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BLOOD TRANSFUSION SERVICES

Resolution CSP21.R29 was adopted by the XXI Pan American Sanitary Conference in September 1982. In this resolution, the year 1990 was determined as the goal for achieving effective blood transfusion services in the countries of the Region. A regional program of work designed to achieve this goal was outlined. A subsequent consultation meeting on strategies to expand blood transfusion services in Latin America and in the Caribbean by the year 1990 was held in Washington in February 1983. These latter proposals were approved in general, on the basis of a summary document, in October 1983 by the XXIX Meeting of the Directing Council (Resolution CD29.R15). It was recognized that the implementation of the program would, to a large extent, have to depend on extrabudgetary funds that could be matched by adequate funding made available by the health authorities. Resolution CD29.R15 also requested that the progress made by the project be reported to the 92nd Meeting of the Executive Committee. The purpose of the present document is to summarize the accomplishments since the project initiated its activities.

The program on blood transfusion services initiated its activities on 1 January 1984. The main lines of action are listed below:

1. Policies
2. Collaborating centers
3. PAHO technical cooperation
4. External assistance
5. Information and publications
6. Evaluation and future course of action.

## 1. Blood Services Policies

In 1975, the Twenty-eighth World Health Assembly urged Member States to "promote the development of national blood services based on voluntary non-remunerated donation of blood, the enactment of effective legislation governing the operation of blood services and to take action to protect and promote the health of blood donors and of recipients of blood and blood products." New instances of plasma export from Central American countries have been reported. It is said that other countries export thousands of liters of plasma annually (International Society of Blood Transfusion and League of Red Cross Societies Joint Memorandum on World Blood Policies, 1984).<sup>\*</sup> In addition to ethical, social and economic reasons there are medical reasons to strive for the "self sufficiency" of national blood services. The incidence of diseases such as hepatitis B and hepatitis non-A non-B, as well as the increasing reporting of AIDS, has emphasized the risk that exists in using products imported from countries where the remuneration of donors considerably increases the risk of transmission of infectious diseases. There is reason to reinforce the policy adopted by the World Health Assembly in 1975 and to increase the efforts in this field. In consonance with this approach, a memorandum of world policies (see Annex I) prepared by LRCS and the ISBT as well as the code of ethics (see Annex II) prepared by the ISBT that was discussed at the 71st session of the Executive Board of the WHO (1983) were sent to each health authority in the Region. The ministries of health were invited to approve as well as to promote the application of the principles enunciated in the code of ethics. PAHO has indicated its readiness to cooperate with the Member Governments in the formulation of national policies on blood and has urged them to identify specific areas of technical cooperation they would like to receive from PAHO.

The Argentine authorities promulgated new legislation in October 1983 to regulate national policies on collection, management and use of blood and blood derivatives in the country. The merit of the new law is that the system of blood transfusion it serves has banned commercial blood-letting; has imposed controls on plasmapheresis; and is based on voluntary, profit-free donations made by altruistic donors. The new legislation is mindful of the principles enunciated in the code of ethics and has made provision for financing as well as for establishing a surveillance system for monitoring adverse reactions. In view of the interest of Central American countries in reorganizing their blood services, copies of the Argentine legislation have been provided to Guatemala, El Salvador, Honduras and Panama.

The Inter-American Committee of Red Cross Experts on the blood program (CICREPS) recommended that the Governing Bodies of the Red Cross Societies approve Resolution CSP21.R29 setting the year 1990 as the target for achieving effective services in the Region, and to cooperate

with the Governments to put the resolution into effect. It also recommended promotion of Resolution CD29.R15 of the XXIX Meeting of the Directing Council urging Governments to formulate and implement national programs for blood transfusion. It is expected that by endorsing these recommendations the General Assembly of the League of Red Cross Societies will confirm the partnership role of the Red Cross. In addition it will provide, at the national level, the grounds for a joint approach by PAHO and the Red Cross to implement the Regional program on blood. Efforts will be pursued with other non-profit organizations in the private sector to secure their support for the PAHO program.

## 2. The Designation of Collaborating Centers

The regional project which PAHO has designed envisages the establishment of a network of collaborating centers. These blood banks would, of course, include the establishment of national centers, the recognition of such centers by the World Health Organization and the designation of one or more regional collaborating blood banks. The practice of such designation by WHO has been in abeyance for quite some years. Because of the renewed interest of the countries in Latin America and the Caribbean, PAHO is negotiating the reactivation of such centers with WHO. Apart from the World Health Organization, it is of considerable importance to bring into this scheme the League of Red Cross Societies, the International Society of Blood Transfusion, blood banks, and the International Society of Haematology to facilitate exchanges as well as support by pairing selected national centers with advanced counterpart centers in industrial nations. The collaboration between centers could make available a range of very valuable services. During the current biennium the cooperation PAHO is providing aims at concentrating the inputs made by international and regional organizations into two main areas that are critical in the development of the program, namely, the training of middle-level technicians and self-reliance in blood grouping reagents of good quality. Technical competence and consistency in the quality of performance are important criteria for the designation of collaborating laboratories. Up to now there are only seven laboratories that have been identified which meet these criteria in the Region. These are:

Brazil:	Hemope/Recife, Province of Pernambuco
Colombia:	Red Cross Central Blood Bank
Costa Rica:	Red Cross National Blood Bank, San José
Cuba:	Hematology and Immunology Institute, Havana
Ecuador:	Red Cross Blood Bank, Quito
Jamaica:	Central Blood Bank National Blood Transfusion Services, Kingston
Nicaragua:	Red Cross Central Blood Bank, Managua.

The blood banks listed above have been recommended for recognition by WHO as national collaborating centers; as other laboratories meet the above criteria they will also be proposed for designation as national centers.

While PAHO and international collaborating institutions provide technical support, these centers should receive financial support from the health authorities in order to defray the local costs for courses, reproduction of educational materials, distribution of blood grouping reagents, etc.

### 3. PAHO Technical Cooperation

The response of the countries in the Region to two surveys had helped gather information on the organization of the services as well as on the centers where personnel can be trained in blood transfusion services. In many countries in the Region services need to be coordinated. Very few examples of coordinated blood transfusion systems exist in Latin America. Examples in the public sector are found in Brasil, Cuba, Jamaica, and Uruguay. Similar situation may be found in the non-profit private sectors, such as the Red Cross organization in Costa Rica, Panama, and Nicaragua.

Training courses in blood banking and blood transfusion services are held regularly in Argentina, Brazil (Recife, Rio de Janeiro, Sao Paulo), Costa Rica, Cuba, Jamaica, and Venezuela, and in some other countries.

As a first step to reorganization of the blood services several Governments requested PAHO technical cooperation for an evaluation of existing services. PAHO has made arrangements for four experts in blood transfusion to undertake this assignment. The experts--who have been recruited from the same geographical areas in which they will be serving--shall cooperate with the respective authorities in carrying out the following tasks:

1. Draw up a plan of action for a national policy and a program on blood;
2. Evaluate educational facilities and estimate the medium- and long-term needs for the different levels of training;
3. Identify one blood bank that functions as a national center for servicing ABO and Rh reagents to the network of blood banks.

The countries that have so far indicated their interest are:

	Mexico
Caribbean	
Sub-region:	Barbados, Dominica, Dominican Republic, Grenada, Haiti, Jamaica, Trinidad and Tobago.
Central America:	Nicaragua, Belize
South America:	Argentina, Brazil, Chile, Colombia, Venezuela, Uruguay

The experts on blood services who met in Washington in February 1983 recognized that management skills were the weakest point in terms of the educational background and experience of many managers of blood transfusion services. It was also recognized that directors of blood banks require additional skills in planning and international coordination if they are to assume an advisory role in assisting health authorities in the development and regulation of blood services. In order to meet these specific needs, PAHO, with the technical cooperation of the ISBT, the American and Canadian Red Cross, WHO and LRCS, has made arrangements to hold a 10-day seminar on management for directors of blood transfusion services on 10-21 September 1984. The meeting, which is proposed to be held in Costa Rica, is expected to achieve a twofold objective: the directors will attend an intensive course on management and some time will be set aside for a workshop on human resources development.

#### 4. External Assistance (Bilateral Cooperation)

PAHO is trying to mobilize external resources to support the development of blood transfusion services at intermediate levels. In the context of the regional program designed by PAHO, a draft project proposal has been submitted to the Government of Netherlands for possible assistance during the period 1984-1989, under its program of Category III.C Aid.

The project proposed for assistance by the Government of Netherlands comprises three different components:

##### Component I

It is proposed to extend blood transfusion services to the intermediate and, particularly, the peripheral levels in priority areas in accordance with the national plans for the development of basic health services. The countries involved are Bolivia, Colombia, Haiti and Nicaragua. The total cost of assistance amounts to \$678,000 through 1989.

## Component II

It is proposed to establish production of ABO and Rh blood grouping reagents and cryoprecipitate and their quality assurance for safety and efficacy. The countries involved are Bolivia, Colombia, Haiti and Nicaragua. Total cost of Netherlands' assistance is estimated at \$45,000.

## Component III

This component includes a feasibility study for production of disposable bags for separation of blood into components and separation of cryoprecipitate. The project involves the transfer and development of three basic technologies, namely: plasticizing polyvinyl chloride (PVC) resin available as a product of the petrochemical industry; extrusion of tubes and manufacture of disposable needles; and the production of bags. The cost is estimated at \$9,000, to cover the cost of a team of two experts, one engineer and one hematologist to undertake the study in the countries of the Andean Region.

An additional \$9,000 was requested to assist Brazil to improve the safety of blood bags they produce in the private sector. This is the only national industry of blood bags in Latin America that is self-reliant.

Countries that receive Netherlands' aid will have to ensure that the project is an integral part of the National Blood Transfusion Services and forms part of the overall plan of development of health services at national level; also, Governments should provide adequate facilities and the manpower that is required and assume responsibility for running the services.

PAHO is following up with WHO/Geneva the progress made in its negotiation with the Netherlands authorities. The beneficiary countries will be kept posted of the decision reached by the parties.

## 5. Information and Publications

Audiovisual units (slides, tapes and lectures) produced by Health Education Resources (HER) in cooperation with the American Association of Blood Transfusion have been made available to a group of training centers. The set on blood banking has been distributed to Hemope, Pernambuco, Brazil; Central Blood Bank Blood Transfusion Service, Kingston, Jamaica; and Central Blood Bank, Red Cross, Bogotá, Colombia. All of these centers run a course for training intermediate-level personnel in blood banking procedures. Arrangements are being made for the set on blood banking to be produced in Spanish. Another set of

audiovisual material on hematology, also produced by the same groups, has been distributed to Hemope/Pernambuco, which runs a course for directors of blood transfusion banks. PAHO has obtained permission from HER to publish the audiovisual material in Spanish.

The Canadian Red Cross publication "Blood" is being evaluated by Jamaica and Haiti. The Canadian publication, which is available in French and Spanish, is most valuable for phlebotomists and for the education of nurses in basic hematology and hemotherapy including blood components. PAHO has received permission from the Canadian Red Cross to reproduce and distribute the publication to the English- and French-speaking Caribbean.

#### 6. Evaluation and Course of Action

The start of the program on blood has been rather brisk, perhaps because of the concern of the health authorities over the danger of emerging diseases such as AIDS and the increasing incidence on non-A non-B hepatitis in recipients of blood. Until such time when specific laboratory tests for detection of AIDS and hepatitis are available, donors in population groups that are known to have a greater carrier rate for these diseases should be discouraged to donate blood. A transfusion service based on altruistic donation and regulated by adequate legislation drawing on the principles of the Code of Ethics recommended by the ISBT and the LORCS is to date the best safeguard to human rights --namely, the right of the donor to protect his dignity and the right of the recipient not to endanger his safety.

The implementation of the program on blood services requires the mobilization and pooling of talents and expertise in different aspects of blood transfusion. Experts from Latin America and the Caribbean should be taking a greater share of responsibility in the activities of the program. With this in view, PAHO is canvassing the countries to identify human resources and institutions that can promote national programs and participate more actively in the work of WHO and of PAHO.

Wherever possible and in the context of their national program in health, health authorities should entrust a national blood bank with the task of elaborating a national program. Authorities should also designate an official to manage the program and advise the Government on matters related to policy, regulations, legislation, international assistance, and coordination with non-profit organizations such as the Red Cross.

# Memorandum on World Blood Policies

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## Introduction

1. In 1975, the 28th World Health Assembly urged member states to "promote the development of national blood services based on voluntary non-remunerated donation of blood, and 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 of recipients of blood and blood products".

2. The WHO resolution of 1975 certainly had results. Many governments paid attention to the exploitation of poor donors by commercial blood banks. Many of these infamous enterprises were forced to close their doors. Some countries enacted legislation to rule out all commercial activities. Other countries, while allowing commercial plasmapheresis under strictly-controlled conditions, have either achieved the goal of an entirely non-profit supply of whole blood collected from unpaid donors or are well on their way to achieving it.

3. As will be clear from this memorandum, there is reason to reinforce the policy adopted by the World Health Assembly in 1975 and to increase the efforts in this field. This is why the League of Red Cross and Red Crescent Societies (LRCS) submitted together with the International Society of Blood Transfusion (ISBT) a document concerning the ISBT Code of Ethics on Blood Donation and Transfusion to the WHO Director General. The Code of Ethics had been unanimously approved by the General Assembly of ISBT in 1980 and adopted by the General Assembly of LRCS as well as by the International Conference of the Red Cross in 1981. This document was discussed during the 71st Session of the Executive Board of WHO.

## Developments since 1975

4. Things are changing so rapidly that the problems we are facing in the eighties can hardly be compared to those of a decade ago. New preser-

vation and fractionation methods, cytopheresis and plasmapheresis, and consequently more sophisticated component therapies have changed the scene. The tremendous increase in the use of coagulation factors for the treatment of hemophiliacs in developed countries has disturbed the balance between the major products which can be derived from plasma. New developments are to be expected if DNA recombinant research leads to safe and economical techniques for the biotechnological production of plasma proteins. Finally, the development of fast membrane technologies for plasmapheresis, by which the time required for a plasma donation can be reduced significantly, may have great consequences for both the non-profit and profit sectors.

5. The transnational blood processing industry has acquired a strong position in the supply of plasma products. Some developed countries became heavily dependent on imports of these commercial products.

6. The open nature of the international plasma market forces all governments to reconsider their national blood policies. Even countries which have a long tradition of a successful and complete non-profit blood supply have to cope with the international competition between the profit and non-profit systems. This seems all the more urgent for developing countries which are still in the process of building up their own national services.

## Blood trade from developing countries

7. There is good reason to believe that the trade of plasma from developing countries, which aroused the WHA's concern in 1975, has not increased over the past few years. In some countries the commercial collection of plasmapheresis has been stopped completely (for instance in a Central American country which exported more than 200,000 liters of plasma per year).



8. On the other hand, new instances of plasma export from developing countries have been reported, for instance from another Central American country, which is said to export about dozens of thousands liters of plasma annually to the present day. In some cases (e.g. Mexico and U.S. border towns) the commercial collection of blood appears to interfere with the non-profit whole blood supply. Even countries where commercial blood banks are prohibited receive requests from companies that want to start plasmapheresis for export.

### **Non-profit and profit systems of blood supply**

9. The pharmaceutical industry has certainly made an important contribution to the world's plasma supply. The U.S. industry alone is said to produce 4 to 5 million liters of plasma annually. About half of this amount is estimated to be commercially processed in other parts of the world (mainly Western Europe). Total industrial fractionation capacity is said to be even higher (9 million liters according to some experts). Thanks to the regular donation of a few hundreds of thousands of professional donors (many of whom happen to live in the southern states of the U.S.A.) the transnational plasma firms are capable of responding to the increased demand created by the rapid development of coagulation factor concentrates.

10. However important industry's contribution may be, the main stream of donations still comes from voluntary unpaid donors. Non-profit organizations all over the world collect tens of millions of units of blood, an ever growing proportion of which can be used for the preparation of plasma products. Therefore, an integrated non-profit system for the collection of whole blood and plasma is the best guarantee of a rational use of all resources available. If necessary, these organizations can collect additional plasma from voluntary unpaid donors, as the experience in some countries has shown.

11. In some developing countries the major part of the whole blood supply still comes from commercial blood banks that pay their donors. Often there is a high risk of contamination. In many parts of the world it is difficult to enforce regulations concerning the protection of donor and recipient. Although many governments seriously strive for an all-volunteer blood supply and some of them are making progress in this direction, the transition from a commercial to an

entirely non-profit system is sometimes hard to achieve because of lack of financial resources, trained personnel and basic health care facilities.

### **Decommmercialization**

12. Especially in the field of blood transfusion the case for decommmercialization is urgent. As far as the transplantation of human tissues is concerned (blood transfusion is, in fact, the oldest and most developed form of transplantation) there should be "no profiteering from life or death" (Mrs. Indira Gandhi). It is easier to avoid overpromoting, overuse and overpricing when blood transfusion is decommmercialized. Further, non-profit organizations are less likely to overbleed donors. Finally, in a non-profit system the responsibilities for the community's blood supply are more equally shared by the different socio-economic groups.

### **Self-reliance**

13. All countries should strive for self-reliance at least for the supply of the major blood products. Mobilizing the country's own resources is the best way to ensure that blood services "are accessible to all individuals at a cost that the community can afford at every stage of its development", especially in developing countries (Declaration of Alma-Ata IV and VIII).

14. For developing countries it is not necessary to adopt the high technology of blood services in industrialized countries. The first priority should be the provision of an adequate supply of whole blood, secondly the use of component therapy with the preparation of cryoprecipitate (which can be done by relatively simple and cheap methods) and possibly the use of salvaged plasma as the frozen or lyophilized product, and thirdly the production of plasma derivatives through fractionation. The latter can be done in cooperation between countries with similar socio-economic and geographical conditions.

### **Transmittable diseases**

15. In addition to ethical, social and economic reasons, there are also medical reasons to strive for self-sufficiency of national blood services. Since many diseases can be spread through contaminated blood, one should be cautious to import blood products from other countries, especially when these products are derived from paid donor blood. The incidence of diseases like he-

patitis B and hepatitis non A, non B differs from country to country, even between countries with the same standard of living. The outbreak of a new disease referred to as Acquired Immune Deficiency Syndrome has demonstrated this once again.

In this connection, reference can be made to the Recommendation R (83) 8 of the Committee of Ministers of the Council of Europe. This committee advocates, inter alia, to avoid wherever possible the importation of blood products from countries where the remuneration of donors considerably increases the risk of transmission of infectious diseases.

### **Responsibility of Governments and WHO**

16. It is the strong belief of the League and of ISBT that enough voluntary donors in all countries can be recruited to meet the people's reasonable demand for blood and blood products, provided there is a systematic approach based on a regular and continuous campaign. In fact, all our blood needs would be more than satisfied if, on the average, every person medi-

cally fit to give blood were to make only a few donations during his life. It is the responsibility of the governments concerned, whether or not they want to make an optimum use of these resources.

17. Although the opinion expressed by the World Health Assembly in 1975 proves to be of great value, the goal of national self-sufficiency of blood services based on the voluntary non-remunerated donation of blood is still far from being achieved. Of course, it is the responsibility of the member states to formulate and enforce their own blood policies. But the WHO could help them by promoting internationally accepted standards.

18. The governments should be encouraged to adopt an ethical code similar to that formulated by ISBT and adopted by the Red Cross movement and the International Federation of Voluntary Donor Organizations. The WHO has a special responsibility with respect to developing countries. As agreed in 1975, the WHO assists member states in the development of national blood services and in establishing cooperation between countries. The League and the ISBT hopes that the WHO will still increase its efforts in this field.

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A CODE OF ETHICS FOR BLOOD DONATION AND TRANSFUSION

The object of this code is to define the principles and rules to be observed in the field of Blood Transfusion; these should form the basis of national legislation or regulations.

I - The Donor

- 1 - Blood donation shall, in all circumstances, be voluntary; no pressure of any kind must be brought to bear upon the donor.
- 2 - The donor should be advised of the risks connected with the procedure; the donor's health and safety must be a constant concern.
- 3 - Financial profit must never be a motive either for the donor or for those responsible for collecting the donation. Voluntary non-remunerated donors should always be encouraged.
- 4 - Anonymity between donor and recipient must be respected except in special cases.
- 5 - Blood donation must not entail discrimination of any kind, either of race, nationality, religion or sex.
- 6 - Blood must be collected under the responsibility of a physician.
- 7 - The frequency of donations and the total volume of the blood collected according to the sex and weight of the individual, as well as the upper and lower age limits for blood donation, should be defined by regulations.
- 8 - Suitable testing of each donor and blood donation must be performed in an attempt to detect any abnormalities:
  - a) that would make the donation dangerous for the donor,
  - b) that would be likely to be harmful to the recipient.
- 9 - Donation by plasmapheresis should be the subject of special regulations that would specify:
  - a) the nature of additional tests to be carried out on the donor,
  - b) the maximum volume of plasma to be taken during one session,
  - c) the minimum time interval between two consecutive sessions,
  - d) the maximum volume of plasma to be taken in one year.

1) the basis for this code was the resolution passed by the General Assembly of the International Society of Blood Transfusion, Paris 1978 and was approved in its present form by the 18th Congress of the Society at their meeting in Montreal, Quebec Canada, 16 to 22 August 1980

- 10 - Donations of leukocytes or platelets by cytopheresis should be the subject of special regulations that specify:
- a) the information to be given to the donor about any drugs injected and about the risks connected with the procedure,
  - b) the nature of any additional tests to be carried out on the donor,
  - c) the number of sessions within a given time frame.
- 11 - Deliberate immunisation of donors by any foreign antigen with the aim of obtaining products with a specific diagnostic or therapeutic activity should be the subject of special regulations that would specify:
- a) the information to be given to the donor about the substance injected and the risks involved,
  - b) the nature of any additional tests which have to be carried out on the donor.
- N.B. - The purpose of the special regulations in items 9, 10 and 11 above is to safeguard the donor. After indications about the nature of the operation and the risks involved, a statement of informed consent must be signed by the donor. For donors immunised against red cell antigens, a special card should indicate the antibodies and specific details as to the appropriate blood to be used in case the donors need to be transfused.
- 12 - Provision must be made to ensure the donor against the risks inherent in the donation of blood, plasma or cells, as well as the risks of immunisation.

### 11 - The Recipient

- 13 - The object of transfusion is to ensure for the recipient the most efficient therapy compatible with maximum safety.
- 14 - Before any transfusion of blood or blood products, a written request, signed by a physician or issued under his responsibility must be made, which specifies the identity of the recipient and the nature and quantity of the substances to be administered.
- 15 - Except for the emergency use of type 0 blood or red blood cells every red cell transfusion necessitates preliminary tests on the recipient, blood grouping and compatibility tests between the donor and the recipient.

- 16 - Before administration, one must verify that blood and blood products are correctly identified and that the expiry date has not been reached. The recipient's identity must be verified.
- 17 - The actual transfusion must be given under the responsibility of a physician.
- 18 - In case of a reaction during or after the injection of blood or blood products, appropriate investigations may be required to ascertain the origin of the reaction and to prevent its recurrence. A reaction may require the interruption of the transfusion.
- 19 - Blood and blood products must not be given unless there is a genuine therapeutic need. There must be no financial motivation on the part of either the prescriber or of the establishment where the patient is treated.
- 20 - Whatever their financial resources, all patients must be able to benefit from the administration of human blood or blood products, subject only to their availability.
- 21 - As far as possible the patient should receive only that particular component (cells, plasma, or plasma derivatives) that is needed. To transfuse whole blood into a patient who requires only part of it may deprive other patients of necessary components, and may carry some additional risks to the recipient.
- 22 - Owing to the human origin of blood and to the limited quantities available, it is important to safeguard the interests of both recipient and donor by avoiding abuse or waste.
- 23 - The optimal use of blood and blood products requires regular contact between the physicians who prescribe and those who work in blood transfusion centres.

### III - Controls

- 24 - Appropriate controls should be carried out by the Health Authorities to verify that blood transfusion practices meet internationally accepted standards and that the guidelines or regulations issued in accordance with this code are effectively respected.
- 25 - The following should be regularly checked:
  - a) the proficiency of the staff,
  - b) the adequacy of the equipment and premises,
  - c) the quality of methods and reagents, source material and finished products.