Caribbean Regional Standards for Blood Banks and Transfusion Services

Second Edition

Pan American Health Organization

Regional Office of the World Health Organization

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INTRODUCTION TO THE SECOND EDITION

The Caribbean Regional Standards for Blood Banks and Transfusion Services were originally published in 2001 by the Caribbean Epidemiology Center (CAREC), with technical and financial support from the Pan American Health Organization (PAHO). The Standards were prepared by consensus among delegates from the CAREC Member Countries and with the purpose of providing the minimal operational criteria for blood banks and transfusion services.

In 2005, the Directing Council of PAHO adopted the Regional Plan of Action for Transfusion Safety 2006-2010, which included quality assurance among its strategies. This strategy stated that the Caribbean Regional Standards for Blood Banks and Transfusion Services, developed by CAREC, would be implemented in all blood services (annex 2) irrespective of their accreditation status. An initial assessment of the progress of the Regional Plan of Action carried out in 2008 identified weaknesses in the recruitment of voluntary blood donors and in the processing of blood units among the Caribbean countries (annex 2), situations that contributed to the decision of the Directing Council to urge the PAHO Member States to define 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 as a means to improve the implementation at the country level of the Regional Plan of Action 2006-2010. One year later, CAREC revised its mission and concluded that issues pertaining to transfusion safety should not be part of the Center's activities, focusing instead on a primary mandate of public health surveillance.

In 2010 the Director of PAHO appointed an External Evaluation Team to assess advances in areas related to the Regional Plan, identify problems encountered in its implementation, and evaluate opportunities for future action (annex 2). One of the recommendations of the External Evaluation Team was that the Regional Standards be revised and updated to make them coherent with recent technical developments and with the current situation in the countries. To comply with the recommendation, CAREC transferred the copyright of the Caribbean Regional Standards for Blood Banks and Transfusion Services to PAHO. The Regional Office of PAHO compared the content of the Caribbean Regional Standards to that of the requirements of the American Association of Blood Banks and of the Council of Europe (annex 5), and identified potential modifications to the Caribbean Standards. The suggested changes were discussed electronically with the Directors of the Blood Banks in the Caribbean. Their responses and comments were compiled by PAHO and discussed by an Ad Hoc Committee during a 3-day meeting held in October 2011 (annex 4). The Second Edition of the Caribbean Standards is the end result of the consultation process. It includes five annexes that intend to provide both technical and policy guidance to national health authorities and to technical staff in the blood banks and transfusion services. These Standards have the purpose of providing minimal management and operational criteria for blood transfusion safety in the Caribbean Region.

It is expected that the Ministries of Health of the Caribbean countries officially adopt the new version of the Caribbean Regional Standards for Blood Banks and Transfusion Services, and that the Executive Management of each of the centers provides the necessary resources for their implementation. These Standards are applicable to Antigua and Barbuda, Bahamas, Barbados, Belize, British Territories (Anguilla, Cayman Islands, Montserrat, and British Virgin Islands), Dominica, Grenada, Guyana, Haiti, Jamaica, Netherland Antilles (Curacao, Aruba), St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, and Trinidad and Tobago.

INTRODUCTION TO THE FIRST EDITION

The Core Standards provide the foundation on which the CRS have been developed. The twenty-one (21) Core Standards represent universal quality elements and are the Minimum requirements that must be integrated within a Blood Bank's or Transfusion Service's Quality Management System.

The CRS include twenty-one (21) sections each comprised of a core standard; and where relevant, additional specific or technical requirements and/or CRS reference requirements. The components of each section are arranged in the order stated.

The core standards are clearly defined under the sub-heading "Core Standard" and are identified solely by a number, for example: 1.1 or 9.2. These numbers represent core standards under Units 1 and 9 respectively.

The specific or technical requirements were developed by a joint working group of participants drawn from CAREC member countries (CMCs), the American Association of Blood Banks (AABB), the Caribbean Epidemiology Centre (CAREC) and the Regional Program for Laboratory and Blood Services, Division of Health Systems and Services Development, Pan American Health Organization (PAHO). These specific or technical requirements identify the minimal operational criteria for accredited blood banks and transfusion services in CAREC member countries and outline "what" is to be accomplished. These requirements are included under the sub-heading "Additions to Core Standards" and are identified by the "CRS" that precedes the number assigned to the requirement, for example: CRS 9.1 and CRS 3.1 represent specific or technical requirements under Units 9 and 3 respectively.

Where relevant, CRS reference requirements, also developed by the joint working group, follow the specific or technical requirements. Reference Requirements are very specific technical requirements that address "how" a requirement is to be met. These can be identified as follows: The number of the core standard under which the reference requirement is included + the letters "CRS R" (for CRS requirement) + the alphabetical letter corresponding to the positioning of the reference requirement, for example: 9 CRS R-C will refer to the third (C) reference requirement in Section 9 (Process Control).

It is expected that while from edition to edition the core and specific or technical requirements will change minimally, the reference requirements will undergo revision.

As clearly outlined above, the Caribbean Regional Standards integrate both quality management elements with specific technical requirements. All requirements are of equal importance. Once stated, a requirement is not repeated either in the same section or in any later section.

Following is an example of the way in which one concept would be linked in the CRS from the Core Standards to the CRS specific or technical requirement to the CRS reference requirement:

Core Standard 8, Product Identification and Traceability, requires the following: "The Blood Bank shall establish and maintain processes and procedures that make it possible to identify the source, processing and final disposition of any unit of blood or blood component."

CRS Specific or Technical Requirement CRS 8.1.2 that follows the Core Standards states that: "Records of all units of blood and blood components obtained through allogeneic and autologous collection, plasmapheresis, cytapheresis and therapeutic apheresis shall be maintained in conformance with the CRS requirements and Section 16, Control of Records."

CRS Reference Requirement 8 CRS R-A that follows the Specific or Technical Requirement contains a list of what the records for blood collection, cytapheresis and therapeutic apheresis shall include in order to ensure traceability.

ADDITIONS, DELETIONS AND MODIFICATIONS TO THE FIRST EDITION, EFFECTIVE JANUARY 2012

Major changes

Section	Modifications	Additions	Deletions
Section 4			All Section 4 "Design control"
Sections 1, 2, 3, 4, 5, 6, 9, 10, 12, 13,15, 16, 18, 20			All numbered and unnumbered notes
Section headline numbers: Section 5 Section 6 Section 7 Section 8 Section 9 Section 10 Section 11 Section 12 Section 13 Section 14 Section 15 Section 16 Section 17 Section 18 Section 19 Section 20 Section 21	Section 4 Section 5 Section 6 Section 7 Section 8 Section 9 Section 10 Section 11 Section 12 Section 13 Section 14 Section 15 Section 16 Section 17 Section 18 Section 19 Section 20		
Section 3		All agreements shall be in writing	
CRS 7.1.2 7 CRS R – A 15 CRS R – A			Therapeutic apheresis
8 CRS R – C	Updated and expanded list of medications with generic and brand names		
14 CRS R – A	Updated and expanded list of blood components		
		Annex 1. Glossary	

Major changes (continued)

Section	Modifications	Additions	Deletions
		Annex 2. PAHO official documents	
		Annex 3. CAREC transfer of copyright to PAHO	
		Annex 4. Members of Ad Hoc Committee	
		Annex 5. List of recommended references	

Important changes

Section	Modifications	Additions	Deletions
Section 1			
1.2.1		An organizational chart describing the above shall be developed and included in the quality manual.	
CRS 1.1.1.1.	The Blood Bank shall have a director who is qualified by appropriate training or experience.		
Section 2			
CRS 2.2.		Continuous monitoring activities shall be performed according to the specific standards and the results be made available accordingly.	
Section 3			
CRS 3.1	Before release of a blood component or product for transfusion, the Blood Bank shall have a written request from the treating physician. Fax or electronic signatures are permissible. See CRS 8.9.1.		
Section 4			
4.3.		Training of relevant personnel shall be accomplished prior to document changes coming to effect.	

Important changes (continued)

Section	Modifications	Additions	Deletions
Section 5			
CRS 5.1.	Evaluating Supplies		
CRS 5.2.	Evaluating Suppliers		
CRS 5.3.	Purchasing Agreements		
Section 6			
CRS 6.1.3.2.	Autologous units from donor-patients who test positive for any infectious disease marker shall be discarded.		
6 CRS R-A	To be determined by Blood Bank policy and the donor-patient's physician.		
	The last donation shall occur at least 72 hours prior to surgery.		
	The donor-patients shall undergo pre-donation infectious testing and the testing results shall be negative in order for the collection to occur.		
Section 8			
CRS 8.3.2.	Third Party Information About Donors		
	…that will include the discarding any available component, documenting in donor records, and immediately evaluating and informing the donor.		
CRS 8.5.1	Time and storage temperature for component preparation.		
	The Blood Bank shall have processes and procedures to define the condition of storage and storage time allowed prior to blood component preparation.		
CRS 8.6.2.	A sample from each donation shall be stored for a minimum of three years for lookback evaluations.		

Important changes (continued)

Section	Modifications	Additions	Deletions
CRS 8.10.1.1.	The Blood Bank shall establish a process for the visual inspection of all blood components prior to issue. The visual inspection must include: no evidence of hemolysis in red blood cells; no evidence of clots or discoloration in plasma and cryoprecipitate; presence of swirling and absence of clots in platelets.		
CRS 8.10.1.2.		There shall be a process in place to detect bacterial contamination of platelets at time of issue.	
CRS 8.12.1.	…including informed consent…		
8 CRS R-A	…and understood (including importance of accurate donor information); the…		
	…; to assure donor confidentiality…		
CRS R-E	…and II antibody		
	…antigen and antibody		
	…antibody		
	…antigen and antibody		
	6) Treponema specific test for syphilis		
	7) Transfusion-transmissible infections according to local risk		
Section 12			
12.2.2.	A Process shall be created with the purpose of tracking and trending, root cause analysis, preventive and corrective action, and post implementation assessment.		
CRS 12.1	Unavailability of Donor Collection		

Important changes (continued)

Section	Modifications	Additions	Deletions
Section 13			
13.4.		Emergency preparedness	
		The blood bank shall have a plan for emergency preparedness and disaster response.	
Section 17		CRS 17.2. Continuous Education of Blood Bank Staff	
		The blood bank staff shall participate in annual continuous education on topics related to job functions.	

SUMMARY OF THE 20 SECTIONS OF THE CARIBBEAN REGIONAL STANDARDS

Section 1, Management Responsibility, includes requirements relating to the facility quality policy and the responsibility and authority of certain individuals within the facility. It also requires that management review its quality system at defined intervals. CRS requirements relating to a Medical Director are incorporated here.

Section 2, Quality System, requires that the facility has in place a quality system and that there exist processes and procedures for every activity that affects the quality of a product or service provided by the facility. Section 2 also requires that a facility document how quality planning is accomplished for new or changed products or services. Quality planning merely requires that a facility review the requirements (requirements contained in the Standards) and plan how it will meet these requirements. It does not require the creation of an actual plan, only documentation that there was a process for determining how the standard would be met. As an example, a facility that decided to implement a new testing technology should analyze whether any changes in management structure, the quality system, agreements, supplier qualification, resources, etc. were necessary. Quality planning is distinct from Design Control, which merely requires that when new products or services are designed, the facility should define the need for the product or service (input requirements) and then ensure that the actual design of the product or service (output) meets those needs. The added CRS requirement is that all processes and procedures be reviewed annually.

Section 3, Agreement Review, requires that prior to acceptance of an agreement, the facility must ensure that there exists a "meeting of the minds" between the two parties. It does require that all agreements be in writing. The CRS requirement is that there be a written order from the requesting physician before release of a blood component or product for transfusion.

Section 4, Document Control, relates solely to documents (policies and procedures captured in writing or electronically). Records, which are objective evidence that an activity has been performed, are dealt with in Section 15, Control of Records. The purpose of this section is to ensure that documents that describe policies, processes, or procedures are kept up to date and that their approval and distribution is controlled.

Section 5, Obtaining Materials (Including Blood and Blood Components and Services), imposes requirements on facilities to ensure that products and services received by the facility meet the requirements that have been specified for them. It also mandates that the facility evaluate its suppliers.

Section 6, Control and Processing of Customer-Supplied (Autologous) Product, includes all of the requirements relating to autologous and related allogeneic prod-ucts and services. Inherent in this section is the concept that products belonging to a customer that are in the control of the supplier must be handled according to requirements. The CRS reference requirements include donation criteria for donor-patients.

Section 7, Product Identification and Traceability, includes the fundamental requirement of HPC collection/transplantation product traceability. The CRS requirements include specifics regarding the

actual labeling of the product. The reference requirements include records that must be kept to ensure traceability.

Section 8, Process Control, contains much of what is familiar to blood bankers. Broadly stated, process control includes requirements that promote the consistent delivery of quality services and products. Many of the requirements relating to specific products and services have been moved into a general section, CRS Section 8.1 General, that sets forth requirements applicable to all blood collection activities. The remaining sections in CRS Section 9 are organized by "work flow" (e.g., collection, processing, and administration). The majority of the CRS reference requirements (the very detailed requirements relating to how to do something) are found in this section, including expanded requirements for donor selection (8 CRS R-C - 8 CRS R-E).

Section 9, Inspection and Testing, includes requirements that testing and inspection be performed.

Section 10, Control of Equipment, establishes requirements for determining the suitability of critical equipment (which must be identified by the facility) and calibrating inspection, measuring and equipment. The CRS requirement includes the need for preventive maintenance, which is further addressed in the CRS reference requirement 10 CRS R-A.

Section 11, Inspection and Test Status, does not impose a testing requirement. It merely requires that with respect to any product or service, the testing status (tests completed, tests failed, etc.) must be ascertainable at any point in time in the process or delivery.

Section 12, Deviations and Control of Non-Conforming Products or Services, defines how products or services that do not meet defined requirements are to be handled. For the most part, nonconforming products are not transplanted in the blood banking community except under emergency release procedures.

Section 13, Corrective and Preventive Action Plans, requires that a facility have appropriate procedures for implementing corrective and preventive action plans. In addition, this section requires periodic management review of these plans and their implementation.

Section 14, Storage, Distribution and Transportation, sets forth requirements for control of blood components and products to prevent damage or deterioration. The Caribbean Regional Standards only require that the blood bank or transfusion service establish processes and procedures to (1) preserve the function, integrity, and quality of the product; (2) ensure that proper action is taken before blood components or products reach undesirable temperatures; and (3) ensure that appropriate modes of transportation are selected. The reference requirements address specific storage temperatures, transportation temperatures, and expiration time frames for blood components and products.

Section 15, Control of Records, establishes requirements for storing records. Throughout the other sections are requirements for 'maintaining' records; this implies that the records must be created and then they must be controlled according to this section. The record storage requirements relating to the length of time a record is to be held are included in CRS reference requirement 15 CRS R-A.

Section 16, Quality Assessments, mandates periodic internal and external quality assessments. Requirements for a proficiency testing program and for reviewing out-come-related information are found here. CRS requirement 16.2 requires that all transfusing facilities have a transfusion practices committee to document the monitoring of all transfusion practices within the institution as well as conformance with regional reference requirements.

Section 17, Training, requires that a facility identify its training needs, provide appropriate training and maintain training records.

Section 18, Statistical Techniques, CRS 18.1, requires that the facility shall use applicable statistical techniques to demonstrate process control.

Section 19, Safety, incorporates requirements relating to safety of employees, donors, volunteers, and, when applicable, patients. CRS 19.1 requires that the blood bank comply with all applicable PAHO/CAREC requirements, as well as national guidelines.

Section 20, Blood Donor Issues, addresses issues of donor recruitment including education and confidentiality of test results. It prohibits blood banks from offering material incentives to donors. CRS 20.1 states that there must be a designated individual responsible fro for donor recruitment within the blood bank.

SECTION 1. MANAGEMENT RESPONSIBILITY

CORE STANDARD

1.1 Quality Policy

The Executive Management shall define and document the Blood Bank's policy for achieving and maintaining quality in donor education, recruitment and selection, blood collection, blood processing, blood storage, blood distribution, transfusion recipient testing, the transfusion of blood and blood components and the provision of services (hereinafter "the collection, processing and transfusion of blood and blood components and the provision of services"). The quality policy shall describe the Blood Bank's objectives for quality and its commitments to quality. The Blood Bank's Executive Management shall ensure that this quality policy is understood, implemented, and maintained at all levels of the organization.

1.2 Organization

1.2.1 Responsibility and Authority

The Blood Bank shall define and document the responsibility, authority, and relationship of personnel who perform, verify, or manage work covered by these Standards, particularly for personnel who:

a) Ensure that the donor education, recruitment and selection, collection, processing and transfusion of blood and blood components and the provision of services conform to specified requirements (See Section 2.1, General);
b) Identify and maintain records of any problems related to the quality system, the collection, processing and transfusion of blood and blood components or the provision of services;
c) Initiate, recommend, or implement corrective action to these problems
d) Verify the implementation and assess the effectiveness of corrective action;
e) Control work until the problem has been corrected.

An organizational chart describing the above shall be developed and included in the quality manual.

1.2.2 Resources

The Executive Management shall identify and adequate provide resources to perform, verify, and manage any activity covered by these Standards.

1.2.3 Management Representative

The Executive Management shall appoint a member of management who, irrespective of other responsibilities, shall have defined authority for ensuring that the Blood Bank establishes, implements, and maintains a quality system that meets the requirements of these Standards. This individual shall report to Executive Management on the performance of the quality system. Thisreport shall be the basis for management review and improvement of the quality system.

1.2.4 Management Review

The Executive Management shall review the quality system annually to ensure the system meets the requirements of these Standards. Records of these reviews shall be maintained in conformance with Section 15, Control of Records.

ADDITIONS TO CORE STANDARDS

CRS 1. Management Responsibility

CRS 1.1 Responsibility and Authority

CRS 1.1.1 Executive Management

The Blood Bank shall describe its Executive Management. Executive Management shall have ultimate responsibility and authority for the Blood Bank's operations and the authority to establish or make changes to the Blood Bank's quality policy and quality system.

CRS 1.1.1.1

The Blood Bank shall have a director who is qualified by appropriate training or experience.

The Blood Bank shall have a licensed physician who is qualified by appropriate training or experience. The blood bank physician shall have responsibility for all medical issues in the Blood Bank and the support services that relate to the medical care and safety of transfusion recipients or donors.

CRS 1.2 Job Qualifications

The Blood Bank shall identify appropriate qualifications for each job position that affects quality.

SECTION 2. QUALITY SYSTEM

CORE STANDARD

2.1 General
The Blood Bank shall establish, document, and maintain a quality system to ensure that the collection, processing and transfusion of blood and blood components and the provision of services conform to specified requirements. The Blood Bank shall prepare a quality manual that incorporates or references the requirements of these Standards, incorporates or references detailed Blood Bank processes and procedures and outlines the structure of the documentation used in the quality system. The promotion of the importance of blood quality shall be emphasized among personnel

2.2 Quality System Policies, Processes, and Procedures
The Blood Bank shall develop a quality plan to document, and effectively implement policies, processes, and procedures for the quality system to ensure that requirements of these Standards are satisfied.

2.3 Quality Planning for New or Changed Products or Services
The Blood Bank shall define and document how the requirements of these Standards will be ensured for each new or changed product or service. The documentation shall be in a format that suits the nature of the change and the Blood Bank's operation.

ADDITIONS TO CORE STANDARD

CRS 2. Quality system

CRS 2.1 Annual Review
Annual review of each document that affects quality shall be performed by authorized individuals. Records of the review shall be maintained in conformance with Section 15, Control of Records.

CRS 2.2 Continuous monitoring activities
Continuous monitoring activities shall be performed according to the specific standards and the results be made available accordingly.

SECTION 3.AGREEMENT REVIEW

CORE STANDARD

3.1 General
The Blood Bank shall establish and maintain policies, processes, and procedures for reviewing agreements to provide products and services to the Blood Bank's customers. See Section 5, Obtaining Materials (Including Blood and Blood Components) and Services. All agreements shall be in writing.

3.2 Review
Before acceptance of an agreement, the agreement shall be reviewed by the Blood Bank to ensure that:

a) the customer's requirements are adequately defined;
b) any differences between the agreement requirements and the products or services offered under the agreement are resolved;
c) the Blood Bank has the capability to meet the agreement requirements.

3.3 Changes to Agreements
The Blood Bank shall define how changes to agreements are made and communicated to relevant Blood Bank personnel.

3.4 Records
Records of agreements, reviews of, and changes to agreements, shall be maintained in conformance with Section 15, Control of Records.

ADDITIONS TO CORE STANDARD

CRS 3 Agreement Review

CRS 3.1 Release of Units for Transfusion
Before release of a blood component or product for transfusion, the Blood Bank shall have a written request from the treating physician. Fax or electronic signatures are permissible. See CRS 8.9.1, Requests, and CRS 12.2, Control of Nonconforming Product or Service.

SECTION 4. DOCUMENT CONTROL

CORE STANDARD

4.1 General
The Blood Bank shall establish and maintain policies, processes, and procedures to control all documents that relate to the requirements of these Standards.

4.2 Document Approval and Distribution
The Blood Bank shall review and approve all documents prior to issuance. The document control process shall ensure that:

a) documents are identified with the current revision status;
b) appropriate documents are available at all locations where operations covered by these Standards are performed;
c) invalid or obsolete documents are not used;
d) any archived obsolete documents are suitably identified
e) Retention time of documents shall be defined, according to section 16 CRS R-A

4.3 Document Changes
Changes to documents shall be reviewed and approved in the same manner as the original review and approval, unless a different process or procedure is specifically established. Individuals authorized to review and approve changes shall have access to all background information necessary to conduct the review and approval.

Training of relevant personnel shall be accomplished prior to document changes coming to effect.

ADDITIONS TO CORE STANDARD

CRS 4 Document Control

CRS 4.1 Processes and Procedures
The Blood Bank shall maintain a list of all policies, processes, and procedures relating to these Standards. All processes and procedures written by the Blood Bank shall be in a standardized format within the facility.

CRS 4.2 Retention
The facility shall determine which, if any, documents shall be selectively archived, or made obsolete. Copies of archived policies, processes, and procedures shall be retained. Refer to CRS 15 (Control of records)

SECTION 5.OBTAINING MATERIALS (INCLUDING BLOOD AND BLOOD COMPONENTS AND SERVICES)

CORE STANDARD

5.1 General
The Blood Bank shall establish and maintain policies, processes, and procedures to ensure that purchased, donated, or otherwise acquired materials or services conform to specified requirements.

5.2 Evaluation of Suppliers
The Blood Bank shall:

a) evaluate and select any supplier of a material or service that is intended for incorporation into the final blood or blood component or service, or that affects the quality of the final blood or blood component or service, on the basis of the supplier's ability to meet specified requirements;
b) define the type and extent of control required over the supplier. The type and extent of control shall depend upon the type of material or service, the impact of the material or service on the quality of the final product or final service, and the previous performance of the supplier;
c) maintain records of acceptable suppliers in conformance with Section 15, Control of Records;
d) report to management with contracting authority of a supplier's failures to meet specified requirements

5.3 Purchasing Information
Purchasing documents shall contain information that clearly describes the material or service ordered. The Blood Bank shall review and approve purchasing documents for adequacy of the specified requirements prior to release.

ADDITIONS TO CORE STANDARD

CRS 5 Obtaining Materials and Services

CRS 5.1 Evaluating Supplies
The Blood Bank shall:

a) evaluate and select any material or service that is intended for incorporation into the blood or blood component or that affects the quality of the blood or blood component on the basis of the supplies meeting specified requirements;
b) assess the impact of the material or service on the quality of the final product or service;
c) maintain records of acceptable materials or services in conformance with Section 15, Control of Records.

CRS 5.2 Evaluating Suppliers
The Blood Bank shall consider the following when obtaining materials or services from suppliers:

a) the supplier's performance history, including the timeliness of delivery;
b) the comparative cost of comparable supplies;
c) the supplier's commitment to provide technical support and service.

CRS 5.3 Purchasing Agreements

The Blood Bank shall include the following information in agreements to procure materials or services:

a) the acceptable expiration date or, if applicable, acceptable shelf life upon receipt;
b) the delivery mechanism;
c) the type and extent of its control over the material or service that is required. The type and extent of control shall depend upon the type of
d) appropriate storage conditions during transport;
e) evaluation or performance criteria;
f) if the material being purchased is blood or a blood component or a service that affects the quality of the blood or blood component, a statement from the supplier that the requirements of these Standards have been met.

SECTION 6. CONTROL AND PROCESSING OF CUSTOMER–SUPPLIED (AUTOLOGOUS) PRODUCT

CORE STANDARD

6.1 General
The Blood Bank shall establish and maintain policies, processes, and procedures to control the verification, processing, storage, and maintenance of customer-supplied products.

6.1.1
The Blood Bank shall report any products that are lost, damaged, or otherwise unsuitable for use to the customer. Records shall be maintained in conformance with Section 15, Control of Records.

ADDITIONS TO CORE STANDARD

CRS 6. Control and Processing of Customer Supplied (Autologous) Product
Section 7. Product Identification and Traceability, applies.

CRS 6.1 Blood Collection for Storage and Later Autologous Transfusion
CRS 8.1, General, applies.

CRS 6.1.1 Qualification of Donor-Patients
The Blood Bank shall establish processes and procedures for donor-patient donation in conformance with CRS Reference Requirements.

6 CRS R-A

CRS 6.1.2 Blood Collection
CRS 8.4, Blood Collection, and CRS 8.5, Preparation of Blood Components, apply

CRS 6.1.3 Testing

CRS 6.1.3.1 Serological Testing
The collecting Blood Bank shall determine ABO group and Rh type in conformance with CRS 8.6.1.

CRS 6.1.3.2 Testing of Units Transfused in the Collecting Blood Bank
The collecting Blood Bank shall perform tests intended to prevent disease transmission of autologous units in conformance with CRS 8.6.2.
Autologous units from donor-patients who test positive for any infectious disease marker shall be discarded.

CRS 6.1.4 Labeling
The Blood Bank shall label autologous units in conformance with the labeling requirements of CRS 8.7, Blood and Blood Component Labeling.

CRS 6.1.4.1 The following additional requirements apply:

a) autologous units shall be labeled with the following statement: "Autologous Donor" or "For Autologous Use Only";
b) autologous units shall be labeled with the name of the donor-patient and, if available, the name of the facility where the patient is to be

transfused and the patient's hospital registration number (or, if unavailable, birth date, or similar identifying information).

CRS 6.1.5 Storage and Distribution

CRS 6.1.5.1

After collection, blood shall be maintained at a temperature and in a manner that prevents deterioration or damage in conformance with CRS Reference Requirements.

14 CRS R-A

CRS 6.1.5.2

The Blood Bank shall segregate autologous collections during storage.

CRS 6.1.6 Pretransfusion Testing

Blood sample identification and collection shall be performed in conformance with CRS Reference Requirements.

8 CRS R-G

Pretransfusion testing shall include obtaining a blood sample from the donor-patient and shall conform with CRS Reference Requirements for determining ABO group and Rh type.

8 CRS R-H

CRS 6.1.7 Transfusion of Autologous Units

The transfusing Blood Bank shall establish processes and procedures to ensure that autologous units are only issued for and transfused to the intended transfusion recipient and that autologous units are transfused before allogeneic units. CRS 8.12, General Conditions of Transfusion, applies.

CRS 6.1.8 Adverse Reactions

The Blood Bank shall establish processes and procedures for the detection, reporting and evaluation of adverse reactions. Symptoms or findings suggestive of an immediate transfusion reaction shall be handled in conformance with CRS Reference Requirements.

8 CRS R-L (3)

6 CRS R-A
Donation Criteria for Donor-Patients

Category	Criteria
Age	No age limit
Volume	No more than 10.5ml per kilogram of body weight
Hemoglobin Concentrations	≥ 11 g/dl or PCV ≥ 33%
Donation Interval	To be determined by Blood Bank policy and the donor-patient‘s physician The last donation shall occur at least 72 hours prior to surgery
Indication	To be determined by Blood Bank policy and the donor-patient‘s physician
Infectious testing	The donor-patients shall undergo predonation infectious testing and the testing results shall be negative in order for the collection to occur

SECTION 7. PRODUCT IDENTIFICATION AND TRACEABILITY

CORE STANDARD

7.1 General
The Blood Bank shall establish and maintain policies, processes, and procedures that ensure the identification and traceability of each product from its source, through all processing steps, to its final disposition.

ADDITIONS TO CORE STANDARD

CRS 7. Product Identification and Traceability

CRS 7.1 Unit Identification

CRS 7.1.1 Unique Identification
The collecting Blood Bank shall affix unique iden-tification to each unit of blood, its components and attached containers. The unique identification shall not be obscured, altered or removed.

CRS 7.1.2 Traceability
Records of all units of blood and blood components obtained through allogeneic and autologous whole blood collection and platelet pheresis shall be maintained in conformance with CRS Reference Requirements and Section 15, Control of Records.

7 CRS R-A

CRS 7.1.3 Special Requirements for Pooled Products
The Blood Bank that pools a specific product shall maintain the identification number of each collecting facility and of each unit in a pool in conformance with Section 15, Control of Records.

CRS 7.2 Sample Identification
Samples drawn for testing (compatibility or otherwise) shall be identified and traceable, in conformance with CRS Reference Requirements. Any additional blood samples collected shall (1) be collected for laboratory tests in containers that are properly labeled before or at the time of collection and (2) be re-identified with the blood container immediately after filling.

8 CRS R-G
7 CRS R-A

7 CRS R-A
Records to Establish Traceability

1) Blood collection records shall include:
   a) name of facility;
   b) name of individual performing each step in a procedure that affects the quality of the blood or blood components.
2) Platelet pheresis records shall include:
   a) identity of the donor;
   b) results of laboratory tests that qualify the donor;
   c) anticoagulants use;
   d) duration of procedure;
   e) volume of component(s);
   g) lot numbers of disposables
   h) reactions that occurred and how they were treated

SECTION 8. PROCESS CONTROL

CORE STANDARD

8.1 General

The Blood Bank shall identify, plan, and validate the policies, processes, and procedures that affect the quality of products and services. The Blood Bank shall ensure that these policies, processes, and procedures are carried out under controlled conditions. Controlled conditions shall include:

a) use of policies, processes, and procedures for the collection, processing, storage, distribution, and administration of blood and blood components and the provision of services;
b) use of suitable equipment and a suitable working environment;
c) compliance with policies, processes, and procedures, and external standards;
d) monitoring and control of suitable process parameters and product characteristics;
e) approval of processes and equipment;
f) criteria for acceptable results;
g) control of equipment.

ADDITIONS TO CORE STANDARD

CRS 8. Process Control

CRS 8.1 General

Section 7, Product Identification and Traceability, Section 9, Inspection and Testing, Section 11, Inspection and Test Status, and Section 14, Storage, Distribution and Transportation, apply.

CRS 8.1.1 Use of Materials

Materials and supplies that are used to collect, process, test or store blood and blood components shall conform to applicable requirements or be used in conformance with the manufacturer's package insert.

CRS 8.1.2 Quality Control and Proficiency Testing

The Blood Bank shall participate in a proficiency testing program for each analyte tested by the laboratory. If there is no external, approved proficiency testing program for an analyte, there shall be a system for determining the accuracy and reliability of test results. CRS 9, Inspection and Testing, applies.

The Blood Bank shall establish a program of quality control that is sufficiently comprehensive to ensure that reagents and equipment function as required.

CRS 8.1.3 Sterility and Toxicity

The Blood Bank shall use aseptic methods that provide maximum assurance of the collection of a sterile unit of blood or blood component. Non-toxic equipment and solutions shall be used.

CRS 8.1.4 Informed Consent and Approvals

Prior to the collection procedure, the Blood Bank shall obtain the informed consent of the donor and all required approvals in conformance with CRS reference requirements. Consent records shall be maintained in conformance with Section 15, Control of Records.

8 CRS R-A

CRS 8.1.5 Care of Donors
All blood donors shall be monitored during and after the collection procedure for prevention and treatment of any adverse events. Provisions for emergency medical care, including equipment and supplies, shall be available at the place of collection.

CRS 8.2 Computer Software

CRS 8.2.1 Computer Software Use in Process Control
The Blood Bank shall ensure validation of computer software that is used in process control. Records of initial validation results and records relating to validation of subsequent software changes shall be maintained in conformance with Section 15, Control of Records.

CRS 8.2.2 Alternative Process Control Systems
The Blood Bank shall establish and maintain an alternative system that ensures continuous operations in the event that computerized functions are not operational. The alternative system shall be tested periodically.

CRS 8.3 Qualification of Donors of Allogeneic Blood and Blood Components

CRS 8.3.1 Donor Education
The Blood Bank shall educate donors prior to collection regarding the risk of transmitting infectious diseases through blood transfusions, and the option of self exclusion shall be emphasized. Such education shall conform to CRS Reference Requirements. Records of donor acknowledgment shall be maintained in conformance with Section 15, Control of Records.

8 CRS R-B

CRS 8.3.2 Third Party Information about Donors
The Blood Bank shall establish a procedure for managing information concerning a donor's suitability that is received from a third party that will include the discarding any available component, documenting in donor records, and immediately evaluating and informing the donor.

CRS 8.3.3 Criteria for Protection of the Donor
On the day of collection, the Blood Bank shall evaluate the history of a prospective donor and examine the donor in conformance with CRS Reference Requirements intended to ensure that the collection will not be detrimental to the donor.

8 CRS R-C

CRS 8.3.4 Criteria for Protection of the Transfusion Recipient
On the day of collection, the Blood Bank shall evaluate the history of the prospective donor and examine the donor in conformance with CRS Reference Requirements intended to protect the safety-of the transfusion recipient.

8 CRS R-C

CRS 8.4 Blood Collection

CRS 8.4.1 Integral Donor Tubing
Blood shall be collected in containers with integral donor tubing.

CRS 8.4.2 Preparation of Tubing for Subsequent Serological Testing

The integral donor tubing shall be filled with antico-agulated blood and sealed in such a manner that it will be available for subsequent serological testing. Any additional blood samples collected shall meet the requirements stated in the manufacturer's package insert of the test being performed. Section 7, Product Identification and Traceability, applies to blood samples.

CRS 8.4.3 Volume

The volume of blood drawn shall be in conformance with CRS Reference Requirements. Units that do not meet such requirements shall be handled in conformance with Section 12, Deviations and Nonconforming Products or Services.

8 CRS R-C (2, 3)

CRS 8.5 Preparation of Blood Components

CRS 8.5.1 Time and storage temperature for component preparation

The Blood Bank shall have processes and procedures to define the condition of storage and storage time allowed prior to blood component preparation

CRS 8.5.2 Seals

The Blood Bank shall use equipment that minimizes the potential for breakage of the seals during transfer of components.

CRS 8.5.3 Welds

If a connection device is used to produce sterile welds between two pieces of compatible tubing, the Blood Bank shall inspect the weld for completeness.

CRS 8.6 Testing of Donor Blood

CRS 8.6.1 ABO, Rh and Antibody Testing

The ABO group and Rh type shall be determined in conformance with CRS Reference Requirements on each unit collected. If the unit is tested for unexpected antibodies to red cell antigens, the method employed shall detect clinically significant antibodies. When such antibodies are found, blood components containing significant amounts of plasma shall be labeled to indicate the antibody detected ("Contains anti-_"). Discrepancies shall be resolved prior to release of blood components.

8 CRS R-D

CRS 8.6.2 Tests Intended to Prevent Disease Transmission

The Blood Bank shall perform tests intended to prevent disease transmission on each collection in conformance with CRS Reference Requirements.

A sample from each donation shall be stored for a minimum of three years for lookback evaluations.

8 CRS R-E

Blood and blood components shall not be released for transfusion unless the results of these tests are negative. Blood and blood components released for emergency transfusion shall be considered nonconforming product. See CRS 12. Control of Nonconforming Product.

A mechanism shall be implemented for confidential donor notification of nonconforming results. Refer to section 12, CRS 12.1.

CRS 8.6.2.1 Collection of Data
The Blood Bank shall participate in the collection of prevalence data on emerging and reemerging transfusion transmitted diseases that shall serve as the basis for determining whether testing should be implemented. Refer to traveling table.

CRS 8.7 Blood and Blood Component Labeling

CRS 8.7.1 General

The Blood Bank shall label blood and blood components in conformance with Blood Bank policies, processes, and procedures.

CRS 8.7.2 Collection and Preparation

At the time of blood or blood component collection and preparation, the container shall be labeled in conformance with CRS Reference Requirements that are designed to ensure:

a) appropriate handling of the unit;
b) appropriate preparation of the unit;
c) the inclusion of information required on the final container.

8 CRS R-F

CRS 8.7.3 Final Container

The final container shall be labeled in conformance with CRS Reference Requirements that are designed to ensure:

a) appropriate storage and handling of the unit;
b) appropriate selection of the unit for a particular transfusion recipient;
c) investigation of adverse reactions in transfused recipients.

8 CRS R-F

CRS 8.7.4 Special Labeling Requirements

CRS 8.7.4.1 Leukocytes Reduced
Components prepared by a method that reduces leukocytes shall be la-beled "Leukocytes Reduced" and shall comply with CRS reference requirements.

8 CRS R-F

CRS 8.7.4.2 Platelets
Pooled platelets shall be labeled in conformance with CR5 Reference Requirements.

8 CRS R-F

CRS 8.8 Selection of Blood and Blood Components for Transfusion

CRS 8.8.1 Compatible Components

The Blood Bank shall establish guidelines to ensure that blood and blood components from the donor and blood samples from the intended transfusion recipient are compatible.

CRS 8.8.1.2
The Blood Bank shall establish a pol-icy for transfusing Rh positive red blood cells to Rh negative patients during times of short supply. Refer to Section 12, CRS 12.2.

CRS 8.8.1.3
The Blood Bank shall establish and maintain criteria for Rh Immune Globulin prophylaxis, if appropriate, for Rh—negative transfusion recipi-ents who receive Rh-positive blood and blood components.

CRS 8.8.1.4
The Blood Bank shall establish and maintain interpretation criteria to prevent the mistyping of an Rh-negative mother as Rh-positive if a large fetomaternal hemorrhage of Rh-positive blood results in a mixed-field agglutination reaction in the test with anti-D reagents.

CRS 8.8.1.4.1.
A postpartum maternal blood sample from all Rh-negative women at risk shall be tested to detect a fetomaternal hemorrhage in an amount sufficient to require more than a single dose of Rh Immune Globulin for effective prophylaxis.

CRS 8.9 Compatibility Process

CRS 8.9.1 Requests

Requests for blood or blood components shall contain sufficient information for positive identification of the transfusion recipient.

CRS 8.9.2 Transfusion Recipient Blood Samples and Testing

Blood samples shall be collected from a positively identified transfusion recipient be labeled for acceptance for transfusion. Recipient and be labeled in conformance with CRS Reference Requirements. The Blood Bank shall establish a procedure to ensure that the completed label is attached to the tube before leaving the side of the transfusion recipient. Records identifying the individual who drew the intended transfusion recipient's blood shall be maintained in conformance with Section 15, Control of Records.

8 CRS R-G

CRS 8.9.2.1
Prior to the Blood Bank accepting the recipient blood samples, identification of the blood sample shall be verified against the request for transfusion.

CRS 8.9.3 Compatibility Testing

CRS 8.9.3.1
Each blood sample consisting of one or more tubes drawn at one time from an intended transfusion recipient shall be tested for ABO group, Rh type and unexpected antibodies to red cell antigens in conformance with CRS Reference Requirements. If unexpected antibodies are detected, their clinical significance shall be determined.

8 CRS R-H

CRS 8.9.3.2
Before a blood or blood component is issued for transfusion, comparison of the interpretation of current tests with previous records, when readily available, shall be performed. Records shall be maintained in conformance with Section 15, Control of Records, for the following transfusion recipient records:

a) ABO and Rh typing done during the past 12 months;
b) difficulty in typing, identification of clinically significant unexpected antibodies, significant adverse reactions to transfusion, and special transfusion requirements.

CRS 8.9.3.3
Prior to transfusion, there shall be a mechanism to ensure that the ABO group of all blood or blood components and the Rh type of such units labeled Rh negative have been confirmed using a blood sample obtained from an attached segment. Confirmatory testing shall be performed after the original ABO and Rh label have been affixed to the units. Discrepancies shall be reported to the collecting facility.

CRS 8.9.3.4
Compatibility testing shall be performed on the transfusion recipient blood sample and donor blood sample by a serologic or electronic process.

Serologic and electronic testing methods shall be in conformance with CRS Reference Requirements.

9?CRS R-I

CRS 8.9.3.4.1 The Blood Bank shall include the interpretation of compatibility tests on the label or tie tag.

CRS 8.9.3.5
Blood samples used for compatibility testing shall be saved for seven days after transfusion.

CRS 8.9.3.6
The Blood Bank shall perform compatibility testing until a transfusion recipient has received an amount of blood approximating the patient's total blood volume within 24 hours. The transfusing Blood Bank shall establish guidelines for compatibility testing after that point.

CRS 8.10 Issue and Reissue of Blood and Blood Components

CRS 8.10.1 Issue of Blood and Blood Components for Transfusion

The Blood Bank shall establish processes and procedures to ensure that blood and blood components are issued for transfusion with sufficient information to permit positive identification of the intended transfusion recipient and the blood component, and any special transfusion requirements.

CRS 8.10.1.1
The Blood Bank shall establish a process for the visual inspection of all blood components prior to issue. The visual inspection must include: no evidence of hemolysis in red blood cells; no evidence of clots or discoloration in plasma and cryoprecipitate; presence of swirling and absence of clots in platelets

CRS 8.10.1.2
There shall be a process in place to detect bacterial contamination of platelets at time of issue

CRS 8.10.2 Emergency Release

Blood and blood components that do not meet the requirements of CRS 9.9.2, Transfusion Recipient Blood Samples and Testing, or that are released as a result of emergency need for blood and blood components shall be utilized for transfusion only in conformance with CRS 12. Control of Non-conforming Product.

CRS 8.10.3 Reissue of Blood and Blood Components

The Blood Bank shall ensure that blood and blood components returned to the Blood Bank are reissued only in conformance with CRS Reference Requirements.

Records of reissuance shall be maintained in conformance with Section 15, Control of Records.

8 CRS R-J

CRS 8.11 Special Considerations for Infants under the Age of 4 months

CRS 8.11.1 Compatibility Testing

Infants under the age of four months shall be tested according to CRS Reference Requirements.

8 CRS R-K (1, 2)

CRS 8.11.2 Selection of Components

Selection of components shall be in accordance with CRS Reference Requirements.

8 CRS R-K (3, 4)

CRS 8.12 General Conditions of Transfusion

CRS 8.12.1 Verification of Comprehensive Transfusion Procedures

The Blood Bank shall ensure, through participation in the development of processes and procedures including informed consent or verification that processes and procedures that the following requirements of CRS 8.12, General Conditions of Transfusion are met.

CRS 8.12.2 Administration

Transfusions shall be prescribed and administered under medical direction.

CRS 8.12.3

Administration of blood and blood components shall include: inspection of blood, blood component or pooled component immediately before transfusion.

Immediately prior to transfusion, two qualified persons shall verify and document in the presence of the transfusion recipient that the information identifying the container with the intended transfusion recipient has been matched in the presence of the transfusion recipient, item by item. Records of such verification shall be maintained in conformance with Section 15, Control of Records; attachment of all identification to the container until the transfusion has been terminated; monitoring of the transfusion recipient during and after the procedure for prevention and treatment of any adverse events. Provisions for emergency medical care, including equipment and supplies, shall be available; maintenance of a clinical transfusion record to include the donor unit or pool identification number; date and time of transfusion, pre- and post-transfusion vital signs, amount transfused, identification of transfusionist and whether a transfusion reaction occurred. Following the transfusion, the record or a copy shall be made part of the transfusion recipient's medical record.

CR5 8.12.4 Administration Set
Blood and blood components shall be transfused through a filter designed to retain particles potentially harmful to the transfusion recipient.

CRS 8.12.5 Intravenous Solutions
Drugs or solutions added during the administration of blood or blood components shall be shown to be safe and efficacious for this use.

CRS 8.12.6 Blood Warming Devices
Blood, if warmed, shall be warmed using a device designed to prevent hemolysis.

CRS 8.12.6.1
Units of blood or blood components shall not be attached to a blood warming device for more than four hours.

CRS 8.12.6.2
The blood warming device, when available, shall be equipped with a visible thermometer and an audible warning system to detect malfunctions.

CRS 8.12.7 Transfusion Reactions

CRS 8.12.7.1
The Blood Bank shall establish a process that conforms to CRS Reference Requirements for the detection, reporting and evaluation of suspected transfusion reactions. Records of such events shall be maintained in conformance with Section 15, Control of Records.

8 CRS R-L

CRS 8.12.7.2
Records of all investigations, evaluations and notifications shall be maintained in conformance with Section 15, Control of Records.

CRS 8.12.7.3
The Blood Bank shall establish a procedure to identify a transfusion recipient of blood or components from a donor who is subsequently found to have infection with HIV, HTLV, hepatitis or other transfusion transmissible infection and to notify the transfusion recipient's physician. Records of notifications shall be maintained in conformance with Section 15, Control of Records.

8 CRS R-A
Acknowledgement, Informed Consent, Requests and Agreements

Requirement	Must have acknowledgement in writing that educational materials were read or verbally explained and understood (including importance of accurate donor information); the donor had opportunity to ask questions; to assure donor confidentiality	Must have Informed Consent prior to collection procedure, which includes: Awareness of tests performed Opportunity to refuse consent	Must have request from donor-patient's physician	We have agreement of Blood Bank representative
Whole blood collection	X	X		
Apheresis Collection	X	X		
Autologous Collection	X	X	X	X

8 CRS R-B
Education of Prospective Donors

Prospective donors shall:

1) Receive educational material about the risks of infectious diseases transmitted by blood transfusions, including the signs and symptoms of HIV disease, and the importance of withdrawing if they think their blood is not suitable for transfusion;
2) Have an opportunity to ask questions about the collection process.

8 CRS R-C
Donor Criteria

Category	Criteria
Age	≥ 17 or country requirements
Donor weight	≥ 50 Kg (110 lb)
Blood volume Collected	No more than 10.5 ml/kg of body weight (minimum 300 mL and maximum 550 mL
	16 weeks for females and 12 weeks for male for allogeneic whole blood donations As a minimum of one week between autologous whole blood donation; and 72 hours prior to surgery ≥ 48 hours after platelet pheresis
	≤ 180 mm Hg systolic ≤ 100 mm Hg diastolic
6) Hgb/Hct	≥ 12.5 g/dl or PCV ≥ 38% (earlobe sample is prohibited)

Donor Criteria (continued)

Category	Criteria
7) Medication History (See reference 6 in annex 5)	Medications must be evaluated Acitretin (Soriatane) – usually given for severe psoriasis. 3 year deferral Dutasteride (Avodart, Jalyn) – usually given for prostate enlargement. 6 month deferral Etretinate (Tegison) – usually given for severe psoriasis. Permanent deferral Finasteride (Proscar) – usually given for prostate enlargement. 1 month deferral Finasteride (Propecia) – usually given for male baldness. 1 month deferral Insulin from Cows (Bovine, or Beef, Insulin) – used to treat diabetes. Permanent deferral Isotretinoin (Accutane, Amnesteem, Claravis, Sotret,) – usually given for severe acne. 1 month deferral For platelet donation or preparation of platelets from whole blood donations: Aspirin and aspirin containing medications – inhibit platelet function; used to reduce pain, fever, arthritis, and chance for heart attack and stroke. 3 day deferral Clopidogrel (Plavix) – inhibits platelet function; used to reduce the chance for heart attack and stroke. 14 day deferral Piroxicam (Feldene, Roxam) – given for mild to moderate arthritis pain. 3 day deferral Ticlopidine (Ticlid) – inhibits platelet function; used to reduce the chance for heart attack and stroke. 14 day deferral
8) Medical History	Must be free of major organ disease, cancer, or abnormal bleeding tendency ≥ 6 weeks following conclusion of pregnancy
CJD	• Duramater, pituitary growth hormones of human organ- Defer indefinitely. • Receipt of blood, blood components or derivative, or other human tissues- 12 month deferral.
Immunizations & Vaccinations	• Receipt of toxoids, or synthetic or killed viral, bacterial, or rickettsial vaccines are acceptable if donor is symptom-free and afebrile • Receipt of live attenuated vaccines- 2 week deferral, except receipt of varicella zoster or rubella – 4 week deferral • Receipt of Hepatitis B Immune Globulin (HBIG) 12 month deferral • Or as recommended by current PAHO guidelines.

Donor Criteria (continued)

Category	Criteria
Infectious Diseases	Prospective donors are indefinitely deferred for the following: • History of viral hepatitis after 11th birthday • Confirmed positive test for hepatitis B surface antigen • Repeatedly reactive test for antibodies to hepatitis B core on more than one occasion, if applicable present or past clinical or laboratory evidence of infection with • Hepatitis C (HCV), if applicable human T-cell lymphotropic virus (HTLV) or human immunodeficiency virus (HIV) • Donated the only unit of blood or blood component that resulted in the apparent transmission of a transfusion-associated disease • A history of babesiosis or Chagas' disease, if applicable evidence of or obvious stigmata of potential drug use • Use of a needle to administer non-prescription drugs
d) Other risk exposures	• Prospective donors are deferred for 12 months from the time of: • Application of a tattoo • Mucous membrane exposure to blood • Non-sterile skin penetration with instruments or equipment contaminated with blood or body fluids other than the donors' own • Residing in the household and/or having sexual contact with an individual with viral hepatitis or a confirmed positive test for Hepatitis B and Hepatitis C • Sexual contact with an individual with HIV infection or at high risk of HIV infection • Being incarcerated in a correctional institution (including jails or prisons) for more that 72 consecutive hours • Completion of therapy treatment of sexually transmitted bacterial infections or a reactive screening test for syphilis in the absence of a negative confirmatory test.
e) Malaria	• Prospective donors who have had a diagnosis of malaria shall be deferred for three (3) years after becoming asymptomatic. • Prospective donors coming from a country in which malaria is considered endemic by local public health authorities may be accepted as blood donors 3 years after departure from the area if they have been free from unexplained symptoms suggestive of malaria.
9) At risk behavior	• Evaluation of prospective donors must be questioned and appropriately deferred if behavior is suggestive of: High risk for transfusion transmissible infections. History of substance abuse or current intoxication History of sexually transmitted bacterial infections Lesions on the skin at the venipuncture site
10) Travel history	• Evaluation of donors having traveled to high risks areas for communicable disease of current public health importance

8 CRS R-D
ABO, Rh and Antibody Detection Testing of Donor Blood

1) To determine ABO group:
   a) test red blood cells with anti-A and anti-B reagents;
   b) test serum or plasma for expected antibodies with A and B red cells.
2) To determine Rh type, test with anti-D reagent.
   a) If anti-D negative, blood shall be tested using a method designed to detect weak D.
   b) If anti-D or weak D positive, shall be interpreted as "Rh-POSITIVE."
   c) If anti-D and weak D negative, shall be interpreted as "Rh-NEGATIVE."
3) Each collection shall be tested for ABO group and Rh type without reference to a donor's previous record. When ABO group and Rh type have been determined, results shall be compared with the last available record of any previous collection. Any discrepancy between the previous record and the current results shall be resolved by using a specimen from an integrally attached segment
4) Appropriate quality control shall be used for ABO, Rh, and antibody testing.

8 CRS R-E
Tests Intended to Prevent Disease Transmission

The Blood Bank shall perform the following tests:

1) HBsAg;
2) HTLV-I and II antibody;
3) HIV-1 antigen and antibody;
4) HIV-2 antibody;
5) HCV antigen and antibody;
6) Treponema specific test for syphilis;
7) Transfusion-transmissible infections, according to local risk.

The Blood Bank shall define, implement and permanently monitor the efficacy of a procedure to detect bacterial contamination of platelets at time of issue. The result of each test shall be recorded immediately, and the final interpretation shall be recorded upon completion of testing. Records shall be maintained in conformance with Section 15, Control of Records.

8 CRS R-F
Labeling of Blood and Blood Components

	Collection and Preparation	Final Product	Pooled Components
Component Name	X	X	X
Numeric or Alphanumeric ID	X	X	X
Anticoagulant or Other Solution	X	X	X
Preparation Manner	X	X	X
Storage Temperature	X	X	X
Expiration Date (if necessary the time)		X	X
ABO/Rh		X	X
Autologous	X	X	
Number of Units in Pool and ABO and Rh Type of Units in Pool			X

8 CRS R-G
Transfusion Recipient Sample Identification and Collection

1) Blood samples shall have a label bearing the following information:
   a) recipient first and last name;
   b) identification number
   c) date of sample collection.
2) A blood sample shall be obtained from the transfusion recipient within three days of the scheduled transfusion if:
   a) the transfusion recipient has been transfused in the preceding three months with blood or a blood component containing allogeneic red blood cells;
   b) the transfusion recipient has previously been identified with clinically significant antibodies;
   c) the transfusion recipient has been pregnant within the preceding three months;
   d) the history of the transfusion recipient is uncertain or unavailable. Day 0 is the day of draw.

8 CRS R-H
ABO, Rh and Antibody Testing for Recipient Blood Samples

1) To determine ABO group:
   a) test red blood cells with anti-A and anti-B reagents;
   b) test serum or plasma for expected antibodies with A and B red cells.
2) To determine Rh type, test with anti-D reagent.
3) To detect unexpected antibodies, reagent red blood cells shall not be pooled. The following steps shall be performed:
   a) the test serum or plasma and the reagent red blood cells shall be incubated at 37° C;
   b) an antiglobulin test shall be performed;
4) Appropriate quality controls shall be used for ABO, Rh, and antibody testing.

8 CRS R-I
Serologic and Electronic Compatibility Testing

1) Serologic compatibility testing shall meet one of the following two requirements:
   a) A sample of the intended recipient's serum or plasma shall be cross matched with a sample of donor cells from an originally attached segment. The cross-match shall use methods that will identify ABO incompatibility and clinically significant antibodies to red cell antigens and shall include an antiglobulin test.
   b) If no clinically significant antibodies are detected, and no record of previous detection of such antibodies exists for the intended recipient, a serological test to detect ABO incompatibility is required.
2) Electronic Compatibility System testing shall meet the following requirements:
   a) the system shall be validated on site;
   b) the system shall have a method to detect ABO incompatibility
   c) the system shall contain:
      1) donor unit number, component name, ABO group, Rh type of the compo-nents;
      2) the interpretation of the ABO confirmatory test;
      3) recipient information, ABO group, and Rh type.
   e) the system shall have a method to verify correct entry of data prior to release of blood or blood components;
   f) the system shall contain logic to alert the user to any discrepancies between donor unit labeling, blood group confirmatory test interpretation and to ABO incompatibilities between the recipient and the donor unit.
3) ABO Process for Electronic Compatibility System
   Two determinations of the recipient's ABO group shall be made, one on a current sample and the second by one of the following methods:
   a) retest same sample;
   b) test a second current sample;
   c) compare sample with previous records.

8 CRS R-J
Reissue of Blood or Blood Components

Reissue of blood or blood components shall occur under the following conditions:

1) the container closure has not been disturbed;
2) Red Blood Cells have not been allowed to warm above 10° C or cool below 1° C during storage or transportation;

3) records indicate that the unit has been inspected prior to reissue;
4) at least one sealed segment of integral donor tubing remains attached to the container.

8 CRS R-K
Compatibility Testing and Selection of Components for Infants Under the Age of 4 Months

1) An initial pretransfusion specimen from the infant shall be tested to determine ABO group and Rh type. For ABO, only anti-A and anti-B reagents are required. The Rh type shall be determined using anti-D and appropriate controls.
2) If a non-group-O infant is to receive non-group-O Red Blood Cells (RBCs), the infant's serum or plasma shall be tested for anti-A and/or anti-B. Test methods shall include an antiglobulin phase using either donor or reagent A and/or B cells. If anti-A or anti-B is detected, RBCs lacking the corresponding ABO antigen shall be transfused.
3) If the initial antibody screen demonstrates clinically significant unexpected red cell antibodies, units shall be prepared for transfusion that either do not contain the corresponding antigen or are compatible by antiglobulin crossmatch until the anti-body is no longer demonstrable in the infant's serum.

8 CRS R-L
Transfusion Reactions

1) Any adverse event experienced by a patient in association with a transfusion shall be regarded as a suspected transfusion reaction. In suspected transfusion reactions, the process shall require:
   a) notification of the physician requesting the transfusion and the transfusing Blood Bank;
   b) notation in the transfusion recipient's medical record;
   c) prompt evaluation of reaction;
   d) immediate notification of collecting Blood Bank to be followed in writing, when suspected transfusion reaction may be due to an attribute of the donor or problem with the collection, processing, or shipment of the blood component;
   e) review of adverse reaction by the Blood Bank physician
2) In the case of immediate reactions, the process shall require:
   a) interruption and evaluation of transfusion;
   b) clinical management of the transfusion recipient;

   c) written protocol indicating under what circumstances additional testing will be done and what that testing will be;
   d) if a hemolytic transfusion reaction is suspected:
1) discontinue transfusion;
2) examine blood container label to determine if there has been an error in identification of the patient;
3) collect post-transfusion recipient sample;
4) send post-transfusion recipient sample to transfusing Blood Bank for
   a) examination of serum or plasma for hemolysis, and
   b) direct antiglobulin test;
5) send blood container, administration set and attached intravenous solutions to transfusing Blood Bank for examination.
   e) notation in the transfusion recipient's medical record.
3) In the case of delayed transfusion reactions not related to transfusion transmitted infection, the process shall require:
   a) a suitable serologic evaluation;

b) report of results to transfusion recipient's physician recorded in the transfusion recipient's medical record

4) In the case of delayed reactions related to suspected transfusion transmitted infection, the process shall require:
   a) prompt investigation including a lookback procedure and documentation of the investigation
   b) notification of blood collecting facility, if transmission is confirmed or not ruled out;
   c) report to collecting facility about units of donor blood components involved in incident;
   d) investigation and reporting of findings to the transfusion facility.

SECTION 9. INSPECTION AND TESTING

9.1 General
The Blood Bank shall establish and maintain policies, processes, and procedures for inspection and testing activities to verify that the specified requirements for blood or blood components and services are met. Records of inspection and testing activities shall be maintained in conformance with Section 15.

CONTROL OF RECORDS

9.2 Inspection and Testing on Receipt of Materials

9.2.1
The Blood Bank shall ensure that incoming materials that are incorporated into the final product or that directly affect the quality of a product are not used until they have been inspected or otherwise verified as conforming to requirements. Verification shall be in accordance with policies, processes, and procedures.

9.2.2
In determining the amount and nature of inspection required upon receipt of any material, consideration shall be given to the amount of control exercised at the supplier's premises and the recorded evidence of conformance provided.

9.2.3
Where a material is used on an emergency basis prior to verification, the material shall be positively identified and recorded in conformance with Section 15, Control of Records, to permit immediate recall and replacement in the event that it is later determined not to conform to established requirements.

9.3 Inspection and Testing of Products

9.3.1 In Process Products
The Blood Bank shall:
a) inspect and test the product during processing as required by policies, processes, and procedures,
b) quarantine the product until any required inspection and tests have been completed or necessary reports received and verified, except when the product is released pursuant to Section 9.2.3.

9.3.2 Final Products
The Blood Bank shall carry out all final inspection and testing for products in accordance with policies, processes, and procedures. These policies, processes, and procedures shall require that all specified inspection and tests, including those required for materials and in-process products, have been carried out and that the results meet specified requirements.

9.3.2.1
No product shall be released until the activities specified in processes or procedures and the associated records have been completed.

9.4 Inspection and Testing of Services
The Blood Bank shall carry out all inspection and testing for services, including laboratory testing services, in accordance with policies, processes, and procedures. These policies, processes, and procedures shall require that all specified inspection and tests, including any that might be required during the provision of the service, have been carried out and that the service meets specified requirements.

Testing and services provided to others may include contracted laboratory testing services, irradiation services or reference laboratory services.

9.5. Inspection and Test Records
The Blood Bank shall maintain records in conformance with Section 15, Control of Records, that provide evidence that the product or service has been inspected or tested and the service has been provided in accordance with specified requirements. These records shall show clearly whether the product or service has passed or failed any inspection or tests or whether a service has been provided in accordance with specified requirements.

Where a product fails to pass any inspection or test, the policies, processes, and procedures for control of nonconforming product, Section 12.2.1, Review and Disposition of Nonconforming Materials and Products, shall apply.

Where a service fails to pass any inspection or test, the policies, processes, and procedures for a nonconforming service, Section 12.2.2, Review and Disposition of Nonconforming Services, shall apply.

Where a service fails to pass any inspection or test, the policies, processes, and procedures for a nonconforming service, Section 12.2.2, Review and Disposition of Nonconforming Services, shall apply.

Records shall identify the individual(s) responsible for the release of the product or provision of the service, as appropriate.

SECTION 10. CONTROL OF EQUIPMENT

CORE STANDARD

10.1 Control of Equipment
The Blood Bank shall establish and maintain policies, processes, and procedures to control, calibrate and maintain critical equipment that is used to collect, process, and transfuse blood and blood components or to determine whether materials or products (incoming, in-process or final) conform to the requirements established by the Blood Bank.

The equipment shall be used according to the manufacturer's instructions.

Inspection, measuring and test equipment shall be used in a manner that ensures that the measurement limitations are known and are consistent with the measurement capability that is required.

10.1.1 Elements of Control
The Blood Bank shall:
a) identify all equipment that can affect product or service quality;
b) prior to use and at prescribed intervals, calibrate and adjust equipment;
c) define the process used for the calibration of equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory;
d) identify equipment with a suitable indicator to show the calibration status;
e) maintain calibration records for equipment in conformance with Section 15, Control of Records;
f) ensure that the handling, maintenance, and storage of equipment is such that the equipment remains fit for use;
g) safeguard equipment from adjustments that would invalidate the calibration setting;
h) assess the conformance of products and services provided when equipment is found to be out of calibration. Records shall be maintained in conformance with Section 15, Control of Records.

10.1.2 Inspection, Measuring, and Test Equipment
For equipment used to inspect, measure, or test, the Blood Bank shall also
a) determine the measurements to be made and the accuracy and precision required and then select appropriate equipment that is capable of meeting those requirements;
b) assess the validity of previous test results and inspection when equipment is found to be out of calibration. Records shall be maintained in conformance with Section 15, Control of Records;
c) calibrate the equipment using certified equipment that has a known valid relationship to nationally recognized standards. Where no such standards exist, the basis for calibration shall be recorded;
d) ensure that environmental conditions are suitable for the calibrations, inspections, measurements, and tests carried out.

ADDITIONS TO CORE STANDARD

CRS 10. Control of Critical Equipment and Inspection, Test and Measuring Equipment

CRS 10.1 Preventive Maintenance

The Blood Bank shall establish and implement in cooperation with manufacturers and suppliers, and in conformance with CRS Reference Requirements, a preventive maintenance program including appropriate staff training for equipment that is identified as critical to the collection, processing and transfusion of blood and blood components and to the provision of services.

User logs shall be maintained and be accessible for reference.

10 CRS R-A

C10 CRS R-A

Critical Equipment

The following equipment, at a minimum, shall be identified as critical equipment:

a) scales/balances
b) water baths
c) thermometers
d) centrifuges/hematocrit serofuges
e) pipettes/dispensers
f) timers
g) refrigerators
h) freezers
i) incubators
j) biosafety cabinets
k) readers/washers
l) plasma thawers
m) microwaves
n) autoclaves
o) coolers
p) microscopes
q) sphygmomanometers
r) analyzers
s) information systems

SECTION 11. INSPECTION AND TEST STATUS

CORE STANDARD

11 .1 General
The inspection and test status of all materials and products shall be identifiable throughout the collection, processing and transfusion of blood and blood components to ensure that only materials and products that have passed the required inspections and tests are released.

The inspection or test status of all materials and blood and blood components shall be identified by suitable means to indicate the conformance or nonconformance. In the case of a nonconformance, the reason for the nonconformance shall be identified.

SECTION 12. DEVIATIONS AND NONCONFORMING PRODUCTS OR SERVICES

CORE STANDARDS

12.1 Deviations
The Blood Bank shall have a process to ensure the capture, assessment, investigation, and monitoring of events that deviate from accepted policies, processes, or procedures or that fail to meet the requirements of the Blood Bank, these Standards, or applicable laws and regulations. Deviations shall be reported in accordance with specified requirements.

12.2 Control of Nonconforming Products or Services
The Blood Bank shall establish and maintain policies, processes, and procedures to ensure that materials and products or services that do not conform to specified requirements are prevented from unintended use or release. This control shall provide for identification, documentation, evaluation, segregation, (when practical), and disposition of nonconforming materials and products. The Blood Bank shall establish and maintain policies, processes, and procedures to address non-conforming services. Deviations shall be reported as required in accordance with specified requirements.

12.2.1 Review and Disposition of Nonconforming Materials or ProductThe responsibility for review of and authority for the disposition of nonconforming materials or products shall be defined. A nonconforming material or product shall be evaluated for appropriate disposition in accordance with policies, processes, and procedures. A nonconforming material or product may be:

a) reworked to meet the specified requirements; or
b) accepted by the customer, after disclosure of the nonconformance; or
c) relabeled, in conformance with applicable requirements; or
d) destroyed.

Products that are determined after release not to conform to specified requirements shall be reported to the customer. Records of the nature of nonconformances and subsequent actions taken, including acceptance for use shall be maintained in conformance with Section 15, Control of Records. Reprocessed, retested, or reworked products shall be reinspected in accordance with policies, processes, and procedures.

12.2.2 Review and Disposition of Nonconforming Services
The responsibility for review of and authority for the handling of nonconforming services shall be defined.

A nonconforming service shall be evaluated for appropriate action in accordance with policies, processes, and procedures. A nonconforming service may be repeated or accepted by the customer. A process shall be created with the purpose of tracking and trending, root cause analysis, preventive and corrective action, and post implementation assessment.

The repeat of a service that does conform to specified requirements shall be reported to the customer where required by agreement. Records of the nature of nonconformances and subsequent actions taken, including acceptance for use, shall be on standardized reporting forms and maintained in conformance with Section 15, Control of Records, to denote the actual condition.

12.2.3 Reinspection

Reworked products shall be reinspected in accordance with policies, processes, and procedures.

ADDITIONS TO CORE STANDARD

CRS 12. Deviations and Nonconforming Products or Services

CRS 12.1 Unavailability of Donor Collection Testing Results

Blood or blood components intended for autologous or allogeneic transfusion that are nonconforming due to the unavailability of final testing results required in CRS 8.6.2, Tests Intended to Prevent Disease Transmission, shall be released only in an emergency and with physician's documented notification and acceptance. A pretransfusion sample must be obtained from the intended recipient. This sample will be retained until the donor testing results become available. Testing shall be completed and the transfusion recipient's physician notified of the final test results. The donor shall be notified when such test results are reactive/positive. The container label shall indicate that testing has not been completed.

CRS 12.2 Non-availability of Compatibility Test Results

Blood or blood components that are nonconforming due to the non-availability of final compatibility test results that otherwise conform to CRS 8.9, Compatibility Process, may be transfused when a delay in transfusion could be detrimental to the transfusion recipient. The following additional requirements shall apply:

a) a transfusion recipient whose ABO group is not known shall receive Group O Red Blood Cells. Children and women of child-bearing age shall receive Group O Rh negative red blood cells. Refer to to Section 8, CRS 8.8.1.2;
b) the requesting physician shall indicate in writing that the clinical situation is sufficiently urgent to require release of blood or blood components before completion of compatibility testing. Records of the request shall be maintained in conformance with Section 15, Control of Records;
c) the container label shall indicate that compatibility testing has not been completed.

CRS 12.3 Nonconforming Volume Units

Blood or blood components that are nonconforming because of volume requirements shall be processed in a manner consistent with the following:

If 300-400 ml have been collected into an anticoagulant volume calculated 450 ± 45 ml, the Red Blood Cells may be used for transfusion if a label is affixed stating Low Volume Unit: _____ mL Red Blood Cells." Other blood components shall not be made from low-volume units.

SECTION 13. CORRECTIVE AND PREVENTIVE ACTION PLANS

CORE STANDARD

13.1 General
The Blood Bank shall establish and maintain policies, processes, and procedures for implementing corrective and preventive action plans. Management shall review relevant information on corrective or preventive actions taken.

Any corrective or preventive actions taken to eliminate the causes of actual or potential non-conformances shall be appropriate for the problems and the risks encountered.

The Blood Bank shall implement any changes to the policies, processes, and procedures resulting from corrective and preventive action. Records shall be maintained in conformance with Section 15, Control of Records.

13.2 Corrective Action
The process for corrective action shall include:

a) the effective handling of deviation reports and product nonconformances;
b) investigation of the cause of nonconformances relating to product, process, and the quality system. Records shall be maintained in conformance with Section 15, Control of Records;
c) investigation of customer complaints;
d) determination of the corrective action needed to eliminate the cause of nonconformances;
e) ensuring that corrective action is taken and that it is effective.

13.3 Preventive Action
The process for preventive action shall include:

a) the use of appropriate sources of information such as policies, processes, and procedures that affect product or service quality, assessment results, proficiency testing results, quality control records and customer complaints to detect, analyze, and eliminate potential causes of nonconformances;
b) determination of steps needed to deal with any problems requiring preventive action;
c) initiation of preventive action and application of controls to ensure that it is effective.

13.4 Emergency preparedness
The blood bank shall have a plan for emergency preparedness and disaster response.

SECTION 14. STORAGE, DISTRIBUTION, AND TRANSPORTATION

CORE STANDARD

14.1 General
The Blood Bank shall establish and maintain policies, processes, and procedures for storage, distribution, and transportation of materials, and in-process and final products.

14.2 Storage
The Blood Bank shall use designated storage areas to limit deterioration of and prevent damage to materials, and in-process and final products. The Blood Bank shall control access to such areas and control removal of products from these areas.

In order to detect deterioration, the condition of material and product in stock shall be assessed at appropriate intervals.

14.3 Distribution and Transportation
The Blood Bank shall use policies, processes, and procedures for handling material and product that are intended to limit deterioration and prevent damage. The Blood Bank shall control packing to the extent necessary to ensure conformance with specified requirements. The Blood Bank shall arrange for protection of the quality of material and product during transport and after final inspection and release.

ADDITIONS TO CORE STANDARD

CRS 14. Storage, Distribution and Transportation

CRS 14.1 Storage
The Blood Bank shall establish and maintain processes and procedures for storing blood and blood components from the time of collection to the point of administration. The storage duration and temperature shall be for periods of time and at temperatures that conform to CRS Reference Requirements that are designed to be optimal for the function and safety of the blood and blood components. There shall be provisions for power failures and other disruptions.

14 CRS R-A

CRS 14.1.1 Refrigerator Requirements
Refrigerators for storage of blood and blood components shall be of capacity and design to ensure that the proper temperature is maintained throughout the refrigerator.

CRS 14.1.2 Temperature Monitoring
Refrigerators, freezers and platelet incubators shall have a system to monitor temperature continuously.

The temperature shall be recorded, at a minimum, every 4 hours.

Ambient air temperature in open storage areas shall be maintained between 20°C-24C and recorded every 12 hours in conformance with Section 15, Control of Records.

CRS 14.1.3 Alarms

Refrigerators, freezers and platelet incubators shall be equipped with alarms that activate at appropriate temperatures.

CRS 14.1.3.1

The Blood Bank shall establish and maintain procedures that will allow proper action to be taken when an alarm is activated and before the blood and blood components reach undesirable temperatures.

CRS 14.1.4 Container Integrity Requirements

Blood and blood components shall be stored in a manner that protects the integrity of the container.

CRS 14.2 Distribution and Transportation

The Blood Bank shall establish processes and procedures for distributing and transporting blood and blood components at temperatures in conformance with CRS Reference Requirements that are designed to be optimal for the function and safety of the blood and blood components.

14 CRS R-A

14 CRS R-A
Storage, Distribution & Transportation

Product	Additional Criteria	Storage	Transport	Expiration
RBC, closed system (including leukoreduced)		1-6°C	1-10°C	According to anticoagulant solution CPD: 21 days CPDA-1: 35 days Additive solution: 42 days
RBC, irradiated	25 Gy	1-6°C	1-10°C	According to anticoagulant but not to exceed 28 days after collection for CPDA-1 and additive solution irradiated < 14 d after donation max 28 d; irradiated> 14 d after donation: max 24 h
RBC, Open System (including leukoreduced, irradiated, washed, and/or thawed deglycerolized)		1-6°C	1-10°C	24 hours

14 CRS R-A (continued)

Product	Additional Criteria	Storage	Transport	Expiration
Platelets (pheresis or whole blood derived), closed system (including leukoreduced and/or irradiated)		20-24°C with continuous gentle agitation	20-24°C, maximum time without agitation 24 hours	Pheresis: 24 hrs – 5 days dependent on collection system Prepooled -5 days Whole blood derived -5 days
Fresh Frozen plasma (FFP) or frozen plasma (FP)	FFP: Frozen within 8 hours of collection CPD, CP2D, CPDA-1 FP: frozen within 24 hours of collection – ACD	≤ -18°C or ≤ -65°C	Maintain frozen state	12 months (-18°C) 7 years (-65°C)
Solvent Detergent-treated Pooled Plasma (SDPP)		≤ -18°C	Maintain frozen state	12 months
FFP or FP, SDPP, Thawed	Thaw @ 30-37°C or in a microwave device approved for this purpose	1-6°C	1-10°C	24 hours
Thawed Plasma	Collected by Closed System	1-6°C	1-10°C	>24 hr < 5 days
Liquid Plasma		1-6°C	1-10°C	5 days after expiration of RBC
Cryoprecipitate AHF	Thaw the FFP @ 1-6°C Re-freeze cryopre-cipitate within 1 hour	≤ -18°C	Maintain frozen state	12 months
Cryoprecipitated AHF, single unit, thawed	Thaw @ 30-37°C	20-24°C	20-24°C	6 hours
Cryoprecipitate AHF, thawed	Thaw @ 30-37°C	20-24°C	20-24°C	4 hours if open system and/or pooled

SECTION 15. CONTROL OF RECORDS

CORE STANDARD

15.1 Original Records
The Blood Bank shall establish and maintain policies, processes, and procedures for identification, collection, indexing, access, filing, storage (including off-site storage for backup data), maintenance, and disposition of records. A summary of records shall be maintained.

Records shall be maintained to demonstrate that a material, product, or service conforms to specified requirements and that the quality system is effectively operating. Pertinent records from suppliers shall be an element of this information.

All records shall be legible and shall be stored and retained in such a way that they are readily retrievable. Records shall be stored in a suitable environment to prevent damage or deterioration and to prevent loss. Retention time of records shall be established and recorded.

Records shall be maintained and protected from accidental or unauthorized modification.

15.2 Copies
Prior to destruction of the original records, the Blood Bank shall ensure that cop-ies of records in any medium are verified to be copies of the original records.

ADDITITONS TO CORE STANDARD

CRS 15 Control of Records

CRS 15.1 Confidentiality
The Blood Bank shall establish processes and procedures to ensure the confidentiality of the donor and the transfusion recipient's records.

CRS 15.2 Record Retention
Records shall be retained for appropriate periods of time in conformance with CRS Reference Requirements. Other records not included in CRS Reference Requirements shall be retained by the Blood Bank for a length of time determined by its individual business.

A system shall be maintained for the management of discard of records. 15 CRS R-A applies.

CRS 15.3 Retrieval time of records
The Blood Bank shall specify the maximum acceptable retrieval time of records.

15 CRS R-A

15 CRS R-A
Retention of Records

1) Records that must be retained at a minimum for 15 years shall be:
   a) donors' identifying information, and unit numbers of all donated components;
   b) blood and blood components received from outside sources, including numeric or alphanumeric identification of a blood unit, and identification of the collecting facility;
   c) information to identify facilities that carry out any part of the preparation of blood components and the function performed;
   d) final disposition of each unit of blood or blood component, and if issued by the facility for transfusion, the identification of the recipient;
   e) a record of donors who have been permanently deferred and prospective donors who have been indefinitely deferred for the protection of the potential recipient or placed on surveillance;
   f) notification to transfusing facility of previous receipt of units from a donor subsequently found to be confirmed positive for HIV or HTLV-I or repeatedly reactive for HIV-1-Ag;
   h) difficulty in patient blood typing, clinically significant antibodies, adverse reactions to transfusion, and special transfusion requirements;
   i) names, signatures, and initials or identification code, and inclusive dates of employment of those authorized to sign or initial or review reports and records.
   j) severe adverse reactions to donation;
   k) donor ABO group and Rh type;
   l) Other records of prospective blood donors who have been temporarily deferred for the protection of the potential recipient shall be maintained for the required deferral period, including interpretations of prescreening or qualifying tests.
2) Records that must be retained for a minimum for 5 years shall be:
   a) records of blood component inspection prior to issue;
   b) transfusion recipient's name, identification number, ABO group and Rh type;
   c) interpretation of compatibility testing;
   d) temperatures of storage and results of inspection of blood and component units;
   e) control testing of components, reagents, and equipment and proficiency testing surveys (including dates, tests performed, observed results, interpreta-tions, identification of personnel carrying out the tests, and any appropriate corrective action taken).
3) The Blood Bank must determine retention times for the following records
   a) Executive Management's review of quality system
   b) annual review of processes and procedures that affect quality
   c) agreement reviews
   d) acceptable suppliers
   e) identification of source and processing for units of blood or blood component
   f) records of all units of blood and blood components obtained through allogeneic and autologous collection
   g) identification number of each unit in pooled components
   h) computer validation results
   i) individual who draws intended recipient's blood for compatibility testing
   j) reissuance of blood
   k) platelet pheresis processes and procedures
   l) product released for emergency use
   m) hardware validation
   n) calibration records for inspection, measuring and test equipment
   o) nonconforming units that are accepted for transfusion

p) nonconforming service that is accepted
q) changes to processes and procedures resulting from corrective and preventive action
r) results of assessments
s) follow-up after corrective action
aa) training
bb) evaluation of continued competence
cc) all superseded policies and procedures

SECTION 16. QUALITY ASSESSMENTS

CORE STANDARD

16.1 General
The Blood Bank shall perform quality assessments that verify whether the quality system and the collection, processing, and transfusion of blood and blood components and the provision of services comply with requirements, and that determine the effectiveness of the quality system.

The Blood Bank shall establish and maintain policies, processes, and procedures for scheduling and conducting internal quality assessments. These internal quality assessments shall verify whether the quality system and the collection, processing, and transfusion of blood and blood components comply with requirements and shall determine the effectiveness of the quality system.

Internal quality assessments shall be planned at minimum annually according to a specific schedule or more frequently on the basis of the importance of the activity to the quality of the product or service. The results of the internal assessments shall be reviewed by personnel independent of those having direct responsibility for the activity being assessed.

The results of internal quality assessments shall be reviewed by Executive Management. The results of the assessments shall be recorded in conformance with Section 15, Control of Records, and reviewed by the personnel having responsibility for the area assessed. The management personnel responsible for the area shall take timely corrective action on nonconformances found during the assessment.

Follow-up action shall verify and record the implementation and effectiveness of the corrective and preventive action taken in conformance with Section 15, Control of Records.

ADDITIONS TO CORE STANDARD

CRS 16. Quality Assessments

CRS 16.1 Assessments
The Blood Bank shall participate in an external assessment program conducted by a recognized independent source. Records shall be maintained in conformance with Section 15, Control of Records.

CRS 16.2 Transfusion Practices Committee
All transfusing facilities shall have a transfusion practices committee that documents the monitoring of transfusion practices for all categories of blood and blood components in conformance with CRS Reference Requirements.

16 CRS R-A

16 CRS R-A
Transfusion Practices Committee
The Transfusion Practices Committee shall evaluate:

1) blood requesting practices;
2) specimen collection;
3) usage including discard;
4) blood administration policies;
5) ability of services to meet transfusion recipient needs.

SECTION 17. TRAINING

CORE STANDARD

17.1 General
The Blood Bank shall establish and maintain policies, processes, and procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training, or experience. These should be accomplished prior to job commencement or procedure changes. Records shall be maintained and updated in conformance with Section 15, Control of Records.

ADDITIONS TO CORE STANDARD

CRS 17. Training and Education

CRS 17.1 Training/Competence assessment Program

The Blood Bank shall have a training program which shall include the following elements:

a) identification of job functions which must be included in the training program;
b) initial competence assessment prior to independent job performance;
c) continuous competence assessment of incumbent personnel against performance standards at regular intervals;
d) training development and delivery appropriate for process changes/performance.

Records of training and competence assessment shall be maintained in conformance with Section 15, Control of Records.

CRS17.2 Continuous Education of Blood Bank Staff

The blood bank staff shall participate in annual continuous education on topics related to job functions.

SECTION 18. STATISTICAL TECHNIQUES

CORE STANDARD

18.1 Identification of Need
The Blood Bank shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics.

18.2 Application of Statistical Techniques
When statistical techniques are used, the Blood Bank shall establish and maintain policies, processes, and procedures to implement and control the application of the statistical techniques identified.

ADDITIONS TO CORE STANDARD

CRS 18. Statistical Techniques

CRS 18.1

The Blood Bank shall use applicable statistical techniques to demonstrate process control.

SECTION 19. SAFETY

CORE STANDARD

19.1 General
The Blood Bank shall establish and maintain policies, processes, and procedures designed to minimize risks or manage events related to the health and safety of employees, donors, volunteers, and other persons affected within the work environment. Suitable quarters, environment, and equipment shall be available to maintain safe operations.

The policies, processes, and procedures shall address biological, chemical, and, where applicable, radiation safety, and appropriate interventions to mitigate exposure, and shall include a system for monitoring training and compliance.

Biohazardous materials shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

ADDITIONS TO CORE STANDARD

CRS 19. Safety

CRS 19.1 Safety

The Blood Bank shall comply with all applicable national guidelines and legislation relating to safety issues

SECTION 20. BLOOD DONOR ISSUES

CORE STANDARD

20.1 General
The Blood Bank shall have responsibility for encouraging and retaining adequate numbers of volunteer donors. Donors shall be recruited and retained in a manner that recognizes the unique nature of their contribution and the right of the donor to be treated with dignity and in a fair and cordial manner, respecting their privacy. Donors shall be informed in a timely manner of any medically significant abnormality detected during precollection evaluation or as a result of laboratory testing and records kept in accordance with CRS-15.

The Blood Bank shall provide counseling and/or referral for a donor who during interview is identified as potentially at risk, or has any positive or confirmed reactive infectious disease marker.

The Blood Bank shall ensure that Donors understand the donation process and agree in writing to the donation process prior to donation. The following issues shall be addressed in the agreement:

a) what tests will be performed on their donated blood;
b) under what circumstances they will be informed of test results;
c) what information shall be released to third parties and under what circumstances.

Donor test results shall be maintained in a confidential manner and in conformance with the laws of the country. Donors shall be provided with appropriate post-donation advice and information about possible adverse reactions.

Donors shall be appropriately recognized for their contribution. No Blood Bank shall offer material incentives.

ADDITIONS TO CORE STANDARD

CRS 20. Blood Donor Issues

CRS 20.1 Donor Recruitment

The Blood Bank shall appoint an individual responsible for donor recruitment. Section 17, applies.

ANNEX 1: GLOSSARY

Audit:	An independent process for evaluating the compatibility of a quality management system to its objectives and to determine the gaps between what was revealed and what is required.
Autologous blood donation:	Process by which an individual deposits blood or a blood component with the intention of having the deposited blood or component transfused solely to her\himself.
Blood bank:	Service that recruits, educates, and selects blood donors, and collects, processes, stores and distributes blood and blood components intended for transfusion.
Calibration:	The comparison of a measurement instrument or system of unverified accuracy to a measurement instrument or system of a known accuracy to detect any variation from the required performance specification.
Competence:	Demonstrated ability to apply knowledge skills. [ISO 9000:2000].
Compliance:	To be in agreement.
Conformance:	An affirmative indicator or judgment that a product, program, or service has met the agreed-upon requirements of a customer, or a relevant specification, contract, or regulation.
Corrective action:	Action taken to eliminate the cause of a detected nonconformity or other undesirable situation.
Customer:	Organization or person that receives a product. [ISO 9000:2000].
Directed blood donation:	Process by which and individual gives blood or a blood component with the intention of having the donated blood or blood component transfused to a predetermined specific patient.
Document:	Information and its supporting medium. A set of documents is often called documentation. [ISO 9000:2000].
Establish:	Define, document (in writing or electronically), and implement. [FDA QSR].
Executive management:	The person or group of persons with ultimate responsibility for the appropriate operation of a service.
Inspection:	Conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging. [ISO 9000:2000].
Nonconformity:	A non-fulfillment of a requirement where a result was not achieved according to a specific requirement.
Preventive action:	Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.
Procedure:	Precise, concise, clear description of the material, equipment, conditions, activities and requirements for obtaining a product or service of specific quality and characteristics.
Process:	Set of interrelated or interacting activities which transforms inputs into outputs (products).
Product:	A result of a process.
Quality manual:	A document containing the quality policy, quality objectives, organizational structure diagram, and description of the quality system and its relation to the main processes.

Quality plan:	A document specifying which procedures and related resources should be applied by whom and when to a specific project, product, process or contract.
Quality planning:	Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources in order to fulfill the quality objectives.
Quality policy:	Overall intention and direction of an organization related to the quality management system as formally expressed and published by the organization's top management.
Record:	A document stating results achieved or providing evidence of activities performed.
Review:	Activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives. [ISO 9000:2000].
Standard:	Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.
Supplier:	Organization or person that provides a product. [ISO 9000:2000].
Traceability:	Ability to trace the history, application or location of that which is under consideration. [ISO 9000:2000].
Transfusion service:	Service that issues blood and blood components for appropriate patient care.
Validation:	Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. [ISO 9000:2000].
Verification:	Confirmation, through the provision of objective evidence that specified requirements have been fulfilled. [ISO 9000:2000].
Voluntary blood donation:	Process by which a person gives blood or a blood component of his own free will, without intention of benefiting any specific patient, and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute of money.

ANNEX 2: OFFICIAL DOCUMENTS OF THE DIRECTING COUNCIL OF THE PAN AMERICAN HEALTH ORGANIZATION

PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION

46th DIRECTING COUNCIL

57th SESSION OF THE REGIONAL COMMITTEE

Washington, D.C., USA, 26-30 September 2005

Provisional Agenda Item 4.11

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

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

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

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

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

CONTENTS

Background

1. For the last 30 years, the World Health Assembly has given priority to the utilization and supply of human blood and blood products, urging Member States to promote the development of nationally coordinated blood services based on voluntary, nonremunerated donation of blood and quality assurance, to enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and recipients of blood and blood products, as well as to confront the HIV/AIDS epidemic.

2. At the 25th Pan American Sanitary Conference, the Strategic and Programmatic Orientations of the Pan American Health Organization for 1999-2002 were approved. Among the goals related to health policies and services, the Conference included: (a) all blood for transfusion will be analyzed to detect infections by hepatitis B and C viruses, syphilis, *Trypanosoma cruzi* and HIV, and (b) all blood banks will be participating in quality control programs.

3. In October 1999, Resolution CD41.R15, "Strengthening Blood Banks in the Region of the Americas," was adopted by the 41st Directing Council of PAHO. This resolution urged Member States to promote the development of national blood programs and transfusion services, based on the voluntary, nonremunerated, and repeated donation of blood, as one indicator of human development and on quality assurance. The resolution also included a request to the Director of PAHO to cooperate with the Member States in strengthening the national blood programs and transfusion services; assist in the strengthening of national programs for voluntary, nonremunerated, repeated blood donations; and promote universal, accurate, and efficient screening of the units of blood donated in the Region.

4. Taking into consideration the Strategic and Programmatic Orientations and the resolutions, and with the financial support from the Pan American Health and Education Foundation (PAHEF), PAHO, together with the coordinators of the national blood programs of Latin America, the directors of the blood banks in the Caribbean, the Collaborating Centers, and potential partners from academic and professional institutions, developed a plan of action to respond to the request of the Governing Bodies. The specific expected results of the plan were:

(a) Coverage of screening: 100% coverage of screening of blood units for HIV, HBV, HVC, and syphilis in the Region; and 100% coverage of screening for Chagas' disease in Latin America.

(b) External Evaluation of Performance: 100% of the blood banks that screen blood for transfusion will participate in the external evaluation of performance of

serological tests for HIV, HBV, HCV, syphilis, and Chagas' disease, as appropriate.

(c) Donors: 50% of donors in each country of the Region will be voluntary, altruistic, and nonremunerated.

(d) Infections in high-risk groups: High-risk groups for transfusion-transmitted infections will be identified and monitored for incidence of HCV infection.

5. The collaborative plan of action was submitted as a grant proposal to the Bill and Melinda Gates Foundation, which provided support for work to be carried out between January 2001 and July 2004.

Progress from 2000

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

Coverage of Screening

7. Laboratory testing for infectious markers contributes to blood safety by eliminating those units that are collected from individuals that may be the source of transfusion-transmitted infection (TTI). Screening, however, does not fully eliminate the risk of TTI as blood may be collected from infected donors during the window* period and, thus, the value of laboratory testing depends on the incidence and prevalence of the infections among the blood donors.

8. Despite improvements in the coverage of testing for TTI markers, the goal of universal screening of blood in the Americas has not been attained. By 2003, the proportion of units tested for HIV was 99.93% (up from 99.66% in 2000); for hepatitis B, 99.86% (up from 99.65% in 2000); for hepatitis C, 99.52% (up from 98.79% in 2000); and for syphilis markers; 99.84% (up from 99.57% in 2000). The lowest coverage was for T.cruzi in Latin America: 88.09% up from 78.98% in 2001 (see Annex and Tables 1 and 2).

9. Only 19 countries and territories screened all units of blood collected for all required markers, up from 16 in 2000. Anguilla, Antigua and Barbuda, Belize, Montserrat, and Saint Kitts and Nevis reported zero screening for hepatitis C in 2003. Only seven Latin American countries tested all units for T. cruzi in 2003 (Table 3).

* The time between infection and when markers of infection become detectable.

10. The median number of blood banks in Latin America is 48 per country (range 23-578). With the exception of Cuba, that has an average of 13,338 units collected per bank, the mean yearly blood collection ranges between 606 and 7,988 units per bank in Latin America. PAHO developed an assessment guideline and provided technical and financial support to examine the financial efficiency of the current national blood systems in countries in Latin America. In general, the current overall average cost of processing a blood unit is US$ 750, twice the investment that would be needed in a model with fewer blood banks. Nine Latin American countries (47%)—Argentina, Bolivia, Chile, Colombia, El Salvador, Mexico, Nicaragua, Peru, and Uruguay—have adopted a policy to reduce blood processing centers.

11. Eighteen countries in Latin America have laws that regulate blood services. Analyses of the adequacy of the laws, compared to a "model law" developed by PAHO, however, show that the current legal frameworks are deficient in setting up a national system, its organization, functions, financial support, and the overall oversight.

External Evaluation of Performance

12. The pillars of quality assurance are quality control, external evaluation of performance, audits, and continued education of staff. External evaluation of performance allows the retrospective comparison of the ability of the participating centers to correctly analyze controlled samples. PAHO established the Regional Program for External Evaluation of Performance (PEEP) for TTI, aimed at national reference blood banks in Latin America (Table 4). PAHO supported the training of Latin American personnel from central laboratories and/or blood banks in the technology and administrative processes to established national PEEP. In the four-year period, 16 of the 19 Latin American countries had their national PEEP established, with participation increasing from 24% (1,129/4,738 banks) in 2000 to 53% (1,330/2,509 banks) in 2003 (Table 5).

13. PAHO also established subregional PEEP programs for immunohematology for Latin America, with the help of the Blood Center in Valencia, Spain, and for the Caribbean with the support of the Collaborating Center in the United Kingdom and the Caribbean Epidemiology Center (CAREC) (Tables 6 and 7).

14. Adoption of national quality standards and quality assurance (QA) policies were monitored as indicators of national quality systems in 41 countries (Table 8). Training of personnel on QA issues and quality management was done in regional or subregional workshops, and then promoted at the national level. Distance learning, as well as face-to-face courses, was developed to train personnel from blood banks.

Donors

15. The promotion of voluntary blood donation is central to blood safety since voluntary blood donors are less likely to be carriers of TTI (Table 9). Voluntary, nonremunerated donors have increased from 15% of the units of blood collected in Latin America and the Caribbean in 2000 to 36% in 2003. But, Bolivia, Honduras, Panama, Paraguay, and Peru reported paid donors that accounted for 0.3% of all units (Table 10). The countries that reported over 50% voluntary blood donors (VBD) in 2003 were Aruba, Bermuda, Brazil, Cayman Islands, Cuba, Curação, Saint Lucia, and Suriname.

16. PAHO developed and supported the application in 15 countries of guidelines to investigate public knowledge, beliefs, attitudes, and practices regarding blood donation, as well as to assess the readiness of the blood banks to provide good service to blood donors. Educational materials and public service announcements specifically targeted at school children, young adults, and the elderly or for the population at large were produced.

17. The main activities conducted by PAHO have been to identify and train national coordinators for the promotion of voluntary blood donation nationally, to develop national plans for the promotion of voluntary donation, and to organize national workshops to train promoters of voluntary blood donation in their respective countries. The legal frameworks regarding blood donation and blood collection do not cover the critical issues about promoting voluntary blood donation, although their stated intention is to pursue it.

Infections in High-Risk Groups

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

19. Recommendations for national blood programs on how to develop and implement guidelines for the clinical use of blood were developed by PAHO as well as the concept of hemovigilance.

Safety and Availability of Blood

20. The true safety of blood and blood transfusions can only be established by the longitudinal follow-up of patients who receive blood and of individuals who give blood. This approach is presently impossible in the Caribbean and Latin America due to the lack of countrywide information. Under the current circumstances, the best estimate of the safety of blood for transfusion comes from a combination of prevalence of infectious markers among blood donors and the coverage of screening for each of those markers.

21. The estimated risks for HIV-contaminated transfusion in Latin America and the Caribbean decreased from 0.47 per 100,000 donations in 2000 to 0.08 in 2003; from 21.18 to 0.30 per 100,000, for hepatitis B; and from 131.32 to 28.22 per 100,000 for *T. cruzi*. The risk for hepatitis C was 3.29 in 2000 and 2.00 in 2003 (Table 12). These findings, coupled with those from the study of multitransfused patients, clearly indicate that better selection of blood donors and extension of screening coverage should be priorities in the Region.

22. On the other hand, screening of blood prevented approximately 135,000 viral infections in the four-year period, including 13,058 by HIV. If we consider the cost of antiretroviral drugs alone—not taking drug delivery into consideration—at $400 per person per year, the estimated investment to treat those individuals is $5,223,200.

23. Although past work in the Region did not have the specific objective of increasing the number of blood units collected, the available data allow an estimation of the availability of blood in each country and in the Region. The international standard proposed by the International Federation of Red Cross and Red Crescent Societies and WHO is for a community to have enough blood, to collect a number of blood units equivalent to 5% of the population, or 50/1,000. The overall donation rate in the Latin American and Caribbean countries is 14, with no major changes in the last four years (Table 13). Except for Cuba, which has a donation rate above 50, 53% of the countries have donation rates under 10, and 44%, donation rates between 10 and 19.

Lessons Learned and Critical Issues

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

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

25. One of the consequences is that the general population prefers to "save their blood for a family or friend" and not give altruistically, creating a shortage of blood even when efforts are made to promote voluntary donation by nonhospital-based institutions. This induced, artificial unavailability of blood in turn provides the rationale for hospital-based blood banks not to share their blood with other centers. The final consequence is that up to 12% of units of red blood cells may be discarded in a country, because they become outdated. In other instances, because the blood is available to the clinicians, transfusions are given to patients who do not need them.

26. For 2002, countries that had at least 98% voluntary blood donors had a prevalence of HIV reactive donors of 2 per 100,000 donors; the rate for the countries with paid donors was 350; the figure for the countries with replacement donors was 340. This means that replacement and paid donors are more likely to be positive for any of the markers of infectious agents that may be transmitted through transfusions. More blood is discarded after screening in the latter two groups of countries. Thus, nonvoluntary blood donation has an impact on safety and availability of blood as well as economical consequences.

27. The existence of an excessive number of hospital-based blood banks has negative consequences for blood availability and safety.. Additionally, it contributes to diminished efficiency of scarce resources, including the augmented purchase prices of the testing kits. Data obtained from seven countries show that the cost, per test, of HIV reagents varies from $1.30 to $3.69; for HVC the range is $1.55 to $8.72. Other direct and indirect costs are also higher in blood banks that process a small number of units per year.

28. The multiplicity of blood banks also hinders the implementation of quality programs at the national level. Implementing quality programs in services that collect a few units of blood daily is very expensive and inefficient. Training of personnel, maintenance of equipment, audits, and external evaluation of performance would amount to a gigantic effort and investment of already limited resources. It is not surprising, then, that smaller blood banks are more likely to produce inaccurate results in the screening tests for infectious markers, as shown by the national PEEP.

29. The improvement of blood safety in the Region requires systematic, multidisciplinary national approaches that (a) promote voluntary blood donation by educating the public, training personnel, and setting up donor-friendly blood collecting sites; (b) facilitate quality assurance and efficient preparation of blood components;

(c) ensure oversight of the use of resources, including blood; and (d) optimize the number of blood banks.

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

The Way Forward

31. The First Pan American Conference on Blood Safety was held in PAHO Headquarters in February 2003. Delegates from the countries of the Region, technical partners, and PAHO country staff participated in the evaluation of the progress of the plan developed in 1999, and in the planning for 2004-2010. The purpose of the plan of action for the coming years is to contribute to the reduction of mortality and to the improvement of patient care in Latin America and the Caribbean, by making safe blood for transfusion available in a timely manner for all those patients who need it. The objectives set forth are:

(a) Assure appropriate collection and preparation of blood components in sufficient quantities to treat patients who need blood transfusions.

(b) Assure timely access to blood components by patients who need blood transfusions.

(c) Assure the highest level of safety of blood products to avoid transmission of infectious diseases and other untoward effects associated with transfusions.

(d) Promote the appropriate clinical use of blood.

(e) Improve the efficiency of the national resources.

32. The indicators of progress of the plan are:

(a) 100% of the countries will have a national estimate of the geographic and temporal needs for blood and blood components.

(a) 95% of all units of blood collected will be fractionated into components.

(c) 100% of the countries will have implemented a quality assurance plan that comprises all blood services in the country.

(d) At least 50% of the blood units collected in each country will come from voluntary, altruistic, nonremunerated donors.

(e) 100% of the countries will have established hemovigilance to assess the health impact of transfusions, in accordance with the national system organization and set up.

(f) 100% of the countries will have revised their legal and regulatory framework.

(g) 100% of the countries will have operational transfusion committees, in accordance with the national system organization and set up.

(h) 100% of the countries will have implemented guidelines for the clinical use of blood in every transfusion service.

(b) 100% of Latin American countries will have implemented regional blood collection and processing systems to cover the needs of patients of geographically distinct areas.

33. The proposed strategies are:

Planning and Management of the National Blood Network System

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

Promotion of Voluntary Blood Donation

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

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

Quality Assurance

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

Appropriate Use of Blood and Blood Components

37. The ministry of health of each country will develop the national guidelines for clinicians, which will be adapted to each health care facility by the hospital transfusion committee. Training of medical personnel will be carried out using the distance-learning model, the materials developed by WHO, national guidelines, and teleconferences.

38. All these strategies will be pursued in collaboration with the International Federation of Red Cross and Red Crescent Societies, Rotary Clubs, the Ibero American Collaborative Group for Transfusion Medicine; the Hemocenter in São Paulo, Brazil; the United Kingdom Performance Testing Center; the Spanish Blood Transfusion Services; the United Blood Services Blood Bank in El Paso, Texas; and other centers.

Action by the Directing Council

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

Annexes

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Budget for regional activities

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

Available for regional activities, July 2005

Regular funds. US $ 115,000 per biennium.

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

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

Human resources

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

PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION

136th SESSION OF THE EXECUTIVE COMMITTEE

Buenos Aires, Argentina, 20-24 June 2005

CD46/16 (Eng.)
Annex C

RESOLUTION

CE136.R6

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

THE 136th SESSION OF THE EXECUTIVE COMMITTEE,

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

RESOLVES:

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

THE 46th DIRECTING COUNCIL,

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

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

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

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

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

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

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

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

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

RESOLVES:

1. To urge Member States to:

(a) analyze the progress and challenges in the pursuit of sufficiency, quality, safety, and appropriate use of blood and blood products in their countries;

(b) officially adopt the Regional Plan of Action for Transfusion Safety 2006-2010, and appropriately allocate and efficiently use resources to obtain its objectives;

(c) promote the participation of the public and private sectors, ministries of education, labor and social development, and civil society in the international, national, and local activities undertaken to implement the Regional Plan;

(d) Strengthen blood services and improve their efficiency, while promoting a culture of voluntary, non-remunerated blood donation.

2. To request the Director to:

(a) cooperate with the Member States in the development of their national blood policies and strategies, and the strengthening of blood services to ensure transfusion safety;

(a) promote the application at the local level of quality standards and validated methodologies for the improvement of the safety of blood products and blood transfusion, utilizing a multidisciplinary approach;

(c) work with Member States to monitor the development of the national blood programs and transfusion safety;

(d) report periodically to the Governing Bodies on the progress of implementation of the Regional Plan of Action for Transfusion Safety**,** including constraints;

(e) mobilize resources in support of the Regional Plan of Action for Transfusion Safety.

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PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION

46th DIRECTING COUNCIL
57th SESSION OF THE REGIONAL COMMITTEE

Washington, D.C., USA, 26-30 September 2005

RESOLUTION

CD46.R5

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

THE 46th DIRECTING COUNCIL,

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

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

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

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

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

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

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

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

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(a) analyze the progress and challenges in the pursuit of sufficiency, quality, safety, and appropriate use of blood and blood products in their countries;

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(c) promote the participation of the public and private sectors, ministries of education, labor and social development, and civil society in the international, national, and local activities undertaken to implement the Regional Plan;

(d) strengthen blood services and improve their efficiency, while promoting a culture of voluntary, nonremunerated blood donation.

2. To request the Director to:

(a) cooperate with the Member States in the development of their national blood policies and strategies, and the strengthening of blood services to ensure transfusion safety;

(b) promote the application at the local level of quality standards and validated methodologies for the improvement of the safety of blood products and blood transfusion, utilizing a multidisciplinary approach;

(c) work with Member States to monitor the development of the national blood programs and transfusion safety;

(d) report periodically to the Governing Bodies on the progress of implementation of the Regional Plan of Action for Transfusion Safety**,** including constraints;

(e) mobilize resources in support of the Regional Plan of Action for Transfusion Safety.

(Eighth meeting, 29 September 2005)

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

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

CD48/11 (Eng.)
Annex B

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)

G. REGIONAL INITIATIVE AND PLAN OF ACTION FOR TRANSFUSION SAFETY 2006-2010: FINAL EVALUATION

Introduction

109. In 2005, the 46th Directing Council of the Pan American Health Organization (PAHO) approved the Regional Plan of Action for Transfusion Safety 2006-2010 (*1*, *2*). The purpose of the plan was to contribute to reducing mortality and improving patient care in Latin America and the Caribbean by making safe blood for transfusion available in a timely manner to all patients who needed it. The plan had five objectives and nine progress indicators. Although progress was made after 2005 in terms of the number and safety of blood units collected in the Region, national blood systems were considered inefficient, and access to blood was still suboptimal by 2008 (*3*). Therefore, Member States agreed to modify their approaches to meet the goal and objectives of the plan (*4*).

110. The Director of PAHO appointed an External Evaluation Team to assess advances in areas related to the Regional Plan, identify problems encountered in its implementation, and evaluate the opportunities for future action. The Team, which was operational from January to June 2011, analyzed the official national data submitted to PAHO by the countries (*5*-*10*). Process and progress indicators for each of the strategic lines of the Regional Plan were assessed. The evaluation exercise included surveys of PAHO/WHO Representatives and focal points, national health authorities, and local staff with regard to the technical cooperation program associated with the Regional Plan. The anonymous surveys were designed to elicit information on the extent of knowledge about the plan, the institutional support provided/received to meet its goals, the quality of technical publications, the efficiency of information gathering and sharing, and the factors that affected national outcomes.

111. This document summarizes the progress made by the national blood systems since 2005, as officially reported by the countries, and taking into consideration the findings of the External Evaluation Team.

Background

112. The World Health Assembly (WHA) first addressed issues pertaining to transfusion safety in 1975, urging Member States to promote the development of national blood services based on voluntary blood donation and to enact efficient legislation governing their operation. The 28th WHA also requested the Director-General to take steps to develop good manufacturing practices for blood and blood components in order to protect the health both of blood donors and of transfusion recipients (*11*). Three

subsequent documents (*12-14*) stressed the importance of blood transfusion services and national transfusion programs in preventing HIV infections.

113. The 58th WHA considered availability, accessibility and safety of blood, taking a comprehensive view, (*15*) in 2005, and adopted Resolution WHA58.13, Blood Safety: proposal to establish World Blood Donor Day (*16*), which urged Member States to introduce legislation, provide adequate financing, promote multisectoral collaboration, ensure proper use of blood and support the full implementation of well-organized, nationally coordinated and sustainable blood programs with appropriate regulatory systems. At the same time, the Director-General was asked to provide support for the countries to strengthen their capacity to screen all donated blood against major infectious diseases in order to ensure the safety of all blood collected and transfused. These concepts were reiterated in 2010 (*17, 18*).

114. The Governing Bodies of PAHO have addressed issues of blood transfusion safety since 1998. The Strategic and Programmatic Orientations for the Pan American Sanitary Bureau 1999-2002 called for all blood for transfusion to be screened for hepatitis B and C, syphilis, *Trypanosoma cruzi*, and HIV, and for all blood banks to participate in quality control programs (*19*). In 1999, the Directing Council adopted Resolution CD41.R15 and urged Member States to give higher priority to blood safety; to promote the development of national blood programs and transfusion services, voluntary blood donation, and quality assurance; to strengthen blood bank infrastructure; to allocate the necessary resources; and to ensure training of medical providers in the use of blood (*20, 21*).

115. In 2005, the Directing Council adopted Resolution CD46.R5 urging the Member States to analyze the progress and challenges in the pursuit of sufficiency, quality, safety, and appropriate clinical practice; to adopt the Regional Plan of Action for Transfusion Safety 2006-2010; and to allocate and use resources to meet its objectives (*2*). In 2008, considering that the concepts of previous resolutions still applied, and recognizing that modifications in current national approaches were needed to achieve the goals set for 2010, the Directing Council adopted resolution CD48.R7 (*4*) in which the Member States were urged to define an entity in their ministries of health as responsible for the efficient operation of the blood system; estimate the need for blood; establish a network of volunteers to educate the community; and terminate mandatory donation, with the goal of 100% voluntary, altruistic, non-remunerated donors.

Situation Analysis

116. An analysis of the situation up to 2009 was carried out using data from 35 countries and territories *(1, 5-10*). Canada, the United States of America, including Puerto Rico, and the French Territories were not included in this analysis.

117. In the Caribbean subregion, where 27 blood collection and processing centers exist, only Guyana, Jamaica, Netherlands Antilles and Suriname have a legal framework for blood services. Haiti has a national blood safety program within the Ministry of Health. In all other countries, the National Blood Transfusion Service, the National Public Health Reference Laboratory or the major hospital blood banks have the responsibility of coordinating national activities. Guyana and Haiti, which receive support from a multi-year international grant, and Netherlands Antilles and Suriname, whose blood banks are managed by the Red Cross, report having sufficient financial resources for the operation of their blood processing centers.

118. All Latin American countries except for Chile, El Salvador, and Mexico have national laws to regulate blood banks and transfusion services. However, challenges remain with regard to the steering capacity of the health authorities, even though Argentina, Bolivia, Brazil, Chile, Cuba, Dominican Republic, Guatemala, Honduras, Paraguay, Peru, Uruguay, and Venezuela have specific units within their Ministries of Health to oversee the national blood system, and the Caja Costarricense del Seguro Social, the Colombian National Institute of Heath, the Ecuadorian Red Cross Hemocenter, the Unit of Laboratory Surveillance in El Salvador, the National Blood Transfusion Center in Mexico, and the National Diagnosis and Reference Center in Nicaragua are responsible for coordinating blood services in their respective countries. Human and financial resources allocated for blood transfusion at the national level are considered to be insufficient for the appropriate operation of the services.

119. In the Latin American countries, the centers that collect and process blood are part of the Ministry of Health, the Social Security, the Armed Forces, the National Police, the public sector, or national or international non-governmental organizations. The multiplicity of actors, coupled with limited oversight by health authorities, represents a major obstacle to the appropriate use of national resources.

120. One of the indicators of progress of the Regional Plan of Action 2006-2010 was that all Latin American countries would have implemented regional blood collection and processing systems to cover the needs of patients of geographically distinct areas. In 2005, there were 2,522 blood processing centers in the 19 Latin American countries. The mean number of blood units processed by center inversely correlated with availability of blood, and also with the proportion of voluntary blood donors at the national level (*1*), a clear indication that creating more blood banks does not result in improvements in blood availability.

121. In 2009, the number of blood processing centers in Argentina, Brazil, Chile, Colombia, Nicaragua, Paraguay, and Uruguay diminished by 351. Argentina (80 centers) and Brazil (167 centers) accounted for 70% of the reduction. In Nicaragua, the Ministry of Health closed all 21 hospital-based blood banks and set up a national network with

three centers managed by the Red Cross. Costa Rica, Dominican Republic, Ecuador, Guatemala, Honduras, Mexico, and Venezuela reported a combined total of 113 more processing facilities in 2009 than in 2005 (Table 1, Annex).

122. In Latin America, the mean numbers of blood units processed per center in a year were 3,163 in 2005 and 3,974 in 2009, equivalent to 12-15 units per center per day. In general, the efficiency of the blood services is deficient in all countries other than Nicaragua, where three Red Cross centers processed 69,932 collections in 2009 (Table 1, Annex).

123. Blood availability is determined by the extent of collection, the prevalence of infectious markers among blood donors, and the separation of whole blood units into components—red blood cells, plasma, and platelets. From 2005 to 2009, blood collection increased in the Caribbean and Latin American countries by 14%, from 8,059,960 units to 9,166,155, with the overall collection rate for those years being 145.0 and 157.4 per 10,000 inhabitants respectively (Table 2, Annex). National collection rates increased more than 10% in 24 countries (range: 10.2% - 143.9%), remained unchanged in Belize, Brazil, British Territories, Costa Rica, El Salvador, Guatemala, Honduras, Uruguay, and Venezuela, and decreased in Cuba (18.7%) and Netherlands Antilles (15.7%). Despite the reductions in the two latter countries, they nevertheless showed the highest national collection rates in 2009: 359.7 and 295, respectively (Table 3, Annex).

124. In 2005, national blood collection rates ranged from 11.5 to 442.5, with a median of 109.3. Fifteen countries had collection rates below 100 per 10,000 inhabitants. In 2009, the national rates varied from 21.4 to 359.7; the median rate was 145.3. Only eight countries, Bolivia (70.0), Dominican Republic (84.4), Guatemala (65.3), Haiti (21.4), Honduras (78.1), Jamaica (91.5), Peru (75.9) and St. Vincent and the Grenadines (93.5) collected fewer than 100 units per 10,000 inhabitants (Table 3, Annex).

125. In 2009, the national prevalence of markers of transfusion-transmissible infections (TTI) varied from 0, in Netherlands Antilles, to 16.6% in Paraguay (median = 3.1%) (Table 1, Annex). TTI markers were detected in 319,996 (3.5%) units. The availability of blood in the Caribbean and Latin American countries thereby dropped to 8,846,159. In addition to the eight countries with the lowest blood collection rates mentioned above, Guyana, Paraguay, and St. Kitts and Nevis had fewer than 100 units available per 10,000 inhabitants.

126. It is estimated that the 319,996 units that were discarded in 2009 because they were positive for infectious markers represented wastage of US$ 19,919,776 (Table 2, Annex). Factors that determine the high prevalence of markers among blood donors include poor recruitment and selection, and inadequate quality in the laboratory testing methodology.

127. Since national needs for blood for transfusion are determined by characteristics of the national health systems, by the local epidemiology of the clinical conditions that require blood transfusions, and by demographics, it is not appropriate to suggest a figure as a target for blood collection or blood availability rate. The Regional Plan of Action for Transfusion Safety 2006-2010 included the estimation of geographic and temporal needs for blood as one of its objectives.

128. There is an inverse relationship between national blood availability rates and maternal mortality ratios in the Latin American and Caribbean countries that have information on maternal deaths (*22*). Eight of the nine countries with maternal mortality ratios above 83 per 100,000 live births (*23*) have blood availability rates below 100 per 10,000 inhabitants. (Figure 1, Annex).

129. The median proportion of blood units separated into components among Caribbean and Latin American countries was 77% in 2005, as compared to 90% in 2009, when Brazil, Cuba, El Salvador, Grenada, Netherlands Antilles, St. Lucia, St. Vincent and the Grenadines, and Suriname prepared red blood cells from at least 95% of units collected. Argentina, Colombia, Costa Rica, Dominica, Mexico, Nicaragua, and Panama reported obtaining red blood cells from 90%-94% of whole blood units. Barbados (38%), Belize (32%), Dominican Republic (39%), Honduras (39%), Jamaica (48%), and St. Kitts and Nevis (14%) prepared components from less than 50% of the blood units they collected (Table 4, Annex).

130. Of the 11 countries with availability rates below 100 units per 10,000 inhabitants, Bolivia (89%), Dominican Republic (39%), Guatemala (87%), Guyana (74%), Haiti (52%), Honduras (39%), Jamaica (48%), Paraguay (74%), Peru (79%), and St. Kitts and Nevis (14%) prepared components from less than 90% of their units, further limiting the national availability of blood for transfusion (Tables 3 and 4, Annex).

131. Despite the apparent limited availability of blood at the country level, 981,253 units of red blood cells expired in 2009, at an estimated cost of $54,950,168 (Table 2, Annex). The multiplicity of blood collecting centers, the lack of standardized operating procedures at the hospitals and the limited oversight by health authorities contributed to this situation.

132. The Regional Plan of Action 2006-2010 aimed to improve the quality of blood components by increasing donor safety and extending the coverage and precision of laboratory testing.

133. Screening of blood for markers of transfusion-transmissible infections improved in the Region (Table 5). In 2005, 87,875 units were not tested for HIV, a figure that had dropped to 1,708 units in 2009. The corresponding figures for hepatitis B in 2005 and

2009 were 93,949 and 1,371; and for hepatitis C, 95,962 and 2,861. For syphilis, 159,929 units went unscreened in 2005 and only 1,535 in 2009. There was also a reduction in the number of units not tested for *Trypanosoma cruzi,* declining from 959,662 in 2005 to 288,405 in 2009. However, the goal of universal screening for those agents set in 1998 remains to be achieved. Additional resources to ensure continuous access to laboratory supplies combined with a renewed commitment from countries in applying national norms will be necessary to achieve the goal of universal screening.

134. In 2009, four countries—Antigua and Barbuda, Dominica, Peru, and St. Kitts and Nevis—did not screen all blood units for hepatitis C (5). This represented the potential transfusion of 16 HCV infected units in that year compared to 482 in 2005. Peru was the only country that reported incomplete screening for HIV and HBsAg. As a consequence, 10 HIV-positive units and seven hepatitis B-positive units might have been transfused. The risk of a transfusion being contaminated by a virus in 2009 was 1:277,762 donations, compared to 1:11,784 in 2005. Mexico and Peru did not test all units for Trypanosoma cruzi, a fact that might have resulted in 1,187 infected units in 2009, compared to 2,362 in 2005, with the respective risks being 1:7,166 and 1:3,377.

135. These estimates are calculated based on the proportion of units not screened and the prevalence of antibodies against the virus among donors. In 2009, 36,327 donors were positive for HIV, 31,823 for hepatitis B, and 50,628 for hepatitis C. The median prevalence of hepatitis C antibodies among donors in countries with more than 50% voluntary donation was 0.3%, while in countries with less than 50% voluntary donation it was 0.5%. For the other markers, the corresponding figures were 0.1% and 0.2% for HIV, 0.2% and 0.3% for HBsAg, and 0.6% and 0.9% for syphilis.

136. There were 2,950,018 voluntary blood donors in 2005, compared with 3,308,996 in 2009, representing a 12% net increase over the five-year period. The regional proportion of voluntary blood donation, however, remained unchanged, 36.6% in 2005 and 36.1% in 2009 (Table 2, Annex).

137. Nine countries/territories reported more than 50% voluntary donors in 2009: Colombia (65%), Costa Rica (76%), Cuba (100%), Guyana (68%), Haiti (70%), Netherlands Antilles (100%), Nicaragua (87%), St. Lucia (64%), and Suriname (100%). Twenty countries had less than 25% voluntary donations, with Antigua and Barbuda (5%), Belize (8%), Dominica (3%), Guatemala (4%), Mexico (3%), Panama (5%), Peru (5%), St. Vincent and the Grenadines (5%), and Venezuela (6%) reporting less than 10%.

138. Remunerated donors were reported in 2009 by Dominican Republic (3,300), Honduras (294), Panama (7,641) and Peru (88). The 11,323 paid donors accounted for 0.1% of all donations. The proportion of paid donors was 0.2% in 2005 (Table 2, Annex).

139. The widespread requirement by hospitals for patients to provide blood replacement continues to be the major obstacle to voluntary blood donation. As demonstrated in Nicaragua, where replacement donation was terminated in March 2009, a well planned transition strategy that includes the active recruitment of blood donors and the participation of qualified personnel to service them can result in important changes in the blood donation system.

140. Although the purpose of the Regional Plan of Action for Transfusion Safety was to contribute to reducing mortality and improving patient care in Latin America and the Caribbean by making safe blood available in a timely manner for all those patients who need it, there is limited information on transfusion practices and outcomes. In 2009, only Anguilla, Antigua and Barbuda, Barbados, Belize, Grenada, Guyana, Paraguay, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, and three of the British Territories provided information on the age distribution of patients who received transfusions (Table 6, Annex).

141. The limited interaction between national health authorities with transfusion services at the hospital level hinders the estimation of national needs for blood and prevents a structured allocation and efficient use of resources.

142. The External Evaluation Team made several recommendations, including the need to develop a Regional Plan of Action 2012–2017 based on the progress and lessons learned during the Initiative. It also emphasized the critical contribution of blood services to achieving Millennium Development Goals 4, 5, and 6.

Action by the Directing Council

143. The Directing Council is requested to take note of this report, to thank the members of the External Evaluation Team, and to recommend that the Regional Plan of Action on Blood Safety for 2012–2017 be included in the proposed topics for the Governing Bodies meetings to be held during 2012.

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Annexes

ANNEX: TABLES AND FIGURES

Table 1. Number of blood processing centers and number of units processed per center per year, Latin American countries 2005 and 2009.

	NUMBER OF CENTERS		NUMBER OF UNITS PROCESSED/CENTER/YEAR	
COUNTRY	**2005**	**2009**	**2005**	**2009**
Argentina	480	400	761	2,254
Bolivia	22	20	2,126	3,449
Brazil	562	395	6,652	9,270
Chile	78	38	2,283	5,438
Colombia	110	91	4,797	7,604
Costa Rica	17	27	3,186	2,195
Cuba	48	46	10,320	8,762
Dominican Republic	58	65	1,071	1,309
Ecuador	22	33	5,669	5,302
El Salvador	32	29	2,504	2,853
Guatemala	47	60	1,664	1,525
Honduras	22	24	2,378	2,429
Mexico	550	560	2,457	2,857
Nicaragua	24	3	2,255	23,274
Panama	26	26	1,645	1,975
Paraguay	16	11	4,706	6,075
Peru	92	90	1,953	2,453
Uruguay	76	57	1,259	1,615
Venezuela	240	302	1,495	1,528
All countries	2,522	2,277	3,163	3,974

Table 2. Indicators of performance, national blood systems in the Caribbean and Latin America.

VARIABLE	2005	2009	Difference
Units collected	8,059,960	9,166,155	+ 1,106,195
Blood donation rate*	145.0	157.4	+ 12.4
Voluntary donors Number (%)	2,950,018 (36.6%)	3,308,996 (36.6%)	+ 358,978 (0)
Remunerated donors Number (%)	15,507 (0.2%)	11,323 (0.1%)	- 4,184 - (0.07%)
Units separated into components (median)	77%	90%	+ 13
Units with TTI markers Number Prevalence (median)	238,696 (3.1%)	319,996 (3.1%)	+ 81,300 - (0.02%)
Number of expired units of red blood cells	610,375	981,253	+ 370,878
Total annual discard Number of units Estimated cost (US$ 56/unit)	849,071 47,547,976	1,301,279 72,869,944	+ 452,178 25,321,968

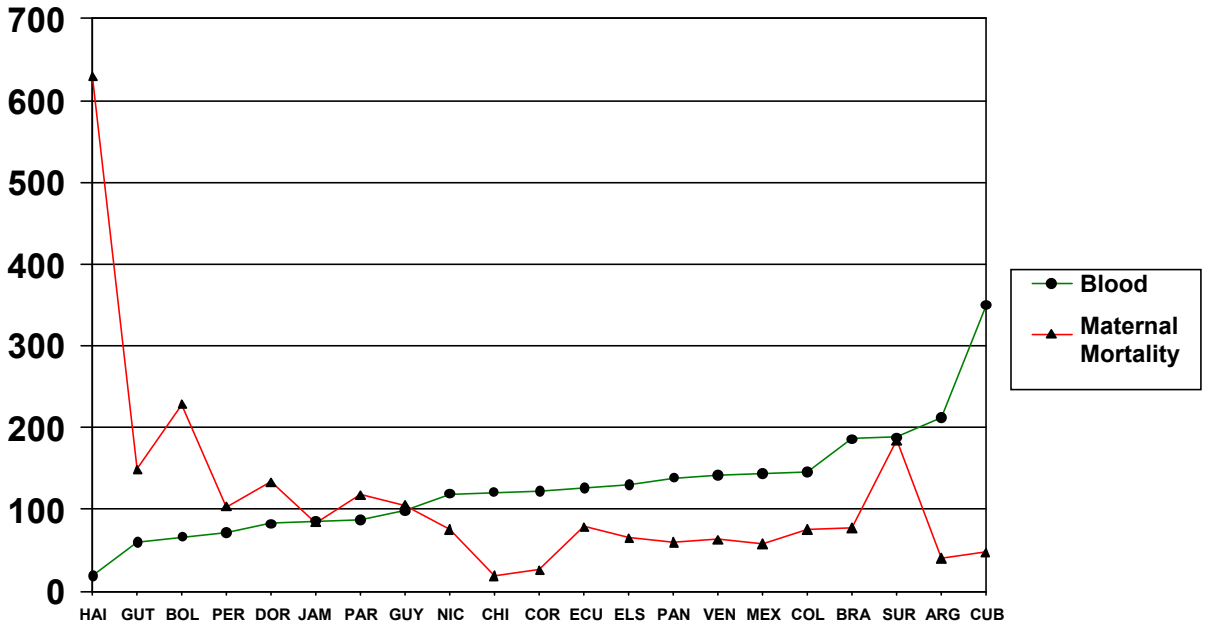
* per 10,000 inhabitants

Table 3. Blood collection in the Caribbean and Latin American countries, 2005 and 2009.

	Number of units collected		Donation rate	
COUNTRY	**2005**	**2009**	**2005**	**2009**
Antigua and Barbuda	1,020*	1,321	124.4*	153.6
Argentina	365,313	926,941	94.3	230.0
Bahamas	5,152	6,914	158.5	202.2
Barbados	4,164*	4,781	148.2*	167.8
Belize	3,107	4,364	125.2	129.6
Bolivia	46,764	69,073	50.9	70.0
Brazil	3,738,580	3,661,647	200.9	189.0
Chile	178,079	206,676	109.3	121.8
Colombia	527,711	692,487	122.6	151.7
Costa Rica	54,170	59,336	125.2	129.6
Cuba	495,343	403,060	442.5	359.7
Dominica	757	977	105.1	133.8
Dominican Republic	62,120	85,169	65.2	84.4
Ecuador	124,724	174,960	95.5	128.4
El Salvador	80,142	82,757	132.3	134.3
Grenada	835	1,426	79.5	133.3
Guatemala	77,290	91,554	60.8	65.3
Guyana	5,267	7,700	68.9	101.0
Haiti	10,823	21,471	11.5	21.4
Honduras	52,317	58,317	75.9	78.1
Jamaica	22,155	24,881	83.0	91.5
Mexico	1,351,204	1,602,071	128.3	146.2
Netherlands Antilles	9,393	6,702	350.0	295.0
Nicaragua	54,117	69,932	99.2	121.2
Panama	42,771	51,539	132.3	149.2
Paraguay	47,060	66,873	79.7	105.3
Peru	179,721	221,266	64.6	75.9
St. Kitts and Nevis	423	510	88.1	104.1
St. Lucia	1,914	2,446	121.9	152.9
St. Vincent and the Grenadines	822	982	77.5	93.5
Suriname	7,525	9,774	150.5	188.0
Trinidad and Tobago	13,625	22,368	103.4	167.1
Uruguay	95,686	92,073	287.8	273.9
Venezuela	403,625	461,481	151.0	161.4
British Territories				
Anguilla	114	117	87.7	83.6
Virgin Islands	447	484		
Cayman Islands	864	981	196.4	196.9
Montserrat	79*	94	158.0*	188.0

*Data for 2006

Figure 1. Blood availability rates and maternal mortality ratios, selected Caribbean and Latin American countries 2009.



Spearman correlation test, p=0.002

Table 4. Blood units separated into components (proportion of red blood cells prepared), Caribbean and Latin American countries, 2005 and 2009.

COUNTRY	2005	2009	Difference
Antigua and Barbuda	30*	61	+31
Argentina	87	90	+3
Bahamas	87	81	-6
Barbados	14**	38	+24
Belize	35	32	-3
Bolivia	67	89	+22
Brazil	38	95	+57
Chile	95	100	+5
Colombia	39	90	+51
Costa Rica	89	94	+5
Cuba	43**	95	+52
Dominica	94	92	-2
Dominican Republic	78	39	-39
Ecuador	77	NR	
El Salvador	93	96	+3
Grenada	99	100	+1
Guatemala	84*	87	+3
Guyana	62	74	+12
Haiti	28	52	+24
Honduras	32	39	+7
Jamaica	46	48	+2
Mexico	88	94	+6
Netherlands Antilles	100	100	0
Nicaragua	78	90	+12
Panama	33*	91	+58
Paraguay	55	74	+19
Peru	72*	79	+7
St. Kitts and Nevis	42	14	-28
St. Lucia	98	100	+2
St. Vincent and the Grenadines	98	97	-1
Suriname	98	100	+2
Trinidad and Tobago	65**	79	+14
Uruguay	87	NR	
Venezuela	81	-80	-1
British Territories			
Anguilla	62	61	-1
Virgin Islands	NR	16	
Cayman Islands	83	91	+24
Montserrat	NR	1	

* Data for 2004 **Data for 2006

Table 5. Coverage of screening for markers of transfusion-transmissible infections, Caribbean and Latin American countries, 2005 and 2009.

MARKER	2005	2009
HIV	98.9%	99.9%
HBsAg	98.9%	99.9%
HCV	98.8%	98.9%
Syphilis	98.0%	99.9%
Trypanosoma cruzi	87.1%	96.6%

Table 6. Number of units of red blood cells and whole blood transfused, according to age of patients, countries that submitted data, 2009.

	AGE (years)					
COUNTRY	**< 5**	**5-14**	**15-44**	**45-59**	**>59**	**No data**
Antigua and Barbuda	56	0	478	288	471	
Barbados	201	167	4,259	0	0	
Belize	244	144	1,566	595	519	
Grenada	46	27	347	276	466	
Guyana	203	301	2,076	924	1,756	
Paraguay	5,433	2,640	18,951	8,970	14,213	420
St. Kitts and Nevis	0	9	9	144	86	149
St. Lucía	0	61	59	969	545	656
St. Vincent and the Grenadines	0	157	57	526	216	342
Suriname	0	381	263	4,349	2,171	2,569
British Territories						
Anguilla	0	1	24	11	62	
Cayman Islands	3	8	258	204	416	
Montserrat	0	0	0	23	29	

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ANNEX 3: TRANSFER OF COPYRIGHTS FROM CAREC TO PAHO

CARIBBEAN EPIDEMIOLOGY CENTRE (CAREC)

Pan American Health Organization
Regional Office of the World Health Organization

PAHO/WHO INTEROFFICE MEMORANDUM

TO:	Dr. Jose Ramiro Cruz Regional Advisor, Blood Services	**OUR REF:**	CEC/134/11/DO
FROM:	Dr. Beryl Irons Director	**YOUR REF:**	
ORIGINATOR:	Dr. Beryl Irons	**DATE:**	June 6th, 2011
SUBJECT:	**Caribbean Regional Standards for Blood Banks and Transfusion Services**		

Further to our telephone discussion and the request of CAREC for its written authorization to revise the Caribbean Regional Standards, authorization is hereby given for the Pan American Health Organization to take the lead for the following activities:

1. Revise the Caribbean Regional Standards for Blood Banks and Transfusion Services, in consultation with CAREC and staff from the Caribbean countries and territories
2. Prepare, edit and publish a new edition of the Caribbean Standards
3. Keep the copyright of any future editions of the Caribbean Standards
4. Distribute future editions of the Standards to Caribbean member countries and to other interested parties through the CAREC and PAHO channels, including our electronic website

However, CAREC will remain integral to the process and wish to be involved from the beginning of the process. The CAREC contact person for this activity will be Ms. Sacha Wallace-Sankarsingh our interim Laboratory Manager.

Best regards.

ANNEX 4: AD HOC COMMITTEE FOR REVISION OF THE CARIBBEAN REGIONAL STANDARDS FOR BLOOD BANKS AND TRANSFUSION SERVICES, 2011

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ANNEX 5: LIST OF RECOMMENDED REFERENCES

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Pan American Health Organization

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World Health Organization