



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

2020–2023

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Contents

Abbreviations	iv
Executive summary	v
1. Context	1
2. Current challenges and WHO responses	4
Challenge 1. Deficiencies in national policy, governance and financing	5
Challenge 2. Insufficient supply of safe, effective and quality-assured blood products for transfusion	7
Challenge 3. Deficiencies in blood product safety, effectiveness and quality	9
Challenge 4. Insufficient availability of PDMPs	11
Challenge 5. Suboptimal clinical practices in transfusion of blood components	12
Challenge 6. Insufficient access to blood during emergency situations	14
3. Proposed actions	16
Strategic objective 1: an appropriately structured, well coordinated and sustainably resourced national blood system	16
Strategic objective 2: an appropriate national framework of regulatory controls, national standards and quality assessment programmes	17
Strategic objective 3: functioning and efficiently managed blood services	18
Strategic objective 4: effective implementation of patient blood management to optimize clinical practice of transfusion	19
Strategic objective 5: effective surveillance, haemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection systems	20
Strategic objective 6: partnerships, collaboration and information exchange to achieve key priorities and jointly address challenges and emerging threats at global, regional and national levels	21
4. Organizational capacity, management and implementation	23
4.1 Organizational capacity	23
4.2 Management and implementation	23
References	25
Annex 1	28
Log frame of strategic objectives, activities, outputs, and outcomes	28
Tables	
Table 1. Funding available per blood collection for countries in World Bank income groups	6
Table 2. Population and blood donations for countries in World Bank income groups	8
Table 3. Percentages of global population and whole blood donations for countries in WHO regions	8
Table 4. Median percentage of blood donations with markers of transfusion-transmissible infections by World Bank income group	10
Table 5. Number of countries by WHO region reporting less than 100% donation testing for a major transfusion-transmissible infection	10
Table 6. Number (and %) of countries by WHO region reporting existence of quality assurance standards and monitoring activities for blood	11
Table 7. Proportion of whole blood used for red cell transfusions by countries in World Bank income groups	13

Abbreviations

GBT	Global Benchmarking Tool
GDBS	Global Database on Blood Safety
HBV	hepatitis B virus
HCV	hepatitis C virus
IVD	in vitro diagnostic
PDMP	plasma-derived medicinal product
SDG	Sustainable Development Goal
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 to provide appropriate 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 resolutions since 1975. In response to the recommendations of these resolutions and calls for action from Member States, the World Health Organization (WHO) has developed important guidelines, aides-memoires 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, 38 WHO biological reference preparations 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 of blood availability and safety. The global forums for blood have organized and successfully convened relevant global stakeholders to discuss challenges and 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 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 2015 WHO GDBS point to a number of inadequacies related to the supply and safety of blood, particularly related to gaps in policy, regulations, governance and financing of a national blood system; insufficient collection and availability of blood for transfusion; 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 haemovigilance and pharmacovigilance systems.

The WHO Action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023 aims to provide strategic direction to global efforts to address present barriers to the safety and availability of blood products. The WHO Action Framework aligns with the WHO 13th General Programme of Work 2019–2023 and the WHO five-year plan to help build effective and efficient regulatory systems (Delivering Quality-Assured Medical Products for All 2019–2023), and speaks to the implementation of a series of national, regional and international resolutions, goals and strategies to ensure safe blood, as integral to the achievement of the Sustainable Development Goals.

The WHO Action Framework focuses on six strategic objectives with related activities, outcomes and outputs. The Action Framework will guide the development and implementation of context-specific actions to address the needs of regions and countries. Reaching the overall goal of universal access to safe, effective and quality-assured blood products can only 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 ensure access to safe blood products worldwide.

The six strategic objectives are:

- ① an appropriately structured, well coordinated and sustainably resourced national blood system;
- ② an appropriate national framework of regulatory controls, national standards and quality assessment programmes;
- ③ functioning and efficiently managed blood services;
- 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 systems;
- ⑥ partnerships, collaboration and information exchange to achieve key priorities and jointly address challenges and emerging threats at global, regional and national levels.

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