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HEMOVIGILANCE: THE PRACTICE OF THE TRANSFUSIONAL AUDIT PROCESS IN THE HEMOPA FOUNDATION

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ABSTRACT

This work analyzed the practice of the transfusion audit carried out by the Hemovigilance and Supervision Department of the HEMOPA Foundation. It is a descriptive, documental, retrospective, quantitative study that analyzed the monthly reports of the transfusion audits conducted between 2015 and 2017. In this period, the hemovigilance sector visited 20 health institutions in the metropolitan region of Belém, which performed 36,217 transfusions, 7.3% of which were audited and 78.8% of them presented inadequacies or nonconformities in the process. In the ambulatory of the HEMOPA Foundation, there were 4,071 transfusions, 94.3% were audited and 34.8% of these transfusions were considered nonconforming. It was found that the inadequacies are mainly related to failures in the registration of information pertaining to the transfusion. Thus, the transfusion audit process of the HEMOPA Foundation is essential for the monitoring of the practice of transfusions, by identifying the risk factors related to the procedure and thus contributing to the elaboration of prevention and control measures, stimulating the improvement of hemotherapy and favoring quality of services provided to the population.

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INTRODUCTION

Hemotherapy consists of the therapeutic use of blood components and their derivatives, which has favored the clinical management of adult and pediatric patients throughout history and has been increasing in the last decades (VERAN, 2012), becoming an effective therapeutic specialty in the treatment of some pathologies and in the replacement of blood components and blood products essential to the maintenance of life (BRITO, 2015). However, the performance of the transfusion procedure may subject the receptor to serious complications such as exposure to transmissible diseases, immune or non-immune reactions, immunological sensitization, and therapeutic failure (BESERRA *et al.,* 2014). In Brazil in 2011, of the 5,340 transfusion reactions registered in the Hemovigilance System, there were 24 acute hemolytic reactions and five cases of transmission of diseases by blood, observing the frequency of one death per year attributed to this type of transfusion reaction (Silva JÚNIOR *et al.,* 2016).

Because of this, hemotherapy services are complex, highly regulated systems and require vigilance because even though transfusions are currently a safe practice, the risks are inherent in this process. Thus, it is essential to recognize and monitor them to avoid incidents that could compromise the health of donors and patients, and the need for constant vigilance is unquestionable, due to the nature of the procedure (SILVA JÚNIOR *et al.,* 2016). In this context, the importance of haemovigilance is highlighted, which consists of a set of procedures to verify the blood cycle that monitors and creates corrective actions for any non-conformity, aiming to make the transfusion procedure safer and more effective (Martins *et al.,* 2013). This system aims to take measures that prevent the occurrence and / or recurrence of adverse effects and can be considered as a method of quality control and transfusion safety (BESERRA *et al.,* 2014). It is noted that the therapeutic success obtained from the blood transfusion also increased the number of unnecessary requests. Thus, strategies such as transfusion audits were implemented, since the presence of

professionals with knowledge in this area could help improve the services that perform blood transfusion, improving the short- and long-term results for all actors in this system (BRUM, 2011). In view of this, an institutional protocol was developed at the HEMOPA Foundation to perform the transfusion audits by the team of the Department of Hemovigilance and Supervision (GEHES), composed by 4 nurses. During the audit, 10 conformity control items of the transfusion process are observed, which generally assess whether blood transfusions are being performed as recommended by the legislation, according to the following items: 1) Medical prescription; 2) Registration of pre-transfusional blood sample collection in medical records; 3) Checking the beginning of the transfusion; 4) Checking the end of the transfusion; 5) Vital signs before transfusion; 6) Vital signs after transfusion; 7) Identification label of the receiver attached to medical records; 8) Identification tag correctly filled out by the technician who installed the transfusion; 9) Identification of blood components according to the request; 10) Number of blood bag registered in the medical record (PARÁ, 2018). In addition, it was established at the institution that 10% of the total transfusions occurred each month should be audited in the Health Care Establishments of the Metropolitan Region of Belém, assisted by the coordinating blood center. The transfusions that are performed in the HEMOPA Foundation Ambulatory must be 100% audited, according to the Annual Hemovigilance Report of 2017 (PARÁ, 2017). The management of nonconformities, that is, the recording and treatment of any non-compliant situation, is essential because it enables the analysis of causes and the proposition of corrective and preventive actions, favoring the improvement of the work process, as well as the search for solutions and continuous improvement of hemotherapy service offered to the population (SILVA, 2018). In this perspective, this study had as objective to analyze the practice of the transfusional audit performed by the Hemovigilance and Supervision Management of the Center of Hemotherapy and Hematology of Pará, from 2015 to 2017.

METHODS

The proposed study was descriptive, documentary, retrospective and quantitative, developed at the Center for Hemotherapy and Hematology of Pará (HEMOPA), which is responsible for the coordination of the State Blood Policy and consists of a Hemocenter Coordinator in the capital Belém, three Regional Hemocenters in the municipalities of Castanhal, Santarém and Marabá, five Hemotherapy Nucleus in Capanema, Altamira, Tucuruí, Abaetetuba and Redenção (PARÁ, 2017). In order to obtain the data, the monthly reports of the internal and external transfusion audits performed by the institution's Hemovigilance and Supervision Management (GEHES) were analyzed, as well as the books of compliance control of the transfusion process and the computerized systems of the HEMOPA Foundation – Blood Bank System (SBS.Web) and System of Indicators (SISIND) - for blood transfusions carried out from 2015 to 2017, in the ambulatory of the HEMOPA Foundation and in Health Care Institutions located in the Metropolitan Region of Belém assisted by the Hemocenter Coordinator. The collected data was inserted into a Microsoft Office Excel 365 worksheet and subsequently exported to the BioEstat program (version 5.0). For data analysis, the statistical tests were used: Mean, Median, Standard Deviation and Chi-square test, establishing the p-value ≤ 0.05. The data obtained were demonstrated from graphs and tables. The data collection began after authorization from the Teaching and Research Center of the HEMOPA Foundation. Since there was no contact with the patients of the institution and no data from their medical records were used, it was requested the dispensation the use of the Informed Consent Form.

RESULTS AND DISCUSSION

The HEMOPA Foundation meets the transfusion demand of Health Care Establishments located in the Metropolitan Region of Belém and during the period from 2015 to 2017 the team of the haemovigilance sector visited 20 of these health institutions to carry out the external transfusion audits, which were 14 hospitals who do not have Transfusional Agency, 4 nephrology clinics and 2 Emergency Care Units.

Transfusion Audit

In health care services in the metropolitan area of Belém, except for the ambulatory of the HEMOPA Foundation, 36,217 transfusions were performed between 2015 and 2017, and in the first year there was a greater frequency of transfusion, 14,850 (41%). The transfusions that were audited totaled 2,640 (7.3%), with a highlight for the year 2017 with 1,458 (14,1%) transfusions audited, in the same way, this year found the highest frequency of transfusions that presented nonconformities, 1,354 (92.9%), according to the items of control of the transfusion process used in the audit performed by GEHES. In the ambulatory of the HEMOPA Foundation, 4,071 transfusions were performed during this period, of which 3,838 (94.3%) were audited and 1,341 (34.9%) were non-compliant (Table 1). The data obtained showed that there was a reduction of 4,758 (32%) transfusions in the metropolitan area of Belém over the course of 2015 to 2017. This can be justified by the decrease in the total number of health institutions that were attended by the coordinating hemocenter throughout the three years, since a private hemotherapy service started to meet the demand for blood components from some of these establishments and others were closed. In the ambulatory of the HEMOPA Foundation, the occurrence of transfusions remained stable during this period. Regarding the audit of the transfusions performed in the health services of the metropolitan region, it is noticed that there was significant variation of the total each year, standing out 2016 with the lowest frequency of audited transfusions, 330 (2.9%). This was due to the HEMOPA Foundation having undergone SBS.WEB system implementation in this period and transfusion requests occurred in contingency, as justified in the audit reports. As a result, only 34 external audit visits were performed by the hemovigilance management in the first semester (Table 1). Consequently, the reduction in the frequency of transfusion nonconformities was observed in 2016, and 195 (59.1%) were considered nonconforming (Table 1). It should be noted that transfusions are considered inadequate if one or more nonconformities are found among the 10 control items that are used to evaluate the transfusion process during the audit. The HEMOPA Foundation established a goal of transfusions to be audited in 10% in the health services of the metropolitan area of Belém and 100% audit in the institution's outpatient clinic. According to the data found, it can be stated that only the external audit goal was achieved in 2017 (Table 1). It is stressed that failure to reach the goals set by the institution did not represent a negative evaluation of the results of transfusion audits, since the calculation of the sample from the mean

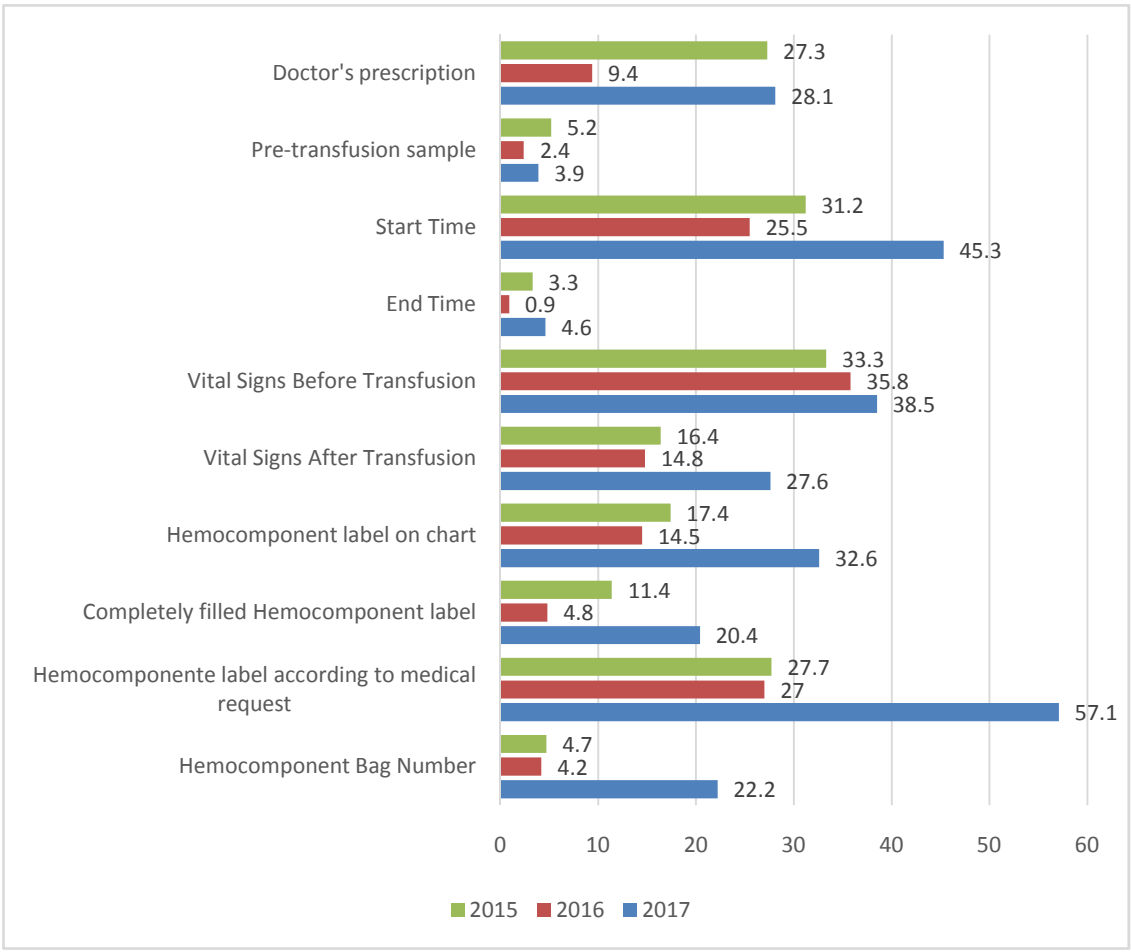
Table 1. Transfusions occurred, audited and inadequate by year of occurrence in health care establishments in the metropolitan area of Belém and in the outpatient clinic of the HEMOPA Foundation, from 2015 to 2017

	Health Care Establishments			Ambulatory of HEMOPA Foudation		
	N	%		N	%	
Transfusions Occurred						
2015	14850	41,0	ẋ= 12072,3	1280	31,4	ẋ= 1357
2016	11275	31,1	DP ± 2477,2	1560	38,3	DP ± 177,5
2017	10092	27,9		1231	30,2	
TOTAL	36217	100,0		4071	100,0	
Audited Transfusions						
2015	852	5,7	ẋ= 880,0	1234	96,4	ẋ= 1279,3
2016	330	2,9	DP ± 564,5	1483	95,1	DP± 185,2
2017	1458	14,4		1121	91,1	
TOTAL	2640	7,3		3838	94,3	
Inadequate Transfusions						
2015	531	62,3	ẋ= 693,3	60	4,9	ẋ= 447
2016	195	59,1	DP ± 596,3	609	41,1	DP± 336,6
2017	1354	92,9		672	59,9	
TOTAL	2080	78,8		1341	34,9	

Table 2. Minimum percentage of transfusions to be audited annually by the Hemovigilance and Supervision Management of the HEMOPA Foundation

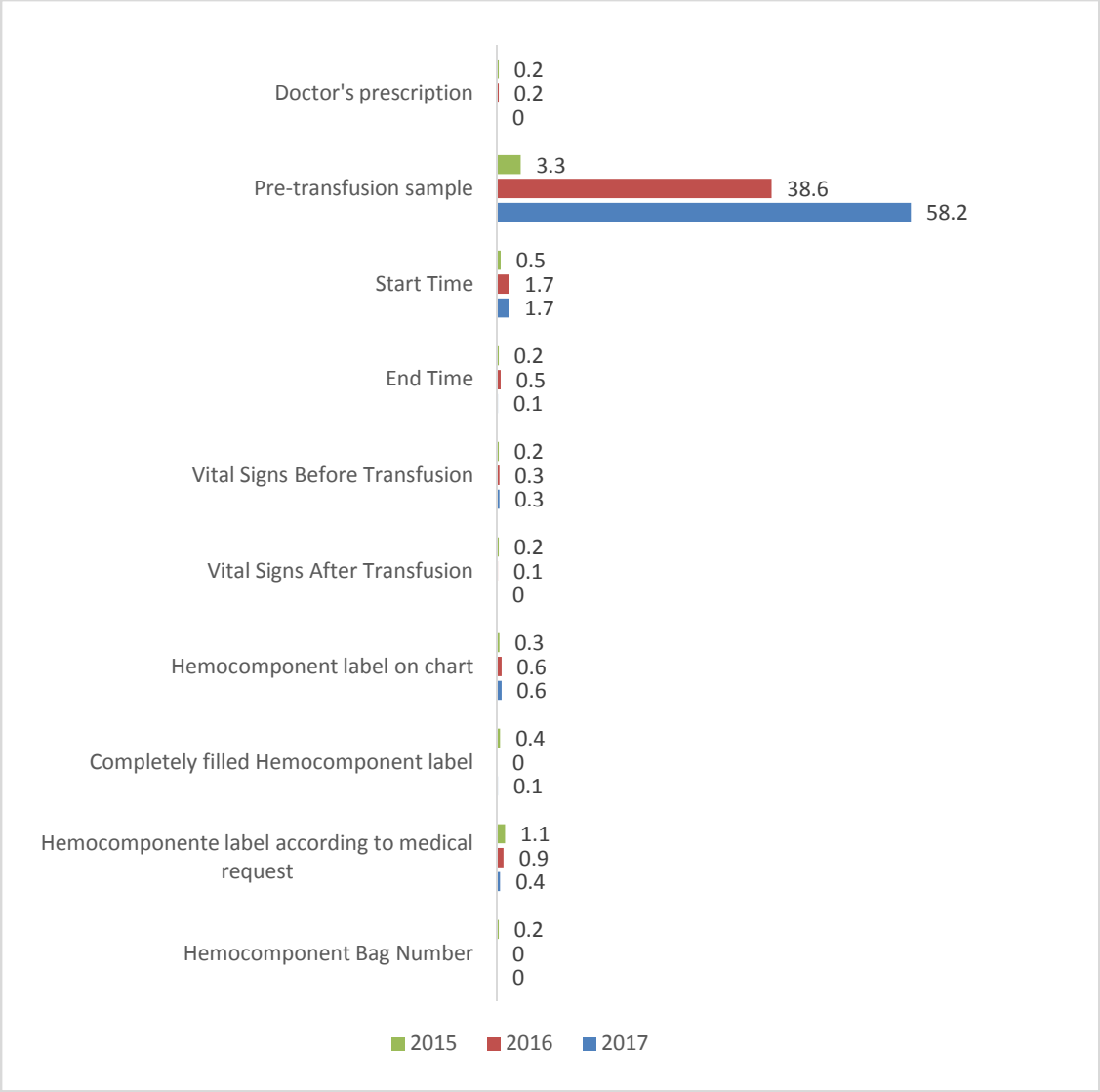
	Average transfusions occurred (2015-2017)	Annual transfusions to be audited	Monthly transfusions to be audited	Minimum annual target (%)
Health Care Establishments	12072,3	629	53	5,2
Ambulatory of HEMOPA Foudation	1357	446	38	33

Source: Internal Reports of Transfusion Audit of the HEMOPA Foundation, 2018.
The sample calculation was performed in the program Bioestat version 5.0, considering sample error of 5% and confidence level of 99%.



Source: HEMOPA Foundation External Transfusion Audit Reports, 2018.

Graph 1. Frequency of compliance control items in the Health Care Facilities of the metropolitan area of Belém per year of occurrence, in the period from 2015 to 2017



Source: HEMOPA Foundation External Transfusion Audit Reports, 2018.

Graph 2. Frequency of Compliance Control Items in the HEMOPA Foundation Outpatient Clinic by year of occurrence, from 2015 to 2017

transfusions occurred in the period from 2015 to 2017 demonstrated that the minimum annual goal of transfusions to be audited in the health services of the metropolitan area of Belém would be 5.2% and in the ambulatory of the HEMOPA Foundation the goal would be to audit 33% of the transfusions occurred (Table 2).

Transfusion Process Control Items

The analysis of the external audit reports showed that, during the 3 years, among the control items that presented the highest frequencies of nonconformities, the following should be highlighted: pre-transfusional sample collection, vital signs after the end of the transfusion, the nameplate of the hemocomponente completed by the technician who installed it, and the item referring to the number of the bag registered in the medical records, mainly in 2015 and 2017 (Graph 1). According to Article 128 of Health Vigilance Agency75 of 2016, all transfusions must be requested by a physician, however, in relation to this item, there was a frequency of 4.7% of nonconformity in 2015, 4.2% in 2016 and 22.2% in 2017 (Graph 1). Regarding the blood sample collection records for the pre-transfusion tests, according to Annex IV of the Consolidation Order 5 of 2017 these have validity of up to 72 hours (BRAZIL, 2017). It was found, however, that 57.1% of transfusions that were audited in 2017 did not record the samples collected, which made it impossible to monitor this data (Graph 1). Another important data to be recorded in patients' records are the notes of the beginning and end of the transfusion, since according to current legislation the blood components have an infusion time, as for example each unit of Blood Cell Concentrate must be transfused of 60 to 120 minutes and of Platelet Concentrate should be 30 minutes (BRAZIL, 2015). However, it was observed that, mainly in 2017, the percentage of non-conformances referring to these items was high: check of the start time (20.4%) and time of end of the transfusion (32.6%), characterizing a fragility in this transfusion process (Graph 1).

Amaral (2016) states that vital signs should be checked and recorded in the medical record for comparison if the patient develops any type of transfusion reaction. The results of Beserra *et al*. (2014) showed a description of 45 different symptoms of adverse reactions to transfusion, mainly fever (55.6%), dyspnea and urticaria (8.9% each). In the analysis of this research, especially in the year 2017, a considerable percentage of non-compliance regarding these data was found, constituting an important failure of the transfusion process,

since the lack of registration of these parameters impairs the recognition of possible transfusion reactions (Graph 1). Regarding the identification label that accompanies the blood component, it is noted that in the majority it is attached to the patient's medical record and the blood component is according to the request made by the physician. However, it is not correctly filled, incomplete or blank (Graph 1). In the same way, the number of transfused blood components was a non-compliant item recorded in 27.3% of medical records in 2015, 9.4% in 2016 and 28.1% in 2017 (Graph 1). As the pocket number record is an important data for traceability in cases of seroconversion of a blood donor or recipient with suspected transfusional disease by transfusion, this is, for the retrovigilance process. Corroborating the results found in a study carried out in the public hospital of the interior of Minas Gerais, Brazil, where 1,012 transfusion monitoring cards were analyzed, of which 53.4% had filling failures, 6% of the infusions were started after the recommended time and 9.3% of the patients did not have vital signs recorded. We identified deficiencies in the process of recording transfusion monitoring that may favor the occurrence of adverse events related to the administration of blood components (REIS *et al.,* 2016). In this context, it is valid to emphasize that the health service that performs the transfusion procedure must keep in the recipient's records the records related to the transfusion: date in which it occurred, start and end times, vital signs at the beginning and at the end, origin and identification of transfused blood bags, identification of the professional who carried out the transfusion, and record of adverse reactions, when applicable (BRAZIL, 2016). At the ambulatory of the HEMOPA Foundation outpatient clinic, the item referring to the hemcomponent identification tag according to the request was the one with the highest frequency of non-compliance in 2016 and 2017 (38.6% and 58.2%), due to lack of identification of erythrocyte phenotypes in the chart attached to the medical record. Important data to verify if the request made by the doctor was answered, considering that the patients of the institution in most of them require phenotyped transfusion (Graph 2). The Annex IV of the Consolidation Order 5 of 2017 recommends the identification of irregular antibodies and the phenotyping of blood to be transfused, in the case of alloimmunized patients, which should be free of the corresponding antigens (BRASIL, 2017). For this reason, the inclusion of the phenotype information on the patient's label, which according to the transfusion audit reports, was requested by the Information Technology Management (GETIN) of the HEMOPA Foundation.

Conclusion

Transfusion of blood components is a recurring practice in the daily routine of health care, however, it is not a risk-free procedure. Thus, the transfusion audit practice carried out at the HEMOPA Foundation is an important monitoring instrument, a gain for improving the quality of care and consequently for increasing patient safety. An important result of the research refers to the percentage of transfusions to be audited both in the health services of the metropolitan area of Belém and in the outpatient clinic of the HEMOPA Foundation, because it would be possible to audit fewer transfusions, without impairing the level of reliability according to the results found through the sample calculation, which indicate the projection of the annual target of 5.2% for external audits and 33% for internal audits, in contrast with the one currently recommended by the institution. This result contributes to the management of the haemovigilance sector, in the possibility of reassessing the annual goal of transfusion auditing and optimizing the productivity, since in order to be high requires a significant investment of work of the professionals who work in this activity. Regarding the analysis of the items of control of the transfusion process, it was verified that there are important failures in the registry of information pertinent to the transfusion, expressed by the frequency of nonconformities found in the audit reports. The repetition of these failures evidences the difficulty faced by the services in involving the professionals that act in the transfusion process to monitor more effectively the activities inherent in blood transfusion. In this sense, it is considered that the process of transfusion auditing implanted in the HEMOPA Foundation is paramount for the monitoring and evaluation of the practice of transfusions. The identification of risk factors related to the transfusion process can contribute to the elaboration of prevention and control measures, stimulating the improvement of hemotherapy and favoring the quality of the services provided to the population. It is valid to reinforce the relevance of haemovigilance in the monitoring of the transfusion practice and to emphasize that studies related to the transfusion audit process are still incipient, which represented an important limitation for this research due to the scarce literature found. Therefore, it is assumed that the data resulting from this research can contribute to future studies that contemplate the subject matter.

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