

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



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“Together for a healthier world”

Dr Tedros Adhanom Ghebreyesus



Key Themes of WHO's 13th General Programme of Work 2019-2023

Mission

Promote Health - Keep the World Safe - Serve the Vulnerable

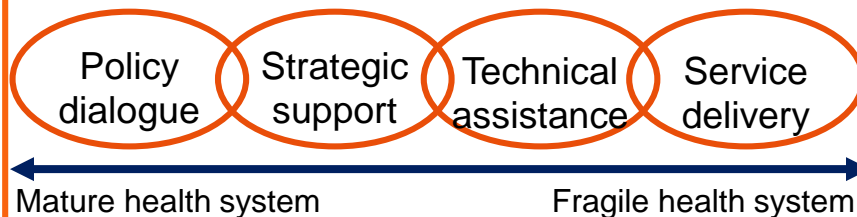
Strategic Priorities

Health Coverage: 1 billion more people with health coverage
Health Emergencies: 1 billion more people made safer
Health Priorities: 1 billion lives improved

Strategic Shifts

Set up global leadership

Drive impact in every country



Focus global public goods on impact



- **Background: Challenges –**
Why WHO Action Framework is needed
- **Aims of the Action Framework**
- **Strategic Objectives and their outcomes**
- **Next steps**



Background: Blood transfusion & blood products

- Critical for:
 - birth delivery for both the mother and baby
 - life-threatening conditions e.g. haemophilia, thalassemia, immune deficiency and cancer
 - severe injuries
 - medical and surgical procedures
- Plasma Derived-Medicinal Products (PDMPs)
 - Albumin: Protein/volume replacement
 - Blood Coagulation Factors
 - Immunoglobulins
 - ...



Challenges: data from WHO Global Database on Blood Safety (GDBS)



Inadequacy in policy, regulations, governance & financing

- ❑ **71-77%** MSs with blood policy / reg. oversight
- ❑ **60%** MSs with specific legislation
- ❑ **Most MSs unable** to collect or review information on costs of blood

Insufficient supply of blood products

- ❑ **66 MSs** with donation rate < 10 per 1,000
- ❑ **LMICs** 30% of global blood donations **vs 50%** population
- ❑ Donor recruitment, cultural resistance, education, logistics

Deficiencies in safety, effectiveness and quality

- ❑ Blood donations from low-risk donors & adequate testing; donated blood only **80%** tested in LMICs
- ❑ Public education
- ❑ Epidemiologic monitoring for TTIs
- ❑ Pre-donation screening & risk assessment of donors

Challenges: data from WHO Global Database on Blood Safety (GDBS)



Lack of availability of PDMPs

- ❑ Limited **use** of components to recover plasma
- ❑ Failure to meet global **standards** for blood collection, blood component preparation & cold chain
- ❑ High cost and complexity of **apheresis**



Sub-optimal clinical practices

- ❑ Limited **training** in transfusion medicine and Patient Blood Management (**PBM**)
- ❑ Absence of national **guidelines** for transfusion
- ❑ Absence of transfusion **committees** in hospitals

Poor access to blood during emergency

- ❑ **Containment** or civil and healthcare **infrastructures** disrupting mobility, transportation and service provision
- ❑ Means of **communication** may not be reliable
- ❑ Overall healthcare **system** may become overburdened

Wastage of plasma (data per year)

GDBS 2011:

- ❑ 21.6 million litres plasma could be recovered from WB collection:
 - ❑ 4.2 million litres are **transfused**
 - ❑ 8.1 million units are sent for **fractionation**
 - ❑ 9.3 million litres are **discarded** annually (~ 40% of the world resources) → USD 650 to 1020 million



Unethical and waste of valuable human resources

WHO Responses

WHA Resolutions

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

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**By donating blood,
you can save lives!**



Everyone should have access to safe blood
transfusions, when and where they need them.



Safe Blood For All

World Blood Donor Day
SEPTEMBER 14, 2024



Why this Action Framework is needed ?

- ❑ Countries that implement WHO Resolutions and guidance documents on blood (mostly developed countries) are making **progress** in providing safe blood and blood products

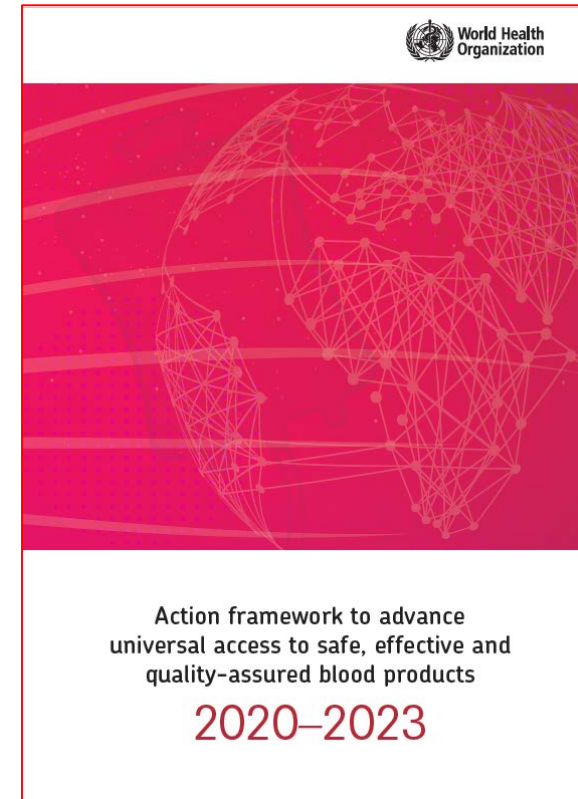
BUT...

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

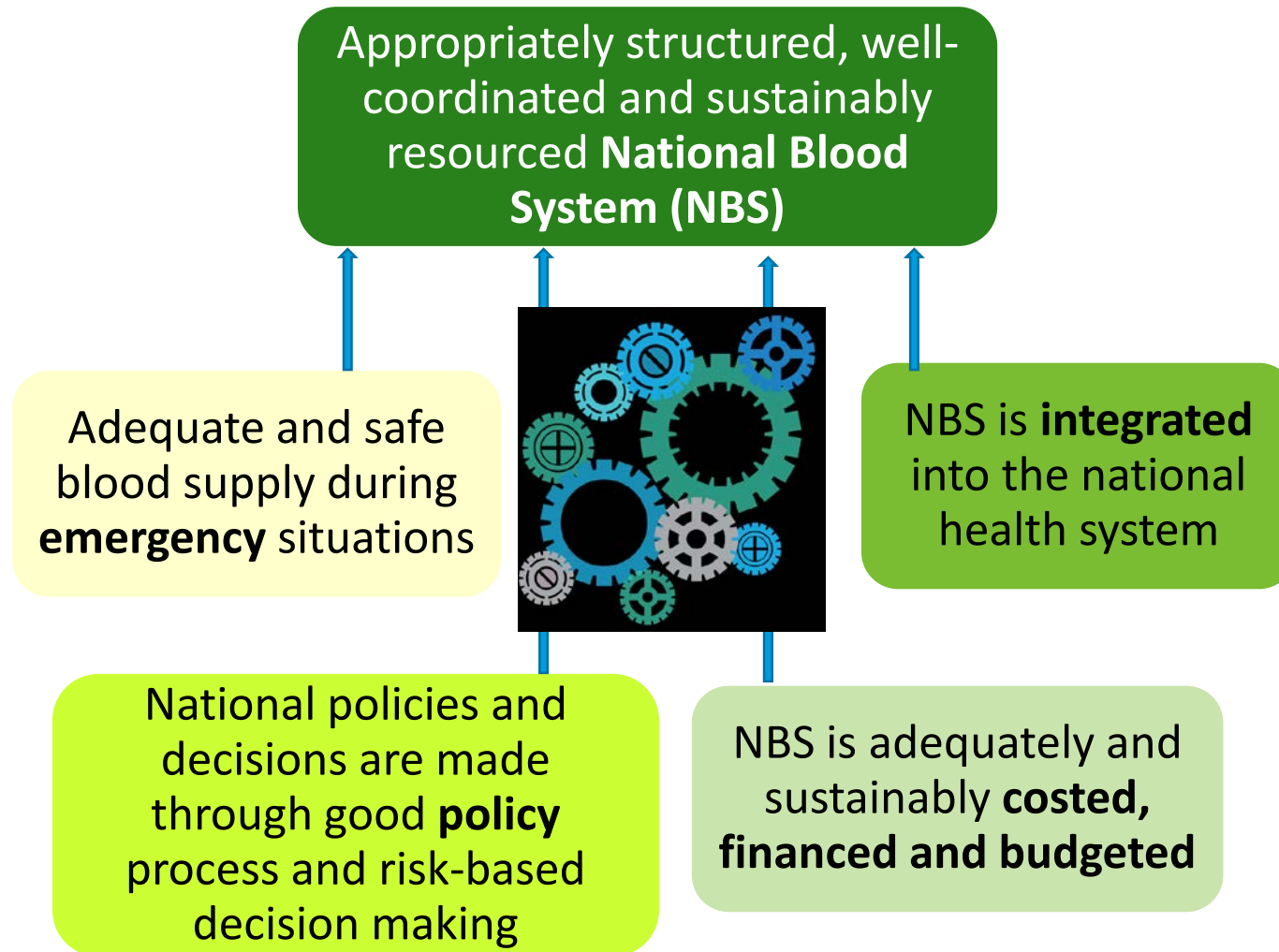


[Link to the AF Doc: https://www.who.int/bloodproducts/en/](https://www.who.int/bloodproducts/en/)

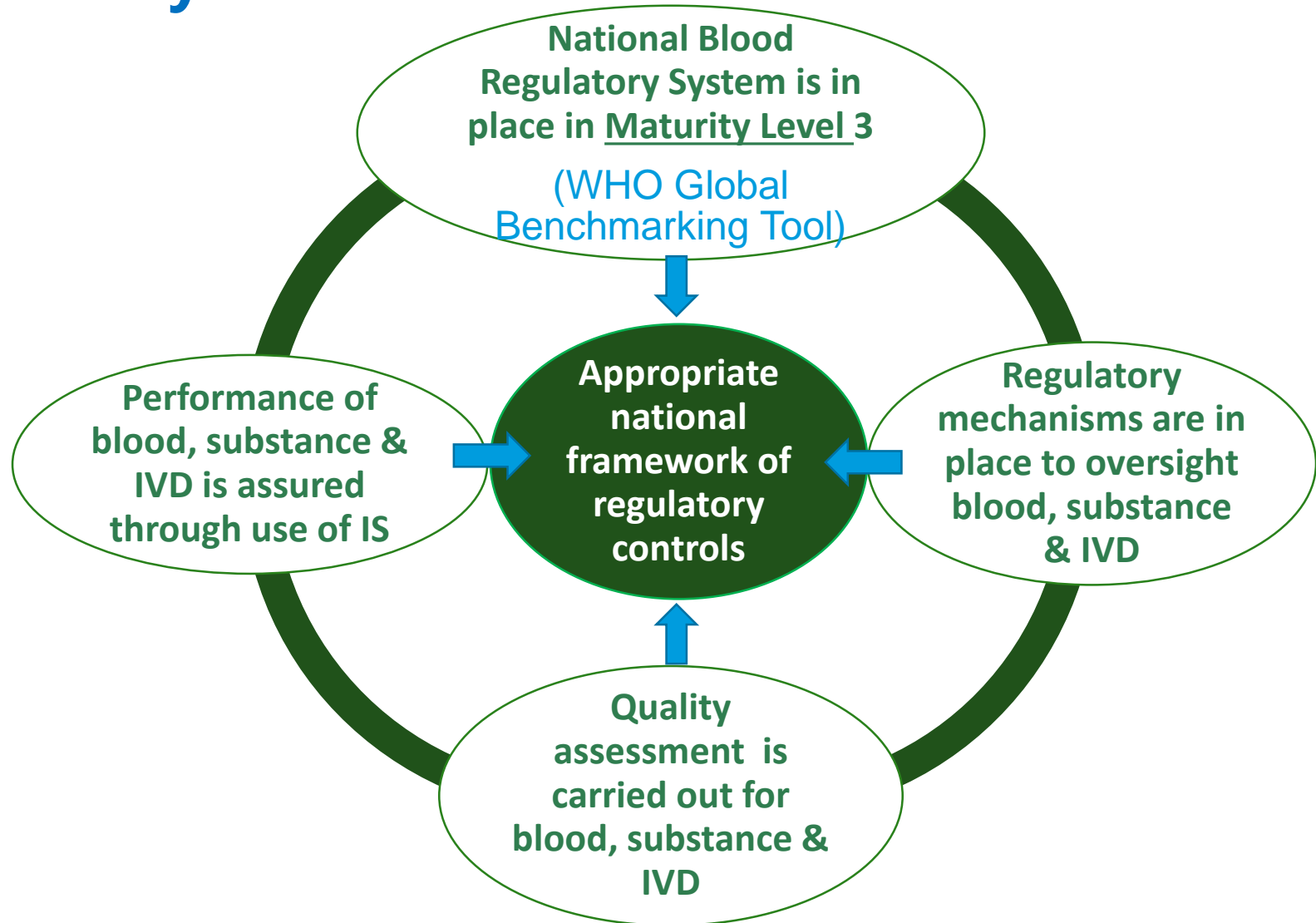
PROPOSED ACTIONS : 6 STRATEGIC OBJECTIVES

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

OUTCOME OF STRATEGIC OBJECTIVE 1: National Blood System (NBS)

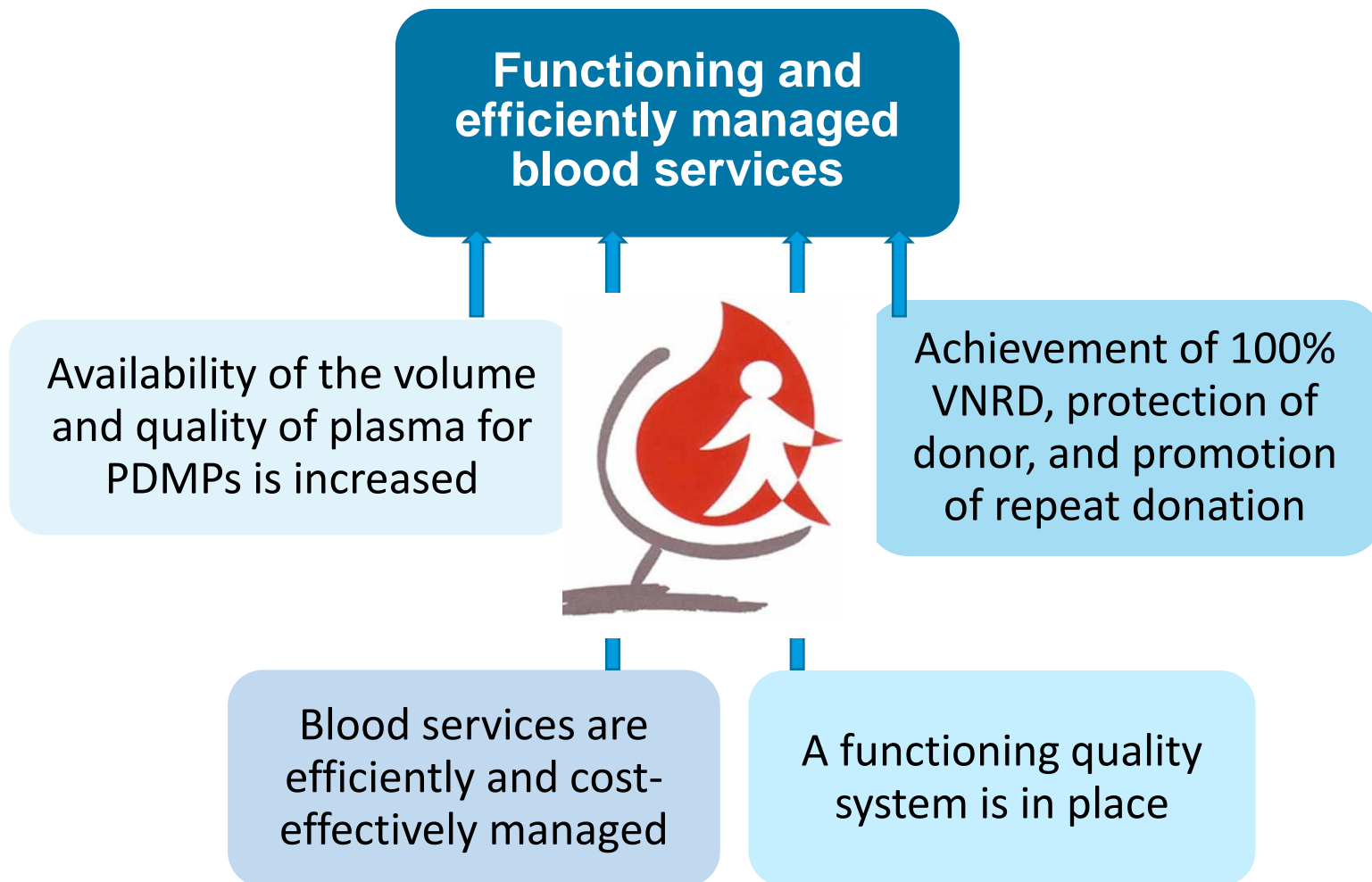


OUTCOMES OF STRATEGIC OBJECTIVE 2: **Regulatory Framework**

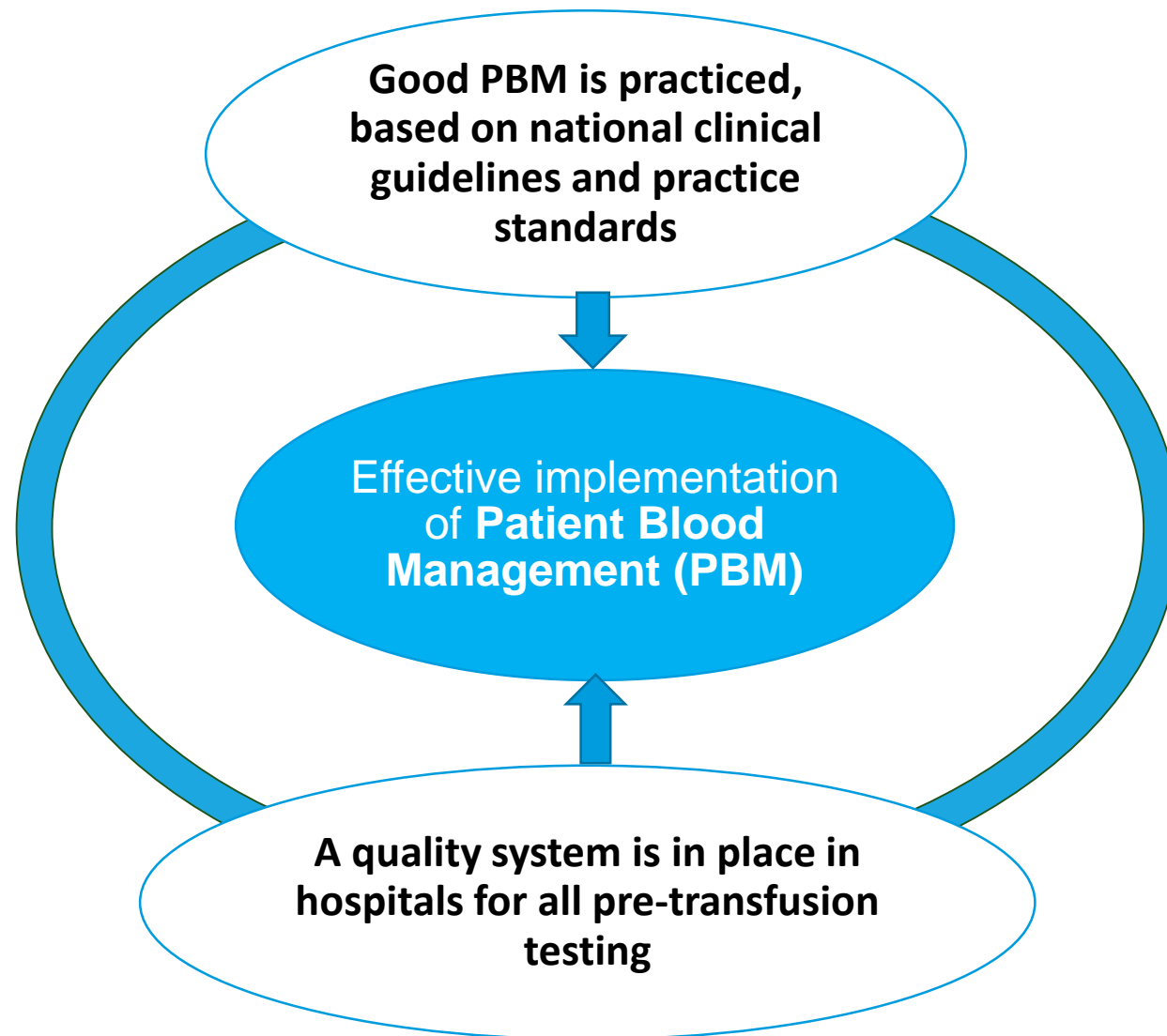


OUTCOME STRATEGIC OBJECTIVE 3:

Blood services



OUTCOME STRATEGIC OBJECTIVE 4: **Patient Blood Management (PBM)**



OUTCOME OF STRATEGIC OBJECTIVE 5: Surveillance & haemovigilance



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

WHO GDBS provides
comprehensive & accurate
data on global status of blood
availability, safety & quality

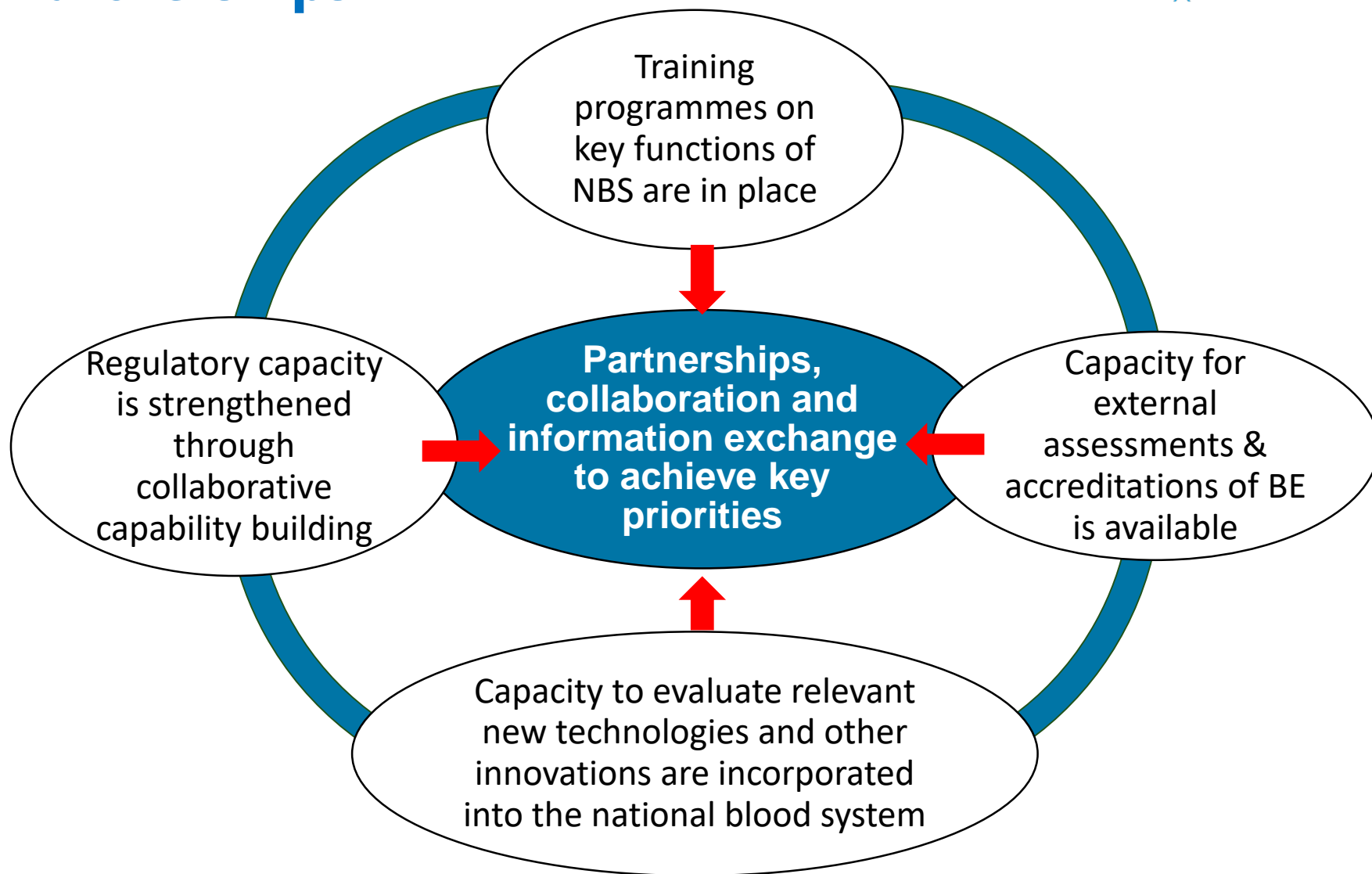
A national system for
standardized data collection
reporting, and mechanisms is in
place

Systems for traceability,
surveillance, haemovigilance
& pharmacovigilance are in
place

A guide to establishing
a national
haemovigilance system



OUTCOMES OF STRATEGIC OBJECTIVE 6: Partnerships



Development of Guidelines

Strategic Objective	8 Guidelines to develop
1	Guidelines on costing of blood services
	Guideline on preparedness of an adequate and safe blood supply during emergency situations.
2	Guideline on quality assessment of blood products and associated substances and medical devices, including IVD devices.
3	Guidelines on development of centers that carry out consolidated blood donation testing and processing.
	White Paper on increasing the volume and quality of recovered plasma for fractionation to manufacture plasma-derived medicinal products (PDMPs).
4	Revised WHO guidelines on clinical use of blood.
5	Guidelines on Patient blood management. White paper on standardized and harmonized data definition, consistency and comparability (GDBS, haemovigilance)

Technical assistance to Member States



There are 16 Technical assistance activities to be conducted at all three WHO levels (global, regional, national) and in the 6 WHO Regions :

- ☐ Workshops
- ☐ Twinning Program on Consolidation of blood testing and processing
- ☐ Assistance in improving quality of plasma for fractionation
- ☐ Training Program

NEXT STEPS & ONGOING ACTIVITIES



- ❑ Approach funding donors to get support, with support options based on donor interest in:
 - Specific WHO regions (AMR, AFR, EMR, EUR, SEAR, WPR)
 - Specific countries
 - Specific topics (e.g. regulation, technical, clinical aspect)
- ❑ Conducting budget supported activities listed in the work plan:
 - Development of WHO Guidance through Teleconferences
 - Transforming Face to Face Workshops into Webinar platform
- ❑ Developing the WHO guidance on COVID-19 blood related topics



World Health
Organization

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THANK YOU

www.who.int