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Seroprevalence of markers of transfusion transmissible infections in blood bank in Colombia

ABSTRACT

OBJECTIVE: To determine the seroprevalence of markers of transfusion transmissible infections in donors of a blood bank in Medellín, Colombia, between 2007 and 2010.

METHODS: A cross-sectional secondary data source, based on the results of biological testing of donors to a blood bank in Medellín. We determined the seroprevalence of markers of infection and were compared by sex and type of donor through frequency analysis, chi square, Fisher and prevalence ratios.

RESULTS: The base population was 65,535 donors, and 3.3% had at least one positive biological test. The most prevalent marker in the blood bank testing was syphilis (1.2%), followed by trypanosomiasis (1.0%), hepatitis C virus (HCV) (0.6%), human immunodeficiency virus (HIV) 0.5% and hepatitis B virus (HBV) (0.2%). Based on the reference laboratory found a prevalence of 0.6% for syphilis, 0.1% for (HBV) and 0% for (HCV), (HIV) and Chagas. We found statistical differences in the prevalence of (HBV) and syphilis by sex and type of donor.

CONCLUSIONS: The results are consistent with the prevalences given by Pan American Health Organization and can be correlated with the global prevalence of transfusion-transmitted infections. The results founds by the blood bank lead to a transfusion risk reduction but limit the optimization of resources by excluding donors classified as false positives.

DESCRIPTORS: Blood Donors. *Trypanosoma cruzi*. *Trypanosoma pallidum*. Hepatitis B virus. Hepacivirus. HIV. Seroepidemiologic Studies.

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INTRODUCTION

The World Health Organization (WHO) reported 33 million people infected with HIV worldwide in 2009.²¹ They estimate that there are currently more than 350 million infected with hepatitis B (HBV), hepatitis C (HCV) or both. The annual incidence of syphilis is 12 million²¹ and the prevalence of American trypanosomiasis is 10 million infected people, most of them in Latin America.²⁰

The global panorama of these infections, added to the growing need for blood products, brings with it the need to limit, as far as possible, the possibility of transmission via blood transfusion, especially as these types of infection may be present in otherwise healthy individuals with no symptoms. This is why various health organisations have implemented measures with the aim of offering safer blood products.^{2,7-10,17}

Studies have been carried out on the epidemiology of these infections in the blood and blood product donor population, which, in some way, may reflect epidemiological behaviour in the general population. This is the case in Saudi Arabia, which reported a prevalence of HBV and HCV infection of 3% and 18.7% respectively in 2007.⁹ Studies carried out in Nigeria in 2009 showed a prevalence of 18.6%, 6% and 3.1% for HBV, HCV and HIV respectively,³ while in Southern and Central Africa the prevalence was 0.10% for HBV and 15% for HCV.²⁰ India, in turn, reported a prevalence of 1.47% and 0.57% for HBV and HCV in 2010.¹⁴ In contrast, the prevalence of HIV in Europe, in 2004, was 8.7 per 100,000 blood donations while in the United States in 2008 the prevalence was 2.2/100,000 and 2.0/1,000 for HIV and HCV respectively.²⁵

Studies in Latin America give a closer view of the scale of the problem in the region. Mexico recorded a prevalence of 0.07% for HIV, 0.13% for HBV and 0.31% for HCV in 2004,¹⁶ similar to figures recorded for Chile in 2006 and Brazil in 2008.^{13,18}

In Colombia, this area has been little studied. A prevalence of 0.15% for HIV, 0.72% for HBV and 0.39% for HCV was recorded in 1996, compared with data from a later study by the same group in 1999, which found prevalence of HIV of 2.25/1,000, 3.81/1,000 of HBsAg and 9.84/1,000 HCV in the donor population.^{7,8} There are few studies which deal with this topic in the Department of Antioquia, demonstrating the novelty of the profile of markers of transfusion transmitted infections in the area.

The WHO and the Ministerio de Salud de la República de Colombia decree 1,571 of 1993 established that

every unit of blood or blood product should be tested for serological markers of transfusion-transmissible infections. There remain four possible risks: the immunological window period (the period during which serological tests are negative in an infected donor); donors who are asymptomatic chronic carriers whose serology tests are negative; atypical infections or mutant strains and technical errors in the laboratory.² Negative results in screening do not completely rule out risk, there are other strategies which can improve the safety of transfusions, among them promoting voluntary donation and surveys of selected donors as well as verifying physical criteria and the donor's history and self-exclusion. The former allows staff at the blood bank to be aware of and assess some factors which may pose a transfusion risk.

According to the Pan-American Health Organisation's (PHO) last report,¹⁵ (2010), voluntary donation in Colombia had increased, probably due to intensive educational campaigns and extramural work on the part of the blood banks to promote voluntary donation. However, demand for blood products exceeds supply. Moreover, various studies show the altruistic donors and women represent lower transfusion risk than replacement donors, paid donors and men.^{1,3,12,14,19,23}

The different institutions need to know the epidemiological behaviour of the donors in order to implement strategies which enable their continuation as well as increasing the number of altruistic donors.

This study aims to estimate the seroprevalence of markers of transfusion-transmissible infections and its association with demographic aspects.

METHODS

A transversal study with 65,535 donors from the Institución Prestadora de Salud (IPS) Universitaria sede Clínica León XIII^a blood bank, between 2007 and 2010. The majority of the donors were from Valle de Aburrá, and especially from Medellín, Colombia. Those records which did not include the results of the screening, due to self-exclusion or alterations in the physical exam were excluded from the reference population.

A secondary source of information was used, based on the blood banks records using Delphyn®^b software. The results of tests for markers of transfusion-transmissible infections carried out at the blood bank and confirmatory tests from the reference laboratory, Laboratorio

^a Category A blood bank according to the Ministerio de Salud de la República de Colombia decree 1571 of 1993, categorised as fulfilling all requisites for the collection, analysis, separations storage and transfusión.

^b Specialist software for the administration of donations, donor and recipient information, including socio-demographic parameters and clinical and immunological tests, as well as an inventory of the units of blood.

Departamental de Salud Pública de Antioquia for the period in question were checked.

The techniques used in the blood bank for detecting markers of infection were third-generation enzyme immunoassays for hepatitis B surface antigen (HBsAg) (100% sensitivity and 99.5% specificity), HCV antibodies (100% sensitivity and 99.63% to 99.8% specificity), HIV-1 and HIV-2 antibodies (100% sensitivity and 99.92% specificity), IgG and IgM antibodies against *Treponema pallidum* (syphilis) (99.4% sensitivity and 99.8% specificity) and *Trypanosoma cruzi* (Chagas disease) antibodies (sensitivity 100% and specificity 98.2%) from the Biokit Werfen Group®. To confirm positive results from the screening, the reference laboratory carried out tests for total and IgM HBV antibodies HBV, total HCV antibodies, Western Blot tests for HIV, FTA-Absorption tests for *T. pallidum* and indirect immunofluorescence assay for *T. cruzi*.

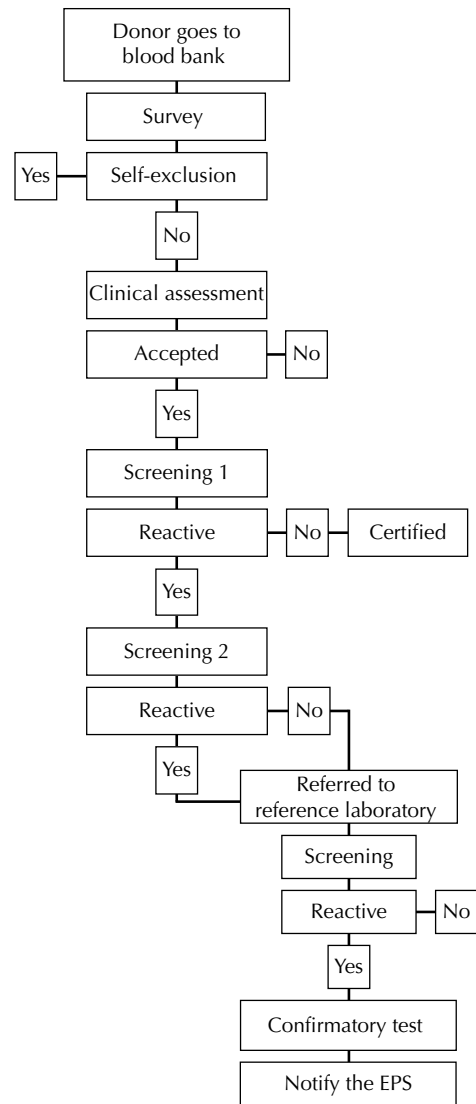
Figure shows a flowchart of the biological tests carried out on each unit of blood donated. The data was collected with the assistance of blood bank staff, highly trained in the software and the institutions internal data, overseen by the blood bank's head of quality control – all with the aim of guaranteeing the accuracy of the data and the internal validity of the study. There was the performance of 25,213 Nucleic Acid Testing (NAT) tests for detecting viral infections (HBV, HCV and HIV) between June 2009 and December 2010. These tests are not part of the institute's routine analysis.

In univariate analysis, relative and absolute frequencies were calculated to describe the group based on socio-demographic characteristics. Overall and specific prevalence of positives for each of the markers in question from the blood bank tests, the reference laboratory tests and the NAT tests was calculated.

Overall prevalence and specific prevalence of the infection markers (blood bank tests, reference laboratory tests and NAT tests according to sex and type of donor) were compared in the bivariate analysis using chi-square and Fisher's exact tests. The analysis was broken down by test type. The confirmation showed the true epidemiological situation, while analysis of the screening tests proved to be highly relevant to internal quality control at the blood bank, as it reflected the behaviour of the rejected units.

The prevalence of the above-mentioned marker, according to sex and donor type, was compared through Prevalence Ratios.

The data was stored and analysed in the Statistical Package for the Social Sciences for Windows, software SPSS version 19.0. The level of statistical significance was established in 0.05.



EPS: health promoting entity

Figure. Flowchart of the biological quality control in the blood bank. Medellín, Colombia, 2007-2010.

During the study, the principles of the Republic of Colombia Ministry of Health decree 8,430 of 1993 and of the Declaration of Helsinki were adhered to. The project had the support of the Bioethical Committee of the Sede de Investigación Universitaria (SIU) de la Universidad de Antioquia and the Investigations Committee of the IPS Universitaria, Clínica León XIII (Minute 11-35-335 approved on February 4th, 2011). Moreover, each individual in the survey of selected donors gave permission for their data to be used for both therapeutic and investigative ends.

RESULTS

In total, the results of 65,535 donors, mainly from Valle de Aburrá, and especially from the city of Medellín

Table 1. Absolute and relative frequency of socio-demographic and hematologic characteristics of the study population. Medellín, Colombia, 2007-2010.

| Variable | Absolute frequency | Relative frequency |
|-----------------------------------|--------------------|--------------------|
| Sex | | |
| Male | 33,348 | 50.9 |
| Female | 32,187 | 49.1 |
| Provenance | | |
| Antioquia | 65,294 | 99.6 |
| Not from Antioquia or the country | 241 | 0.4 |
| Sub-region | | |
| Valle de Aburrá | 61,957 | 94.5 |
| East | 2,144 | 3.3 |
| South East | 316 | 0.5 |
| West | 156 | 0.2 |
| North | 671 | 1.0 |
| Other sub-regions of Antioquia | 46 | 0.5 |
| Municipality | | |
| Medellín | 43,308 | 66.1 |
| Bello | 6,584 | 10.0 |
| Itagüí | 3,699 | 5.6 |
| Envigado | 3,226 | 4.9 |
| Caldas | 1,263 | 1.9 |
| Copacabana | 1,258 | 1.9 |
| La Estrella | 849 | 1.3 |
| Sabaneta | 878 | 1.3 |
| Other | 4,470 | 6.8 |
| Classification ABO Rh | | |
| O+ | 29,251 | 53.7 |
| O- | 4,003 | 7.3 |
| A+ | 14,786 | 27.1 |
| A- | 1,648 | 3.0 |
| B+ | 3,428 | 6.3 |
| B- | 470 | 0.9 |
| AB+ | 807 | 1.5 |
| AB- | 95 | 0.2 |
| Type of donor | | |
| Altruistic | 37,699 | 57.5 |
| Replacement | 27,625 | 42.2 |
| Other | 211 | 0.3 |

were studied. There was a 49.1% prevalence of females and 57.5% were altruistic donors (Table 1); of these, 2.2% were allogeneic apheresis. Of the replacement donors, 0.14% were autologous, targeted, autologous apheresis and plasmapheresis donations.

Table 2. Overall positive and specific prevalence of infection markers detected in the study population in the blood bank and reference laboratory tests. Medellín, Colombia, 2007-2010.

| Prevalence | Blood bank | | Reference laboratory | |
|----------------|------------|---------|----------------------|---------|
| | # | Per mil | # | Per mil |
| Overall | 1,812 | 33 | 468 | 9 |
| HBV | 132 | 2 | 50 | 1 |
| HCV | 344 | 6 | 3 | 0 |
| HIV | 247 | 5 | 27 | 0 |
| Syphilis | 643 | 12 | 308 | 6 |
| Chagas disease | 520 | 10 | 4 | 0 |
| Total donors | 54,499 | | | |

HBV: hepatitis B virus; HVC: hepatitis C virus; HIV: Human immunodeficiency virus

Of the total potential donors, 11,036 were not included in the bivariate analysis either because of self-exclusion or alterations in the physical examination. Of the donors, 53.7% were O positive, followed by A positive at 27.1%. the AB negative group was the least common (0.2%) (Table 1).

Overall prevalence of infection markers was 33/1,000 in the tests from the blood bank, 9/1,000 in the confirmatory tests and 0/1,000 in the NAT tests. The prevalence of markers was statistically higher in the tests from the blood bank (12/1,000 for syphilis, 10/1,000 for Chagas disease, 6/1,000 for HCV, 5/1,000 for HIV and 2/1,000 for HBV) compared with the confirmatory tests (syphilis 6/1,000 and 0/1,000 for HCV, HIV and Chagas) (Table 2). The results of the NAT tests were significantly lower than those of the other tests (nine positives for HBV and two for HIV).

Three cases of co-infection HBV/HCV, three of HIV/HBV, two of HIV/HCV, six of HIV/Chagas, four of HIV/Syphilis, two of HBV/Syphilis and 40 of HCV/Chagas were found in the blood bank tests; two cases of co-infection were found in the confirmatory tests, one of HIV/HBV and one of HIV/Syphilis.

The frequency analysis of markers of infection according to sex showed statistically significant differences in the overall positivity of the blood bank, reference laboratory and NAT tests, in syphilis according to the blood bank and the reference laboratory tests, in Chagas disease according to the blood bank and in HBV and HIV according to the reference lab tests (Table 3). Statistically significant differences were found in the overall positivity, HBV and syphilis in the screening and confirmatory tests and in the overall and HBV positivity according to the NAT tests based on the type of donor (Table 4).

Table 3. Comparison of the frequency of infection markers in the blood bank and reference laboratory tests according to sex. Medellín, Colombia, 2007-2010.

| Test | Result | Sex | | | | X ² | Prevalence Ratio | 95%CI |
|----------------------|----------|--------|------|--------|-------|--------------------|------------------|------------------------|
| | | Female | | Male | | | | |
| Blood bank | | # | % | # | % | | | |
| Overall | Negative | 25,119 | 47.7 | 27,568 | 52.3 | 0.000 ^b | 1.24 | 1.13;1.36 ^b |
| | Positive | 765 | 42.2 | 1,047 | 57.8 | | | |
| HBV | Negative | 25,828 | 47.5 | 28,539 | 52.5 | 0.243 | 1.23 | 0.87;1.73 |
| | Positive | 56 | 42.4 | 76 | 57.6 | | | |
| HCV | Negative | 25,722 | 47.5 | 28,433 | 52.5 | 0.881 | 1.02 | 0.82;1.25 |
| | Positive | 162 | 47.1 | 182 | 52.9 | | | |
| HIV | Negative | 25,775 | 47.5 | 28,477 | 52.5 | 0.289 | 1.15 | 0.89;1.47 |
| | Positive | 109 | 44.1 | 138 | 55.9 | | | |
| Syphilis | Negative | 25,626 | 47.6 | 28,230 | 52.4 | 0.000 ^b | 1.35 | 1.15;1.58 ^b |
| | Positive | 258 | 40.1 | 385 | 59.9 | | | |
| Chagas disease | Negative | 25,683 | 47.6 | 28,296 | 52.4 | 0.000 ^b | 1.44 | 1.20;1.71 ^c |
| | Positive | 201 | 38.7 | 319 | 61.3 | | | |
| Reference laboratory | | | | | | | | |
| Overall | Negative | 25,714 | 47.6 | 28,317 | 52.4 | 0.000 ^b | 1.59 | 1.31;1.91 ^b |
| | Positive | 170 | 36.3 | 298 | 63.7 | | | |
| HBV | Negative | 25,870 | 47.5 | 28,579 | 52.5 | 0.006 ^b | 2.33 | 1.26;4.31 ^b |
| | Positive | 14 | 28.0 | 36 | 72.0 | | | |
| HCV | Negative | 25,882 | 47.5 | 28,614 | 52.5 | 0.462 ^a | 0.64 | 0.13;3.15 |
| | Positive | 2 | 66.7 | 1 | 33.3 | | | |
| HIV | Negative | 25,882 | 47.5 | 28,590 | 52.5 | 0.000 ^b | 1.76 | 1.59;1.96 ^b |
| | Positive | 2 | 7.4 | 25 | 92.6 | | | |
| Syphilis | Negative | 25,774 | 47.6 | 28,417 | 52.4 | 0.000 ^b | 1.63 | 1.29;2.05 ^b |
| | Positive | 110 | 35.7 | 198 | 64.3 | | | |
| Chagas disease | Negative | 25,881 | 47.5 | 28,614 | 52.5 | 0.352 ^a | 0.30 | 0.03;2.90 |
| | Positive | 3 | 75.0 | 1 | 25.0 | | | |
| NAT | | | | | | | | |
| Overall | Negative | 12,386 | 49.1 | 12,815 | 50.9 | 0.040 ^c | 4.35 | 0.94;20.12 |
| | Positive | 2 | 18.2 | 9 | 81.8 | | | |
| HBV | Negative | 12,386 | 49.1 | 12,817 | 50.9 | 0.180 ^a | 1.53 | 1.08;2.17 ^b |
| | Positive | 2 | 22.2 | 7 | 77.8 | | | |
| HCV | Negative | 12,388 | 49.1 | 12,824 | 50.9 | - | No data | |
| | Positive | 0 | 0.0 | 0 | 0.0 | | | |
| HIV | Negative | 12,388 | 49.1 | 12,822 | 50.9 | 0.500 ^a | 4.83 | 0.23;100.60 |
| | Positive | 0 | 0.0 | 2 | 100.0 | | | |

X²: Chi square^a Fisher exact^b The statistic and the prevalence ratio are significant at a level of 0.01^c The statistic and the prevalence ratio are significant at a level of 0.05

HBV: hepatitis B virus; HVC: hepatitis C virus; HIV: human immunodeficiency virus

The prevalence of markers of transfusion-transmissible infections were great among men than women, and in replacement donors compared to altruistic donors, both in the tests from the blood bank and in the confirmatory and NAT tests. The ratios of prevalence were greater for these latter two tests than for the screening.

DISCUSSION

This study, in general terms, allowed us to better understand the epidemiological behaviour of the population in question during the period of the study and managing the supply of blood. This has favourable implications

Table 4. Comparison of the frequency of infection markers in the blood bank, reference laboratory and NAT tests according to type of donor. Medellín, Colombia, 2007-2010.

| Test | Result | Type of donor | | | | χ^2 | Prevalence ratio | 95%CI |
|----------------------------|----------|---------------|------|-------------|------|---------------------|------------------|-------------------------|
| | | Altruistic | | Replacement | | | | |
| Blood bank | | # | % | # | % | | | |
| Overall | Negative | 30,987 | 58.8 | 21,692 | 41.2 | 0.001 ^b | 1.17 | 1.06;1.28 ^b |
| | Positive | 995 | 54.9 | 817 | 45.1 | | | |
| HBV | Negative | 31,923 | 58.7 | 22,436 | 41.3 | 0.001 ^b | 1.34 | 1.15;1.56 ^b |
| | Positive | 59 | 44.7 | 73 | 55.3 | | | |
| HCV | Negative | 31,794 | 58.7 | 22,353 | 41.3 | 0.127 | 1.18 | 0.95;1.46 |
| | Positive | 188 | 54.7 | 156 | 45.3 | | | |
| HIV | Negative | 31,827 | 58.7 | 22,417 | 41.3 | 0.194 | 0.84 | 0.65;1.09 |
| | Positive | 155 | 62.8 | 92 | 37.2 | | | |
| Syphilis | Negative | 31,645 | 58.8 | 22,203 | 41.2 | 0.001 ^b | 1.15 | 1.06;1.25 ^b |
| | Positive | 337 | 52.4 | 306 | 47.6 | | | |
| Chagas disease | Negative | 31,693 | 58.7 | 22,278 | 41.3 | 0.147 | 1.24 | 0.96;1.35 |
| | Positive | 289 | 55.6 | 231 | 44.4 | | | |
| Reference laboratory | | | | | | | | |
| Overall | Negative | 31,759 | 58.8 | 22,264 | 41.2 | 0.000 ^b | 1.56 | 1.30;1.87 ^b |
| | Positive | 223 | 47.6 | 245 | 52.4 | | | |
| HBV | Negative | 31,967 | 58.7 | 22,474 | 41.3 | 0.000 ^b | 1.69 | 1.41;2.02 ^b |
| | Positive | 15 | 30.0 | 35 | 70.0 | | | |
| HCV | Negative | 31,980 | 58.7 | 22,508 | 41.3 | 0.629 ^a | 0.91 | 0.26;3.22 |
| | Positive | 2 | 66.7 | 1 | 33.3 | | | |
| HIV | Negative | 31,969 | 58.7 | 22,495 | 41.3 | 0.266 | 1.53 | 0.72;3.26 |
| | Positive | 13 | 48.1 | 14 | 51.9 | | | |
| Syphilis | Negative | 31,836 | 58.8 | 22,347 | 41.2 | 0.000 ^b | 1.58 | 1.26;1.97 ^b |
| | Positive | 146 | 47.4 | 162 | 52.6 | | | |
| Chagas disease | Negative | 31,980 | 58.7 | 22,507 | 41.3 | 0.547 ^a | 1.42 | 0.20;10.09 |
| | Positive | 2 | 50.0 | 2 | 50.0 | | | |
| NAT (Nucleic Acid Testing) | | | | | | | | |
| Overall | Negative | 17,607 | 69.9 | 7,593 | 30.1 | 0.004 ^{ab} | 6.18 | 1.64;23.28 ^b |
| | Positive | 3 | 27.3 | 8 | 72.7 | | | |
| HBV | Negative | 17,608 | 69.9 | 7,594 | 30.1 | 0.004 ^{ab} | 8.11 | 1.68;39.02 ^b |
| | Positive | 2 | 22.2 | 7 | 77.8 | | | |
| HCV | Negative | 17,610 | 69.9 | 7,601 | 30.1 | - | no data | |
| | Positive | 0 | 0.0 | 0 | 0.0 | | | |
| HIV | Negative | 17,609 | 69.9 | 7,600 | 30.1 | 0.512 ^a | 2.32 | 0.15;37.03 |
| | Positive | 1 | 50.0 | 1 | 50.0 | | | |

χ^2 : Chi square

^a Fisher exact

^b The statistic and the prevalence ratio are significant at a level of 0.0

HBV: hepatitis B virus; HVC: hepatitis C virus; HIV: human immunodeficiency virus

for defining public health policies in this area: it generates information relevant to public health decision making based on evidence; enables the assessment, improvement and/or planning of health services related to transfusional medicine; it demonstrates the need to maintain and perfect the internal quality management

systems of blood banks and promotes the implementation of educational programmes in diverse communities to encourage voluntary blood donation.

The results of this study can be extrapolated to other blood banks in the city and the country, as the donors at

this institution comply with standardised selection procedures, which means that the donors share characteristics with the base population, especially with regards to physical health. In addition, all blood banks are subject to national norms, leading to their homogenisation.

Being one of the leading health care institutions in the city means the blood bank has a steady flow of citizens from Medellín, which explains the provenance of many of the donors. The screening of 54,499 units of blood was performed in this service between 2007 and 2010, which corresponds to 13,625 units analysed per year. This is partly due to the complexity of the service and the mobile blood donation campaigns the blood bank carries out weekly in the city.

According to the PHO, 32.22% of the donations recorded in Latin America in 2009 were altruistic and 67.78% replacement. According to this organisation, Colombia was the country with the third highest percentage of voluntary donation (75.7%) behind Cuba (100.0%) and Nicaragua (87.1%). The lowest rate of voluntary donation recorded was in Mexico, with 2.75%.¹⁵ The increase in voluntary donation in Colombia may be due to education and the implementation of campaigns aiming to raise awareness and promote voluntary donation, and even more so with the awareness that the environment in which the blood bank finds itself is one marked by high levels of crime and accidents.

According to the National Institute of Health, 32.1% of donations in Antioquia in 2002 were voluntary. In 2009, this increased to 55.2%,¹⁵ data which is in keeping with that found in this study, in which the percentage of voluntary donation was 57.5%. The Department, and the blood bank both had lower rates of voluntary donation than that of the country as a whole, which leads to strengthening those educational strategies aimed at increasing repeated, voluntary donations.

The most common blood type was O positive (53.7%) and the least common AB negative (0.2%), results similar to those expected for the population of Valle del Aburrá in which the most prevalent blood type is O.⁴ This demonstrates the necessity of promoting repeated donation by those individuals with less common blood types and to increase the availability of blood products.

In 2010 the PHO reported prevalence in Colombia of 0.25%, 0.2%, 0.45%, 1.06% and 0.45% respectively for HIV, HBV, HCV, syphilis and Chagas disease.¹⁵ These data are in keeping with those found by this study (overall prevalence of 0.9%), with the highest levels being found for syphilis (0.6%) and the lowest for HBV (0.2%). There was a greater prevalence in replacement donors and men.

The results show a greater prevalence of infections in men compared to women. On comparing this

percentage with other studies from this country and from Latin America, an increase in these infections in the female population is evident.^{1,5,11,24} The increase in female donors can be attributed to greater knowledge in the general population regarding the benefits of donation. The increase of positive markers of infection in the female population is related to the increasing sexual liberty of the modern woman.

The results of this study, compared to a similar study in Colombia by Zambrano-Plata et al²⁴ in 1999, show a reduction in the seroprevalence of HBV (1.2%) and Chagas disease (2.62%), while levels for syphilis (1.64%) and HCV (0.54%) remained the same and HIV increased.

According to the PHO 2010 report "Provision of blood for transfusion in the Caribbean countries and Latin America 2006, 2007, 2008 and 2009", the picture of positive markers of infection in Colombia is similar to that of Mexico and Nicaragua, whilst in Brazil there is a higher percentage for HIV and a lower percentage for syphilis.¹⁵

The findings of this study reveal positive results for syphilis and Chagas disease, through screening, of 1.2% and 1.0%, in contrast to the findings of the confirmatory tests which were 0.6% for syphilis and 0% for Chagas disease. This difference may be due to the high level of sensitivity of the screening tests (94.4% for syphilis and 100% for *T. cruzi*). The false positives given in screening for syphilis and Chagas disease may have different causes such as the presence of autoimmune diseases like lupus, Hashimoto's thyroiditis and rheumatoid arthritis, the presence of other parasites or microbial contamination, which may produce cross-reactivity. Moreover, the test uses recombinant antigens, which may react with non-specific antibodies present in our population. It is necessary to use tests for syphilis and Chagas disease which are equally sensitive, but more specific in order not to discard units of blood.⁶

The results of the tests for viral markers did not show any significant differences between the screening and the confirmatory tests. The screening tests for the infections in question showed greater sensitivity and specificity, which enabled a better selection of donated units and better use of resources, preserving the quality of the accepted units.

Zou et al²⁵ (2010) reported a reduction of immunological window period for NAT tests, from 16 to 9.1 days for HIV and of 51 to seven days for HCV, which reduces transfusion risk. These tests are more efficient, but they are of higher costs, reducing the use of these techniques in our region. These tests were used during a period of one and a half years in the blood bank. However, the results obtained were not significant when compared to the screening and confirmatory tests for viral markers.

Positive results in a screening test may suggest asymptomatic infection or the existence of interfering factors (possible cross-reactivity) leading to a false positive. Faced with a suspicious positive in the screening test, the safety of the patient prevails above the economic cost, meaning that the particular unit of blood is not used for transfusions and the donor is disqualified. A negative result in the screening does not rule out the risk of infection 100%, due to the immunological window period. A positive result from the reference laboratory confirms the existence of infection. The results from the screening tests compared with the confirmatory tests show that the former provide the possibility of significantly reducing transfusion risk. However, they limit the optimisation of resources and disqualify potential donors as unfit.

Among the main limitations of this investigation are those connected to the type of study it was. The statistical analyses carried out are not confirmatory but rather

explored factors which may affect the prevalence of markers of the infections in question.

The results obtained were in concordance with the expected prevalence according to PHO reports on the donor population, especially for HIV. The findings show that Colombia is a low prevalence country for this infection. It is recommended to conduct such studies that allow knowing the epidemiological behaviour of the population attended in blood banks and thereby strengthen and improve the donor selection protocols for the certification of blood units and enhance the promotion and education regarding altruistic and repetitive donation.

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