World Health Organization

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

2020–2023

World Health Organization

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

2020–2023

Action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023

ISBN 978-92-4-000038-4 (electronic version)
ISBN 978-92-4-000155-8 (print version)

Suggested citation. Action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Photo credits: Pages 1, 4 and 16 © World Health Organization; p. 23 © iStock

Design and layout by L'IV Com Sàrl

Printed in Switzerland

Contents

Tables

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.

Context

A blood product is any therapeutic substance derived from human blood, including whole blood and other blood components for transfusion, and plasma-derived medicinal products (PDMPs) *(1–3)*. Medicinal (medical therapeutic) products derived from human donations of blood and plasma play a critical role in health care and are fundamental for achieving universal health coverage. Safe, effective and quality-assured blood products contribute to improving and saving millions of lives every year, as they:

- address child mortality and maternal health;
- dramatically improve the life expectancy and quality of life of patients suffering from a wide spectrum of serious and life-threatening inherited disorders, such as haemophilia, thalassaemia and immune deficiency, and acquired conditions such as cancer and traumatic haemorrhage;
- support complex medical and surgical procedures, including transplantation.

In high-income countries, blood products are most commonly used to support advanced medical and surgical procedures, including treatments of cancer and haematological diseases, trauma resuscitation, cardiovascular surgery and transplantation. In lower-income countries where diagnosis and treatment options are limited, a greater portion of blood is used to treat women with obstetric emergencies and children suffering from severe anaemia, often resulting from malaria and malnutrition. The importance of blood products is further emphasized by the inclusion of whole blood, red blood cells, platelets and fresh frozen plasma in the World Health Organization (WHO) Model List of Essential Medicines *(4)*.

Blood transfusion is an essential part of patient care, and sometimes the only option for survival. When used correctly, it saves lives and improves health. However, it also carries a potential risk of complications and transfusion-related infections. Safety measures in blood collection, processing and testing minimize the risk of transmission of HIV, hepatitis viruses, malaria agents and other bloodborne pathogens by transfusion. Although recent advances in patient

blood management have decreased the demand for blood transfusions in high-income countries, globally, changing population demographics and more advanced surgical and medical procedures have increased the need for blood transfusion. In all countries, avoiding misuse of blood transfusions through good clinical practices contributes to patient safety while conserving the blood supply. However, blood donations in many countries are insufficient to meet even the nation's most basic requirements for blood. In addition, many health care systems are over-reliant on the use of transfusions, which compromises patient outcomes and increases health care costs.

PDMPs are critical in the prevention and treatment of serious medical conditions associated with a wide range of inherited and acquired medical disorders and diseases. Unlike whole blood and blood components for direct transfusion, PDMPs are manufactured at an industrial level from pools of thousands of plasma units. The WHO Model List of Essential Medicines includes normal immunoglobulin, anti-D immunoglobulin, anti-rabies immunoglobulin, anti-tetanus immunoglobulin, coagulation factor VIII and coagulation factor IX *(4)*. Nevertheless, supplies of essential PDMPs are inadequate in many low- and middle-income countries. At the same time, because of barriers in their production, a large percentage of human plasma separated from whole blood is categorized as waste material and destroyed instead of being used to produce these essential blood products.

To ensure access to safe, effective and quality-assured blood products, a functioning national blood system is required.[1] National blood systems must be developed as an integral part of the health care system based on the principles of primary health care, in line with the WHO comprehensive approach to strengthening health systems. The development and strengthening of national blood systems is essential for overall health system strengthening and the achievement of universal health coverage. A robust national and regional blood service and blood regulator, with effective haemovigilance[2] and pharmacovigilance *(5)*[3] systems for monitoring the safety of blood donations and blood product use, is also key to building and strengthening national and regional capacities to respond to emergency situations, including natural disasters, humanitarian crises and emerging infectious threats.

Access to blood products, which includes equitable availability and affordability *(6)*, is imperative to safeguard public health. However, a major imbalance exists between higher-income and lower-income countries in access to safe, effective and quality-assured blood products. The World Health Assembly adopted its first resolution addressing the issue of blood safety in 1975, namely resolution WHA28.72 on utilization and supply of human blood and blood products. WHO is strongly committed to the improvement of blood product safety, effectiveness and quality in countries around the world, and has provided a great number of guidelines, biological reference standards, training and technical support in past decades. However, progress in blood regulation and availability has been slow in many parts of the world. For that reason, the WHO Action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023 proposes a renewed effort to scale up programme implementation and improve access to blood products. The Action Framework provides an overview of the main challenges faced at this time, including WHO responses to date, and establishes six strategic objectives for the coming years to guide the strategic efforts of WHO, in collaboration with its partners.

The WHO Action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023 responds to a series of World

[1] A blood system encompasses blood regulatory systems; blood supply systems or "services"; blood transfusion systems, including hospital blood banks and clinical transfusion services; related laboratories; and allied industries, including providers of related substances, reagents and medical devices.

[2] Haemovigilance is a set of surveillance procedures covering the entire transfusion chain from the donation and processing of blood and its components to their provision and transfusion to patients and their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events and adverse reactions related to the donation, processing and transfusion of blood, and taking action to prevent their occurrence or recurrence.

[3] Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects and any other drug-related problems *(5)*.

Health Assembly and WHO regional resolutions,[4] including resolution WHA63.12 (2010) on availability, safety and quality of blood products, which requests WHO and its Member States to improve the availability, safety and quality of blood products. The WHO Action Framework aligns with the WHO 13th General Programme of Work 2019–2023 *(7)*, which highlights universal health coverage and appropriate access to affordable and quality-assured medicines, vaccines and health products, including blood products. The WHO Action Framework also speaks to the draft roadmap for access to medicines, vaccines and other health products 2019–2023 *(8)*; the WHO Essential Medicines and Health Products Strategic Framework 2016–2030 *(9)*; and the WHO five-year plan to help build effective and efficient regulatory systems (Delivering Quality-Assured Medical Products for All 2019–2023) *(10)*. Medicinal products derived from human donation of blood and plasma play a critical role in health care and therefore in the realization of the Sustainable Development Goals (SDGs) *(11)*, in particular SDG target 3.8 (achieve universal health coverage).

[4] World Health Assembly resolution WHA28.72 on utilization and supply of human blood and blood products (1975); Executive Board resolution EB79.R1 on blood and blood products (1987); World Health Assembly resolution WHA48.27 on Paris AIDS Summit (1995); Pan American Health Organization/WHO Regional Office for the Americas (PAHO/AMRO) resolution CD41.R15 on strengthening blood banks in the Region of the Americas (1999); World Health Assembly resolution WHA53.14 on HIV/AIDS: confronting the epidemic (2000); Regional Committee for Africa resolution AFR/RC51/R2 on a blood safety strategy for the African Region (2001); World Health Assembly resolution WHA55.18 on quality of care: patient safety (2002); World Health Assembly resolution WHA56.30 on a global health sector strategy for HIV/AIDS (2003); World Health Assembly resolution WHA58.13 on blood safety: proposal to establish World Blood Donor Day (2005); World Health Assembly resolution WHA60.29 on health technologies (2007); World Health Assembly resolution WHA63.12 on availability, safety and quality of blood products (2010); PAHO/AMRO resolution CE154.R16 on a plan of action for universal access to safe blood (2014); and WHO Regional Office for the Eastern Mediterranean (EMRO) resolution EM/RC63.R5 on a strategic framework for blood safety and availability 2016–2025.

2 Current challenges and WHO responses

WHO's current work on blood safety emerged from the WHO Global Programme on AIDS and the Global Blood Safety Initiative in the late 1980s. In 2000, safe blood was declared an Organization-wide priority and blood safety was designated the theme of World Health Day. Following its resolution WHA58.13 of 2005, the World Health Assembly designated 14 June as World Blood Donor Day, serving to thank blood donors for their voluntary, lifesaving gift of blood; to raise awareness of the need for safe blood for transfusion; and to emphasize the importance for each country of establishing nationally coordinated, well organized blood services based on voluntary non-remunerated donation.

The International Conference of Drug Regulatory Authorities is instrumental in guiding WHO and national regulatory authorities in the regulation of blood and associated substances and medical devices, including in vitro diagnostic (IVD) devices. The need for haemovigilance systems to monitor the safety of blood donation and blood transfusion was highlighted in the recommendations of the most recent meeting of the International Conference of Drug Regulatory Authorities in 2018. In 2006, the WHO Blood Regulators Network was established in response to a request by the WHO Expert Committee on Biological Standardization for a global network of blood regulatory authorities.

The importance of blood components and PDMPs as medical products for the global population was underscored in 2013 by the inclusion of whole blood, red blood cells, platelets and fresh frozen plasma in the 18th edition of the WHO Model List of Essential Medicines, in addition to the previously listed PDMPs.

Since 1998, WHO has collected and analysed data on blood and blood product safety and availability from Member States through the online WHO Global Database on Blood Safety (GDBS) *(12)*, providing evidence-based data for action to improve blood transfusion services globally. The worldwide status based on the 2013 GDBS was reported in the WHO *Global status report on blood safety and availability* 2016 *(13)*. However, the present document cites an interim analysis of the more recent 2015 GDBS. Whilst the WHO GDBS has a number of acknowledged

limitations,[5] the 2015 survey benefited from an 89% response rate[6] and provides high-level insights and guidance to global efforts to ensure access to safe blood products, identifying a series of current challenges:

1. deficiencies in national policy, governance and financing;
2. insufficient supply of safe, effective and quality-assured blood products for transfusion;
3. deficiencies in blood product safety, effectiveness and quality;
4. insufficient availability of PDMPs;
5. suboptimal clinical practices in transfusion of blood components;
6. insufficient access to blood during emergency situations.

These challenges, and the actions taken to address them to date, are presented below.

Challenge 1. Deficiencies in national policy, governance and financing

A national blood system is a prerequisite for safe, effective and quality-assured blood products in a country. Barriers to a well functioning national blood system include:

- lack of political commitment and awareness of the essential role of a national blood system in the larger health system;
- failure to appreciate the societal cost of blood insufficiency versus the cost of providing an adequate and safe blood supply;
- inadequate legal and regulatory frameworks for a national blood system;
- resource limitations, including in the areas of financing and infrastructure, and insufficient numbers of qualified and trained personnel functioning as health workers and as national experts for policy and planning in blood product safety and transfusion practice.

In the 2015 survey, 123 (71%) of 173 countries reported the existence of a national blood policy. There was notable regional variation, with existence of a national blood policy reported in 53% of countries in the Region of the Americas; 74% of countries in the Western Pacific Region; 68% of countries in the Eastern Mediterranean Region; 71% of countries in European Region; 73% of countries in the South-East Asia Region; and 84% of countries in the African Region. Additionally, 77% of Member States worldwide reported having a government unit with responsibility for overseeing blood products. Furthermore, 60% of Member States reported having specific legislation related to the safety, effectiveness and quality of blood transfusion, again with regional variations: 38% in the Region of the Americas; 49% in the African Region; 52% in the Western Pacific Region; 63% in the Eastern Mediterranean Region; 64% in the South-East Asia Region; and 93% in the European Region.

In WHO Member States, many health authorities have provisions for a safe blood supply as a priority strategy in their national health plans. However, very few blood establishments are able to collect or review information relating to capital and recurrent costs. Therefore, an adequate budget cannot be provided, whether through budgetary allocation, a cost recovery system or a combination of the two. There is often also an incorrect perception that, since blood is donated voluntarily, costs are minimal. The WHO GDBS shows that total funding available per blood collection is directly related to the income status of Member States (Table 1). Sources of funding[7] varied greatly. The survey indicated that 59% of countries in the European Region financed the blood system partially or entirely through cost recovery; conversely, 40% of countries in the African Region financed the blood system solely through government budget allocations. In the case of 56 countries, financial support was received from international or other external sources (three in the European Region;

[5] Acknowledged limitations of the data and survey included in the WHO *Global status report on blood safety and availability* include inherent dependence on reporting by national health authorities without the ability to obtain independent verification; differences in scope and effectiveness of country-level data collection systems; national reporting in some countries versus reporting based on a subset of blood centres in other countries; and incomplete responses to the survey constraining the analysis.

[6] In total, 173 of 195 WHO Member States responded. If no data were available for 2015, data from 2014 (17 countries) and 2013 (17 countries) were included.

[7] Including government budget, cost recovery and external support.

four in the Eastern Mediterranean Region; five in the Region of the Americas; six in the Western Pacific Region; seven in the South-East Asia Region and 31 countries in the African Region). Overall, roughly half of countries reported systems of licensing for blood establishments and half reported systems of regular inspections of blood establishments by a national regulatory agency or other entity.

Table 1. Funding available per blood collection for countries in World Bank income groups

Country income group	Funding per collection and median (interquartile range) in US$
High-income (24 countries reported)	293 (164–407)
Upper middle-income (18 countries reported)	66 (48–113)
Lower middle-income (21 countries reported)	35 (26–67)
Low-income (21 countries reported)	31 (23–54)

WHO response to date: strengthening national blood systems

World Health Assembly resolution WHA63.12 (2010) paved the way for major blood system reforms by committing governments to the strengthening of leadership and management to improve national blood systems. WHO has provided policy guidance on good policy processes for blood safety and availability *(14)* and organized a global consultation on universal access to safe blood transfusion *(15)*. WHO has also provided policy guidance on developing a national blood system *(16)*, as well as technical assistance and capacity-building to strengthen national blood policies and related governance, including leadership and management *(17)*. Together with global partners, WHO has provided technical support for blood system reform and strengthening in many countries. In 1998, in response to the challenge of financing blood services, WHO published the document *Safe blood and blood products: costing blood transfusion services (18)* to assist blood establishments in performing a cost analysis on which to base cost collection for their services. Broadly, the cost of blood components for transfusion includes both the direct product acquisition costs and the additional cost of activities associated with provision of transfusions. Cost collection and cost analysis will provide governments and funding agencies with the information needed to develop and maintain sustainable national blood systems.

WHO guidelines on good manufacturing practices for blood establishments were published in 2011 *(19)*, complemented by capacity-building for national regulatory authorities and national blood services. At country level, WHO has reviewed existing blood legislation in the Eastern Mediterranean countries, and a template for legislation is now available for use by countries to ensure and promote adherence to good manufacturing practices and harmonization across countries. Inclusion of blood products (including red cells, platelets, fresh frozen plasma and certain PDMPs) as essential medicines on the WHO Model List of Essential Medicines *(4)* contributes to improving blood safety, effectiveness and quality by encouraging Member States to make the necessary investments to build and sustain quality assurance systems in blood establishments.

Blood regulation is recognized as an essential element of a national blood system that helps to optimize the safety, effectiveness and quality of blood products. Effective blood regulation functions to ensure the health and safety of blood donors and patients; address the national need for blood; promote efficiency of the blood service; ensure that plasma derivatives are safe and effective; and enable the use of quality plasma to produce PDMPs. Additionally, effective blood regulation will monitor the status of the blood system, including collection of data from blood donors and blood product recipients, through haemovigilance and pharmacovigilance, and permit timely and effective responses to emerging blood safety threats. More specifically, WHO has published assessment criteria for national blood regulatory systems *(1)*.

In line with its renewed focus on strengthening regulatory systems, WHO supports countries to develop regulatory frameworks, including enforcement and implementation of good manufacturing practices in blood establishments that collect, process, distribute and store blood products, and regulation of blood safety-related IVD devices. Mandated by World Health Assembly resolution WHA67.20 on regulatory system strengthening (2014), WHO has developed a Global Benchmarking Tool (GBT) for evaluation of national regulatory systems *(20)*. Assessment criteria for blood regulation have now been integrated into GBT revision VI, which will be called the Global Benchmarking Tool Plus Blood. A prototype version of the GBT Plus Blood was pilot-tested in 10 African countries, confirming

its utility for identifying gaps in blood regulation. Under the GBT Plus Blood, indicators are provided for assessing the maturity of the blood regulator in establishing and implementing relevant functions (for example, approval of blood components and plasma for fractionation). An overall maturity level of 3 on a scale of 1–4 would indicate the presence of a fully competent national blood regulator.[8] Based on an external, officially assessed maturity level of 3 or greater, WHO will list authorities on which less developed regulators can rely in making their own product evaluations.

Since 2018, WHO has supported development of the African Blood Regulators Forum. The aim of this forum, which was established officially in October 2019, is to facilitate access to quality, safe and affordable blood products for all people of Africa through information sharing and reliance for strengthening and harmonizing regulatory systems for blood products. The forum should provide advocacy and communications targeted to policy-makers and the general public to enhance understanding of and support for blood regulation, and will strengthen the capacity of national blood regulators through external assessment against the GBT Plus Blood and cooperation in addressing identified gaps and deficiencies.

Challenge 2. Insufficient supply of safe, effective and quality-assured blood products for transfusion

High-income countries with well structured health systems and blood transfusion services based on voluntary blood donations are generally able to meet the demand for blood products. In contrast, in low- and middle-income countries, chronic blood shortages are common. These countries generally do not have structured blood donor programmes and as a result cannot attract sufficient numbers of donors to meet the need for blood in emergencies, planned surgery and regular transfusion. Health care facilities often rely on practices of on-demand family or replacement donation or paid donation. Paradoxically, despite a markedly inadequate blood supply in many countries, unnecessary blood transfusions are often given when the availability and use of simpler, less expensive treatments would provide equal or greater benefit to a patient's health. This not only exposes patients needlessly to the risk of potentially fatal transfusion reactions, it also widens the gap between supply and demand and contributes to shortages of blood and blood products for patients who really need them.

A total of 66 countries have an annual blood donation rate of less than 10 per 1000 population, which is the rate generally considered as necessary to meet a nation's basic requirements for blood *(21)*. Barriers to adequate blood collection include:

- ineffective donor recruitment strategies with low rates of voluntary non-remunerated donation;
- cultural resistance or lack of education affecting willingness to donate;
- family or replacement and paid collection instead of community-based donation to maintain an available inventory;
- absence of support for voluntary non-remunerated donation with repeat donation as the basis of a sustainable system;
- absence of a nationally coordinated blood service;
- logistical complexity of blood collection in non-urban areas (particularly in low- and middle-income countries);
- lack of government commitment to a nationally coordinated blood service that optimizes resources and minimizes destructive competition amongst multiple service providers.

Moreover, in many countries, ageing populations and increasingly stringent donor selection criteria have reduced the pool of eligible donors. Furthermore, the volume of blood collection is often not well matched with the estimated population-based transfusion requirements for blood, and inadequate to support health care needs.

It is estimated that 41.8% of blood is collected in high-income countries, which make up 16.3% of the global population (Table 2). Conversely, only 2.3% of blood

[8] Consistent with ISO 9004 guidance, WHO characterizes maturity level 3 under the GBT as a systematic approach for regulatory oversight of medical products in which regulatory processes and procedures are well established and documented for all essential functions. At maturity level 4, the regulatory system operates at an advanced level of performance that includes use of electronic databases, stakeholder and public transparency, risk-based management, outcome monitoring and continuous improvement.

Table 2. Population and blood donations for countries in World Bank income groups

	Low-income	Lower middle-income	Upper middle-income	High-income
% of global population	8.9	39.4	35.4	16.3
% of global donations	2.3	25.2	30.7	41.8
Mean donations/year per 1000 population (range among countries)	4.4 (0.4–7.0)	8.1 (1.2–40.0)	15.1 (4.0–36.6)	32.6 (7.3–61.2)

Table 3. Percentages of global population and whole blood donations for countries in WHO regions

	Africa	Americas	Eastern Mediterranean	Europe	South-East Asia	Western Pacific
% of global population	13.8	13.7	8.7	11.0	26.9	25.9
% of global donations	5.2	18.4	8.1	26.9	16.0	25.4

is collected in low-income countries, which comprise 8.9% of the global population, and only 55.9% of blood is collected in middle-income countries, which comprise 75.8% of the global population. The greatest disparities between population and blood collection are observed in the African Region and the South-East Asia Region: in the African Region, 13.8% of the world population has access to only 5.2% of globally collected blood, and in the South-East Asia Region, 26.9% of the world population has access to only 16.0% of globally collected blood (Table 3). Rates of annual blood collection lower than the level thought necessary to meet basic needs (roughly estimated at a level of 10 per 1000 population) were reported in 66 countries (four in the European Region, five in the Eastern Mediterranean Region, six in the Western Pacific Region, seven in the Region of the Americas, seven in the South-East Asia Region, and 37 countries in the African Region).

The proportion of whole blood collected from voluntary non-remunerated donors was 62% in the Eastern Mediterranean Region, 68% in the Region of the Americas and74% in the African Region, compared with 82% in the South-East Asia Region, 97% in the European Region and 97% in the Western Pacific Region. The proportion of voluntary non-remunerated donors increases with national income, with 67% in low-income countries, 75% in lower middle-income countries, 83% in upper middle-income countries, and 96% in high-income countries. Worldwide, 58 countries depend on family or replacement donation and paid donation to cover more than 50% of their population's need for blood. The percentage of whole blood donations given by regular (repeat) voluntary non-remunerated donors varies greatly (from 0.1% to 100%) among countries, with both low rates (0.1–12%) and high rates (85–100%) reported in countries of each WHO region.

WHO response to date: increasing the supply of safe, effective and quality-assured blood for transfusion

To support the national self-sufficiency of blood products and voluntary non-remunerated donation, WHO issued an expert consensus statement providing the global definition, strategies and mechanisms for achieving self-sufficiency in blood products based on voluntary non-remunerated donation *(22)*. Furthermore, in 2013, a high-level policy-makers' forum was organized to discuss the strategies to achieve self-sufficiency in safe blood and blood products based on voluntary non-remunerated donation. Guidelines on blood donor selection *(23)* and donor counselling *(24)* have been published, with related training materials for blood donor management. World Blood Donor Day is celebrated in a growing number of countries to promote voluntary non-remunerated donation and improved blood donor management. WHO has been providing technical assistance and capacity-building to countries since 2010 to strengthen their blood services based on voluntary non-remunerated donation and careful selection of healthy donors at low risk of infection with a transfusion-transmissible disease. Recruitment of family or replacement donors to become regular voluntary non-remunerated donors is increasingly recognized as a strategy that supports gradual transition towards 100% voluntary non-remunerated donation.

Challenge 3. Deficiencies in blood product safety, effectiveness and quality

Selection of low-risk donors and laboratory testing of donations for evidence of transfusion-transmissible infection are fundamental strategies to ensure blood safety, effectiveness and quality. Practices of family or replacement donation and paid blood donation contribute to risks of transfusion-transmissible infection compared with repeated collections from voluntary non-remunerated donation. As noted above, among countries, the proportion of blood donations by voluntary non-remunerated donation varies directly with income level. Barriers to ensuring that blood is collected from low-risk donors include:

- costs of donor recruitment;
- insufficient public education and outreach to promote awareness and to overcome fears and cultural biases;
- inadequate pre-donation screening and risk assessment of donors;
- absence of epidemiological monitoring for transfusion-transmissible infections in the general population and in the blood donor population, hindering public health efforts to identify and recruit low-risk donors.

Recruiting and maintaining safe donors requires a national strategy on donor recruitment, cooperation with blood donor organizations, pre-donation health screening and risk assessments, policies on donor deferrals for risk of transfusion-transmissible infections and positive laboratory tests, and post-donation management, including donor counselling and record keeping.

Deficiencies in the quality of laboratory testing can result in failures to detect transfusion-transmissible infections in donors, and infectious transmissions from transfusions may go unrecognized. Barriers to quality-assured infectious disease, blood grouping, and compatibility testing of blood donations include:

- insufficient regulatory and professional oversight;
- absent or poorly implemented legislative and regulatory frameworks;
- unreliable supply management of reagents and assays (for example, test kits for donation screening and blood grouping reagents);
- weak or absent controls of reagents and assays and related laboratory practices;
- poor ease of use of available laboratory systems relative to skill levels;
- weak or absent quality management systems in blood collection and preparation of blood components;
- lack of haemovigilance monitoring to identify safety issues and drive improvements.

Constraints in resources, infrastructure and trained personnel further complicate these issues in low- and middle-income countries.

The prevalence of markers of transfusion-transmissible infectious diseases in blood donations varies inversely by the income status of Member States (Table 4). WHO recommends that 100% of blood donated by donors should be screened for infections with HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), and syphilis to avoid the transmission of such infections from blood donors to patients through transfusion *(25)*. However, the survey indicated that in some countries not all quality-assured testing procedures were followed; more particularly, 99.8% of blood donations in high-income countries and 99.9% of blood donations in upper middle-income countries were screened following basic quality-assured procedures, compared to 83% of blood donations in lower middle-income countries and 76% in low-income countries. Furthermore, 28 countries reported stock-outs of screening assays (one in the South-East Asia Region, two in the Eastern Mediterranean Region, three in the European Region, five in the Region of the Americas, six in the Western Pacific Region and 11 in the African Region). The use of rapid tests for all or part of the blood donations was reported in 25 of 141 countries[9] (three in the Eastern Mediterranean Region, four in South-East Asia Region, nine countries in the African Region, and nine in the Western Pacific Region). Most of these 25 countries are low-income (eight countries) and lower middle-income (15 countries). Widespread use of less sensitive rapid diagnostic tests in many low- and middle-income countries contributes to risk

[9] The GDBS survey on the use of rapid tests does not include countries in the WHO Region of Americas, except Canada and the United States of America.

Table 4. Median percentage of blood donations with markers of transfusion-transmissible infections by World Bank income group

	HIV	HBV	HCV	Syphilis
High-income countries	0.002	0.02	0.02	0.02
Upper middle-income countries	0.10	0.36	0.24	0.44
Lower middle-income countries	0.14	2.27	0.39	0.70
Low-income countries	0.86	3.64	0.93	0.62

Note: Marker rates are elevated over true positive rates due to reporting by some countries of reactive screening test results without additional confirmation of positivity.

Table 5. Number of countries by WHO region reporting less than 100% donation testing for a major transfusion-transmissible infection

Infection	Region (number of countries reporting)					
	Africa (45)	Americas (34)	Eastern Mediterranean (19)	Europe (41)	South-East Asia (11)	Western Pacific (20)
HIV-1/2	2	0	0	0	0	1
HBV	3	0	0	0	0	1
HCV	4	0	0	0	0	2
Syphilis	4	0	1	0	0	1

of transfusion-transmissible infections, as does use of suboptimal testing strategies (for example, with regard to the choice of tests and testing algorithms) (Table 5).

Blood safety, quality and efficacy depend critically on preparation practices and procedures that meet WHO or other internationally recognized standards applicable to the entire blood transfusion chain (from recruitment of donors to clinical administration of the blood) *(2, 19, 23)*.[10] The assurance that blood for transfusion meets standards for safety and quality depends on the existence of national standards and systems of monitoring, including integrity of the cold chain during storage and transportation of blood products. Globally, 86% of countries reported existence of standards for preparation of blood products; 68% reported existence of national external quality assessment schemes for transfusion-transmissible disease testing; and 60% reported existence of national external assessments of blood group serology and compatibility testing. As stated above, roughly half of countries reported systems of licensing for blood establishments and half reported systems of regular inspection of blood establishments by a national regulatory agency or other entity. Across the WHO regions, 36% of countries in Africa, 43% in the Western Pacific, 47% in the Eastern Mediterranean, 53% in the Americas, 55% in South-East Asia, and 85% in Europe reported the existence of a system of licensing; and 33% of countries in Africa, 44% in the Americas, 45% in South-East Asia, 58% in the Eastern Mediterranean, 61% in the Western Pacific, and 80% in Europe reported the existence of certain systems of inspection. Additionally, only 32% reported that national blood transfusion services were accredited. Among reporting countries, 65% reported programmes of continuing education for personnel involved in blood transfusion and 40% had educational programmes that offered degrees or diplomas in blood transfusion medicine or science. WHO regions vary in the extent to which these elements of quality assurance and monitoring are in place (Table 6).

WHO response to date: improving the quality and safety of blood products

In addition to good manufacturing practices for blood establishments *(19)*, WHO has issued specific recommendations on screening of donated blood for transfusion-transmissible infections *(25)*, maintenance

[10] Standards can relate to ethical aspects of blood donation, donor suitability assessment, collection and component preparation, donation testing, labelling, storage, distribution and shipping (including an assured cold chain), appropriate clinical use, haemovigilance reporting and investigation of adverse reactions in donors and recipients, and look-back and trace-back procedures "from vein to vein".

Table 6. Number (and %) of countries by WHO region reporting existence of quality assurance standards and monitoring activities for blood

	Africa	Americas	Eastern Mediterranean	Europe	South-East Asia	Western Pacific
National standards	38 (84)	25 (74)	16 (84)	39 (95)	10 (91)	21 (91)
Licensing	16 (36)	18 (53)	9 (47)	35 (85)	6 (55)	10 (43)
Regular inspection	15 (33)	15 (44)	11 (58)	33 (80)	5 (45)	14 (61)
External accreditation	6 (13)	8 (24)	9 (47)	21 (51)	4 (36)	8 (35)

of the blood cold chain *(26)*, and strategies to protect the blood supply during infectious disease outbreaks *(27)*.

WHO tools and training materials *(28, 29)* to enhance the quality of blood transfusion service management are used in the development of national standards and quality management systems in many countries. Furthermore, to increase awareness of the importance of safety of blood products, the WHO Expert Committee on Biological Standardization has established guidelines on estimation of residual risk in blood components for transfusion-transmissible viruses *(30)*, as well as international reference preparations for benchmarking of blood products and in vitro diagnostic assays, including those needed for detection of pathogens in disease outbreaks.

WHO has also worked to strengthen national blood transfusion services in countries affected by the Ebola virus disease, and provided emergency guidance during the outbreak of Zika virus disease. At regional levels, the Plan of Action for Universal Access to Safe Blood 2014–2019 for the Region of the Americas, and the Regional Strategic Framework for Blood Safety and Availability 2016–2025 for the Eastern Mediterranean Region, provide strategic guidance and reflect political commitment. Likewise, in the South-East Asia Region, WHO has strengthened capacities among national blood programme managers to review the existing capacities of blood transfusion services to identify challenges and develop action plans.

Challenge 4. Insufficient availability of PDMPs

Ensuring an adequate supply of essential PDMPs is critical to meeting a population's health needs. Replacement products also are needed for deficiencies of fibrinogen (in massive haemorrhage, including traumatic and peripartum) and von Willebrand factor. However, availability of these medicinal products is insufficient in numerous low- and middle-income countries, and shortages still occur in high-income countries. WHO reports continued and extensive use of locally prepared and non-pathogen-reduced cryoprecipitate as the sole available or affordable therapeutic product for patients with haemophilia A, von Willebrand disease and fibrinogen deficiencies in low- and middle-income countries *(3)*. The World Federation of Hemophilia has indicated for years that 70–75% of patients with haemophilia globally do not receive any form of appropriate treatment *(31)*. Simultaneously, reports suggest that over 9 million litres of plasma collected in low- and middle-income countries are discarded for lack of acceptability for fractionation *(3)*. Production of PDMPs faces numerous challenges related to traceability of donors, testing, regulatory controls, quality systems, good manufacturing practices, and required freezing and cold chain conditions. Consequently, in low- and middle-income countries a large percentage of human plasma, separated from whole blood, is categorized as waste material and destroyed *(3)*. Collaboration between countries, through appropriate regulatory standards and transfer of technology, will be required to build local capacity in such countries for production of plasma suitable as a source material for manufacture of PDMPs through contract or domestic fractionation, including plasma separated from whole blood and plasma obtained by apheresis.

Barriers to the provision of plasma for fractionation include:

- limited use of component preparation to generate recovered plasma;
- failure to meet internationally recognized standards for blood collection and blood component preparation necessary to ensure quality of recovered plasma acceptable to a contract fractionator;

- poor cold chain and supply chain logistics;
- high cost and complexity of apheresis to generate plasma;[11]
- absence of regulatory oversight precluding assurance that appropriate standards are met.

Providing plasma for fractionation (in addition to or as an alternative to external procurement) can be part of a strategy to secure a national supply of PDMPs. The feasibility of this strategy depends on the determination by a fractionator that plasma collected in a country[12] meets quality standards for use in fractionation. Concurrently, this determination is an indicator of optimization of blood collection by avoiding wastage of surplus plasma collected in excess of clinical need, and additional specific collection of plasma for fractionation by apheresis. However, the 2015 survey indicated that only 50 countries used domestically collected plasma for fractionation through different arrangements. The survey also showed that among the 24 countries reporting on their national supply of albumin, intravenous immune globulin and factor VIII, only eight reported that 70% or more of at least two of these essential medicines were obtained through fractionation of domestically collected plasma. Worldwide experience also indicates that global sufficiency of PDMPs cannot be achieved without large-scale programmes of plasmapheresis. The current and ongoing escalation of demand for PDMPs (particularly normal immunoglobulin products) also highlights the need for effective management and use of PDMPs through appropriate clinical guidelines.

WHO response to date: improving availability of quality-assured plasma for fractionation

Production of PDMPs requires plasma as a raw starting material that must fulfil requirements in terms of minimal batch volume, safety and quality. Implementation of good manufacturing practices in blood establishments and regulatory oversight of blood establishments is necessary to ensure the safety, effectiveness and quality of plasma suitable for fractionation. In 2002–2005 WHO implemented the Achilles project, which aimed to assist countries in improving the quality of plasma for fractionation through strengthening regulation. WHO is currently working with regulatory authorities and national blood services in Africa, Asia and Latin America to ensure implementation of blood regulatory systems as a strategy to strengthen quality systems in blood establishments, thus enhancing local production of good-quality plasma from whole blood donations in low- and middle-income countries. Related efforts are continuing to promote establishment of centres that carry out consolidated blood donation testing and component preparation and to promote regional self-sufficiency in production of PDMPs.

WHO international biological reference preparations are the basis of a uniform system to ensure the quality of biological products, including PDMPs. Reference preparations are established by the WHO Expert Committee on Biological Standardization and designed, prepared and validated by a responsible WHO collaborating centre. They serve as a comparator against results from laboratories, regardless of location or methods employed, and are an important tool in quality testing. These biological reference preparations are generally in limited supply and are only distributed to qualified laboratories, namely national control laboratories and manufacturers of biological medicinal products. Since 2010, 38 WHO biological reference preparations have been produced to reinforce quality control in the areas of blood products and blood safety-related IVD devices. WHO promotes reference standards for blood products and related IVD devices through an online catalogue *(32)*, as well as through workshops and interactions with international professional organizations. Moreover, the WHO Expert Committee on Biological Standardization has established guidelines on management of blood products as essential medicines *(2)*.

Challenge 5. Suboptimal clinical practices in transfusion of blood components

Blood transfusions are essential to patient care, and often lifesaving. However, suboptimal clinical practices compromise patient safety and make inappropriate use of the already scarce blood products available. Furthermore, many health care systems are over-reliant on use of transfusions, whereas a more holistic approach to patient care should be considered. As a result, patient outcomes are affected, and health care costs increase.

[11] The high cost, technical complexity and volume requirements of fractionation facilities are barriers to development of domestic fractionation.

[12] Either by separation from whole blood or by apheresis.

Barriers to appropriate clinical use of blood transfusions include:

- limited training and knowledge in transfusion medicine;
- lack of awareness and training on patient blood management;
- absence of national evidence-based guidelines for transfusion;
- absence of effective transfusion committees in hospitals;
- poor practices in blood component preparation, storage and handling, including maintenance of the cold chain.

The role-specific education and training needs of medical, nursing, scientific and technical staff in the availability of safe blood for transfusion need to be recognized and addressed. In the 2015 GDBS, existence of degree programmes in blood banking and transfusion medicine was reported by only 40% of countries. Moreover, most Member States have no comprehensive haemovigilance system, reflecting the absence of national commitment, funding and infrastructure for reporting, as well as a lack of awareness on the importance of haemovigilance.

The use of evidence-based practices for transfusion is reflected in the existence of national transfusion guidelines and the presence of transfusion committees in hospitals. However, the recent survey indicated that globally only 45% of hospitals reported having transfusion committees, more specifically 12% of hospitals in the African Region; 17% in the Region of the Americas; 40% in the Western Pacific Region; 57% in the Eastern Mediterranean Region; 68% in the European Region; and 79% in the South-East Asia Region. Additionally, in low- and middle-income countries, the levels of activity or effectiveness of these committees is largely unknown. Globally, 71% of countries reported existence of national guidelines on clinical use of blood, including 50% in the Region of the Americas; 71% of countries in the African Region; 74% in the Eastern Mediterranean Region ;74% in the Western Pacific Region; 83% in the European Region; and 91% in the South-East Asia Region.

Although use of fresh whole blood has advantages in the setting of massive acute haemorrhage, use of concentrated red cells in additive solutions (rather than whole blood) is considered as a best transfusion practice for the optimal use of collected blood in most conditions *(33)*. In countries where commercial clotting factor concentrates are unavailable or unaffordable, locally prepared cryoprecipitate offers an alternative for patients with haemophilia A, von Willebrand disease or fibrinogen deficiencies, albeit with increased infectious disease risk unless treated to inactivate transfusion-transmissible agents.

Processing of whole blood into components varied by WHO region (62% of countries in the South-East Asia Region; 73% in the African Region; 90% in the Region of the Americas; 91% in the Eastern Mediterranean Region; 92% in the Western Pacific Region; and 99% in the European Region). The proportion of whole blood use correlates inversely with country income group (Table 7).

Table 7. Proportion of whole blood used for red cell transfusions by countries in World Bank income groups

Income group (no. countries reporting)	Median proportion of whole blood transfusions
Low-income countries (25)	77.1%
Lower middle-income countries (36)	13.2%
Upper middle-income countries (36)	0.6%
High-income countries (42)	< 0.2%

Surveillance procedures for blood transfusion, also called haemovigilance, are an important part of a national blood system, and cover the entire blood transfusion chain. A national haemovigilance system promotes optimal clinical practices through monitoring of blood use and safety outcomes of blood donation and transfusion. Data collection and aggregated reporting enable countries to monitor and improve their haemovigilance and overall blood systems. A performing haemovigilance system provides surveillance on blood collections, marker rates of transfusion-transmissible infectious diseases in blood donors, and adverse reactions in blood donors and transfusion recipients. It also enables the identification of epidemiological trends and benchmarking of performance across countries. Absence of a haemovigilance system is therefore an indicator of suboptimal clinical practices. Globally, the survey showed that only 46% of countries had a national haemovigilance system, including 21% of countries in the Region of the Americas; 36% in the South-East Asia Region; 38% in the African

Region; 48% in the Western Pacific Region; 53% in the Eastern Mediterranean Region; and 76% in the European Region.

Patient blood management, which was endorsed by the World Health Assembly in resolution WHA63.12 (2010), is defined as a set of evidence-based practices to optimize medical and surgical patient outcomes through preservation of the patient's own blood *(34)*. Patient blood management rests on three pillars: diagnosis and treatment of anaemia (especially iron deficiency anaemia), minimization of blood loss, and avoidance of unnecessary transfusions. Patient blood management is increasingly recognized as a fundamental element of good clinical practice in transfusion. Furthermore, it plays a key role in primary health care, given its importance for the treatment of anaemia in pregnant women and children aged under 5 years in areas with malaria.

Implementation of robust patient blood management strategies can lead to improvements in patient outcomes and a reduction in health care costs while ensuring that blood is available for the people who need it most. In many countries, professional societies have already developed comprehensive clinical guidelines for patient blood management.

WHO response to date: implementing appropriate use of blood products, haemovigilance systems and patient blood management

WHO has provided policy guidance on the appropriate clinical use of blood components for transfusion and patient blood management *(35)*; has convened a global forum on patient blood management; has provided technical assistance and capacity-building to countries for safe transfusion practice and patient safety; and has supported the development of systems and capacities for the appropriate use of blood. WHO is currently updating the WHO handbook on the clinical use of blood *(33)* in collaboration with the International Society of Blood Transfusion. Data point to a recent increase in countries with national transfusion guidelines, as well as hospitals with transfusion committees. The important role of nurses was highlighted in the WHO 2010 interregional consultation on strengthening the role of nurses and midwives in ensuring safe clinical transfusion and patient safety *(36)*. A key point is that there should be a designated national transfusion nurse and transfusion safety officer at each hospital.

In 2012, WHO and key international partners organized a global consultation on haemovigilance in collaboration with the International Haemovigilance Network and the International Society of Blood Transfusion to provide guidance on establishing national haemovigilance systems. In 2016, WHO published guidance on establishing national haemovigilance systems and on implementing external quality assessment programmes for screening donated blood for transfusion-transmissible infections *(37, 38)*, and a consultation was held to promote its use in the Eastern Mediterranean Region. Several countries have received technical assistance to develop and work towards implementation of haemovigilance systems. Consistent with such investments, data indicate an increase in the number of countries with national haemovigilance systems (from 57 countries in 2008 to 80 countries in 2015).

WHO has taken steps to increase awareness of patient blood management as a central concept and strategy in clinical use of blood and will expand its efforts in this area *(34)*.

Challenge 6. Insufficient access to blood during emergency situations

Globally, the number of people affected by emergency situations and blood service disruptions, including infectious disease outbreaks, natural disasters and humanitarian crises, is increasing. During an emergency, the need for blood transfusions can increase significantly. Therefore, safe and quality blood products to treat those affected are of lifesaving importance. However, ensuring a safe blood supply often proves to be challenging, as:

- the emergency may have damaged the available civil and health care infrastructure, disrupting mobility, transportation and service provision;
- the population may not come forward to donate blood, due to either fear or illness;
- the means of communication may not be reliable;
- the overall health care system may become overburdened.

Depending on the specific context of the country and the type of emergency, such factors as economic and political instability, or even blockades and sanctions, may result in other barriers to access. Emergency situations can impact the availability and safety of blood more indirectly as well – for example, during displacement primary hygiene is often compromised, increasing the risk of infectious disease outbreaks. Considering these and other challenges, it is crucial that Member States enhance their preparedness and take adequate measures to ensure a safe blood supply during emergency situations.

WHO response to date: emergency preparedness

In response to the increasing incidences of emergency situations and blood service disruptions, including infectious disease outbreaks, natural disasters and humanitarian crises, WHO has developed a number of tools to guide national and international efforts to ensure access to and supply of safe blood in emergency situations. These include Maintaining a safe and adequate blood supply during pandemic influenza: guidelines for blood transfusion services *(39)*; *Maintaining a safe and adequate blood supply during Zika virus outbreaks: interim guidance (40)*; *Protecting the blood supply during infectious disease outbreaks: guidance for national blood services (27)*; *Guidelines on estimation of residual risk of HIV, HBV or HCV infection via cellular blood components and plasma (30)*; and the *Laboratory biosafety manual, third edition (41)*. Whilst these guidelines focus on protecting the blood supply from infectious diseases, more comprehensive guidance will be required to address blood shortages and blood service disruptions at baseline and in the context of natural disasters and humanitarian crises and to ensure the safety of blood products throughout the transportation network, including an intact cold chain.

3 Proposed actions

Establishment and maintenance of a national blood system requires a broad range of societal, scientific and medical competencies that span behavioural science, epidemiology, serological and gene-based diagnostic methods, operational and quality systems management, risk-based decision-making, clinical training, surveillance tools, and business skills, all of which must operate under local physical, social, political and financial conditions and constraints. Given the breadth and scope of the issues and challenges, an interactive set of strategies is needed.

The *overall goal* of this WHO Action Framework is to advance universal access to safe, effective and quality-assured blood products, contributing to the triple billion goals as defined in the WHO 13th General Programme of Work. Access to blood products is essential specifically to achieve the first of the three goals: one billion more people benefiting from universal health coverage. The WHO Action Framework focuses on *six strategic objectives*, with related activities, outputs, intermediate outcomes and high-level outcomes, and will guide the development and implementation of context-specific actions to address the needs of regions and countries. The six strategic objectives are presented below. Annex 1 provides a log frame with details on the strategic objectives and related activities, outputs, intermediate outcomes and high-level outcomes.

Strategic objective 1. An appropriately structured, well coordinated and sustainably resourced national blood system

An appropriately structured, well coordinated and sustainably resourced national blood system ensures access to safe, effective and quality-assured blood products to support the national health system. Strong leadership, political will and governance at the national level are essential to guide the establishment, coordination and management of the national blood system.

First, the national blood system must be appropriately structured and integrated into the national health system, with clearly defined roles and accountabilities

for all its key functions, institutions and organizations. Effective coordination at the national level promotes uniform standards, economies of scale, consistency in quality and safety of blood products and best transfusion practices.

Second, appropriate financing frameworks that are integrated within the financial structure of the health system, supported by sound costing and budgeting practices, are critical in ensuring that the national blood system is adequately and sustainably resourced to perform its functions, including provisions for ongoing personnel training.

Third, national blood policies, legislation, regulation, risk management, decision-making and governance frameworks should be in place and integrated into the wider strategic health system planning to ensure good stewardship, systematic assessment of national blood needs, uniform standards, performance management, and appropriate allocation of resources. The governance structure is strengthened by local stewardship and performance management systems that include hospital transfusion committees, community and stakeholder engagement, quality improvement, blood utilization evaluations and organizational blood drive participation. Policies and decisions affecting quality, safety, efficacy, availability and accessibility of blood products should be made in the interests of public health through a structured policy process of risk-based decision-making that is in accordance with national health system policies, level of development of the national blood programmes, and optimal use of available resources.

Finally, the role of the national blood system during emergencies must be clearly defined and part of national emergency preparedness and response planning, thus ensuring available safe blood in emergency situations such as infectious disease outbreaks, natural disasters and humanitarian emergencies.

WHO will, with partners, provide tools, resources, technical assistance and capacity-building on how to establish and develop an appropriately structured and well coordinated national blood system that is sustainably resourced and has adequate governance and oversight, including adequate costing, budgeting and financing of the national blood service and blood regulator. The WHO Guidelines on Costing of Blood Services (1998) will be revised and updated and made available to Member States and relevant stakeholders.

To achieve strategic objective 1, the following high-level outcomes have been identified.

1.1 The national blood system is appropriately structured, well coordinated and integrated into the national health system.

1.2 The national blood system is adequately and sustainably costed, financed and budgeted.

1.3 National policies and decisions involving blood products are made through good policy process and risk-based decision-making.

1.4 There is an adequate and safe blood supply during emergency situations such as infectious disease outbreaks, natural disasters and humanitarian emergencies.

The log frame in Annex 1 provides a more detailed overview of the outcomes, outputs and activities related to strategic objective 1.

Strategic objective 2. An appropriate national framework of regulatory controls, national standards and quality assessment programmes

An appropriate national framework of regulatory controls, national standards and quality assessment programmes is crucial in ensuring the safety and quality of blood products, associated medical devices and testing reagents.

To this end, each Member State should have a functioning national regulatory authority established in law, which has the authority and capability to set and enforce blood standards and to monitor donor and product safety effectively. This would be consistent with a GBT Plus Blood maturity level of at least 3. Moreover, regulatory mechanisms should be established where necessary to undertake pre-market review, register, license and certify blood establishments and blood products, as well as associated substances such as reagents, tests kits and medical devices used in the collection, processing, testing, storage and administration of blood products. National standards and minimum product and performance specifications should be developed and implemented for blood product services, processes and systems, and national guidelines developed for good manufacturing

practices in blood services and hospitals, transfusion practices and clinical use of blood, haemovigilance, pharmacovigilance, and quality management. Compliance with regulations and standards is enforced through regulatory inspections of blood services and plasma fractionation facilities, external accreditation where appropriate, and participation in external quality assessment schemes and proficiency testing programmes. Technical and scientific capacity at national or regional level is also necessary to evaluate and monitor the performance of blood establishments and blood products, as well as associated substances and medical devices, including IVD devices. These should be strengthened through capacity-building, utilization of reference biological standards, and proficiency testing via participation in external quality assessment schemes.

WHO will, with partners, provide tools, resources, and technical assistance and build blood regulatory capacities, including use of the GBT Plus Blood. WHO will continue to develop international standards and reference reagents (biological reference preparations) for use as benchmarks for quality control and regulation of blood products and related IVD devices. WHO will continue to support the establishment of regional regulatory forums, such as the African Blood Regulators Forum.

To achieve strategic objective 2, the following high-level outcomes have been identified.

2.1 The national blood regulatory system is in place and functions at an externally assessed maturity level of 3 or 4 under the GBT Plus Blood.

2.2 Regulatory mechanisms are in place for comprehensive oversight of blood products, associated substances and medical devices, including IVD devices.

2.3 Quality assessment of blood products, associated substances and medical devices, including IVD devices, is carried out by relevant authorities and national control laboratories.

2.4 Performance of blood products and associated substances and medical devices, including IVD devices, is assured through use of reference biological standards and external quality assessment schemes.

The log frame in Annex 1 provides a more detailed overview of the outcomes, outputs and activities related to strategic objective 2.

Strategic objective 3. Functioning and efficiently managed blood services

A well functioning and efficiently managed blood service ensures the timely and adequate availability of safe and effective blood products of high quality for clinical use. Blood services should be efficiently and cost-effectively managed, with suitable infrastructure and adequate qualified and trained staff.

First, a safe and stable blood supply depends on blood collected from voluntary and non-remunerated blood donors from low-risk populations. Where this has not yet been achieved, strategies should be developed to convert family or replacement donors to voluntary donors and eliminate paid donation. Programmes to protect the health and safety of the blood donor and to promote repeat blood donation from voluntary non-remunerated donors include donor education and motivation, donor selection and deferral, donor care, notification, counselling and referral, and confidentiality. These should also be accompanied by public health measures on surveillance of iron deficiency and anaemia, preventive care, and transfusion alternatives that contribute towards avoiding the need for transfusion.

Second, efficient procurement, supply and distribution chain systems should also be in place to ensure continuity of supplies. Furthermore, reference centres must be available at national level to provide specialized testing, including confirmatory testing, for infectious disease screening. One strategy to optimize resources and promote quality is to consolidate blood processing and testing in facilities that have achieved effective implementation of quality systems. Centres that carry out consolidated blood donation testing and processing should also be established to promote achievement of quality in blood donation testing and blood component processing.

Blood should be processed into blood components based on the clinical needs of the health care system, appropriately processed and tested to ensure patient safety, and stored and distributed efficiently to minimize wastage. Efficient inventory management ensures optimum blood stocks and minimizes wastage, and an effective and reliable blood cold

chain maintains safe storage and transportation of blood components. Functioning liaison and collaboration with hospitals and clinical users will ensure appropriate clinical transfusion and patient management practices, including quality-assured compatibility testing and evidence-based practices of transfusion. Quality systems should be in place across the entire blood transfusion chain and all activities performed in a quality-focused way and continuously monitored. These include compliance with good manufacturing practices; maintenance of a cold chain in handling and transportation; and haemovigilance and pharmacovigilance. Systems and standardized procedures should be established for donor selection, blood collection, processing, testing, storage and transportation to ensure consistent quality, safety and efficacy of blood components.

To ensure sufficient access to and availability of PDMPs, strategies must be planned and coordinated at national level, which may involve a combination of strategies to strengthen domestic plasma production capacity and procurement of commercially available PDMPs. Measures to strengthen domestic plasma production capacity include enhancing the volume and quality of recovered plasma suitable for manufacture and suitable arrangements for fractionation of surplus plasma recovered from whole blood. Where PDMPs are unavailable or not affordable, interim solutions such as local production of pathogen-reduced cryoprecipitate and immune globulins from small plasma pools may be considered to provide therapies in some conditions. Coordinated efforts are therefore necessary at global and regional levels, between countries and with fractionation organizations, to improve the volume of plasma suitable for manufacture of PDMPs and facilitate access to fractionation facilities through appropriate regulatory standards, contract manufacturing and technology transfer.

WHO will, with partners, provide tools, resources, technical assistance and capacity-building on how to increase safe blood donations and establish and manage a quality blood management system. This will be supported by implementation of the WHO and International Federation of Red Cross and Red Crescent Societies global framework for action towards 100% voluntary and repeat blood donation *(21)*, the WHO guidelines on assessing donor suitability for blood donation *(23)*, and the WHO guidelines on good manufacturing practices for blood establishments *(19)*. Furthermore, WHO will develop and disseminate guidelines and other relevant knowledge and build capacities to enhance countries' preparedness for safe blood supplies during emergency situations.

To achieve strategic objective 3, the following high-level outcomes have been identified.

3.1 There has been achievement of 100% voluntary, non-remunerated blood donation, protection of blood donor health and safety, and promotion of repeat donation.

3.2 A functioning quality system is in place across the entire blood transfusion chain.

3.3 Blood services are efficiently and cost-effectively managed, and donated blood processed according to clinical need with minimal wastage.

3.4 Availability of the volume and quality of plasma for manufacture into PDMPs has been increased.

The log frame in Annex 1 provides a more detailed overview of the outcomes, outputs and activities related to strategic objective 3.

Strategic objective 4. Effective implementation of patient blood management to optimize clinical practice of transfusion

Patient blood management is essential to optimize patient outcomes and patient safety by ensuring appropriate transfusion. Therefore, efforts need to be made to implement patient blood management effectively.

Patient blood management should be routinely practised by clinicians and other relevant health care providers (such as nurses, midwives, transfusion safety officers, laboratory scientists and technicians). This includes diagnosis and correction of iron deficiency and anaemia; consideration of alternatives for transfusion; use of adjuvant drugs and devices to reduce or avoid the need for blood; appropriate clinical use of blood; and effective management of patients in need of a blood transfusion. Patient awareness and involvement in blood management is also strengthened through communication of relevant safety information (risks and benefits of transfusion)

and obtaining acknowledgement and consent. Clinical practices should be in accordance with national guidelines and standards on the clinical use of blood products and alternatives to blood transfusion, with evidence-based risk–benefit considerations. Moreover, hospital transfusion committees should be established to provide oversight and drive the implementation of transfusion guidelines.

Quality systems should be in place in hospitals for compatibility testing and issue of blood, storage and handling of blood units, rational use of blood products, safe transfusion practices, and patient monitoring and follow-up. This includes a system for patient and product identification and traceability. Quality systems for the clinical transfusion process include standardized procedures, blood requests, labels and records. Monitoring of quality indicators, such as transfusion rates and indications, provide better understanding of the status of patient blood management efforts. Critical supplies should be available for transfusion alternatives, reagents and materials for pre-transfusion testing, and administration of blood products. Pharmaceuticals and devices to minimize the need for blood should be regularly evaluated for quality, safety, efficacy and availability.

WHO will, with partners, provide tools, resources, technical assistance and capacity-building to improve clinical use by clinicians and other relevant health care providers.

To achieve strategic objective 4, the following high-level outcomes have been identified.

4.1 Good patient blood management is practised, based on national clinical guidelines and practice standards.

4.2 A quality system is in place in hospitals for all pre-transfusion testing and clinical transfusion processes, including hospital blood bank laboratories.

The log frame in Annex 1 provides a more detailed overview of the outcomes, outputs and activities related to strategic objective 4.

Strategic objective 5. Effective surveillance, haemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection systems

Effective systems are needed to facilitate monitoring and evaluation of the blood system, including donor safety, blood product quality and safety, and transfusion safety. Data are crucial in order to understand the current status of and trends in access to quality blood products at the national, regional and global levels. Availability of good data is also essential for understanding the status of clinical practices, such as pre-operative anaemia and transfusion rates, and assessing the effectiveness of patient blood management programmes.

The existence of a data collection and reporting system is an important element of a well managed, nationally coordinated blood transfusion programme. Adequate national data on blood availability and safety allow countries to set priorities and to further strengthen the national blood system. There is a need to establish systems of surveillance on the incidence and prevalence of HIV, HBV, HCV and other infections in blood donors and vigilance on the transfusion outcomes of recipients, including post-transfusion risk of infection. Information on clinical transfusion forms the basis for the monitoring of clinical transfusion practice and provides critical performance measures to influence desirable changes in prescribing and administration of blood and reduce variations in transfusion practice. There is a need for national blood transfusion services to provide greater structure and support for the information management system and for hospitals to establish mechanisms for improving data collection, donor tracking, traceability and overall haemovigilance.

Adverse events and reactions in blood donors and patients should also be monitored to ensure adequate action is taken to address these and to protect the health of future blood donors and patients. Systems for haemovigilance and pharmacovigilance should be established at organizational and national levels to monitor adverse events, adverse reactions and known threats to blood availability and safety, and to enable informed decisions. The ability to effect end-to-end traceability from collection to use, and to carry out surveillance, are important prerequisites to such systems. To support this, blood collection

centres and hospitals must also have systems to monitor, investigate and assess adverse events, and to train clinical staff in the recognition, management, investigation and reporting of adverse events and adverse reactions in blood donors and in recipients of blood products.

The WHO GDBS is an important tool for data collection and analysis, and depends on the collection, analysis and reporting of data at the national level. There should therefore be a national system for standardized data collection and reporting, and mechanisms to ensure uniform implementation. Robust and secure data management and information reporting systems on availability, utilization, safety and quality of blood products should be implemented in blood services and hospitals to facilitate this. To enable more consistency and comparability of reported information, data definitions need to be improved, through common good practices and greater collaborative efforts to develop more standardized and harmonized terminology.

WHO will, with partners, provide tools, resources, technical assistance and capacity-building to establish and strengthen systems for national data management, haemovigilance and pharmacovigilance. WHO will also continue to coordinate the collection of data from national blood establishments into the WHO GDBS and provide an analysis and summary in the periodic *Global status report on blood safety and availability*.

To achieve strategic objective 5, the following high-level outcomes have been identified.

5.1 There is a national system for standardized data collection and reporting, and mechanisms to ensure uniform implementation.

5.2 There are systems for traceability, surveillance, haemovigilance and pharmacovigilance at national and organizational levels.

5.3 The WHO GDBS provides comprehensive and accurate data on the global status of blood product availability, safety and quality

The log frame in Annex 1 provides a more detailed overview of the outcomes, outputs and activities related to strategic objective 5.

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

The overall goal of universal access to safe, effective and high-quality blood products can only be achieved through effective collaboration and information exchange between WHO, Member States and a wide network of relevant stakeholders and partner organizations. These partnerships are particularly relevant to a number of outcomes, which are listed under strategic objective 6.

The knowledge and skills of blood transfusion staff are vital factors contributing to the availability of safe, effective and quality-assured blood products. In many countries, however, there are considerable variations in the quality of performance, especially among staff, who may have received inadequate basic training or have had no further training. In addition, the knowledge and skills required for safe and efficient transfusion practice are constantly changing. Therefore, training is fundamental to every aspect of blood safety, and there is a need to set up educational programmes on key functions of the national blood system.

External assessment of the performance of blood establishments is needed to ensure that quality standards are fully met. To this end, Member States should aim to develop the capacity to carry out external assessments and accreditation of national blood establishments. Where this is not possible, this may be provided through regional or international organizations.

Scientific and technological innovations have yielded remarkable advances in blood products and blood systems. At the same time, emerging pathogens and other disease threats can lead to urgent situations that require rapid responses. However, technical information and the scientific evidence needed are frequently not available. There may also be difficulties in judging the merits of the consequences of adoption of new technologies in ways that will improve patient access and health outcomes in the country. Drawing on the capacity of relevant global and regional organizations, countries should be supported in the assessment of new technologies and other innovations in order to overcome local impediments.

Training, qualification and capacity-building are essential to strengthen national regulatory competencies and support regulatory mechanisms. Cooperation among regulators in different Member States is an effective mechanism to promote national capacity-building. Additionally, harmonization and regulatory reliance are strategies to reduce burdens on Member States that are advancing national blood regulation.

WHO will draw on its network of experts and partners to provide guidance and technical assistance to the development of training programmes, and to facilitate training of trainers on key functions of the national blood system. The Organization will also help Member States to identify organizations as a resource for external assessment and accreditation. Drawing on the capacities of both regional and global organizations, WHO will continue to support Member States to identify and assess new blood safety technologie[13] and other innovations, and to help incorporate them in the national blood system.

To achieve strategic objective 6, the following high-level outcomes have been identified.

6.1 Training programmes on key functions of the national blood system are in place.

6.2 Capacity to carry out external assessment and accreditation of national blood establishments is available.

6.3 The capacity to evaluate relevant new technologies and other innovations is incorporated into the national blood system to overcome local impediments and to address urgent situations.

6.4 Regulatory capacity is strengthened through collaborative capability-building and harmonization initiatives, including use of reliance.

The log frame in Annex 1 provides a more detailed overview of the outcomes, outputs and activities related to strategic objective 6.

[13] Such as molecular detection for transfusion-transmissible infectious disease agents, pathogen inactivation, and automated data collection and analysis systems.

4 Organizational capacity, management and implementation

4.1 Organizational capacity

WHO has served as the directing and coordinating authority for health within the United Nations system since its establishment in 1948, providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends. WHO, governed by 194 Member States, has a unique decentralized structure comprising six regional offices and presence in 150 countries, territories and areas. WHO believes in strong collaboration between all three levels of the Organization in order to deliver strong results. WHO draws on an extensive network of technical expertise through the WHO Expert Committee on Biological Standardization; the WHO Expert Advisory Panel on Blood Transfusion Medicine; the WHO Blood Regulators Network; the International Conference of Drug Regulatory Authorities; the European Centre for Disease Prevention and Control; the United States Centers for Disease Control and Prevention; WHO collaborating centres worldwide; and a network of non-State actors, including nongovernmental organizations in official WHO relations. With ministries of health as its national counterpart, and the political support expressed through a series of World Health Assembly resolutions, WHO is best placed to coordinate global action towards universal access to quality and safe blood products.

4.2 Management and implementation

The overall implementation of the proposed WHO Action Framework will be under the responsibility of the WHO Secretariat, in close collaboration with specialized staff in WHO regional offices and country offices, and relevant external partners. WHO technical and managerial expertise will address a spectrum of knowledge and capacities required to guide global action on blood availability and safety. These areas include blood donor recruitment, retention and counselling; blood donor selection and laboratory-based screening; blood component preparation and banking; prequalification of IVD devices and oversight of laboratory quality; clinical practice of transfusion

medicines; patient blood management and patient safety; and production, control and regulation of human plasma for fractionation. Underlying knowledge and capacity include information technology; behavioural science; regulatory systems strengthening, including good manufacturing practices; development of norms and standards; and programme management and coordination.

A WHO programme management group will be established with operational responsibility, including technical and financial planning, implementation, monitoring, evaluation and donor reporting. Project management will be supported by the WHO Global Management System, an enterprise management system based on common rules and procedures for the entire organization at country, regional and global levels that supports strategic and operational planning, programming and budgeting, implementation, monitoring, reporting and allocation of resources. Financial management in WHO adheres to the International Public Sector Accounting Standards, representing leading international accounting practices for the public sector and United Nations specialized agencies.

References

1. Assessment criteria for national blood regulatory systems. In: WHO Expert Committee on Biological Standardization: sixty-second report. WHO Technical Report Series No. 979. Geneva: World Health Organization; 2013 (https://apps.who.int/iris/handle/10665/89156, accessed 9 December 2019).

2. Guidelines on management of blood and blood components as essential medicines. In: WHO Expert Committee on Biological Standardization: sixty-seventh report. WHO Technical Report Series No. 1004. Geneva: World Health Organization; 2017 (http://apps.who.int/medicinedocs/documents/s23322en/s23322en.pdf, accessed 9 December 2019).

3. Improving access to safe blood products through local production and technology transfer in blood establishments. Geneva: World Health Organization; 2016 (https://www.who.int/phi/publications/improving_access_safe_blood_products/en/, accessed 9 December 2019).

4. WHO Model List of Essential Medicines: 21st list 2019. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/handle/10665/325771, accessed 9 December 2019).

5. The WHO Programme for International Drug Monitoring. Geneva: World Health Organization (https://www.who.int/medicines/regulation/medicines-safety/about/drug_monitoring_prog/en/, accessed 9 December 2019).

6. How to develop and implement a national drug policy. Geneva: World Health Organization; 2001 (https://apps.who.int/iris/handle/10665/42423, accessed 9 December 2019).

7. Thirteenth General Programme of Work, 2019–2023: promote health, keep the world safe, serve the vulnerable. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/handle/10665/324775, accessed 9 December 2019).

8. Draft roadmap for access to medicines, vaccines and other health products, 2019–2023. Geneva: World Health Organization; 2019.

9. Towards access 2030: WHO Essential Medicines and Health Products Strategic Framework 2016–2030. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/258757, accessed 9 December 2019).

10. Delivering Quality-Assured Medical Products for All 2019–2023: WHO's five-year plan to help build effective and efficient regulatory systems. Geneva: World Health Organization; 2019 (https://www.who.int/medicines/news/2019/WHO_ActionPlan.pdf?ua=1, accessed 9 December 2019).

11. About the Sustainable Development Goals. New York: United Nations (https://www.un.org/sustainabledevelopment/sustainable-development-goals/, accessed 9 December 2019).

12. Global Database on Blood Safety. Geneva: World Health Organization (https://www.who.int/bloodsafety/global_database/en/, accessed 9 December 2019).

13. Global status report on blood safety and availability 2016. Geneva: World Health Organization; 2017 https://apps.who.int/iris/handle/10665/254987.

14. Aide-mémoire: good policy process for blood safety and availability. Geneva: World Health Organization; 2011 (https://www.who.int/bloodsafety/publications/who_eht_08_02/en/, accessed 10 December 2019).

15. Universal access to safe blood transfusion. Geneva: World Health Organization; 2008 (https://apps.who.int/iris/handle/10665/69747, accessed 10 December 2019).

16. Aide-mémoire for ministries of health: developing a national blood system. Geneva: World Health Organization; 2011 (https://www.who.int/bloodsafety/publications/am_developing_a_national_blood_system.pdf, accessed 10 December 2019).

17. Management of national blood programmes: proceeding of three WHO workshops (ĐĐ2007–2009)ĐĐ. Manila: WHO Regional Office for the Western Pacific; 2010 (https://extranet.who.int/iris/restricted/handle/10665/207609, accessed 10 December 2019).

18. Safe blood and blood products: costing blood transfusion services. Geneva: World Health Organization, Blood Safety Unit; 1998 (https://apps.who.int/iris/handle/10665/65533, accessed 10 December 2019).

19. WHO guidelines on good manufacturing practices for blood establishments. WHO Technical Report Series No. 961, Annex 4. Geneva: World Health Organization; 2011 (https://www.who.int/bloodproducts/publications/GMP_Bloodestablishments.pdf, accessed 10 December 2019).

20. WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems. Geneva: World Health Organization (https://www.who.int/medicines/regulation/benchmarking_tool/en/, accessed 10 December 2019).

21. Towards 100% voluntary blood donation: a global framework for action. Geneva: World Health Organization and International Federation of Red Cross and Red Crescent Societies; 2010 (https://apps.who.int/iris/handle/10665/44359, accessed 10 December 2019).

22. Expert consensus statement on achieving self-sufficiency in safe blood and blood products, based on voluntary non-remunerated blood donation (VNRBD). Geneva: WHO Expert Group on self-sufficiency in safe blood and blood products based on VNRBD; 2012.

23. Blood donor selection: guidelines on assessing donor suitability for blood donation. Geneva: World Health Organization; 2012 (https://apps.who.int/iris/handle/10665/76724, accessed 10 December 2019).

24. World Health Organization, Centers for Disease Control and Prevention, and International Federation of Red Cross and Red Crescent Societies. Blood donor counselling: implementation guidelines. Geneva: World Health Organization; 2014 (https://apps.who.int/iris/handle/10665/163001, accessed 10 December 2019).

25. Screening donated blood for transfusion-transmissible infections: recommendations. Geneva: World Health Organization; 2009 (https://apps.who.int/iris/handle/10665/44202, accessed 10 December 2019).

26. Aide-memoire for national blood programmes. Geneva: World Health Organization; 2002 (https://apps.who.int/iris/handle/10665/66698, accessed 11 December 2019).

27. Protecting the blood supply during infectious disease outbreaks: guidance for national blood services. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/handle/10665/311443, accessed 11 December 2019).

28. Safe blood and blood products. Establishing a distance learning programme in blood safety: a guide for programme coordinators. Geneva: World Health Organization; 2009.

29. Quality management training for blood transfusion services: facilitator's toolkit. Geneva: World Health Organization; 2005 (https://apps.who.int/iris/handle/10665/69887, accessed 11 December 2019).

30. Guidelines on estimation of residual risk of HIV, HBV or HCV infections via cellular blood components and plasma. In: WHO Expert Committee on Biological Standardization, sixty-seventh report, Annex 4. WHO Technical Report Series No. 1004. Geneva: World Health Organization and WHO Expert Committee on Biological Standardization; 2017 (https://apps.who.int/iris/handle/10665/255657, accessed 11 December 2019).

31. Faber JC, Burnouf T. Bitter progress in the treatment of haemophilia A in low-income countries. Lancet Haematology. 2018;5(6):e239.

32. Catalogue of International Reference Preparations. Geneva: World Health Organization (https://www.who.int/bloodproducts/catalogue/en/, accessed 11 December 2019).

33. The Clinical use of blood: handbook. Geneva: World Health Organization, Blood Transfusion Safety Team; 2001 (https://apps.who.int/iris/handle/10665/42396, accessed 11 December 2019).

34. Global Forum for Blood Safety: patient blood management. Concept paper. Geneva: World Health Organization; 2011 (https://www.who.int/bloodsafety/events/gfbs_01_pbm/en/, accessed 11 December 2019).

35. Aide-mémoire for national health authorities and hospital management. Geneva: World Health Organization; 2010 (https://www.who.int/bloodsafety/clinical_use/who_eht_10_05_en.pdf?ua=1, accessed 11 December 2019).

36. Strategic directions for strengthening nursing and midwifery services 2011–2015. Geneva: World Health Organization; 2010 (https://apps.who.int/iris/handle/10665/70526, accessed 11 December 2019).

37. A guide to establishing a national haemovigilance system. Geneva: World Health Organization; 2016 (https://apps.who.int/iris/handle/10665/250233, accessed 11 December 2019).

38. Establishing external quality assessment programmes for screening of donated blood for transfusion-transmissible infections: implementation guide. Geneva: World Health Organization; 2016 (https://apps.who.int/iris/handle/10665/246169, accessed 11 December 2019).

39. Maintaining a safe and adequate blood supply during pandemic influenza: guidelines for blood transfusion services. Geneva: World Health Organization; 2012 (https://www.who.int/bloodsafety/publications/WHO_Guidelines_on_Pandemic_Influenza_and_Blood_Supply.pdf, accessed 11 December 2019).

40. Maintaining a safe and adequate blood supply during Zika virus outbreaks: interim guidance. Geneva: World Health Organization; 2016 (https://apps.who.int/iris/handle/10665/204436, accessed 11 December 2019).

41. Laboratory biosafety manual, third edition. Geneva: World Health Organization; 2004 (https://apps.who.int/iris/handle/10665/42981, accessed 11 December 2019).

Annex 1

Log frame of strategic objectives, activities, outputs, and outcomes

Action framework to advance universal access to safe, effective and quality-assured blood products (2020–2023)			
Overall goal: Universal access to safe, effective and quality-assured blood products			
Activities	**Output**	**Intermediate outcome**	**High-level outcome**
Strategic objective 1: an appropriately structured, well coordinated and sustainably resourced national blood system			
Disseminate WHO guidelines and other knowledge products relevant to the establishment and sustainment of a national blood system that is appropriately structured, well coordinated and integrated into the national health system. This includes: • WHO aide-mémoire for ministries of health on developing a national blood system; • WHO aide-mémoire for national health policy-makers on good policy process for blood safety and availability; • WHO aide-mémoire for national blood programmes: blood safety.	WHO guidelines and other knowledge products.	Member States have the knowledge and capacity to establish and sustain a national blood system that is appropriately structured, well coordinated and integrated into the national health system, with clearly defined roles and accountabilities, and regulatory, decision-making and governance frameworks.	1.1. The national blood system is appropriately structured, well coordinated and integrated into the national health system.
Mobilize, convene and provide technical assistance to Member States relevant to the establishment of a national blood system that is appropriately structured, well coordinated and integrated into the national health system.	Technical assistance missions; expert arrangements; knowledge sharing.		
Disseminate knowledge products relevant to the development of national blood policies, legislation and regulation. This includes: • WHO aide-mémoire for national health policy-makers: good policy process for blood safety and availability.	WHO guidelines and other knowledge products.	Member States have the knowledge and capacity to develop national blood policies, legislation and regulation.	
Mobilize, convene and provide technical assistance to Member States to build capacity on the development of national blood policies, legislation and regulation.	Technical assistance missions; expert arrangements; knowledge sharing.		
Revise and update the WHO guidelines on costing of blood services to include guidance on the financing and budgeting of the national blood system.	Revised and updated WHO guidelines on costing of blood services.	Member States have the knowledge and capacity to establish a sustainable financing framework and mechanisms, and to carry out the adequate costing, financing and budgeting of the national blood system.	1.2. The national blood system is adequately and sustainably costed, financed and budgeted.
Disseminate WHO guidelines and other knowledge products relevant to the costing, financing and budgeting of the national blood system to Member States and other relevant stakeholders. This includes: • the revised and updated WHO guidelines on costing of blood services; • information on establishing sustainable financing frameworks and mechanisms.	WHO guidelines and other knowledge products.		
Mobilize, convene and provide technical assistance to Member States on adequate costing, financing and budgeting of the national blood system (i.e. visits by technical experts; expert arrangements; knowledge sharing), and on establishing sustainable financing frameworks and mechanisms.	Technical assistance missions; expert arrangements; knowledge sharing.		

Action framework to advance universal access to safe, effective and quality-assured blood products (2020–2023)			
Overall goal: Universal access to safe, effective and quality-assured blood products			
Activities	**Output**	**Intermediate outcome**	**High-level outcome**
Disseminate WHO guidelines and other knowledge products relevant to the development of adequate policies and key guidelines and standards on the national blood system to Member States. This includes: • WHO aide-mémoire for national health policy-makers on good policy process for blood safety and availability; • WHO risk-based decision-making support tool for blood safety.	WHO guidelines and other knowledge products relevant to the development of adequate policies and key guidelines and standards on the national blood system are available to Member States and other relevant stakeholders.	Member States have the knowledge and capacity to develop adequate policies and key guidelines and standards on the national blood system based on good policy process and risk-based decision-making.	1.3. National policies and decisions involving blood products are made through good policy process and risk-based decision-making.
Mobilize, convene and provide technical assistance to Member States relevant to the development of adequate policies and key guidelines and standards on the national blood system to Member States.	Technical assistance missions; expert arrangements; knowledge sharing.		
Develop WHO guidelines on ensuring a safe blood supply during emergency situations, such as infectious disease outbreaks; natural disasters; and humanitarian emergencies.	WHO guidelines on ensuring a safe blood supply during emergency situations, such as infectious disease outbreaks, natural disasters, and humanitarian emergencies.	Member States and other relevant stakeholders have the knowledge and capacity to enhance preparedness of an adequate and safe blood supply during emergency situations, such as infectious disease outbreaks, natural disasters, and humanitarian emergencies.	1.4. There is an adequate and safe blood supply during emergency situations such as infectious disease outbreaks, natural disasters and humanitarian emergencies.
Disseminate WHO guidelines and other knowledge products relevant to enhancing the preparedness of a safe blood supply during emergency situations, such as infectious disease outbreaks, natural disasters, and humanitarian emergencies, to Member States and other relevant stakeholders. This includes: • WHO guidelines on protecting the blood supply during infectious disease outbreaks; • WHO guidelines on estimation of residual risk of HIV, HBV or HCV infection via cellular blood components and plasma, and the laboratory biosafety manual.	WHO guidelines and other knowledge products.		
Mobilize, convene and provide technical assistance to Member States to enhance preparedness of a safe blood supply during emergency situations, such as disease outbreaks, natural disasters, and humanitarian emergencies.	Technical assistance missions; expert arrangements; knowledge sharing.		
Strategic objective 2: an appropriate national framework of regulatory controls, national standards and quality assessment programmes			
Disseminate knowledge products relevant to the regulation of the national blood system to Member States and other relevant stakeholders. This includes: • WHO aide-mémoire on strengthening national regulatory authorities; • the assessment criteria for national blood regulatory systems, TRS 979 (2013), Annex 7.	WHO guidelines and other knowledge products.	Member States have the knowledge and capacity to develop the national blood regulatory system to an externally assessed maturity level of 3 or 4.	2.1. The national blood regulatory system is in place and functions at an externally assessed maturity level of 3 or 4 under the GBT Plus Blood.
Mobilize, convene and provide technical assistance to Member States on the establishment of a national blood regulatory system.	Technical assistance missions; expert arrangements; knowledge sharing.		

Action framework to advance universal access to safe, effective and quality-assured blood products (2020–2023)			
Overall goal: Universal access to safe, effective and quality-assured blood products			
Activities	**Output**	**Intermediate outcome**	**High-level outcome**
Mobilize, convene and provide technical assistance to relevant authorities on the regulation of the national blood system, including the implementation of the Global Benchmarking Tool (GBT) Plus Blood.	Technical assistance missions; expert arrangements; knowledge sharing.	Relevant authorities have adequate knowledge and capacity of the GBT Plus Blood and use it in self-benchmarking and official regulatory benchmarking exercises for blood product regulation.	2.1. The national blood regulatory system is in place and functions at an externally assessed maturity level of 3 or 4 under the GBT Plus Blood.
Disseminate knowledge products relevant to the GBT Plus Blood and its use in self-benchmarking and official regulatory benchmarking exercises for blood product regulation. This includes: • the GBT Plus Blood.	WHO guidelines and other knowledge products.		
Disseminate knowledge products relevant to the regulation of the national blood system to relevant authorities and other relevant stakeholders. This includes: • WHO guidelines on good manufacturing practices for blood establishments.	WHO guidelines and other knowledge products.	Relevant authorities have the knowledge and capacity to implement the WHO guidelines on GMP applicable to blood product regulation.	
Mobilize, convene and provide technical assistance to relevant authorities on the implementation of the WHO guidelines on good manufacturing practices (GMP) for blood establishments.	Technical assistance missions; expert arrangements; knowledge sharing.		
Disseminate knowledge products relevant to the development of regulatory mechanisms applicable to oversight of blood establishments and blood products.	WHO guidelines and other knowledge products.	Relevant authorities have the capacity and knowledge to establish regulatory mechanisms for pre-market review, registration, licensing, certification and compliance measures applicable to blood establishments and blood products.	2.2. Regulatory mechanisms are in place for comprehensive oversight of blood products, associated substances and medical devices, including IVD devices.
Mobilize, convene and provide technical assistance to national regulatory authorities to develop regulatory mechanisms applicable to blood establishments and blood products.	Technical assistance missions; expert arrangements; knowledge sharing.		
Disseminate knowledge products relevant to the development of regulatory mechanisms applicable to oversight of associated substances and medical devices, including in vitro diagnostic (IVD) devices. This includes: • regulation and licensing of biological products in countries with newly developing regulatory authorities, TRS 858 (1995), Annex 1; • WHO guidelines on procedures and data requirements for changes to approved biotherapeutic products, TRS 1011 (2018), Annex 3; • WHO aide-mémoire on quality and safety of blood products and related substances.	WHO guidelines and other knowledge products.	Relevant authorities have the capacity and knowledge to establish regulatory mechanisms for pre-market review, registration, licensing, certification and compliance measures applicable to associated substances and medical devices, including IVD devices.	
Mobilize, convene and provide technical assistance to relevant authorities to develop regulatory mechanisms applicable to associated substances and medical devices, including IVD devices.	Technical assistance missions; expert arrangements; knowledge sharing.		

Action framework to advance universal access to safe, effective and quality-assured blood products (2020–2023)			
Overall goal: Universal access to safe, effective and quality-assured blood products			
Activities	**Output**	**Intermediate outcome**	**High-level outcome**
Disseminate WHO guidelines and other knowledge products relevant to quality assessment of blood products, associated substances and medical devices, including IVD devices. This includes: • WHO International Biological Standards for use in quality assessment and regulation of blood products and related IVD devices for blood screening; • WHO aide-mémoire for national blood programmes: quality systems for blood safety; • WHO aide-mémoire on quality and safety of blood products and related substances; • WHO guidelines on establishing an external quality assessment scheme in blood group serology; • WHO implementation guide on establishing external quality assessment programmes for screening of donated blood for transfusion-transmissible infections; • WHO manual for organizing a national external quality assessment programme for health laboratories and other testing sites; • guidelines for national authorities on quality assurance for biological products, TRS 822 (1992), Annex 2; • requirements for the collection, processing and quality control of blood, blood components and plasma derivatives, TRS 840 (1994), Annex 2; • WHO global model regulatory framework for medical devices, including in vitro diagnostic medical devices.	WHO guidelines and other knowledge products.	WHO guidelines and other knowledge products relevant to the quality assessment of blood products and associated substances and medical devices, including IVD devices, are available to Member States and other relevant stakeholders.	2.3. Quality assessment of blood products, associated substances and medical devices, including IVD devices, is carried out by relevant authorities and national control laboratories.
Mobilize, convene and provide technical assistance to relevant authorities and national control laboratories to carry out quality assessment of blood products, associated substances and medical devices, including IVD devices.	Technical assistance missions; expert arrangements; knowledge sharing.	Relevant authorities and national control laboratories have the knowledge and capacity to carry out quality assessment of blood products, associated substances and medical devices, including IVD devices.	
Develop the WHO International Biological Standards needed for use in quality assessment and regulation of blood products and related IVD devices for blood screening. These reference preparations will be developed in collaboration with selected WHO collaborating centres.	WHO International Biological Standards for use in quality assessment and regulation of blood products and associated medical devices, including IVD devices for blood screening.	Member States have the knowledge and capacity to assure the performance of blood products and associated substances and medical devices, including IVD devices, through use of reference biological standards and external quality assessment schemes.	2.4. Performance of blood products and associated substances and medical devices, including IVD devices, is assured through use of reference biological standards and external quality assessment schemes.
Develop guidelines on participation in external quality assessment schemes, including secondary reference materials and working reagents benchmarked against WHO International Biological Standards.	Guidelines on participation in external quality assessment schemes, including secondary reference materials and working reagents benchmarked against WHO International Biological Standards.		

Action framework to advance universal access to safe, effective and quality-assured blood products (2020–2023)			
Overall goal: Universal access to safe, effective and quality-assured blood products			
Activities	**Output**	**Intermediate outcome**	**High-level outcome**
Strategic objective 3: functioning and efficiently managed blood services			
Disseminate WHO guidelines and other knowledge products relevant to the achievement of 100% voluntary non-remunerated blood donation, protection of blood donor health and safety, and promotion of repeat donation to Member States and other relevant stakeholders. This includes: • WHO guidelines on assessing donor suitability for blood donation; • WHO implementation guidelines on blood donor counselling; • WHO-IFRC global framework for action towards 100% voluntary and repeat blood donation; • universal access to safe blood transfusion: scaling up the implementation of the WHO strategy for blood safety and availability to improve patient health and save lives; • plan of action for universal access to safe blood; • universal access to safe blood transfusion; • WHO global status report on blood safety and availability 2016; • WHO fact sheet on blood safety and availability (updated 29 May 2019).	WHO guidelines and other knowledge products.	Member States and other relevant stakeholders have the knowledge and capacity to develop and establish measures to achieve 100% voluntary non-remunerated blood donation, protect blood donor health and safety, and promote repeat donation.	3.1. There has been achievement of 100% voluntary non-remunerated blood donation, protection of blood donor health and safety, and promotion of repeat donation.
Organize a series of a national/regional workshops for national blood establishments to build capacity to achieve 100% voluntary non-remunerated blood donation, protect blood donor health and safety, and promote repeat donation.	Technical assistance missions; expert arrangements; knowledge sharing.		
Quality management system in national blood establishments and hospitals: disseminate WHO guidelines and other knowledge products relevant to the key functions of the quality management system to Member States and other relevant stakeholders. This includes: • WHO guidelines on good manufacturing practices for blood establishments; • PIC/S GMP guide for blood establishments; • WHO handbook: good laboratory practice; • WHO guidelines on drawing blood; the practical guidance on venapuncture for blood donation; • WHO aide-mémoire for national blood programmes on blood safety; • WHO guidelines on blood screening; • WHO manual on the management, maintenance and use of blood cold chain equipment; • WHO guidelines on the management of blood and blood components as essential medicines; • guidelines on viral inactivation and removal procedures intended to assure the viral safety of human blood plasma products, TRS 924, Annex 4; • aide-mémoire for national blood programmes: blood cold chain; • aide-mémoire for national health authorities: safe blood components.	WHO guidelines and other knowledge products.	National blood establishments have the knowledge and capacity to carry out key functions of the quality system across the entire blood transfusion chain, from recruitment of blood donors and product processing to the distribution/transportation of blood products, including cold chain.	3.2. A functioning quality system is in place across the entire blood transfusion chain.
Organize a series of a national/regional workshops for national blood establishments to build capacity on carrying out key functions of the quality management system, starting from the recruitment of blood donors, to the distribution/transportation of blood and blood components. Specifically, this includes workshops on the implementation of the WHO guidelines on good manufacturing practices (GMP) for blood establishments, and the WHO handbook on good laboratory practices (GLP).	Technical assistance missions; expert arrangements; knowledge sharing.		

Action framework to advance universal access to safe, effective and quality-assured blood products (2020–2023)			
Overall goal: Universal access to safe, effective and quality-assured blood products			
Activities	**Output**	**Intermediate outcome**	**High-level outcome**
Disseminate WHO guidelines and other knowledge products relevant to processing of blood into components according to clinical need and patient safety, with minimum wastage.	WHO guidelines and other knowledge products.	National blood establishments have the knowledge and capacity to appropriately process blood into components according to clinical need and patient safety, with minimum wastage.	3.3. Blood services are efficiently and cost-effectively managed, and donated blood processed according to clinical need with minimal wastage.
Mobilize, convene and provide technical assistance to national blood establishments on processing of blood into components according to clinical need and patient safety, with minimum wastage.	Technical assistance missions; expert arrangements; knowledge sharing.		
Disseminate WHO guidelines and other knowledge products relevant to the efficient and cost-effective management of blood services.	WHO guidelines and other knowledge products.	National blood establishments have the knowledge and capacity to manage blood services efficiently and cost-effectively.	
Mobilize, convene and provide technical assistance to national blood establishments on the efficient and cost-effective management of blood services.	Technical assistance missions; expert arrangements; knowledge sharing.		
Develop WHO guidance on the establishment of one or more centres of excellence for blood processing and testing.	WHO guidelines and other knowledge products.	One or more centres that carry out consolidated blood donation testing and processing.	
Disseminate WHO guidelines and other knowledge products relevant to the establishment of one or more centres that carry out consolidated blood donation testing and processing. This includes: • WHO aide-mémoire for national health authorities on safe blood components.	WHO guidelines and other knowledge products.		
Twinning programme: facilitate a twinning programme on the establishment of a centre that carries out consolidated blood donation testing and processing.	Knowledge exchange between Member States on the establishment of one or more centres that carry out consolidated blood donation testing and processing.		
Disseminate knowledge products relevant to increasing the volume and quality of recovered plasma for fractionation to manufacture plasma-derived medicinal products (PDMPs) to Member States and other relevant stakeholders. This includes: • WHO recommendations for the production, control and regulation of human plasma for fractionation; • WHO report on improving access to safe blood products through local production and technology transfer in blood establishments; • WHO information sheet on the plasma contract fractionation programme; • WHO information sheet on ensuring the quality and safety of PDMPs.	WHO guidelines and other knowledge products.	National blood establishments have the knowledge and capacity to increase the volume and quality of plasma intended for manufacture into PDMPs.	3.4. Availability of the volume and quality of plasma for manufacture into PDMPs has been increased.
Mobilize, convene and provide technical assistance to Member States to provide quality recovered and apheresis plasma to manufacture PDMPs. This includes support to in-country initiatives of PDMP manufacturing, as well as contracting of manufacturers in other countries (e.g. under the Achilles project).	Technical assistance missions; expert arrangements; knowledge sharing.		
Convene and facilitate a global consultation on increasing the availability of plasma for fractionation.	Global consultation on increasing the availability of plasma for fractionation.		

Action framework to advance universal access to safe, effective and quality-assured blood products (2020–2023)			
Overall goal: Universal access to safe, effective and quality-assured blood products			
Activities	**Output**	**Intermediate outcome**	**High-level outcome**
Organize a series of a national/regional workshops on assessment of national/regional needs for PDMPs, and develop strategies to provide adequate supplies of essential PDMPs, and targets for national/regional production of plasma suitable for fractionation to meet a proportion of the needs.	Technical assistance missions; expert arrangements; knowledge sharing.	National /regional targets are established for collection of plasma for fractionation from national/regional communities to meet a defined proportion of PDMPs based on clinical need within their communities.	3.4. Availability of the volume and quality of plasma for manufacture into PDMPs has been increased.
Strategic objective 4: effective implementation of patient blood management to optimize clinical practice of transfusion			
Disseminate WHO guidelines and other knowledge products relevant to the appropriate clinical use of blood to Member States and other relevant stakeholders. This includes: • WHO aide-mémoire for national health authorities and hospital management on clinical transfusion process and patient safety; • WHO aide-mémoire for national health programmes on the clinical use of blood; • WHO manual and handbook on clinical use of blood; • WHO recommendations on developing a national policy and guidelines on the clinical use of blood; • WHO guidelines on management of blood and blood components as essential medicines; • the module on clinical use of blood in general medicine, obstetrics, paediatrics, surgery and anaesthesia, trauma and burns; • the guide for midwives and doctors on managing complications in pregnancy and childbirth (WHO, UNFPA and UNICEF joint publication).	WHO guidelines and other knowledge products.	Member States have the knowledge and capacity to develop appropriate national clinical guidelines and practice standards, and to establish effective hospital transfusion committees.	4.1. Good patient blood management is practised, based on national clinical guidelines and practice standards.
Mobilize, convene and provide technical assistance to Member States and other relevant stakeholders relevant to the development and organization of appropriate clinical use of blood products.	Technical assistance missions; expert arrangements; knowledge sharing.		
Disseminate WHO guidelines and other knowledge products relevant to the establishment of supply systems to support transfusion practice and transfusion alternatives to Member States and other relevant stakeholders. This includes: • WHO Global Forum for Blood Safety: Concept paper, structured observations and priorities for action on patient blood management, 2011; • National Blood Authority, Australia: Patient blood management guidelines, 2011; • American Association of Blood Banks: Guidelines for patient blood management and blood utilization, 2011.	WHO guidelines and other knowledge products.	Member States have the knowledge and capacity to establish supply systems to support good transfusion practice and use of appropriate transfusion alternatives.	
Mobilize, convene and provide technical assistance to Member States relevant to the development of a sustainable national blood system with the necessary supply systems to ensure safety and quality of blood product administration and the availability of appropriate transfusion alternatives.	Technical assistance missions; expert arrangements; knowledge sharing.		

Action framework to advance universal access to safe, effective and quality-assured blood products (2020–2023)			
Overall goal: Universal access to safe, effective and quality-assured blood products			
Activities	**Output**	**Intermediate outcome**	**High-level outcome**
Disseminate WHO guidelines and other knowledge products relevant to the appropriate clinical use of blood products to Member States and other relevant stakeholders. This includes: • WHO aide-mémoire for national health authorities and hospital management on clinical transfusion process and patient safety; • WHO aide-mémoire for national health programmes on the clinical use of blood; • WHO manual and handbook on clinical use of blood; • WHO recommendations on developing a national policy and guidelines on the clinical use of blood; • WHO guidelines on management of blood and blood components as essential medicines.	WHO guidelines and other knowledge products.	Clinicians and other relevant health care providers have the knowledge and capacity to practise good patient blood management.	4.1. Good patient blood management is practised, based on national clinical guidelines and practice standards.
Mobilize, convene and provide technical assistance to Member States and other relevant stakeholders relevant to the appropriate clinical use of blood.	Technical assistance missions; expert arrangements; knowledge sharing.		
Organize a series of a national/regional workshops for hospitals to build capacity on carrying out key functions of the quality system. This includes the implementation of the WHO guidelines on good manufacturing practices for blood establishments as well as the adequate storage, testing and distribution/transportation of blood and blood components.	Technical assistance missions; expert arrangements; knowledge sharing.	Hospitals have the knowledge and capacity to carry out key functions of the quality system for all pre-transfusion testing and clinical transfusion processes, including hospital blood bank laboratories.	4.2. A quality system is in place in hospitals for all pre-transfusion testing and clinical transfusion processes, including hospital blood bank laboratories.
Strategic objective 5: effective surveillance, haemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection systems			
Mobilize, convene and provide technical assistance to build/strengthen data management on the national blood system in Member States. This includes increasing the amount and frequency of data fed into the WHO Global Database on Blood Safety (GDBS) by Member States on national blood systems.	Technical assistance missions; expert arrangements; knowledge sharing.	Member States have the knowledge and capacity to establish and maintain a national system for standardized data collection and reporting, and mechanisms to ensure uniform implementation.	5.1. There is a national system for standardized data collection and reporting, and mechanisms to ensure uniform implementation.

Action framework to advance universal access to safe, effective and quality-assured blood products (2020–2023)			
Overall goal: Universal access to safe, effective and quality-assured blood products			
Activities	**Output**	**Intermediate outcome**	**High-level outcome**
Disseminate WHO guidelines and other knowledge products relevant to the establishment and management of national haemovigilance and pharmacovigilance systems to monitor adverse reactions in donors and patients. This includes: • WHO aide-mémoire for ministries of health on a national haemovigilance system; • WHO guidelines on establishing a national haemovigilance system; • WHO: The importance of pharmacovigilance: safety monitoring of medicinal products, 2002; • WHO: Pharmacovigilance: ensuring the safe use of medicines - WHO perspectives on medicines, 2004.	WHO guidelines and other knowledge products relevant to the establishment and management of national haemovigilance and pharmacovigilance systems are available to Member States and other relevant stakeholders.	National blood establishments and national regulatory authorities have the knowledge and capacity to establish and manage systems for traceability, surveillance, haemovigilance and pharmacovigilance at national and organizational levels.	5.2. There are systems for traceability, surveillance, haemovigilance and pharmacovigilance at national and organizational levels.
Mobilize, convene and provide technical assistance to build/strengthen the capacity of national blood regulatory establishments and relevant authorities to establish and manage national haemovigilance and pharmacovigilance systems to monitor adverse reactions in donors and patients.	Technical assistance missions; expert arrangements; knowledge sharing.		
Disseminate WHO guidelines and other knowledge products relevant to the monitoring of adverse reactions in blood donors and blood product recipients. This includes: • WHO aide-mémoire for ministries of health on a national haemovigilance system; • WHO guidelines on establishing a national haemovigilance system.	WHO guidelines and other knowledge products relevant to the establishment and management of a national haemovigilance and pharmacovigilance system are available to Member States and other relevant stakeholders.	National blood establishments and hospitals have the knowledge and capacity to monitor, investigate and assess adverse events and adverse reactions in blood donors and blood product recipients.	
Mobilize, convene and provide technical assistance to build/strengthen the capacity of national blood establishments and hospitals to monitor adverse reactions in blood donors and blood product recipients.	Technical assistance missions; expert arrangements; knowledge sharing.		
WHO will continue to coordinate the collection and analysis of data from national blood establishments to feed the WHO GDBS.	Data from national blood establishments fed into the WHO GDBS.	Member States have the knowledge and capacity to manage data on the national blood system and improve the accuracy and volume of data fed into the WHO GDBS.	5.3. The WHO GDBS provides comprehensive and accurate data on the global status of blood product availability, safety and quality.
Mobilize, convene and provide technical assistance to build/strengthen data management on the national blood system in Member States. This includes increasing the amount and frequency of data fed into the WHO GDBS by Member States on national blood systems.	Technical assistance missions; expert arrangements; knowledge sharing.		
Collaborative efforts with international groups to streamline and adopt standardized and harmonized data definitions.	Meetings, dialogue.	Data definitions are standardized and harmonized to improve the consistency and comparability of reported information, including harmonization of data elements with other international systems.	

Action framework to advance universal access to safe, effective and quality-assured blood products (2020–2023)			
Overall goal: Universal access to safe, effective and quality-assured blood products			
Activities	**Output**	**Intermediate outcome**	**High-level outcome**
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			
Disseminate WHO guidelines and other knowledge products relevant to the development and implementation of training programmes on key functions of the national blood system. This includes: • WHO distance learning materials on safe blood and blood products: 1 Introductory module: guidelines and principles for safe blood transfusion practice 2. Module 1: safe blood donation 3. Module 2: screening for HIV and other infectious agents 4. Module 3: blood group serology • WHO guidance on quality management training, facilitators guide and modules.	WHO guidelines and other knowledge products relevant to the development and implementation of training programmes on key functions of the national blood system are available to Member States and other relevant stakeholders.	Member States and other relevant stakeholders have the knowledge and capacity to develop and implement training programmes on key functions of the national blood system.	6.1. Training programmes on key functions of the national blood system are in place.
Mobilize and convene technical assistance to Member States and other relevant stakeholders on the development and implementation of learning programmes on key functions of the national blood system.	Technical assistance missions; expert arrangements; knowledge sharing.		
Identify relevant organizations that can play a role in the development and implementation of training programmes, and provide training of trainers on key functions of the national blood system, or facilitate training of trainers to be provided by other institutions with adequate capacity.	Training of trainers by WHO or other institutions with relevant capacity on key functions of the national blood system to relevant organizations that can play a role in the development and implementation of training programmes.		
Provision of information to Member States that do not have the capacity to carry out external assessment and accreditation of national blood establishments on Member States or actors that have this capacity available.	Information on Member States and actors that have the capacity to carry out external assessment and accreditation of national blood establishments is available to Member States that do not have this capacity.	Member States that do not have the capacity to carry out external assessment and accreditation of national blood establishments have knowledge on, and are linked to, other Member States and actors that have this capacity available.	6.2. Capacity to carry out external assessment and accreditation of national blood establishments is available.
Active linking of Member States that do not have the capacity to carry out external assessment and accreditation of national blood establishments to Member States and actors that have this capacity available.	Member States that do not have the capacity to carry out external assessment and accreditation of national blood establishments are actively linked to Member States and actors that have this capacity available.		

Action framework to advance universal access to safe, effective and quality-assured blood products (2020–2023)			
Overall goal: Universal access to safe, effective and quality-assured blood products			
Activities	**Output**	**Intermediate outcome**	**High-level outcome**
New technologies and innovation: In collaboration with partners, support ongoing processes to identify, assess and promote new technologies and other innovations to overcome local impediments to the operating of the national blood system. This includes the identification and mobilization of relevant global/regional organizations to assess new technologies and other innovations; the organization of regional stakeholder consultations; the facilitation of the sharing of knowledge; and the promotion of new technologies and other innovations.	A list of relevant global/ regional organizations to assess new technologies and other innovations; - regional stakeholder consultations; - the sharing of recommendations on new technologies and other innovations; - the promotion of new technologies and other innovations.	Member States and other relevant stakeholders have adequate information on global/ regional organizations able to assess new technologies and other innovations; adequate knowledge on new technologies and other innovations; and the capacity to incorporate relevant new technologies and other innovations into the national blood system.	6.3. The capacity to evaluate relevant new technologies and other innovations is incorporated into the national blood system to overcome local impediments and to address urgent situations.
Mobilize, convene and provide technical assistance to develop blood regulatory forums.	Blood regulatory forums.	Blood regulatory forums have the knowledge and capacity to contribute to strengthening of national blood regulatory systems.	6.4. Regulatory capacity is strengthened through collaborative capability-building and harmonization initiatives, including use of reliance.
Coordination of regional regulatory forums, including convening of regular meetings, and the facilitation, mobilization, and provision of technical assistance to build capacity of the forums.	Regular meetings of the regional blood regulatory forums; technical assistance missions; expert arrangements; knowledge sharing.		

CONTACT

World Health Organization
Department of Health Products Policy and Standards
20 avenue Appia
CH-1211 Geneva 27
bloodproducts@who.int
https://www.who.int/bloodproducts

9789240000384