** to monitor and assess the blood system, including adverse reactions in donors and patients
6. **Partnerships, collaboration and information exchange** to achieve key priorities

Implementation of the Action Framework 2020-2021



Development of Written Norms and Standard

1. Guidance on Centralization of blood donation testing and processing
2. Guidance on increasing supply of plasma-derived medicinal products (PDMPs) in LMICs through fractionation of domestic plasma
3. Education Module on Update clinical use of blood
4. Policy Brief: the urgent need to implement Patient Blood Management
5. User Guide for navigating resources on Stepwise implementation of Haemovigilance Systems
6. Guidance on ensuring adequate and safe blood supply during emergency situations

Implementation of the Action Framework 2020-2021

Country Assistance (by WHO headquarters, Regional Offices and Country Offices)



Webinars

1. Maintaining a safe and adequate blood supply and collecting convalescent plasma in the context of the COVID-19 pandemic
2. Collection of Covid-19 Convalescent Plasma
3. Strengthening blood system through effective blood regulation
4. Centralization of blood donation testing and processing
5. Voluntary blood donation (in collaboration with the Italian National Blood Centre)
6. Stepwise access to safe plasma protein in resourced-constrained countries (in collaboration with the International Society of Blood Transfusion)
7. Global Benchmarking Tools for blood

Country assistance

1. Training on Self-assessment using the Global Benchmarking Tools for Blood
2. AFRO: Training on Hemovigilance systems
3. SEARO:
 - Training on Quality assurance in transfusion transmitted infections testing; Blood component separation and fractionation
 - Quality assurance in immunohematology testing
4. EMRO: Assisting Egypt to set up plasma fractionation program
5. AMRO: Promotion of voluntary blood donation
6. WHO headquarters, AFRO in partnership with the International Coalition run a Revive Achilles Project
 - For Dakar-Senegal: on Local preparation of pathogen-reduced cryoprecipitate

Partnership, Collaboration and information exchange



- ❑ **Advisory Group for Blood Regulation Availability and Safety (AG-BRAS)**, functions to support program and activities in blood regulation and transfusion medicine. Members from 6 WHO regions

- ❑ **Non-State Actors in official relationship with WHO for Blood Program:**
 - ISBT (International Society of Blood Transfusion)
 - ISTH (International Society of Thrombosis and Haemostasis)
 - ICCBBA (International Council for Commonality in Blood Banking Automation)

- ❑ **Collaborating Centres:**
 - Paul-Ehrlich-Institute, Germany
 - Health Science Authority, Singapore
 - Korean Red Cross, The Republic of Korea
 - Shanghai Blood Centre, People's Republic of China
 - Établissement Français du Sang, France
 - WHO CCs under WHO regional offices

- ❑ Collaboration and information exchange with other **international, regional blood related institutions or organizations** (e.g., USAID, AABB, IPFA, PPTA, FIODS, WFH, IPOPI, etc)

Way forward

- **Increase support for country to implement the action framework**
 - Training and implementation of Good Manufacturing Practices (GMP) and self-assessment of blood regulatory using the Global Benchmarking Tools for Blood
 - Development and implementation of tools to identify challenges and possible solutions of blood services
 - Expansion of a Revive Achilles project to other countries
 - Twinning program: assistance from experienced country on certain aspect (e.g., GMP, Centralization of testing and processing, blood component preparation, stepwise implementation of plasma fractionation, etc)

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Thank you