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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 will be screened for infection with hepatitis B and C, syphilis, *Trypanosoma cruzi*, and HIV, and all blood banks will participate in quality control programs. Furthermore, 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 is requested to comment on the Secretariat's initiative that will make it possible 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 transfusions. 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 period 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 *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 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 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.

In only a small proportion of countries and territories in the Region of the Americas is blood for transfusion universally obtained from voluntary, non-remunerated 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 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, HBV, HCV, 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 the Hemocentro de São 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 Programs on Laboratory and Blood Services, Communicable Diseases, AIDS/Sexually Transmitted Diseases, and Public Policy and Health. 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.

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, HBV, HCV, 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 the English-speaking Caribbean countries where there is only one blood bank per country, screening of blood units should be done in coordination with the hospital diagnostic laboratory service. Records, however, must be kept separated in the two services, to allow for easy identification of positive donors, for the analyses of resource needs and of operational costs. In Latin America, efforts should be directed towards the reduction of the number of centers that perform screening tests. Blood banks that analyze blood units should be chosen on the basis of location, and infrastructure, and taking population and geographic aspects into consideration. Proper logistical steps should also be made to ensure timely and acceptable shipping of samples, strict traceability of incoming specimens, and timely and accurate communication of results. Important aspects to consider are the procurement of reagents, the availability of equipment, the level of staff training, and general aspects of quality assurance.

In order to guarantee the accuracy 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, so 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.

It is necessary to consider the steering role of the ministry of health and the need to assure the quality of blood bank services in all sectors. National norms for blood banks should specifically include the requirement for blood banks from every sector to participate in programs of external evaluation of performance. Financial and technical resources should be provided to support those programs. Quality assurance activities and personnel should be completely independent from operational functions, with the responsible institution having sufficient authority to enforce remedial measures. In the English-speaking Caribbean countries, a subregional approach is warranted because of the small number of national blood banks.

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, 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, and also 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, and 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 the 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 years. 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 Required of the Executive Committee

The Executive Committee is requested to comment on the Secretariat's initiative on blood safety 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.