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FINAL REPORT
RETREAT ON BLOOD SAFETY

Antigua Guatemala, Guatemala

18-20 October 1999

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PAHO/WHO 41st Directing Council – Document CD41/13

PAHO Action Plan for Improving the Safety of Blood for Transfusion
in the Region of the Americas. 1999-2001

I. INTRODUCTION

The safety of blood products for transfusion and their appropriate use are major global concerns. The appearance of the acquired immunodeficiency syndrome (AIDS) in the 1980's and the recognition that its etiologic agent, the human immunodeficiency virus (HIV), can be transmitted through transfusions contributed to increased awareness of the risks associated with receiving blood products. It is now clear that other infectious agents, such as hepatitis B and C viruses, human T cell lymphotropic virus, cytomegalovirus, and *Trypanosoma cruzi* can also be transmitted through transfused blood. Efforts have been and are being made to develop and implement in the blood banks technology that permits sensitive and specific screening of blood donors, in such a way that the blood from those who are infected is not used to treat patients. Information derived from epidemiological studies has provided the basis for pre-donation interviews that discourage potentially infected donors from giving blood. Such deferral can be either temporary or permanent. Donor recruitment –from low risk populations-, donor selection, donor education, donor retention, and efficient screening and processing of blood are the pillars for the safety of blood products.

Donor recruitment and selection are especially important issues. The World Health Organization estimates that, in order for a country or a community to have sufficient blood products and derivatives to cover its needs, the number of blood units collected in a year should represent five percent of its population. In the Region of the Americas, only Cuba meets that criterion; Curaçao and the United States get donations over four percent of their total population, with the majority of countries (28) having 1.5% or less. Furthermore, in the setting of the American countries, voluntary, non-remunerated donors have lower risk for transfusion-transmitted infections (TTI) than replacement donors do. Nevertheless, only Aruba, Canada, Cuba, Curaçao and the United States report that all the blood donors are voluntary, non-remunerated. A few countries – Bolivia, Chile, Honduras, Panama and Peru- recognize the existence of remunerated “donors”. Two main factors contribute to the overall situation in the Region: the absence of national programs for voluntary, non-remunerated blood donation, and the policy of the hospitals to require the “replacement” –before or after providing services - of the blood that the patients may be given. Blood banks are, in general, not prepared to work with voluntary donors and, in many instances, their personnel attitudes may be detrimental.

Availability of appropriate laboratory resources to screen donated blood for infectious markers is also a very important issue, especially in those countries and services where voluntary blood donation is practically non-existent. Information made available by the National Blood Programs/Authorities to the Pan American Health Organization (PAHO) indicates that, in 1998, over one million blood units were transfused without being screened for hepatitis C. Although the numbers are lower for hepatitis B and HIV, there are still countries that do not screen 100% of the collected blood units for those two viruses. Lack of diagnostic kits is the main reason for failure to screen.

An additional concern is the accuracy of screening results, since quality control measures are not generally applied. Quality control is considered more an added cost to the limited- resourced blood banks than an essential component of routine work. The void in quality assurance programs, including manuals of standard operating procedures, hinders the implementation of good laboratory and manufacturing practices.

Despite the facts that the number of blood donations is insufficient to cover the actual needs of the population, and that a high proportion of donated blood units is not screened for major infectious agents, blood transfusions are given in situations when they are not strictly necessary. Although the information pertaining to blood use in the Region is generally scarce, the limited data available to PAHO show that most transfused patients receive only one unit of whole blood or its components and, therefore, are unnecessarily exposed to potential risks. On the other hand, chronically ill patients who require blood derivatives, such as coagulation factors, depend on local products that are likely to be contaminated. The continuous usage of such products represents a very high risk for contracting infectious diseases, especially hepatitis C.

The countries of the Region have initiated organized efforts to address these important issues. Initially, most Latin American countries have passed laws aimed at introducing order into their national blood programs. National Blood Commissions, National Blood Committees or National Blood Centers have been given the responsibility of setting up national policies and strategies to strengthen blood banks and transfusion services. In the Caribbean countries, where only a small number of blood banks exist, the implementation of a national program is closely related to the institutional policy of the major hospitals. The task is not an easy one for Latin American countries where the numbers of blood banks is excessive for the population. In some instances, less than 300 blood units are collected and processed annually. Furthermore, the Ministry of Health, the Social Security, the Armed Forces, the private sector and non-governmental organizations may run blood banks. The need for national blood programs –based on voluntary, non remunerated donation, and quality assurance programs- has been recognized by the health authorities, as demonstrated by the Resolution of PAHO's Directing Council adopted in San Juan, Puerto Rico on October 1, 1999. (Annex III)

The Red Cross is active in blood programs in some countries of the Region – Bolivia, Chile, Colombia, Ecuador, El Salvador, Dominican Republic, Guatemala, Honduras, Haiti, Nicaragua, Peru, and Suriname. With the support of the Spanish Red Cross and the International Federation of Red Cross and Red Crescent Societies (IFRCRCS) the “Interamerican Network of Red Cross Blood Programs” has been formed. Its purpose is to facilitate common approaches towards efficient Red Cross blood programs, including the recruitment and selection of voluntary blood donors.

In the Caribbean, the Caribbean Epidemiology Center (CAREC), based in Trinidad, plays a central role in support of the national blood banks, with technical cooperation activities that emphasize training and quality assurance.

The American Association of Blood Banks (AABB) has extended its mission to work in areas outside the United States of America. The AABB has lent its expertise in developing quality management and technical standards for blood banks and transfusion services by producing "Core Standards" that are compatible with ISO 9000 which have been further developed into the Latin American standards and the Caribbean Standards in collaboration with PAHO and CAREC.

The Hemocentro, Sao Paulo, Brazil, has been instrumental in implementing the PAHO Regional Program for External Evaluation of Performance (EEP) of Serology for ITT. Similar National Programs of EEP have been started in several countries with the support of the Hemocentro.

The Banco de Sangre de Baleares has, likewise, implemented the EEP for immunohematology and has also provided technical support to the national programs.

The World Federation for Hemophilia (WFH) and the Mount Sinai Hemophilia Center in New York have undertaken activities to strengthen treatment of hemophiliacs, not only in the Americas but also in other parts of the world. The WFH is an international not-for-profit organization dedicated to introducing, improving and maintaining care for people with hemophilia and related bleeding disorders around the world. Officially recognized by the World Health Organization, the WFH represents national hemophilia organizations in 88 countries. Most Latin American countries are represented.

The WFH has greatly increased its program activities to promote sustainable improvement in countries where access to hemophilia care is limited. The WFH is also becoming more involved in key issues, such as safety and supply of blood products, which are critical to the hemophilia community worldwide. The WFH has established a strong international network of volunteers from the medical and lay communities, national hemophilia organizations, hemophilia treatment centers, government officials and pharmaceutical companies.

The USA Centers for Disease Control and Prevention (CDC) in Atlanta are involved in several fields related to blood safety, with an especial interest on accuracy of Chagas Disease testing.

The "Grupo Colaborativo Ibero Americano de Medicina Transfusional" brings together professionals –physicians, laboratorians, nurses– that work in various fields of transfusion medicine in Latin America and Spain. The mission of the Group is to improve the knowledge, attitudes and practices among transfusion specialists.

Personnel from the blood banks at the M. D. Anderson Cancer Center, Houston, and the Danbury Hospital, in Connecticut, have trained Latin American personnel and, more recently, have supported PAHO-sponsored activities in the countries.

With the purpose of developing a common strategy that would foster collaboration, avoid duplication of efforts and promote information exchange, PAHO

sponsored a ~~three~~-day retreat with the participation of all the above mentioned institutions (See Annex I - List of participants). After detailed discussions (See Annex II - Agenda of Work), consensus was reached on what are the barriers that curtail efficient national blood programs, what are the issues that need to be addressed, and how each of the institutions may contribute. A Steering Committee, formed by AABB, IFRCRCS, WFH and coordinated by PAHO, was appointed with the specific task of developing a 5 year-work proposal and to search for funds to implement the plan of action.

II. GOAL

Appropriate use of effective, adequate, available and affordable blood products.

III. OBJECTIVE

Develop and strengthen National Blood Programs to accomplish the goal.

IV. ISSUES

The issues that the group identified as important were grouped in four categories:

1. Political and Cultural Issues
2. Economic and Financial Issues
3. Technical Issues
4. Managerial Issues

1. POLITICAL AND CULTURAL ISSUES

- Political Commitment
- Advocacy
- Marketing
- Stakeholders involvement and participation
- Accountability
- Integrated legislation (dumping, local production)
- Awareness among consumers (non-remunerated donors, mass media)
- Recognition of public health importance of blood programs
- Strategic alliances
- Economic arguments (cost/benefit analyses)
- Regionalization
- Human resource policies

2. ECONOMIC AND FINANCIAL ISSUES

- Financial resources for national programs
- Supplies, operations
- Financial strategies (to ensure access by all, equity, sustainability)

3. TECHNICAL ISSUES

- Education and training of medical and technical personnel, including pre and post graduate and continuing education
- Working standards and guidelines
- Information systems (data analyses, monitoring)
- Data collection and hemovigilance
- Public education (blood donors, blood recipients)
- Quality assurance programs
- Biosafety
- Programs of voluntary, non remunerated blood donation
- Diagnostic kit evaluation
- Appropriate reagents
- Availability of component therapy

4. MANAGERIAL ISSUES

- Appropriate quality management systems
- Good management practices, including
- Personnel
- Coordination
- Responsibility
- Accountability
- Planning, implementation and evaluation of programs
- Organizational structures
- Intra and inter sectoral coordination (private, public, NGO's)
- Preventive equipment maintenance programs

To address the political issues, the approved resolution CDV1/R15 (See copy) must be put into action. The first target is to increase awareness of the public health importance of the "GOAL" through advocacy and stakeholder involvement and marketing. The national authorities should be encouraged to develop a national policy to achieve the "GOAL" by passing integrated legislation, and by inducing the efficient use of existing national resources through regionalization of blood banks and the creation of strategic alliances. The National Blood Programs/Authorities must play a leading role, with support from PAHO, CAREC, IFRCRCS, AABB, GCIAMT and WFH.

To address cultural issues, anthropological studies should be conducted in the countries to identify knowledge, attitudes and practices regarding blood donation, blood transfusion and mechanisms to involve the public in advocacy. With the leadership of national blood programs and the participation of academic centers, PAHO, CAREC, IFRCRCS, GCIAMT should provide technical cooperation by developing research models, supporting local studies and analyzing the information to construct a regional plan.

Facilitating workshops, discussion groups and the creation of strategic alliances should strengthen the managerial skills of blood bank and transfusion service directors. The development and implementation of quality management systems should be encouraged. PAHO, CAREC, AABB and IFRCRCS should provide technical support.

The "GOAL" should be addressed by quality systems, taking actual needs of the population into consideration. PAHO, CAREC, IFRCRCS, AABB and the collaborating centers should facilitate the development and implementation of national work standards, national programs for EEP, and the formal structure to oversee compliance with those standards.

The analysis of the current financial strategies and of the real needs of the population is necessary to improve the efficiency of the national blood programs. All the links of the transfusion chain –blood donor recruitment and selection, blood donor education, blood processing and storage and transfusion practices- should be taken into consideration. The national programs should work together with PAHO, CAREC, IFRCRCS, AABB to carry out the analyses.

For the development of human resources, PAHO, CAREC, AABB, the collaborating centers, with support from the private sector, should plan, carry out and evaluate regional seminars, national workshops, and ad hoc short-term internships. Specific aspects that need to be addressed include, but are not limited to, standards managerial and technical aspects, as well as transfusion practices.

PAHO and AABB should continue the development of regional standards, with support from CAREC, IFRCRCS and GCIAMT. The implementation of national standards should be promoted also. The standards should address process control.

The data collection and analysis are the responsibility of the national blood programs. PAHO, AABB and IFRCRCS can facilitate the process, and can contribute with supranational analyses.

Quality assurance programs should continue to be strengthened, both regionally and nationally. The implementation of standards should be used as the basis, but EEP, internal quality control, audits and continuing education should be in place to guarantee quality of the products and services provided by blood banks and transfusion centers. PAHO, CAREC, AABB, IFRCRCS, GCIAMT and collaborating centers should be involved.

For biosafety issues, PAHO and CAREC should provide guidelines, training and other technical support to national authorities and programs.

The education of the public is the responsibility of all institutions and individuals involved in transfusion medicine. All opportunities should be taken to outreach professional associations, health providers, and national groups –including chronically ill patients.

It will be necessary to review the currently available training materials (AABB, CAREC, GCIAMT, MD Anderson, Danbury Hospital), to accredit training centers (PAHO) and to set up websites and teleconferences (AABB, PAHO, collaborating centers).

ANNEX I

List of Participants

**Retreat on Blood Safety
Antigua Guatemala, Guatemala**

18-20 October 1999

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ANNEX II

Agenda

Retreat on Blood Safety
Hotel Casa Santo Domingo
Antigua Guatemala, Guatemala
18-20 October 1999

Agenda

Sunday, 17 October

Arrival in Antigua Guatemala

Monday, 18 October

8:30h Welcome and Purpose of the Retreat
 José Ramiro Cruz, PAHO

International Activities

9:00- 9:20 Banco de Sangre de Baleares
 Francisco Carbonell, España

9:20- 9:40 Hemocentro de Sao Paulo
 Amadeo Saez Alquezar, Brazil

9:40-10:00 International Federation Red Cross and Red Crescent Society
 Marcela García, Switzerland

10:00-10:30 Coffee

10:30-10:50 Red Interamericana de Cruz Roja
 José Luis Fernández Tonda, Guatemala

10:50-11:10 American Association of Blood Banks
 Karen Lipton, USA

11:10-11:30 Caribbean Epidemiology Center
 Wendy Piggott, CAREC

11:30-11:50 Centers for Disease Control and Prevention
 Barbara Herwaldt, USA

11:50:12:10 Grupo CIAMT
 Bernardo Camacho, Colombia

12:10-12:30 New York Center for Hemophilia
Louis M. Aledort, USA

12:30-14:00 Lunch

14:00-14:20 World Federation for Hemophilia
Line Robillard, Canada

14:20-15:00 PAHO Activities for 1999-2001
José Ramiro Cruz, PAHO

15:00-15:30 Discussion

15:30-16:00 Coffee

16:00-17:00 Discussion (continued)

Tuesday, 19 October

Collaborative Work

9:00-12:30 General Discussion: Major Issues Affecting Blood Safety
Moderator: José Ramiro Cruz, PAHO

10:30-11:00 Coffee

12:30-14:00 Lunch

14:00-16:00 Discussion Groups

15:30-16:00 Coffee

16:00-17:30 Plenary

Wednesday, 20 October

Future Actions

9:00-12:30 **Moderator:** José Ramiro Cruz, PAHO

10:30-11:00 Coffee

12:30-14:00 Lunch

14:00-15:30 Development of Action Plan
Moderator: José Ramiro Cruz, PAHO

15:30-16:00

Coffee

16:00-17:30

Conclusions

José Ramiro Cruz, PAHO

Thursday 21 October

Departure

ANNEX III
PAHO/WHO 41ST Directing Council
Documents



PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION



41st DIRECTING COUNCIL

San Juan, Puerto Rico, 27 September-1 October 1999

Provisional Agenda Item 4.8

CD41/13 (Eng.)
19 July 1999
ORIGINAL: ENGLISH

STRENGTHENING BLOOD BANKS IN THE REGION OF THE AMERICAS

Strengthening blood banks in the Region of the Americas is necessary to achieve the goal adopted by the 25th Pan American Sanitary Conference and contained in the Strategic and Programmatic Orientations for the Pan American Sanitary Bureau, 1999-2002, namely that, in support of the policies to promote Health for All and equitable access to quality health services, all blood for transfusions be screened for infection with hepatitis B and C, syphilis, *Trypanosoma cruzi*, and human immunodeficiency virus, and all blood banks participate in quality control programs. The Strategic and Programmatic Orientations also indicate that the safety of blood banking services should be improved.

The present document summarizes the role of blood banks, their current situation in the Region, and the proposed strategies to achieve the maximum possible level of safety of blood used for transfusion. Voluntary, non-remunerated blood donation, universal screening of donated blood, quality assurance of the processes, and appropriate use of blood are the pillars to achieve safety of blood banking services. The Executive Committee reviewed this document and proposed a resolution (CE124.R7) for the consideration of the Directing Council that endorses the Secretariat's initiative to move toward the elimination of inequities in the delivery of blood services to the peoples of the Americas.

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1. Strategic Importance of Blood Banks

The transfusion of blood products is used in the treatment of patients with serious medical conditions that cannot be corrected with other drugs. Despite the availability of certain blood substitutes that make it possible to maintain the volume and consistency of blood, the biological activity of most of the cellular and plasmic components of human blood makes them the most efficient treatment for a wide variety of medical conditions. In general, emergencies associated with accidents or violence or with major surgery, chronic diseases, clotting disorders, or the complications of pregnancy and childbirth require the use of some blood products. For this reason, the availability in health facilities of blood products for transfusion to patients is essential for preventing mortality or major complications in seriously ill patients.

The administration of allogenic blood to patients is, in many ways, similar to organ transplantation in that the biological product is obtained from a human being who, in the majority of cases, is not genetically related to the patient and who, moreover, may have been exposed to infectious agents that can be transmitted through transfusion. In addition, blood products must retain their structural and physiological integrity, as well as their sterility, during processing and storage until they are transfused into the patient. Transfusion medicine, as a result, is based on the appropriate use of blood products that pose the minimum possible risk to the patient who receives them.

The mission of blood banks is the efficient and timely preparation of safe blood products. Their functions include the recruitment, selection, retention, education, and registry of donors, as well as the collection of blood, its processing into components, its immunohematological and serological analysis, and its storage and release in a manner that protects the donor, the patient, and blood bank personnel from the potentially adverse effects of exposure to human blood. For blood banks to fulfill their mission effectively and perform with quality in a timely and efficient manner, the ministries of health must exercise a steering role, especially in countries where blood banks are run by the social security system, nongovernmental organizations, the armed forces, or private enterprise. The existence of a national blood commission, a national technical committee, and standards and procedures facilitates harmonization of the work of blood banks.

The safety of blood products depends chiefly on the quality of the blood donors. A number of infectious agents can be transmitted through blood but, in most cases, the presence of these microorganisms in the bloodstream is associated with disease in the infected individuals, rendering them unsuitable as blood donors. However, some pathogens have a long incubation period in which the infected individuals are asymptomatic but their blood is infectious, permitting transmission of the pathogen through transfusions. Examples of such pathogens are the human immunodeficiency virus

(HIV), hepatitis B (HBV) and hepatitis C (HCV) viruses, human T-cell lymphotropic virus (HTLV), and *Trypanosoma cruzi*. Epidemiological studies have made it possible to identify behaviors associated with a higher risk of acquiring HIV, HBV, and HCV infections and, as a result, to reject potential donors who may be asymptomatic carriers. Since there is a time lapse between infection by the above-mentioned infectious agents and the appearance of markers of infection in the human body, the so-called “window period,” informing potential donors about this and conducting a careful interview prior to the blood donation reduces the number of donations by infected individuals. It is generally accepted that nonremunerated volunteers who donate blood repeatedly are the safest, in contrast to people who give blood for a particular patient (replacement donor) or for remuneration.

Once the blood is obtained from a donor, the blood bank should screen the units for the presence of serological markers for specific infections. Highly sensitive and specific laboratory techniques have been developed for the diagnosis of HIV, HBV, HCV, and HTLV; there is also sensitive technology available for *T. cruzi* and syphilis. In order to minimize the probability that pathogens will be present in the donated blood, blood banks should analyze all units of blood individually, with a degree of sensitivity that eliminates false negatives. Furthermore, it is essential to safeguard the sterility of the blood, protecting it from possible contamination by microorganisms present in the skin of the donor or of the phlebotomist, or in the work environment. In this regard, the strictest standards—including aseptic techniques and the use of sterile, closed systems—should be applied, which means that procedures and results should adhere to rigorous quality control standards that include external performance evaluation, quality control measures, and audits.

Adverse reactions to blood transfusions are not limited to infections. Some genetically determined antigens present in blood products can provoke immunological and allergic reactions in patients; as a result, it is important to determine blood types and blood groups to ensure that patients receive compatible blood, especially immunodeficient patients such as newborns and cancer and transplant patients.

2. Current Situation of Blood Banks in the Region

Three markedly different situations of blood banks coexist in the Region of the Americas. The level of development of health technology in general, and of transfusion medicine in Canada and the United States, is also represented in blood banking. In Canada, 17 blood centers collect approximately 1,000,000 units of blood yearly. In the United States, 688 blood banks—530 of them associated with hospitals and 158 independent centers—collected 12,602,000 units of blood in 1997. Strict national

standards of work exist in both countries, as well as institutional mechanisms that ensure compliance with the requirements.

There are few blood banks in the English-speaking countries of the Caribbean—often just one per country, usually located in the national reference hospitals. Belize has six blood banks, Guyana five, and Bahamas three. In Latin America, the number of blood banks ranges from 30 to 300 in the majority of the countries, with higher numbers for countries such as Brazil (1,928), Mexico (668), and Argentina (551).

Current law in all the countries of Latin America, except for El Salvador and Nicaragua, ensures that the ministries of health regulate blood bank operations, prohibits the marketing of blood and blood products, and recognizes voluntary donation as the optimal mechanism for obtaining blood. The national legal frameworks, moreover, specify the types of screening that blood banks must conduct in order to protect patients.

In general, blood banks are operated by the social security system, nongovernmental organizations (such as the Red Cross), the armed forces, and private companies, in addition to the public sector. In some cases, the ministry of health has delegated functional responsibility for the blood programs to autonomous institutions that may be independent of one another and located in one province or another. In other cases, the majority of blood banks are privately operated and, as in the case of blood banks in hospitals or public health facilities, their level of complexity varies widely. This variability affects the technical and financial efficiency of the blood banks; thus, the estimated cost of processing a unit of blood ranges from US\$ 30 to \$150. A rather significant consequence of this situation is the inequity in the quality of blood bank services and in the blood products that are transfused into patients.

In only a small proportion of countries and territories in the Region of the Americas is blood for transfusion universally obtained from voluntary, nonremunerated donors. At the national level only Aruba, with 3,100 donations in 1996; Curaçao, with 5,696; Cuba, with around 600,000/year for 1990-1997; Canada, with 1,000,000; and the United States, with 12,600,000, report 100% voluntary donations. Although some countries still acknowledge the existence of as much as 24% remunerated donors, the vast majority of the units of blood obtained in the Region comes from replacement donors. The proportions of the different donor types vary from country to country, province to province, and institution to institution, even within a single country. This situation reflects not only how proactive a role the blood banks play in educating the population, but their general capacity—including the physical plant and infrastructure—to care for those who seek to donate blood.

The implications of blood safety are clear. The economic situations of individuals who use the blood banks to obtain income are precarious; low socioeconomic status in

itself is a risk factor for acquiring infections that then can be transmitted through transfusions. Furthermore, when the motivation is economic, potential donors may deny

risk behaviors and undermine the purpose of the pre-donation interview. Similarly, the pressures of family or friendship that are exerted on replacement donors do not make for optimal selection. Published data on infection markers in different types of donors in the Region of the Americas are limited. However, analysis of the national information from Ecuador for 1996 and 1997, for example, has made it possible to determine that in blood banks where 99% or more of the donors are replacement donors, the risk of finding a marker for HIV, HBV, and HCV is 17 to 58 higher times than in blood banks where less than 40% of the donors are replacement donors.

These observations reveal the importance of screening all units of blood collected by blood banks for transfusion-transmitted infections. Only 16 countries—eight in the English-speaking Caribbean, six in Latin America, Canada, and the United States—report screening 100% of donated units for HIV, HBV, and HCV. The available data for the Region, excluding Canada and the United States, indicate that 99% of all units of blood collected are screened for HIV and HBV and 60% for HCV. This means that, annually, around 50,000 units are transfused that have not been screened for HIV and HBV, and around 1,500,000 that have not been screened for HCV. Knowing the proportion of units that are not screened and the rate of positive markers for infection in the fraction that is actually screened, it is possible to estimate the burden of infection associated with blood for transfusion. In 1993 it was estimated that there were 6,335 transfusion-transmitted infections with the three viruses in 12 Latin American countries. The screening situation for *T. cruzi* is very similar to that for HCV, with the added complication that it is impossible to identify donors infected with the parasite through a pre-donation interview, especially when the migration of individuals from areas endemic for Chagas' disease toward areas considered nonendemic is taken into account. It is clear, then, that in countries where serological testing is not conducted on all units of blood transfused there are blood products of a different quality—some with a higher risk of transmitting infections to patients—than can be found in blood banks in other institutions or geographical areas.

In addition to the coverage of screening for transfusion-transmitted infection, it is vitally important to consider the quality of the results of the serological testing. For example, to offset the cost of laboratory reagents, it is common practice to pool several samples when testing for HCV. This affects the sensitivity of the tests. In addition, the lack of internal quality control mechanisms for serological procedures leads to false negative results, which permits the transfusion of infectious units. Less medically significant, but with implications for the operating costs of the services, are false positives. The reference blood banks of 13 countries participate in the Regional Program

Assistance will be provided for the in-service training of health workers, primarily through the Distance Learning Program and the “Safe Blood and Blood Products” modules published by WHO. In this way an effort will be made to reach the staff of all

blood banks in the Region. It is appropriate to involve academic institutions that are responsible for the training of health personnel and that may also have experience with distance learning activities. Professional associations should also participate in order to guarantee that the training reaches physicians, nurses, laboratorians, and those who attend blood donors, and to ensure validated certification of trainees.

Activities will be fostered to promote voluntary, nonremunerated, and repeated blood donation. These activities should encourage countries to develop national blood donation programs with appropriate contents for educating the population and health workers and strengthening the technical areas and infrastructure devoted to the care of blood donors.

Although national regulations clearly emphasize voluntary donation as vitally important for the safety of blood for transfusion, regional practices are not consistent with this position. The first responsibility of the health sector is to ensure that the donation areas are accessible, comfortable, and safe; permit confidentiality; and are open with a donor-friendly schedule. Secondly, it is of vital importance that the common practice of requiring replacement donation be terminated. Thirdly, the training of personnel should emphasize their responsibility regarding the protection of the donor and related information. National programs of voluntary donation should involve other sectors, such as education and labor, as well as mass media communicators.

At the country level, an analysis of the costs involved in producing blood products for transfusion will be promoted to improve equity, efficiency, and effectiveness in the allocation and use of resources. In this regard, it is necessary to determine how blood and its products are used in clinical settings. The misuse and abuse of transfusions contributes to elevated costs, as does the discarding of expired units.

5. Strategic Partnerships and Mechanisms for Coordination with Other Institutions

In order to strengthen external performance evaluation activities at the regional level, the following institutions will collaborate: the PAHO/WHO Collaborating Center for Reference on Quality Control of Blood Bank Serology of São Paulo, Brazil; the Blood Bank of the Balearic Islands; and the Caribbean Epidemiology Center (CAREC) in Trinidad and Tobago. At the national level, interinstitutional collaboration will be

expanded to include the social security systems, the national health institutes, local Red Cross institutions, and the private sector, in addition to the ministry of health in its steering role. Other aspects of the quality assurance programs, such as internal control measures and audits, will be strengthened with the support of academic institutions and professional associations. At the Regional level, work will continue with the Ibero-

American Collaborative Group for Transfusion Medicine, an umbrella group for professional associations, and the American Association of Blood Banks (AABB). Efforts in the countries will be made in collaboration with the professional associations. PAHO, moreover, will continue to promote technical cooperation among countries, especially in areas related to the regulation and implementation of quality assurance programs and human resources education.

With respect to training, the cooperation of academic institutions and professional associations will be promoted to ensure the continuity of the educational activities.

In order to promote voluntary blood donation, PAHO will work at the regional level with the International Federation of Red Cross and Red Crescent Societies. At the country level, it will be necessary to collaborate with academic institutions, professional associations, and the communications media, in addition to the conventional actors in the blood banks.

6. PAHO Resources Allocated to this Area for Technical Cooperation

The Regional Adviser on Laboratory and Blood Services in the Division of Health Systems and Services Development, Program on Essential Drugs and Technology (HSE/LAB), deals with matters related to blood banks and diagnostic laboratories. This adviser is the focal point for activities to strengthen the Region's blood banks. Blood bank activities have been planned, carried out, and evaluated in collaboration with the Communicable Diseases and AIDS/STD programs of PAHO that assign staff to this area on a part-time basis at the regional and country level through the PAHO/WHO Representative Offices. In February 1999, the Director of PAHO appointed an interprogrammatic committee to undertake the activities related to blood safety. The regional programs currently have regular budgetary resources and "over-the-ceiling" allocations (OTC) of \$150,000 per year. In order to implement future lines of action to respond to the needs of the countries of the Region, it will be necessary to seek additional support.

7. Challenges for Future Action

Screening the units of blood collected for HIV, HBV, HCV, *T. cruzi*, and syphilis requires sufficient resources (personnel, equipment, and reagents) of appropriate quality in all the centers that conduct serological testing in each country. The first factor that must be considered is adequate procurement and use of diagnostic reagents by blood banks in the different sectors, institutions, and geographical and political units. It will be necessary to develop strategies and mechanisms that ensure the efficiency of the economic investment in the serological screening as well as the implementation of national quality assurance programs. The functional capacity of the national blood commissions and ongoing support from the national technical committees are vital for carrying out the activities and achieving the goals in each country.

The greatest challenges for the promotion of voluntary blood donation are mass communication and the structure of the services that care for potential donors in the blood banks. Appropriate messages will have to be developed for the populations of the countries, so that they will understand and accept blood donation—messages that will lead to the desired changes in behavior. Social marketing studies with a solid content will be required to determine knowledge, attitudes, and practices with respect to blood donation. It will also be necessary to modify the physical infrastructure of the areas that care for donors, as well as the behavior of health workers in order to discourage replacement donation and retain and educate volunteer donors.

8. Action Requested of the Directing Council

The Directing Council is requested to adopt the resolution on strengthening blood banks recommended by the Executive Committee during its 124th Session, that will make it possible to move toward the elimination of inequities in the delivery of blood bank services to the peoples of the Americas.

Annex

- (d) promote universal, accurate, and efficient screening of the units of blood donated in the Region;
- (e) document the progress of the national blood programs.

(Adopted at the seventh meeting, 24 June 1999)

- (c) strengthen the national blood bank infrastructure in order to implement the national blood programs;
 - (d) ensure the appropriate allocation and efficient use of resources for the acquisition of safe blood products and their use in the population that needs them;
 - (d) ensure training of medical providers in appropriate clinical use of blood products.
2. To request that the Director:
- (a) cooperate with the Member States in strengthening the national blood programs and transfusion services, with the collaboration of international institutions, especially in the mobilization of financial resources;
 - (b) assist in the strengthening of national programs for voluntary, nonremunerated, repeated blood donation;
 - (c) establish regional standards for the quality of blood banks and transfusion services, as well as for the blood products used in transfusions;
 - (d) promote universal, accurate, and efficient screening of the units of blood donated in the Region;
 - (e) document the progress of the national blood programs.

(Ninth meeting, 1 October 1999)



PAN AMERICAN HEALTH ORGANIZATION
Pan American Sanitary Bureau, Regional Office of the
WORLD HEALTH ORGANIZATION

**ACTION PLAN FOR IMPROVING THE SAFETY OF BLOOD FOR
TRANSFUSION IN THE REGION OF THE AMERICAS
1999-2001**

Prepared by the Interprogrammatic Committee on Safe Blood coordinated by the
Division of Health Systems and Services Development, Program on Essential Drugs and
Technology, Laboratory and Blood Services

the blood donation reduces the number of donations by infected individuals. It is generally accepted that non-remunerated volunteers who donate blood repeatedly are the safest, in contrast to people who give blood for a particular patient (replacement donor) or for remuneration.

Once the blood is obtained from a donor, the blood bank should screen the units for the presence of serological markers for specific infections. Highly sensitive and specific laboratory techniques have been developed for the diagnosis of HIV, VHB, VHC, and HTLV; there is also sensitive technology available for *Trypanosoma cruzi* and syphilis. In order to minimize the probability that pathogens will be present in the donated blood, blood banks should analyze all units of blood individually, with a degree of sensitivity that eliminates false negatives. Furthermore, it is essential to safeguard the sterility of the blood, protecting it from possible contamination by microorganisms present in the work environment. In this regard, the strictest standards should be applied, which means that procedures and results should adhere to rigorous quality control standards that include external performance evaluation, quality control measures, and audits.

Adverse reactions to blood transfusions are not limited to infections. Some genetically determined antigens present in blood products can provoke immunological and allergic reactions in patients; as a result, it is important to determine blood types and blood groups to ensure that patients receive compatible blood, especially immunodeficient patients such as newborns and cancer and transplant patients.

2. Current Situation of Blood Banks in the Region

There are few blood banks in the English-speaking countries of the Caribbean—just one per country, usually located in the national reference hospitals. Belize has six blood banks, Guyana five, and Bahamas three. In Latin America, the number of blood banks ranges from 30 to 700 in the majority of the countries, with higher estimates for nations such as Brazil, Mexico, and Argentina. Current law in all the countries of Latin America, except for El Salvador and Nicaragua, ensures that the ministries of health regulate blood bank operations, prohibit the marketing of blood and blood products, and recognizes voluntary donation as the optimal mechanism for obtaining blood. The national legal frameworks, moreover, specify the types of screening that blood banks must conduct in order to protect both donors and patients. In general, the blood banks are operated by the social security system, non-governmental organizations such as the Red Cross, the armed forces, and private companies, in addition to the public sector. In some cases, the ministry of health has delegated functional responsibility for the blood programs to autonomous institutions that may be independent of one another and located in one province or another. In other cases, the majority of blood banks are privately operated and, as in the case of blood banks in hospitals or public health facilities, their level of complexity varies widely. This variability affects the technical and financial efficiency of the blood banks; thus, the estimated cost of processing of a unit of blood ranges from US\$ 30 to \$150. A rather significant consequence of this situation is the

inequity in the quality of blood bank services and in the blood products that are transfused into patients.

Only small proportions of donors in the region of the Americas are volunteers. At the national level only Aruba, with 3,100 donations in 1996; Curaçao, with 5,696; and Cuba, with around 600,000/year for 1990-1997, report 100% voluntary donations. Although some countries still acknowledge the existence of as much as 24% remunerated donors, the vast majority of the units of blood obtained in the region come from replacement donors. The proportions of the different donor types vary from country to country, province to province, and institution to institution, even within a single country. This situation reflects not only how proactive a role the blood banks play in educating the population, but their general capacity—including the physical plant and infrastructure—to care for those who seek to donate blood.

The implications of blood safety are clear. The economic situations of individuals who use the blood banks to obtain income are precarious; low socioeconomic status in itself is a risk factor for acquiring infections that then can be transmitted through transfusions. Furthermore, when the motivation is economic, potential donors may deny risk behaviors and undermine the purpose of the pre-donation interview. Similarly, the pressures of family or friendship that are exerted on replacement donors do not make for optimal selection. Published data on infection markers in different types of donors in the Region of the Americas are limited. However, analysis of the national information from Ecuador for 1996 and 1997, for example, has made it possible to determine that in blood banks where 99% or more of the donors are replacement donors, the risk of finding a marker for HIV, VHB, and VHC is 17 to 58 higher times than in blood banks where less than 40% of the donors are replacement donors.

These observations reveal the importance of screening all units of blood collected by blood banks for transfusion-transmitted infections. Only 14 countries—eight in the English-speaking Caribbean and six in Latin America—report screening 100% of donated units for HIV, VHB, and VHC. The available data for the region indicate that 99% of all units of blood collected are screened for HIV and VHB and 60% for VHC. This means that, annually, around 50,000 units are transfused that have not been screened for HIV and VHB, and around 1,500,000 that have not been screened for VHC. Knowing the proportion of units that are not screened and the rate of positive markers for infection in the fraction that is actually screened, it is possible to estimate the burden of infection associated with blood for transfusion. In 1993 it was estimated that there were 6,335 transfusion-transmitted infections with the three viruses in 12 Latin American countries. The screening situation for *T. cruzi* is very similar to that for VHC, with the added complication that it is impossible to identify donors infected with the parasite through a pre-donation interview, especially when the migration of individuals from areas endemic for Chagas' disease toward areas considered non-endemic is taken into account. It is clear, then, that in countries where serological testing is not conducted on all units of blood transfused there are blood products of a different quality—some with a higher risk of transmitting infections to patients—than can be found in blood banks in other institutions or geographical areas.

In addition to the coverage of screening for transfusion-transmitted infection, it is vitally important to consider the quality of the results of the serological testing. For example, to offset the cost of laboratory reagents, it is common practice to pool several samples when testing for VHC. This affects the sensitivity of the tests. In addition, the lack of internal quality control mechanisms for serological procedures leads to false negative results, which permits the transfusion of infectious units. Less medically significant, but with implications for the operating costs of the services are false positives. The reference blood banks of 13 countries participate in the Regional Program for External Evaluation of Performance on Serology for Transfusion-Transmitted Infections (TTI), sponsored by PAHO. Ten countries have a similar national program.

3. Principal Results of PAHO Activities in this Field

As a result of PAHO's initiative, laws, regulations, and standards governing blood transfusions in the Latin American countries have been promulgated or amended. El Salvador and Nicaragua have already prepared draft legislation that will be reviewed by their respective legislatures, and that legislation is expected to be enacted soon. In several countries national blood commissions have been set up as coordinating agencies, and in others, technical committees have been formed whose objective is to stimulate discussions that will lead to the issue of regulations, guidelines, and work standards and the proposal of mechanisms that will ensure ongoing improvements in the quality of the blood banks.

Of major importance is the significant rise in the proportion of units of blood screened for HIV, VHB, VHC, and T. cruzi in the past four years. As a vital element, the Regional Program for External Evaluation of Performance on Serology for TTI was established, with the collaboration of Hemocentro de Sao Paulo, Brazil. Thirteen countries are participating in this Program. Training for national personnel and logistical support from PAHO have made it possible to establish national programs for external evaluation of performance on serology of TTI in seven countries, using raw materials that can be obtained locally at no additional cost. Without a doubt, these actions have reduced the number of TTI throughout the Region. As a complement to this, in the area of in service human resources education, the Distance Learning Program on Safe Blood and Blood Products has been set up in 11 countries, using materials developed by WHO and translated into Spanish by Latin American professionals. The implementation of national information systems has made it possible to evaluate the progress of the activities in each country and to identify priority areas for intervention.

4. Future Lines of Action for the Technical Cooperation Program

The strengthening of blood banks in the Region of the Americas will remain a collaborative effort among the PAHO Regional Laboratory and Blood Services Program; Communicable Diseases, AIDS/Sexually Transmitted Diseases, and Public Policy and Health, all of them represented in the Interprogrammatic Committee appointed by the

Director of PAHO. With this approach the regional goals adopted by the 25th Pan American Sanitary Conference and contained in the Strategic and Programmatic Orientations for 1999-2002 in the areas of health policies and systems, health systems and services development, and disease prevention and control will be pursued.

5. Expected Results

a) Coverage of screening

100% coverage of screening of blood units for HIV, HBV, HCV and syphilis in the Region, and 100% coverage of screening for Chaga's disease in continental Latin America, at the end of 2,001.

In support of the policies to promote health for all and equitable access to quality health services, efforts will give priority to ensuring that 100% of the units of blood collected for transfusion in the Region are screened for the presence of HIV, VHB, VHC, and syphilis markers. Screening for *Trypanosoma cruzi* will be conducted in all units collected in geographical areas where there is a risk of its transmission by transfusion, whether endemic areas or areas where significant numbers of infected individuals have migrated.

The most important consideration in this regard is the financial and technical efficiency of the laboratory screening processes. In terms of costs, it is advisable to limit the number of centers that screen blood for infectious markers, especially in cases where only a few hundred units are processed each year. Geographic and communication issues should be considered in determining the number of centers that screen blood in each country. In reducing the numbers of blood banks that carry out screening tests, the efforts to standardize and quality control the processes are minimized, as is the need for specialized equipment and personnel. The set up of a national system for screening of blood used for transfusion requires the leadership of the Ministry of Health and the active participation of the various institutions and sectors currently involved in transfusion medicine. Local seminars must be held to develop the most appropriate mechanisms for implementation of the national system.

The legal framework should also be strengthened in most of the countries of the Region, to guarantee universal coverage of blood screening, and to improve the protection of donors, of users and of institutions responsible for blood management and control.

Lastly, efforts should be made to reduce the costs of screening blood samples. This is especially true for hepatitis C antibodies. Therefore, the identification and validation of locally produced testing kits will be promoted and, if results are satisfactory, distributed to national blood programs at non-profit prices.

b) External evaluation

100% of blood banks that screen blood for transfusion will participate in programs of external evaluation of performance of serological tests for HIV, HBV, HCV, syphilis and Chaga's disease by the end of 2001

In order to guarantee the efficacy of the results of serological screening, the Regional Program for External Evaluation of Performance of ITT Serology will be strengthened to ensure the participation of the national reference blood banks of all the countries. Moreover, the development of national quality assurance programs will be promoted and supported to ensure that the reference blood banks have the technical and administrative capacity to establish the national programs for external evaluation of performance on serology of TTI. It is expected that every blood bank in the Region will routinely participate in this activity. The national programs will be complemented with internal quality control measures, including the preparation and updating of procedure manuals.

For this purpose, personnel working in national reference blood banks will be trained on the production of testing panels using those blood units that are found to be positive for markers of HIV, HBV, HCV, syphilis and Chaga's diseases in the routine screening. Furthermore, personnel will also be trained in the principles and ways to prepare and use the performance reports to improve quality of testing. Training will also be done on the principles of safe blood and safe transfusion, using the distance learning modules developed by WHO.

c) Donors

By the end of 2,001, 50% of blood donors in each country of the Region will be voluntary, altruistic and non-remunerated

Activities will be fostered to promote voluntary, non-remunerated, repeated blood donation. These activities should encourage countries to develop national blood donation programs with appropriate contents for educating the population and health workers and strengthening the technical areas and infrastructure devoted to the care of blood donors.

In the field of public education, instruments for formative (knowledge, attitudes and practices) studies will be developed, validated and applied in at least six countries of Latin America. Regional guidelines for designing public education programs will be produced.

The infrastructure, organization and function of the blood donation services must be adapted to the needs of the voluntary, non-remunerated donor and taking accessibility, comfort and donor satisfaction into consideration. Regional guidelines for recruitment and selection of potential blood donors will be developed.

d) Incidence of HCV infection in high risk groups

By the end of 2,001 high-risk groups for transfusion-transmitted infections will be identified and monitored for incidence of HCV infection.

Currently, there are not mechanisms to determine the untoward reactions of blood transfusions in the countries of Latin America and the Caribbean, including post-transfusion infections. Nevertheless, and since most countries of the Region still use non-processed whole plasma to treat severe bleeding disorders, such as hemophilia, it is expected that multi-transfused individuals will be at higher risk of acquiring HCV infections. These patients can be monitored as sentinel groups of transfusion-transmitted infections and indicator of the actual safety of blood products used for transfusion. National registry of high risk groups will be implemented, as well as the establishment of institutional systems to monitor adverse reactions to transfusions.

6. Strategic Partnerships and Mechanisms for Coordination with Other Institutions

In order to strengthen external performance evaluation activities at the regional level, the following institutions will collaborate: PAHO/WHO Collaborating Center for Reference on Quality Control of Blood Bank Serology, Sao Paulo, Brazil, the Blood Bank of the Balearic Islands, and the Caribbean Epidemiology Center (CAREC) in Trinidad and Tobago. At the national level, interinstitutional collaboration will be expanded to include the social security systems, the national health institutes, local Red Cross institutions, and the private sector, in addition to the ministry of health in its steering role. Other aspects of the quality assurance programs, such as internal control measures and audits, will be strengthened with the support of academic institutions and professional associations. At the Regional level work will continue with the Ibero-American Collaborative Group for Transfusion Medicine, an umbrella group for professional associations, and the American Association of Blood Banks (AABB). Efforts in the countries will be made in collaboration with the professional associations. PAHO, moreover, will continue to promote technical cooperation among countries, especially in areas related to the regulation and implementation of quality assurance programs and human resources education.

With respect to training, the cooperation of academic institutions and professional associations will be promoted to ensure the continuity of the educational activities.

In order to promote voluntary blood donation, PAHO will work at the regional level with the International Federation of Red Cross and Red Crescent Societies. At the country level it will be necessary to collaborate with academic institutions, professional associations, and the communications media, in addition to the conventional actors in the blood banks.

