

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 Health, 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.**

COUNTRY	NUMBER OF CENTERS		NUMBER OF UNITS PROCESSED/CENTER/YEAR	
	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

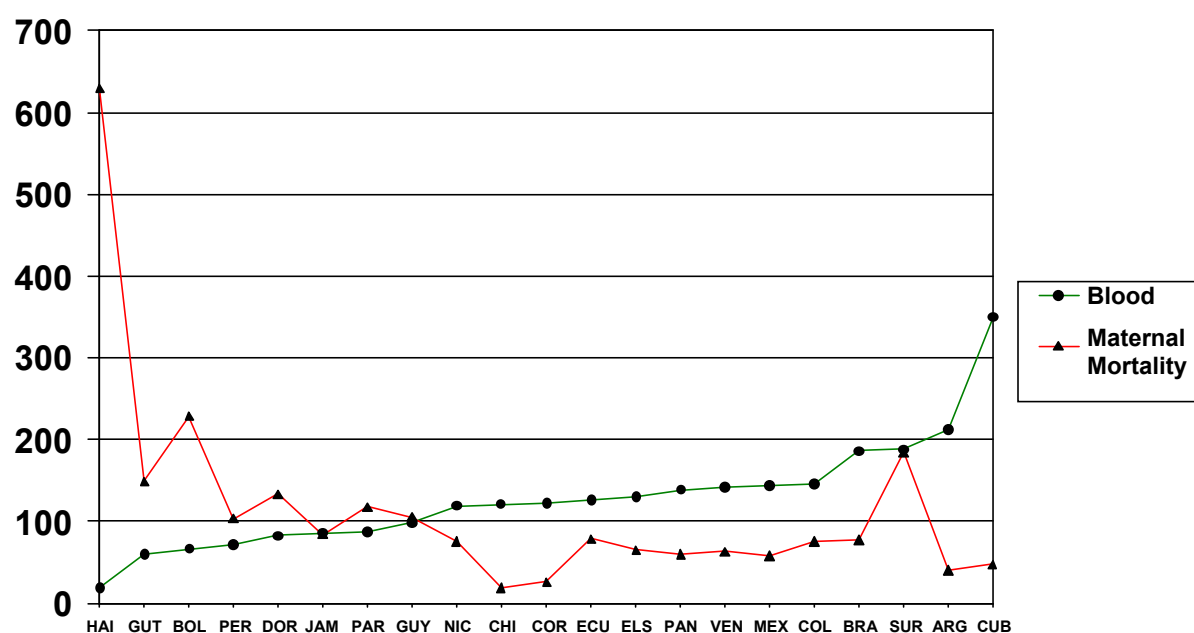
* per 10,000 inhabitants

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

COUNTRY	Number of units collected		Donation rate	
	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				
<i>Anguilla</i>	114	117	87.7	83.6
<i>Virgin Islands</i>	447	484		
<i>Cayman Islands</i>	864	981	196.4	196.9
<i>Montserrat</i>	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			
<i>Anguilla</i>	62	61	-1
<i>Virgin Islands</i>	NR	16	
<i>Cayman Islands</i>	83	91	+24
<i>Montserrat</i>	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%
<i>Trypanosoma cruzi</i>	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.

COUNTRY	AGE (years)					
	< 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						
<i>Anguilla</i>	0	1	24	11	62	
<i>Cayman Islands</i>	3	8	258	204	416	
<i>Montserrat</i>	0	0	0	23	29	
