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## PLAN OF ACTION FOR UNIVERSAL ACCESS TO SAFE BLOOD

## Introduction

- 1. This document is presented with a two-fold purpose: for the countries of the Region to use this Plan as a reference when drafting their national plans and strategies, tailoring it to their own needs; and for them to monitor and evaluate its implementation in order to reach the targets set for 2019.
- 2. The countries of the Region reaffirmed their commitment to universal health coverage at the last PAHO/WHO Directing Council in 2013. The commitment of the Member States is also expressed in the targets of the PAHO/WHO Strategic Plan 2014-2019, in which universal health coverage is one of the main unifying elements. Universal access to blood transfusions and safe blood products is an essential service for universal health coverage, helping to save millions of lives and improving the health of people who need them. Blood transfusions have been identified as one of the eight key life-saving interventions in health centers that offer emergency obstetric services (1).
- 3. Transfusions are also necessary for the care of: a) children with severe anemia; b) patients with hemoglobin disorders such as thalassemia and sickle cell anemia; c) people injured in accidents; d) cancer patients; e) people who undergo major surgery and other surgical interventions such as transplants; and f) patients with chronic age-related diseases such as bleeding resulting from vascular problems or orthopedic surgery, among other causes. These groups are particularly vulnerable to blood scarcity and unsafe blood, since they are exposed to transfusion-transmitted infections such as HIV and hepatitis B and C.
- 4. In light of the above, this Plan of Action seeks to promote universal, timely access to safe blood in order to save lives and improve the health conditions of all patients who need it.

5. In this regard, the Plan is the result of: *a)* the systematization of the priorities and recommendations of the WHO Global Strategic Plan for Universal Access to Safe Blood Transfusion (2); *b)* the work done in the Region for over a decade (3); *c)* the results of the evaluation of the Regional Plan of Action for Transfusion Safety 2006-2010 (4); *d)* the contributions made by the PAHO/WHO expert group and external experts; and *e)* the contributions received from the national blood programs in the Region.

## Background

- 6. Every year, over 500,000 women die worldwide during pregnancy, childbirth, or the postpartum period, and 99% of these deaths occur in the developing world. An estimated 25% of these deaths are due to hemorrhage during delivery, the most common cause of maternal mortality, accounting for 21% of maternal deaths in Latin America and the Caribbean. If not addressed, this problem could compromise both the achievement of the Millennium Development Goal (MDG) 5 target of reducing maternal mortality and the enjoyment of the right to life, personal integrity, and the highest attainable standard of health, among other human rights. Maternal mortality from hemorrhage and the subsequent lack of blood for transfusion can be considered a human rights violation (5). An inversely proportional relationship is observed between the maternal mortality ratio and the availability of blood; in countries where the availability of blood is low, maternal mortality is higher (Figures 1 and 2 available at: <a href="www.paho.org/figures-tables-regional-blood-plan">www.paho.org/figures-tables-regional-blood-plan</a>).
- 7. To achieve universal access to safe blood for transfusions key strategies must be strengthened, among them: ensuring self-sufficiency in blood and blood products through voluntary non-remunerated blood donation; improving the quality of donated blood (from the donor's arm to the recipient's arm); maximizing appropriate blood use; strengthening human resources; adopting new advances; and establishing strategic partnerships with the different sectors involved in the area.
- 8. Since 1975, the World Health Assembly (WHA) and the WHO Executive Board have considered various documents and adopted numerous resolutions related to blood safety: WHA28.72 [1975], EB79.R1 [1987], WHA40.26 [1987], WHA45.35 [1992], WHA48.27 [1995], WHA53.14 [2000], WHA55.18 [2002], WHA56.30 [2003], WHA58.13 [2005], WHA63.12 [2010], WHA63.18 [2010], and WHA63.20 [2010] (6 to 17).
- 9. Several resolutions on this matter have also been adopted in the Region of the Americas: CD41.R15 (1999), CD46.R5 (2005), CE142.R5 (2008), and CD48.R7 (2008). This issue is also related to the Strategy and Plan of Action for Chagas Disease Prevention, Control and Care (CD50/16 [2010]); the Plan of Action to Accelerate the Reduction of Maternal Mortality and Severe Maternal Morbidity [CE148/16 (2011)]; and the PAHO Regional Strategic Plan for HIV/AIDS/STI, 2006-2015 (18-24).

10. Finally, in 2011, a group of external experts in transfusion medicine from different countries and organizations evaluated the Regional Plan of Action for Transfusion Safety 2006-2010. Their evaluation was presented to the 51st Directing Council in document CD51/INF/5 (25), with the following recommendations: *a*) to continue the strengthening of blood collection, screening, and processing; *b*) to achieve the goal of 100% voluntary donation (mainly repeat donations); and *c*) to establish quality control systems. If these basic recommendations are followed, it will be possible for the Region to obtain sufficient quantities of safe blood in a timely fashion (25-27).

## **Situation Analysis**

- 11. In 2012 every country in Latin America had specific national blood legislation, but only four Caribbean countries did (Belize, Curaçao, Guyana, and Suriname). In that same year, 15 of the 41 countries and territories in Latin America and the Caribbean had an integrated, intersectoral, national strategic blood plan with resources for its implementation, monitoring, and evaluation. In 27 of the 41 countries and territories, a specific health ministry entity was responsible for planning, monitoring, and evaluating the national blood system; national intersectoral blood commissions were operating in only 14 countries (28).
- 12. Furthermore, despite the demonstrated benefits of reducing the number of services that process blood—in terms of quality, safety, and lowering costs—the number of processing centers rose from 1,763 in 2010 to 1,772 in 2011. These benefits are demonstrated by considering the number of units produced per blood bank/year: Brazil, Colombia, Cuba, Ecuador, Nicaragua, and Paraguay have a higher production per bank, resulting from the reorganization of blood services and certain blood-related processes, and consolidation of blood banks. Production in the other countries is less than 5,000 units/bank/year, a figure that some studies have shown not to be cost-effective and that can compromise blood quality and safety (29, 30) (Table 1, available at: <a href="https://www.paho.org/figures-tables-regional-blood-plan">www.paho.org/figures-tables-regional-blood-plan</a>). For the Caribbean countries, the number of units processed per blood bank/year shows that Curaçao, Guyana, Haiti, Jamaica, Suriname, and Trinidad and Tobago have the highest production, while the other countries are below 3,000 units/bank/year (Table 2, available at: <a href="https://www.paho.org/figures-tables-regional-blood-plan">www.paho.org/figures-tables-regional-blood-plan</a>).
- 13. When reorganizing blood services networks, each country should give particular consideration to its specific needs, including its geographic and demographic characteristics, communication channels, and regional needs to ensure that blood is available and accessible where it is needed (30). By 2011, only nine of the 19 countries in Latin America had reorganized their blood services networks (28).
- 14. In 2011, 9,275,914 units of blood were collected in Latin America and the Caribbean, representing a 3.2% increase in the Region over 2010, with a more significant increase in the Caribbean countries (31%) than in Latin America (2.8%). This increase put the 2011 blood donation rate at 15 per 1000 population in Latin America and 18 per 1000 in the Caribbean (Table 3, available at: <a href="www.paho.org/figures-tables-regional-">www.paho.org/figures-tables-regional-</a>

<u>blood-plan</u>). When compared with global data, these figures put the Region at about average for middle-income countries and at the lower end for high-income countries (30).

- 15. The first studies estimating blood needs in Latin America and the Caribbean were conducted in 2010; to date, only four Latin American and two Caribbean countries have reported calculating these needs.<sup>1</sup>
- 16. The percentage of volunteer blood donors in Latin America and the Caribbean remained at around 41.4% in 2010-2011, meaning that the number of volunteer donors has not increased (Table 3, available at: <a href="www.paho.org/figures-tables-regional-blood-plan">www.paho.org/figures-tables-regional-blood-plan</a>).
- 17. Thirty of 41 countries and territories in Latin America and the Caribbean reported having implemented some components of quality systems. However, certain aspects require greater development, for example, achieving 100% screening for transfusion-transmitted infections such as the human immunodeficiency virus (HIV), hepatitis B HBsAg, hepatitis C (HCV), and syphilis. In 2011, 99.7% of blood was screened in Latin America and the Caribbean, which indicates that 107,702 blood units are not being screened for some of these infectious agents. With regard to *T. cruzi*, 202,610 units were not screened for this marker in Latin America in 2011. (Table 3, available at: <a href="www.paho.org/figures-tables-regional-blood-plan">www.paho.org/figures-tables-regional-blood-plan</a>). In that same year, the average prevalence of infectious markers in Latin America and the Caribbean did not differ significantly from 2010. (Table 4, available at: <a href="www.paho.org/figures-tables-regional-blood-plan">www.paho.org/figures-tables-regional-blood-plan</a>). This situation can perhaps be explained by low growth in the number of repeat volunteer donors (28).
- 18. It should be pointed out that there is insufficient evidence in the Region to support the regulation of hepatitis E screening in high-risk groups, such as patients who undergo transplants and similar surgical interventions, patients on dialysis, and pregnant women who need surgery. As a result, research should be conducted in order to reach timely conclusions on this subject.
- 19. With regard to the separation of blood units into components, a figure of 92.9% was achieved for red blood cell concentrates in 2011 in Latin America and 67.04% in the Caribbean. As a result, Latin America and the Caribbean did not achieve 95% separation of units (the Plan 2006-2010 target).
- 20. When the increased availability of red blood cells is compared with the number of units of red blood cells discarded due to expiration, it is observed that (in 27 of 41 countries and territories in Latin America and the Caribbean) 10.3% was discarded in 2011—a slight improvement in this indicator over the 14.1% in 2009. This indicates that 799,738 units of red blood cells were no longer available for transfusion to patients because they had passed their expiration date (Tables 5 and 6, available at: www.paho.org/figures-tables-regional-blood-plan) (28). In 2011, discarded blood

<sup>&</sup>lt;sup>1</sup> Information provided directly by the national blood programs to PAHO Headquarters in 2013.

represented a loss of US\$44,785,328<sup>2</sup> (at an average cost of \$56/unit), in addition to the cost in terms of blood availability, timely transfusions to patients, and the social value that this represents. This finding could reflect poor planning that does not allow for correlations between needs and the blood supply. This underscores the importance of prioritizing better management of the blood supply through organized networks and estimates of blood needs (Tables 5 and 6, available at: <a href="www.paho.org/figures-tables-regional-blood-plan">www.paho.org/figures-tables-regional-blood-plan</a>) (28).

- 21. Concerning the rational use of blood and blood products, 20 of the 41 countries and territories in Latin America and the Caribbean reported having guidelines for the clinical use of blood, while only seven have transfusion committees in 75% of hospitals at the national level. From the information available in the countries, it is not possible to characterize blood recipients by age, sex, and pathology or determine the epidemiological factors that affect needs or the estimated number of units transfused by event.
- 22. Concerning the public health functions involved in health surveillance and hemovigilance, 20 of the 41 countries and territories (12 in Latin America and eight in the Caribbean) have programs for the inspection, monitoring, and oversight of blood services. Concerning the monitoring of adverse transfusion-related events, only two countries reported having information, research, and analysis mechanisms for timely decision-making (28) (Tables 7 and 8, available at: <a href="www.paho.org/figures-tables-regional-blood-plan">www.paho.org/figures-tables-regional-blood-plan</a>). This situation underscores the need to integrate and harmonize blood and other public health indicators to improve hemovigilance and health surveillance. This would make it possible to determine whether the blood supply is self-sufficient, accessible, timely, and safe, and how it is affecting national morbidity and mortality. It would also make it possible to design risk management plans aimed at identifying and managing the risks associated with the transfusion chain in terms of blood safety and adverse events in donation and transfusion, which are related to blood supply, access, and availability, as well as emergencies and disasters (30).

## **Plan of Action (2014-2019)**

### Goal

- 23. The goal of this Plan is to promote universal access to safe blood through voluntary non-remunerated donations to help save lives and improve the health of patients who need them.
- 24. This Plan advocates appropriate blood use and greater leadership by health authorities, urging them to implement quality management programs in the transfusion chain (from promoting blood donation to monitoring patients) and to integrate the blood system into the national health system. Ultimately, this Plan calls for the restructuring of blood services, based on efficient and sustainable models.

<sup>&</sup>lt;sup>2</sup> Unless otherwise indicated, all monetary figures in this report are expressed in United States dollars.

## **Strategic Lines of Action**

- 25. Given this background and consistent with the progress made in the Region toward maintaining achievements and tackling new challenges, the regional Plan 2014-2019 focuses on the following critical areas:
- a) effective and sustainable integration of national blood programs and services into the national health system to achieve blood self-sufficiency, safety, efficiency, availability, and universal access to blood and blood products;
- b) self-sufficiency in safe blood and blood products through 100% voluntary non remunerated donations;
- c) Quality management in the national blood system and screening for transfusion-transmitted infections;
- d) Health surveillance, hemovigilance, risk management, monitoring, and evaluation.

Strategic Line of Action 1: Effective and sustainable integration of national blood programs and services into the national health system to achieve blood self-sufficiency, safety, efficiency, availability, and universal access to blood and blood products.

26. The intention is to guarantee, through greater political will and the participation of the ministries of health and other sectors, the countries' commitment to making it a national priority to achieve blood self-sufficiency, safety, availability, and universal access to blood and blood products, given that blood for transfusions is an indispensable cross-cutting health intervention and a basic requirement for guaranteeing the right to the enjoyment of the highest attainable standard of health and other related human rights.

*Objective 1.1.* Strengthen planning, implementation, monitoring, and evaluation processes in national blood programs.

#### Indicators:

- 1.1.1 Number of countries that have a specific functioning entity in the ministry of health that is responsible for planning, monitoring, and evaluation of the national blood system.
  - (Baseline: 27/41. Target: 36 countries)
- 1.1.2 Number of countries that have a functioning intersectoral national blood commission or advisory mechanism.
  (Baseline: 14/41. Target: 21 countries)
- 1.1.3. Number of countries whose blood policy includes self-sufficiency, availability, and universal access to safe blood and blood products.

  (Baseline: 18/41. Target: 26 countries)

*Objective 1.2.* Include the issue of safe blood in national health plans in order to ensure resources and intersectoral support.

### *Indicator:*

1.2.1 Number of countries that have an integrated intersectoral national strategic blood plan that includes human resources training, monitoring and evaluation of the plan, and guaranteed resources for its implementation.

(Baseline: 13/41. Target: 21 countries)

*Objective 1.3.* Organize and consolidate an integrated blood services network within the health services network, tailored to the needs of each country.

#### Indicator:

1.3.1. Number of countries with more than one processing center that have increased the average number of units processed per blood bank/year (including screening) to over 5,000 units as a result of the restructuring of the blood services network.

(Baseline: 12/25. Target: 17 countries)

## Strategic Line of Action 2: Self-sufficiency in safe blood and blood products through 100% voluntary non-remunerated donations.

27. The supply of blood and blood products should be based on voluntary non-remunerated donations to ensure blood self-sufficiency, availability, and safety; and on the promotion of healthy lifestyles, participation, and public solidarity.

*Objective 2.1.* Calculate the country's need for blood and blood products to achieve self-sufficiency in safe blood.

### Indicator:

2.1.1 Number of countries that have calculated their blood needs at the national and regional level.

(Baseline: 6/41. Target: 12 countries)

*Objective 2.2.* Reach blood self-sufficiency through non-remunerated voluntary blood donations.

## Indicator:

2.2.1 Number of countries that reach 100% non-remunerated voluntary blood donations.

(Baseline: 8/41. Target: 16 countries).

## Strategic Line of Action 3: Quality management in the national blood system and screening for transfusion-transmitted infections.

28. This is aimed at fostering the countries' commitment to ensuring that their national blood system operates under a quality management framework and achieves 100% screening for the infections listed in PAHO/WHO recommendations, with a view to achieving blood self-sufficiency, safety, and availability, and universal access to blood and blood products.

*Objective 3.1.* Establish, monitor, and evaluate the quality management system in the blood services network, which includes screening for HIV, HBV, HCV, syphilis, and *T. cruzi* (the latter in endemic areas).

### *Indicators:*

3.1.1 Number of countries that screen 100% of blood units for transfusion for HIV, HBV, HCV, syphilis, and *T. cruzi*. (Baseline: 39/41. Target: 41 countries)

3.1.2 Number of countries that have a national program for external serology performance evaluations.

(Baseline: 22/41. Target: 27 countries)

3.1.3 Number of countries that have a national program for external immunohematology performance evaluations.
(Baseline: 12/41. Target: 18 countries)

*Objective 3.2.* Adopt the necessary mechanisms to increase the availability and appropriate use of blood and blood products.

#### Indicators:

3.2.1 Number of countries that have functioning transfusion committees in at least 75% of hospitals that perform daily transfusions.
(Baseline: 7/41. Target: 12 countries)

3.2.2 Number of countries that have national guidelines in place for the appropriate use of blood and blood products.

(Baseline: 20/41. Target: 30 countries)

3.2.3 Five percent (5%) reduction, in the Region, in the number of red blood cell units discarded due to expiration.
(Baseline 10.3%. Target: 5.3%)

## Strategic Line of Action 4: Health surveillance, hemovigilance, risk management, monitoring, and evaluation.

29. The purpose of this strategic line is to strengthen the surveillance, evaluation, and monitoring system in order to obtain information to identify and implement timely and

appropriate interventions that will ensure sufficient supply, safety, and availability of blood, and universal access to blood and blood products.

*Objective 4.1.* Strengthen the national blood system so that health surveillance is included in blood services.

### Indicator:

4.1.1 Number of countries that have a national model for inspection, surveillance, and oversight in blood services.

(Baseline: 20/41. Target: 30 countries)

*Objective 4.2.* Strengthen the national blood system to integrate hemovigilance in blood services.

## Indicator:

4.2.1 Number of countries that have a national hemovigilance system (Baseline: 2/41. Target: 7 countries)

*Objective 4.3.* Establish a mechanism to enable countries to monitor the implementation of their national plan.

## Indicator:

4.3.1 Number of countries that annually report the indicators of their national plan in response to the implementation of the regional Plan 2014-2019.

(Baseline: 0/41. Target: 41 countries)

*Objective 4.4.* Draft risk management plans based on the information generated by the haemovigilance system.

## Indicator:

4.4.1 Number of countries that have drafted risk management plans based on hemovigilance information.

(Baseline: 0/41. Target: 7 countries)

## **Monitoring and Evaluation**

- 30. This Plan of Action will help achieve Category 4 of the PAHO Strategic Plan 2014-2019 and is directly related to program area 4.3 and outcomes 4.3.1, 4.3.3, and 4.3.4. Within that same category, it will also help achieve program areas 4.1, 4.2, 4.4. Annex C lists other outcomes to which this Plan contributes at the level of the Organization.
- 31. This Plan of Action 2014-2019 will help meet the global priorities set in the WHO Global Strategic Plan for Universal Access to Safe Blood Transfusion 2008-2015.

32. Monitoring and evaluation of this Plan is consistent with the Organization's results-based management framework and its performance, monitoring, and evaluation processes. Accordingly, PAHO/WHO plans to conduct a mid-term and final evaluation, and the countries are expected to prepare annual progress reports on the achievement of the indicators.

## **Financial Implications for the Organization**

33. The estimated cost to the Organization of implementing the proposal over the five-year period includes \$8 million in expenditures on technical and administrative staff and on cooperation activities. With regard both to budgetary implications and implementation of the interventions, the commitment and support of the Member States, as well as the collaborating centers and partners in this area, are essential. Since this regional plan cannot be undertaken by the Pan American Sanitary Bureau alone, it will be necessary for the more economically developed countries in the Region to invest in the blood safety through multilateral or bilateral cooperation. That investment—in addition to the support provided by the Bureau through its technical capacity to promote cooperation among countries and the creation and strengthening of networks in the Region—would provide the financial coverage needed to meet the Plan's targets and goals. (The financial and administrative aspects are described in Annex B).

## **Action by the Directing Council**

34. The Directing Council is requested to review the information in this document and consider adopting the proposed resolution in Annex A.

Annexes

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## 53rd DIRECTING COUNCIL

## 66th SESSION OF THE REGIONAL COMMITTEE OF WHO FOR THE AMERICAS

Washington, D.C., USA, 29 September-3 October 2014

CD53/6 Annex A Original: Spanish

## **PROPOSED RESOLUTION**

## PLAN OF ACTION FOR UNIVERSAL ACCESS TO SAFE BLOOD

## THE 53rd DIRECTING COUNCIL,

Having reviewed the *Plan of Action for Universal Access to Safe Blood* (Document CD53/6);

Observing the importance of effectively and sustainably integrating national blood programs and services into national health systems to achieve blood self-sufficiency, safety, efficiency, and availability, and universal access to blood and blood products, when and where these are needed to help save lives and improve the health condition of all people who need them, including children with severe anemia, the chronically ill, patients with hemoglobin disorders, injuries, or cancer; pregnant women, and patients who undergo major surgery;

Considering blood transfusion to be one of the eight key interventions in emergency obstetric care;

Aware of the efforts made by the Pan American Sanitary Bureau and the national blood programs of the Member States to strengthen national blood systems to improve access to blood, and its availability and safety;

Taking into account the joint evaluation of the implementation of the Plan of Action for Transfusion Safety 2006-2010, conducted in 2011 and presented to the 51st PAHO Directing Council in Document CD51/INF/5; and the achievements and challenges identified in the evaluation, which serve as a starting point for drafting the Plan of Action for Universal Access to Safe Blood 2014-2019;

Recognizing the need to adjust current national approaches to achieve sufficient blood supply, appropriate quality, and safe transfusion;

Concerned that in order to achieve self-sufficiency in blood and blood products, it will be necessary to increase the number of volunteer donors in the Region of the Americas, and considering that the collected blood is routinely processed to be transformed into blood components;

Motivated by the spirit of Pan-Americanism, the internationally agreed development goals stated in the U.N. Millennium Declaration, binding universal and regional human rights instruments, and the challenge of achieving universal access to safe blood and blood products,

#### **RESOLVES:**

- 1. To approve the *Plan of Action for Universal Access to Safe Blood* and its implementation in the context of the particular conditions of each country.
- 2. To urge the Member States, taking into account their national context and priorities to:
- a) renew their commitment to supporting the establishment of well-organized, nationally coordinated, and sustainable blood programs and services that are integrated into the health system with appropriate legal and regulatory framework necessary to advance toward ensuring universal access to blood and blood products through sufficient supply, quality and safety, and the appropriate use of blood and blood products;
- b) allocate the necessary resources for the proper functioning and development of the system, including:
  - i. financial resources to ensure the viability and transparent management of the system to prevent the sale of blood and resulting profiteering, except where national law so allows,
  - ii. ensuring the availability of trained human resources by supporting educational efforts and measures to avoid high staff rotation in blood services;
- c) promote only non-remunerated, preferably repeated, voluntary blood donations; and discourage remunerated and family/replacement donations, except where protected by the national regulatory system;
- d) set up quality management systems that ensure: universal screening of blood for the markers that PAHO/WHO has stipulated for the Region; the implementation of national programs for external performance evaluation; and the appropriate use of blood and blood products to promote patient safety;

- e) promote intersectoral participation (public and private sector, other ministries, civil society, among others) to strengthen resources and achieve synergies that benefit the national blood system;
- f) establish a regulatory framework that strengthens the health surveillance system to ensure regulation and oversight of the transfusion chain;
- g) ensure mechanisms to implement a non-punitive hemovigilance system in which transfusion reactions are reported in order to identify timely interventions and take corrective action to minimize risks;
- h) allocate and use, as appropriate, resources to achieve the objectives of the Plan of Action for Universal Access to Safe Blood 2014-2019;
- i) establish mechanisms to monitor and evaluate implementation of the Plan of Action for Universal Access to Safe Blood 2014-2019.
- 3. To request the Director to:
- a) cooperate with the Member States, as needed, in the implementation of this Plan 2014-2019, taking a multidisciplinary approach and considering health promotion, human rights, gender equity, and the social determinants of health;
- b) promote the implementation of this Plan of Action and guarantee its cross-cutting nature through the Organization's program areas and the different regional, subregional, and national contexts, and through collaboration with and among the countries in strategy design and the sharing of competencies and resources;
- c) continue advocating for active resource mobilization and promote partnerships that support the implementation of this resolution;
- d) monitor and evaluate the implementation of this Plan of Action and report periodically to the Governing Bodies on the progress made and the obstacles to the implementation of the Plan, and on any necessary adaptations to new contexts and needs.





CD53/6 Annex B

# Report on the Financial and Administrative Implications of the Proposed Resolution for PASB

1. Agenda item: 4.4 - Plan of Action for Universal Access to Safe Blood

## 2. Linkage to Program and Budget 2014-2015:

a) Category: 4. Health systems. Strengthening health systems based on primary care; focusing health governance and financing toward progressive realization of universal health coverage; organizing people-centered, integrated service delivery; promoting access to and rational use of health technologies; strengthening health information and research systems and the integration of evidence into health policies and health care; facilitating transfer of knowledge and technologies; and developing human resources for health (HSS).

**Expected outcomes:** Health Systems and Services/Medicines and Health Technologies (HSS/MT).

4.3. Improved access to and rational use of safe, effective, and quality medicines, medical products, and health technologies:

## **OPT:**

- 4.3.1. Countries enabled to develop/update, implement, monitor, and evaluate national policies for better access to medicines and other health technologies.
- 4.3.3. Countries enabled to assess their national regulatory capacity for medicines and other health technologies.
- 4.3.4. Countries enabled to implement processes and mechanisms for health technologies assessment, incorporation, and management, and for rational use of medicines and other health technologies.

## 3. Financial implications:

a) Total estimated cost for implementation over the lifecycle of the resolution (estimated to the nearest US\$ 10,000, including staff and activities):

For 2014-2019 quinquennium, approximately US\$ 8 million would be needed, considering what has been invested in the past and what should be invested to achieve the proposed objectives.

b) Estimated cost for the 2014-2015 biennium (estimated to the nearest US\$ 10,000, including staff and activities):

US\$ 3.9 million.

## c) Of the estimated cost noted in b), what can be subsumed under existing programmed activities?

All funds allocated for the present biennium (2014-2015) are to support products and services linked to the achievement of the Plan's objectives.

## 4. Administrative implications:

## a) Indicate the levels of the Organization at which the work will be undertaken:

Since this regional plan cannot be implemented by the Pan American Sanitary Bureau alone, it will be necessary for the more economically developed countries of the Region to invest in the area of blood safety through multilateral or bilateral cooperation. That investment—in addition to the support provided by the Bureau through its technical capacity to promote cooperation among countries, as well as the creation and strengthening of networks in the Region—will provide the financial coverage needed to meet the Plan's targets and goals. (The financial and administrative aspects are described in Annex B).

The work will be undertaken with the countries and focus on the priority countries, based on the situation analysis. The same will be done at the subregional level and at Headquarters, with ongoing support from the collaborating centers and partners in the area.

There will be integration with other units of the Health Systems and Services department and with other departments, such as Family, Gender, and Life Course; Communicable Diseases and Health Analysis; Noncommunicable Diseases and Mental Health; and Emergency Preparedness and Disaster Relief.

## b) Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile):

- One regional adviser for blood services
- Administrative support
- Four subregional advisers for blood services (one in the Caribbean, one in Central America, one in the Andean zone, and one in the Southern Cone).

## c) Time frames (indicate broad time frames for the implementation and evaluation):

- 2014: Approval of Plan 2014-2019: Implementation of the Plan
- 2017-2018 Mid-term evaluation
- 2020 Final evaluation and presentation of results and recommendations





CD53/6 Annex C

## ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL MANDATES

- 1. Agenda item: 4.4. Plan of Action for Universal Access to Safe Blood
- **2. Responsible unit:** Health Systems and Services/Medicines and Health Technologies (HSS/MT)
- **3. Preparing officer:** Dr. María Dolores Pérez-Rosales
- 4. List of collaborating centers and national institutions linked to this Agenda item:
- Advancing Transfusion and Cellular Therapies Worldwide (AABB)
- Health surveillance agencies of the member countries
- Spanish Association of Hematology and Hemotherapy
- National professional associations of the member countries
- Centers for Disease Control and Prevention (CDC)
- Blood Transfusion Center of Valencia (Spain)
- Blood Transfusion Center of Seville (Spain)
- International Federation of Red Cross and Red Crescent Societies
- World Federation of Hemophilia
- Thalassemia International Federation
- International Federation of Blood Donor Organizations (FIODS)
- Global Health Initiative (national health institutes of member countries)
- Ibero-American Collaborative Group on Transfusion Medicine (GCIAMT)
- ProSangue blood center/foundation, São Paulo, Brazil. PAHO/WHO Collaborating Center for Quality Control of Serology in Blood Banks
- International Hemovigilance Network
- International Society for Blood Transfusion (ISBT)
- National reference laboratories of member countries
- National programs of member countries
- National Red Cross societies of member countries

## 5. Link between Agenda item and Health Agenda for the Americas 2008-2017:

Human rights, universal access, and inclusion: The Plan of Action for Universal Access to Safe Blood 2014-2019 seeks to guarantee the right to health and other related basic human rights through the availability of and access to blood for transfusions in the Region of the Americas, without distinction of age, gender, ethnicity, political ideology, economic or social condition, religion, or sexual orientation, or any other kind of discrimination that invalidates or undermines the enjoyment of the right to health or other related human rights (Resolution CD50.R8: "Health and Human Rights").

**Pan American solidarity**: The Plan promotes cooperation among countries in the Americas with the participation of PAHO collaborating centers and professional associations.

*Equity in health*: The Plan seeks to eliminate differences among and within countries in terms of availability, access, timeliness, and quality of blood for transfusions with a public health approach.

**Social participation**: An organized social network is essential for achieving 100% voluntary blood donations and blood self-sufficiency.

Strengthening the health authority: The Plan of Action 2014-2019 includes four strategic lines. The first line directly refers to strengthening planning, implementation, monitoring, and evaluation processes in national blood programs, which requires strong leadership from the ministries of health.

**Health determinants approach: Reducing the risk and burden of disease:** Blood safety depends mainly on the quality of the donated blood. National blood requirements depend on the overall health of the population. Health promotion, health education, and interventions to protect the population will result in safer blood donors and less need for blood products. Safe blood helps reduce HIV, HBV, HCV, *T. cruzi*, and other infections.

Increasing social protection and access to quality health services; reducing health inequities among and within countries: Blood availability and access in the Region vary within and among countries. The overall objective of the Plan of Action 2014-2019 is to promote universal access to safe blood and blood products without distinction of age, gender, ethnicity, political ideology, economic or social condition, religion, or sexual orientation.

## 6. Link between Agenda item and the PAHO Strategic Plan 2014-2019:

This Plan of Action is directly linked to Category 4 (Health Systems) and outcome 4.3 (Improved access to and rational use of safe, effective, and quality medicines, medical products, and health technologies). Also within Category 4, it contributes to the achievement of outcomes 4.1, 4.2, 4.4, and 4.5. In categories 1, 2, and 3, it contributes to program areas and outcomes 1.1, 1.4, 2.3, 3.1, 3.2, 3.3, 3.4, and 3.5 of the PAHO Strategic Plan 2014-2019.

## 7. Best practices in this area and examples from countries within the Region of the Americas:

- Organization of blood services: Argentina, Bolivia, Brazil, Canada, Chile, Ecuador, Nicaragua.
- Blood self-sufficiency based on voluntary nonremunerated donation: Bermuda, Canada, Cayman Islands, Colombia, Monserrat, Netherlands Antilles, Nicaragua, Suriname, USA.
- Quality management: Brazil, Canada, Colombia, Netherlands Antilles, Nicaragua, USA.
- Health surveillance and hemovigilance: Brazil, Canada, and USA.

## 8. Financial implications of this Agenda item:

The estimated cost to the Organization of implementing the proposal over the five-year period includes \$8 million in expenditures on technical and administrative staff and cooperation activities. With regard both to budgetary implications and the implementation of the interventions, it is essential that the member countries, as well as collaborating centers and partners in this area, provide their commitment and support. Since this regional plan cannot be undertaken by the Pan American Sanitary Bureau alone, it will be necessary for the more economically developed countries of the Region to invest in the area of blood safety through multilateral or bilateral cooperation. This investment—in addition to the support provided by the Bureau through its technical capacity to promote cooperation among countries and the creation and strengthening of networks in the Region—will provide the financial coverage needed to meet the Plan's targets and goals. (The financial and administrative aspects are described in Annex B).

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