CLINICAL MICROBIOLOGY REVIEWS, Jan. 2005, p. 12–29 Vol. 18, No. 1
0893-8512/05/$08.00+0 doi:10.1128/CMR.18.1.12–29.2005

Safety of the Blood Supply in Latin America

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The 28th World Health Assembly of the World Health Organization approved resolution WHA28.72 in 1975; this resolution relates to the utilization and supply of human blood and blood products. Through this resolution, member states are urged to promote the development of national blood services based on voluntary nonremunerated donation of blood, to enact effective legislation governing the operation of blood services, and to make other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products (121).

In continental Latin American countries, 29 years later, and in spite of progress made, some of these goals still need to be met. Preventing the transmission of infectious diseases through blood transfusion in developing countries is difficult, given that the resources needed may not be available, even when policies and strategies are in place (41).

Transfusion of blood and blood products is an essential part of health care for patients deficient in one or more blood components. Therefore, organization of blood transfusion services must be based on a national blood policy, including relevant legislation, rules and regulations, which in turn must be an integral part of any national health policy. The national blood program, the administrative entity that covers the national needs for blood and blood components, may be part of different structures of blood services: from government blood transfusion services or hospital (public or private) blood banks to nonprofit organizations such as the Red Cross or others (39, 40). Those structures are going to be responsible for carrying out the necessary activities to implement the collection, storage, processing, distribution, and appropriate transfusion of blood and blood products to fulfill the country's needs (22, 23). They have the unique responsibility to act as intermediary between the healthy donor who provides the blood and the patient who needs blood or one or more of its components. Their responsibility includes taking care of the donor before and after donation, making the gift (the blood and components) available promptly and with a guarantee of quality and safety, and monitoring that it is used appropriately (39). Whenever the country structure is responsible for the activities of the blood program, it must (i) employ qualified professionals to direct centers making up the total service; (ii) provide appropriate premises and plant and technical infrastructure and must organize and implement donor recruitment; (iii) provide a professional management body responsible for the technical supervision of the service; (iv) ensure collaboration among blood services professionals and their clinical counterparts; and (v) secure funding for investment and running costs of blood services, encourage training and development, and promote research in blood-related fields (39). In fact, for practical purposes, we may consider that the status of the blood supply may well be based on (i) the existence of a sufficient pool of donors, making the supply sufficient for covering the country needs; (ii) mandatory screening of blood donors for infectious diseases, following quality assurance procedures; and (iii) appropriate use of blood.

There are different factors that intervene in the safety of the blood supply worldwide. First, there is the existence of government policies, decrees, and regulations, as well as standards set up by professional societies that provide the legal framework for blood banking and transfusion medicine. Second, there are repeat, voluntary, altruistic donors who provide blood and procedures for the selection or elimination of potentially tainted units and for ensuring the safety of biological products that can be used for transfusion. Third, there is the ability of health personnel to prescribe blood when it is really needed. Last, but not least, there is the public at large, who provide the raw material for all of the above functions to be in place. Each of these factors may have pitfalls that could contribute to unsafe blood. Weaknesses may arise from the inability of governments to enforce laws, regulations, and/or norms. They also may come from staff who are not aware or are unable to follow quality assurance and/or good manufacturing practices. Other problems may develop from untrained health personnel who may not follow known standards of medical practice for prescribing blood or blood products. The lack of altruistic repeat blood donors, who have been shown to be healthier than re-

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placement donors and more appropriate than paid donors as source of safe blood, is also a contributing factor (6, 17, 18, 33).

The emergence of the human immunodeficiency virus (HIV)/AIDS epidemic transformed blood transfusion. While blood services have continued to basically provide the amount of blood and blood products needed to cover historic needs, transfusion safety is seen in a much more stringent way in all Latin America. Criminal judicial investigations of government officials and industry leaders accused of delaying the implementation of blood safety measures have been made (115), and the widespread publication of news articles on "accidents" that occurred in Europe, the United States, and South and Central America (11, 26, 34, 72, 73, 91, 97, 98, 99, 100, 101, 102) has paved the way for an increased interest by the general public as well as of the ministries of health and health personnel in preventing the transfusion of tainted blood.

Since 1993 to 1995, 13 Latin American countries have reported nationwide information on the number of blood donors, percentage of donors screened for infectious diseases, and prevalence of serological markers among donors (48, 58, 59, 60, 61, 62, 63, 64, 66, 67, 87, 88, 89). In later years, the number of reporting countries as well as the type of information provided increased (64, 87, 88, 89). Since 1997, the category of donors and the number of blood banks have also been reported (64). Now, for the first time, the availability of these data from 17 countries up to 2001 to 2002 (48, 58, 59, 60, 61, 62, 63, 64, 66, 67, 87, 88, 89) allows a regional analysis of the overall situation on blood safety; it also provides the baseline against which progress or drawbacks can be measured in subsequent years. We review here the status of blood safety in the 17 Latin American countries of the continental Western Hemisphere, comparing their situation with that in the developed countries of Europe and North America.

THE REGULATORY SYSTEM, ORGANIZATION, AND DONOR RECRUITMENT

In several European countries, such as Belgium, Finland, and Switzerland, the Red Cross is responsible for the blood program. In others, such as France, Hungary, Ireland, and the United Kingdom, the responsibility for blood services falls directly to the health authorities. In yet others, such as Denmark and Sweden, there is a system based on hospital blood banks (39). In the United States, with its traditional high respect for private initiatives, either the Red Cross or community-based nonprofit organizations are responsible for obtaining and processing the blood and blood products under strict supervision by government and professional societies (24, 39). In Canada, implementation of activities related to blood and blood products was done by the Canadian Red Cross until the responsibility switched to the central government (Canadian Blood Services) and one provincial government (Hema-Quebec) because of safety concerns (24, 32).

In several of those countries, hemovigilance is an integral part of the blood program (24). "Hemovigilance" is a term used to define a set of surveillance procedures covering the whole transfusion chain. This term includes the donation of blood and blood components and the follow-up of recipients of transfusion. It also includes the collection and assessment of information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products. In addition, hemovigilance includes the prevention of the occurrence or recurrence of such incidents. The aims of hemovigilance are to collect data on serious sequelae of blood component transfusion and contribute to improving the safety of the transfusion process, influencing policy, improving standards, and aiding the formulation of guidelines (24). Hemovigilance requires a surveillance system based on the routine and standardized collection and analysis of data on the prevalence and incidence of infectious diseases in blood donors, adverse events associated with transfusion (including those originating in errors), and product-related side effects (24).

In Europe, the 15 countries of the European Union in 1999 had laws on the subject, and there were proposals for a European Blood Directive that mention the notification of adverse reactions and events. In Austria and Germany, blood products are considered medicinal products and are the subject of pharmacovigilance (24). Hemovigilance was operational in Denmark, France, Greece, Ireland, Luxembourgh, Netherland, Sweden, and the United Kingdom in 1999 (24). However, the organization of the system may differ from country to country. In France it is mandatory to report every side effect (16), while in the United Kingdom the system functions on a voluntary basis. In Austria, Germany, and Sweden, reporting is also mandatory, but in another nine countries it is voluntary. Seven countries report all events; two report severe reactions only; and one reports only infections. Of the 15 countries, 12 have a system of rapid alert in place. Traceability may be a central (single type of institution) or shared (more than one type of institution) responsibility. There is also a European Haemovigilance Network with the participation of several countries that share information on hemovigilance; it functions as an information channel for a Very Rapid Alert System and dissemination of information on emerging threats (24). In a bid to restore long-term public confidence in transfusion amid concerns about contamination from the agent of Creutzfeld-Jakob disease, the European Union approved legislation that established standards for blood and blood products in 2002 (116).

In the United States, the three main organizations dealing with blood (American Red Cross, Council of Community Blood Centers, and America Blood Centers) for many years reported blood-related accidents and incidents. The Red Cross alone, which covers 50% of the hospitals in the United States, collects information for hemovigilance in the hospitals that it serves. The Food and Drug Administration (FDA) also undertakes a thorough collection of data related to the use of blood and blood products. In addition, information from other sources such as the Retrovirus Epidemiology Donor Survey provides data used for establishing residual risk (24).

The FDA introduced a concept of "zero-risk blood supply" as the industry goal. Regulatory agencies, such as the FDA, the Center for Medicare and Medicaid Services, and the State Departments of Health, and accrediting agencies, such as the American Association of Blood Banks, the College of American Pathologists, and the Joint Commission on Accreditation of Health Care Organizations, require blood banks and transfusion services to establish and follow a quality control and quality assurance program for their licensing, certification, and accreditation (21). The system for detecting, reporting, and preventing errors is decentralized, but the FDA requires re-

porting of all errors or accidents affecting the safety, purity, and potency of blood components that have been released or made available for distribution by blood centers. In addition, complications of blood transfusion resulting in a fatality must be reported to the FDA promptly (45).

Countries in continental Latin America have a regulatory framework that mandates the safe use of blood and blood products through the adequate selection of donors, screening for infectious diseases, and the use of the blood or blood products according to good clinical practices (57, 75). Blood transfusion-related activities are government regulated, while implementation of activities is the responsibility of either a government central blood bank, hospital blood banks, nongovernmental institutions such as the Red Cross, or a combination of all of the above. Professional societies may play an advisory role.

Laws, decrees, norms, and/or regulations related to blood transfusion began to appear in the 1960s (in Argentina, Brazil, Chile, and Costa Rica), 1970s (in Bolivia, Colombia, Ecuador, Paraguay, Uruguay, and Venezuela), 1980s (in Honduras, Mexico, and Nicaragua), and 1990s (in Guatemala, Panama, and Peru). In El Salvador, the only aspect mentioned by the law was voluntary donation in 1988 (57, 75). These laws, decrees, norms, and/or regulations appeared first because of concerns about transmission of infectious diseases such as syphilis and Chagas' disease. These concerns were followed by worries about hepatitis in the 1970s and then HIV in the 1980s. The laws have evolved through time, from focusing at the beginning on disease screening to concentrating later on mandates regarding voluntary donations, and on quality assurance. On the other hand, enforcement of the laws, decrees, and regulations varies from stringent (very few) to lax, and most countries do not have a well-trained group of inspectors, such as Brazil has.

Blood collection and processing centers in Latin America are part of a variety of institutions that may or may not be involved in patient care. Blood banks may belong to the Ministry of Health, Social Security, the Armed Forces, the private sector, or nongovernmental organizations such as the Red Cross. Although the Ministries of Health are nominally responsible for their oversight, the administrative and financial independence of the centers that are not run by the Ministries of Health makes implementation and enforcement of its norms, requirements, guidelines, and recommendations difficult. Hospital-based blood banks, although part of the blood services of the national system, are structured to respond to the hospital's needs, and so their resources are allocated and managed accordingly. Hospital blood banks are closer to clinical development trends and thus are able to respond quickly to changing needs. However, there are also disadvantages: blood donor recruitment is not sufficiently appreciated in hospital settings; hospital premises may make healthy donors apprehensive, and so they may not be willing to donate; and small, numerous, and independent blood banks may compete for donors with medium and large blood services that are more efficient (39).

The situation is further complicated by decentralization, especially in federal countries such as Argentina, Brazil, and Mexico, where states or provinces have their own local authorities, including those dealing with health issues. With few exceptions, such as the National Agency for Health Surveillance in Brazil and the National Blood Programs in Chile, and Uruguay, the Ministries of Health lack the human and material resources needed to oversee the organization, functioning, and performance of all existing blood banks, independent of their administrative association. In other instances, such as Ecuador, Honduras, and Nicaragua, the Ministries of Health rely on the local Red Cross to run the national blood program, in addition to collecting, processing, and distributing blood.

Information available from nine countries since 1993, four more in 1994, one each in 1995 and 1997, and two more in 1999 allows an analysis of the overall situation (48, 58, 59, 60, 61, 62, 63, 64, 66, 67, 87, 88, 89). For example, establishing the ratio of blood banks to donations in a given country would provide an indirect measure of the efficiency of the system as a whole. A measure of the existence of a sufficient pool of donors can be made by establishing the ratio of donations to overall population in each Latin American country in comparison with a world standard (50 donations per 1,000 population, or a yearly average of 50,000 donations per million population) (96). How safe is this pool? An answer to this question would be based on the percentage of the different categories of donors, the percentage of donors screened, the prevalence of the different serological markers in the different countries, and how the situation evolves through time (87, 88, 89). Therefore, routine collection of information actually done by the countries provides information needed as part of the hemovigilance process.

The variety of institutions and the decentralized models of administration result in an excessive number of blood collection and processing centers (62). For instance in 2002 in Chile, 53 (50%) of the blood banks were run by the Ministry of Health and 44 (42%) were run by the private sector; 6 banks belong to the Armed Forces, and 1 belongs to the Red Cross. Each year, the 53 public centers collect 70% of the units of blood. In Honduras, there are 27 blood banks that collect around 40,000 units each year; the 21 public blood banks collect 19,000 units and the 2 run by the Red Cross collect 19,000 units yearly; the 4 private blood banks collect only 2,000 units (64). In Venezuela, there are 270 blood banks, 86 (32%) of which are public and collect around 48% of the blood units in the country. In 14 other countries, the number of blood banks varies from 578, 2,583, 151, 524, and 172 in Argentina, Brazil, Colombia, Mexico, and Peru, respectively, to 23 to 49 blood banks in the rest of the countries (64). By contrast, the number of blood banks in Canada is 14 (64). Up to now, all efforts to rationalize the number of blood banks by decreasing their number have failed, even though small local blood banks are wasteful and costly. Economies of scale can be significant for collection, processing, and testing of blood donations, and quality assurance procedures are much more effective if a significant number of samples are involved (33). In general, the mean number of blood units collected yearly by Latin American blood banks is around 2,000 (15, 64), although wide variations such as those mentioned above exist.

The multiplicity of organizations running blood banks, the large number of blood banks, their hospital-oriented mission, and the variability in dedicated resources result in poorly standardized protocols and a deficient infrastructure for blood donor recruitment, selection, and retention (28). Table 1 shows the total number of donors per country, and Table 2 shows the donation of blood units per 1,000 inhabitants per year, using

TABLE 1. Total number of blood donors by country and year in Latin America from 1993 to 2002

Country[a]	Total no. of donors[g] in:			
	1993–1995[b]	1997	1999	2001/2002
ARG	**811,850**[c]	742,330	810,259	804,018[e]
BOL	**37,948**	40,056	20,628	24,747[e]
BRA			**1,663,857**[f]	3,014,184
CHI	**217,312**	220,686	218,371	226,119
COL	**352,316**	422,300	353,991	424,899
COR	**50,692**	58,436	93,518	53,465
ECU	**98,473**[d]	110,619	103,448	76,257
ELS	**48,048**	34,091	67,224	73,594
GUT	**45,426**		31,939	71,959
HON	**27,885**	27,963	40,933	40,755
MEX			**1,092,741**	1,027,253
NIC	**46,001**	46,539	45,000	48,921
PAN	**26,333**[d]	42,342	43,921	42,867
PAR	**32,893**[d]	39,904	45,597	45,533[e]
PER		**203,690**	311,550	149,077
URU	**110,309**[d]	115,490	116,626	101,669
VEN	**204,316**	262,295	302,100	369,440

[a] Argentina (ARG), Bolivia (BOL), Brazil (BRA), Chile (CHI), Colombia (COL), Costa Rica (COR), Ecuador (ECU), El Salvador (ELS), Guatemala (GUT), Honduras (HON), Mexico (MEX), Nicaragua (NIC), Panama (PAN), Paraguay (PAR), Peru (PER), Uruguay (URU), Venezuela (VEN).
[b] All data from 1993 unless otherwise specified.
[c] Data from 1995.
[d] Data from 1994.
[e] Data from Argentina, Bolivia, and Panama from 2001; all the other countries from 2002.
[f] Blood donors from the public sector only.
[g] Bold type indicates baseline data for the country, i.e., the first time nationwide information was available.

population data from the United Nations (108). This can be considered a proxy for availability of blood. As a result, none of the countries collects blood in the amount that meets the standards of 50 blood units per 1,000 inhabitants per year (the United States collects 45.90 units/1,000 population) (15). It is therefore not unexpected that lack of blood strongly contributes to maternal mortality. Hemorrhages during pregnancy, delivery, and the puerperium were the most common causes of maternal mortality in five countries and the second most common in two others (51).

TABLE 2. Number of blood donations per 1,000 population[a]

Country[b]	No. of donations/1,000 in:			
	1993–1995[c]	1997	1999	2001/2002[d]
ARG	23a	21	22	21c
BOL	5	5	3	29c
BRA			10	17
CHI	16	15	15	14
COL	9	11	9	10
COR	15	16	24	13
ECU	9b	9	8	6
ELS	9	6	11	11
GUT	5	0	3	6
HON	5	5	7	6
MEX			11	10
NIC	11	10	9	9
PAN	10	15	15	14c
PAR	7b	8	9	8
PER		8	12	6
URU	35b	35	35	30
VEN	10	11	13	15

[a] Population data obtained from reference 108.
[b] Abbreviations for countries are given in Table 1, footnote *a*.
[c] Numbers followed by "a" were from 1995; those followed by "b" were from 1994; all others were from 1993.
[d] Numbers followed by "c" were from 2001; all others were from 2002.

TABLE 3. Type of donors in Latin America from 1997 to 2001/2003

Country[a]	% of donors in the different categories[b]								
	1997			1999			2001/2002[c]		
	Paid	Rep.	Vol.	Paid	Rep.	Vol.	Paid	Rep.	Vol.
ARG	NI[d]	NI	NI		93	7	NI	NI	NI
BOL	24	69	7	5	92	0.4	13	76	10
BRA	75		25		100			53	47
CHI	0.10	89	0.90	0.10	97.90	2.0		98	2
COL		80	20		99			57	41
COR		100			60	40		52.3	47.7
ECU		59	41		81	20		58.5	41.5
ELS		71	29		91.5	8.5		90	10
GUT		93	7		79	21		96	4
HON	10	58	32	9	73	18	9	69	22
MEX		95	5		96	4		97	3
NIC		57	43		49.5	50.5		41	56
PAN	25	70	5	51	47	2	47	51	2
PAR	1.4	97	1.6		98.3	1.7		97	3
PER	5	95		2	86	8	3	90	6
URU		92	8		92	8		65	35
VEN		100			100			89	11

[a] Abbreviations for countries are given in Table 1, footnote *a*.
[b] Rep., replacement donors; Vol., volunteer donors. When the total is less than 100%, it is because the rest are autologous donations.
[c] Data from Argentina, Bolivia, and Panama are from 2001; all others were from 2002.
[d] NI, no information available.

Voluntary blood donors are a minority in Latin America, in spite of ample evidence that they are more healthy than paid or replacement donors (Table 3). Paid donors, because of the financial incentive to donate, may withhold information that could otherwise result in their deferral. Replacement donors, friends or family of the recipients, are recruited to replace blood used or to be used. Because of peer pressure to donate, they may also be unwilling to provide information that could lead to their deferral (33).

In 1997, more than 89% of blood donations in Chile, Costa Rica, Guatemala, Mexico, Paraguay, Peru, Uruguay, and Venezuela came from replacement donors, i.e., relatives or friends of patients. In Colombia, Ecuador, El Salvador, Honduras, Nicaragua, and Panama, this proportion varied between 57 and 80%. In 1999, voluntary donors varied from 40 to 50% in Costa Rica and Nicaragua to 18 to 21% in Ecuador, Guatemala, and Honduras. In 2002, the largest proportion of voluntary donors was found in Costa Rica (48%), Colombia and Ecuador (41%), followed by Honduras (22%) (64). In all the other countries, the percentage of voluntary donors was less than 10%. Moreover, the number of voluntary donors may vary from year to year. For example, voluntary donors from El Salvador were reported to make up 29% of all donors in 1997 to 1998 but only 8.5 and 10% in 1999 and 2002, respectively (64).

Although a few countries still report paid blood donors in 2002 (12.55% in Bolivia and 47.00% in Panama in 2001, and 8.77% in Honduras and 3.22% in Peru) (64), the vast majority

of the blood for transfusion is obtained through replacement donations (15, 64) (Table 3). Even in countries that reported >20% of voluntary donors in 2002 (Brazil, Colombia, Costa Rica, Ecuador, Honduras, Nicaragua, and Uruguay), no information was provided on whether they were first-time or repeat donors. Nationwide comparisons between infection rates in repeat and first-time blood donors is impossible, since national, provincial, and even institutional blood donor registries may be weak or nonexistent.

In spite of initial efforts in Argentina, Brazil, Colombia, Ecuador, Mexico, and Uruguay to establish a system for reporting incidents and adverse events related to the administration of blood, information on the subject is not officially reported by these countries. Therefore, the potentially negative impact of blood transfusions on the patient and on public health are not known. An audit of the appropriate use of blood products at the main public tertiary-care hospital in Valencia, Venezuela, found that the overall prevalence of appropriate use of blood was 51%; packed red cells and fresh-frozen plasma were the products with the lowest rate of appropriate use, and the highest risk of inappropriate use was in the emergency and obstetrics departments (46). These findings strongly suggest that surveillance of inappropriate use of blood must be implemented together with surveillance of accidents and adverse events.

BURDEN OF DISEASE

Since 1993, countries began to provide nationwide data on the total number of donors, percentage of donors screened (screening coverage), and prevalence of infectious diseases markers for HIV, hepatitis B virus (HBV) (HBsAg), hepatitis C virus (HCV), and *Trypanosoma cruzi* (48, 58, 59, 60, 61, 62, 63, 64, 66, 67, 87, 88, 89). Those diseases and syphilis were the minimum selected for surveillance by the Regional Standards for Blood Banks (56).

How important are each of those diseases (HIV, HBV, HCV, and *T. cruzi*) in the health context of Latin America and the Caribbean? In a comprehensive World Bank report with data from 1990 (103), the burden of a disease was measured by comparing the disability-adjusted life years (DALYs) lost by death and disability from different diseases. For this purpose, the incidence of cases by age, sex, and demographic region was estimated and then the number of years of healthy life lost was obtained by multiplying the potential duration of the disease until cure or death by a severity weight that measured the severity of the disability in comparison with loss of life (103). One DALY can be thought of as one lost year of "healthy" life, and the burden of disease can be thought of as a measurement of the gap between the current health of the population and an ideal situation where everyone in the population lives to old age in full health (126). In 1990, the burden of disease attributed to HIV/AIDS in Latin America and the Caribbean was 4.4×10^6 DALYs; the burden from Chagas' disease was 2.7×10^6 DALYs; and that from hepatitis (without mentioning which type) was 160,000 DALYs (104). Similar estimates were made by the World Health Organization in later years, but instead of reporting the burden of disease with a breakdown for Latin America and the Caribbean, the figures included the region of the Americas as a whole. In any case, the burden caused by each disease in the Western Hemisphere in 1999 was 2.8×10^6 DALYs for HIV/AIDS, 677,000 DALYs for Chagas' disease, and 212,000 DALYs for hepatitis (123). These numbers can also be used as a rough estimate of the relative burden of each disease in Latin America. Also in 1999, the number of deaths from HIV, Chagas' disease, and hepatitis in the Americas was 81,000, 21,000, and 12,000, respectively (123). Another estimate, made in 2001, indicated that the burden of disease in the Americas was 2.767×10^6 DALYs for HIV; 648,000 for Chagas' disease; 125,000 for HBV; and 99,000 for HCV (126). In 2001, the number of deaths was 88,000 for HIV, 13,000 for Chagas' disease; and 6,000 each for HVB and HCV (126). Taking into account those parameters in Latin America and the Caribbean, the highest overall disease burden was produced by HIV/AIDS, followed by Chagas' disease and then by hepatitis. In spite of the above, the potential impact of transfusion-transmitted infections is higher for HIV, HCV, and HBV (infectivity, 90%) than for Chagas' disease because of the lower potential infectivity of *T. cruzi*, which is 20% (1, 20, 90, 122).

TRANSFUSION-TRANSMITTED INFECTIONS, 1993 TO 2001/2002

Data were obtained from published reports on the total number of donors (Table 1), screening coverage (Table 4), and the prevalence of serological markers for HIV, HBV, HCV, and *T. cruzi* (Table 5) from 1993 to 2002 (48, 58, 59, 60, 61, 62, 63, 64, 66, 67, 87, 88, 89). Numbers for HIV in Chile and Uruguay up to 2002 and from El Salvador in 1996 refer only to confirmed cases (63, 66, 67, 88).

Evaluating trends in infectious-disease rates in blood donors is essential for monitoring the safety of the blood supply and donor screening effectiveness (28a). Estimates for syphilis were not included, since it was assumed that the storage of blood at 4°C for 24 to 48 h ensures complete inactivation of spirochetes except when platelets, which are stored at 20 to 24°C, are used. However, no information is available to estimate the risk of receiving *Treponema pallidum* through platelet transfusion.

The first year for which information was available nationwide was 1993 for Bolivia, Chile, Colombia, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Venezuela (87); 1994 for Ecuador, Panama, Paraguay, and Uruguay; 1995 for Argentina (87); 1997 for Peru (89); and 1999 for Brazil (public sector only) and Mexico (64).

The absolute number of donations increased during the period from 1993 to 2002 (64, 87, 88, 89) (from >10 to 150%) in some of the countries reporting, such as Colombia, El Salvador, Guatemala, Honduras, Panama, and Paraguay; it remained basically unchanged in Argentina, Chile, Costa Rica, Nicaragua, and Uruguay. The increase in the reported number of donations (64) may be due to improvements in the information system or may suggest strong blood donor drives during those years (Colombia in 1997 and 2002; Costa Rica in 1999; and Venezuela in 1999, 2000, and 2002). In Brazil, the number of donors doubled between the baseline year (1999) and 2002 because information became available from the private sector (54). The decrease in the number of donors in Bolivia from 1993 to 1999–2002 and in Ecuador from 1994 to 2002 may be

explained by the increase in the fractionation of blood (64) (Table 1).

In most cases, the results of calculations were rounded to the nearest whole number. Screening coverage rates were calculated as the percentage of donors screened for each infectious-disease serological marker (Table 4). From the countries whose baseline data correspond to 1993 to 1995, 10 have 100% screening coverage for HIV, 3 for HBV, 1 for HCV, and 4 for *T. cruzi*. In 2001/2002, 13 countries reported 100% screening coverage for HIV, 2 reported >99%, 1 reported 93%, and another one reported 86%. Eleven countries screened 100% of donors for HBV, 3 screened >99%, and 3 screened 84, 93, and 95%, respectively. Nine countries screened all donors for HCV; six screened ≥90%, and two screened 49 and 74%, respectively. Screening coverage of donors for *T. cruzi* was 100% in seven countries, ≥99% in three, 75 to 95% in four, and 25 to 34% in three (Table 4).

The lowest and highest prevalence of serological markers per 1,000 donors in different countries and years are shown in Table 5. No obvious trends could be found in these prevalence rates, which for HIV ranged from 0.04 to 3.90 per 1,000 donors in Nicaragua and Honduras, respectively, in the period from 1993 to 1995; for HVB, from 2.0 to 14.4 per 1,000 in Chile and Venezuela, respectively; and for HCV from 0.5 to 9.4 per 1,000 in Honduras and Venezuela, respectively. On the other hand, the lowest and highest prevalence for HIV in 2001 to 2002 was 0.3 and 5.0 per 1,000 in Chile and Guatemala; for HBV, 0.70 and 11 per 1,000 in Chile and Guatemala; and for HCV, 1.3 and 11 per 1,000 in Chile and Colombia. In 1993 to 1995, the highest prevalence for *T. cruzi* was in Bolivia, at 148 per 1,000 donors, and the lowest was in Panama, at 1.3 per 1,000. In 2001 to 2002, the highest prevalence in blood donors continued to be in Bolivia (99 per 1,000) but the lowest prevalence was reported from Ecuador, at 1.5 per 1,000 donors. Prevalence may or may not reflect the actual prevalence of the disease in each country, because the answers to a questionnaire applied before donation may be used to screen unsuitable donors. The existence of a functioning centralized data registry of blood donors that allows the deferral of volunteers who have previously tested positive for any of the infectious diseases under surveillance may also have the same effect. Unfortunately, such a registry is not available in most countries.

In the United States, the decrease in HIV and HCV prevalence rates from 1991 to 1996, combined with the previously documented lower rates of infection from first-time donors compared with the general population, suggests the continued benefit of behavioral risk factor screening (28a). Data from the American Red Cross (1995 to 2001) (19), England (1993 to 2001) (93), and France (1986 to 2000) (70, 71) also showed a decline over time in the prevalence rate for all markers, but the rates remained higher in voluntary first-time donors than in repeat donors. In fact, the same happened all over Western Europe (53).

As shown from the above results, this decline does not seem to occur nationwide in Latin America, although it may be found in individual blood banks (82) or a subregion from a country (36, 37). In addition, the relatively high prevalence of some infections, such as HBV in Argentina, Panama, Peru, and Venezuela and *T. cruzi* in Argentina, Bolivia, Honduras, and Paraguay for several years, is an indication that screening of

TABLE 4. Percentage of donors screened (screening coverage) for blood-borne infectious diseases serological markers in Latin America from 1993 to 2001/2002

Country[a]	% of donors screened for:											
	HIV			HBV			HCV			*T. cruzi*		
	1993–1995[b]	1997	1999	2001/2002[d]	1993–1995[b]	1997	1999	2001/2002[d]	1993–1995[b]	1997	1999	2001/2002[d]	1993–1995[b]	1997	1999	2001/2002[d]
ARG	84.52a	98.0	100	100	83.71a	98.5	99.9	99.90	69.92a	97.8	93.3	98.33	100	100.0	100	100
BOL	36	35.0	28.83	86	14.5	16.0	28.8	84			9.6	49.03	29.4	44.0	23.18	86.10
BRA[c]			100	100			100	100			100	100		100	100	100
CHI	100	100	99.00	100	98.7	100	99.0	100	34.0	100	99.0	100	76.7	79.8	87.00	75.18
COL	98.8	100	99.96	99.72	98.3	100	99.95	99.80	24.7	100	100	99.70	1.4	99.2	99.89	99.75
COR	100	100	100	100	100	100	100	100	0	100	100	100	0.0	6.9	7.00	25.08
ECU	89.5b	100	99.26	100	88.2b	100	98.75	100	33b	90.0	98.7	100	51.0b	72.3	90.30	100
ELS	100	100	100	100	96.0	100	100	100	31.4	100	100	100	42.5	100	100	100
GUT	100		100	93.42	79.8		100	93.4	37.2		69.38	92.95	75.0		100	92.73
HON	100	100	100	100	83.5	97.2	100	100	27.8	86.2	92.0	95.45	100.0	99.0	99.36	100
MEX[c]			100	100			100	100			100	100			13.18	27.00
NIC	100	100	100	100	53.1	100	100	95.0	53.1	62.0	100	74.00	58.4	62.1	100	95.00
PAN	100b	100	100	100	85.0b	100	100	100	21.0b	94.0	99.4	100	24.0b	0.7	17.00	34.00
PAR	100b	100	99.20	99.45	92.9b	100	98.9	99.40	0.0b	25.0	45.1	96.94	87.0b	100	99.80	99.80
PER		100		100		100	100	100		60.0	99.5	99.40		60.0	99.80	99.40
URU	100b	100	100	100	100b	100	100	100	100b	100	100	100	100	100	100	100
VEN	100	100	100	100	100	100	100	100	31.0	100	100	100	100	100	100	100

[a] Abbreviations for countries are given in Table 1, footnote *a*.
[b] Numbers followed by "a" were obtained in 1995; those followed by "b" were obtained in 1994; all others were obtained in 1993.
[c] Baseline data for Brazil and Mexico were obtained in 1999.
[d] Data from Argentina, Bolivia, and Panama were obtained in 2001; all other data are from 2002.

TABLE 5. Prevalence of serological markers for blood-borne infectious diseases in blood donors in Latin America in 1993 to 2001/2002

Country[a]	Prevalence of serological markers per 1,000 donors[b]															
	HIV				HBV				HCV				*T. cruzi*[g]			
	1993–1995[c]	1997	1999	2001/2002[d]	1993–1995[c]	1997	1999	2001/2002[d]	1993–1995[c]	1997	1999	2001/2002[d]	1993–1995[c]	1997	1999	2001/2002[d]
ARG	2.42a	3.36	1.1	1.8	9.8a	9.05	6.1	6.0	7.7a	16.6	6.6	6.6	49.2a	44.0	55.0	45.0
BOL[e]	0.10	0.1	0.4	0.4	2.0	5.7	5.7	5.7	2.8	2.8	2.8	2.8	147.9	172.0	454.6	99.1
BRA			4.9	4.6			6.6	5.0			9.2	5.2			7.6	6.1
CHI[f]	3.40	1.3	0.4	0.3	2.0	1.5	9.5	0.7	6.4	6.8	1.4	1.3	12.0	9.7		4.7
COL	2.00	2.9	3.0	4.6	7.0	6.8	6.0	6.2	9.0	8.5	6.0	11	12.0	11.1	1.0	9.8
COR[g]	0.34	1.0	1.2	0.9	4.5	3.8	3.1	2.6	3.0	4.6	2.4	6.6	8.0	25.7	1.4	3.6
ECU	1.00b	1.5	2.4	2.8	3.8b	3.9	3.3	2.2	1.4b	2.1	2.5	2.6	2.0b	1.3	1.3	1.5
ELS	1.30	1.2	1.4	1.5	8.0	3.8	3.0	2.9	2.5	1.3	2.8	1.5	14.7	19.0	25.0	3
GUT	3.00		0.9	5.0	7.0		9.9	11.3	8.0		1.2	8.0	14.0		8.1	10.2
HON	3.90	3.6	5.4	2.6	2.7	3.5	6.6	3.9	0.5	1.9	6.2	6.2	12.4	11.9	20.5	8.7
MEX			3.0	3.6			5.2	4.6			8.0	6.9			3.8	2.4
NIC	0.04	1.4	0.7	2.8	4.0	3.1	3.9	4.4	4.4	4.1	9.3	5.0	2.4	3.9	3.5	4.9
PAN	1.0b	0.7	0.9	1.0	4.0b	6.7	17.0	1.7	4.0b	5	5.0	6.0	1.3b	17.0	14.0	9.0
PAR[h]	0.7b	2.5	2.0	1.5	13.0b	5.6	5.0	3.7	3.0b	4.3	3.0	8.6	45.0b	37.7	47.0	28
PER		2.0	1.5	3.4		10.2	9.2	4.2		3.1	2.7	6.7		2.0	1.4	2.6
URU	0.8b	0.8	0.7	0.6	4.1b	4.1	2.4	3.1	4.2b	4.9	3.3	3.5	6.2b	6.5	4.5	4.7
VEN	2.10	2.7	2.1	2.6	14.4	7.5	6.9	7.7	9.4	6.6	6.7	5.1	13.2	7.8	6.0	6.7

[a] Abbreviations for countries are given in Table 1, footnote *a*.
[b] Blank spaces indicate that information was not available.
[c] Numbers followed by "a" were obtained in 1995; those followed by "b" were obtained in 1994; all others were obtained in 1993.
[d] Data from Argentina, Bolivia, and Panama were obtained in 2001; all other data are from 2002.
[e] Prevalence rate for HIV used for Bolivia in 1997 was from 1996, and that in 1999 was from 2001; the rate used for HBV in 1997 and 1999 was from 2001; and for HCV in all years was from 2001. For *T. cruzi* in 1997 the prevalence rate used was that from 1996.
[f] The reported prevalence for *T. cruzi* in Chile is given, but prevalence used in calculations was 1/1,000, which was the prevalence assumed in the areas of nonendemicity where serological testing for *T. cruzi* is not done.
[g] In Costa Rica, the HCV and *T. cruzi* prevalence rate stated in 1993 is that from 1995 and the rate for *T. cruzi* in 1999 is that for 1998.
[h] In Paraguay, the HCV prevalence rate for 1993 is that from 1995.

donors prior to donation must improve. The methods and estimates for 1993 to 1997 are those reported previously (87, 88, 89). Estimates from 1999 to 2001/2002 were obtained by using the same method with data provided by the countries for 1999 to 2001/2002 (64). Since the majority of blood donors in most of Latin America are one-time donors, it was assumed that there was no real difference between the rates estimated for donors or for donations, and the two rates are used interchangeably. The comparison of prevalence estimates among countries is not straightforward, because reagents and laboratory procedures used in the different countries may vary in sensitivity and specificity (87–89). Therefore, to estimate the potential risk of blood transfusion-related transmission of infectious diseases, the best possible scenario was considered. Personnel who perform the serological tests were well trained, and the reagents were of excellent sensitivity and specificity considering the year when the tests were performed (87–89, 109). The different tests were assumed to have the following sensitivity and specificity: for HIV, a third-generation enzyme immunoassay (EIA) had a sensitivity of 99.99% and a specificity of 99.90% (109, 118, 119); for HBV, a fourth-generation assay had a sensitivity and specificity of 99.90% (119, 124); and for HCV, a second- generation EIA (used in 1993 to 1994) had a sensitivity of 90% and a specificity of 99.84% (87, 109) and a third-generation EIA (used from 1995 onward) had a sensitivity and specificity of 98.52 and 99.40%, respectively (14, 89, 109, 110, 114, 125). The serology for *T. cruzi* in 1993 to 1995 was assumed to have a 90% sensitivity and a 95% specificity by EIA or by indirect hemagglutination (IHA) (42, 43). In subsequent years, with improved reagents for EIA and IHA, the sensitivity was assumed to be 99.72%, and the specificity was assumed to be 98.82% (74, 77). The prevalence of serological markers for nonscreened populations was assumed to be equivalent to that reported for screened donors. The only exception was for Chile, where information was available on the seroprevalence rates for *T. cruzi* in blood donors from areas where the infection was not endemic (0.6 to 1.5 per 1,000) (13, 84, 111). Therefore, the estimates assumed that the seroprevalence of *T. cruzi* in areas with no vector transmission where screening for *T. cruzi* was not done was 1.0 per 1,000, about 1/10 of that from areas where infection was endemic (87, 89).

It was also assumed that each blood donation was used for a single transfusion to one recipient, since the availability of official data on the fractionation index of blood units varied widely from country to country in the different years. In years when screening coverage in a country was zero, prevalence rates used for calculations were from the nearest year for which data were available for that country. For example, in Bolivia, prevalence rates for HCV from 1993 to 1999 were those established in 2001 (64), the first year in which the actual rates were known. Calculations took into account the infectivity rate, i.e., the likelihood of contracting an infection when receiving an infected transfusion unit (87, 88, 89). This infectivity rate was assumed to be 90% for HIV (20), 90% for HBV (90), 90% for HCV (1), and 20% for *T. cruzi* (122). The infectivity rate of *T. cruzi* has been reported to be higher and lower by different authors (5, 10, 44, 86, 128). When donor screening was 100%, it was considered that the rate of transfusion-transmitted infections was zero since residual infectivity for lack of sensitivity of diagnostic reagents was not taken into account.

Estimates were obtained of the probability of receiving a tainted transfusion unit, *P(R)*; the probability of acquiring a transfusion-transmitted infection *P(I);* the absolute number of potential infections induced by transfusion in a given year; and an index of infectious diseases spreading through blood transfusion that provides an indication of the health risk associated with blood transfusion (87, 88, 89). To compare the status of potential transmission of blood-borne diseases at different times in the countries and among them, the ratio of transmitted infections per donation by country was also established (89).

The highest risk of receiving a virus- or *T. cruzi*-infected unit of blood and of contracting a transfusion-transmitted infection occurred when the screening coverage was nonexistent or low and the prevalence for that specific disease in the donor pool was high (Table 6). In 1993 to 1995, the probability of receiving an HIV-infected unit of blood or of acquiring an HIV infection was highest in Argentina, at 3.7 and 3.4, respectively, per 10,000 donations. For HBV the probability of receiving an infected unit or of transmitting an infection was highest in Nicaragua, at 19 and 17 per 10,000 donations, respectively. Colombia presented the highest risk of receiving a blood unit infected with HCV and of contracting that infection: 74 and 66 per 10,000 donors, respectively; while Bolivia had the highest risk for receiving a unit of blood infected with *T. cruzi* or for acquiring an infection with that organism; i.e., 1,096 and 219 per 10,000 donors, respectively. Among viral diseases, the risk of receiving an infected unit of blood was usually higher for HCV, except for Bolivia, where the risk was higher for HBV in 1997 and 1999 (Table 6).

Major improvements in risk estimates for transfusion-related *T. cruzi* infection were found in Colombia, Ecuador, Nicaragua, and Paraguay from 1993–1994 to 2001–2002. However, there was a risk of 60 per 10,000 donors in Panama, 54 per 10,000 donors in Costa Rica, and 138 per 10,000 donors in Bolivia in 2001 to 2002. In fact, Panama was the only country in which the risk of receiving a unit infected with *T. cruzi* increased from 10 per 10,000 donors in 1994 to 60 per 10,000 donors in 2001 (Table 6), probably due to improvements in the information system, which generate more data. The largest number of transfusion-transmitted infections was estimated in Argentina for HIV and HBV and in Colombia for HCV and *T. cruzi* in 1993 to 1995. Potential blood-transmitted HIV infections were deemed possible in 4 of the 17 countries with available information in 1993 to 1995; the numbers were in 11 and 10 of the 17 countries, respectively, for HBV and *T. cruzi*; and in 13 of 17 countries for HCV (Table 7). The incidence of transfusion-transmitted infections decreased in the subsequent years. Only in 2 and 4 countries of the 17 was there potential transmission of HIV in 1997 and 1999, respectively. For HBV there was transmission in three and six countries, respectively, during the same years, but HCV and *T. cruzi* continue to infect units in a larger number of countries (Table 7). In 2001 to 2002, the largest number of potential infections by HIV (21 cases) and HBV (49 cases) would have been in Guatemala; the largest number for HCV (87 cases) would have been in Argentina; and the largest number for *T. cruzi* (360 cases) would have been in Mexico. On the other hand, when comparing the

TABLE 6. Risk of receiving an infected unit or developing an infection after receiving an infected unit of blood in Latin America in 1993 to 2001/2002

Country[a]	Risk of receiving infected unit or developing infection per 10,000 donors[b]															
	1993–1995[c]				1997				1999				2001/2002[c]			
	HIV	HBV	HCV	*T. cruzi*	HIV	HBV	HCV	*T. cruzi*	HIV	HBV	HCV	*T. cruzi*	HIV	HBV	HVC	*T. cruzi*
ARG	**3.7**a, 3.4	**16**a, 14	**23**a, 21	0a	**0.7**, 0.6	**1.4**, 1.2	3.6, 3.2	0	0	**0.06**, 0.05	**5**, 4	0	0	**0.07**, 0.06	**1.2**, 1	0
BOL	**0.7**, 0.6	**17**, 15	**30**, 27	**1,096**, 219	**0.6**, 0.6	**48**, 43	**28**, 25	**964**, 193	**2.8**, 2.6	**41**, 37	**28**, 25	**3,496**, 699	**0.55**, 0.5	**9**, 8	**16**, 14	**138**, 28
BRA[d]									0	0	0	0	0	0	0	0
CHI	0	**0.3**, 0.2	**46**, 41	**2.45**, 0.49	0	0	0	**2.0**, 0.4	**0.04**, 0.04	**0.9**, 0.8	**0.15**, 0.14	**1.3**, 0.3	0	0	0	**2.5**, 0.5
COL	**0.2**, 0.2	**1.2**, 1	**74**, 66	**124**, 25	0	0	0	**0.1**, 0.02	**0.01**, 0.01	**0.03**, 0.03	**0.01**, 0.01	**0.01**, 0	**0.07**, 0.07	**0.10**, 0.09	**0.24**, 0.22	**0.13**, 0.03
COR	0	0	**33**, 29	**84**, 17	0	0	0	**240**, 48	0	0	0	**13**, 3	0	0	0	**54**, 11
ECU	**1**b, 0.9	**4.5**b, 3.4	**10**b, 9	**10**b, 2	0	0	**2.1**, 1.9	**4**, 0.7	**0.18**, 0.16	**0.41**, 0.37	**0.35**, 0.32	**1.2**, 0.2	0	0	**0.02**, 0.02	**0.40**, 0.08
ELS	0	**3.2**, 2.9	**19**, 17	**89**, 18	0	0	0	0	0	0	0.	0	0	0	0	0
GUT	0	**14**, 13	**55**, 49	**37**, 7					0	0	**4**, 3.6	0	**13**, 11	**6**, 5.5	**9**, 8	**11**, 2
HON	0	**4.4**, 4.0	**4**, 3.5	0	0.	**1**, 0.9	**3**, 2	**1**, 0.2	0	0	**5.4**, 4.9	**1.2**, 0.2	0	0	**1.5**, 1.3	0
MEX[d]									0	0	0	**33**, 7	0	0	0	**4**, 0.9
NIC	0	**19**, 17	**22**, 20	**10**, 2	0	0	**16**, 14	**15**, 3	0	0	0	0	0	0	9, 8	**0.36**, 0.07
PAN	0b	**6**b, 5	**34**b, 31	**10**b, 2	0	0	**3**, 2.7	**169**, 34	0	0	**0.33**, 0.29	**116**, 23	0	0	0	**60**, 12
PAR	0b	**9**b, 8	**33**b, 29	**61**b, 12	0	0	**33**, 29	0	**0.16**, 0.14	**0.55**, 0.5	**18**, 16	**0.9**, 0.2	**0.16**, 0.14	**0.9**, 0.8	**10**, 9	**4**, 0.7
PER					0	0	**13**, 11	**8**, 1.6	0	0	**0.15**, 0.13	**0.03**, 0.01	0	0	0	0
URU	0b	0b	0b	0b	0	0	0	0	0	0	0	0	0	0	0	0
VEN	0	0	**71**, 64	0	0	0	0	0	0	0	0	0	0	0	0	0

[a] Abbreviations of countries are given in Table 1, footnote *a*.
[b] Numbers in bold are the risk of receiving an infected unit; those in lightface are the risk of infection. When the risk is 0, the possibility of residual risk because of residual transmission was not taken into account.
[c] Numbers followed by "a" were obtained in 1995; those followed by "b" were obtained in 1994; all others were obtained in 1993.
[d] Baseline data from Brazil and Mexico are from 1999.
[e] Data from Argentina, Bolivia, and Panama are from 2001; the rest are from 2002.

numbers with the baseline data, there was a 100% decrease in transmission of HIV in Ecuador, of HBV in Chile, Ecuador, El Salvador, and Nicaragua, of HCV in Chile, Costa Rica, Ecuador, El Salvador, Panama, and Venezuela, and of *T. cruzi* in Ecuador, El Salvador, and Peru.

There was an important decrease in the estimated number of cases that could have originated by transfusion in Latin America from 1993–1995 to 2001–2002. This was most marked in Chile, Colombia, Ecuador, El Salvador, and Venezuela, with a reduction of the number of potential cases close to 100%; the percentages were 97% in Argentina and 92% in Paraguay (Tables 7 and 8).

The index of infectious diseases spreading through blood transfusion decreased steadily over time in most countries, in parallel to the increase in screening coverage. These findings are also consistent with the increase observed in the ratio of cases to donations. However, the spreading index was still more than 10 of 10,000 donors in Bolivia, Guatemala, Nicaragua, and Panama in 2001 to 2002. This was due mainly to limited screening for HBV, HCV, and *T. cruzi* in Bolivia; all of the above plus HIV in Guatemala, HCV in Nicaragua, and *T. cruzi* in Panama (Table 8).

Given the fact that laboratory procedures and reagents used in blood banks operating in the countries vary, it is possible that the risk percentages presented in this report are under- or overestimated. The results may have also been influenced by the lack of a quality assurance system and routine performance evaluations for serological testing in blood banks. A potential cause of underestimating the risk of transfusion of infected blood or blood components is not to include information on the fractionation of blood. The same infected blood unit could have generated several by-products, and more than one recipient could have been exposed to the risk of receiving a tainted transfusion (88). In addition, no consideration was given to the potential residual risk of transmission of viral diseases during the window period, when markers are still not detectable, even when 100% of the donors were screened (38, 90). The reported average window period for the assays used for screening is 20 to 25 days, 82 to 84 days, and 51 days for HIV, HBV, and HCV, respectively (38, 90, 109).

Transmission during the window period can be estimated by studying the seroconversion of donors and recipients over time (8). However, for this to be possible, it is necessary to follow up repeat donors who, almost without exception, are volunteers. This is very difficult in Latin America. Most donations are by replacement donors, and, even when they are voluntary donors, there are no official nationwide statistics on single and repeat blood donors than can indicate if the follow-up is possible. In addition, the lack of a national registry of donors does not allow a proper evaluation of seroconversion rates (89). Even in Nicaragua (1997), where 50% of donors were reported to be altruistic (64) (supposedly repeat donors), analysis of conversion rates would have been difficult given the time required and the large number of individuals to be enrolled.

Prevalence rates and therefore infection risk also could have been underestimated for HBV, assuming that no test for anti-core antibodies were reported. Only two countries reported nationwide results of screening for HBV anti-core antibodies in 1996 (67), and none reported results thereafter. Only in 5 of

TABLE 7. Estimates of the potential number of transfusion-transmitted infections by country and year based on the lack of screening coverage in Latin America in 1993 to 2001/2002

Country[a]	No. of transfusion-transmitted infections in[b]:															
	1993–1995[c]				1997				1999				2001/2002[e]			
	HIV	HBV	HCV	*T. cruzi*	HIV	HBV	HCV	*T. cruzi*	HIV	HBV	HCV	*T. cruzi*	HIV	HBV	HCV	*T. cruzi*
ARG	273a	1,166a	1,841a	0a	46	92	243	0	0	4	351	0	0	4	87	0
BOL	2	58	104	832	2	173	102	772	5	75	51	1,442	1	20	35	68
BRA[d]									0	0	0	0	0	0	0	0
CHI	0	5	899	11	0	0	0	9	1	19	3	6	0	0	0	11
COL	8	38	2,338	875	0	0	0	8	0	1	0	1	5	5	14	2
COR	0	0	149	85	0	0	0	28	0	0	0	244	0	0	0	29
ECU	9b	40b	90b	20b	0	0	21	8	2	4	3	3	0	0	0	0
ELS	0	14	81	85	0	0	0	0	0	0	0	0	0	0	0	0
GUT	0	58	223	33					0	0	11	0	21	49	40	11
HON	0	11	10	0	0	2	7	1	0	0	20	1	0	0	11	0
MEX[d]									0	0	0	722	0	0	0	360
NIC	0	78	93	10	0	0	66	14	0	0	0	0	0	0	62	2
PAN	0b	14b	81b	5b	0	0	12	143	0	0	1	102	0	0	0	52
PAR	0b	27b	97b	40b	0	0	117	0	1	2	74	1	0	1	12	1
PER					0	0	229	33	0	0	4	0	0	0	6	0
URU	0b	0b	0b	0b	0	0	0	0	0	0	0	0	0	0	0	0
VEN	0	0	1,298	0	0	0	0	0	0	0	0	0	0	0	0	0

[a] Abbreviations of countries are given in Table 1, footnote *a*.
[b] When transmission is zero, the possibility of residual transmission is not taken into account.
[c] Numbers followed by "a" were obtained in 1995; those followed by "b" were obtained in 1994; all others were obtained in 1993.
[d] Baseline data from Brazil and Mexico are from 1999.
[e] Data from Argentina, Bolivia, and Panama are from 2001; the rest are from 2002.

the 17 countries included in this report was detection of HBV anti-core antibodies mandatory in 2000 (65).

For *T. cruzi*, the probability that a person may donate blood during the window period is remote. Most infections occur during childhood or adolescence and are most common in rural areas. However, a few *T. cruzi*-positive cases may have been missed when only one test for screening was used. Even if a very-high-sensitivity test for *T. cruzi* is used, a second assay would be necessary, since the different assays detect antibodies of different specificities. No single test has been shown to be sensitive enough to prevent the transmission of *T. cruzi* in urban centers, and the use of a parallel test would increase the sensitivity of diagnosis (83, 117, 122). Even in countries with 100% screening coverage for *T. cruzi*, there is residual infectivity because of limited sensitivity of the diagnostic reagents used in 2001 to 2002. However, even in Argentina and Brazil, where two tests were mandatory, 50 to 55% of blood transfusion services surveyed in the late 1980s and early 1990s indicated that only one test was performed for diagnosis (52, 69). The World Health Organization recommended only one test, an EIA, for blood bank screening in 2002 (127).

Residual infectivity may also occur after serological testing for HCV, even when using third-generation reagents. In 2001 to 2002, with the reagent sensitivity reported here, HCV reactive tests would be missed in 230, 105, and 28 blood donations in Brazil, Mexico, and Venezuela, respectively, and in 4 or 5 donors in each of the six other countries with 100% screening coverage for HCV. Since the purpose of serological testing in blood banks is the screening of potentially positive donors, estimates were based on results of the screening only. Some samples that give positive results by screening are likely to be negative after confirmatory assays. Countrywide results of the screening, as well as of confirmed positive serological tests of HIV, were available only from two countries in 1993 and three countries in 1997 (66, 67). The proportion of samples positive for HIV by serological screening that were also positive by a confirmatory test varied widely from country to country. Chile confirmed 25% of those positive by the screening test, Costa Rica confirmed, 29%, Ecuador confirmed 78%, and Nicaragua confirmed 8% in 1996 (67). In 1997, Chile confirmed 46% of its seropositive donors by screening, El Salvador and Panama confirmed 100%, while Nicaragua confirmed only 10.3% (66). A blood bank from Sao Paulo, Brazil, confirmed 4 (12%) of 34 samples positive by screening of 236,001 blood donors in 2001 (82). Nationwide results of confirmatory tests for HBV or HCV have not been reported up to 2002. However, in studies of blood donors from Argentina, half of those who were HCV seropositive by screening were considered to have given false positive results (94). Records from testing more than 1.4 million donors in Spain indicated that only 5.7, 38.8, and 34.8% were confirmed for HIV, HBV, and HCV, respectively (49). With *T. cruzi*, since there is no single test that can be used as a confirmatory test, it is assumed that a true-positive unit is one that is positive by more than one test (69, 83). Following these criteria, the rates of true positives for *T. cruzi* among blood donors may vary from 25% to more than 90% (31, 81, 83).

Another source of overestimation of the risk of transfusion-transmitted infections is the possibility that some potential blood recipients have already been infected. If one assumes that the overall prevalence of infectious diseases among blood recipients is similar to the donor population, the estimated number of potential new infections induced by transfusion would be reduced by the proportion of recipients already positive. This was particularly important for *T. cruzi* in Bolivia, where 20% or more of the general population is already infected with this parasite (86, 87, 128).

TABLE 8. Estimates of the total number of cases of blood-borne transmitted diseases, spreading index, and case/blood donation ratio by country and year in Latin America in 1993 to 2002[a]

Country[b]	1993–1995[c]			1997			1999			2001/2002[d]		
	No. of cases	Spreading index/10^4	Infection/donation ratio	No. of cases	Spreading index/10^4	Infection/donation ratio	No. of cases	Spreading index/10^4	Infection/donation ratio	No. of cases	Spreading index/10^4	Infection/donation ratio
ARG	3,280a	40a	1:248a	381	5	1:1,948	355	4	1:2,282	91	1	1:8,835
BOL	996	262	1:38	1,049	262	1:38	1,573	763	1:13	124	50	1:200
BRA							0	0	0	0	0	0
CHI	915	42	1:237	9	0	1:24,521	29	1	1:7,530	11	0	1:20,556
COL	3,259	93	1:108	8	0	1:52,788	2	0	1:176,996	26	1	1:16,342
COR	234	46	1:217	281	48	1:208	244	26	1:383	29	5	1:1,844
ECU	159b	16b	1:619b	29	3	1:3,814	12	1	1:8,621	0	0	0
ELS	180	37	1:267	0	0	0	0	0	0	0	0	0
GUT	314	69	1:145				11	3	1:2,904	121	17	1:595
HON	21	8	1:1,328	10	4	1:2,796	21	5	1:1,949	11	3	1:3,705
MEX							722	7	1:1,513	360	4	1:2,853
NIC	181	39	1:254	80	17	1:582	0	0	0	64	13	1:764
PAN	100b	38b	1:263b	155	37	1:273	103	23	1:426	52	12	1:824
PAR	164b	50b	1:201b	117	29	1:341	78	17	1:585	14	3	1:3,252
PER				262	13	1:777	4	0	1:77,888	6	0	1:24,846
URU	0b	0b	0b	0	0	0	0	0	0	0	0	0
VEN	1,298	64	1:157	0	0	0	0	0	0	0	0	0

[a] When transmission is 0, possibility of residual transmission is not taken into account.
[b] Abbreviations of countries are given in Table 1, footnote *a*.
[c] Numbers followed by "a" were obtained in 1995; those followed by "b" were obtained in 1994; all others were obtained in 1993.
[d] Data from Argentina, Bolivia, and Panama are from 2001; the rest are from 2002.

The information from Brazil and Mexico was available later than that from the other countries. Brazil reported 100% screening for infectious diseases in the public sector, covering approximately 1.6 million donations, in 1997 and 1999 (50, 64). However, the overall total number of donations in the country, 3,014,184, was reported only in 2002 (64), when donations from the private sector were included. In Argentina, where private and public sector nationwide information on prevalence and screening coverage was reported separately from 1995 to 1997, screening coverage was higher in the private sector but, with a few exceptions, prevalence rates were higher in the public sector (88). In 1995, the probability of a transfused patient receiving an HIV- infected unit was 8.6 per 10,000 donations and the probability of acquiring an infection was estimated to be 7.7 per 10,000 donations in the public sector, but was considered to be zero in the private sector (88). In Paraguay, the only country other than Brazil where the number of donors from the public and private sector (11% of the total number of donors) were reported separately in 2002, only the prevalence rate for HBV was lower in the public sector than in the private one (54).

Mexico did not report national screening coverage or prevalence of any of the serological markers until 1999. At that time, screening coverage for viral serological markers was 100%, but it was incomplete for *T. cruzi* (64). Data from 1994 suggest that 12,750 individuals would have received a *T. cruzi*-tainted transfusion and that around 1,912 individuals would have been infected by *T. cruzi* (30). Based on data for 2000, with 1,234,414 reported blood donors, 14.7% of donors screened for *T. cruzi*, and a prevalence of positive serology for *T. cruzi* of 6 of 1,000 donors (64), it can be estimated that 1,265 cases of *T. cruzi* infection were transmitted by blood transfusion during that year. The lower estimates of the number of transmitted cases reported in 1999 and 2002 than in 2000 may originate in the lower prevalence in blood donors reported for those years (3.8 of 1,000 and 2.4 of 1,000, respectively [64]).

How does this situation compare to what happens in developed countries? In England, the overall risk of infectious donations entering the blood supply was reduced from 1 in 5,000 to an estimated 1 in 100,000 (113), and the risk for contracting HIV infection was reduced from 1 in 100,000 to 1 in 2,500,000 (113). Other estimates of the frequency of infectious donations entering the blood supply in England in 1993 to 2001 were 1 in 260,000 for HBV and 1 in 8,000,000 for HIV. For HCV, infectious donations decreased from 1 in 520,000 during 1993 to 1998 to 1 in 30,000,000 during 1999 to 2001 (Table 9) (93). In France, the residual risk for 1994 to 1996 was estimated to be 1 in 180,000 donations for HBV, 1 in 200,000 donations for HCV, and 1 in 1,000,000 donations for HIV (1 in 311,000 in 1990) (70). Another report with data from 1998 to 2000, estimated the residual risk to be 1 in 470,000 donations for HBV, 1 in 860,000 donations for HCV, 1 in 1,370,000 donations for HIV, zero for human T-cell leukemia virus (HTLV), and 1 in 250,000 donations for the four viruses combined (Table 9). Implementation of nucleic acid amplification-based testing (NAT) in 2001 predicted a reduction in the residual risk to 1 in 2,700,000 for HIV and 1 in 8,300,000 for HCV (71). In the United States, the estimated risk in donations from repeat donors for HBV was estimated at 1 in 205,000 screened units, for HCV it was 1 in 276,000 (antibody test only), and for HIV

TABLE 9. Residual infectivity in Latin America in 2001/2002 and in selected industrialized countries

Country (reference)	Yr	Residual infectivity				
		HIV	HBV	HCV	*T. cruzi*	Overall
Latin America[a]	2001/2002					
Southern Cone		1/49,567	1/496,712	1/24,179	1/101,592	1/13,626
Andean Countries		1/50,821	1/882,318	1/21,175	1/169,631	1/13,443
Central America and Mexico		1/50,326	1/522,405	1/20,821	1/423,306	1/13,912
Industrialized countries						
England (93,113)	1988	1/2,500,000				1/100,000
	1993/2001	1/8,000,000	1/260,000	1/30,000,000[b]		
	1993/1998			1/520,000		
France (70,71)	1998–2000	1/1,370,000	1/470,000	1/860,000		1/250,000
	1994–1996	1/1,000,000	1/180,000	1/200,000		
United States (19)	Before NAT	1/1,468,000	1/205,000	1/276,000		
	After NAT	1/2,135,000[c]		1/1,935,000[c]		

[a] Results showing the residual-risk infectivity assume that screening coverage in the three subregions is 100%. Comparisons between industrialized countries on one hand and the Latin American subregions on the other can be made only for HIV, since the calculation took into consideration infected units based on false-negative results and the potential infectivity of units because donors were in the window period.
[b] 1999–2001.
[c] NAT is available.

it was 1 in 1,468,000 (antibody plus p24 antigen detection) before the use of NAT; it may have been reduced to 1 in 1,935,000 for HCV and 1 in 2,135,000 for HIV after NAT implementation in 2001 (Table 9) (19). Introduction of NAT for blood screening of HIV and HCV RNA has considerably decreased the risk of transmission of these two viruses through blood donated during the window period (19, 29, 71, 76, 93, 95).

In Italy, the estimated risk for an infectious blood unit not being detected by testing was 2.45 in 1,000,000 (1 in 408,163) for HIV, 4.35 in 1,000,000 (1 in 229,885) for HCV, and 15.78 in 1,000,000 (1 in 63,371) for HBV from 1994 to 1999. The overall risk for any of the three viral infection was 22.58 in 1,000,000 (1 in 44,287) (107). Another estimate from the same country indicated that the residual risk of donating antibody-negative infectious blood was 1 in 127,000 donations for HCV and 1 in 435,000 for HIV from 1996 to 2000 (112).

The published estimates are for national blood donor pools. Nevertheless, in England the risk of receiving an infectious unit was sevenfold higher for blood collected from first-time donors than that estimated for blood obtained from repeat donors (93). In Latin America, a study of 11,286 repeat donors from southern Brazil showed that the residual risk of HIV-positive transfusion decreased from 1 in 5,000 in 1991 to 1994 and 1 in 3,794 in 1995 to 1996 to 1 in 48,777 in 1997 to 1999 (36). Another retrospective study with the same donors indicated that the residual risk of acquiring HBV or HCV through contaminated blood was 1 in 2,077 and 1 in 13,721, respectively, in the late 1990s (37). These numbers clearly indicate that repeat donors may also be a source of tainted blood.

Risk estimates in industrialized countries such as England (113), France (71), and the United States (19) are based on data from millions of donors. In Latin America, only Brazil and Mexico collected more than 1 million units of blood per year (64). To do some comparisons, countries included in the present report were grouped by their geographical locations, taking into consideration any subregional economic integration efforts. The Southern Cone was composed of Argentina, Brazil, Paraguay, and Uruguay; the Andean Countries were represented by Bolivia, Chile, Colombia, Ecuador, Peru, and Venezuela; and Meso America included Costa Rica, El Salvador, Guatemala, Nicaragua, and Panama, together with Mexico. The total number of donors in 2001 to 2002 was 3,965,404 for the Southern Cone, 1,270,539 for the Andean Countries, and 1,358,814 for Meso America. For each subregion, we estimated the potential residual risk of infected units resulting from false-negative tests, since the sensitivity of diagnostic reagents used for the screening was less than 100% (0.01% less for HIV, 1.48% for HCV, 0.10 for HBV, and 0.28 for *T. cruzi*). For that purpose, we used data from 2001 for Argentina, Bolivia, and Panama and from 2002 for the other countries regarding total number of donors (Table 1) and the prevalence of each of the different serological markers (Table 5). Since the numbers in developed countries refer to confirmed cases only, in order to allow for some comparisons with developing countries the results of the screening in the Latin American subregions were adjusted by assuming that infected units were confirmed by repeating the test used for screening and, when positive, by further testing by Western blotting for HIV (19, 105, 106), a neutralization assay for HBV (19), recombinant immunoblot assay for HVC (19, 105, 106), and a second conventional test (indirect immunofluorescence and/or IHA and/or EIA) based on a different principle from the one used for the screening for *T. cruzi* (81, 83, 122, 127). Confirmation rates for HIV in developed countries, where repeat donors are the norm, are usually less than 10% (49, 95). To put our estimates for developing countries in Latin America in a proper perspective, we used a confirmation rate of 16%, the rate which has been found among, first-time blood donors in the United States (92). The reported confirmation rates for HBV in developed countries are 34% (92) and 38.8% (49); the latter rate was selected for use here. The confirmation rate selected for HCV was 50%, consistent with the median of what has been previously reported (49, 92, 94, 106), and the confirmation rate selected for *T. cruzi* was 25% (31). Calculations for HIV were also adjusted on the basis of a report from Southern Brazil, with case confirmation similar to that mentioned above, indicating an estimated residual risk of 1 in 50,000 because of

the window period (36). On the other hand, the calculations made did not use the residual risk originating in the window period reported from Southern Brazil for HBV and HCV (37), because the confirmation protocol used in that report did not match the assumptions for serological confirmation made here. The results showing the residual risk were obtained by assuming that screening coverage in the three subregions is 100% (Table 9).

Comparisons between industrialized countries on the one hand and the Latin American subregions on the other can be made only for HIV, where the risk is much higher in the latter. For the other two viruses, because the window period was not taken into account in the calculations, comparisons cannot be made; therefore, the numbers reported underestimate the risk. However, even with the underestimate, the risk of contracting HCV in Latin America is higher than in industrialized countries. The overall risk for the four diseases combined was 1 in 13,626, 1 in 13,443, and 1 in 13,912 for the Southern Cone, Andean Countries, and Meso America, respectively, much higher than the overall risk in Europe (Table 9).

It has been claimed in England that accuracy of residual risk estimates is imperfect due to uncertainty in some assumptions and to the small number of infections (93). However, that report provided some quantification of the risk of HBV, HCV, and HIV transmission by transfusion and allowed comparison of these risks for each infection over time (93). Difficulties and limitations for the use of public health data for policy decision making are well recognized. The numbers reviewed here, while an approximation to the problem, are the only available national estimates, with data provided by the countries themselves, of the risk associated with transfusion of tainted blood in Latin America.

QUALITY ASSURANCE

Sensitive screening tests and a mandatory quality assurance system are essential for maintaining the safety of the blood supply (113). The multiplicity of blood banks, coupled with the weaknesses in regulatory and technical oversight by the health authorities, also result in variations in laboratory methods in use for blood screening. With very few exceptions, procurement of testing kits used by blood banks in Latin America is done considering their cost rather than their quality and appropriateness for blood screening. Rapid tests for HIV, HBsAg, and HCV are commonly used. Up to seven different brands of EIA HIV tests may be in use in a single country. Furthermore, kit evaluation by national central or local quality laboratories is not done routinely before distribution. In addition, an unintended consequence of descentralization was that the purchase of reagents is now done locally and therefore in smaller quantities. This in turn does not allow for savings based on economy of scale.

For quality assurance it is necessary to exercise exhaustive control over the entire process, developing protocols for procedures, techniques, reagents, equipment use and maintenance, and personnel, and to participate in performance evaluation programs that make it possible to periodically assess the suitability of techniques, reagents, and training in relation to the validity of the results obtained.

A regional program addressing performance evaluation in immunohematology began in 1995 and has grown since then. It sent unknown samples to 13 blood banks in different countries in Latin America in 1998, to 20 in 1999, and to 24 in 2000. A total of 7 and 6% erroneous results were reported in 1998 and 1999 in the detection of irregular antibodies (no mistakes were reported in 2000). On the other hand, 17.5, 12.5, and 5.2% mistaken results in identifying those irregular antibodies were reported in 1998, 1999, and 2000, respectively. No mistakes in the Coombs test were found in 1999 and 2000; $\leq$6% errors were found in identifying Rh and Kell in 1998 and 1999, and no errors were reported in 2000 (27).

An international performance evaluation program on serological testing for infectious diseases with participation, depending on the year, of 13 to 21 national reference centers from 11 to 16 Latin American countries was active from 1997 to 2000 (65, 79). Five panels with 24 unknown samples each, 2 or 3 of which were negative samples, were sent to participating institutions; 81% of them sent the results of the five panels back; and 87 to 100% of the institutions responded on time (within 60 days of receiving the panel) (65). Results showed false-negative results in 0.7% of 687 tests positive for HIV, 2.9% of 381 tests positive for HBsAg, 4.0% of 275 tests positive for anti-HBc, 1.07% of 468 tests positive for HCV, 6.25% of 576 tests positive for syphilis, and 3.22% of 527 tests positive for *T. cruzi*. False-positive results for those markers were 2% of 1,833 negative samples for HIV, 5.3% of 1,572 negative samples for HCV, 2.5% of 1,731 negative samples for HBsAg, 3.22% of 589 negative samples for anti-HBc, 2.90% of 2,112 negative samples for syphilis; and 0.73% of 2,329 negative samples for *T. cruzi* (65, 79).

Until 2001, 11 Latin American countries had programs of performance evaluation for the serological testing of infectious diseases in blood banks: Argentina, Bolivia, Brazil, Colombia, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Paraguay, and Venezuela (65, 79). In Chile, all blood banks participate in a proficiency testing program for clinical laboratories (65). The panel used in most countries has positive or negative samples for HIV, HBV, HCV, *Treponema pallidum*, and *T. cruzi*. In Argentina and Brazil the panels have positive and negative samples for HTLV-1 and HTLV-2, and in Argentina the panels have positive and negative samples for P24 and brucellosis (65). It is unfortunate, however, that not all blood banks in a given country participate. From fewer than 50% of them in Argentina, Colombia and Venezuela to 90% or more in El Salvador and Paraguay participated in the programs (65).

A comparison of results from six blood banks with the results from a reference laboratory in the central region of Brazil showed that the sensitivity of screening for *T. cruzi* ranged from 50 to 100%, thus suggesting that transmission of *T. cruzi* could be occurring despite serological screening by blood banks (78). A blind panel containing positive samples for blood-borne diseases distributed to 57 major public blood banks in four sequential programs showed 64 false-negative results for *T. cruzi* (3.7%) (78). Another performance evaluation program instituted in Brazil (1999 to 2001), with the participation of 116 private and public institutions, showed that 1.6% of 5,406 positive samples for *T. cruzi* were reported as negative in 58 laboratories while 0.32% of 32,855 negative samples had been reported as false positive (80). In 2002, 131 institutions received three panels of six unknown samples each;

the first was to be tested for HIV, HTLV, and Chagas' disease; the second was to be tested for the markers of HBV and HCV; and the third was to be tested for syphilis. The results showed that of the 123 participants, 6.7% had discordant HIV results and 17.9% had discordant Chagas' disease results. With the two other panels, 6.7 and 14.7% had discordant results for HBsAg and syphilis, respectively; 11.8% of 121 institutions had discordant results for anti-HBc; while 8.4% of 120 institutions had discordant results for HCV (54). The percentage of accurate results detected by the participants was 99.1% for HIV, 96% for Chagas' disease, 98.5% for HBsAg, 98.2% for anti-HBc, 98.2% for HCV, and 96,6% for syphilis. The largest numbers of false-negative results were for Chagas' disease and syphilis (54).

Another program was conducted in Colombia in 1998, with blind positive and negative samples for HIV, HBV, HCV, HTLV, syphilis, and *T. cruzi* sent to 46 blood banks, of which 43 responded to the survey. There were 49 false-positive results (5%) and 12 false-negative results (3%). Of the false negatives, six were for syphilis, two were for Chagas' disease, two were for anti HVBc, one was for HCV, and one was for HBsAg (7). In Argentina, 30% of participating institutions (52 in 1999, 102 in 2000, and 118 in 2001) to which a panel similar to the one in Colombia but including *Brucella* was sent gave at least one false-negative result (55). The results of those national and international performance evaluation programs in Latin America strongly suggest that there is still room for improvement.

Infectious diseases are not the only cause of transfusion risk in developed countries. Prevention of ABO-incompatible transfusion is of serious concern for all transfusion services. Errors may occur along the chain of activities, from taking pretransfusion blood samples from patients to the transfusion of blood into patients (113, 120). The risk of ABO-incompatible death is 1 in 500,000 in the United Kingdom (47) and the United States (85). There is evidence, however, that the risk in the United Kingdom may be higher (120). The same may happen in the United States, where only 1% of adverse incidents are reported (35). Hemovigilance must make every effort to detect and analyze such events so that corrective measures can be implemented (3).

COSTS OF PREVENTING INFECTIONS IN SELECTED COUNTRIES

In 1993 to 1994, the unitary cost for serological screening was estimated solely on the basis of expenditures on the least expensive laboratory reagents in each country, and taking into account the prevalence rates reported by the countries (87). At that time, the cost of screening was \$0.9 to \$2.4 for an HIV EIA, \$0.5 to \$3.5 for HBV screening (EIA, radioimmunoassay, or IHA), \$3.5 to \$10.0 for HCV EIA, and \$0.25 to \$1.0 for a *T. cruzi* test (EIA or IHA) (87). Using other diagnostic tests may increase costs. Rapid tests, for example, are usually more costly than EIA. The value of preventing the transfusion of one infected unit represents the cost of detecting one positive unit for any one of the infections studied in each country by using one diagnostic test for each infectious disease. Using more than one test, for example one for antibody detection and one for antigen detection for HIV, increases the cost by \$2 to \$3 per donor. Detection of *T. cruzi* was the least expensive (\$11 to \$209 per positive unit of blood), followed by HBV (\$90 to \$407 per unit), HCV (\$438 to \$7,136 per unit), and HIV (\$232 to \$23,000 per unit) in 1993 (Table 10) (87). In Chile, the cost of a single EIA for HIV and HBV was \$2.3 and \$1.2, respectively. Thus, preventing one unit infected with HIV would cost \$676 and preventing one unit infected with HBV would cost \$599. In Costa Rica, the cost of a single EIA for HIV and HBV was \$1.0 and \$0.5 respectively; therefore, preventing one unit infected with HIV would cost \$3,280 and preventing one unit infected with HBV would cost \$111. The lower the prevalence of the infection, the higher the cost of preventing it.

Another cost estimate was done using data from 1997. At that time, the cost of reagents per unit test was based on the costs incurred by a blood bank from one of the countries with a volume of 20,000 donations per year. This was found to be \$1.10 for HIV (EIA), \$0.75 for HBV (EIA), \$3.85 for HCV (EIA), and \$1.00 for *T. cruzi* (EIA) (88). If an institution processes a larger number of units per month, the cost would be lower. In small countries or institutions, these costs would be higher since economies of scale for purchasing reagents for testing for blood donations can be significant.

There was not much difference in price for 2001/2002, except that the cost of HCV testing decreased to around \$2.5. In small countries (or institutions), however, the cost of a single HCV test can still be \$5 or more. Estimates of the total cost of screening (except for syphilis) of the whole donor pool (reagents only) would vary from \$187,000 in Honduras, \$229,000 in El Salvador, and \$268,000 in Bolivia to \$1.7 million in Venezuela, \$2.9 million in Colombia, and \$5 million in Argentina, if all donors were screened. Based exclusively on the cost of reagents, estimates of the cost of preventing one HIV, HBV, HCV, or *T. cruzi*-infected unit by country for 1997 are shown in Table 11. The highest cost of preventing an infection with HIV was still \$11,000 in Nicaragua, \$500 in Chile for HBV, \$2,962 in El Salvador for HCV, and \$769 in Ecuador for *T. cruzi*. The wide variation in cost by country reflects differences in the prevalence of each infection, except in the case of HCV, for which the cost of testing is higher than for any of the other diseases.

One question that may arise is whether those expenses for blood screening are cost-effective. Blood-borne infections discussed here have different patterns of evolution. While all HIV-infected individuals are expected to get AIDS at some point during their lives (68), 50 of those infected with HBV and 30 to 38% of those infected with HCV will get posttransfusional hepatitis (4). On the other hand, 20 to 30% of those infected with *T. cruzi* will get Chagas' disease (86, 122, 127). For example in Chile, *T. cruzi* serological testing in blood donors is not mandatory outside areas of endemic infection because it is suspected that the number of *T. cruzi*-infected donors from those areas is small. In fact, it is smaller (0.6 to 1.5 per 1,000 donors) (13, 84, 111) than in the areas of endemic infection in Chile (9.7 to 12 per 1,000) (64, 87, 89). Therefore, among the 176,107 donors from the area of endemic infection (9.7 per 1,000 with a positive serological test for *T. cruzi*), 1,708 with a positive serological test for *T. cruzi* should have been detected by screening in 1997. Assuming 1 in 1,000 positive serological tests for *T. cruzi* in the areas where infection is not endemic, serological testing for *T. cruzi* could have detected 44

TABLE 10. Estimated unitary cost of preventing transfusion-transmitted infections in selected countries in 1993[a]

Country[b]	Cost ($) of preventing infection by:							
	HIV		HBV[c]		HCV		*T. cruzi*	
	Single test	Preventing 1 infected unit	Single test	Preventing 1 infected unit	Single test	Preventing 1 infected unit	Single test	Preventing 1 infected unit
ECU[d]	1.7	1,708	1.0	263	10.0	7,136	0.35[e]	175
ELS	2.0	1,550	1.9	238	4.5	1,802	1.0[e,f]	68
GUT	1.8	601	1.7	243	3.5	438	0.9[e]	36
HON	0.9	232	0.9/0.5[f]	334/186	3.5	6,971	0.45[f]	36
NIC	1.0	23,000	0.5[f]	125	3.5	797	0.5[f]	209
VEN	1.3	619	1.3	90	4.5	479	0.5/0.3[e]	38/23

[a] Cost of preventing (i.e., detecting) one infected unit. All costs refer to EIA, unless otherwise indicated.
[b] Abbreviations for countries are given in Table 1, footnote *a*.
[c] HBsAg only.
[d] Cost from 1993, but prevalence for calculations from 1994.
[e] IHA.
[f] Radioimmunoassay (88).

positive donors among the 44,579 unscreened blood donors. Of those who receive the 44 infected units, 20% will acquire the infection. Three of those, at the most, if they survive 10 to 20 years, could develop Chagas' disease. To prevent nine potential infections, three of which could potentially result in Chagas' disease, would cost $44,579 at $1 per test for reagents alone. The cost of preventing each potential infection would be $4,953, and the cost of preventing a potential case of Chagas' disease would be $14,900. From the point of view of cost-effectiveness, it is understandable that *T. cruzi* screening is not done in the areas of Chile where infection is not endemic. Nevertheless, it is far more difficult to explain this concept to the recipient of a *T. cruzi*-infected blood unit.

Brazil spent $516,682,000 in prevention and control activities for Chagas' disease from 1975 to 1995 (2). Of this amount, 18.5% was devoted to strengthening hematological services and blood banks and the rest was devoted to vector control and related activities. It was estimated that in 1978 there were 3,573,000 individuals infected with *T. cruzi* in the country, or 3.1% of the population. By contrast, the seropositive rate decreased to 1.3%, or 1,961,000 infected individuals, in 1995. Between 1975 and 1995, vector control prevented 277,000 new infections and 88,000 deaths, while the expenditures prevented (expected benefits) were $847 million (2). During the same period, screening in blood banks prevented 5,470 new infections and originated $18.6 million in savings. If the government payment schedule to account for the economic benefit of the program (health care expenditures prevented) were substituted by the private payment schedule, vector control activities would have saved $3.015 million while blood bank activities would have saved $79 million. The cost-benefit analysis demonstrated that for each dollar spent in vector control, there were $2.01 in savings. Blood banks returned $0.19 for each dollar spent (2). Although it was concluded that prevention of *T. cruzi* infection through blood donor screening alone was not cost-effective, screening of blood donors for *T. cruzi* still is mandatory in Brazil.

Advances in protecting against existing and emerging blood safety risks contribute to rising costs, which would be expected to rise further in the future (29). It has been already shown that screening blood donors for West Nile virus improved blood safety (9). There are few doubts that the virus would travel to Latin America on migratory birds. Screening for HTLV-1 and HTLV-2 will also expand to other countries. However, of more immediate concern from the economic point of view is the potential use of NAT for HIV and HCV RNA (3). In Brazil alone, this test would increase the cost of blood donor testing by $50 million per year (25). It would be a challenge to the authorities to reach a political decision to implement NAT when this and other tests overburden limited funds in trying to achieve zero risk.

CURRENT STATUS: IS TAINTED BLOOD STILL USED?

From the data presented herein, it is obvious that the situation has improved in Latin America since 1993. One element for which countries must be commended is in establishing an information system that, although still incomplete (there are no official reports on adverse events and incidents), periodically allows for a partial follow-up of the status of the blood supply. Until now, most improvements originated in better screening for infectious diseases, including quality assurance. The ratio of infections to donations increased in all countries for most serological markers, as did the screening coverage.

TABLE 11. Estimates of the cost of preventing transfusion of an infected blood unit in selected countries in Latin America in 1997

Country[a]	Cost ($) of preventing infection by:			
	HIV	HBV	HCV	*T. cruzi*
ARG	327	83	232	23
BOL	11,000	132	1,375	6
CHI	846	500	566	
COL	379	110	453	90
COR	1,100	197	837	39
ECU	733	192	1,833	769
ELS	917	197	2,962	53
HON	306	214	2,026	84
NIC	786	242	939	256
PAN	1,571	112	770	59
PAR	440	134	895	27
PER	550	74	1,242	500
URU	1,375	183	786	154
VEN	407	100	583	128

[a] Abbreviations of countries are given in Table 1, footnote *a*.

On the other hand, the spreading index decreased. However, available information and estimates suggest that blood-borne infections via transfusion continue to occur. Based on the results of the lack of screening, tainted blood may have caused infections in 11 of the 17 countries in 2001/2002. In those years, paid donors still existed in Bolivia, Honduras, Panama, and Peru. Replacement donors made up >75% of the blood donors from Bolivia, Chile, El Salvador, Guatemala, Mexico, Paraguay, Peru, and Venezuela in 2001/2002. No country reported the number of voluntary donors that were repeat donors, i.e., the healthiest category. Moreover, all efforts to decrease the number of blood banks have failed, even though larger blood banks are more efficient.

NEW CHALLENGES

Every country should increase the number of voluntary repeat donors to ≥5% of the population in order to avoid blood shortages. The number of blood banks must decrease in most countries to take advantage of economies of scale. In developed countries, remarkable improvements in transfusion safety because of better donor selection and screening of infectious diseases justifies the concern about other safety problems. However, this is not the case in Latin America. Improvements must still be made in donor selection and screening while at the same time devoting efforts to improve safety issues of other origins. Screening coverage for at least the prevalent infectious diseases must be universal and based on a system of quality assurance that supports all activities related to blood banking. Hemovigilance of adverse events and incidents must be also strengthened.

Continuous collection and analysis of the type of information reviewed here, which was only partially available before 1993, are essential for obtaining the support needed to maintain or expand the quality of the blood supply in Latin America.

ACKNOWLEDGMENTS

We thank Roxane Salvatierra Gonzalez for editorial assistance and Carmen Chand for collecting the references.

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