WHO ACTION FRAMEWORK TO ADVANCE UNIVERSAL ACCESS TO SAFE, EFFECTIVE AND QUALITY ASSURED BLOOD PRODUCTS 2020-2023

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• Introduction
• Global challenges in Blood Services – WHO Action Framework to advance access to safe, effective and quality assured blood products: 2020-2023
• Aims, Strategic Objectives and Outcomes of the Action Framework
• Implementation
INTRODUCTION

- Blood and blood components are critical for:
  - Treatment of bleeding due to birth delivery, severe injuries, and surgical procedures
  - Managing life-threatening conditions, e.g. hemophilia, thalassemia, immune deficiency and cancer

- Plasma Derived-Medicinal Products (PDMPs):
  - Albumin, Blood Coagulation Factors, Immunoglobulins, etc. are important for managing certain medical conditions

- WHA 63.12, 2010, urges Member States to achieve self sufficiency in blood, blood component and PDMPs
GDBS 2015
Challenges in Blood Services

- Inadequacy in policy, regulations, governance & financing
- Insufficient supply of blood products
- Deficiencies in safety, effectiveness and quality
- Lack of availability of PDMPs
- Limited use of blood component → low volume of plasma for fractionation
- Poor access to blood during emergency
- Sub-optimal clinical practices
- Only 60-70% MSs with blood policy, legislation, oversight system
- Insufficient supply of blood products
- There are still 66 MSs with blood donation rate <10/1,000 population
- Only 80% of donated blood was tested in LMICs
- No blood supply preparedness system
- CUB, HV system and Patient Blood Management are not implemented
WHO Responses

- WHO Guidelines
- WHO Aides Memoires
- Information sheets, general documents on strategies & plans
- Training materials
- Workshops, training programs, site visits, etc

Milestones:

- **WHA 28.72 (1975)** on utilization & supply of human blood and blood products
- **WHA 58.13 (2005)** on designation of 14 June as World Blood Donor Day
- **WHA 63.12 (2010)** on availability, safety and quality of blood products
- **2013**: inclusion of whole blood, red blood cells, platelets and fresh frozen plasma in WHO Model List of Essential Medicines
- **2018**: International Conference of Drug Regulatory Authorities (ICDRA) call for strengthening haemovigilance systems to monitor the safety of blood donation and blood transfusion
Countries that implement WHO Resolutions and guidance documents on blood (mostly developed countries) are making progress in providing safe blood and blood products.

- BUT...

Progress in establishing and strengthening national blood systems has been slow in many countries.

Need to push for implementation of WHO guidance at country level - particularly in low and middle-income countries (LMICs).
Aims of the action framework

- **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
- Aligns with **13th WHO GPW** and **Strategic Plan** for Regulatory Support Activities for Health Products 2019-2023
- **Implementation** of resolutions, goals & strategies
- To be used for **partnership and fundraising**

[Link to the AF Doc: https://www.who.int/bloodproducts/en/](https://www.who.int/bloodproducts/en/)
PROPOSED ACTIONS:
6 STRATEGIC OBJECTIVES

1. Appropriately structured, well-coordinated and sustainably resourced national blood system (NBS)
2. Appropriate national framework of regulatory controls
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
OUTCOMES OF STRATEGIC OBJECTIVE 1:

SO1: Appropriately structured, well-coordinated and sustainably resourced National Blood System (NBS)

- Adequate and safe blood supply during emergency situations
- NBS is integrated into the national health system
- National policies and decisions are made through good policy process and risk-based decision making
- NBS is adequately and sustainably costed, financed and budgeted
OUTCOMES OF STRATEGIC OBJECTIVE 2:

- **SO2:** Appropriate national framework of regulatory controls
  - National Blood Regulatory System is in place in Maturity Level 3
  - Regulatory mechanisms are in place to oversight blood, substance & IVDs
  - Performance of blood, substance & IVD is assured through use of IS
  - Quality assessment is carried out for blood, substance & IVDs

Blood regulatory system is stable, well functioned and integrated into health regulatory system.
OUTCOME STRATEGIC OBJECTIVE 3:

SO3: Functioning and efficiently managed blood services

- Availability of the volume and quality of plasma for PDMPs is increased
- Blood services are efficiently and cost-effectively managed
- A functioning quality system is in place
- Achievement of 100% VNRD, protection of donor, and promotion of repeat donation
OUTCOME STRATEGIC OBJECTIVE 4:

SO4: Effective implementation of Patient Blood Management (PBM)

- Good PBM is practiced, based on national clinical guidelines and practice standards
- A quality system is in place in hospitals for all pre-transfusion testing
OUTCOME OF STRATEGIC OBJECTIVE 5:

**SO5:**
Effective surveillance, haemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection systems

- A national system for standardized data collection reporting, and mechanisms is in place
- WHO GDBS provides comprehensive & accurate data on global status of blood availability, safety & quality
- Systems for traceability, surveillance, haemovigilance & pharmacovigilance are in place
OUTCOMES OF STRATEGIC OBJECTIVE 6:

- Training programmes on key functions of NBS are in place
- Capacity for external assessments & accreditations of BE is available
- Regulatory capacity is strengthened through collaborative capability building
- Capacity to evaluate relevant new technologies and other innovations are incorporated into the national blood system

SO6: Partnerships, collaboration and information exchange to achieve key priorities
## PROGRESS IN IMPLEMENTATION OF THE ACTION FRAMEWORK: DEVELOPMENT OF GUIDANCE DOCUMENTS

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<th>IMPLEMENTATION</th>
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<td><strong>Strategic Objective 1</strong></td>
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<tr>
<td>Structured, well coordinated and sustainably resourced NBS</td>
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<td>Guidance on costing of blood services</td>
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<td><strong>Strategic Objective 2</strong></td>
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<td>Appropriate national framework of regulatory controls</td>
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<td>Guidance on quality assessment of blood products and associated substances and medical devices, including IVD devices.</td>
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<tr>
<td><strong>Strategic Objective 3</strong></td>
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<td>Functioning and efficiently managed blood services</td>
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<td>Guidance on Centralization of blood donation testing and processing.</td>
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<td>Guidance on increasing supply of plasma-derived medicinal products (PDMPs) in LMICs through fractionation of domestic plasma</td>
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<td>Effective implementation of patient blood management</td>
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<td>Education Module on Update clinical use of blood.</td>
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<td><strong>Policy Brief</strong> and Guideline on Implementation of Patient Blood Management</td>
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<td>Effective surveillance, HV, and pharmacovigilance</td>
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<td>Tools to stepwise implementation of Hemovigilance System</td>
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Published: ICRDA 2021
PROGRESS IN IMPLEMENTATION OF THE ACTION FRAMEWORK: Technical assistance to Member States

- Conducted by three WHO levels of 6 Regions:
  - Webinars (some were recorded and translated into WHO languages)
    - Strengthening Blood Systems through Effective Blood Regulation
    - Haemovigilance System
    - Voluntary Non Remunerated Donation
    - Self assessment using the GBT Plus Blood
  - Country Assistance
    - Assist Egypt on improvement of plasma quality for fractionation
Training on Self Assessment using the GBT + Blood: 26-30 July 2021

- Attended by 9 Countries: Botswana, Egypt, Ghana, Indonesia, Iran, Kenya, Mozambique, Namibia, Zambia

Common challenges:

- No clear Regulatory authorities incharge on blood
- Blood and blood components have not been included into National List of Essential Medicines
- NRA Lot release of blood products
- Approval of blood and blood components (products & processes approval)
- Regulatory oversight of associated substances and medical devices including IVDs
BLOOD ACTIVITIES RELATED TO COVID-19

- Communication and coordination with RAs, BRN, EAP on TM, ISBT, EU, ECDC, EDQM → development of IG (March 2020); 1st Update (July 2020) & 2nd Update (February 2021)
  - WHO strongly recommends limiting use of CCP to RCTs; if it is infeasible, structured observational studies can be considered
  - Where clinical studies are not possible, patient outcomes should be documented and blood samples from donors and recipients archived for future characterization
  - CCP can be made available on an experimental basis through local production provided that medical, legal and ethical safeguards are in place both for the CCP donors and the patients who receive it.
  - Temporary donor deferral after COVID-19 vaccination

- Webinars
  - May 2020: promotion of the 1st Interim Guidance,
  - July 2020: promotion of guidance on collection and use of CCP,

https://apps.who.int/iris/handle/10665/339793
THANK YOU
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