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Original research

External quality control program in infectious diseases screening at laboratories and blood banks in Latin America: an analysis of the past 5 years

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ABSTRACT

Objective. To evaluate the screening of blood samples for infectious disease markers at laboratories and blood banks in Latin America per the findings of an External Quality Assessment Program (EQAP).

Methods. This qualitative analysis used data from the EQAP coordinated by the *Fundação Pro Sangue Hemocentro de São Paulo* with the support of the Pan American Health Organization to assess the performance of blood screening for infectious diseases from 2014 to 2018 in Latin America. Each participating laboratory or blood bank received an identical blind panel with 24 blood samples with variable reactivity for all the screening parameters. Panels were processed at each participating facility and results were returned to the *Fundação Pro Sangue Hemocentro de São Paulo* for individual and joint analyses. Two types of discrepant results were potential failures: false positive results (FPRs) and false nonreactive results (FNRRs).

Results. A total of 23 136 samples were evaluated. Global rates of FPR, FNRR, and concordant results were 0.3%, 1.0% and 98.7%, respectively. Seven FNRRs were found for HBsAg (1.0%), 12 for syphilis (2.6%), and 21 for Chagas disease (2.9%). No FNRRs were found for the HIV, HCV, and HTLV viruses. The average accuracy of all the laboratories and blood banks participating in the EQAP during the study period was 99.5% (standard deviation, 0.5%).

Conclusion. The findings of this qualitative analysis are positive for blood safety in Latin America, with an average accuracy of 99.5% among the participating laboratories and blood banks. This report reflects an important improvement in blood bank serological screening EQAP-PAHO report since the 2003.

Keywords Blood donors; blood transfusion infections; quality control; blood safety; Latin America.

Blood transfusion saves lives and improves health. However, it carries a potential risk for complications and transfusion-related infections. Regulation requires that 100% of blood donated be screened for infectious diseases that are transmissible by blood transfusion. Tests used for screening must be developed and approved to identify donors and donated components that may harbor infectious agents. An infectious agent present in the donated blood that is not detected by the screening process may be transmitted directly to recipients. After screening, blood banks must ensure that blood components with positive test results will not be released for transfusion.

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Most assays currently in use for the serological detection of antibodies or antigens are enzyme and luminescent immunoassays performed in automatic or semi-automatic platforms, which allow for a high throughput and a short time for results. The infectious disease tests approved for blood donor screening are designed to detect infected individuals and minimize false-negative results. However, the assays also occasionally react with blood samples from uninfected individuals, producing a false-positive result.

Tests for the detection of infectious markers in blood donors must be performed by trained professionals and must be accompanied by appropriate internal quality control procedures to ensure the accuracy of the results. Laboratories that perform those tests must also participate in an External Quality Assessment Program (EQAP). An EQAP provides regular and independent assessment of performance and allows for the identification of problems related to processes, techniques, and reagents. The main objective of an EQAP is to improve performance and ensure blood safety. Additionally, an EQAP allows for comparisons of performance among participating laboratories and different testing systems, encourages best practices, and raise the credibility of a laboratory or blood bank with a good track record. The EQAPs use well-characterized panels that contain samples for all parameters that require screening (1).

With the support of the Pan American Health Organization (PAHO) since 1997, the *Fundação Pro Sangue Hemocentro de São Paulo* (FPS) has coordinated an EQAP for laboratories and blood banks that screen for infectious markers in blood donations throughout Latin America and the Caribbean (2). The objective of this study was to evaluate the accuracy of blood screening at the participating laboratories and blood banks (PLs) and to present the EQAP findings for 2014 to 2018.

METHODS

This qualitative analysis used data from the EQAP managed by the FPS to assess the performance of blood screening for infectious diseases at PLs from 2014 to 2018. The study was reviewed and approved/exempted by the ethics committee of the *Fundação Pro Sangue Hemocentro de São Paulo*. The confidentiality of individual test results was maintained. The study did not focus on assessing the sensitivity of the tests used.

The EQAP delivered panels of serum samples to each PL annually. Each panel was composed of 24 serum samples with randomly variable reactivity (nonreactive/negative and reactive samples) for all screening parameters: Chagas disease, hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV), total hepatitis B core antibody (HBc), human immunodeficiency virus (HIV), human T-lymphotropic virus type 1 (HTLV), and syphilis. Negative (nonreactive) and reactive samples were obtained from plasma bags that were discarded for presenting reactivity or being nonreactive for some of the parameters on the serologic screening. Once selected, reactive samples were well characterized by different commercial tests, and results were confirmed by supplementary tests. Plasma units were transformed into serum through a recalcification process and subsequent dialysis. Samples were shipped frozen in duly-labeled polyproline cryotubes.

After receiving the panels, the PL processed the samples according to its normal routine. Results obtained by each PL were sent to the FPS for individual and joint analysis. Only the PL responses with results for five or more parameters (Chagas, HIV, HCV, HbsAg, and syphilis) were included in this analysis. The HTLV and anti-HBc were not considered mandatory because only 90% and 81%, respectively, of the countries in Latin America routinely perform these tests (3). The following criteria excluded PLs: did not perform one or more of the mandatory serologic screening tests; responded to fewer than five serologic parameters; used rapid tests for screening; or did not submit any results for the panels.

Because the serological tests used for screening are qualitative, potential failures for each infectious marker were the identification of two types of discrepant results: false positives results (FPRs) and false nonreactive results (FNRRs) (4). Inconclusive results from positive samples were classified as correct, and from negative samples, as false positives. The percentage of FPRs was calculated based on the number of negative samples tested and the percentage of FNRRs on the number of positive samples tested. The accuracy or concordant results rate was obtained from the count of concordant results divided by the total of determinations performed.

Statistical analysis

The performance of each PL was evaluated according to the qualification criteria recommended by PAHO/WHO (1): A = 100% accurate results (no FPRs and no FNRRs); B1 = FPRs reported for 5% or fewer of the total determinations for negative samples ; B2 = FPRs reported for more than 5% of the total determinations for negative samples; and C = any FNRR reported. The performance of each was calculated using a Z-score approach for the accuracy of each PL and the average accuracy and standard deviation (SD) of all PLs during the program (5, 6). All analyzes were performed using R, version 1.3.959 (The R Foundation for Statistical Computing).

Each PL received a template to check its results and critically analyze the data obtained. The final report for each evaluation was sent to all PLs along with instructions on how to confirm each result.

RESULTS

Between 2014 and 2018, a total of 189 serum sample panels were sent to the laboratories participating in the assessment. Of those, 155 (82%) responses from 33 PL were considered valid for this analysis and 34 (18%) were excluded. The PLs were in 17 different countries in Latin America (Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, El Salvador, Ecuador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay, and Venezuela).

The overall characterization of panels, PLs included, and the samples analyzed for each parameter are presented in Table 1. A total of 23 136 samples were evaluated, of which 19 081 (82.5%) were negative and 4 055 (17.5%) were positive. The most frequent technology used by the PLs for Chagas, Hepatitis B and C, HIV, HTLV, and syphilis screening were the automated assays: chemiluminescence (ChLIA), enzyme immune assay (EIA), and electrochemiluminescence (EChLIA). Only 1.9% of the samples were analyzed for Chagas by manual technology, using the Indirect Hemagglutination Method (IHA). For syphilis, the most frequent technique used was the automated or semi-automated (69%) method; however, 31% used a manual

TABLE 1. Overall characteristics and results of the External Quality Assessment Program for laboratories and blood banks in Latin America in the past 5 years, São Paulo, Brazil, 2021

Characteristic	Total, No. (%)	2014	2015	2016-I	2016-II	2017	2018
PLs, No.	33	25	26	27	27	25	20
Participating countries, No.	17	16	16	16	15	16	14
Panels, No.	155	26	27	27	28	26	21
Samples evaluated	23 136 (100)	3 912 (100)	3 936 (100)	4 080 (100)	4 176 (100)	3 912 (100)	3 120 (100)
Negative results	19 081 (82.5)	3 183 (81.4)	3 238 (82.3)	3 400 (83.3)	3 457 (82.8)	3 207 (82.0)	2 596 (83.2)
Positive results	4 055 (17.5)	729 (18.6)	698 (17.7)	680 (16.7)	719 (17.2)	705 (18.0)	524 (16.8)
False positive rate[a]	55 (0.3)	11 (0.3)	5 (0.2)	7 (0.2)	19 (0.5)	8 (0.2)	5 (0.2)
False nonreactive rate[b]	42 (1.0)	11 (1.5)	0 (-)	6 (0.9)	12 (1.7)	11 (1.6)	2 (0.4)
Serologic markers evaluated							
HIV	3 720 (16.1)	624 (15.9)	648 (16.5)	648 (15.9)	672 (16.1)	624 (15.9)	504 (16.1)
Chagas	3 720 (16.1)	624 (15.9)	648 (16.5)	648 (15.9)	672 (16.1)	624 (15.9)	504 (16.1)
Syphilis	3 720 (16.1)	624 (15.9)	648 (16.5)	648 (15.9)	672 (16.1)	624 (15.9)	504 (16.1)
HCV	3 720 (16.1)	624 (15.9)	648 (16.5)	648 (15.9)	672 (16.1)	624 (15.9)	504 (16.1)
HBsAg	3 720 (16.1)	624 (15.9)	648 (16.5)	648 (15.9)	672 (16.1)	624 (15.9)	504 (16.1)
HBc	2 304 (9.9)	432 (11.0)	336 (8.5)	432 (10.6)	408 (9.8)	408 (10.4)	288 (9.2)
HTLV	2 232 (9.6)	360 (9.2)	360 (9.1)	408 (9.3)	408 (9.8)	384 (9.8)	312 (10.0)

Abbreviations: HBc, total hepatitis B core antibody; HbsAg, hepatitis B surface antigen; HCV, hepatitis C virus; HIV, human immunodeficiency virus; HTLV, human T-lymphotropic virus type 1; PL, participating laboratory.
[a] False positive rate = positive results count ÷ negative samples.
[b] False nonreactive rate = negative results count ÷ positive samples.
Source: Prepared by the authors from the study results.

technique with the nontreponemal test and IHA. The global rates of FPRs, FNRRs, and concordant results in the 23 136 samples analyzed were 0.3%, 1.0%, and 98.7%, respectively. The rates of FPRs and FNRRs according to parameter evaluated are shown in Table 2.

A higher incidence of FPRs was found for HIV (0.6%) and HBsAg (0.5%). Results of these two parameters, by assay type used, are shown in Table 3. Most samples with FPRs for HIV (15/17) were analyzed using the ChLIA. Sample 4 on panel OPAS0114 was responsible for 7 of 17 (41%) of the total HIV FPRs. The incidence rates of FPRs for Chagas, HBc, HCV, HTLV, and syphilis were very low (≤ 0.2%; Table 2). Two FPRs for Chagas were due to incorrect result transcriptions.

No FNRRs were observed for the HCV, HIV, and HTLV viruses. However, we found 7 FNRRs for HBsAg (1.0%), 12 for syphilis (2.6%), and 21 for Chagas disease (2.9%). All samples with FNRRs for HBsAg were analyzed using EIA, luminescent assays, or enzyme-linked fluorescent assay (Table 3). Three of seven FNRRs for HBsAg occurred with the same sample (sample 23 on panel OPAS0117) with signal/cutoff ratio (S/CO) ChLIA = 4.17. One FNRR for HBsAg was due to incorrect result transcription. For Chagas disease, 90% (19/21) of FNRRs were analyzed using the automatic technique (EIA and ChLIA), and 10% (2/21) using the IHA (Table 3). Seven FNRRs for Chagas disease were in the same sample (sample 15 on panel OPAS0114) with S/CO ChLIA = 5.26.

We observed 20 discordant results for syphilis, 8 FPRs (0.2%) and 12 FNRRs (2.6%) (Table 2). Most of the discordant results for syphilis were performed with the manual technique using nontreponemal tests (75% of FPRs and 92% of FNRRs) (Table 3). The lower incidence of discordant results was observed for HBC (0.2%), HCV (0.2%), and HTLV (0.2%) (Table 2).

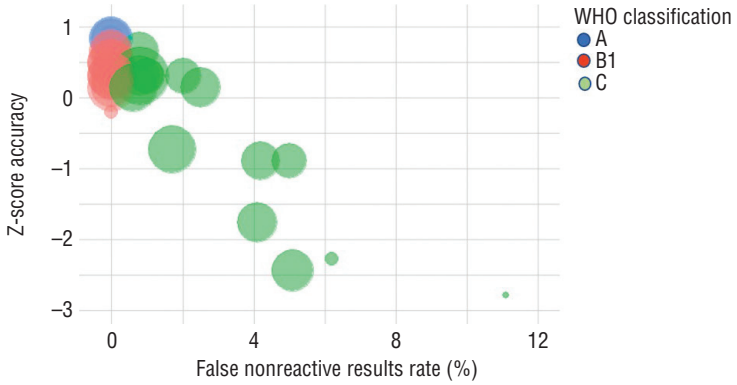
According to the qualification criteria recommended by PAHO/WHO, 6 (18%) PLs were classified as A; 12 (36%) as B1; and 15 (45%) as C. The average (SD) accuracy of all PLs during

TABLE 2. False positive and false nonreactive rates according to parameter evaluated, São Paulo, Brazil, 2021

Parameter	Negative samples	False positive results[a]	Positives samples	False nonreactive results[b]	Concordant results
HIV	3 074 (82.6)	17 (0.6)	646 (17.4)	0	3 703 (99.5)
Chagas	2 992 (80.4)	4 (0.1)	728 (19.6)	21 (2.9)	3 695 (99.3)
Syphilis	3 255 (87.5)	8 (0.2)	465 (12.5)	12 (2.6)	3 700 (99.5)
HCV	3 102 (83.4)	6 (0.2)	618 (16.8)	0	3 714 (99.8)
HBsAg	3 021 (81.2)	15 (0.5)	699 (18.9)	7 (1.0)	3 698 (99.4)
HBc	1 821 (79.0)	2 (0.1)	483 (21.0)	2 (0.4)	2 300 (99.8)
HTLV	1 816 (81.4)	3 (0.2)	416 (18.6)	0	2 229 (99.9)

[a] False positive rate = positive results count ÷ negative samples.
[b] False nonreactive rate = negative results count ÷ positive samples.
Source: Prepared by the authors from the study results.

FIGURE 1. Samples evaluated by each participating laboratory (PL), and accuracy as determined by the quality control program,[a] Z-score



Abbreviations: FNRR, false nonreactive result; FPR, false positive result; WHO, World Health Organization.
[a]The WHO scale: A, 100% correct results, no FPR or FNRR; B1, FPR was reported (≤ 5% of total test results); B2, FPR was reported (> 5% of total test results); and C, any FNRR was reported. Each PL is represented by a circle the size of which denotes the number of samples evaluated by each PL by the quality control program. The x and y axes present the FNRR rate and the Z-score accuracy, respectively. Findings showed three PLs that were two or more Z-scores distant from the others.
Source: Prepared by the authors from the study results.

the program was 99.5% (0.5%), with 76% (25/33) of PLs showing accuracy higher than 99.5% (Table 4). Only three (10%) PLs had an unsatisfactory performance (2 or more Z-scores from the others; Figure 1).

DISCUSSION

Serological screening for transfusion-transmissible infections of all blood donations must be in a quality-insured laboratory. External quality assessment forms an integral part of the monitoring of the overall laboratory quality system.

Each laboratory participating in EQAP received an identical blind panel with various samples that would be processed in the same manner as routine blood donor specimens to ensure that the laboratory's performance in the EQAP accurately reflected its usual performance. After the panels are tested, PLs send the results back to the program coordinator. Participation in the EQAP makes it possible to identify deficiencies

TABLE 3. Results of HIV, Chagas, HbsAG, and syphilis screening, São Paulo, Brazil, 2021

Assay	Distinct assays, No.	Total samples	False positive results	False nonreactive results	Concordant results
HIV					
ChLIA	3	2 256 (60.6)	15/1 873 (0.8)	0/383	2 241 (99.3)
EIA	9	1 272 (34.2)	2/1 042 (0.2)	0/230	1 270 (99.8)
EChLIA	1	96 (2.6)	0/80	0/16	96 (100)
ELFA	1	96 (2.6)	0/79	0	96 (100)
Chagas					
ChLIA	2	2 064 (55.5)	4/1 664 (0.2)	2/400 (0.5)	2 058 (99.7)
EIA	9	1 536 (41.3)	0/1 229	17/307 (5.5)	1 519 (98.9)
IHA	1	72 (1.9)	0/59	2/13 (15.4)	70 (97.2)
EChLIA	1	48 (1.3)	0/40	0/8	48 (100)
HbsAg					
ChLIA	3	2 304 (61.9)	4/1 875 (5.5)	1/429 (0.2)	2 299 (99.8)
EIA	8	1 200 (32.3)	8/970 (0.8)	3/230 (1.3)	1 189 (99.1)
EChLIA	1	72 (1.9)	1/59 (1.7)	1/13 (7.7)	70 (97.2)
ELFA	1	144 (3.9%)	2/117 (1.7)	2/27 (7.4)	140 (97.2)
Syphilis					
ChLIA	3	1 872 (50.3)	1/1 630 (0.06)	0/242 (-)	1 871 (99.9)
Nontreponemal	7	936 (25.2)	6/817 (0.7)	11/119 (9.2)	919 (98.2)
EIA	8	624 (16.8)	1/555 (0.2)	0/69 (-)	623 (99.8)
IHA	4	216 (5.8)	0/191 (-)	1/25 (4.0)	215 (99.5)
EChLIA	1	72 (1.9)	0/62 (-)	0/10 (-)	72 (100)

Abbreviations: ChLIA, chemiluminescence; EIA, enzyme immune assay; EChLIA, electrochemiluminescence; ELFA, enzyme-linked fluorescent assay.
Source: Prepared by the authors from the study results.

TABLE 4. Overall description of participating laboratory (PL) performance in the quality control program, São Paulo, Brazil, 2021

PL No.	Negative samples	FPR	FPR, %	Positive samples	FNRR	FNRR, %	CR	Accuracy %	Z-score accuracy	WHO classification[a]
1	300	0	0	60	0	0	360	100	0.828	A
2	552	0	0	120	0	0	672	100	0.828	A
3	275	0	0	61	0	0	336	100	0.828	A
4	136	0	0	32	0	0	168	100	0.828	A
5	693	0	0	147	0	0	840	100	0.828	A
6	595	0	0	125	0	0	720	100	0.828	A
7	693	0	0	147	0	0	840	100	0.828	A
8	552	0	0	120	1	0.8	671	99.9	0.655	C
9	690	1	0.1	150	0	0	839	99.9	0.655	B1
10	597	1	0.2	123	0	0	719	99.9	0.655	B1
11	809	2	0.2	175	0	0	982	99.8	0.483	B1
12	809	2	0.2	175	0	0	982	99.8	0.483	B1
13	477	1	0.2	99	0	0	575	99.8	0.483	B1
14	498	0	0	102	2	2	598	99.7	0.31	C
15	1 247	2	0.2	265	2	0.8	1 508	99.7	0.31	C
16	811	3	0.4	173	0	0	981	99.7	0.31	B1
17	473	1	0.2	103	1	1.0	574	99.7	0.31	C
18	497	1	0.2	103	1	1.0	598	99.7	0.31	C
19	598	1	0.2	122	1	0.8	718	99.7	0.31	C
20	829	3	0.4	179	0	0	1 005	99.7	0.31	B1
21	597	2	0.3	123	0	0	718	99.7	0.31	B1
22	598	3	0.5	122	0	0	717	99.6	0.138	B1
23	829	4	0.5	179	0	0	1 004	99.6	0.138	B1
24	829	3	0.4	179	1	0.6	1 004	99.6	0.138	C
25	598	0	0	122	3	2.5	717	99.6	0.138	C
26	136	1	0.7	32	0	0	167	99.4	-0.207	B1
27	829	6	0.7	179	3	1.7	999	99.1	-0.724	C
28	475	1	0.2	101	5	5.0	570	99	-0.897	C
29	554	2	0.4	118	5	4.2	665	99	-0.897	C
30	598	6	1	122	5	4.1	709	98.5	-1.759	C
31	136	1	0.7	32	2	6.2	165	98.2	-2.276	C
32	654	8	1.2	138	7	5.1	777	98.1	-2.448	C
33	117	0	0	27	3	11.1	141	97.9	-2.793	C

Abbreviations: CR, concordant result; FNRR, false nonreactive result; FPR, false positive result; WHO, World Health Organization.
[a]The WHO scale: A, 100% correct results, no FPR or FNRR; B1, FPR was reported (≤ 5% of total test results); B2, FPR was reported (> 5% of total test results); and C, any FNRR reported.
Source: Prepared by the authors from the study results.

or improvement opportunities within the laboratory processes. The main objective of the EQAP is to improve performance and ensure blood safety. Moreover, it allows for performance comparisons among PLs and different testing systems.

We observed that most of the PLs used automatic techniques (i.e., EIA, ChLIA, EChLIA) to perform screening. The high sensitivity of the third and fourth generation tests greatly decreased the FNRRs, which are the worst failure type for blood safety. Most of the PLs presented results concordant with the template, with 76% showing accuracy higher than 99.5% and 55.0% with classification A or B based on the qualification criteria used. Only three PLs had unsatisfactory performance, with scores at more than two Z-scores from the others.

The global rate of FPRs was 0.3%, with higher incidences for HIV and HBsAg. Evaluation of the FPRs for HIV showed that sample 4 on panel OPAS0114 contributed 41% of the discrepancies. On closer analysis of the position of positive samples on panel OPAS0114, we found that sample 4 was located between two true HIV positive samples. This high FPR occurring with the same sample by different PLs may have been due to sample-handling problems. We observed that the global FPR rate by automated methods was 0.27% (49 of 18 014) versus 0.56% (6 of 1 067) by manual techniques. One important consideration is that an FPR should not only be attributed to an analytical error, but also to pre- and post-analytical errors, which are often missed. Although an FPR has a minor effect on transfusion safety, it causes unnecessary blood disposal—at a time when donors and blood donations are increasingly scarce—in addition to unnecessary expenses due to confirmatory analysis.

For performance monitoring, there should be no differentiation between incorrect results due to technical or procedural errors (e.g., the incorrect transcription of results or the transposition of materials), although they may be analyzed and reported

separately. An incorrect result in the blood transfusion laboratory can have the same serious consequences, regardless of the reason for the error. We had three discrepant results due to incorrect transcription, two FPRs for Chagas and one FNRR for HBsAg. For this reason, performance monitoring must be based on interpretations rather than on serological reactions recorded for each test.

On the other hand, FNRRs can cause a new infection transmitted by blood transfusion in the recipient, representing one of the greatest daily challenges in transfusion medicine. An excellent finding of this analysis is that there were no FNRRs for HIV, HCV, and HTLV. The global incidence of FNRRs was low (1.0%) and was mainly associated with Chagas and syphilis, followed by HBsAg. The same result was observed by Bello-Lopez and colleagues (7) in a recent study in Mexico. The global rate of FNRRs was 0.7% (28 of 3 898) by automated techniques and 8.9% (14 of 157) by manual methods. This is expected given that manual techniques depend on human action, and are therefore more prone to errors or discrepant results. Three of seven (43%) FNRRs for HBsAg were from the same sample (sample 23 on panel OPAS0117), as well as 7 of 21 (30%) FNRRs for Chagas, also in the same sample (sample 15 on panel OPAS0114), both with low S/CO in ChLIA. Supplementary tests used for confirming sample reactivity also showed low reactivity. These findings need additional attention and discussion. Although it is advisable that blind panels contain specimens with variable reactivity for all screening parameters to ensure the exact reproduction of routine screening conditions, samples with low reactivity may be responsible for FNRRs. Positive samples chosen for the panels must preferentially have medium or high reactivity and be very well characterized by different supplementary tests; otherwise, they may cause systematic discrepancies in the PL's results.

Serological screening is the most important strategy for blood safety regarding Chagas disease in endemic areas. The serology assay most widely used in blood banks for Chagas screening is EIA, with parasite homogenates, as well as recombinant antigens. We observed 21 of 728 (2.9%) samples with FNRRs for Chagas disease. Although this is a low incidence of FNRRs, it represents a real risk of blood transmission. The use of a second parallel EIA technique with another antigenic composition could assist in the final classification of samples. A positive result in two EIA tests with different antigenic compositions is considered sufficient to corroborate a result and define whether a donor or patient is infected. In addition, it could help reduce FNRRs and cross-reactions. In endemic areas, local health authorities must evaluate the cost and benefit of implementing a second EIA test in the serological screening for Chagas disease.

Regarding the marker for syphilis, most PLs had adopted the automatic technique for syphilis screening (69% of the samples evaluated); however, the manual technique was still being used, mostly for nontreponemal tests. The manual technique, was responsible for 85% (17/20) of the discrepant results, representing 92% (11 of 12) of FNRRs for syphilis. We can conclude that nontreponemal tests, with a FNRR rate of 9.2% (11 of 119) (Table 3), did not perform well for syphilis screening compared with the other tests used. This finding is consonant with the data recently published by Attie and colleagues (8) who concluded that there is a risk of transfusion-transmitted syphilis in blood banks that exclusively use the venereal disease research laboratory (VDRL) test for donor screening. According to Tuddenham and colleagues (9) the prevalence of FNRRs by nontreponemal syphilis tests is relatively rare (< 0.85%). The prozone phenomenon can explain VDRL FNRRs.

Currently, the value of donor screening for syphilis is controversial (10, 11). Although numerous cases of transfusion-transmitted syphilis were reported before World War II, no cases have been reported in more than 40 years. The low transmission risk is probably related to a declining incidence of syphilis in donors, as well as the limited survival of the *T. pallidum* spirochete during blood storage (12). However, syphilis rates have been increasing since 2000, particularly among the population of men who have sex with men, dampening hopes for eliminating syphilis screening of blood donation (13). One issue that has been considered is whether syphilis screening improves blood safety by serving as a surrogate marker of high-risk sexual activity. However, studies have demonstrated that donor screening for syphilis does not provide incremental value in detecting other bloodborne and sexually transmitted infections (i.e., HIV, HBV, HCV, or HTLV) (14, 15).

It is important to emphasize that an FPR, or even an FNRR, does not necessarily indicate a kit or methodology failure. As mentioned before, the cause can be pre-, post-, or even analytic. So, it is very important to carry out internal quality control and participate in an EQAP to quickly identify issues and resolve them.

Limitations

A limitation of this study is that, given the great variability among tests and the small number of samples evaluated, we could not evaluate the sensitivity or specificity of the tests used by the PLs.

Conclusions

We conclude that these data show a good result for blood safety in Latin America, with a mean accuracy of 99.5% among the PLs, an important improvement in blood bank serological screening compared with the 2003 analysis of the EQAP-PAHO reported by Saéz-Alquezar and colleagues (2). Currently, automated or semi-automated techniques prevail over manual techniques. In 2003, FPR and FNRR rates for HIV were 1.8% and 0.7%, respectively, with 9.1% of FNRRs for HTLV. Other markers also showed a higher incidence of discrepant results compared with our more recent data. This improvement can be attributed to the use of third and fourth generation technologies in serological screening, ongoing training for laboratory technicians, and implementation of a quality system, including participation in the EQAP.

This report highlights the importance of monitoring the progress of blood safety measures through external assessment programs developed at the national level or through this PAHO/WHO program. PAHO and FPS will continue training PLs to carry out the EQAP in every country in the Region of the Americas as they strive to reach all blood banks and laboratories.

Lastly, PAHO/WHO recommends that all blood banks implement a quality system that includes good manufacturing practices with internal and external quality control. Every national blood system should promote the uniform

implementation of standards and consistency in the quality and safety of blood and blood products.

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Programa de control externo de la calidad en el tamizaje de enfermedades infecciosas en laboratorios y bancos de sangre de América Latina: análisis de los últimos 5 años

RESUMEN

Objetivo. Evaluar el tamizaje de muestras de sangre en las que se analizan marcadores de enfermedades infecciosas en laboratorios y bancos de sangre de América Latina según los resultados de un programa de evaluación externa de la calidad (EQAP, por su sigla en inglés).
Métodos. Este análisis cualitativo utilizó datos del EQAP —coordinado por la *Fundação Pro Sangue Hemocentro de São Paulo* con el apoyo de la Organización Panamericana de la Salud— para evaluar la eficacia del tamizaje sanguíneo para la detección de enfermedades infecciosas que se realizó entre el 2014 y el 2018 en América Latina. Cada laboratorio o banco de sangre participante recibió un panel idéntico para análisis a ciegas compuesto por 24 muestras de sangre con reactividad variable para todos los parámetros del tamizaje. Los paneles se procesaron en cada establecimiento participante y los resultados se enviaron a la *Fundação Pro Sangue Hemocentro de São Paulo* donde se realizaron análisis individuales y conjuntos. Había dos tipos de resultados discrepantes que eran posibles fallas del tamizaje: los positivos falsos (PF) y los negativos falsos (NF).
Resultados. En total se evaluaron 23 136 muestras. Las tasas generales de PF, NF y resultados concordantes fueron, respectivamente, del 0,3%, 1,0% y 98,7%. Se obtuvieron siete NF en casos de HBsAg (1,0%), 12 en casos de sífilis (2,6%) y 21 en casos de enfermedad de Chagas (2,9%). No se obtuvieron NF en casos de infección por virus del VIH, el VHC o el VLTH. La precisión promedio de todos los laboratorios y bancos de sangre participantes en el EQAP durante el periodo de estudio fue del 99,5% (desviación típica: 0,5%).
Conclusión. Los resultados de este análisis cualitativo son positivos en lo referente a la seguridad sanguínea en América Latina, con una precisión promedio del 99,5% entre los laboratorios y bancos de sangre participantes. Este informe refleja la considerable mejora del tamizaje serológico que se realiza en los bancos de sangre, en comparación con los resultados del informe del EQAP que contó con el apoyo de la OPS y se publicó en el 2003.

Palabras clave Donantes de sangre; transfusión sanguínea; control de calidad; seguridad de la sangre; América Latina.

Programa externo de controle de qualidade na triagem de doenças infecciosas em laboratórios e bancos de sangue da América Latina: análise dos últimos 5 anos

RESUMO

Objetivo. Avaliar a triagem de marcadores de doenças infecciosas em amostras de sangue realizada em laboratórios e bancos de sangue da América Latina de acordo com os resultados de um Programa Externo de Avaliação de Qualidade (EQAP, na sigla em inglês).
Métodos. Esta análise qualitativa usou dados do EQAP coordenado pela Fundação Pró-Sangue Hemocentro de São Paulo, com o apoio da Organização Pan-Americana da Saúde, para avaliar o desempenho da triagem de sangue quanto a doenças infecciosas no período de 2014 a 2018 na América Latina. Cada laboratório ou banco de sangue participante recebeu um painel cego idêntico com 24 amostras de sangue de reatividade variável para todos os parâmetros de triagem. Os painéis foram processados em cada estabelecimento participante e os resultados foram devolvidos à Fundação Pró-Sangue Hemocentro de São Paulo para análises individuais e conjuntas. Dois tipos de resultados discrepantes representavam falhas em potencial: resultados falso-positivos e resultados falso-negativos (não reativos).
Resultados. Foram avaliadas 23.136 amostras. As taxas globais de resultados falso-positivos, falso-negativos e concordantes foram de 0,3%, 1,0% e 98,7%, respectivamente. Foram encontrados sete resultados falso-negativos para HBsAg (1,0%), 12 para sífilis (2,6%) e 21 para doença de Chagas (2,9%). Não houve resultados falso-negativos para os vírus HIV, HCV e HTLV. A acurácia média de todos os laboratórios e bancos de sangue que participaram do EQAP durante o período do estudo foi de 99,5% (desvio padrão de 0,5%).
Conclusões. Os resultados desta análise qualitativa são positivos para a segurança do sangue na América Latina, com uma acurácia média de 99,5% entre os laboratórios e bancos de sangue participantes. Este relatório reflete uma melhoria importante na triagem sorológica dos bancos de sangue em relação aos resultados do relatório do EQAP apoiado pela OPAS que foi publicado em 2003.

Palavras-chave Doadores de sangue; transfusão de sangue; controle de qualidade; segurança do sangue; América Latina