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# PROGRESS REPORT ON THE REGIONAL INITIATIVE FOR BLOOD SAFETY AND PLAN OF ACTION FOR 2006-2010

The Strategic and Programmatic Orientations of the Pan American Health Organization for 1999-2002, approved by the 25th Pan American Sanitary Conference, included the goals that (a) all blood for transfusion will be analyzed to detect infections by hepatitis B and C viruses, syphilis, *Trypanosoma cruzi*, and HIV, and (b) all blood banks will be participating in quality control programs as means to increase the safety of blood.

A Regional Plan of Action for 2000-2004 reiterated those goals. Despite progress, universal screening of blood for transfusion and participation of blood banks in quality programs has not been achieved. By 2003, the estimated risk of receiving a transfusion contaminated with human immunodeficiency virus (HIV), hepatitis B (HBV), or hepatitis C (HCV) due to the lack of screening in the Caribbean and Latin American countries diminished to 1:41,858 from 1:4,011 in the year 2000. The estimated risk for *T. cruzi* in Latin America decreased from 1:762 to 1:3,360. The estimated risks for 2003 are still unacceptably high. Lack of screening and high prevalence of markers of infectious diseases among blood donors contribute to the risk, which may be greater than estimated if quality of testing were to be taken into consideration. Only 53% of existing blood banks participate in programs of external evaluation of performance, and, among those which do, inaccurate results are common.

The most important constraint to achieving the goal of blood safety is the lack of a well coordinated national blood system, which results in a multiplicity of hospital-based blood banks being responsible for procurement of supplies, including blood. Implementation of quality assurance in that setting is very difficult.

A well-coordinated national blood system is required to achieve sufficiency, opportunity, quality, and safety of blood for transfusion in the Caribbean and Latin American countries. The Directing Council is requested to examine the Progress Report on the Regional Initiative for Blood Safety and the plan of action for 2006-2010, and to consider the resolution proposed by the Executive Committee.

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#### **Background**

- 1. For the last 30 years, the World Health Assembly has given priority to the utilization and supply of human blood and blood products, urging Member States to promote the development of nationally coordinated blood services based on voluntary, nonremunerated donation of blood and quality assurance, to enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and recipients of blood and blood products, as well as to confront the HIV/AIDS epidemic.
- 2. At the 25th Pan American Sanitary Conference, the Strategic and Programmatic Orientations of the Pan American Health Organization for 1999-2002 were approved. Among the goals related to health policies and services, the Conference included: (a) all blood for transfusion will be analyzed to detect infections by hepatitis B and C viruses, syphilis, *Trypanosoma cruzi* and HIV, and (b) all blood banks will be participating in quality control programs.
- 3. In October 1999, Resolution CD41.R15, "Strengthening Blood Banks in the Region of the Americas," was adopted by the 41st Directing Council of PAHO. This resolution urged Member States to promote the development of national blood programs and transfusion services, based on the voluntary, nonremunerated, and repeated donation of blood, as one indicator of human development and on quality assurance. The resolution also included a request to the Director of PAHO to cooperate with the Member States in strengthening the national blood programs and transfusion services; assist in the strengthening of national programs for voluntary, nonremunerated, repeated blood donated in the Region.
- 4. Taking into consideration the Strategic and Programmatic Orientations and the resolutions, and with the financial support from the Pan American Health and Education Foundation (PAHEF), PAHO, together with the coordinators of the national blood programs of Latin America, the directors of the blood banks in the Caribbean, the Collaborating Centers, and potential partners from academic and professional institutions, developed a plan of action to respond to the request of the Governing Bodies. The specific expected results of the plan were:
- (a) Coverage of screening: 100% coverage of screening of blood units for HIV, HBV, HVC, and syphilis in the Region; and 100% coverage of screening for Chagas' disease in Latin America.
- (b) External Evaluation of Performance: 100% of the blood banks that screen blood for transfusion will participate in the external evaluation of performance of

- serological tests for HIV, HBV, HCV, syphilis, and Chagas' disease, as appropriate.
- (c) Donors: 50% of donors in each country of the Region will be voluntary, altruistic, and nonremunerated.
- (d) Infections in high-risk groups: High-risk groups for transfusion-transmitted infections will be identified and monitored for incidence of HCV infection.
- 5. The collaborative plan of action was submitted as a grant proposal to the Bill and Melinda Gates Foundation, which provided support for work to be carried out between January 2001 and July 2004.

#### **Progress from 2000**

6. The activities undertaken during the four-year period have resulted in considerable progress towards attaining the goals, and a summary of the achievements for each of the expected results of the plan of action follows:

## Coverage of Screening

- 7. Laboratory testing for infectious markers contributes to blood safety by eliminating those units that are collected from individuals that may be the source of transfusion-transmitted infection (TTI). Screening, however, does not fully eliminate the risk of TTI as blood may be collected from infected donors during the window\* period and, thus, the value of laboratory testing depends on the incidence and prevalence of the infections among the blood donors.
- 8. Despite improvements in the coverage of testing for TTI markers, the goal of universal screening of blood in the Americas has not been attained. By 2003, the proportion of units tested for HIV was 99.93% (up from 99.66% in 2000); for hepatitis B, 99.86% (up from 99.65% in 2000); for hepatitis C, 99.52% (up from 98.79% in 2000); and for syphilis markers; 99.84% (up from 99.57% in 2000). The lowest coverage was for T.cruzi in Latin America: 88.09% up from 78.98% in 2001 (see Annex and Tables 1 and 2).
- 9. Only 19 countries and territories screened all units of blood collected for all required markers, up from 16 in 2000. Anguilla, Antigua and Barbuda, Belize, Montserrat, and Saint Kitts and Nevis reported zero screening for hepatitis C in 2003. Only seven Latin American countries tested all units for T. cruzi in 2003 (Table 3).

<sup>\*</sup> The time between infection and when markers of infection become detectable.

- 10. The median number of blood banks in Latin America is 48 per country (range 23-578). With the exception of Cuba, that has an average of 13,338 units collected per bank, the mean yearly blood collection ranges between 606 and 7,988 units per bank in Latin America. PAHO developed an assessment guideline and provided technical and financial support to examine the financial efficiency of the current national blood systems in countries in Latin America. In general, the current overall average cost of processing a blood unit is US\$ 750, twice the investment that would be needed in a model with fewer blood banks. Nine Latin American countries (47%)—Argentina, Bolivia, Chile, Colombia, El Salvador, Mexico, Nicaragua, Peru, and Uruguay—have adopted a policy to reduce blood processing centers.
- 11. Eighteen countries in Latin America have laws that regulate blood services. Analyses of the adequacy of the laws, compared to a "model law" developed by PAHO, however, show that the current legal frameworks are deficient in setting up a national system, its organization, functions, financial support, and the overall oversight.

## External Evaluation of Performance

- 12. The pillars of quality assurance are quality control, external evaluation of performance, audits, and continued education of staff. External evaluation of performance allows the retrospective comparison of the ability of the participating centers to correctly analyze controlled samples. PAHO established the Regional Program for External Evaluation of Performance (PEEP) for TTI, aimed at national reference blood banks in Latin America (Table 4). PAHO supported the training of Latin American personnel from central laboratories and/or blood banks in the technology and administrative processes to established national PEEP. In the four-year period, 16 of the 19 Latin American countries had their national PEEP established, with participation increasing from 24% (1,129/4,738 banks) in 2000 to 53% (1,330/2,509 banks) in 2003 (Table 5).
- 13. PAHO also established subregional PEEP programs for immunohematology for Latin America, with the help of the Blood Center in Valencia, Spain, and for the Caribbean with the support of the Collaborating Center in the United Kingdom and the Caribbean Epidemiology Center (CAREC) (Tables 6 and 7).
- 14. Adoption of national quality standards and quality assurance (QA) policies were monitored as indicators of national quality systems in 41 countries (Table 8). Training of personnel on QA issues and quality management was done in regional or subregional workshops, and then promoted at the national level. Distance learning, as well as face-to-face courses, was developed to train personnel from blood banks.

#### **Donors**

- 15. The promotion of voluntary blood donation is central to blood safety since voluntary blood donors are less likely to be carriers of TTI (Table 9). Voluntary, nonremunerated donors have increased from 15% of the units of blood collected in Latin America and the Caribbean in 2000 to 36% in 2003. But, Bolivia, Honduras, Panama, Paraguay, and Peru reported paid donors that accounted for 0.3% of all units (Table 10). The countries that reported over 50% voluntary blood donors (VBD) in 2003 were Aruba, Bermuda, Brazil, Cayman Islands, Cuba, Curação, Saint Lucia, and Suriname.
- 16. PAHO developed and supported the application in 15 countries of guidelines to investigate public knowledge, beliefs, attitudes, and practices regarding blood donation, as well as to assess the readiness of the blood banks to provide good service to blood donors. Educational materials and public service announcements specifically targeted at school children, young adults, and the elderly or for the population at large were produced.
- 17. The main activities conducted by PAHO have been to identify and train national coordinators for the promotion of voluntary blood donation nationally, to develop national plans for the promotion of voluntary donation, and to organize national workshops to train promoters of voluntary blood donation in their respective countries. The legal frameworks regarding blood donation and blood collection do not cover the critical issues about promoting voluntary blood donation, although their stated intention is to pursue it.

#### Infections in High-Risk Groups

- 18. The study of patients that receive multiple transfusions provides an indirect measure of the safety of blood available for their treatment. Chronic patients who have been exposed to transfusions for prolonged periods of time can be studied to have an approximation of the past safety of blood. PAHO supported a multicenter study on the prevalence on HCV, HIV, and HBV among multitransfused individuals. Ten groups of investigators in Argentina, Bolivia, Brazil, Colombia, Cuba, Honduras, Mexico, Nicaragua, Peru, and Uruguay were chosen to carry out a standardized protocol of a study population of 3,501 patients. The overall prevalence rates of infections were 1.7% (58 positive), 13.1% (457), and 24.1% (842) for HIV, HBV, and HCV, respectively (Table 11).
- 19. Recommendations for national blood programs on how to develop and implement guidelines for the clinical use of blood were developed by PAHO as well as the concept of hemovigilance.

#### Safety and Availability of Blood

- 20. The true safety of blood and blood transfusions can only be established by the longitudinal follow-up of patients who receive blood and of individuals who give blood. This approach is presently impossible in the Caribbean and Latin America due to the lack of countrywide information. Under the current circumstances, the best estimate of the safety of blood for transfusion comes from a combination of prevalence of infectious markers among blood donors and the coverage of screening for each of those markers.
- 21. The estimated risks for HIV-contaminated transfusion in Latin America and the Caribbean decreased from 0.47 per 100,000 donations in 2000 to 0.08 in 2003; from 21.18 to 0.30 per 100,000, for hepatitis B; and from 131.32 to 28.22 per 100,000 for *T. cruzi*. The risk for hepatitis C was 3.29 in 2000 and 2.00 in 2003 (Table 12). These findings, coupled with those from the study of multitransfused patients, clearly indicate that better selection of blood donors and extension of screening coverage should be priorities in the Region.
- 22. On the other hand, screening of blood prevented approximately 135,000 viral infections in the four-year period, including 13,058 by HIV. If we consider the cost of antiretroviral drugs alone—not taking drug delivery into consideration—at \$400 per person per year, the estimated investment to treat those individuals is \$5,223,200.
- 23. Although past work in the Region did not have the specific objective of increasing the number of blood units collected, the available data allow an estimation of the availability of blood in each country and in the Region. The international standard proposed by the International Federation of Red Cross and Red Crescent Societies and WHO is for a community to have enough blood, to collect a number of blood units equivalent to 5% of the population, or 50/1,000. The overall donation rate in the Latin American and Caribbean countries is 14, with no major changes in the last four years (Table 13). Except for Cuba, which has a donation rate above 50, 53% of the countries have donation rates under 10, and 44%, donation rates between 10 and 19.

#### **Lessons Learned and Critical Issues**

24. Substantial progress has been made in blood safety in the Region of the Americas. Although each year more units of blood are tested for the markers of infectious agents, the regional goal set in the Strategic and Programmatic Orientations for 1999-2002 of universal blood screening has not been achieved. An unacceptably high number of blood units are transfused without being tested for TTI due to (a) the absence of a permanent stock of blood in the blood banks, a fact associated with the lack of voluntary, altruistic donors; and (b) a lack of testing reagents in the blood banks. Because the vast majority of blood banks are hospital-based, the emphasis is not on promoting voluntary blood

donation, but on replacing the limited number of units made available by the relatives, friends, and acquaintances of the patients.

- 25. One of the consequences is that the general population prefers to "save their blood for a family or friend" and not give altruistically, creating a shortage of blood even when efforts are made to promote voluntary donation by nonhospital-based institutions. This induced, artificial unavailability of blood in turn provides the rationale for hospital-based blood banks not to share their blood with other centers. The final consequence is that up to 12% of units of red blood cells may be discarded in a country, because they become outdated. In other instances, because the blood is available to the clinicians, transfusions are given to patients who do not need them.
- 26. For 2002, countries that had at least 98% voluntary blood donors had a prevalence of HIV reactive donors of 2 per 100,000 donors; the rate for the countries with paid donors was 350; the figure for the countries with replacement donors was 340. This means that replacement and paid donors are more likely to be positive for any of the markers of infectious agents that may be transmitted through transfusions. More blood is discarded after screening in the latter two groups of countries. Thus, nonvoluntary blood donation has an impact on safety and availability of blood as well as economical consequences.
- 27. The existence of an excessive number of hospital-based blood banks has negative consequences for blood availability and safety. Additionally, it contributes to diminished efficiency of scarce resources, including the augmented purchase prices of the testing kits. Data obtained from seven countries show that the cost, per test, of HIV reagents varies from \$1.30 to \$3.69; for HVC the range is \$1.55 to \$8.72. Other direct and indirect costs are also higher in blood banks that process a small number of units per year.
- 28. The multiplicity of blood banks also hinders the implementation of quality programs at the national level. Implementing quality programs in services that collect a few units of blood daily is very expensive and inefficient. Training of personnel, maintenance of equipment, audits, and external evaluation of performance would amount to a gigantic effort and investment of already limited resources. It is not surprising, then, that smaller blood banks are more likely to produce inaccurate results in the screening tests for infectious markers, as shown by the national PEEP.
- 29. The improvement of blood safety in the Region requires systematic, multidisciplinary national approaches that (a) promote voluntary blood donation by educating the public, training personnel, and setting up donor-friendly blood collecting sites; (b) facilitate quality assurance and efficient preparation of blood components;

- (c) ensure oversight of the use of resources, including blood; and (d) optimize the number of blood banks.
- 30. Most of the achievements in the Region were made possible by the collection and use of data provided by the national blood programs, monitoring of the regional and country situation, sharing of experiences among countries and all stakeholders, promotion of technical cooperation among countries and collaboration with multiple partners, and development of agreed-upon short- and medium-term plans of action. Partners include: the International Federation of Red Cross and Red Crescent Societies (Geneva); U.S. Rotary Club District 7620 (Maryland); Rotarians in El Salvador, Colombia, and Uruguay; United Blood Services (El Paso, Texas); American Association of Blood Banks; University of Texas Medical Branch (Galveston, Texas); Benemérita Universidad Autónoma de Puebla; Red Cross Blood Bank Foundation of Curação; universities in Bolivia, Ecuador, El Salvador, Guatemala, Honduras, Nicaragua, and Panama; and our Collaborating Centers in Brazil, Spain, and the United Kingdom.

#### The Way Forward

- 31. The First Pan American Conference on Blood Safety was held in PAHO Headquarters in February 2003. Delegates from the countries of the Region, technical partners, and PAHO country staff participated in the evaluation of the progress of the plan developed in 1999, and in the planning for 2004-2010. The purpose of the plan of action for the coming years is to contribute to the reduction of mortality and to the improvement of patient care in Latin America and the Caribbean, by making safe blood for transfusion available in a timely manner for all those patients who need it. The objectives set forth are:
- (a) Assure appropriate collection and preparation of blood components in sufficient quantities to treat patients who need blood transfusions.
- (b) Assure timely access to blood components by patients who need blood transfusions.
- (c) Assure the highest level of safety of blood products to avoid transmission of infectious diseases and other untoward effects associated with transfusions.
- (d) Promote the appropriate clinical use of blood.
- (e) Improve the efficiency of the national resources.
- 32. The indicators of progress of the plan are:
- (a) 100% of the countries will have a national estimate of the geographic and temporal needs for blood and blood components.

- (a) 95% of all units of blood collected will be fractionated into components.
- (c) 100% of the countries will have implemented a quality assurance plan that comprises all blood services in the country.
- (d) At least 50% of the blood units collected in each country will come from voluntary, altruistic, nonremunerated donors.
- (e) 100% of the countries will have established hemovigilance to assess the health impact of transfusions, in accordance with the national system organization and set up.
- (f) 100% of the countries will have revised their legal and regulatory framework.
- (g) 100% of the countries will have operational transfusion committees, in accordance with the national system organization and set up.
- (h) 100% of the countries will have implemented guidelines for the clinical use of blood in every transfusion service.
- (b) 100% of Latin American countries will have implemented regional blood collection and processing systems to cover the needs of patients of geographically distinct areas.
- 33. The proposed strategies are:

#### Planning and Management of the National Blood Network System

34. In order to attain the expected result, it is necessary to develop, implement, and consolidate a national network model for blood services delivery based on local needs and headed by the ministry of health, with the participation of the institutions that are involved in the collection, processing, and transfusion of blood and blood products. This will include the adjustment of the legal framework; analyses of the financial efficiency of the current national blood system and of regionalized models; optimization of the collection and processing of blood units to allow timely delivery of blood, blood products, and blood substitutes to the health care services; and a locally appropriate information system to manage data within the individual blood services and in the national network to monitor and evaluate efficiency, efficacy, safety, and timeliness of the blood products and services.

#### Promotion of Voluntary Blood Donation

35. In conjunction with the activities carried out for the planning of the national blood network system, the current legal and regulatory framework will be revised and modified, where needed, to facilitate voluntary, altruistic, nonremunerated blood donation by members of the community. It will include the implementation of extramural blood collection drives and extended donor service hours in upgraded premises, development of

national strategic plans to promote repeat, voluntary, altruistic blood donation in partnership with the ministries of education, labor, and social development, along with nongovernmental organizations, social clubs, religious groups, and other members of the community.

#### Quality Assurance

36. The Caribbean Regional Standards for Blood Banks and the Estándares de Trabajo para Bancos de Sangre (Work Standards for Blood Banks), developed by CAREC and PAHO, respectively, will be implemented in all blood services. Good manufacturing practices will guide the preparation of plasma derivatives. Specific systems to monitor compliance with norms and standards of blood donor recruitment, and blood collection, processing, storage, distribution, and transfusion will be developed and and efficient screening Universal for transfusion-transmitted infections—HIV/AIDS, hepatitis B and C, and syphilis—will be carried out in all countries, countries will also screen all units of blood for T. cruzi, while the Caribbean islands will screen for human T-cell lymphotropic virus, types I and II (HTLV I/II). The Regional Programs for External Evaluation of Performance will continue. National external evaluation of performance of TTI serology programs for immunohematology will include all testing centers in each country. Untoward reactions to transfusions will be monitored though hemovigilance.

#### Appropriate Use of Blood and Blood Components

- 37. The ministry of health of each country will develop the national guidelines for clinicians, which will be adapted to each health care facility by the hospital transfusion committee. Training of medical personnel will be carried out using the distance-learning model, the materials developed by WHO, national guidelines, and teleconferences.
- 38. All these strategies will be pursued in collaboration with the International Federation of Red Cross and Red Crescent Societies, Rotary Clubs, the Ibero American Collaborative Group for Transfusion Medicine; the Hemocenter in São Paulo, Brazil; the United Kingdom Performance Testing Center; the Spanish Blood Transfusion Services; the United Blood Services Blood Bank in El Paso, Texas; and other centers.

#### **Action by the Directing Council**

39. The Directing Council is requested to examine the progress report on the Regional Initiative for Blood Safety and the plan of action for 2006-2010, and to consider the adoption of the annexed resolution, as recommended by the Executive Committee.

Annexes

Table 1. Number and Percent of Blood Units Screened in the Region, 2000-2003

|                      | 2000      | 2001      | 2002      | 2003      |
|----------------------|-----------|-----------|-----------|-----------|
| Units Collected (N)  | 6 409 596 | 6 138 881 | 7 207 771 | 7 325 093 |
| Units Tested for HIV | 6 387 790 | 6 132 361 | 7 198 388 | 7 320 292 |
|                      | (99.66)   | (99.89)   | (99.87)   | (99.93)   |
| Units Tested for HBV | 6 387 247 | 6 129 619 | 7 194 120 | 7 315 191 |
|                      | (99.65)   | (99.85)   | (99.81)   | (99.86)   |
| Units Tested for HCV | 6 332 331 | 6 084 348 | 7 170 766 | 7 290 038 |
|                      | (98.79)   | (99.11)   | (99.49)   | (99.52)   |
| Units Tested for     | 6 381 752 | 6 115 972 | 7 200 963 | 7 313 335 |
| Syphilis             | (99.57)   | (99.63)   | (99.90)   | (99.84)   |

Table 2. Number and Percent of Blood Units Screened for *T. cruzi* in Latin America, 2000-2003

|                        | 2000      | 2001      | 2002      | 2003      |
|------------------------|-----------|-----------|-----------|-----------|
| Units to Be Tested (N) | 5 700 259 | 5 444 869 | 6 474 882 | 7 097 339 |
| Units Tested           | 4 502 114 | 4 325 486 | 5 584 274 | 6 251 932 |
|                        | (78.98)   | (79.44)   | (86.24)   | (88.09)   |

Table 3. Number and Percent of Countries Reporting Universal Screening, 2000-2003

|          | 2000         | 2001         | 2002         | 2003         |
|----------|--------------|--------------|--------------|--------------|
| HIV      | 31/37 (83.8) | 29/33 (87.9) | 32/38 (84.2) | 33/38 (89.2) |
| HBV      | 30/37 (81.1) | 27/33 (81.8) | 31/38 (81.6) | 33/38 (89.2) |
| HCV      | 19/37 (51.3) | 15/33 (45.4) | 21/38 (55.3) | 23/38 (62.5) |
| Syphilis | 32/37 (86.5) | 27/33 (81.8) | 32/38 (84.2) | 33/38 (89.2) |
| T. cruzi | 6/17 (35.3)  | 6/16 (37.5)  | 6/17 (35.3)  | 7/17 (41.2)  |

Table 4. Participation in Regional PEED for TTI, 2000-2003

|                                      | 2000 | 2001 | 2002 | 2003 |
|--------------------------------------|------|------|------|------|
| Number of Latin American Countries   | 18   | 18   | 16   | 18   |
| Number of Caribbean Countries        | 0    | 17   | 16   | 18   |
| Number of Latin American Blood Banks | 20   | 21   | 17   | 20   |
| Number of Caribbean Blood Banks      | 0    | 20   | 17   | 22   |

Table 5. Participation in National PEEP for TTI, 2000-2003

|  | 2000  | 2001  | 2002  | 2003  |
|--|-------|-------|-------|-------|
| Number of Blood Banks in Latin America | 4,738 | 5,574 | 4,844 | 2,509 |
| Number of Participating Blood Banks    | 1,129 | 1,162 | 1,258 | 1,330 |
| % of Participation                     | 23.82 | 20.84 | 25.97 | 53.01 |
| Number of Countries with National PEEP | 11    | 15    | 15    | 16    |

Note: When the 58 Caribbean blood banks are taken into account, the rates of participation in PEEP were 23.57%, 21.15%, 26.04% and 52.67%, respectively, for the 4 years.

Table 6. Number of Participants in Regional PEEP for Immunohematology in Latin America and the Caribbean, 2000-2003

|                | 2000 | 2001 | 2002 | 2003 |
|----------------|------|------|------|------|
| Latin American | 24   | 25   | 25   | 30   |
| Caribbean      | 0    | 24   | 24   | 24   |

Table 7. Number of Countries and Blood Banks Participating in National PEEP for Immunohematology in Latin America, 2000-2003

|             | 2000 | 2001 | 2002  | 2003  |
|-------------|------|------|-------|-------|
| Countries   | 6    | 6    | 8     | 8     |
| Blood Banks | 325  | 350  | 1 093 | 1 190 |

Table 8. Number of Countries Having Implemented a National Quality Assurance System with Standards or a QA Policy, 2000-2003

|                  | 2000    | 2001    | 2002    | 2003    |
|------------------|---------|---------|---------|---------|
| With Standards   | 14 (34) | 18 (44) | 23 (56) | 26 (63) |
| With a QA policy | 9 (22)  | 11 (27) | 13 32)  | 21 (51) |

Table 9. Median Prevalence (Percent) of Markers for HIV, Hepatitis B and C, and Syphilis in Countries Having at Least 50% Voluntary Blood Donors, Compared to the Rest of the Countries, 2000-2003

| Marker   | Countries with | 2000 | 2001 | 2002 | 2003 |
|----------|----------------|------|------|------|------|
| HIV      | < 50% VBD      | 0.21 | 0.20 | 0.30 | 0.28 |
|          | >50% VBD       | 0.13 | 0.01 | 0.00 | 0.01 |
| HBsAg    | < 50% VBD      | 0.60 | 0.85 | 0.60 | 0.60 |
|          | >50% VBD       | 0.37 | 0.30 | 0.40 | 0.18 |
| HCV      | < 50% VBD      | 0.56 | 0.59 | 0.51 | 0.56 |
|          | >50% VBD       | 0.10 | 0.23 | 0.02 | 0.06 |
| Syphilis | < 50% VBD      | 0.97 | 0.92 | 1.07 | 0.92 |
|          | >50% VBD       | 0.55 | 0.24 | 0.00 | 0.13 |

Table 10. Number and Percent of Voluntary and Paid Donors, 2000-2003

|                      | 2000      | 2001      | 2002      | 2003      |
|----------------------|-----------|-----------|-----------|-----------|
| Units Collected (N)  | 6,409,596 | 6,138,881 | 7,207,771 | 7,325,093 |
| Voluntary Donors (N) | 989,8 85  | 902,816   | 2,463,777 | 2,641,739 |
| (%)                  | (15.44)   | (14.71)   | (34.18)   | (36.06)   |
| Paid Donors (N)      | 31,725    | 32,059    | 31,690    | 24,925    |
| (%)                  | (0.50)    | (0.52)    | (0.44)    | (0.34)    |

Table 11. Prevalence (Number and Percent) of Infected Individuals by Patient Group

|           | Hemophilia | Hemodialysis | Hemoglobino-<br>paties | Oncology  | Acute<br>Bleeding |
|-----------|------------|--------------|------------------------|-----------|-------------------|
|           | N=662      | N=505        | N=310                  | N=1 555   | N=469             |
| HIV only  | 22 (3.3)   | 1 (0.2)      | 3 (1.0)                | 7 (0.5)   | 5 (1.0)           |
| HBV only  | 120 (18.1) | 50 (9.9)     | 17 (5.5)               | 151 (9.7) | 7 (1.5)           |
| HCV only  | 337 (50.9) | 166 (32.9)   | 77 (24.8)              | 115 (7.4) | 21 (4.5)          |
| HIV+HBV   | 1 (0.2)    | 0            | 0                      | 1 (.01)   | 0                 |
| HIV+HCV   | 13 (2.0)   | 0            | 1 (0.3)                | 1 (.01)   | 0                 |
| HBV+HCV   | 58 (8.8)   | 15 (3.0)     | 13 (4.2)               | 22 (1.4)  | 1 (0.2)           |
| 3 viruses | 2 (0.3)    | 0            | 1 (0.3)                | 0         | 0                 |
| Total HIV | 38 (5.7)   | 1 (0.2)      | 5 (4.2)                | 9 (0.6)   | 5 (1.0)           |
| Total HBV | 179 (27.0) | 65 (12.9)    | 31 (10.0)              | 174(11.2) | 8 (1.7)           |
| Total HVC | 408 (61.6) | 181 (35.8)   | 92 (29.7)              | 139 (8.9) | 22 (4.7)          |

Table 12. Estimated Indicators of Blood Safety, 2000-2003

| Variable                       | 2000   | 2001   | 2002   | 2003   |
|--------------------------------|--------|--------|--------|--------|
| HIV infections prevented (N)   | 2,694  | 2,431  | 3,800  | 4,133  |
| HIV infections transfused (N)  | 30     | 12     | 6      | 6      |
| Risk of HIV/ per 100,000       | 0.47   | 0.19   | 0.08   | 0.08   |
| HBV infections prevented       | 19,571 | 16,470 | 19,083 | 20,535 |
| HBV infections transfused      | 1 357  | 25     | 29     | 22     |
| Risk of HBV/ per 100,000       | 21.18  | 0.40   | 0.40   | 0.30   |
| HCV infections prevented       | 15,277 | 14,482 | 12,928 | 14,355 |
| HCV infections transfused      | 211    | 147    | 87     | 147    |
| Risk of HCV/ per 100,000       | 3.29   | 2.39   | 1.21   | 2.00   |
| T. cruzi infections prevented  | 30,776 | 31,629 | 32,411 | 34,490 |
| T. cruzi infections transfused | 7,483  | 864    | 1,371  | 2,193  |
| Risk of T. cruzi/ per 100,000  | 131.23 | 15.87  | 21.18  | 28.22  |

Table 13. Availability and Safety of Blood, 2000-2003

|                                     | 2000      | 2001      | 2002      | 2003      |
|-------------------------------------|-----------|-----------|-----------|-----------|
| Number of units collected           | 6,409,596 | 6,138,881 | 7,207,771 | 7,325,093 |
| Donation rate per 1,000             | 12.68     | 12.15     | 14.08     | 13.86     |
| Risk of viral transfusion           | 1: 4,011  | 1: 33,363 | 1: 59,080 | 1: 41,858 |
| Risk of <i>T. cruzi</i> transfusion | 1: 762    | 1: 6,301  | 1: 4,722  | 1: 3,340  |

## **Budget for regional activities**

| Approach      | Year 1    | Year 2    | Year 3  | Year 4  | Year 5  | Total     |
|---------------|-----------|-----------|---------|---------|---------|-----------|
| Revision of   | 250,000   | 305,000   | 190,000 | 100,000 | 0       | 845,000   |
| the legal and |           |           |         |         |         |           |
| regulatory    |           |           |         |         |         |           |
| framework     |           |           |         |         |         |           |
| Needs         | 400,000   | 450,000   | 0       | 0       | 0       | 850,000   |
| assessment    |           |           |         |         |         |           |
| Tool          | 110,000   | 250,000   | 50,000  | 0       | 0       | 410,000   |
| development   |           |           |         |         |         |           |
| Tool          | 750,000   | 730,000   | 600,000 | 500,000 | 395,000 | 2 975,000 |
| deployment    |           |           |         |         |         |           |
| Program       | 196,300   | 225,550   | 109,200 | 78,000  | 51,350  | 660,400   |
| support       |           |           |         |         |         |           |
| costs         |           |           |         |         |         |           |
| TOTAL         | 1 706,300 | 1 960,550 | 949,200 | 678,000 | 446,350 | 5 740,400 |

Available for regional activities, July 2005

Regular funds. US \$ 115,000 per biennium.

Funds from the Spanish Agency for International Cooperation (AECI), for 30 months. Euro 226,000.

Funds from Chiron Foundation: for 9 months: US \$ 98,000

#### **Human resources**

Regional Advisor, Blood Services. Salary paid by regular funds. Technical officers (1.5) and administrative assistant (0.5). Salaries paid by the PEPFAR project, four years.

## 136th SESSION OF THE EXECUTIVE COMMITTEE

Buenos Aires, Argentina, 20-24 June 2005

CD46/16 (Eng.) Annex C

#### **RESOLUTION**

#### CE136.R6

# PROGRESS REPORT ON THE GLOBAL SAFE BLOOD INITIATIVE AND PLAN OF ACTION FOR 2005-2010

#### THE 136th SESSION OF THE EXECUTIVE COMMITTEE,

Having analyzed Document CE136/15, Progress Report on the Global Safe Blood Initiative and Plan of Action for 2005-2010,

#### **RESOLVES:**

To recommend to the Directing Council the adoption of a resolution along the following lines:

#### THE 46th DIRECTING COUNCIL,

Noting the importance of blood transfusions for appropriate patient care, survival, and quality of life;

Having studied the report of the Director on the progress of the Blood Safety Initiative;

Recognizing the achievements in the screening of infectious markers in blood and the reduction in the potential risk of transfusion-transmitted infections in the Region;

Aware of the efforts made by the Secretariat and the National Blood Programs of the Members States to jointly assess previous work and to develop a regional plan of action for the improvement of transfusion safety in the Americas by the year 2010;

Concerned that the goals identified by the World Health Assembly in 1975 and by the Governing Bodies of the Pan American Health Organization in the past decade have not been achieved in the Region;

Recognizing that in order to achieve sufficient supply, appropriate quality of blood, and appropriate safety of transfusions, the current national approaches need to be revised and adjusted;

Recognizing that the number of voluntary donors in the Region of the Americas is still limited;

Welcoming World Health Assembly Resolution WHA58.13 Blood Safety: Proposal to Establish World Blood Donor Day; and

Motivated by the spirit of Pan Americanism, equity, and the internationally agreed health-related development goals in the United Nations Millennium Declaration,

#### **RESOLVES:**

- 1. To urge Member States to:
- (a) analyze the progress and challenges in the pursuit of sufficiency, quality, safety, and appropriate use of blood and blood products in their countries;
- (b) officially adopt the Regional Plan of Action for Transfusion Safety 2006-2010, and appropriately allocate and efficiently use resources to obtain its objectives;
- (c) promote the participation of the public and private sectors, ministries of education, labor and social development, and civil society in the international, national, and local activities undertaken to implement the Regional Plan;
- (d) Strengthen blood services and improve their efficiency, while promoting a culture of voluntary, non-remunerated blood donation.
- 2. To request the Director to:
- (a) cooperate with the Member States in the development of their national blood policies and strategies, and the strengthening of blood services to ensure transfusion safety;

- (a) promote the application at the local level of quality standards and validated methodologies for the improvement of the safety of blood products and blood transfusion, utilizing a multidisciplinary approach;
- (c) work with Member States to monitor the development of the national blood programs and transfusion safety;
- (d) report periodically to the Governing Bodies on the progress of implementation of the Regional Plan of Action for Transfusion Safety, including constraints;
- (e) mobilize resources in support of the Regional Plan of Action for Transfusion Safety.

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