

Article / Artigo

Physical and operational infrastructure of transfusion services of the public blood bank network in the State of Minas Gerais, Brazil, 2007/2008

Infraestrutura física e operacional das agências transfusionais da hemorrede pública do Estado de Minas Gerais, Brasil, 2007/2008

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Introduction: Within the context of transfusion safety, the immunohematological study of donors and recipients of blood products is currently the most fragile link in the transfusion chain of the public blood bank network of Minas Gerais. Objective: The objective of this work was to provide a critical and situational overview of the physical and operational infrastructure of the transfusion services in the state. Method: This was an observational cross-sectional, evidence-based study covering 226 transfusion services; only 19 belong to the Hemominas Foundation and 207 are non-Hemominas transfusion services. The investigation involved the application of questionnaires and red cell panel tests. Results: The results revealed considerable non-compliance with the national law and with the norms of Hemominas. These findings were obtained for the two groups studied; however the frequencies were higher among non-Hemominas transfusion services. Conclusion: The study provides information about the situation of the physical and operational infrastructure of transfusion services that may be used to help plan effective measures for improvement and serve as the basis for an evaluation of the impact of future interventions regarding the quality, reliability and safety of transfusions. As primordial factors, we propose compliance with the law, qualified personnel and investment in further qualifications, a review of training methods, and more rigorous inspection of transfusion services. As a suggestion, we propose the establishment of an External Quality Control Program in Immunohematology for the entire network of blood banks in the state and the adoption of the methods presented in this study as a tool to monitor transfusion service performance.

Keywords: Blood banks/organization & administration; Blood banks/legislation & jurisprudence; Infrastructure; Safety; Blood transfusion; Quality control

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Introduction

Transfusion became a plausible treatment method only after the immunological reactions between blood donors and recipients became known and understood. This permitted human interventions to eliminate or minimize adverse immunological effects of transfusion. The immunohematological study of donor blood products and recipients is an essential part of transfusion safety. Compatibility tests, testing for rare antibodies in blood samples from donors and recipients and ABO and RhD typing of blood products became mandatory in Brazil with the publication of the decree 721/89⁽¹⁾ in 1989. After that and the laws that followed it, norms and procedures were introduced in the hemotherapy routine in order to increase the safety of transfusions.⁽¹⁻¹⁰⁾ However, despite these norms and laws, transfusion therapy still involves risks.⁽²⁾

Incomplete or incorrectly performed pre-transfusion tests, poor conservation and manipulation of reagents, inadequate equipment calibration, low technical qualifications and insufficient training of professionals with consequent clerical errors are factors that may prejudice the entire process. Care with the conservation, manipulation and infusion of blood products is equally important and incorrect care may damage the cellular and plasma components. Mistakes in these processes can generate serious or even fatal transfusion incidents, with social, criminal and civil repercussions.^(1,2,10-16)

Transfusion Services (TSs), the focus of the present study, are structures, preferentially located inside a hospital, which receive blood supplied by more complex Hemotherapy Services. They are responsible for the transportation and storage of blood products, for compatibility testing of donors and recipients and for the release of products for transfusion.^(7,10) As they are often located in small hospitals or in urban centers, with limited human and technological resources, mistakes may occur more frequently.

In view of the few publications on this subject both in the international and Brazilian literature, the objective of the current study was to provide a critical situational overview of the physical and operational infrastructure and of the technical procedures of TSs of the Public Blood Bank network in the State of Minas Gerais.

Methods

The present investigation was a cross-sectional observational study which was part of the research project "Transfusion safety: evaluation of the physical and operational transfusion services of the public blood bank network of the State of Minas Gerais", implemented in the Hemominas Foundation (Hemominas) during the period from January 2007 to April 2009.

Minas Gerais is one of 27 Brazilian states. It has an area of 586,528 km² divided into 853 municipalities and is thus the fourth largest state.⁽¹⁰⁾ Additionally, in 2007 it had more than 19 million inhabitants and was considered the second most populous state in the country.⁽¹⁰⁾

In 2008, the Hemominas Foundation, the government agency of Hematology and Hemotherapy of the state of Minas Gerais, was responsible for providing blood products to 490 transfusion services – some of which stored blood bags and performed pretransfusion tests. A total of 267,497 blood units were collected in 2008, 700,634 blood components were prepared and 416,112 blood transfusions were performed (Internal Data - Hemominas).

For the purpose of the present study, all public, private and charitable TSs using blood and blood products collected by the hemotherapy services of the public network of Minas Gerais, i.e., Hemominas, were included in the investigation.

The study was planned to include all TSs that contracted the services of Hemominas to supply blood products, as well as the units of the institution itself that performed transfusion services. All services surveyed were first contacted in order to schedule inspections.

Questionnaires, based on legislation and technical regulations, were developed specifically for this study and applied in loco by the researchers and their students, after theoretical and practical training in this type of research. The questionnaires were filled out using an evidence-based procedure during the period of data collection between July 2007 and August 2008 and the data were stored in a notebook. Later they were sent via email to the coordinators of the project, who created a centralized database. The model was tested and validated in a pilot study with an analysis of reproducibility and overall agreement (Kappa coefficient) giving an average value of 0.65.⁽¹⁷⁾

The information obtained with the questionnaires were related to registration and organizational data, human resources, physical area, equipment, consumables supplies, stock, production and release of blood products, transportation, tests and methods, records, work processes, quality control, and requests for blood and blood products.

Together with completing the questionnaires, panels of immunohematological tests using four 5% red cell suspensions and plasma corresponding to two recipients and two donors were carried out by professionals of the TSs. Produced by Hemominas and characterized as routine situations, the results demonstrated the technical performance of these professionals. The methodology used to prepare the panels was the same as that of the External Quality Control Program of the National Agency of Sanitary Surveillance of the Brazilian Ministry of Health.

A systematic conglomerate sampling was performed for the collection of questionnaire data regarding records,

requests, production and release of blood and blood products. The selection of the sample of transfusion requests was based on the total number for the year 2006 and on the requests in the month preceding this study. For statistical analysis, a 95% confidence limit, a 1.4 "design effect" and an expected prevalence of 50% were considered.⁽¹⁸⁾ The reference year of 2007 was used to calculate the population size.⁽¹⁹⁾

As the original investigation evaluated 935 variables, only those of greater technical importance were included in the present study. The criteria of compliance were defined on the basis of the current legislation and on the contract between Hemominas and the transfusion service to provide specialized services.

A descriptive study was used to determine the distribution of variables. For analysis, the TSSs were divided into two groups: those that belonged to Hemominas (BH) and those that did not (Non Hemominas Services - NHS) but had a contract to receive blood products from Hemominas. This division is justified by the fact that BH TSSs are considered to be reference services that are responsible for the guidance and training of professionals in regards to the installation of NHS and for periodical supervision of their activities. Differences between groups were assessed using the chi-square or Fisher exact tests with the level of significance set at 5%.

The sample size was calculated using the Microsoft Office Excel 2007 software, the EpiData software version 3.1 was used for data entry, and SPSS 17.0 and Epiinfo 6.4 were used for statistical analysis.

Results

Of the 243 TSSs initially considered for the study, three participated in the pilot study, one refused to participate, three, although installed, were not functioning, and 10 were not inspected due to difficulties in communication or to expired or terminated contracts with Hemominas. Thus, the study was carried out for 226 TSSs, corresponding to 93.0% of the total number of services first identified.

The TSSs are located in 177 of the 853 municipalities of Minas Gerais and one is in the state of Espírito Santo, but was also on contract as it was close to a Hemominas unit. One hundred and twenty-three (69.1%) municipalities had populations of five to 50 thousand inhabitants, with none having fewer inhabitants (Figure 1).

The most important results in respect to the topics considered were:

Organizational structure: 19 (8.4%) were BH and 207 (91.6%) were NHS with 132 of the latter (63.8%) being registered charities. Eleven BH (57.9%) and 132 NHS (63.8%) had current authorization as granted by the local public health department and five (26.3%) and 28 (13.5%),

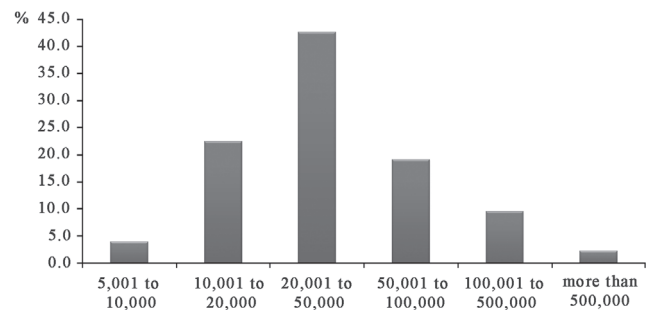


Figure 1. Distribution of municipalities visited according to population

respectively, had no authorization. Of the remaining TSSs, the document had expired. In the previous year, according to the data of the current investigation, 45 (22.0%) NHS had been inspected by Hemominas, while 125 (61.0%) had not been inspected previously.

Human resources: All BH and 197 (95.2%) NHS had technicians in charge, with six (31.6%) and 121 (58.5%) of these professionals being absent at the time of inspection, respectively. Forty-three TSSs (19.0%) had 56 of the hematologists/hemotherapists that work in the public blood bank network on their payroll. Eleven BH (57.9%) employed 14 (25.0%) of these professionals and 32 (15.5%) NHS employed 42 (75.0%). In the BH TSSs, 12 (63.2%) of the physicians had not been trained in the previous year, with this number rising to 117 (56.5%) for NHS. Biochemists, biologists and biomedical professionals were working in nine (47.4%), two (10.5%) and two (10.5%) of the BH TSSs and in 136 (65.7%), nine (4.3%) and 15 (7.2%) of the NHS. Among the BH services, 16 (84.2%) had laboratory technicians, five (26.3%) had laboratory assistants, and six (31.6%) had both a technician and a technical nurse, who performed pre-transfusion tests. In the NHS, 77 (37.2%) had laboratory technicians, 35 (16.9%) had laboratory assistants, 67 (32.4%) had both technicians to perform pre-transfusion tests and 42 (20.3%) had technical nurses. When considering the 148 individuals belonging to the above professional categories in the BH TSSs, they represented 107 (72.3%), 13 (8.8%), 13 (8.8%) and 15 (10.1%), respectively, and the 570 in the NHS represented 252 (44.2%), 65 (11.4%), 173 (30.4%), and 80 (14.0%), respectively.

Physical area: All BH TSSs had a specific physical area for their activities, whereas among the NHS, 36 (17.4%) were established in non-exclusive areas. Of these, 35 (97.2%) were located in clinical analysis laboratories. All 19 (100.0%) BH TSSs had central or wall-mounted air conditioning but 73 (35.3%) of NHS had no air conditioning systems. Only sixteen (84.2%) BH and 126 (61.1%) NHS were compliant to legislation as they had Formica, granite or stainless steel worktops.

Equipment: All 19 (100.0%) BH TSs and 204 (98.6%) NHS had a refrigerator exclusively for blood conservation. Additionally, all BH and 172 (84.3%) NHS maintained the temperature at $4 \pm 2^\circ\text{C}$, with 13 (68.4%) and 92 (53.5%), respectively, checking the temperature every 4 hours.

In addition to red cell concentrates, one BH (5.3%) also stored reagents and 14 (6.8%) NHS stored reagents, biological samples, antibiotics, and insulin or anti-rabies serum in the same refrigerator. Domestic refrigerators were present in all BH and in 198 (95.7%) NHS; the temperature was kept at $5 \pm 3^\circ\text{C}$ in 18 (94.7%) and 165 (83.3%) of them, respectively, and 11 (63.2%) BH and 76 (51.3%) NHS checked the temperature every 4 to 6 hours. Sixteen (8.1%) NHS stored in addition to red cell concentrates, plasma, platelets, clotting factor, medications, vaccines, reagents for the clinical analysis laboratory, and even food in these refrigerators. Eighteen (94.7%) BH and 189 (91.3%) NHS stored samples and reagents in the same refrigerator. All BH and 132 (63.8%) NHS had air conditioning in the cross-test laboratory. Preventive maintenance of the refrigerator used for the conservation of blood bags existed in all BH and in 51 (25.0%) NHS; of the refrigerators used for the storage of reagents and samples in 13 (68.4%) and 33 (16.7%); of an independent freezer in 18 (94.7%) and 29 (14.24%); of the table centrifuge in 17 (89.5%) and 44 (21.6%), and an automatic pipette in seven BH TSs (36.8%) and 12 NHS (6.0%), respectively.

Consumable supplies: Eleven (57.9%) BH and 191 (92.3%) NHS TSs used antisera, no BH and one (0.5%) NHS TS used cards, and 8 (42.1%) BH and 15 (7.2%) NHS TSs used both. Eighteen (94.7%) BH services and 174 (84.1%) NHS used RhD sera and Rh control of the same manufacturer and one (5.3%) BH and 72 (36.7%) NHS TSs manually prepared "O" red cell suspensions for irregular antibody screening.

Blood product stock: Expired blood products were detected in one (5.3%) BH and in 24 (11.6%) NHS TSs. All BH services discarded blood products as biological material and nine (5.6%) NHS discarded them as common refuse. A blood sample from each bag was stored in the refrigerator for at least three days in about 95.0% of both service types and a sample from the recipient was similarly stored in all BH TSs and in 94.2% of the NHS. All BH TSs and 101 (48.8%) NHS returned red cell concentrates (RCC) that were not transfused to stock. Established norms for hemolysis tests were employed by four (21.1%) BH and by seven (6.9%) NHS; visual inspection of the bag by nine (47.4%) and 12 (11.9%), and using a closed system by six (31.6%) and six (5.9%) services, respectively.

Production and release of blood products: Fourteen (73.7%) BH and 70 (34.3%) NHS released incompatible RCC in special situations. Of these, four (28.6%) and nine (12.9%),

respectively released products with the authorization of the technician in charge and the patient's doctor. Fifteen (78.9%) BH and 142 (68.6%) NHS released blood products without a compatibility test, with 10 (66.6%) and 73 (51.4%) of the services, respectively, following this procedure only upon written authorization by the patient's doctor. In case of non-compliance in the pre-transfusion tests, ten (52.6%) BH and 61 (29.5%) NHS communicated the fact to the technician in charge.

Transportation: Two BH TSs did not request blood or blood products from other Hemominas Units and therefore had no need of transportation. Of the other 224 centers, 17 (100.0%) BH and 203 (98.1%) NHS used polyurethane boxes as containers for blood components, although eight (47.1%) of the BH and 29 (14.0%) NHS used Styrofoam boxes. Eleven (64.7%) and 146 (70.5%) used thermometers and 12 (70.6%) and 164 (79.2%) used ice, respectively.

Tests and methods: The 19 (100%) BH TSs reclassified RCC bags and performed direct cross matching and RhD tests, with 12 (63.2%) of them doing so only with negative RCC, and seven (36.8%) performed a reverse test. Among the NHS, these numbers were 195 (94.7%), 194 (99.5%), and 188 (96.4%), respectively with 51 (27.1%) following this procedure only for negative RCC, and 43 (22.1%) performing the reverse test. All BH services and 188 (90.8%) NHS classified each new patient sample. Three (15.8) BH and 48 (23.2%) NHS used slides to perform the test. A constituted Transfusion Committee was detected in 17 (89.5%) BH TSs and in 127 (61.4%) NHS.

Records: The charter in the transfusion logbook regulated by the state health department by means of "discretionary power" and later mandatory filing were observed in 19 (100.0%) BH TSs and in 182 (87.9%) and 197 (95.6%) NHS, respectively. All BH TSs and 176 (85.0%) NHS had forms for the notification of transfusion reactions; 17 (89.5%) and 65 (31.4%) notified transfusion reactions, respectively; 15 (78.9%) and 32 (15.5%) investigated the reactions, and seven (36.8%) and 93 (44.9%) released each RCC bag with the signature of the Technician in Charge, respectively.

Working processes: Standard Operational Procedures (SOP) for ABO reclassification of the bag were present in 14 (73.7%) BH and in 92 (44.4%) NHS and SOP for RhD were present in 13 (68.4%) BH and in 89 (43.0%) NHS. Regarding patient tests, 18 (94.7%) BH and 137 (66.2%) NHS had SOP for ABO and RhD classification. Three (15.8%) BH and 57 (27.5%) NHS had SOP for conduct in the presence of immediate transfusion reactions and one (5.3%) and 23 (11.1%), respectively, had SOP for the investigation of transfusion reactions.

Table 1. Compliance and non-compliance with the law of transfusion services belonging to the Hemominas Foundation and those that contracted the services of the foundation and participate in the public blood bank network of Minas Gerais

Items analyzed	Hemominas transfusion services (n=19)		Non-Hemominas transfusion service (n=207)		p-value
	Compliant (%)	Non-compliant (%)	Compliant (%)	Non-compliant (%)	
Licence to operate	11 (57.9)	8 (42.1)	132 (63.8)	75 (36.2)	0.611
Supervision/verification of Hemominas in the last year	7 (36.8)	12 (63.2)	45 (22.0)	160 (78.0)	0.158
Exclusive physical area	19 (100.0)	0 (0.0)	171 (82.6)	36 (17.4)	0.049
No. of square meters of the area ¹	19 (100.0)	0 (0.0)	109 (63.7)	62 (36.3)	0.001
Ventilation system	19 (100.0)	0 (0.0)	134 (64.7)	73 (35.3)	0.001
Worktop surface	16 (84.2)	3 (15.8)	126 (61.2)	80 (38.8)	0.046
Presence of a Technician in Charge	19 (100.0)	0 (0.0)	197 (95.2)	10 (4.8)	1.000
Presence of a Laboratory Technician	16 (84.2)	3 (15.8)	77 (37.2)	130 (62.8)	<0.0001
Current authorization granted by the local public health department	19 (100.0)	0 (0.0)	182 (87.9)	25 (12.1)	0.141
Completion of transfusion logbook	19 (100.0)	0 (0.0)	197 (95.6)	9 (4.4)	1.000

¹ Only transfusion services with an exclusive physical area were considered

Table 2. Compliance and non-compliance with the law of transfusion services belonging to the Hemominas Foundation and those that contracted the services of the foundation and participate in the public blood bank network of Minas Gerais

Items analyzed	Hemominas transfusion services (n=19)		Non-Hemominas transfusion services (n=207)		p-value
	Compliant (%)	Non-compliant (%)	Compliant (%)	Non-compliant (%)	
Expired blood products	18 (94.7)	1 (5.3)	183 (88.4)	24 (11.6)	0.702
Disposal of blood products ¹	19 (100.0)	0 (0.0)	153 (94.4)	9 (5.6)	0.600
Refrigerated storage of bag samples and recipient samples	18 (94.7)	1 (5.3)	193 (93.2)	14 (6.8)	1.000
Classification of each new patient sample	19 (100.0)	0 (0.0)	188 (90.8)	19 (9.2)	0.380
Use of a slide for testing	16 (84.2)	3 (15.8)	159 (76.8)	48 (23.2)	0.576
Obligatory pre-transfusion tests in RCC transfusion ²	19 (100.0)	0 (0.0)	176 (85.0)	31 (15.0)	0.083
Obligatory pre-transfusion tests ³	14 (73.7)	5 (26.3)	71 (35.5)	129 (64.5)	0.001
Transportation of blood products	10 (58.8)	7 (41.2)	140 (67.6)	67 (32.4)	0.457
Laboratory analysis of antisera for at least each lot ⁴	8 (42.1)	11 (57.9)	24 (11.6)	183 (88.4)	0.001
Laboratory analysis of red cell suspensions	7 (36.8)	12 (63.2)	10 (4.8)	197 (95.2)	<0.0001
Use of RhD serum and Rh control of the same manufacturer	18 (94.7)	1 (5.3)	174 (84.1)	33 (15.9)	0.321
Manual preparation of "O" red cells for IAS ⁵	18 (94.7)	1 (5.3)	124 (63.3)	72 (36.7)	0.005
Maintenance and temperature check of a refrigerator used for blood bag storage ⁶	13 (68.4)	6 (31.6)	92 (45.1)	112 (54.9)	0.051
Maintenance and temperature check of a domestic refrigerator ⁷	11 (57.9)	8 (42.1)	76 (38.4)	122 (61.6)	0.097

¹ Forty-four non-Hemominas transfusion services did not provide evidence about the procedure of disposal

² RCC = Red cell concentrates; ABO and RhD for donated blood and ABO, RhD, IAS and Compatibility Test for the recipient

³ Seven non-Hemominas transfusion services did not provide the results of the tests

⁴ Use of a polyurethane and/or Styrofoam box, a thermometer and ice; Two Hemominas transfusion services did not use blood products from other centers

⁵ Nine non-Hemominas transfusion services did not use the "O" suspension and two had the response disregarded

⁶ Three non-Hemominas transfusion services did not have a refrigerator to store blood bags

⁷ Nine non-Hemominas transfusion services did not have a domestic refrigerator

Quality control: Laboratory analysis of antisera and of red cell suspensions of at least each lot was performed by eight (42.1%) and seven (36.8%) BH and by 24 (11.6%) and 10 (4.8%) NHS. Four BH (21.1%) and 47 (22.5%) NHS services had SOP for quality control of the reagents and

three (75.0%) and 16 (34.0%) of them were up to date, respectively. Conduct protocols for reagent non-compliance were present in three (15.8%) BH and in six (2.9%) NHS. All BH and 55 (26.6%) NHS participated in Programs of External Quality Control.

Table 3. Compliance and non-compliance with the law of transfusion services belonging to the Hemominas Foundation and those that contracted the services of the foundation and participate in the public blood bank network of Minas Gerais

Items analyzed	Hemominas transfusion services (n=19)		Non-Hemominas transfusion services (n=207)		p-value
	Compliant (%)	Non-compliant (%)	Compliant (%)	Non-compliant (%)	
Presence of norms for the return of RCC to stock ¹	6 (31.6)	13 (68.4)	4 (4.0)	97 (96.0)	0.001
Presence of notification of transfusion reactions	17 (89.5)	2 (10.5)	65 (31.4)	142 (68.6)	<0.0001
Investigation of reaction in the last year	15 (93.8)	1 (6.3)	32 (66.7)	16 (33.3)	0.048
Signature of the technician in charge on every RCC bag released	7 (36.8)	12 (63.2)	93 (44.9)	114 (55.1)	0.497
Up-to-date SOP for obligatory tests	10 (52.6)	9 (47.4)	40 (22.7)	136 (77.3)	0.010
Evidence of a constituted Transfusion Committee	17 (89.5)	2 (10.5)	127 (61.4)	80 (38.6)	0.014
Communication to the technician in charge of non-compliance in pre-transfusion tests	10 (52.6)	9 (47.4)	61 (29.5)	146 (70.5)	0.037
Participation in an External Quality Control Program	19 (100.0)	0 (0.0)	55 (26.6)	152 (73.4)	<0.0001

RCC = red cell concentrates; SOP = Standard operational procedures

¹ One hundred and one non-Hemominas transfusion services returned red cell concentrates to stock
Visual inspection of the bag and verification of the sealed system

Performance regarding pre-transfusion tests (panel): of the 226 TSs studied, 219 (96.9%) presented the results of pre-transfusion tests but seven NHS did not return the questionnaire with the results. Fourteen (73.7%) BH and 71 (35.5%) NHS correctly performed ABO and Rh classification of donor and recipient, irregular antibody screening of the recipient, and the compatibility test.

The parameters that were statistically different (p < 0.05) on comparing BH and NHS TSs were: physical area, worktop surface, ventilation system, presence of a laboratory technician, obligatory pretransfusion testing, laboratory analysis of the antisera of at least every lot, laboratory analysis of red blood cell suspensions and manual preparation of suspension of "O" red blood cells for immunoadsorption (IAS). Additionally the following parameters were statistically significant: norms for the return of RCC to stock, notification of transfusion reactions, investigation of transfusion reactions in the preceding year, up-to-date SOPs for obligatory testing, evidence of a constituted Transfusion Committee, participation in external quality control programs and communication of non-compliance in pretransfusion tests to the technician in charge. Maintenance and calibration of the temperature of refrigerators for blood bag storage had borderline statistical significance.

The data regarding non-compliance for the items analyzed above, both in the BH and NHS, are presented in Tables 1, 2 and 3.

Discussion

This was probably the most comprehensive diagnostic study of Transfusion Services conducted in Brazil. It provides a critical situational overview of the physical and operational infrastructure of the TSs of the public blood bank network of Minas Gerais. This topic has not been investigated much in

Brazil as a literature review did not reveal relevant data regarding structural aspects of TSs of this or most of the other states of the country. A similar situation was observed at the international level.

The descriptive study clearly permitted us to learn about the reality of the situation of the physical and operational infrastructure of the TSs of Minas Gerais. This study may contribute to the planning of effective actions to improve and serve as a basis to evaluate the impact of future interventions regarding the quality, reliability and safety of transfusion.

The present findings revealed expressive percentages of non-compliance with current legislation and with the norms established by Hemominas. Except for a few cases, these shortcomings were more frequently observed in NHS. The information obtained indicated that the BH TSs, although considered to be reference services and to be responsible for the installation process, the training of professionals and the inspection of NHS, also presented problems that might impinge on correct transfusion.

Draws attention among non-conformities found: lack of or expired health department certificates; absence of supervision/inspection by Hemominas; lack of laboratory technicians; use of slides for tests; use of inadequate material for the transportation of blood products; erroneous maintenance and calibration of refrigerators for the conservation of blood bags and the use of domestic refrigerators, and failure to communicate to the technician in charge of non-compliance in immunohematological testing. Another source of concern was the performance of the services regarding obligatory pre-transfusion tests.

The following shortcomings were particularly important, especially in the NHS: pre-transfusion tests performed in a clinical analysis laboratory, lack of technician in charge, failure to perform mandatory tests for RCC transfusion, use of RhD serum and Rh control from different manufacturers, manual

preparation of "O" red blood cell suspensions for irregular antibody screening, lack of a constituted transfusion committee, and lack of participation in External Quality Control Programs.

The following factors are considered to be of primordial importance in order to guarantee the quality and safety of the pre-transfusion process: ^(4,5,7,10,13-16,20-25)

- Compliance with current legislation and technical norms and with the contract obligations with Hemominas;
- Personnel with qualifications in hemotherapy (educational level: high school and higher education) and investment in training;
- Engagement in the management of TSSs, with awareness of the risks inherent to hemotherapy;
- More stringent supervision/verification and inspection by both Hemominas and the public health department as a healthcare regulatory organ, to detect, record, correct and prevent errors and non-compliance;
- Implementation of Internal and External Quality Control Programs;
- Investment in blood inspection programs;
- Installation of Multidisciplinary Transfusion Committees.

In summary, to increase the safety of blood transfused at the TSSs of Minas Gerais, we suggest: 1) the use of the present data to develop better tools to standardize procedures with a review of training methods based on the correction and standardization of conduct for the entire state; 2) adoption of a methodology as an instrument to monitor TS performance, with a definition of the criteria of "compliance" and "criticality" focused on an assessment of the efficiency and efficacy of inspections, and 3) External Quality Control Program in Immunohematology (Proficiency Program), for the entire network of blood banks in the state.

Resumo

Introdução: No contexto da segurança transfusional, o estudo imuno-hematológico do doador e do receptor de hemocomponentes é hoje o elo mais frágil da cadeia transfusional na hemorrede pública de Minas Gerais. Objetivo: O objetivo deste trabalho foi traçar panorama crítico e situacional da infraestrutura física e operacional das Agências Transfusionais (ATs) do estado. Método: Estudo observacional transversal, baseado em evidências, abrangeu 226 ATs, sendo 19 próprias da Fundação Hemominas (PH) e 207 não próprias da Hemominas (NPH), com aplicação de questionários e testes de painel de hemácias. Resultados: Os achados do presente estudo mostraram percentuais expressivos de não conformidades com a legislação vigente no país e com as normas estabelecidas pela Hemominas. Estas foram encontradas nos dois grupos estudados, com algumas exceções, apresentando maiores frequências entre as ATs NPH. Conclusão: O estudo possibilitou o conhecimento da situação da infraestrutura física e operacional das ATs, podendo subsidiar o planejamento de ações efetivas de

melhorias, bem como servir de base para avaliar o impacto de futuras intervenções, com vistas à qualidade, confiabilidade e segurança transfusional. Para isto, propôs como fatores primordiais, o cumprimento da legislação vigente, recursos humanos qualificados e investimentos na sua capacitação, revisão das metodologias de treinamento e maior rigor nas verificações e inspeções das ATs. Como sugestão, propõe ainda a criação, pela Hemominas, de Programa de Controle de Qualidade Externo em Imunohematologia para toda hemorrede do estado e adoção da metodologia deste estudo como instrumento de monitoramento da performance das ATs.

Descritores: Bancos de sangue/organização & administração; Bancos de sangue/legislação & jurisprudência; Segurança; Transfusão de sangue; Controle de qualidade

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