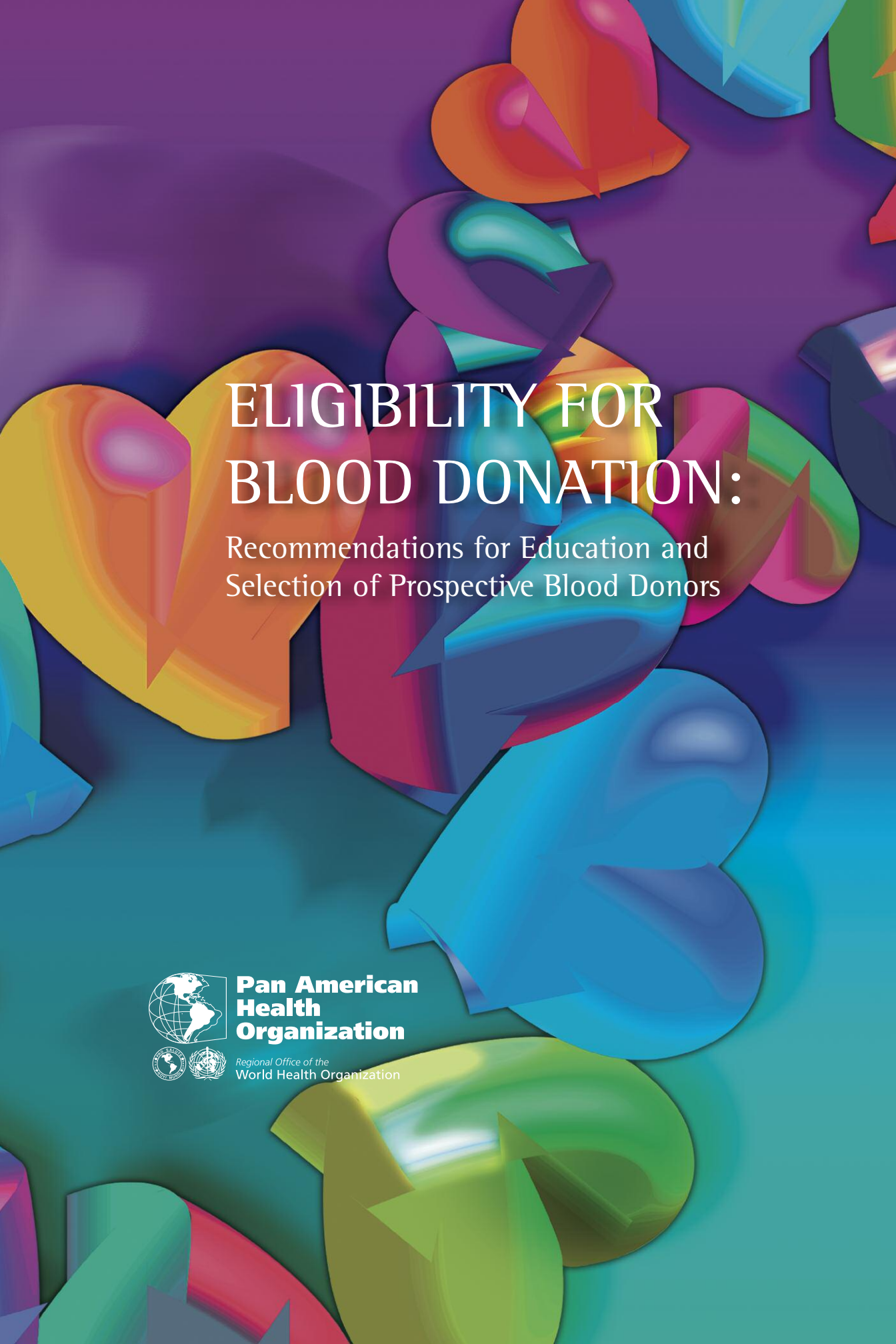
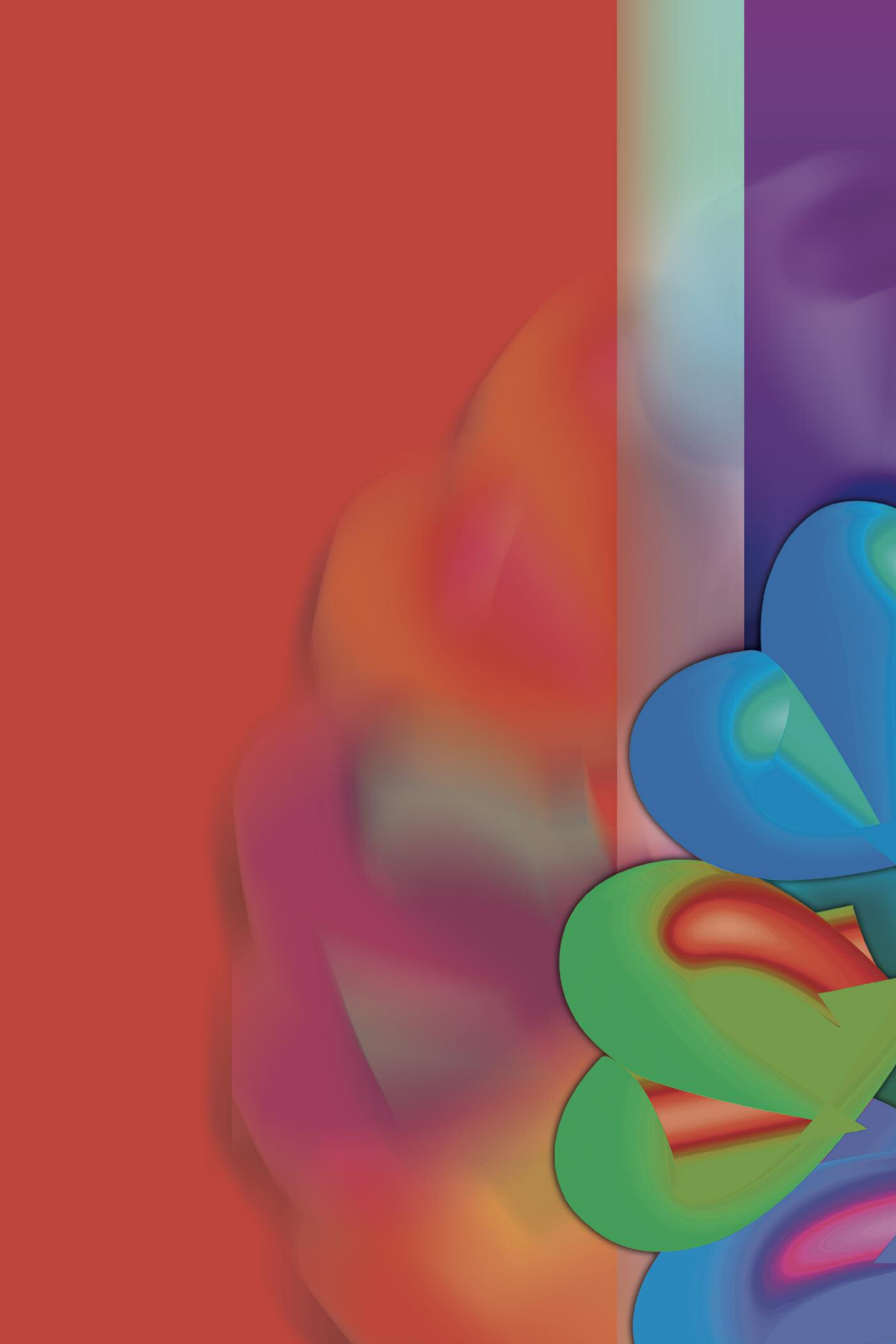


ELIGIBILITY FOR BLOOD DONATION:

Recommendations for Education and Selection of Prospective Blood Donors

Pan American Health Organization

Regional Office of the World Health Organization



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- International Society of Blood Transfusion (ISBT) - "A Code of Ethics for Blood Donation and Transfusion"

ACRONYMS

AABB	American Association of Blood Banks
ACT	Artemesin-based Combination Theraphy
AIDS	Adquired Immunodeficiency Syndrome
ARC	Australian Red Cross
BSE	Bovine Spongiform Encephalopathy
CJD	Creutzfeldt–Jakob Disease
CoE	Council of Europe
CRS	Caribbean Regional Standards
H-Q	Hema-Quebec
HBcore	Hepatitis B Antigen Core
HBsAg	Hepatitis B surface Antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HTLV	Human T cell-Lymphotropic Virus
ISBT	International Society for Blood Transfusion
NAT	Nucleic Acid Testing
PAHO	Pan American Health Organization
STD	Sexually Transmitted Disease
TSE	Transmissible Spongiform Encephalopathy
TTI	Transfusion-Transmitted Infections
UK	United Kingdom
VCJD	Variant Creutzfeldt-Jakob Disease

INTRODUCTION

Background

In the Region of the Americas, efforts have been made to improve the safety and availability of blood for transfusion (1). The work done at the regional level resulted in a significant increase of annual donations and of voluntary blood donations in the Caribbean and Latin American countries during the first years of the 21st century (Figures 1a and 1b), (1, 2).

Blood donation in the Caribbean and Latin America 2000–2005

Figure 1a

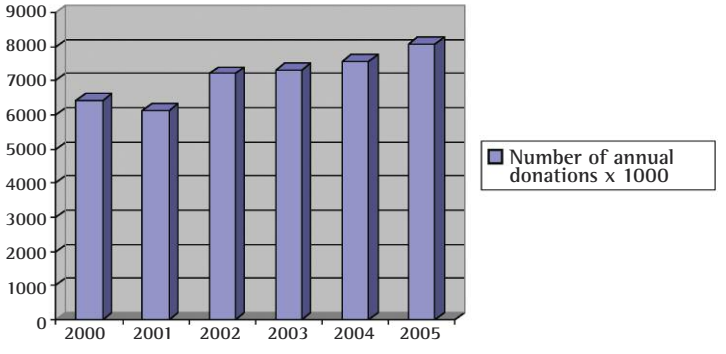
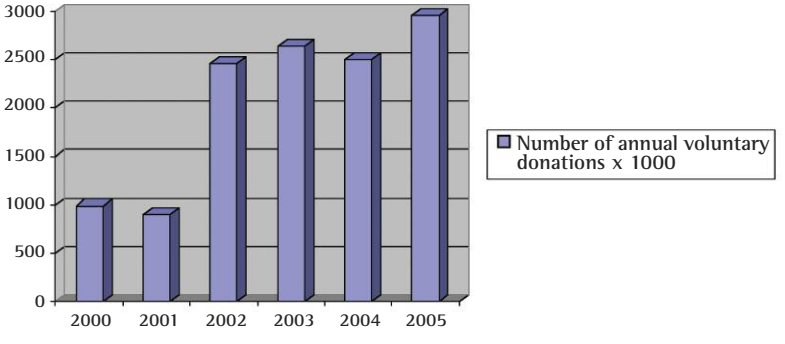
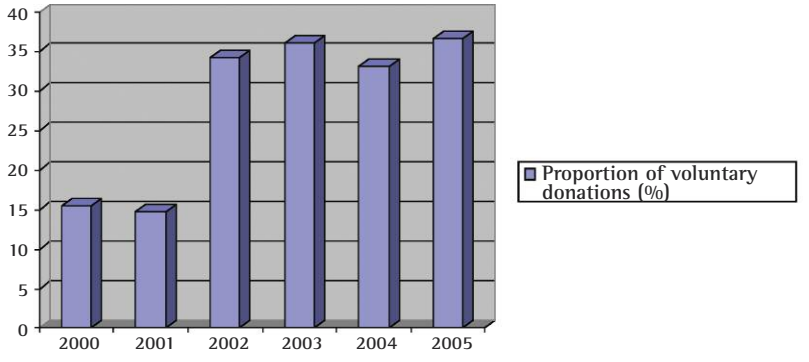


Figure 1b



Although the proportion of blood units collected from voluntary donors increased from 15% in 2001 to 34% in 2002, it remained unchanged during the following four years (Figure 1c) (3–5).

Figure 1c



The proportion of voluntary blood donations at the national level improved only in a few instances during the 2002 to 2005 period. Tables 1 and 2 summarize the data for the Caribbean and Latin American countries, respectively.

Table 1

Proportion (%) of voluntary blood donations in the non–Spanish speaking Caribbean countries

Country	2002	2003	2004	2005
Anguilla	Not Reported	0	10	10
Antigua and Barbuda	6	6	12	Not Reported
Aruba	100	100	100	100
Bahamas	10	16	24	15
Barbados	Not Reported	Not Reported	Not Reported	Not Reported
Belize	6	9	9	9
Bermuda	Not Reported	98	Not Reported	Not Reported
British Virgin Islands	99.9	24	21	0
Cayman Islands	98	99.6	100	100
Curacao	100	100	100	100
Dominica	5	Not Reported	4	5
Grenada	30	39	35	30
Guyana	16	22	19	22
Haiti	5	5	5	15
Jamaica	10	12	11	10
Montserrat	0	0	0	Not Reported
St. Kitts and Nevis	18	3	6	3
St. Lucia	69	79	83	82
St. Vincent and the Grenadines	7	12	15	13
Suriname	100	100	100	100
Trinidad and Tobago	17	Not Reported	Not Reported	13
Turks and Caicos Islands	50	32	Not Reported	Not Reported

Table 2
Proportion (%) of voluntary blood donations in Latin American countries

Country	2002	2003	2004	2005
Argentina	6	8	7	8
Bolivia	24	16	23	28
Brazil	47	51	46	53
Chile	2	6	7	9
Colombia	41	42	50	58
Costa Rica	48	49	57	59
Cuba	100	100	100	100
Dominican Republic	17	18	20	20
Ecuador	41	30	29	Not reported
El Salvador	10	10	11	10
Guatemala	4	4	2	1
Honduras	22	19	16	15
Mexico	3	4	4	4
Nicaragua	56	45	42	44
Panama	2	2	2	3
Paraguay	1	6	6	10
Peru	6	5	4	5
Uruguay	35	32	26	26
Venezuela	11	4	7	7

Based on the reports of 28 Caribbean and Latin American countries (4), it is estimated that over 1.2 million prospective donors were deferred in 2005. If the donor interview lasted an average of 15 minutes, the staff in the blood services invested 1,200 hrs. each working day in conversations with individuals that were not in condition to donate blood. Furthermore, those donors that were allowed to donate were very likely to carry markers of infections that have the potential to be transmitted through blood transfusion (median proportion of reactive donors was 3.11%, range 0.03% to 11.00%). In addition to the risk for the safety of the blood supply, the 230,000 reactive units that were discarded in 2005 represent US$ 13.4 million in wasted supplies used for blood collection and processing (5).

The stagnation in the proportion of voluntary blood donors at the regional level, the overall high rates of donor deferral, and the prevalence of infectious disease markers the national level, clearly indicate that the processes involved in blood donor recruitment and selection need improvement.

This is also one of the main conclusions of socio–anthropological studies carried out in 17 countries of the Region of the Americas (6–23). The findings of these surveys were very similar among them and can be summarized in the following manner:

The population:

- has a positive attitude towards blood donation;
- considers that giving blood is useful;
- is willing to help to achieve blood sufficiency;
- donates blood when it is necessary;
- lacks knowledge about blood donation issues;
- is interested in learning more about blood donation;
- prefers being given opportunities to donate over material incentives; and
- requires transparency of the national blood systems.

The prospective donors demand information on the requirements to become blood donors, the reasons for deferral, the risks and physical consequences of donating blood, the community need of blood, and the places, frequency and procedures for blood donation. The public suggests that workshops and group discussions be used to involve the community and that mobile collections be implemented to avoid blood collection in hospitals. The location, working schedule and the environment of the facilities where blood is currently collected are considered deterrents for blood donation, as are the poor service provided by the staff and the lack of standardized blood collection procedures (6–23).

Taking this information into consideration the document IMPROVING BLOOD AVAILABILITY AND TRANSFUSION SAFETY IN THE AMERICAS (5), presented by the Director of the Pan American Health Organization to the Directing Council in 2008, recommended that:

a. the coutries make efforts to estimate their annual need for blood and blood components;
b. the number of repeat donors be estimated at least as 50% of the national need of red blood cells;
c. a national program be put in place to educate and recruit healthy individuals as regular donors and to have them donate at least twice a year; and
d. a social network of volunteers be established to help educate the community, to promote voluntary blood donation and to service the donor.

The 48th Directing Council of the Pan American Health Organization (PAHO) on 2 October 2008 adopted resolution CD48.R7 (24) which urges the Member States to:

a. Proactively implement the Regional Plan of Action for Transfusion Safety 2006–2010 by:
    i. defining a specific entity within the normative level of their ministries of health as responsible for the planning, oversight, and overall efficient operation of the national blood system;
    ii. estimating the annual need for blood components and the financial resources to cover those needs; and
    iii. establishing a network of volunteers to educate the community, to promote voluntary blood donation and to service the donors, with special attention to youth programs.
b. Terminate replacement and paid donation by the end of 2010.
c. Terminate mandatory patient replacement of transfused blood by the end of 2010.

Education of prospective blood donors

The approach recommended by PAHO for the education of allogeneic blood donors requires a shift in the way the national health systems currently procure blood in most of the countries of Latin America and the Caribbean.

TRADITIONAL APPROACH	NEW APPROACH
• The patient needs blood • The hospital orders blood donations • Relatives and friends of the patients are required to provide blood • The blood bank collects the blood specifically for a hospital and/or patient • The hospital uses the blood	• The country needs blood • The national community educates voluntary blood donors • The health system promotes and encourages blood donation • The blood services cater to blood donors • The country uses the blood

The concept that the country needs blood encompasses the estimation of the quantity of blood components that is required to provide appropriate and timely treatment to all the patients, irrespective of their geographic, economic, social and cultural position. It is the hospitals, therefore, that should determine the annual, monthly and weekly requirements of blood components.

The blood services should define the number of blood donors to be educated and provide the leadership to the national community – Ministry of Health, Ministry of Education, Ministry of Labour, academic institutions, churches, patient organizations, human rights organizations, social and sports clubs, municipalities – for the education efforts. The blood donor service staff within the national blood services should train community coordinators and volunteers and support their work to educate the donors (25–31).

The desired profile of the voluntary blood donor is "An individual who:

- has the capacity and the competence to decide to be a blood donor;
- knows that she/he is healthy and wants to remain healthy;
- is well informed on the measures to maintain her/his health, on how to avoid unhealthy behaviors and risks;
- knows what the need, requirements, process and risks of blood donation are;
- is positively motivated to donate blood;
- decides voluntarily to donate blood; and
- donates blood repeatedly."

All the appropriate information and the opportunity to ask questions regarding blood donation should be provided to all prospective blood donors, prior to recruitment, in structured presentations for groups of 40–45 individuals.

Detailed explanations of the value of blood transfusions, the estimated need of blood components in the community, the specific processes of donor interview and blood donation, its physiological consequences and its potential untoward reactions are necessary during the education phase (32–35). Prospective donors should receive information regarding infections transmitted by blood transfusion (TTI) such as the viruses of the human immunodeficiency (HIV), hepatitis B (HBV), hepatitis C (HCV), human T cell-lymphotropic type I and type II (HTLV I/II), *Trypanosoma cruzi* and malaria. The information should include means of transmission, incubation and window periods, signs and symptoms, risk behaviors, preventive measures, and the importance of withdrawing from the donation if they believe that either the collection or the transfusion of their blood may pose a risk for them or for the patients, respectively. The International Society for Blood Transfusion (ISBT) adopted a Code of Ethics for blood donation and transfusion that aims to protect blood donors, blood recipients and blood for transfusion as a public good (36). The Code should be provided to prospective donors during the education phase.

Blood services must also inform the donor about the tests that will be performed on donated blood, under which circumstances the donor will be informed of test results, and what information will be released to third parties. Donors have the right to be informed in a timely manner of any medically significant abnormalities that may be detected during the interview and the general health asessment (37, 38). PAHO recommends that any clinically significant findings detected during the pre–donation evaluation or during the blood testing should be released. Blood services should refer for appropriate follow–up donors who have indications of clinically significant conditions, including reactive infectious markers. It is vital, however, that test results not be used as a motivational tool for blood donation, as this would encourage donations from people who engage in risky behaviours, thereby increasing the possibility of TTI (39, 40). Prospective blood donors should also be explained about their rights and those of the patients that may receive blood transfusions (41–49).

At the end of the education session, prospective donors should be asked to become regular donors. Experiences from the United Kingdom and Paraguay show that 78% of individuals who attend 45–50 minute sessions do become blood donors (50, 51). Specific arrangements for the selection of those who will actually donate blood should be made immediately.

Selection of blood donors

The aim of donor selection in the blood donation process is to determine whether prospective donors are in good health, and to assure that blood donation will not harm them. Additionally, blood donor selection seeks to prevent any risk of tranfusion–associated untoward reactions in the blood recipient patient, including transmission of infections or the effects of drugs which could be detrimental to them (52–54). To ensure these objectives, and following the education phase, blood services must carry out a confidential pre–donation interview and a general health assessment of all potential blood donors prior to their donation (55).

The selection process must start with the prospective blood donor filling a self–administered form to collect his/her demographic, general and contact information, as well as to initially determine if he/she complies with all criteria for blood donation. This step should last approximately five minutes (56). The second step involves a confidential interview with a trained member of the blood services staff who knows that the blood donors have the right to be treated with dignity, fairness and respect. The interviewer should make sure that the prospective donors understand the process of blood donation, the questions in the self–administered form, and that his/her responses are adequate; the level of hemoglobin should then be determined. This step should last approximately 12 minutes (56). If all parameters are acceptable, the prospective donor should be asked to sign the informed consent form (38) and proceed to donate blood.

Aim of the present document

PAHO considers it essential to provide the National Blood Programs with resources that allow them to develop appropriate programs for blood donor education, recruitment and selection. This document summarizes the rationale for the parameters and conditions that should be taken into consideration in the education and selection of blood donors, in the level of detail that should allow blood service staff, community volunteers and prospective blood donors to understand them. As illustration of how the parameters are applied in various countries, the selection criteria of the American Association of Blood Banks (AABB), Council of Europe (CoE), Héma–Québec (H-Q) (Canada), the Australian Red Cross (ARC), the Caribbean Regional Standards (CRS) and the *Estándares de Trabajo para Servicios de Sangre* are presented as examples (57–62). In addition, the document includes recommendations made by PAHO to the national health authorities and the national blood programs in order to promote multidisciplinary and coordinated approaches for health promotion, public education, universal and regional human and patient rights —as applicable to blood donors and recipients—, quality assurance and financial efficiency in the issues pertaining to sufficiency, availability, access, quality, safety, and timeliness of blood for transfusion. It is important to keep in mind that these recommendations should be reevaluated when additional information or evidence becomes available.

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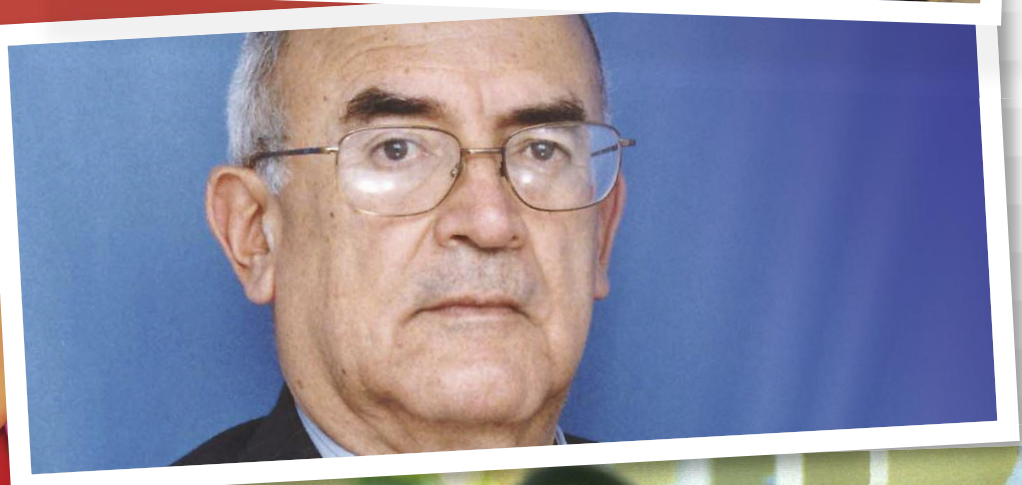

THE BASIC REQUIREMENTS

AGE

Blood donation is a voluntary procedure that may have untoward effects on the blood donor and, therefore, requires informed consent by the individual. It is necessary to establish a minimum age for blood donation to assure that the donor has both the competence and the capacity to provide informed consent. Likewise, it is necessary to establish a maximum age for blood donation in order to assure that blood collection does not either have a negative long–lasting effect on the health of the donor or increases the potential risk of adverse reactions to blood donation.

The American Association of Blood Banks (AABB) and the Australian Red Cross (ARC) have the lower age limit to donate blood at 16 years. The Caribbean Regional Standards (CRS) establish 17 years as the minimum age, while the Council of Europe (CoE) and Hema–Quebec (H–Q) have set it at 18 years. The AABB and CRS do not list an upper age limit. The maximum age to donate blood varies from 65 (CoE) to 81 years (ARC).

PAHO Recommendation: Prospective donors should be at least 17 years old. The maximum age to donate blood for the first time and for repeat blood donation should be established based on the health conditions of the local donor population. Individuals of legal age or the guardians of minors willing to become blood donors should provide informed consent before their first donation.

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BODY WEIGHT

(SEE BLOOD VOLUME TO BE COLLECTED)

The amount of blood that circulates in the human body is proportional to body weight (70 mL per kg). To avoid untoward reactions in donors as a consequence of donating excesive blood volumes it is necessary to establish the minimum body weight for collection of a standard blood unit from an individual. A standard unit of blood usually corresponds to 450+/-50 mL, which should be no more than 12.5% of the total volume of blood circulating in the body.

ARC sets the minimum body weight at 45 kg. For AABB, CoE, CRS and H-Q the lower body weight limit is 50 kg.

> PAHO RECOMMENDATION: Prospective donors should weight at least 50 kg. Individuals with an involuntary weight loss of >10 kg in the six months previous to the donation should be deferred and referred for medical assessment.

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FASTING

It is common for blood services to defer prospective donors because they have ingested foods and liquids before blood donation. This practice was established because hospital-based blood banks usually collected blood during limited early morning hours, using diagnostic laboratory approaches. This practice is unacceptable, may induce a decrease in donor return rates and disrupt blood collection activities. Vomiting is the least common clinical characteristic of adverse reactions to donation. It is desirable that the donors do not donate during a prolonged fast. The ingestion of 475-500 mL of water before the donation reduces the rate of adverse reactions.

None of the documents consulted as examples of international, national and institutional criteria includes food ingestion as factor for donor deferral.

> PAHO Recommendation: Donors should not be asked to fast for the purpose of donating blood. It is highly recommended that, on the day of donation, prospective donors be given 16 oz (473 mL) of drinking water when they first arrive in the blood collection facilities. This practice not only reduces the rate of adverse reactions to donation but also promotes early friendly interaction between blood service staff and blood donors.

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ABO BLOOD GROUP

Blood is composed of red blood cells, white blood cells, platelets, and plasma. Red blood cells carry oxygen from the lungs to the tissues, and carbon dioxide from the tissues back to the lungs. White blood cells fight infections and other foreign substances that may enter the body. Platelets play a central rol in coagulation. Plasma, the liquid component of blood, is rich in proteins that help to keep the body healthy and functioning well, carries nutrients to tissues, and transports substances that should be eliminated from the body through excretions.

Human beings have different inherited chemical markers in the membranes of their red blood cells. The major markers are called A and B and define the major blood groups. Individuals may have one, the two or none of these markers in all their red blood cells and, therefore, blood groups are called A, B, AB and O, respectively. Persons with group A red blood cells carry anti–B antibodies in their plasma. Persons with group B red blood cells carry anti–A antibodies in their plasma. Persons with AB type blood do not have either anti–A or anti–B. Persons without any of the two erythrocyte markers have anti–A and anti–B antibodies in their plasma. The presence of red blood cell markers and of plasma antibodies determines the major compatibility of blood for transfusion, since antibodies in plasma bind to foreign erythrocytes and induce their destruction. Nevertheless, persons with AB blood can receive red blood cells, but not whole blood, from donors who have A, B or O blood group. Similarly, O red blood cells can be transfused to patients of all four blood groups.

It is common for blood services to defer prospective donors based on their ABO blood group. This practice was established because hospital–based blood banks usually collect blood units that are intended to be transfused to patients whose blood group is already known to the service.

None of the documents consulted as examples of international, national and institutional criteria includes blood group or type as factor for donor deferral.

PAHO Recommendation: Prospective donors should not be deferred because of their blood group. Deferring prospective donors based on their ABO blood group may induce a decrease in donor return rates and disrupt blood collection activities.

Procedures and mechanisms for defining the local needs of blood components and for monitoring the local blood inventory should be established. This involves good communications with hospitals to anticipate changes in the complexity, reduction or expansion of their health services. A regional blood center approach facilitates blood inventory management. The implementation of national standards for the collection, processing and storage of components will allow the exchange of units among different blood services.

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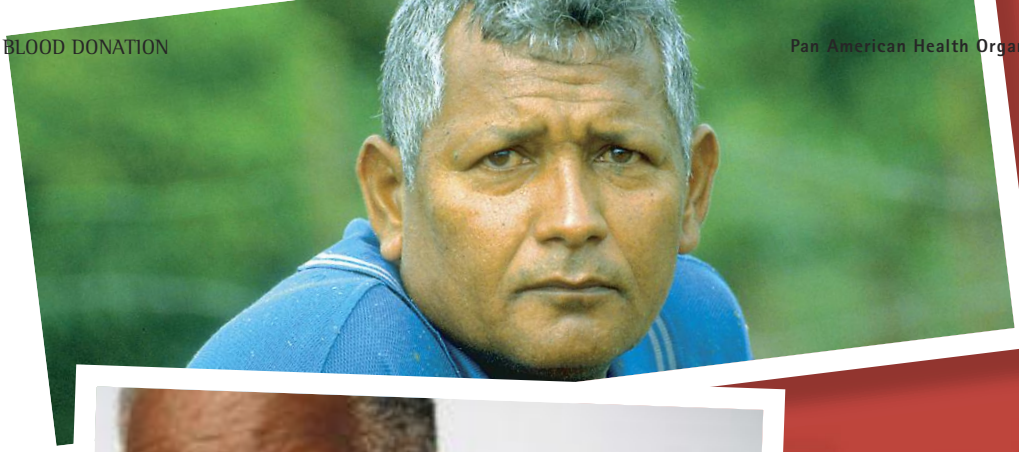

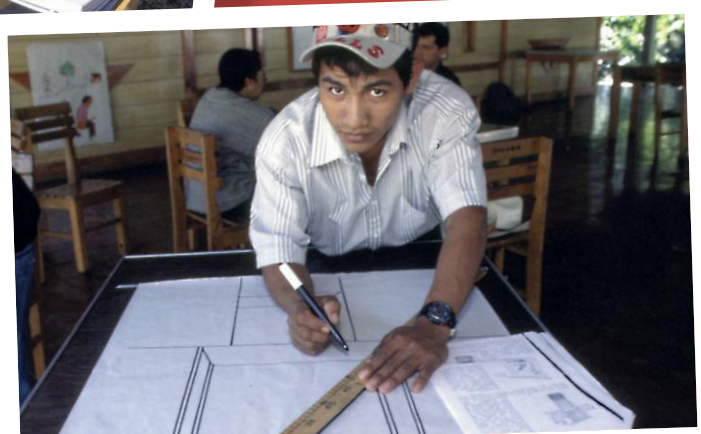

FOR FEMALES ONLY

MENSTRUAL PERIOD

(SEE HEMOGLOBIN LEVEL, INTERVAL BETWEEN DONATIONS, BLOOD VOLUME TO BE COLLECTED, BODY WEIGHT)

Most healthy menstruating women lose less than 40–50 mL of blood per menstrual period and, therefore, the average annual blood loss does not normally exceed 650 mL. There is no reason to defer a woman during her period unless she reports discomfort or pain, both of which are more likely to happen in women with heavy menstrual bleeding. Menorrhagia is defined as blood loss exceeding 80 mL per period and may be related to inherited bleeding disorders or other clinical conditions.

PAHO Recommendation: Women who are willing to donate blood during their menstrual period should not be deferred as blood donors, if they feel well at the time of donation and fullfill all other donor selection criteria. Factors that must be given special consideration are hemoglobin/hematocrit levels, interval between donations, and body weight. Women who report routine excessive menstrual bleeding and are found to have low hemoglobin levels should be referred for medical evaluation.

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PREGNANCY

Human gestation is a period of dynamic physiologic changes designed to support the development of the fetus. The maternal respiratory, gastrointestinal, circulatory, and musculoskeletal systems adapt in order to respond to the augmented metabolic needs of the mother and the fetus. Physiologic changes during pregnancy include insulin resistance, thrombophilia, immunosuppression, and hypervolemia, and result in modified nutritional requirements in the mother. Blood donation during pregnancy may negatively affect the fetus. There should also be a deferral period after childbirth and lactation, to allow time for maternal iron stores to replenish.

AABB and CRS require a 6-week deferral. H-Q has a 6-month deferral period, while ARC sets a 9-month deferral.

> PAHO Recommendation: Pregnant women should not donate blood because of their increased requirement of nutrients, especially of iron, during gestation. In addition, it is necessary to avoid any potential stress on the maternofetal circulatory system. After delivery, mothers should avoid donating blood not only to allow time for their iron stores to replenish, but also to promote successful lactation of their infants.

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BREASTFEEDING
(SEE PREGNANCY)

Breastfeeding promotes better child development. Breast milk protects infants against infections and allergies, and provides the appropriate types and quantities of nutrients for at least six months after birth. Reduced incidence of juvenile onset insullin dependent diabetes, hypertension and obesity has been associated with breastfeeding. Children who have been breastfed show improved cognitive development, while women who breastfeed have lower risk of breast and ovarian cancers. Nutrients in breast milk are derived from the mother's blood stream, a fact that underlines the importance of appropiate maternal nutrition especially during pregnancy and lactation. Certain types of medicines, illegal drugs and alcohol taken by the mother can also be transferred through breast milk to the baby and cause harm. HIV and tuberculosis can be transmitted through breast milk of infected mothers.

To avoid additional nutritional stress to lactating women, mothers who are breast–feeding should not be considered as blood donors.

AABB defers mothers for six weeks and H-Q for six months after delivery. For ARC the deferral period is at least nine months or until the baby gets most of his/her nutrition form solid foods.

> PAHO Recommendation: Women who are breastfeeding should be deferred from donating blood. Exclusive breastfeeding is recom–mended for six months after delivery. Mixed feeding –breast milk and other foods– of infants should be continued at least until the child is 2 years old.

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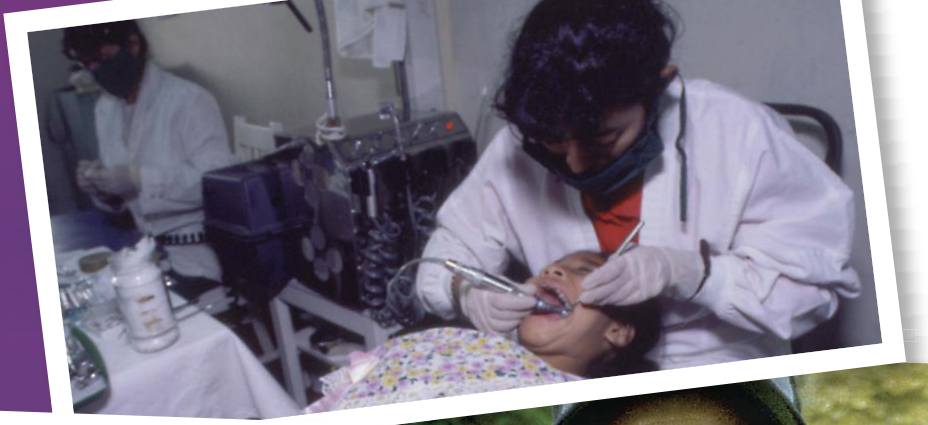

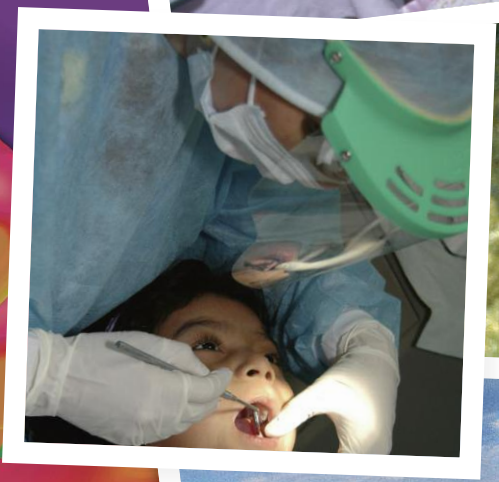

PERSONAL HEALTH CARE ISSUES

DENTAL PROCEDURES

Microorganisms normally exist in the oral cavity. Dental profilaxis, tooth extraction, root canal treatment, and other procedures may create transient, asymptomatic or symptomatic bacteremia in healthy individuals. Immunocompromised or debilitated patients, however, may develop severe diseases when infected by the microorganisms that normally exist in the oral cavity. There are reported associations between dental procedures and bacterial endocarditis.

The criteria for the ARC indicate that only plasma may be used when the donors had dental procedures such as cleaning, fillings, or braces done in the 24 hrs. previous to the donation. For H–Q potential donors are accepted after a filling or cleaning. However, in the case of tooth extraction, dental surgery or root canal, the person is deferred for three days after completing treatment.

PAHO Recommendation: Individuals who had dental procedures done at least 72 hrs. prior to blood donation, who are non–febrile, and who feel well, should be accepted as blood donors, as long as they have not taken aspirin during those 72 hrs. Intake of other medications should be evaluated (see Medication).

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VACCINES/IMMUNIZATIONS

Vaccines are used to make people immune to certain diseases by stimulating the defense systems to recognize pathogenic microoganisms or their toxins. There are vaccines against poliomyelitis, measles, mumps, rubella, hepatitis A, hepatitis B, influenza, varicella, rabies, yellow fever, tetanus, diphtheria, whooping cough, tuberculosis, pneumococcus, menigococcus, typhoid fever, cholera, and some viruses that cause diarrhea and cervical cancer. Some of these vaccines are recommended for infants and children, some for adults, and some for travelers. Vaccines may include microbial products or subunits, and killed or attenuated live microorganisms that do not have the capacity to cause disease to normal humans but are capable of inducing protective immune responses. Attenuated microorganisms do replicate in the human body and, in the case of immunosuppresed or immunodeficient patients, may cause clinical disease. In normal vaccinated individuals, some attenuated vaccine–derived microorganisms may reach the blood stream and, therefore, can potentially be transmitted through transfusions in much higher concentrations than that of the original vaccine.

Vaccines that are required to be considered include:

Vaccines with attenuated bacteria or viruses. Examples: BCG, yellow fever, measles, poliomyelitis, (oral) mumps, typhoid fever and cholera use attenuated virus or bacteria.
AABB: 2–week deferral, 4–week deferral for German measles (rubella) and chicken pox (varicella zoster).
CoE: 4–week deferral.
PAHO and CRS: 2–week deferral, 4–week deferral for varicella zoster or rubella.

Toxoids or killed vaccines. Examples: anthrax, cholera, diphtheria, influenza, para–typhoid fever, pertussis, plague, polio, fever, tetanus, typhoid, and thyphus.
AABB, CoE, CRS, PAHO: No deferral if donor is well.

Other vaccines including unlicensed vaccines.
AABB: 12–month deferral, unless otherwise indicated by medical director.

Use after exposure.
AABB: Rabies or anti–hepatitis B human immunoglobulin defer for 12 months to eliminate the risk of the possible rabies or hepatitis.

> PAHO Recommendation: Individuals who have been vaccinated should be deferred for periods of time that vary according to type of vaccine. Plans for mass vaccination campaigns of adults must include considerations regarding availability of blood donors during the corresponding deferral time.

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MEDICATION

(SEE ALLERGIES, DIABETES, BLOOD PRESSURE [ARTERIAL]/HYPERTENSION, VACCINES/IMMUNIZATIONS)

Medication may be taken by individuals to either cure or prevent illness, and to maintain adequate levels of biological substances that are required for balanced normal metabolism. The potential harm to transfusion recipients of both the underlying medical condition of the donor and of the medication being taken must be assessed when considering collecting blood from individuals who take or have recently taken medication. Most prescribed medicines do not require deferral from donating; however, the underlying condition for which the medication has been prescribed may affect eligibility to donate. This is the case for donors taking antibiotics, anticoagulants, insulin, systemic corticosteroids, for example. In general, persons who take medications with a cumulative effect and those that are teratogenic should not donate blood for transfusions.

The medications that are considered in the blood donation process are:

Aspirin irreversibly inactivates platelet function.
AABB: Accept 36 hrs. after ingestion of aspirin.
CRS: Aspirin–containing medications or those that inhibit platelet function if ingested within three days, preclude use as sole source of platelets.

Acitretin (Soriatane) is used in severe psoriasis, including erythrodermic and generalized pustular types. Acitretin is known to cause serious birth defects in unborn babies. Donated blood containing acitretin given to a pregnant woman may cause birth defects in the unborn baby.
AABB, CRS: Defer for three years.

Bovine insulin, manufactured in the United Kingdom (UK) preparations may contain prions, the causative agents of transmissible spongiform encephalopathies (TSE).
AABB: Permanent deferral.

Dutasteride (Avodart), is used to treat the enlarged prostate, a condition called benign prostatic hyperplasia. Any contact with this drug by a pregnant woman could result in abnormal external sex organs of the developing male fetus.
AABB: Accept six months after last dosage.

Etretinate (Tegison), used for acne and psoriasis treatment, is associated with serious birth defects. After prolonged treatment it can accumulate in fat and plasma proteins.
AABB: Permanent deferral.

Finasteride (Proscar, Propecia) and isotretinoin (Accutane, Claravis, Amnesteem, Sotret) used in the treatment of cancer, have teratogenic effects. After prolonged treatment the drugs can accumulate in blood for up to one month.
AABB, CRS: Accept one month after last dose.

Antibiotics.
AABB: As defined by the facility's medical director.

> PAHO Recommendation: Only healthy individuals who are feeling well at the time of donation should donate blood. For calculating deferral periods of potential donors who are or have recently taken medicines, both the type of blood hemocomponent to be prepared and the drug's pharmacokinetics for a given formulation should be considered. The standard operating procedures for blood services should contain a regularly updated list of medications that warrant donor deferral.

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ARTESANIAS CHUC


PROSANGRE

FOR TRAVELERS

TRAVEL

(SEE INFECTIOUS CONDITIONS)

Travel to areas where vector–borne or zoonotic infections are prevalent may result in inadvertent exposure to pathogens, such as malaria, *Leishmania*, yellow fever and *Brucella*. A number of pathogens may result in asymptomatic infections that can be transmitted through blood transfusion.

AABB requires that the prospective donor's travel history must be evaluated for potential risk.

ARC has three areas of concern related to infection risks with overseas travel. These are malaria, HIV and variant Creutzfeldt–Jakob Disease (vCJD).

CoE requires questioning the donor as to the country in which he or she was born, brought up or has visited. Every transfusion center should have a current map of the endemic zones and an alphabetical list of the countries concerned.

H–Q, requires permanent deferral of people who have spent one month or more in the United Kingdom between January 1, 1980 and December 31, 1996. UK includes: England, Scotland, Wales, Northern Ireland, the Isle of Man and the Channel Islands. Also, those who have spent three months or more in France between January 1, 1980 and December 31, 1996, and individuals who have spent six months or more in Western Europe since January 1, 1980, should be deferred on a permanent basis. Western Europe includes: Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Liechtenstein, Luxembourg, Netherlands, Portugal, Spain, United Kingdom and Switzerland. Note that the time spent in the United Kingdom and France since January 1, 1997, must not be included in the cumulative period. Travel to a country where malaria is prevalent also requires permanent deferral.

PAHO Recommendation: Prospective blood donors who have traveled to disease-endemic areas should be deferred according to the infection they have potentially been exposed. Due to the mobility of blood donors it is essential to have available at the blood donation facility an alphabetical list of countries, zones, and cities that are considered of risk for contracting infectious diseases, for consultation when prospective donors report travel. Individuals who will travel to those areas should be advised to follow the international prevention guidelines.

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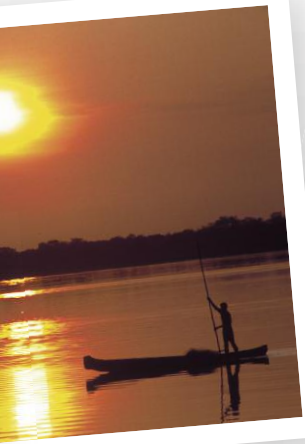

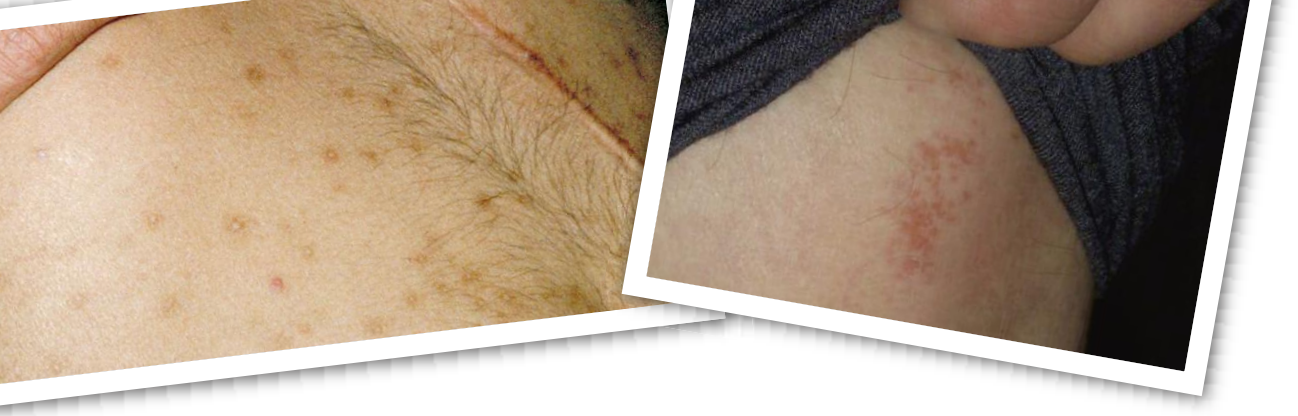

HOW IS YOUR SKIN?

ALLERGIES

The human body is equipped with various mechanisms that are designed to protect it against potential harmulf substances. Both white blood cells and antibodies are programmed to recognize foreign substances and to eliminate them, once they gain entry into the body. In some ocassions, however, the immune system develops a faulty reaction againt certain types of substances, called allergens. Allergens are commonly found in food, medicines, pollen, dust mites, insect bites, pet dander, and mold spores. Allergic reactions develop following the introduction of allergens into the body and the appearance in the blood stream of inflammation mediators. Allergy symptoms include sneezing, watery eyes, hives, asthma and systemic shock, that may be fatal if not managed promptly. Although there is a genetic predisposition to become allergic to some substances, sustained exposure to allergens, especially early in life, are important factors. Pollution and cigarrete smoking contribute to allergies, as does not receiving breast milk during infancy.

Allergens and mediators of inflammatory reactions present in the donor circulation can resist blood processing and storage and, therefore, may be transfused to the recipient of the transfusion.

The CoE requires that individuals with a documented history of anaphylaxis are not accepted as donors. AABB, ARC, CRS, and H–Q do not include allergies among the criteria for donor selection.

> PAHO Recommendation: Individuals with severe systemic signs or symptoms of allergies, such as difficulty breathing or severe skin hives, at the time of donation should be deferred until the signs and symptoms disappear.

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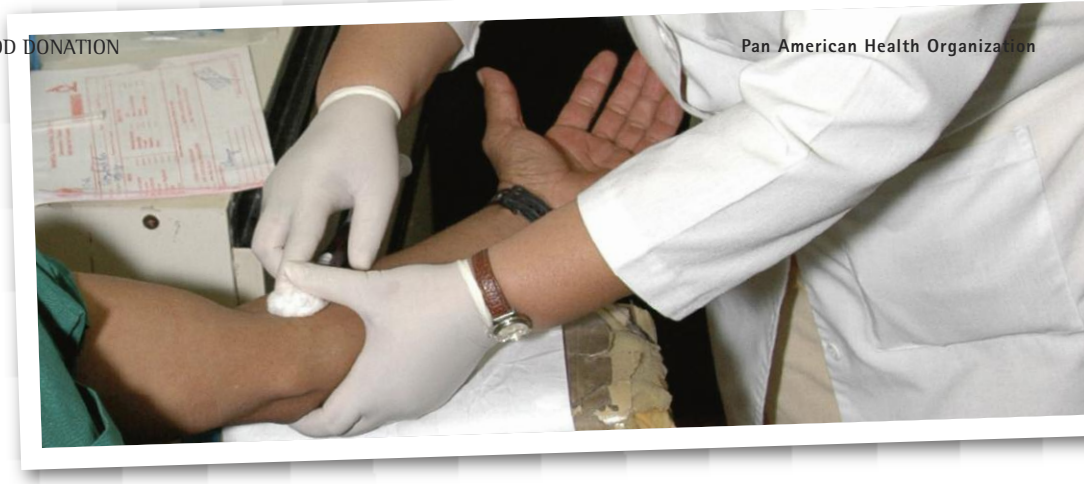

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SKIN LESIONS AT THE VENIPUNCTURE SITE

The major source of bacterial contamination of blood hemocomponents is the skin of the donor's arm. Bacteria from the hands of the phlebotomist may also reach the blood unit. The needle gauge, the quality of the donor's skin asepsis and the collection environment affect the risk of bacteria entering the blood collection bag. Skin lesions may be associated with pathogenic bacteria that may contaminate the unit of blood collected and cause severe disease in the transfused patient.

AABB requires that the venipuncture site be prepared so as to minimize risk of bacterial contamination. Evaluation of the venipuncture site for lesions on the skin is recommended.

CRS state that the blood collection procedure should guarantee the maximum asepsis in the collection environment. Evaluation of the donor skin at the venipuncture site is required.

H–Q requires that the nurse examines the donor´s arm to ensure that there are no signs of intravenous drug use.

PAHO Recommendation: The skin at the site of venipucture should be free of open or active infection. Individuals with obvious active skin infections at the site of venipuncture should be deferred until after the lesions heal. Personnel performig venipuncture/blood collection procedures should be trained in a standardized protocol for cleansing and asepsis of the donor's arm.

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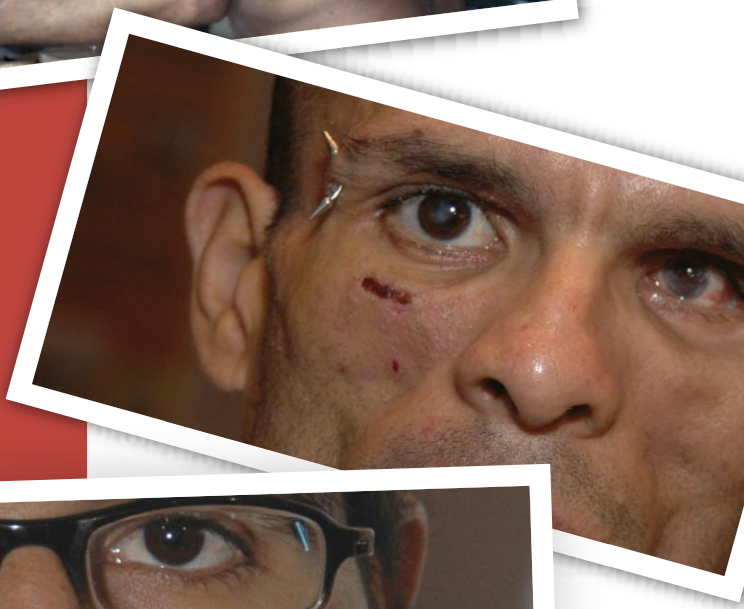

RISKY PRACTICES

BODY PIERCING
(SEE TATTOOS)

Body piercing instruments usually come in contact with blood. It is possible that body piercing facilities that are not regularly inspected and/or licensed do not use sterile equipment. Contaminated equipment may act as a vehicle for transmission of blood-borne infections. To avoid the risk of transfusion-transmitted infections during the window period of the infection, donors with recent body piercing should be temporarily deferred.

AABB, ARC, CoE, and CRS require that donors with body piercing be deferred for 12 months after piercing. The deferral period for H-Q is six months. ARC allows blood donations 24 hrs. after piercing if the procedure is done with a clean, single use, disposable needle.

> PAHO Recommendation: Individuals who have body piercing should be deferred for 12 months after the procedure. Potential blood donors should be made aware of the health risks of body piercing and ways to prevent them.

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TATTOOS

(SEE BODY PIERCING)

The process of tattoing encompasses skin penetration with instruments or equipment which may become contaminated with blood. Body art and permanent make–up, cosmetic tattooing has been associated with bleeding, local infections, and transmission of HCV and HIV. The risk of infection is especially high when the tattoos are performed without the proper infection control procedures, including cleaning and sterilization of instruments, and by untrained individuals.

AABB recommends a 12–month deferral. This includes tattoos or permanent make–up unless applied by state–regulated entity with sterile needle and ink that has not been re–used.

ARC defers donors for 12 months after receiving a tatoo, including permanent cosmetic make–up.

CoE requires a 12–month deferral. 6–month deferral period or less may be adequate to address HIV, HCV and HBV when a validated HCV nucleic acid test (NAT) with a sensitivity of a ≤ 5,000 geq/mL in addition to serological testing is carried out in donated blood.

CRS requires a 12–month deferral from the time of application of a tattoo, while the deferral time is six months for H–Q.

> PAHO Recommendation: Individuals who have tattooed body art or permanent make–up should be deferred for 12 months after the procedure. Potential blood donors should be made aware of the potential health risks of tattooing.

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DRUG USE (RECREATIONAL)

Intravenous illegal drug use and abuse of legal drugs are major public health problems. Use of cocaine or heroin is one of the most significant risk factors for viral hepatitis and human immunodeficiency virus infection, resulting primarily from sharing needles or other paraphernelia that may get contaminated with blood. Any history of use of intravenous drugs not prescribed by a registered medical practitioner should be considered a risk for infections which are highly contagious during the window period and that can be transmitted through transfusions for a prolonged time after the initial infection.

AABB, ARC, CoE, and CRS require permanent deferral of individuals who inject non–prescription drugs.

> PAHO Recommendation: Donors who have used intravenous illegal drugs should be deferred for 12 months after the last use. They should also be encouraged to be tested for HIV, hepatitis B and hepatitis C, and to protect themselves and their partners by practicing safe sex. Prospective donors should be made aware of the health risks of using legal and illegal addictive substances.

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SEXUAL BEHAVIOURS

Human immunodeficiency virus, hepatitis B and hepatitis C viruses can be transmitted during sexual intercourse between male and female as well as between two males. These viruses can be transmitted during the asymptomatic phase of the infection and during the window period. Paying or receiving money or drugs for sex, having multiple sexual partners, having unprotected intercourse, engaging in anal intercourse, and men having sex with men are considered high risk behaviours. The Joint United Nations Programme on HIV/AIDS states that the term "men who have sex with men" describes a social and behavioral phenomenon rather than a specific group of people. It includes no only self–identified gay and bisexual men, but also men who engage in male–male sex and self–identify as heterosexual or who do not self–identify at all, as well as transgender males. Men who have sex with men are found in all countries, yet are invisible in many places."

The established criteria are:

AABB: males who have had sexual contact with another male, even once, since 1977 are deferred permanently. Persons who have ever taken money, drugs, or another form of payment for sex since 1977 are deferred permanently. Persons who have had sex with anyone who, since 1977, was born or lived in some central African countries are deferred permanently. Persons who have had sexual contact with anyone described above are deferred for 12 months.

ARC: 12–month deferral for individuals who have engaged in sexual activity with someone who might answer yes to questions on the use of drugs, partner with HIV, hepatitis B, hepatitis C or HTLV, or treatment with clotting factors. 12–month deferral for males who have sex with males, for persons who have had sexual activity with a male that might be bisexual; for those being male or female sex worker o who have engaged in sex with a male or female sex worker.

CoE: establishes that current sexual partners of people with HIV are deferred. Previous sexual partners of people with HIV are acceptable after 12 months since last sexual contact. Current sexual partners of people with HBV are deferred unless demostrated to be immune. Previous sexual partners of people with HBV are acceptable after six months since last sexual contact. Persons who have ever accepted money or drugs for sex and men who have sex with other men are deferred permanently. Persons who have had sexual contact with someone who is HIV positive or has hepatitis, has injected drugs or has ever received money or drugs for sex are deferred for 12 months.

CRS: state that prospective donors must be questioned and appropriately deferred if behaviour is suggestive of high risk for HIV infection.

H–Q: males who have had sexual contact with other male, even one time, since 1977 are deferred permanently. Persons who have ever taken money or drugs for sex since 1977 are deferred permanently. Persons who have had sexual contact with anyone described above are deferred for 12 months. Females who have had sex with a male who has had sex with another male since 1977 are deferred for 12 months. Persons who have paid money or drugs for sex are deferred for 12 months.

PAHO Recommendation: Persons who engage in risky sexual behaviours should be deferred from donating blood for 12 months after the last occurrence. The blood services should defer for a period of 12 months those females offering to donate blood if their male sexual partners had insertive or receptive anal sex with another male during the previous 12 months. Sexual orientation – hetero–sexuality, bisexuality, homosexuality – should not be used as criterion for blood donor selection since it is not a risk by itself. Individuals should not donate blood for a period of six months after having sex with a new partner. Potential blood donors should be encouraged to protect themselves and their partners by practicing safe sex.

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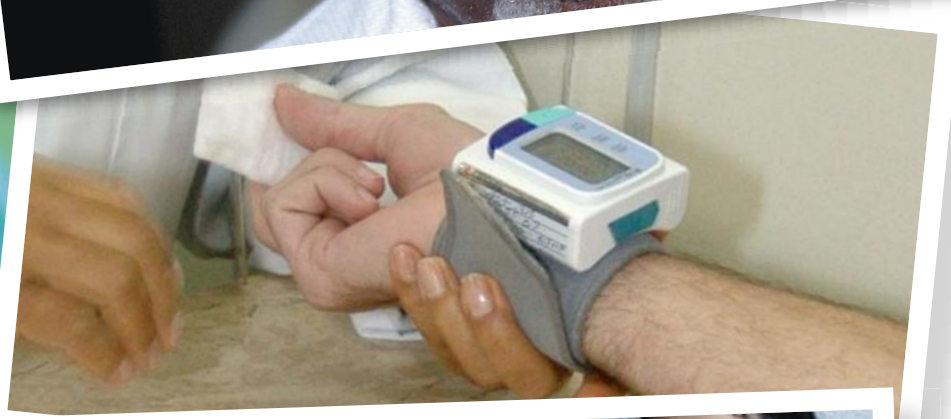

ARE YOU WELL?

BODY TEMPERATURE/FEVER
(SEE INFECTIOUS CONDITIONS)

Fever –elevated body temperature– is one of the body responses to injury and/or infection. Donors with elevated body temperature may be carrying infectious agents or may be suffering from a systemic inflammatory process. Making sure the prospective donor is fever–free protects both the donor and the patient who receives blood transfusions.

AABB, CRS and H–Q define fever as 37.5°C or 99.5°F of oral temperature.

> PAHO Recommentation: Blood donors should feel well and be totally healthy at the time of donation. Individuals with fever, defined as 37.5°C of oral temperature, should be deferred as blood donors and asked to be vigilant about other signs or symptoms of infections and inflammatory processes. Referral for medical assessment should be considered.

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BLOOD PRESSURE (ARTERIAL)/HYPERTENSION

Blood exerts pressure against the wall of the arteries as it flows from the heart to the veins. The pressure exerted when the heart pumps the blood into the arteries is called systolic, while diastolic pressure represents the one when the heart relaxes after a beat. Blood pressure results from a combination of the force of the heart beat and the resistance of the arteries. The optimal readings for human adults are between 90 mm and 120 mm of mercury (mm Hg) for systolic pressure and 60–80 mm for diastolic pressure.

Hypertension is associated with the concomitant occurrence of structural and functional changes in large arteries and small resistance arteries and with other classic hallmarks of organ damage (left ventricular hypertrophy, renal dysfunction, microalbuminuria). Blood collection may precipitate a vascular accident due to a transient reduction of blood pressure. Additionally, high blood pressure reduces the volume of circulating blood and, therefore, blood collection may generate an adverse reaction by further reducing blood volume. It is necessary to establish the maximum systolic and diastolic blood pressure readings acceptable for blood donation.

Low blood pressure, on the other hand, is a clinical condition that usually requires medication. In individuals with low blood pressure, blood donation may activate the parasympatic nervous system and trigger a vaso–vagal reaction. It is necessary to assure that the donor blood pressure is within the NORMAL range to reduce the risk of adverse reactions to blood donation.

ARC criteria indicate that persons taking medication for the control of blood pressure are acceptable as blood donors, provided the blood pressure is adequately controlled and stable. For the CoE a person who presents with blood pressure above the acceptable range should not be accepted as a blood donor. A mild hypertensive individual whose diastolic pressure is maintained at less that 100 mm Hg may be accepted. AABB, CoE, CRS and H–Q require that individuals have no more than 180 mm Hg of systolic pressure and no more that 100 mm Hg of diastolic pressure to donate blood.

PAHO Recommendation: Blood should be collected only from individuals with blood pressure readings that are within the normal range. Systolic pressure should not exceed 180 mm Hg nor should diastolic pressure exceed 100 mm Hg. Blood pressure readings are associated to several variables, including donor anxiety and nervousness. For this reason, before deferring the donor due to high blood pressure, a second measurement should be taken after 10 minutes of rest and calm. Otherwise healthy individuals whose blood pressure is within normal range, even though they may be taking medication to control it, can donate blood.

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PULSE

As a compensatory mechanism to blood loss, the heart reacts with a change in contractility and beat rate. The capacity and resistance of blood vessels also change in response to reductions in volume of circulating blood. Blood donation induces this compensatory mechanism and, therefore, it is necessary to establish acceptable limits of heart beat rate (pulse) in order to assure that the donor's heart is able to manage its cardiac output when blood is collected.

The minimun heart rate establised by AABB, CoE and CRS is 50 beats per minute. CoE and CRS set a maximum heart rate of 100 beats per minute for donating blood.

PAHO Recommentation: Donors with tachycardia should be allowed time to calm. Before deferring the donor due to tachycardia, a second measurement should be taken after 10 minutes of rest. Donors with bradycardia should be asked about their sports activities since athletes present with lower pulse and blood pressure than non–athletes. Individuals whose heart rate persists out of the normal range should be deferred.

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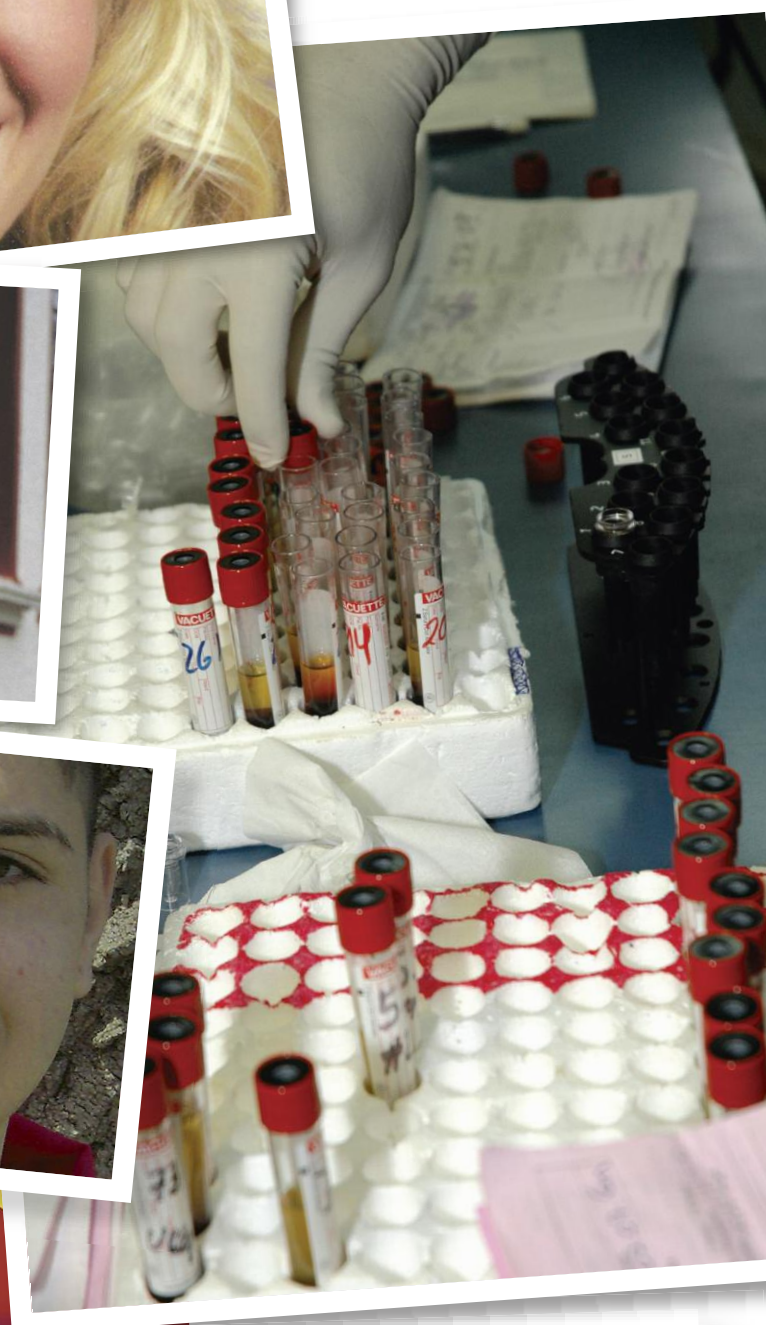

MAKING SURE YOUR BLOOD IS GOOD

HEMOGLOBIN LEVEL/HEMATOCRIT
(SEE INTERVAL BETWEEN DONATIONS)

Hemoglobin is an iron–containing protein in red blood cells that carries oxygen. The quantity of hemoglobin in red blood cells depends on gender, intake, absorption, and storage of iron, as well as on blood losses. Normal hemoglobin values fluctuate between 121 g/L and 151 g/L of blood in females, and between 138 g/L and 172 g/L in males. Hematocit refers to the proportion in volume of red blood cells to total blood volume. Normal values fluctuate between 36.1% and 44.3% in females, and between 40.7% and 50.3% in males. Both hemoglobin and hematocrit levels may be low when the individual is deficient in iron, folate, vitamin B12, or vitamin B6. The inability to produce erythrocytes or bleeding can result in low hemoglobin or hemotocrit. Anemia generally refers to hemoglobin deficiency. Anemia is present when hemoglobin levels are below 120 g/L in adult, non–pregnant females and below 130 g/L in adult males.

In blood donors, hemoglobin concentration or hematocrit level must be sufficient to allow the donation of the required blood volume without inducing anemia in the donor, and to guarantee that the unit of red blood cells prepared for transfusion has an adequate quantity of oxigen–carrying hemoglobin. The gender and physical condition of the donor as well as the altitude above sea level of the place of residence should be considered when determining the levels of hemoglobin or hematocrit that are acceptable for blood donation. Blood samples obtained by earlobe puncture shall not be used for this determination as it may result in an overestimated value.

AABB, CRS and H–Q require that blood donors have at least 125 g/L of hemoglobin and 38% of hematocrit to be accepted as blood donors. The CoE requires 125 g/L of hemoglobin or 38% of hematocrit in females, and 135 g/L of hemoglobin or 40% of hematocrit in males.

PAHO Recommendation: Potential donors who are found to have low hemoglobin/low hematocrit values should be deferred from donating blood and referred for medical evaluation.

In order to avoid iron deficiency in blood donors, particularly in repeat ones and in females of childbearing age, the frequency of donation should not exceed four times per year for males, and three times per year for females. The blood services should promote iron–reach diets among their donors.

The application of more rigorous criteria regarding body mass, as determined by height and weight, and of iron intake is required for donors who volunteer for double–red cell donations.

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BLOOD VOLUME TO BE COLLECTED

(SEE BODY WEIGHT)

The amount of blood that circulates in the human body is proportional to body mass. For practical reasons, weight is used as indicator of body mass and the accepted mean blood volume is 70 mL per kg of body weight. A standard unit of blood usually corresponds to 450+/-50 mL, which should be no more than 12.5% of the total volume of blood circulating in the body. Fainting and other adverse reactions to donation are more common among individuals with blood volumes of less than 3500 mL. To avoid untoward reactions in donors as a consequence of donating excessive blood volumes it is necessary to establish the exact amount of blood to be collected in each donation.

The AABB, CRS and PAHO's Regional Standards require that no more that 10.5 mL of blood per kilogram of donor weight, including samples, be taken. The AABB allows for collection of 405–495 mL of blood. The CoE considers 450–550 mL of blood a standard donation, but requires that no more than 13% of the estimated total blood volume be withdrawn.

PAHO Recommendation: The amount of blood collected should not exceed 10.5 mL per kilogram of body weight. The minimum body weight for blood donors should be determined using the local information on adverse reactions to donation in relation to body mass. The blood volume collected from donors should be measured

by means of the weight of blood entering the collection bag, 472 mL of blood weight, on the average, 500 grams. The use of balances to monitor the total weight of blood while being collected is highly recommended. The blood services should promote iron–reach diets among their donors.

The application of more rigorous criteria regarding body mass, as determined by height and weight, and of iron intake is required for donors who volunteer for double–red cell donations.

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INTERVAL BETWEEN DONATIONS
(SEE HEMOGLOBIN LEVEL/HEMATOCRIT)

A regular whole blood donation removes about 10% of the hemoglobin in the donor's circulation. It takes between four and six weeks for well–fed, healthy individuals to restore hemoglobin to predonation values. Adequate time intervals between donations are necessary to allow the bone marrow sufficient time to replace the blood cells taken during the previous donation, and to avoid iron depletion in the donor. Particular consideration should be given to females in their reproductive years.

AABB requires the following minimun donation intervals: 8 weeks after whole blood donation, 16 weeks after 2 units' red cell collection, 4 weeks after infrequent plasma–pheresis, and 2 days after plasma, platelet or leukapheresis.

CoE recommends limiting the number of donations to four in males and three in females.

The minimun interval between whole blood donations required by CRS is 8 weeks. For collection of plasma, platelet or leuckocytes by apheresis the minimum interval is 48 hrs.

PAHO Recommendation: In order to avoid iron deficiency in blood donors, particularly in females of childbearing age, the frequency of donation should not exceed four times per year for males, and three times per year for females. Mimimum inter–donation intervals should be established based on studies of the local donor population.

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POLYCYTHEMIA VERA

Polycythemia vera is a malignant process of hematopoietic stem cells that results in elevated production of platelets, white cells and erythrocytes. The World Health Organization Diagnostic Criteria include: (1) hemoglobin levels higher than 16.5 g/dL for women and 18.5 g/dL for men or 15 g/dL for women and 17 g/dL for men if associated with a sustained increase of at least 2 g/dL from baseline that can not be attributed to correction of iron deficiency, or (2) presence of a mutation in the Janus Kinase 2 gene. Patients with polycythemia vera suffer from thrombosis and bleeding complications – oral, gastrointestinal bleeding, and coughing up blood are common signs. Elevated red blood cell mass increases blood oxygen–carrying capacity and its viscosity, resulting in decreased delivery of oxygen to the tissues. The microthrombi formation induces dizziness, vertigo, hypertension and severe headaches. Clinical management of polycythemia vera patients includes thrombosis prevention with low dose aspirin and phlebotomy to maintain the hematocrit below 42% in females and below 45% in males. Frequently, polycythemic patients offer their blood for transfusions.

PAHO Recommendation: Individuals with polycythemia vera should not be accepted as donors because their excess blood cells are the result of a myeloproliferative disease.

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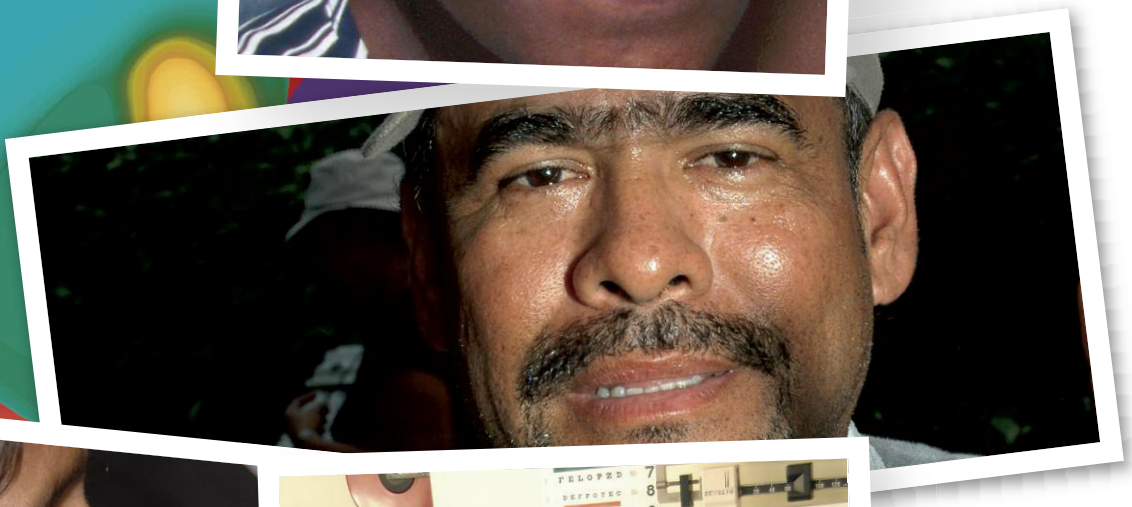

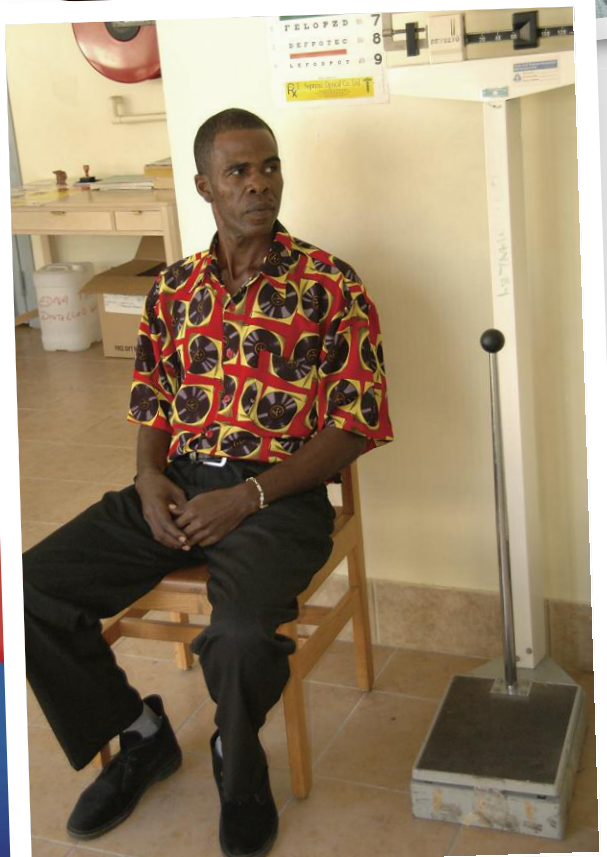
TELOPTO
DEFFOTEC
LETROPTO

CHRONIC ILLNESSES

CANCER

The normal process to maintain a healthy, well performing body includes the production of new cells to replace old ones that have diminished or totally lost their ability to function. When new cells are produced at a higher than needed rate, and the old cells do not die, the excess growth forms a tumor. Tumors that grow in only one place of the body are called benign; those tumors that can invade other tissues or organs are called malignant. Eating healthy foods, staying active, protecting the skin from the sun, avoiding risky behaviors —such as smoking—, and getting screened for cancer, contribute to the reduction of the personal risk of cancer.

Immunosuppression, transmission of oncogenic viruses, and virus activation are potential risks of allogeneic blood transfusions. Receiving blood transfusions has been implicated as a possible risk factor for non-Hodgkin lymphoma. Although cases of cancer transmission have been associated with solid organ transplantation, no case of transmission by transfusion is known. Considering the absence of reported cases to date and based on available data: 1) in situ cancers or localized cancers cured with excision or treatment: accept individual as blood donor if he/she has been succesfully treated, and no further therapy is required; 2) skin cancer, except melanoma: accept if treated, healed and no further treatment is required; and 3) hematological cancers, leukemia, lymphoma: indefinite deferral or accept if cancer free for a defined period of time after completion of treatment and considered cured for ten years.

The ARC considers that, in most cases, people who remain free of cancer five years after the completion of treatment are acceptable as donors. The five-year deferral is to protect the donor's health by ensuring as far as possible that the cancer has gone and will not recur. However, people with a history of cancers, such as leukemia, lymphoma and myeloma, that involve the blood production system directly, are permanently excluded from donating for the benefit of their own health.

For the CoE, cancer usually requires permanent deferral. The physician in charge may make exceptions to this rule in selected cases.

> PAHO Recommendation: Individuals who have recovered from in situ tumors, skin and hematological cancers can donate blood if the cancer has been successfully treated and they are in good health. Potential blood donors should be made aware of the importance of personal healthy habits in the prevention of cancer. Additionally, prevention of certain infections, such as hepatitis B and hepatitis C, and human papilomaviruses, will result in reduced risk of liver and cervical cancer, respectivelly.

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DIABETES

Diabetes mellitus is a term used to describe a group of diseases characterized by high levels of glucose in blood that result from insufficient insulin production or action. Type 1 diabetes arises as a consequence of the pancreas loosing the cells that produce insulin. Patients suffering from Type 1 diabetes must receive insulin injections. Type 2 diabetes results from increased insulin requirements associated with obesity, lack of physical activity or aging. Patients with Type 2 diabetes can control their blood levels of glucose with appropriate diet and exercise and, in some cases, with oral medication.

Diabetes is frequently associated with long–term complications causing damage or failure of various organs, including the eyes, kidneys, heart and nerves. Retinopathy, nephropathy and neuropathy might be considered expressions of the functional and morphological changes at the level of microcirculation. Cardiomyopathy may occur with or without co–existence of vascular diseases. Early diagnosis of diabetes, appropriate diet and insulin therapy prevent progression into severe disease.

Prospective donors who require insulin are deferred by the CoE and H–Q; the ARC requires a consultation to the medical officials. All three institutions allow blood donation by individuals whose diabetes is well controlled through diet or oral medication.

PAHO Recommendation: Individuals with diagnosis of diabetes can be blood donors if the disease is well controlled (absence of permanent thirst and polyuria) by oral medication or diet. Diabetic patients who require insulin or who have serious diabetes–related health issues such as kidney, heart, or eye disease, should not be allowed to donate blood. Appropriate diet and exercise to maintain optimal body weight should be promoted among prospective donors. Periodic determination of blood glucose levels should be encouraged.

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EPILEPSY/SEIZURES

The US National Institute of Neurogical Disorders and Stroke describes epilepsy as "a brain disorder in which a cluster of nerve cells, or neurons, in the brain sometimes signal abnormally. In epilepsy, the normal pattern of neuronal activity becomes disturbed, causing strange sensations, emotions, and behaviors or sometimes convulsions, muscle spasms, and loss of consciousness." Electroencephalocardiograms or brain scans are used to diagnose epilepsy in individuals who have suffered more than two seizures. Partial seizures do not result in loss of consciousness, although the individual may lose awarness for a short period of time. Generalized seizures may result in brief lapses of awareness, sudden jerk of extremities, loss of conciousness, loss of balance, loss of blader control, tongue biting, and body stiffening.

The onset of epilepsy can be associated with several factors, such as meningitis, seizures in infancy due to very high fever, and accidents that result in direct injury to the neurons. Temporary deprivation of oxygen to the brain cells, such as that observed in strokes, may also result in epilepsy. Increased frequency of seizures has been linked to extreme stress, sleep deprivation, excessive use of and withdrawal from alcohol, and use of cocaine. Mantaining overall health, therefore, helps control epilepsy.

Blood donation may induce transitory cerebral hypoxia in epileptic patients which, in turn, may increase the risk for adverse reactions to donation, such as syncope and convulsions.

The CoE allows blood donation three years after treatment if the individual is symptom–free.

> PAHO Recommendation: Individuals with history of epilepsy can donate blood if they have been free of seizures for three years, irrespective of medication.

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HEART AND BLOOD VESSEL DISEASE

Persons with circulatory problems are prone to suffer cardiovascular and vasculocerebral complications as a consequence of acute hemodynamic changes. Therefore, heart disease history should be very carefully evaluated in prospective blood donors. Individuals with a history of heart disease, especially coronary disease, angina pectoris, severe cardiac arrhythmia, history of cerebral vascular diseases, arterial thrombosis or recurrent venous thrombosis should be deferred as blood donors.

ARC and CoE require that individuals who have had a heart attack be deferred permanently. H–Q defers prospective donors who have suffered myocardial infarction orischemic heart failure, or have undergone coronary bypass.

> PAHO Recommendation: Individuals with a history of cardiovascular disease who are symptom–free and willing to become blood donors should get written authorization from their cardiologists before blood donation. The decision to accept or defer persons with a history of cardiovascular disease as blood donors should be made on an individual basis.

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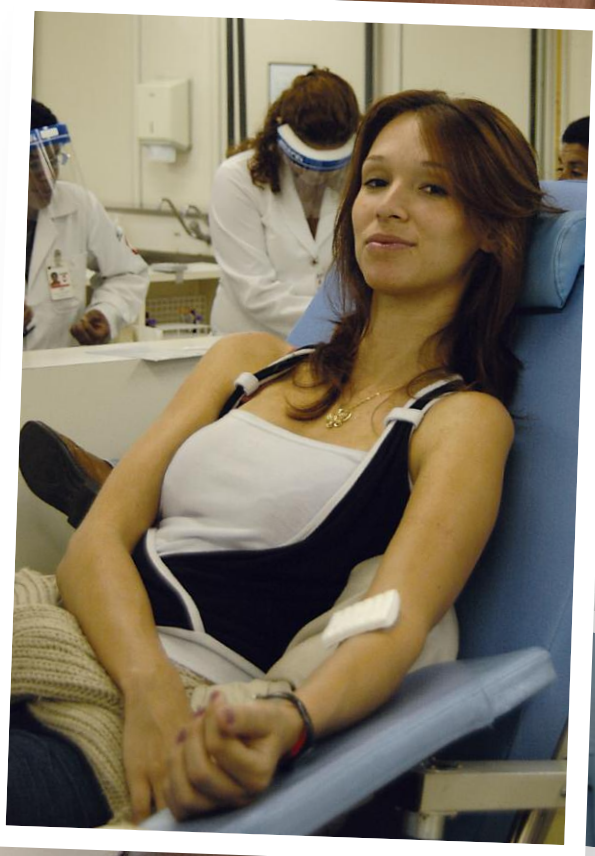

INFECTIOUS CONDITIONS

GENERAL CONSIDERATIONS
(SEE BODY TEMPERATURE/FEVER AND SECTIONS ON SPECIFIC DISEASES)

Prospective donors should be healthy on the day when they donate blood. In the case of infectious conditions, an individual who is sick or recovering from a recent illness and whose blood is taken may not only suffer additional complications of the disease but also have an adverse reaction to blood donation as he/she may be psychologically unprepared to donate blood. On the other hand, blood transfusions pose a risk of transmission of infections when the blood unit is donated by an asymptomatic donor who has infectious pathogenic microorganisms in his/her blood stream.

Prospective donors who are infected may not show any signs or symptoms of disease because they are in the incubation period – the time elapsed between exposure to a pathogenic organism and when symptoms and signs are first apparent. The incubation period can be as short as a few hours or as long as many years, as is the case of AIDS, hepatitis, Chagas' and Creutzfeldt–Jakob diseases.

When exposure to a certain microogranism is suspected because the individual has symptoms, specific laboratory tests can detect the causative agent only after the appearance in sufficient quantities of either complete microorganisms or microbial components at the site of infection or of antibodies in the blood stream. Nevertheless, these markers of infections may take several weeks and even months before they reach levels that are detectable by laborarory diagnostic methods – a time that is called the "window period". Furthermore, individuals who develop symptomatic disease may feel well after a period of time – either because they get antimicrobial treatment or because the disease runs its course– but continue harboring infectious microorganisms.

To prevent the transmision of infectious agents through transfusions, persons who are likely to have come in contact with transfusion–transmisible infectious agents, although they may be feeling well, should be deferred for periods of time that extend beyond the length of the incubation periods. Additionally, individuals who have been diagnosed as being infected by microbes that are capable of producing long lasting and chronic infections should be deferred.

The CoE considers that carriers of HIV 1/2, HTLV I/II, HBV, HCV, *Babesia, Leishmania* (Kala Azar), *Trypanosoma cruzi* (Chagas' disease), and persons whose sexual behavior puts them at high risk of acquiring severe infectious diseases than can be transmitted by blood should be deferred permanently.

PAHO Recommendation: Disease-specific recommendations are given in the following sections.

In addition, it is considered necessary to establish procedures and mechanisms for defining the local criteria for recruitment, selection and deferral of blood donors, in relation to those infectious conditions that may be transmitted through transfusions for which laboratory tests are not routinely done. This involves the analyses of the local and global epidemiological situation, migration and travel patterns of the population, the sensitivity and specificity of the laboratory methods available, and the characteristics of the patients who will receive the blood components. The implementation of national standards for blood donor education, recruitment, selection and deferral is highly recommended. In addition to the diseases and agents listed in the following sections, it is recommended to include *Borrelia*, *Coxiella*, *Bartonella*, and West Nile virus in the situation analysis.

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BABESIOSIS

Babesiosis is a zoonotic infection maintained in nature by a cycle that involves wild animals and ticks that feed on those animals and on humans. The infection can either be asymptomatic or result in illness. When symptoms occur, usually one to eight weeks post infection, they may be flu–like mild and self–limiting; infants, elderely and immunocompromised patients, however, may develop severe illness and die. Chronic, asymptomatic infections lasting over a year have been observed in patients and asymptomatic blood donors. *Babesia* parasites infect the human red blood cells and, therefore, can be efficiently transmitted by transfusion.

AABB, CoE and CRS require permanent deferral of prospective donors who have had diagnosis of babesiosis.

> PAHO Recommendation: Prospective donors who have had diagnosis of babesiosis should be deferred from blood donation. When assessing the risk of transfusion–transmitted infections, despite the limited extension of the geographic area where the various *Babesia* species have been reported, human migration and mobility should be considered by blood services in *Babesia* non–endemic areas to establish criteria for recruitment and selection of blood donors.

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BRUCELLOSIS

Brucellosis is an intracellular bacterial infection transmitted to humans from domestic animals that harbour *Brucella* in their secretions and excrement. Direct contact with infected animals, ingestion of non–pasteurized dairy products or undercooked meat, inhalation of manure particles and exposure though open skin are common means of human infection. In humans, brucellosis can be an acute, sub–acute and/or chronic disease. The incubation period is variable, usually from 5 to 60 days, but in some rare instances symptoms may take several months to surface. The disease is characterized by recurrent episodes of fever, weakness, perspiration, headache, backache, and variable pain in joints, back, and testicles. Viable *Brucella* can persist in the blood stream of asymptomatic persons for prolonged periods of time and, therefore, can be efficiently transmitted by transfusion.

The CoE requires that individuals with history of Brucellosis be deferred for two years following full recovery

> PAHO Recommendation: Individuals with history of *Brucella* infection should be deferred for a year after appropriate treatment for the infection. Asymptomatic individuals who may have been exposed to *Brucella* should be deferred for at least eight weeks after potential exposure. Potential contact with *Brucella*–infected animals or animal products, and signs and symptoms of brucellosis should be investigated among prospective blood donors who come from *Brucella*–endemic areas

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COMMON COLD

The common cold is an infectious syndrome caused by any one of over 100 distinct viruses, the rhinoviruses, which can be transmitted from–person–to–person, by exposure to contaminated aerosols produced by coughing and sneezing, and through contact with contaminated surfaces such as telephones and door knobs. Symptoms, characterized by sore throat, runny nose, nasal congestion, watery eyes and malaise, ussually occur within two days after infection and last around one week. Almost all colds clear up in less than two weeks without complications. Rhinovirus infections are limited to the nasopharynx, middle ear and sinuses because the viruses replicate only at temperatures that are lower than the normal body temperature, 33–35°C. The rhinoviruses do not reach the bloodstream. Persons suffering from common colds should be deferred not only to protect them but also to reduce the possibility of transmitting a more virulent infectious agent, such as *Babesia*, *Brucella*, dengue, malaria, and West Nile virus, which may be causing only a flu–like disease.

ARC, CoE and H–Q accept prospective donors if they are feeling well on the day of donation.

PAHO Recommendation: Individuals who have a common cold should be deferred for two weeks after cessation of symptoms. During dengue season or dengue outbreaks individuals with flu-like symptoms should be deferred for four weeks. Hand washing should be promoted to reduce the risk of transmission of rhinoviruses.

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DENGUE

In nature, dengue is an infection transmitted from humans to humans by the bite of virus-carrying mosquitoes. Exposure of health care workers to infected blood has also been reported as an efficient means of transmission. Dengue, which is caused by four different serotypes of the virus, is endemic in more than 100 countries – in Africa, the Americas, the Eastern Mediterranean, Southeast Asia, and Western Pacific – and is spreading to new areas. The infection may be asymptomatic. After an incubation period of 3–14 days, disease may develop as undifferentiated fever, dengue fever, dengue hemorrhagic fever, or dengue shock syndrome. Dengue fever usually lasts 5–7 days, is self-limiting and characterized by elevated body temperature, intense pain in joints and muscles, inflammation of the lymph nodes, hemorrhagic signs and occasional eruption of the skin. In dengue hemorrhagic fever, or severe dengue, the patient presents with increased vascular permeability. Dengue shock syndrome includes hypothermia, sweating, hepatomegaly and severe abdominal pain. The time of potential transmission of the dengue viruses corresponds to that of viremia in the infected individual, which begins a day before the onset of fever and lasts until about one week after symptoms subside. Studies of blood donors in dengue endemic areas during dengue outbreaks have shown that up to 3 of every 1,000 blood donors may harbour dengue viruses in their blood at the time of donation. There is neither specific antiviral treatment nor vaccine against dengue. Although infection with one dengue serotype stimulates immunologic response to that serotype, infections with any of the other three types of dengue virus may result in disease.

The CoE requires deferring for six months those individuals who have traveled to tropical areas, only if they have not suffered an unexplained fever or illness.

PAHO Recommendation: Defer donation for four weeks after full recovery from clinical dengue. In dengue-endemic areas and during dengue outbreaks, defer for four weeks those individuals with flu-like symptoms. In non-endemic areas, defer for two weeks potential asyntomatic donors whose travel histories place them at risk of dengue infection.

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HEPATITIS

Hepatitis, a generic term that means inflammation of the liver, can be caused by infectious microorganisms, biological toxins, chemical agents, including drugs, and metabolic or autoimmune processes. Although hepatic injury mediated by chemical agents accounts for more than half of the cases of acute liver failure, the main causes of liver damage worldwide are infectious. Infections by hepatitis A, hepatitis B, hepatitis C, hepatitis D, hepatitis E, herpex simplex, cytomegalo-, Epstein–Barr, yellow fever and adeno– viruses, in addition to *Coxiella, Leptospira, and Toxoplama*, can result in acute hepatitis. Hepatitis A virus is acquired by ingesting food or water that has become contaminated with feces from an infected individual. Hepatitis B and hepatitis C viruses may be transmitted by exposure to contaminated blood through blood transfusions, needle sticks, from mother–to–child– and through sex with an infected person. Hepatitis B –in conjunction with hepatitis D– and hepatitis C viruses can cause asymptomatic infection or chronic hepatitis, cirrhosis, liver failure and hepatocarcinoma. Hepatitis B infection is preventable by vaccination.

The requirements of the AABB, ARC, CRS and H–Q are summarized below.

Repeatedly reactive test for anti–HBcore on more than one occasion.
AABB: Permanent deferral. CRS: Permanent deferral.

Confirmed positive test for hepatitis B surface antigen (HBsAg) and/or HCV.
AABB: Permanent deferral. CoE: Permanent deferral. CRS: Permanent deferral.

History of viral hepatitis after 11th birthday.
AABB: Permanent deferral. CRS: Permanent deferral.

History of jaundice or hepatitis.
CoE: individuals may be accepted as blood donors at discretion of the appropriate medical authority, provided approved HBsAg and HCV tests are negative.

Close household contact with hepatitis B (acute or chronic).
AABB: 12–month deferral. CoE: six months from time of contact unless confirmed to be immune.
CRS: 12–month deferral.

Hospital staff coming into direct contact with patients with hepatitis.
CoE: Accepted as a donor at discretion of appropriate competent medical authority, providing they have not suffered an inoculation or mucous injury, in which case they should be deferred for six months.

Current sexual partner of hepatitis B or hepatitis C patient.
AABB: 12–month deferral. CoE: Deferred unless demonstrated to be immune.
CRS: 12–month deferral.

Previous sexual partner of people with hepatitis B.
CoE: six–month deferral since las sexual contact.

PAHO Recommendation: Prospective donors with history of hepatitis B or hepatitis C should be deferred permanently. Prospective donors who have been exposed to individuals with hepatitis B or hepatitis C should be deferred for six months after exposure. Individuals who have engaged in risky behaviours for hepatitis B and hepatitis C should be deferred for 12 months. Individuals with history of jaundice after their 11th birthday should be encouraged to be tested for HBV and HCV infection. Health systems should promote hepatitis B universal vaccination of infants, of health workers who are at risk of being exposed to blood or other body fluids, of household contacts of hepatitis B patients, and of other individuals who engage in high–risk behaviors. Universal precautions should be encouraged among health service staff.

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HUMAN IMMUNODEFICIENCY VIRUS (HIV)

(SEE DRUG USE [RECREATIONAL], BODY PIERCING, TATTOOS, AND SEXUAL BEHAVIOURS)

The HIV epidemic in the Region of the Americas is, for the vast majority of countries, a concentrated epidemic. This means that only in few of them the prevalence of infection is above 1% in the general population. Nevertheless, some groups, known as more at risk populations, are disproportionally affected with prevalence rates many-fold higher than the general population. Infection with HIV occurs via blood, pre-ejaculate, semen, vaginal fluid, or breast milk from infected people. Within these bodily fluids, HIV may be present as both free viral particles and within cells. The major routes of transmission include unprotected sexual intercourse, sharing of contaminated needles, transmission from an infected mother to her baby either at birth or through breast milk, and contaminated blood transfusions. The virus attacks the immune system leading to secondary and opportunistic infections and the development of cancer. The term acquired immunodeficiency syndrome (AIDS) refers to the most advanced stage of the disease, characterized by complications of severe impairment of the host defense mechanisms. The most efficient and cost-beneficial way of protecting the safety of the blood supply is by deferring from donation those individuals, men and women, who may be at high risk of acquiring and, therefore, transmitting HIV and other infections. The risk of an individual acquiring HIV and other infections is directly related to his/her engagement in risk behaviors, such as unsafe sex – practicing unprotected anal sex, having sex with several partners, having sex with a commercial sex worker, men having sex with men-, injecting illegal drugs, tattooing, and receiving unsafe injections or blood transfusions.

The AABB, ARC, CoE and CRS have the following criteria:

Individuals with present or past clinical or laboratory evidence of infection with HIV.
AABB: Permanent deferral. CoE: Permanent deferral. CRS: Permanent deferral.

Individuals who donated the only unit of blood or component that resulted in the apparent transmission of HIV.
AABB and CRS: Permanent deferral.

Current sexual contact with an individual with HIV infection.
ARC and CRS: Deferral for 12 months after last sexual contact.

Previous sexual partner of people with HIV or at high risk of HIV infection.
AABB, ARC, CoE, CRS: Deferral for 12 months after last sexual contact.

> PAHO Recommendation: Individuals with diagnosis of HIV infection should be deferred permanently. Those individuals who have engaged in behaviors that pose a risk for HIV infection should be deferred as blood donors for a period of 12 months after the last occurrence. National public education programs aimed at prevention of risk behaviors and the promotion of voluntary testing at facilities that are separate from blood services are highly recommended.

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LEISHMANIASIS

Leishmaniasis is an intracellular parasitic infection which in nature is transmitted to humans from other infected humans or animals by the bite of sandflies. The endemic areas of the world include Latin America (except Chile and Uruguay), Southern Europe, the Middle East, North and East Africa, and Asia (except Southeast Asia). Human–to–human transmission by infected needles, blood transfusion and organ transplantation has been reported. In humans, the disease is caused by more than 20 species of *Leishmania* and can result in cutaneous, mucocutaneous or visceral symptoms. The incubation period is variable, and may last from a few days to several years. Infected individuals may have viable parasites circulating in their blood for prolonged periods even after clinical recovery.

The CoE requires permanent deferral of prospective donors with history of leishmaniasis.

> PAHO Recommendation: Permanently defer as blood donors those individuals who have had *Leishmania* infections. Defer for two years potential asymptomatic donors whose travel or transfusion histories place them at risk of being infected. Individuals who might be exposed to infected sandflies should be advised to protect themselves from insect bites by using repellent, apropriate clothing, screens and bed nets.

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MALARIA

Malaria is a disease caused by *Plasmodium*, an intracelular parasite transmitted to humans by the bite of infected female anopheles mosquitoes. The disease occurs in Africa, Latin America, the Caribbean, Asia, the Middle East, and some parts of Europe. There are four species of *Plasmodium* which cause human malaria: *P. falciparum, P. malariae, P. ovale, and P. vivax*. In the Americas, the disease is endemic in all countries from Mexico, through Central and South America, to Argentina, with the exception of Chile and Uruguay. The great majority of malaria cases in the Region occur in those countries. In the Caribbean, malaria is endemic only in Hispaniola, the island shared by the Dominican Republic and Haiti. In the Region of the Americas, *P. vivax* is the predominant species, responsible for 75% of reported cases; *P. falciparum* accounts for almost all other illnesses, although some cases of *P. malariae* are also reported from a few countries in South America. *P. falciparum* is the only species found in Hispaniola.

Upon entry to the body, the parasites initially invade liver cells, where they reproduce; the liver cells rupture and release a stage of the parasite capable of infecting circulating red blood cells. The parasites further reproduce in the erythrocytes, break out and enter other circulating red blood cells. Symptoms of malaria may begin 10 to 15 days after infection although the incubation period may last for months. Some infected individuals may not become ill or have only mild disease characterized by fever and malaise. Clinical features of uncomplicated malaria include fever, chills, headache, diarrhea, and vomiting, usually presenting in cold–hot–sweat cycles every two or three days, depending on the infecting species of *Plasmodium*. Severe malaria, usually associated with infection by *P. falciparum*, is the result of organ failure or metabolic and hematologic abnormalities and may result in death. In some cases, *P. ovale* and *P. vivax* parasites remain in the liver and do not produce the red blood cell–infecting stage for periods that may vary from 6 to 36 months. The parasites, however, may reactivate at any time and produce illness. *P. malariae* can persist in the blood stream for many years without inducing symptomatology.

Malaria can be treated with full recovery if the correct diagnosis is made and appropriate treament is initiated promptly. *P. falciparum* parasites found in the Caribbean, Mexico and Central America are susceptible to chloroquine, the most commonly used antimalarial drug. In South America, however, very high levels of treatment failure with chloroquine for the prevalent strain of *P. falciparum* have been scientifically confirmed. Based on that evidence, all countries in South America have changed drug policy and are using Artemesin–based Combination Therapies (ACT's) for infections with that particular parasite. Complete adherence to recommended national treatment regimens for both *P. vivax* and *P. falciparum* is extremely important in order to insure cure of the disease and full recovery.

The AABB, ARC, CoE and CRS have the following criteria:

Individuals who have traveled to a malaria–endemic area.
AABB, CRS: Defer for 12 months after departing malaria–endemic area if free of unexplained symptoms since departure.

Individuals coming from, or who have lived at least five consecutive years in a country in which malaria is considered endemic.
AABB, CRS: Three–year deferral after departure from malaria–endemic area.
CoE: Individuals who lived in a malaria–endemic area within the first five years of life may be accepted as blood donors six months after their last visit to an endemic area provided the result of a validated immunological or molecular genomic test proves negative. If the test is positive, defer permanently as cellular donor. If the test is not available, the individual can be accepted as a blood donor if there is a symptom–free period of a minimum of three months since return from the last visit to an endemic area. All other persons can be accepted as donors six months after returning if they have had no febrile episodes during or after their stay in the area.
ARC: Defer for four months, after which a malaria test is performed. If this test is negative, the donation can be used for transfusion or plasma product production.

Individuals with a history of diagnosis of malaria.
AABB, CRS: Defer for three years after becoming asymptomatic.
CoE: Deferral until asymptomatic and off treatment. They may donate plasma after

three years, and red cells if the result of a validated test is negative. The deferral periods and immunological test mentioned may be omitted for those whose red cells are discarded and the plasma is used exclusively for fractionation into blood products.

PAHO Recommendation: Individuals who might be exposed to malaria–infected mosquitoes should be advised to protect themselves from insect bites by using repellent, appropriate clothing, screens and bed nets.

Due to the mobility of blood donors, it is essential to have available at the blood donation facility an updated map and an alphabetical list of malaria–endemic countries, zones, and cities for consultation when prospective donors report trips lasting more than five days.

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SYPHILIS

(SEE SEXUAL BEHAVIOURS)

Syphilis is a sexually transmitted disease (STD) caused by a bacterium, *Treponema pallidum*. Transmission occurs during vaginal, anal, or oral sex. Nine to 90 days after infection a single lesion, known as chancre, appears in the site of bacterial inoculation –penis, vagina, cervix, perianus, anal canal, mouth-, depending on the gender and sexual practices of the individual. The initial lesion of primary syphilis may disappear four or five weeks later, even if the patient is not treated, but the bacteria remain in the body. Four to eight weeks later, secondary syphilis presents as fever and a

generalized rash that includes the soles, palms and scalp, If untreated, the infection becomes asymptomatic for periods of time of over two years. Tertiary syphilis is then manifested by neurologic, cardiovascular and gummatous symptoms. Pregnant women who are infected with *T. pallidum* may transmit the bacterium to their unborn children. Congenital syphilis can result in miscarriage, stillbirth, prematurity, nasal chondritis, neurological abnormalities, deafness, and dental malformations. The genital ulcers caused by syphilis can bleed easily and, when they come into contact with oral and rectal mucosa during sex, increase the infectiousness of and susceptibility to HIV. *T. pallidum* is inactivated by low temperature and, therefore, is not transmitted by blood stored at 4–6°C for more than 72 hrs. Transmission of the infection by platelet transfusion is possible.

AABB requires that those individuals who have a diagnosis of syphilis be deferred for 12 months.

> PAHO Recommendation: Individuals who are reactive in syphilis antibody screening tests should be deferred permanently. Donors with past clinical evidence of STD other that syphilis can be accepted after 12 months of effective treatement, given that they meet all other criteria for blood donation. Potential blood donors should be encouraged to protect themselves and their partners by practicing safe sex.

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TOXOPLASMOSIS

Toxoplasmosis is a parasitic disease caused by the protozoan *Toxoplasma gondii*. The parasite infects a large number of wild and domestic animals, which are the source of parasites that are infectious for humans. The routes of human infection are ingestion of the parasites, transplacental passage from infected mother to her unborn child, organ and tissue transplantation, and blood transfusion. Undercooked meat of infected

lamb, pork or venison, drinking water that has been contaminated with cat feces, foods that get contaminated during handling, contaminated cat litter boxes and soil are the main sources of infection. Infected cats play a central role in the transmission of *T. gondii* because they excret large numbers of infectious parasites in their feces. Young children and immunocompromised patients, or those who have recently received an organ transplant, may develop severe toxoplasmosis. During acute toxoplasmosis, symptoms are often influenza–like: swollen lymph nodes, or muscle aches and pains that last for a month or more. The acute disease is usually mild or asymptomatic, except for fetal infections transmitted by acutely infected pregnant women, which courses as a devastating disease. The diagnosis of acute toxoplasmosis based on clinical symptomatology and routine laboratory technology has limitations.

AABB, ARC, CoE, CRS do not include a specific requirement for *T. gondii*.

PAHO Recommendation: *Toxoplasma gondii* infection in blood donors represents a risk for transmission to immunocompromised or immunosuppressed blood transfusion recipients. Preparation of blood components intended for these groups of patients should be given special attention. It may be useful to establish a group of anti–*Toxoplasma* negative repeat blood donors.

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TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES

Transmissible Spongiform Encephalopathies (TSE) are human and animal fatal diseases that can arise spontaneously, be inherited or be acquired by infection. TSE are caused by prions –proteinaceous infectious particles that do not have genetic material in the form of nuclei acids. Prions are modified host proteins which become pathogenic. Human TSE include Creutzfeldt–Jakob disease (CJD), Fatal Familial Insomnia, Gerstmann–Straussler–Scheinker Syndrome, and Kuru. Animal TSE are known to affect

mink, deer, elk, cats, sheep, goats, and cows, among other animals. Bovine spongiform enchephalopathy (BSE), also known as "mad cow disease," has been transmitted to humans by contaminated beef, giving rise to a human variant of CJD (vCJD) which has the capacity to accummulate in lymphiod tissue. Prions can be transmitted from human to human via surgical equipment, transplants, and blood transfusions.

AABB, CoE and CRS require permanent deferral for those individuals who have been diagnosed with TSE.

> PAHO Recommendation: Individuals with diagnosis of TSE as well as those who received extract derived from human pituitary gland, dura mater or corneal grafts; those with family risk of human TSE; those with behavioral risk of vCJD; and those who received transfusions in the UK from 1980 to 1996 should be deferred as blood donors.

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TRYPANOSOMA CRUZI/CHAGAS' DISEASE

Chagas' disease is a human parasitic disease which occurs primarily in the mainland of the American continent, from the Southern part of the United States to Argentina and Chile. The etiologic agent, *Trypanosoma cruzi*, is transmitted to humans and other mammals by contaminated feces of the hematophagous bugs of the Reduvid family. These insects, known by numerous local names, such as benchuca, *vinchuca*, *kissing bug*, *chipo*, *pito* and *barbeiro*, defecate as they feed on their host, liberating infectious parasites that reach the blood stream through the punctured skin or the mucosa. *T. cruzi* can also be transmitted through blood transfusion, organ transplantation, from pregnant women to their fetus, by laboratory accidents, and by ingestion of food contaminated with infected Triatominae feces. The human disease occurs in two stages: the acute stage shortly after infection, and the chronic one. Most acute

infections are subclinical. From 5% to 40% of untreated patients may develop serious chronic complications, such as cardiopathy, megaoesophagus, and megacolon, ten or more years after infection. The parasites are regularly present in the blood of infected individuals during the acute period and may persist in very small numbers throughout life in both symptomatic and asymptomatic patients.

AABB, CoE and CRS require that individuals with clinical or serologic diagnosis of *T. cruzi* infection be deferred permanently.

PAHO Recommendation: Individuals with previous diagnosis if *T. cruzi* infection should be deferred permanently. Donors who are reactive in laboratory screening tests should be deferred permanently and referred to a medical facility for further analyses, diagnosis, and follow–up. Children and women relatives of the positive donors should also be evaluated and given anti *T. cruzi* treatment, if necessary. Efforts should be made to recruit blood donors from population groups that have low risk of being infected with *T. cruzi*. In non–endemic areas, travel and place of birth should be included in the predonation interview.

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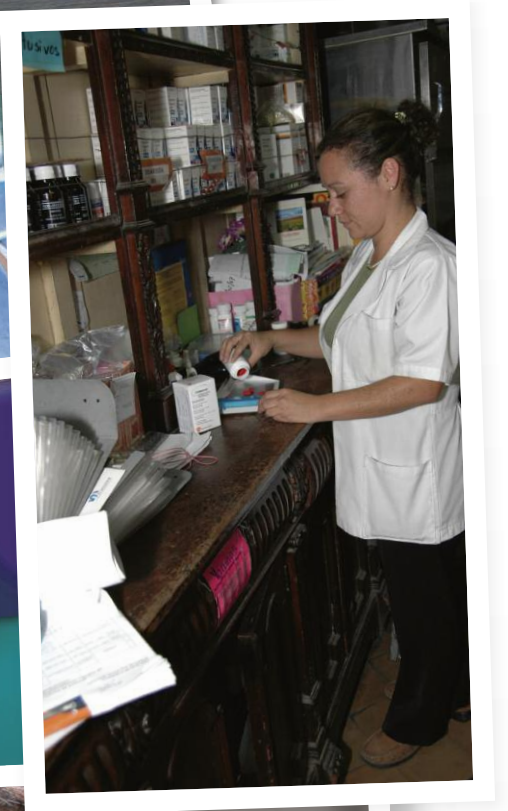

HAVE YOU BEEN TREATED AT A HOSPITAL?

MAJOR SURGERY

(SEE DENTAL PROCEDURES, MEDICATION, TRANSFUSION, TRANSPLANT)

Major surgery involves invasive procedures and support treatment during convalescence. Surgical procedures induce metabolic changes in the patient and are a risk factor for infections. Furthermore, patients who undergo surgical procedures may receive transfusions. For their own protection, surgical patients should consider donating blood only after they have recovered fully.

The CoE requires deferral for six months after surgery. The ARC requires medical examination to determine if the individual is fit to donate blood after surgery.

> PAHO Recommendation: Since many factors intervene in patient recovery (presurgery health and surgical technique, among others) a medical evaluation is necessary before considering blood donation by individuals who undergo major surgery. In general, for uncomplicated surgeries, the donor should be deferred for six months after surgery. If transfusion was received, the deferral period should be extended to 12–months.

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TRANSFUSION
(SEE INFECTIOUS CONDITIONS)

Transfusions represent a risk for acquiring infections that may be asymptomatic for prolonged periods of time, such as HIV, HBV, HCV, HTLV, and *T. cruzi*.

AABB: requires a 12–month deferral. People having received blood transfusions in the UK since 1980 are permantly deferred.

ARC: requires a 12–month deferral.

CoE: is six–month deferral or four–months when a NAT test for hepatitis C is negative.

H–Q: a 12–month deferral is required. People having received a blood transfusion in Western Europe since 1 January 1980 are permanently deferred.

> PAHO Recommendation: Individuals who receive blood transfusions should not be considered as blood donors for 12 months after the transfusion. Individuals who have received blood transfusions should be encouraged to be tested for the transfusion–transmissible infections prevalent in the area at three–month intervals after the transfusion. Special recommendations should be given to sexually active patients to practice safe sex during the deferral period.

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TRANSPLANT
(SEE MAJOR SURGERY, TRANSFUSION,
TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES)

Organ, tissue, and cell transplantation is used to treat patients with severe clinical conditions. Transplants have been shown to be the source of viral, bacterial, parasitic and fungal infections for organ–recipients. Additionally, because patients receive immunosuppressive agents to reduce the risk of graft rejection, microorganisms that may be causing latent infection in the patient before transplantation are very likely to reactivate.

AABB and CRS: require 12–month deferral after receiving a transplant. CoE requires permanent deferral.

> PAHO Recommendation: Solid organ and hematopoietic stem cell recipients should be permanently deferred as blood donors. Recipients of tissue allografts should be deferred for 12 months.

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Chocolate
milk

UNDESIRABLE PAST EXPERIENCES

HISTORY OF SEVERE POST DONATION REACTION

Blood donation is a very safe procedure. Some donors, however, can have adverse reactions, such as dizziness, nausea, vomiting, difficulty breathing, chest pains, loss of bladder control, convulsions, and cardiac arrest. The rates of adverse reactions reported vary from 0.8% to 1.2%, depending on the age, weight, gender, level of hydration, and previous donation history of the donors. Good interpersonal skills of the phlebotomist contribute to the reduction of adverse reactions. Reactions are considered severe in only 3% of all cases. First time and teen–aged donors have a higher rate of adverse reactions to blood donation. Slight reactions, such as dizziness, faiting and hematoma can be prevented by drinking water before donation, good personal relationship with blood collection staff, and skilled blood collection by phlebotomists.

None of the documents consulted as examples of international, national and institutional criteria includes history of adverse reactions to donation as factor for donor deferral.

PAHO Recommendation: Donors who have suffered severe reactions to blood donation are likely to have similar adverse reactions in subsequent donations and, therefore, should be deferred. Interviewers, phlebotomists, and volunteers should be trained to provide the best atmosphere for the blood donors before, during and after the actual process of blood collection. Interpersonal and technical skills of phlebotomists help determine overall donor satisfaction and return rate. A system to document, prevent and treat adverse reactions to blood donation should be established by the blood donor services.

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INCARCERATION

Inmate populations, both male and female, have high rates of hepatitis B, hepatitis C, HIV and other infectious diseases. New inmates usually have high prevalence rates of these infections when entering the correction facilities because they tend to engage in risky behaviours, such as intravenous illegal drug use and unprotected sex. In addition to continued unhealthy personal behaviours while imprisoned, the crowded environment, and the limited access to health promotion may enhace the risk of infection transmission to other inmates.

AABB, ARC, CRS and H–Q require that those individualswho have been incarcerated for longer than 72 consecutive hrs. be deferred as blood donors for 12 months.

PAHO Recommendation: Individuals with history of incarceration during the previous 12 months should be deferred from blood donation. Blood collection drives should not be carried out in correction facilities. Establishing systems for voluntary testing of new inmates for HIV, HBV, HCV, tuberculosis and sexually transmitted infections is encouraged. Prevention measures aimed at both inmates and staff should be promoted.

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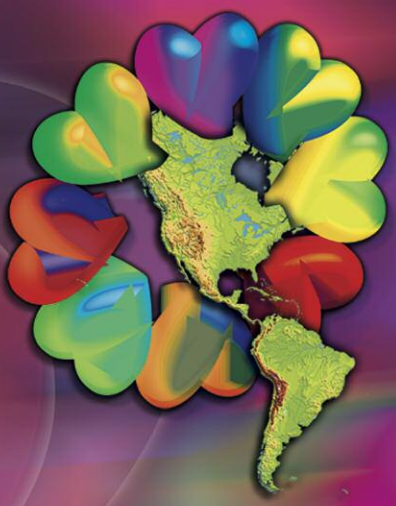
ANNEXES



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WORLD HEALTH ORGANIZATION

48th DIRECTING COUNCIL
60th SESSION OF THE REGIONAL COMMITTEE

Washington, D.C., USA, 29 September-3 October 2008

Provisional Agenda Item 4.7

CD48/11 (Eng.)
6 August 2008
ORIGINAL: ENGLISH

IMPROVING BLOOD AVAILABILITY AND TRANSFUSION SAFETY IN THE AMERICAS

Background

1. Since 1975 the World Health Assembly, the World Health Organization Executive Board and the Directing Council of the Pan American Health Organization have adopted several resolutions urging Member States to promote the establishment of coordinated blood services based on voluntary non-remunerated blood donation and on quality assurance, and to enact legislation and formulate national blood policies that facilitate the cost-effective organization and operation of blood services. The Governing Bodies have made it clear that it is necessary for the Member States to focus on blood transfusion safety as a means to improve patient care and to reduce the burden of HIV and other infections in the general population.

2. In 1999 the PAHO Directing Council adopted Resolution CD41.R15 and a Plan of Action that pursued the universal screening of blood units for HIV, hepatitis B (HBV) hepatitis C (HCV), and syphilis in the Region, and for *T. cruzi* in continental Latin America, universal participation of blood banks in programs of external evaluation of performance, 50% voluntary blood donation and the monitoring of high-risk groups for transfusion-transmitted infections. These expected results were not achieved by 2005.

3. In 2005, the PAHO Directing Council adopted Resolution CD46.R5, which urged the Member States to adopt the Regional Plan of Action for Transfusion Safety 2006-2010 and requested the Director to report periodically to the Governing Bodies on the progress of its implementation.

4. A report on the challenges to achieve blood sufficiency, availability and safety in the Americas was presented to the Executive Committee during its 142nd Session in June 2008. The Executive Committee recommended that the Directing Council adopt a resolution as a means to enhance regional efforts to achieve the objective of the Regional Plan of Action for Transfusion Safety 2006-2010.

5. The objective of the Regional Plan of Action is to contribute to the reduction of mortality and to the improvement of patient care by making safe blood available in a timely manner for all those patients who need it. The Plan involves four strategies: Planning and Management of the National Blood Network System, Promotion of Voluntary Blood Donation, Quality Assurance, and Appropriate Use of Blood and Blood Components, and identified nine indicators of progress based on regional data for the period 2000-2003.

Regional Situation in 2005

Screening Coverage

6. In 2003, 99.93% of the units collected by the Latin American and Caribbean countries that officially submitted reports to the Pan American Health Organization were screened for HIV, 99.86% were screened for HBV, 99.52% were screened for HCV, and 99.84% were screened for syphilis. The proportions of units that were screened for the four markers decreased to below 99% in 2004 and 2005 (Table 1). A negative trend was also observed for *T. cruzi*: the rates of screening were 87.17%, 86.20% and 87.06% in 2003, 2004 and 2005, respectively (Table 2).

7. In 2003 there were 19 (46%) countries that reported universal screening of all markers; there were 17 (41%) and 22 (54%) countries that screened all the collected units in 2004 and 2005, respectively (Table 3). Bolivia, Colombia, Honduras, Mexico, Nicaragua, Paraguay and Peru did not test all units for markers of viral infections in 2005. Nevertheless, two countries—Mexico and Peru—contributed 98.8% and 99.6% of the units that were not screened for HIV in 2004 and 2005, respectively. Anguilla, Belize, Dominica, and Saint Kitts and Nevis reported zero screening for HCV in 2005.

External Performance Evaluation

8. The Regional Programs for External Performance Evaluation continued with support from the Spanish Agency for International Cooperation, the UKNEQAS, the International Consortium for Blood Safety, the Hemocentro in São Paulo, Brazil, and the Sevilla Transfusion Center in Spain (Tables 4 and 6). The purpose of these regional programs is to support the national reference centers that are responsible for organizing the national programs with participation of all local services. Local participation,

nevertheless, is limited: in 2003 there were 1,330 (53.01%) national centers participating in national programs for external performance evaluation of serology for transfusion-transmitted infections. The proportion of participants decreased to 46.66% and 46.42% in 2004 and 2005 (Table 5).

9. Results from both the Regional and National Programs for External Performance Evaluation indicate that the quality of screening for serological markers of transfusion-transmitted infections has improved over the last four years. Some weaknesses remain in the immunohematological assays.

Blood Donors

10. The proportion of voluntary blood donors in Latin American and Caribbean countries was 36.06% in 2003; that same year, 0.34% of blood units were collected from paid donors (Table 7). The proportion of voluntary blood donors remained unchanged between 2003 and 2005, although there was a reduction to 33.05% in 2004. Recognized paid donors accounted for only 0.19% of all units collected in 2005 (Table 7), but the actual number of individuals who receive money in exchange for their blood is unknown. In 2003, there were seven (17%) countries that reported more than 50% voluntary blood donors; Aruba, Brazil, Cayman Islands, Colombia, Costa Rica, Cuba, Curacao, Saint Lucia, and Suriname did so in 2005.

11. The median prevalence rate of infectious markers among blood donors was always higher in countries with less than 50% voluntary donation than in those countries with more than 50% voluntary donors (Table 8). Nevertheless, it is noteworthy that, while the prevalence rates of markers remained unchanged in the former group of countries, the rates for countries with more than 50% voluntary donors tended to increase from 2002 to 2005 (Table 8).

12. The higher rate of prevalence of infectious markers among donors in some countries and the larger number of units that were not screened in 2004 and 2005 resulted in higher estimates of transfusion-transmitted infections. In 2002 and 2003 the estimated numbers of HIV infections associated with transfusions were six per year. The corresponding numbers for 2004 and 2005 were 57 and 55, respectively (Table 9). There were also significant increases in the estimated number of HBV and HCV transfusion-associated infections (Table 9).

Availability and Safety of Blood for Transfusion

13. The number of blood units collected in Latin America and the Caribbean increased from 7,325,093 in 2003 to 8,059,960 in 2005 (Table 10). The corresponding donation rates were 121.5/10,000 inhabitants in 2003 and 145.0/10,000 in 2005. There

was, however, a wide range among national donation rates in 2005: the rate for Haiti was 12.7 and that for Cuba was 439.6. In all, there were 15 (42%) countries with donation rates below 100/10,000 inhabitants and five (14%) with rates above 200 (Table 13).

14. The actual availability of blood at the national level is affected by the prevalence of infectious markers among blood donors –units from donors who are found to have an infectious marker must not be used for transfusions. In 2005, the cumulative proportion of units discarded because they were reactive/positive in the laboratory tests varied from 0.03% in Curacao to 11.00% in Bolivia, with a median of 3.11% (Table 13). There were at least 3,562 (4.28%) units discarded in the Caribbean countries and 235,134 in Latin America due to reactivity/positivity in laboratory tests, although some countries did not test any of the units collected for markers of HCV and HTLVI/II and others reported the rate of donors that were confirmed as positive after being reactive in screening test. The 238,696 units discarded, at a direct cost of basic supplies of US$ 56 per unit, represented a loss of $13.4 million.

15. In the Caribbean and Latin American countries, rates of national availability of blood for transfusion are inversely related to national maternal mortality ratios and proportion of maternal deaths associated with hemorrhage.

16. In Latin America, transfusions are given primarily to treat medical and not surgical conditions; one of every seven patients who receive transfusions is under one year of age. Reduction of infant mortality, therefore, must consider availability of blood.

17. Treatment of road traffic injuries, which are predicted to increase by 67% by the year 2020, requires transfusions. Almost two thirds of blood used among patients of acute trauma is given during the first 24 hours of care. Timely availability of blood at the emergency services is a determinant factor of patient survival.

18. The risk of receiving a blood unit contaminated with HIV, HBV or HCV for lack of laboratory screening increased from 1 in 41,858 donations in 2003 to 1 in 11,784 donations in 2005 (Table 10). The risk was 8.79 times higher for HCV and 2.67 times higher for HBV than for HIV (Table 9). In continental Latin America, the risk of receiving a *T. cruzi* positive transfusion was 1 in 3,377 donations in 2005, which is similar to the risk observed in 2003 (1 in 3,330 donations) (Table 10).

Efficiency of National Blood Systems

19. In Latin America, where countries collected between 42,771 and 3,738,580 units of blood in 2005, there is a wide range in the mean number of units processed by the individual blood services in a year: from 761 units in Argentina to 10,320 in Cuba. The seven countries with lowest mean annual collection per service had an average of

11% voluntary blood donors, while the average voluntary donation was 51% in the six countries with the highest mean annual collection per service (Table 11). The mean donor deferral rate was lower, 7.9%, in the six countries with highest annual collection per service than in the other two groups of countries, 20.1% and 24.7%. Furthermore, the blood donation rate was 100.85 per 10,000 inhabitants in the group of countries with the less efficient blood collection systems, 115.90 in the intermediate group and 186.81 in the group of countries with blood services that collected a mean of 5,888 units per year (Table 11). There was no difference in the proportion of blood units discarded, which fluctuated around 10% in the three groups of countries (Table 11).

20. It is estimated that 603,950 units of red blood cells became outdated and were discarded in Latin America in 2005, for an estimated loss of $33.8 million.

21. In the Caribbean, where countries collected between 114 and 22,155 units of blood in 2005, donor deferral varied between 0% and 53%, with a median of 20%. The estimated number of deferred donors was 29,152 in 2005. Seven countries had deferral rates below 10%; the rate was between 20% and 53% in the other eight countries (Table 12). The median blood donation rate in the first group of countries was 167.6 (range 108.4 – 368.6) per 10,000 inhabitants, and 87.7 (range 12.7 – 118.9) in the second group. The median proportion of units that were reactive for any of the infectious markers was 0.90% (range 0.03% – 6.85%) in the first group and 4.09% (range 0.40% – 10.25%) in the second. Aruba, Cayman Islands, Curacao, and Suriname, the four countries with 100% voluntary blood donors, are in the first group.

22. It is estimated that 6,425 units of red blood cells became outdated and were discarded in the Caribbean countries in 2005, for a loss of $360,000. The median proportion of red blood cells discarded was 5.9% (range 2.0% – 15.7%) among countries with lower blood donor deferral rates, and 10.8% (range 1.8% – 14.7%) among countries with higher proportion of deferred donors (Table 12).

Progress since 2005

23. The Regional Plan of Action 2006-2010 has nine progress indicators:

- In order to strengthen the organizational and functional capacities of the national blood systems, the legal framework is to be revised. Argentina, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Mexico, Nicaragua, Panama, Paraguay, Guyana, Haiti and Jamaica have either started or completed the process. Only Paraguay has enacted a revised blood law.

- To allow the development of national plans, the allocation of resources and appropriate evaluation of the national blood systems, the Regional Plan of Action

included structured surveys to estimate the geographic and temporary blood requirements and blood components in the country. Aruba, Cuba, Curacao, Haiti, Paraguay, and Suriname have those estimates. Argentina, Bahamas, British Virgin Islands, Colombia, Costa Rica, Grenada, Guatemala, El Salvador, Saint Vincent and the Grenadines have either gross or partial estimates that do not take geographic and time variables into consideration.

- Considering that sufficiency and safety of blood can only be achieved through voluntary blood donation, the countries adopted the goal of collecting more than 50% of their blood units from voluntary blood donors. Aruba, Brazil, Cayman Islands, Colombia, Costa Rica, Cuba, Curacao, Saint Lucia, and Suriname have achieved this goal.

- Argentina, Brazil, Colombia, Costa Rica, Cuba, Curacao, Haiti, Paraguay and Suriname have initiated the implementation of national quality assurance programs.

- To facilitate better patient care and planning of the national bloods systems it is necessary to develop national guidelines for the clinical use of blood. Argentina, Aruba, Belize, Bolivia, Brazil, Costa Rica, Cuba, Curacao, Ecuador, El Salvador, Guyana, Haiti, Jamaica, Mexico, Nicaragua, and Paraguay have prepared their guidelines.

- Belize, Costa Rica, Cuba, Guyana, Nicaragua and Suriname have established national blood transfusion committees.

- Brazil, Colombia, Cuba and Nicaragua have implemented hemovigilance systems.

- Colombia, Cuba, Curacao and Nicaragua have prepared components in at least 95% of the blood units collected.

- Nine Latin American countries—Argentina, Brazil, Colombia, Cuba, El Salvador, Mexico, Nicaragua, Panama and Paraguay—have designed a regionalized national system for blood collection and processing.

Lessons Learned, Enablers and Obstacles for Progress, and Recommendations

24. Progress was made in blood safety in the Region of the Americas from 2000 to 2003 (Tables 1, 2, 3, 7, 9, 10). Unfortunately, despite the fact that some countries initiated or achieved universal screening of blood for infectious markers, the overall risk of receiving a virus-contaminated transfusion—estimated by using the number of

unscreened blood units and the prevalence of infectious markers among blood donors—increased almost fourfold from 2003 to 2005 (Table 10).

25. Similarly, the proportion of voluntary blood donors in the Region increased from 15% in 2000 to 36% in 2003, but remained unchanged in the last two years (Table 7). Despite the increase in the number of voluntary blood donors, the proportion of those who are reactive/positive for infectious markers gradually increased from 2003 to 2005 (Table 8). This observation is associated with first-time or sporadic voluntary blood donors and underscores the need to pursue repeated and regular voluntary blood donation.

26. The number of blood units to be collected annually determines resources necessary to recruit blood donors, to procure supplies, and to collect, process, store and distribute blood components. It is difficult to appropriately plan and allocate national resources to blood systems when the need for blood and blood components in the country are unknown.

27. Central national health authorities have difficulties in organizing the different sectors (provincial or state authorities, social security, private and non-profit organizations) to implement national blood collection, processing and transfusion systems because the local factors that determine availability, opportunity, safety and efficacy of blood for transfusions are not taken into consideration for planning. In countries where structured efforts are being made, the political will and the technical skills of those at the normative level within the ministry of health determine the level of success. The permanent technical involvement of the PAHO Country Office is an important factor.

28. Regional work plans approved by the Directing Council in 1999 and in 2005 included the achievement of the goal of 50% voluntary blood donation. This goal was agreed upon by the national blood programs in order to induce gradual changes that would be acceptable to health workers. In retrospect, aiming for 50% voluntary blood donation results in policy, ethical and operational challenges since half of the recipient patients have to provide replacement donors; voluntary and replacement donors are handled differently by the blood services, and the access to blood in healthcare facilities is hindered by administrative processes of cost recovery. Pursuing the goal of 100% voluntary blood donation in the short term will result in the multidisciplinary operational approaches that were identified as vital in 2005.

29. Blood services need to work in three different spheres: (a) the community, to educate, recruit, select and maintain a healthy and committed donor pool; (b) within the blood processing center, as a factory of essential medicaments; and (c) the clinical services where patients are treated. Staffs with appropriate competencies, adequate

infrastructure and sufficient resources are necessary to educate and service voluntary blood donors, to manage blood processing facilities and to administer, monitor and evaluate blood transfusions.

30. The current organizational system results in a loss of financial resources, limits the efficacy of blood transfusions and has negative effects on morbidity and mortality.

31. The concepts of Resolution CD46.R5 still apply to the Region of the Americas but action is required by national authorities to implement the strategies of the Regional Plan of Action for Transfusion Safety 2006-2010, approved by the 46th Directing Council. It is recommended that the Ministries of Health support their national blood systems using the Health Agenda for the Americas 2008-2017 as the general framework.

32. Blood for transfusions should be considered an essential medicament, a national resource and a public good.

33. It is recommended that the Ministries of Health make a specific entity within their normative level responsible for the planning, oversight and overall efficient operation of the national blood system. The normative level must be clearly separated from the operational one.

34. The normative level should be staffed by personnel from multiple disciplines with competences in planning, management and public health. The National Blood Program should work closely with other groups within the Ministry of Health –Health Promotion, Maternal and Child Health, Immunization, Prevention and Control of Communicable Diseases, Cancer Prevention and Control, Adolescent Health, Pharmacovigilance, Patient Safety—and with other sectors—Ministry of Education, Ministry of Labor, Social Security.

35. The operational level should consider: (1) procurement, collection, processing and distribution of blood components, and (2) transfusion services. The processing centers should not be part of the individual hospitals. Consolidated processing facilities should be responsible for distributing sufficient blood components to a determined group of hospitals. In the smaller Caribbean countries the hospital laboratories may be used to process blood units, but the responsibility for donor education, selection and recruitment, and blood collection should be independent from the hospital administration.

36. Efforts should be made to estimate the annual national need for blood and blood components, by geographic area and by month. The national guides for clinical use of blood and the potential number of cases of the clinical conditions that require transfusions, including voluntary and involuntary injuries, should be used as the basis for the estimate. In order to cover unforeseen emergencies—natural or man-made disasters,

infectious outbreaks, emergency vaccination campaigns—it is recommended that the national blood systems have an additional stock equivalent to 4%, or two weeks, of the annual need.

37. The annual estimates of blood needs should take into consideration the expected increases in (a) numbers of the general and elderly population; (b) social inclusion of currently excluded populations; (c) road traffic injuries; and (d) local adoption of medical technologies such as organ transplants. Sufficient financial resources to collect and distribute enough blood components should be made available to the corresponding responsible unit within the Ministry of Health. National financial resources that are currently being wasted should be invested towards this effort.

38. The number of repeat donors needed in each country should be estimated at least as 50% of the national need of red blood cells. A national program should be put in place to educate and recruit healthy individuals as regular blood donors and to have them donate at least twice a year.

39. Ministries of Health should work to terminate replacement and paid donation before the end of 2010, with the goal of 100% voluntary, altruistic, non-remunerated donors, using the information obtained in the socio-anthropological surveys conducted in at least 18 of the Caribbean and Latin American countries.

40. A social network of volunteers should be established to help educate the community, to promote voluntary blood donation, and to service the donor. Youth programs, such as Pledge 25, should be given special attention.

41. National public information strategies should be developed to inform the community on the national needs for blood and blood components, the cost involved in procurement and processing of blood units, the daily level of coverage of the estimated need of blood, and the impact of transfusions on the wellbeing of the patients.

42. Hospital transfusion services should be staffed by medical specialists. Clinical laboratories in hospitals should actively participate in the evaluation of patients both before and after transfusions. Hospital transfusion committees should assess the clinical management of patients and the pertinence of hospital transfusion guidelines.

43. PAHO country offices should have staff specially dedicated to coordinating the technical cooperation given by PAHO on issues pertaining to blood transfusion safety. A coordinated approach is necessary at all levels of the Organization.

44. Local and national data on blood availability and safety and on blood transfusion efficiency should be analyzed periodically by the national health authorities and other stakeholders, including patient groups, blood donors and community volunteers.

Action by the Directing Council

45. The Directing Council, after reviewing the information provided, is invited to consider adoption of the resolution recommended by the 142nd Session of the Executive Committee, in Resolution CE142.R5 (see Annex C.)

Annexes

Table 1: Number and percent of blood units screened in the Region between 2000-2005

	2000	2003	2004	2005
Units collected (N)	6 409 596	7 325 093	7 559 080	8 059 960
Units screened for HIV	6 387 790 (99.66)	7 320 292 (99.93)	7 466 769 (98.77)	7 972 085 (98.91)
Units screened for HBV	6 387 247 (99.65)	7 315 191 (99.86)	7 460 221 (98.69)	7 966 011 (98.83)
Units screened for HCV	6 332 331 ((98.79)	7 290 038 (99.52)	7 448 173 (98.53)	7 963 998 (98.81)
Units screened for syphilis	6 381 752 (99.57)	7 313 335 (99.84)	7 383 987 (97.68)	7 900 040 (98.02)

Table 2: Number and percent of units screened for *T. cruzi* in Latin America between 2000-2005

	2000	2003	2004	2005
Units to be screened (N)	5 700 259	7 097 339	6 888 289	7 419 274
Units screened	4 502 114 (78.98)	6 251 932 (88. 09)	5 938 183 (86.20)	6 459 612 (87.06)

Table 3: Number and percent of countries reporting universal screening between 2000-2005

	2000	2003	2004	2005
HIV	31/37 (83.8)	33/38 (89.2)	29/37 (78.4)	32/36 (88.9)
HBV	30/37 (81.1)	33/38 (89.2)	29/37 (78.4)	32/36 (88.9)
HCV	19/37 (51.3)	23/38 (62.5)	20/37 (54.1)	24/36 (66.7)
Syphilis	32/37 (86.5)	33/38 (89.2)	30/37 (81.1)	31/36 (86.1)
T. cruzi	6/17 (35.3)	7/17 (41.2)	8/17 (47.1)	12/17 (70.6)

Table 4: Participation in Regional PEED for TTI between 2000-2005

	2000	2003	2004	2005
Number of Latin American countries	18	18	18	18
Number of Caribbean countries	0	18	20	20
Number of Latin American centers	20	20	20	21
Number of Caribbean centers	0	22	21	24

Table 5: Participation in national PEED for TTI between 2002-2005

	2000	2003	2004	2005
Number of centers in Latin America	4 738	2 509	3 071	2 546
Number of participating centers	1 129	1 330	1 433	1 182
% participation	23.82	53.01	46.66	46.42
Number of countries with national PEED	11	16	16	17

Table 6: Number of participants in regional PEED for immunohematology in Latin America and the Caribbean between 2000-2005

	2000	2003	2004	2005
Latin America	24	30	29	48
Caribbean	0	24	24	24

Table 7: Number and percent of voluntary and paid donors between 2000-2005

	2000	2003	2004	2005
Units collected (N)	6 409 596	7 325 093	7 559 080	8 059 960
Voluntary donors (N) (%)	989 885 (15.44)	2 641 739 (36.06)	2 498 174 (33.05)	2 950 018 (36.60)
Paid donors (N) (%)	31 725 (0.50)	24 925 (0.34)	25 398 (0.34)	15 507 (0.19)

Table 8: Median prevalence (percent) of markers for TTI according to proportion of voluntary blood donors between 2000-2005

Marker	Countries with	2000	2003	2004	2005
HIV	< 50% VBD	0.21	0.28	0.23	0.26
	> 50% VBD	0.13	0.01	0.01	0.02
HBsAg	< 50% VBD	0.60	0.60	0.62	0.60
	> 50% VBD	0.37	0.18	0.19	0.26
HCV	< 50% VBD	0.56	0.56	0.52	0.58
	> 50% VBD	0.10	0.06	0.08	0.11
Syphilis	< 50% VBD	0.97	0.92	0.97	1.00
	> 50% VBD	0.55	0.13	0.14	0.18

Table 9: Estimated indicators of blood safety between 2000-2005

Variable	2000	2003	2004	2005
HIV infections transfused (N)	30	6	57	55
Risk of HIV per 100,000 donations	0.47	0.08	0.75	0.68
HBV infections transfused (N)	1 357	22	176	147
Risk of HBV per 100,000 donations	21.18	0.30	2.32	1.82
HCV infections transfused (N)	211	147	537	482
Risk of HCV per 100,000 donations	3.29	2.00	7.10	5.98
T. cruzi infections transfused (N)	7 483	2 193	2 374	2 362
Risk of *T. cruzi* per 100,000 donations	131.23	28.22	34.46	31.88

Table 10: Availability and safety of blood between 2000-2005

	2000	2003	2004	2005
Number of units collected	6 409 596	7 325 093	7 559 080	8 059 960
Donation rate per 10,000	126.8	138.6	139.4	145.0
Risk of viral transfusion	1: 4 011	1: 41 858	1: 9 817	1: 11 784
Risk of T. cruzi transfusion	1: 762	1: 3 340	1: 3 150	1: 3 377

Table 11: Efficiency of national blood systems in Latin America, 2005

Variable	Group1 Argentina Dominican Republic Uruguay Venezuela Guatemala Panama Peru	Group 2 Bolivia Nicaragua Chile Honduras Mexico El Salvador	Group 3 Costa Rica Paraguay Colombia Ecuador Brazil Cuba
Mean number of units collected per bank	1,404	2,334	5.888
Mean GNP per capita (US $)	3,664	3,123	2,628
Population x 1,000	121,613	152,079	266,987
Units collected	1.226,526	1.762,623	4.987,588
Donation rate per 10,000	100.85	115.90	186.81
Mean voluntary donors (%)	11.0	18.5	51.3
Mean donor deferral (%)	20.1	24.7	7.9
Mean units discarded (%)	10.7	9.9	10.3

Table 12: Efficiency of national blood systems in the Caribbean, 2005

Group 1	Donor deferral rate (%)	Voluntary donors (%)	Prevalence TTI (%)	Discard rate (%)
St Kitts and Nevis	0	3	6.85	NR
Curacao	0.3	100	0.03	2.0
Aruba	2	100	0.90	2.0
Suriname	4.6	100	0.14	5.9
Bahamas	5	15	2.23	15.70
Dominica	9	5	5.41	7.1
Cayman Islands	10	100	0.11	20.0
Group 2				
St. Vincent and the Grenadines	20	13	6.68	12.7
Guyana	24	22	4.09	6.5
Grenada	26.7	30	4.20	10.8
Haiti	27	15	10.25	7.2
Belize	39.0	9	1.89	11.5
St. Lucia	39.1	82	1.55	14.7
Trinidad and Tobago	44	13	4.69	NR
Anguilla	53	10	0.40	1.8

Table 13: Blood donation rate per 10,000 inhabitants and proportion of units reactive/positive for infectious markers in 2005

Country	Donation rate	% TTI markers	Country	Donation rate	% TTI markers
Anguilla	87.7	0.40	Argentina	94.2	6.49
Aruba	367.8	0.90	Bolivia	50.9	11.00
Bahamas	159.5	2.23	Brazil	200.5	2.93
Belize	115.1	1.89	Chile	109.2	1.54*
British Virgin Islands	194.3	0.22	Colombia	115.7	3.11
			Costa Rica	125.1	0.49*
Cayman Islands	196.4	0.11	Cuba	439.6	1.65*
Curacao	368.6	0.03	Ecuador	94.3	0.39*
Dominica	109.7	5.41	El Salvador	116.5	3.98
Grenada	92.8	4.20	Guatemala	61.3	6.39
Guyana	70.1	4.09	Honduras	72.6	3.98
Haiti	12.7	10.25	Mexico	126.2	1.89
Jamaica	83.6	5.40	Nicaragua	98.6	3.82
St Kitts and Nevis	108.4	6.85	Panama	132.3	1.28
St Lucia	118.9	1.55	Paraguay	76.4	9.98
St. Vincent and the Grenadines	69.0	6.68	Peru	64.2	3.92
			Dominican Republic	69.8	3.74
Suriname	167.6	0.14	Uruguay	276.3	1.32
Trinidad and Tobago	104.4	4.69	Venezuela	150.8	3.71

* Reported tests confirmed as positive. The rest of the countries reported units that were reactive in screening tests.

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

ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL AREAS

1. Agenda Item: 4.7

2. Agenda Title: Improving Blood Availability and Transfusion Safety in the Americas

3. Responsible Unit: THR

4. Preparing Officer: José Ramiro Cruz

5. List of collaborating centers and national institutions linked to this Agenda item: Hemocentro/Fundacion ProSangue, Sao Paulo, Brazil; UK National External Quality Assessment Scheme; International Consortium for Blood Safety, New York; Centro de Transfusion de Sevilla, Spain; CAREC, Trinidad and Tobago; International Federation of Red Cross and Red Crescent Societies, Geneva; International Society for Blood Transfusion Regional Delegation, Caracas, Venezuela; International Blood Transfusion, London, UK; Grupo Cooperativo Ibero Americano de Medicina Transfusional; EUROsociAL, Madrid, Spain; Rotary Clubs in USA, Mexico, El Salvador, Colombia, Ecuador, Chile, Peru, Uruguay, Paraguay, St. Lucia, Cayman Islands; Health Canada, Canadian Blood Services, Hema-Quebec, Canada; USA Center for Disease Control and Prevention, Atlanta, USA; Centro Nacional de Transfusión Sanguínea, Mexico; Programa Nacional de Sangre. Instituto Guatemalteco de Seguridad Social, Guatemala; Laboratorio Central Max Bloch, Cruz Roja Salvadoreña, El Salvador; Programa Nacional de Sangre, Cruz Roja Hondureña, Honduras; Centro Nacional de Diagnóstico y Referencia, Cruz Roja Nicaraguense, Nicaragua; Dirección de Laboratorios, Caja Costarricense del Seguro Social, Costa Rica; Hospital Santo Tomás, Panama; Ministerio de la Protección Social, Instituto Nacional de Salud, Instituto Nacional de Vigilancia de Medicamentos y Alimentos, Cruz Roja Colombiana, Colombia; Programa Nacional de Bancos de Sangre, Venezuela; Ministerio de Salud, Cruz Roja Ecuatoriana, Ecuador; Programa Nacional de Sangre, Bolivia; Programa Nacional de Sangre, Cruz Roja Chilena, Chile; Programa Nacional de Hemoterapia y Bancos de Sangre, Instituto Nacional de Salud, Peru; Programa Nacional de Sangre, Paraguay; Plan Nacional de Sangre, Argentina; Centro Nacional de Transfusión, Uruguay; Coordinacion da Politica Nacional de Sangre e Hemoderivados, Agencia de Vigilancia Sanitaria, HEMOBRAS, Brazil; Instituto Nacional de Hematología e Inmunologia, Cuba; Secretaría Estatal de Salud Pública y Asistencia Social, Cruz Roja Dominicana, Dominican Republic; National Blood Safety Program, Croix Rouge Haitienne, Haiti; Princess Alexandra Hospital, Anguilla; Stichting Bloedbank, Aruba; Princess Margaret Hospital, Bahamas; Belize National Blood Transfusion Service, Belize; Peebles Hospital, BVI; Cayman Islands Hospital, CI; Red Cross Blood Bank Foundation, Curacao; Princess Margaret Hospital, Dominica; Pathology Laboratory, Grenada; National Blood Transfusion Service, Guyana; National Blood Transfusion Service, Jamaica; Joseph N. France General Hsopital, St. Kitts; St. Lucia Blood Bank Service; Milton Cato Memorial Hospital, St. Vincent; National Blood Bank, Suriname; National Blood Transfusion Service, Trinidad and Tobago.

6. Link between Agenda item and Health Agenda of the Americas:

PRINCIPLES

Human Rights, universality, access and inclusion: The Plan of Action for Transfusion Safety 2006-2010 seeks to promote sufficiency, availability, access and opportunity of blood for transfusions in the Region of the Americas, considering the human right to the best attainable level of health.

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

Equity in health: The Plan of Action seeks to eliminate intra and intercountry differences in the availability,

access, opportunity, and quality of blood for transfusions with a public health approach.
Social participation: The document CD48/11 clearly states that a social network is indispensable to attain 100% voluntary blood donation and sufficiency of blood**.**

AREAS OF ACTION
Strengthening the health authority: The Plan of Action 2006-2010 comprises four strategies. The first, Planning and Management of the National Blood Network System, requires a strong leadership of the Ministry of Health. Paragraphs 27, 29, 30, 31, 33, 34, 39 of document CD48/11 refer to steering role of the Ministries of Health.

Tackling health determinants; Reducing the risk and burden of disease: Safety of blood depends primarily on the quality of the blood donor. National blood requirements depend on the overall health status of the population. Health promotion, health education and interventions to protect the population will result in safer blood donors and reduced needs for blood components. Safe blood contributes to the reduction of HIV, HBV, HCV, T. cruzi and other infections. Paragraphs 6-9, 11-18, 24, 29, 34, and 37, and tables 1-5 refer to these issues.

Increasing social protection and access to quality health services; Diminishing health inequities among countries and inequities within them: Blood availability and access vary within and among countries. The overall objective of the Plan of Action 2006-2010 is to promote equitable access considering increased social inclusion. Tables 10-13 and paragraphs 13, 14, 15, 35, 36, 37, and 41 address social protection and access to blood.

Strengthening health security: Blood for transfusions is an essential component for managing emergencies. Paragraph 36 of the document specifically refers to unforeseen emergencies.

Furthermore, document CE48/11 Reads, in paragraph 31:
"31. The concepts of Resolution CD46.R5 still apply to the Region of the Americas but action is required by national authorities to implement the strategies of the Regional Plan of Action for Transfusion Safety 2006-2010, approved by the 46th Directing Council. It is recommended that the Ministries of Health support their national blood systems using the Health Agenda for the Americas 2008-2017 as the general framework."

7. Link between Agenda item and Strategic Plan 2008-2012:

The Regional Plan of Action for Transfusion Safety addresses issues related to

SO1. To reduce the health, social and economic burden of communicable diseases –T.cruzi, HBV, HCV, HTLVI/II by improving donor selection and laboratory screening.
SO2. To combat HIV/AIDS, tuberculosis and malaria by improving donor selection and laboratory screening.
SO3. To prevent and reduce disease, disability and premature death from chronic noncommunicable conditions, violence and injuries by providing enough, safe blood in a timely manner.
SO4. To reduce mortality and improve health during key stages of life, including pregnancy, childbirth, the neonatal period, childhood and adolescence, and improve sexual and reproductive health and promote healthy aging for all individuals by promoting voluntary blood donation and by making safe blood available in a timely manner.
SO5. To reduce the health consequences of emergencies, disasters, crises and conflicts, and minimize their social and economic impact by providing blood for transfusion when necessary.

SO6. To promote health and development, and prevent or reduce risk factors such as use of tobacco, alcohol, drugs and other psychoactive substances, unhealthy diets, physical inactivity and unsafe sex, which affect health conditions by promoting the education of voluntary blood donors

SO7. To address the underlying social and economic determinants of health through policies and programs that enhance health equity and integrate pro-poor, gender-responsive, and human rights-based approaches by ensuring equitable access to safe blood

SO10. To improve the organization, management and delivery of health services by improving the planning and management of the national blood network system.

SO11. To strengthen leadership, governance and the evidence base of health systems by improving the planning and management of the national blood network system.

SO12. To ensure improved access, quality and use of medical products and technologies

8. Best practices in this area and examples from other countries within AMRO:

Canada: Organization of blood services. Aruba, Cayman Islands, Cuba, Curacao, Suriname in voluntary blood donation.

9. Financial implications of Agenda item:

Better planning and management at the country level will result in more efficient use of national resources. Around US$ 48 million were wasted in 2005 by the Caribbean and Latin American countries. Paragraphs 14, 20 and 22 refer to financial resources.

Regular and extrabudgetary funding at the regional should not be further reduced in the coming years. PAHO HQ, PWR's and Subregional initiatives should work to implement coordinated approaches of technical cooperation. Paragraph 43 of the document addresses this issue.

PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION

142nd SESSION OF THE EXECUTIVE COMMITTEE

Washington, D.C., USA, 23-27 June 2008

CD48/11 (Eng.)
Annex C

ORIGINAL: ENGLISH

RESOLUTION

CE142.R5

BLOOD TRANSFUSION SAFETY: PROGRESS REPORT

THE 142nd SESSION OF THE EXECUTIVE COMMITTEE,

Having considered the progress report presented by the Director on Blood Transfusion Safety (Document CE142/20), which summarizes the difficulties observed in the implementation of the Regional Plan of Action for Transfusion Safety 2006-2010;

Concerned about the insufficiency and the poor quality of blood available for transfusions in the majority of countries of the Region; and

Taking into account the Health Agenda for the Americas 2008-2017,

RESOLVES:

To recommend that the Directing Council adopt a resolution along the following lines:

THE 48th DIRECTING COUNCIL,

Having considered the progress report presented by the Director on Blood Transfusion Safety (Document CD48/11), which summarizes the difficulties observed in the implementation of the Regional Plan of Action for Transfusion Safety 2006-2010;

Aware of the central role that transfusions play in the appropriate medical care of patients and in the reduction of mortality among mothers, infants, victims of traffic accidents and other traumas, patients suffering from cancer or clotting disorders, and transplant patients;

Concerned that the current levels of availability and safety of blood for transfusion in the Region are unsatisfactory;

Recognizing that the current national organizational systems limit the efficacy of blood transfusions, have negative effects on morbidity and mortality, and result in major financial losses;

Considering that the concepts of Resolutions CD41.R15 (1999) and CD46.R5 (2005) still apply to the Region of the Americas, and that action is required by national authorities to implement the strategies of the Regional Plan of Action 2006-2010, approved by the 46th Directing Council; and

Recognizing that modifications in current national approaches are needed in order to achieve the regional goals set for transfusion safety by 2010,

RESOLVES:

1. To urge Member States to:

(a) proactively implement the Regional Plan of Action for Transfusion Safety 2006-2010 by:

i. defining a specific entity within the normative level of their ministries of health as responsible for the planning, oversight and overall efficient operation of the national blood system;

ii. estimating the annual national need for blood components, taking into consideration unforeseen emergencies, expected increases of the general and elderly population, social inclusion of currently excluded populations, road traffic injuries, and local adoption of medical technologies, such as

transplants and cancer treatment, and the financial resources necessary to cover those needs;

iii. establishing a network of volunteers to educate the community and to promote voluntary blood donation and service blood donors, with special attention to youth programs;

(b) terminate replacement and paid blood donation before the end of 2010, with a goal of 100% voluntary, altruistic, non-remunerated blood donation, using the information obtained from socio-anthropological surveys conducted in the countries**,** given that blood collection should not be solely the responsibility of hospital medical teams;

(c) share best practices in the recruitment and retention of voluntary blood donors.

2. To request the Director to:

(a) cooperate with the Member States in the implementation of the Regional Plan of Action for Transfusion Safety 2006-2010 using a multidisciplinary and coordinated approach for health promotion, public education, human and patient rights, quality assurance and financial efficiency;

(b) work with Member States and international organizations to assess the implementation of the Regional Plan of Action 2006-2010 and to identify country-specific interventions needed to assure sufficiency and acceptable quality and safety of blood for transfusions at the national level;

(c) prepare annual reports on the situation of blood transfusion safety in the Region.

(Seventh meeting, 26 June 2008)

PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION

48th DIRECTING COUNCIL
60th SESSION OF THE REGIONAL COMMITTEE

Washington, D.C., USA, 29 September-3 October 2008

CD48/11 (Eng.)
Annex D

Report on the Financial and Administrative Implications for the Secretariat of the Resolutions Proposed for Adoption by the Directing Council

1. Resolution: Blood Transfusion Safety: Progress Report.

2. Linkage to program budget

Area of work 21; 01 **Expected result** 3; 5

3. Financial implications

a) Total estimated cost for implementation over the lifecycle of the resolution (estimated to the nearest US$ 10,000; including staff and activities): $1,780,000

b) Estimated cost for the biennium 2008-2009 (estimated to the nearest US$ 10,000; including staff and activities): $1,420,000

c) Of the estimated cost noted in (*b)* what can be subsumed under existing programmed activities? 100%

4. Administrative implications

a) Implementation locales (indicate the levels of the Organization at which the work will be undertaken and identify the specific regions, where relevant): HQ, Subregional Units, PWR's, and Collaborating Centers.

b) Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile): Specific focal points for blood transfusion safety are necessary in each Subregional Unit and PWR.

c) Timeframes (indicate broad time frames for the implementation and evaluation): The implementation of the activities started in 2005 and must continue to 2010. Regional and national progress should be assessed yearly.

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PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION

48th DIRECTING COUNCIL
60th SESSION OF THE REGIONAL COMMITTEE

Washington, D.C., USA, 29 September-3 October 2008

CD48.R7 (Eng.)
ORIGINAL: ENGLISH

RESOLUTION

CD48.R7

IMPROVING BLOOD AVAILABILITY AND TRANSFUSION SAFETY IN THE AMERICAS

THE 48th DIRECTING COUNCIL,

Having considered the report of the Director on blood transfusion safety (Document CD48/11), which summarizes the difficulties observed in the implementation of the Regional Plan of Action for Transfusion Safety 2006-2010;

Aware of the central role that transfusions play in the appropriate medical care of patients and in the reduction of mortality among mothers, infants, victims of traffic accidents and other traumas, patients suffering from cancer or clotting disorders, and transplant patients;

Concerned that the current levels of availability and safety of blood for transfusion in the Region are unsatisfactory;

Recognizing that the current national organizational systems limit the efficacy of blood transfusions, have negative effects on morbidity and mortality, and result in major financial losses;

Considering that the concepts of Resolutions CD41.R15 (1999) and CD46.R5 (2005) still apply to the Region of the Americas, and that action is required by national authorities to implement the strategies of the Regional Plan of Action 2006-2010, approved by the 46th Directing Council; and

Recognizing that modifications in current national approaches are needed in order to achieve the regional goals set for transfusion safety by 2010,

RESOLVES:

1. To urge Member States to:

(a) proactively implement the Regional Plan of Action for Transfusion Safety 2006-2010 by:

i. defining a specific entity within the normative level of their ministries of health as responsible for the planning, oversight and overall efficient operation of the national blood system;

ii. estimating the annual national need for blood components, taking into consideration unforeseen emergencies, expected increases of the general and elderly population, social inclusion of currently excluded populations, road traffic injuries, and local adoption of medical technologies, such as transplants and cancer treatment, and the financial resources necessary to cover those needs;

iii. establishing a network of volunteers to educate the community and to promote voluntary blood donation and service blood donors, with special attention to youth programs;

(b) except in limited circumstances of emergency medical necessity, terminate replacement and paid blood donation by the end of 2010, with a goal of 100% voluntary, altruistic, non-remunerated blood donation, using the information obtained from socio-anthropological surveys conducted in the countries, given that blood collection should not be solely the responsibility of hospital medical teams;

(c) terminate mandatory patient replacement of transfused blood by the end of 2010;

(d) share best practices in the recruitment and retention of voluntary blood donors.

2. To request the Director to:

(a) cooperate with the Member States in the implementation of the Regional Plan of Action for Transfusion Safety 2006-2010 using a multidisciplinary and coordinated approach for health promotion, public education, human and patient rights, quality assurance and financial efficiency;

(b) work with Member States and international organizations to assess the implementation of the Regional Plan of Action 2006-2010 and to identify country-specific interventions needed to assure sufficiency and acceptable quality and safety of blood for transfusions at the national level;

(c) prepare annual reports on the situation of blood transfusion safety in the Region.

(Seventh meeting, 2 October 2008)

A CODE OF ETHICS FOR BLOOD DONATION AND TRANSFUSION

The objective of this code is to define the ethical principles and rules to be observed in the field of Transfusion Medicine.

Blood Centers: donors and donation

1. Blood donation including haematopoietic tissues for transplantation shall, in all circumstances, be voluntary and non-remunerated; no coercion should be brought to bear upon the donor.
   A donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonable needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.
   The donor should provide informed consent to the donation of blood or blood components and to the subsequent (legitimate) use of the blood by the transfusion service.
2. A profit motive should not be the basis for the establishment and running of a blood service.
3. The donor should be advised of the risks connected with the procedure; the donor's health and safety must be protected. Any procedures relating to the administration to a donor of any substance for increasing the concentration of specific blood components should be in compliance with internationally accepted standards.
4. Anonymity between donor and recipient must be ensured except in special situations and the confidentiality of donor information assured.
5. The donor should understand the risks to others of donating infected blood and his or her ethical responsibility to the recipient.
6. Blood donation must be based on regularly reviewed medical selection criteria and not entail discrimination of any kind, including gender, race, nationality or religion. Neither donor nor potential recipient has the right to require that any such discrimination be practiced.
7. Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.
8. All matters related to whole blood donation and haemapheresis should be in compliance with appropriately defined and internationally accepted standards.
9. Donors and recipients should be informed if they have been harmed.
10. Blood is a public resource and access should not be restricted.
11. Wastage should be avoided in order to safeguard the interests of all potential recipients and the donor.

Hospitals: patients

12. Patients should be informed of the known risks and benefits of blood transfusion and/or alternative therapies and have the right to accept or refuse the procedure. Any valid advance directive should be respected.
13. In the event that the patient is unable to give prior informed consent, the basis for treatment by transfusion must be in the best interests of the patient.
14. Transfusion therapy must be given under the overall responsibility of a registered medical practitioner.
15. Genuine clinical need should be the only basis for transfusion therapy.
16. There should be no financial incentive to prescribe a blood transfusion.
17. As far as possible the patient should receive only those particular components (cells, plasma, or plasma derivatives) that are clinically appropriate and afford optimal safety.
18. Blood transfusion practices established by national or international health bodies and other agencies competent and authorised to do so should be in compliance with this code of ethics.

The Code has been elaborated with the technical support and adopted by the WHO.
Adopted by General Assembly of ISBT, July 12, 2000
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