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Evaluation of transfusion incidents and near-misses in a hospital on the coast of Santa Catarina

Abstract

Transfusion medicine is not free of risks and their source could be both technical and human. The near-miss is a deviation from a procedure detected before its occurrence, which could result in an erroneous transfusion and/or a transfusion reaction. The incidents in turn comprise the deviations in the security policy, leading to inadequate transfusions.

This study aimed to evaluate transfusion incidents and near-misses of a transfusion agency on the coast of Santa Catarina, Brazil. The pre-analytical, analytical and post-analytical phases of the pre-transfusion tests and transfusion procedure were evaluated using forms based on the current hemotherapy legislation and filled out locally by the researchers.

The obtained data were sectioned in identifications (IDs) and their respective phases. Among the evaluations, 10,562 on-site observations were counted, and nonconformities were detected in the pre-analytical and analytical phases of the pre-transfusion tests. Nonconformities were detected due to the non-execution of the tests (6.7%), non-identification of the patient prior to biological sample collection (69.9%) and blood component installation (75.3%). Non-follow-up of the initial transfusion was 81.9% of non-compliance. However, there were a low number of near-misses, totaling 0.10%.

In the period of this study it was possible identifying that the in loco evaluation of hemotherapy activities is important to detect incidents and near-misses. In this way, an audit of hemotherapy procedures and the training of professionals can help to reduce incidents and near-misses caused by lack of human attention.

Keywords: blood transfusion, typing, crossed blood reactions, blood banks, hospital administration, risk management

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Introduction

The services of transfusion aim at providing quality and the minimum risk for patients. Although there is no risk free transfusion procedure, the therapeutic benefits are undeniable in face of legislation.[1,2] Studies have demonstrated that these risks could be involved in preparing procedures and hemocomponent transfusion errors, which could compromise the patient's transfusion safety.[3–5] They could be a consequence of inadequate procedures, as well as errors or omissions from professionals in transfusion procedures.[6,7]

When discussed security of transfusion procedures, the subject is not only blood and its hemocomponents but the necessary security during the entire transfusion process, considering the complexity and the countless essential stages for a safe transfusion. These stages facilitate the occurrence of adverse transfusion events, also called incidents and near-misses, jeopardizing lives of hemocomponent receivers.[4,5]

The adverse events that could occur in the different stages of the blood cycle are denominated incidents, that can be divided in adverse reactions, producing damage to receivers in diverse levels, and near-misses that are deviations from the standard procedure detected before initiating the transfusion. Due to the clinical significance of adverse events, the creation of surveillance systems during the entire transfusion process becomes a justifiable measure.[8,9] Most of these adverse events occur in the pre-analytical and post-analytical phases and could result in a negative impact for the patient's health, or even irreparable adverse consequences. The possibility of incidents and near-misses begins in the moment of collecting blood samples for pre-transfusion tests, which includes the proper labeling of samples as a key step in preventing errors during the transfusion.[5,10] Furthermore, unnecessary transfusions are also considered incidents, since there are national protocols for transfusion indication, including protocols of surgical reservations as a support to avoid these events.[11,12]

Errors that could contribute for failure in the pre-analytical phase occur from inappropriate identification of samples to patient's identification errors, resulting in wrong hemocomponent administration. An estimated 14 to 20% of these errors occur before the sample arrival at the laboratory. Although deaths by ABO-incompatible transfusions are rare, estimated in 1 for every 8 millions, this is the biggest risk for patient's integrity.[13,14] Even so, there are the errors detected before initiating the transfusion, not reaching the patient's safety status, also known as near-misses.

The near-miss is a deviation from the standard procedure, detected before the beginning of transfusion, which could lead to a wrong transfusion or transfusion reaction. It is the moment the health professional notices the procedure is not being executed in a proper manner and corrects it before even acting.[5,9] The concept of near-miss began its discussion in 1998 by *The Serious Hazards of Transfusion Steering Group* (SHOT) in the United Kingdom. In this system, through the analysis of notifications, reports were elaborated from the most frequent events, followed by orientation and standardization for every service and health professional targeting the reduction of transfusion errors in the country. This measure was adopted to stimulate hospitals to report their near-misses, having as an explanation the importance of strengths and weaknesses indicators in a process.[15] By contrast, in Brazil the concept began being discussed after the publication of the Conceptual and Operational Mark of Hemovigilance in 2015.[9]

Aiming to assure that hemotherapy resources would be adequately applied, many countries including Brazil have established the Transfusion Committees, constituted by health professionals that periodically meet to define and evaluate transfusion procedures at their institutions. The main responsibility of the Transfusion Committee must be promoting and monitoring the safeness and effective use of blood and its components thereby minimizing errors.[11]

Survey of statistical data of incidents from the Transfusion Committee helps encouraging and setting safety measures in every stages of the cycle, comprising the phases: pre-analytical, analytical, transfusion procedure and post-analytical. Therefore, it is necessary to emphasize the importance of the occurrence of nonconformities or adverse events, and the way these reflect on quality and safety of the product, for either the donor or receiver.[9]

Since 2000, Brazil has discussed the hemovigilance process. From 2003 on, Brazilian legislation made mandatory notifications of donor seroconversions, the occurrence of errors during patient and donor classification procedures, errors in compatibility tests and transfusions (e. g. misidentifying blood), with the same purpose of the British group.[16] Considering the exposed, this study had the objective of obtaining data about the number of transfusions in a hospital of high complexity procedures, taking account of international protocols, as well as the comparison and evaluation of transfusion incidents and near-misses occurred in this institution.

Methods

After approval of this study by the Ethics in Research Committee (CEP) of University of Vale do Itajaí, under registration number 1.530.204, the hospital was randomly selected among those with high complexity hospital services and elevated transfusion demand. Transfusion data were collected from the hemotherapy institution to establish the average monthly transfusions in order to evaluate the hospital complexity.[2] The evaluated period of time was established accordingly with data obtained by hemovigilance of SHOT from 2015, since detection of transfusion incidents was 1:1000 packed red blood cell transfusions during this period.

The evaluated information in this research was obtained from the answers on a form elaborated by the researchers, based on the Conceptual and Operational Mark of Hemovigilance: Guide for Hemovigilance in Brazil in 2015, and valid legislation during the execution of the study.[1,2] The items contained on the forms were validated *in loco* by following up the routine activities of the Transfusion Agency (TA), certifying that the form comprised every adapted stage of the Itinerary of Inspection. After readjusting the forms, since it was necessary including some items non-contained in the legislation but present in the hemotherapy manuals, the researchers applied new validation for 5 more consecutive days *in loco* at the TA. From this moment on, the forms were established in conformity for observational evaluation of the researchers.

Once the forms were validated and the institution selected, this study was initiated at a TA of a hospital on the coast of Santa Catarina, from June 6th to September 23rd, 2016. Previously to the beginning of this study, a meeting with the coordination of the TA was addressed to give reliability to the obtained results from *in loco* observation and as an attempt to avoid interference from daily activities developed by other members of the institution. In this meeting it was defined that only the coordination of the TA would be aware of the real objectives of the researchers in place, according to approved project by the institution and CEP.

The obtained data from the forms were managed with Microsoft Excel® to facilitate their analysis. The data were classified as nonconformities, conformities and transfusion near-misses, and also sub-classified as pre-analytical, analytical and post-analytical. In addition, the transfusion data were segregated by shifts as: morning (08:00 am to 12:00 pm), afternoon (12:01 pm to 06:00 pm) and night (06:01 pm to 10:00 pm).

The collected and identified data and legal requirements were classified in items (IDs), being coded with letters and numbers. The capital letters correspond to the process stage and the numerical order was established according to the chronologically developed activities for execution of hemocomponent transfusion. After obtaining the data from the hemotherapy service, these were registered for determining the percentages of IDs during the research period. The conformities, incidents and near-misses detected in the hemotherapy service in the pre-analytical, analytical and post-analytical phases were evaluated and the inapplicable items were excluded from the results in the respective phases of *in loco* observation.

IDs from Chart 1 and 2 were evaluated separately and concomitantly with the requests of hemocomponent transfusion.

Chart 1 Evaluated items from established requirements from biological sample collection for registration of pre-transfusion tests, classified in their determined phases for hemocomponent releasing and their respective identification codes

Pre-analytical phase	
ID	**Description of evaluated item**
EAP 01	Patient's full name on transfusion requisition
EAP 02	Patient's birthdate on transfusion requisition
EAP 03	Identification of mother's name of patient on transfusion requisition
EAP 04	Patient's diagnosis on transfusion requisition
EAP 05	Laboratory tests, which justify hemocomponent transfusion.
EAP 06	Hemocomponent prescriber's identification on transfusion requisition
EAP 07	Solicitation date on transfusion requisition
EAP 08	Patient's positive identification at the moment of biological sample collection
EAP 09	Identification of biological sample tubes at patient's bed
EAP 10	Patient's legible name on collected biological sample
EAP 11	Patient's full name on collected biological sample
EAP 12	Collection date on collected biological sample
EAP 13	Collection time on collected biological sample
EAP 14	Blood collector's identification on collected biological sample
EAP 15	Installed patient's wristband id at the moment of biological sample collection
Analytical phase	
ID	**Description of evaluated item**
AP 01	Verification of legible name on biological sample and transfusion requisition
AP 02	Verification of patient's full name on collected biological sample and transfusion requisition
AP 03	Verification of collection date on biological sample and transfusion requisition
AP 04	Verification of collection time on biological sample and transfusion requisition
AP 05	Verification of blood collector's identification on collected biological sample
AP 06	Execution of ABO typing

Table Continued.....

Analytical phase	
AP 07	Execution of RhD phenotyping
AP 08	Execution of Irregular Antibodies Test
AP 09	Execution of Compatibility Test
AP 10	Execution of ABO and RhD Retyping of packed red blood cells
AP 11	Selection of hemocomponent specificity according to medical solicitation
AP 12	Releasing of blood bag with positive Test for Irregular Antibodies without Identification of specificity of Irregular Antibodies
AP 13	Visual inspection of hemocomponent to be transfused
Post-analytical phase	
ID	**Description of evaluated item**
TAP 01	Registration of patient's full name on book and/or transfusion computerized system
TAP 02	Registration of patient's birthdate on book and/or transfusion computerized system
TAP 03	Registration of mother's name of patient on book and/or transfusion computerized system
TAP 04	Registration of collection date of biological sample on book and/or transfusion computerized system
TAP 05	Registration of collection time of biological sample on book and/or transfusion computerized system
TAP 06	Registration of blood collector's identification on book and/or transfusion computerized system
TAP 07	Registration of ABO typing results on book and/or transfusion computerized system
TAP 08	Registration of RhD phenotyping results on book and/or transfusion computerized system
TAP 09	Registration of Irregular Antibodies Test results on book and/or transfusion computerized system
TAP 10	Registration of Compatibility Test results on book and/or transfusion computerized system
TAP 11	Registration of ABO and RhD Retyping of hemocomponent results on book and/or transfusion computerized system
TAP 12	Registration of hemocomponent specificity results on book and/or transfusion computerized system
TAP 13	Registration of Irregular Antibody specificity results on book and/or transfusion computerized system
TAP 14	Registration of previous transfusion reactions on book and/or transfusion computerized system

Legend ID: code of legal requirement abbreviated and classified according to the phase of hemotherapy procedure; EAP, pre-analytical phase; AP, analytical phase and TAP, post-analytical phase

Chart 2 Evaluated item from requirements established for execution of the transfusion procedure, classified in their determined phases for hemocomponent transfusion and their respective identification codes

Pre-analytical phase of transfusion procedure	
ID	**Description of evaluated item**
EAPTP 01	Positive patient's identification at the moment before transfusion
EAPTP 02	Verification of patient's wristband id with hemocomponent label
EAPTP 03	Asepsis on puncture area for hemocomponent transfusion
EAPTP 04	Verified patient's temperature
EAPTP 05	Verified patient's arterial pressure
EAPTP 06	Hemocomponent administrated in different via than the used for medication
Analytical phase of transfusion procedure	
ID	**Description of evaluated item**
APTP 01	Hemocomponent administrated in less than 4 hours after installation
APTP 02	Interrupted transfusion in case of transfusion reaction
Post-analytical phase of transfusion procedure	
ID	**Description of evaluated item**
TAPTP 01	Registration of verified patient's temperature on requisition and/or transfusion computerized system
TAPTP 2	Registration of verified patient's arterial pressure on requisition and/or transfusion computerized system
TAPTP 03	Face-to-face monitoring for 10 minutes after hemocomponent installation
TAPTP 04	Registration of transfusion starting time on requisition and/or transfusion computerized system
TAPTP 05	Registration of transfusion starting date on requisition and/or transfusion computerized system
TAPTP 06	Physician requested immediately in case of transfusion reaction
TAPTP 07	Registration of transfusion finalizing time on requisition and/or transfusion computerized system
TAPTP 08	Registration of transfusion finalizing date on requisition and/or transfusion computerized system
TAPTP 09	Notification in case of transfusion reaction

Legend ID: code of legal requirement abbreviated and classified according to the phase of hemotherapy procedure; EAPTP, pre-analytical phase of transfusion procedure; APTP, analytical phase of transfusion procedure and TAPTP, post-analytical phase of transfusion procedure

Results

During the 24 hours per day period of attending time at the TA, from June 6th to September 23rd, 2016, including the shifts in which the researches were not at the TA, 1958 hemocomponents were transfused, being 1474 (75.3%) of them erythrocytes, 305 (15.6%) fresh frozen plasma and 173 (8.8%) platelet hemocomponents. The high complexity services of the institution were established from the number of hemocomponent transfusions, a monthly average of 490 ± 139 hemocomponents.

Among these procedures, the researchers were *in loco* evaluating transfusion operational procedures of 230 hemocomponents. Thereby, 86 (37.4%) hemocomponents were requests from the morning shift, 67 (29.1%) afternoon and 77 (33.5%) night. Furthermore, the procedure records (technical and administrative) and pre-transfusion tests were also evaluate.There were 11,484 (100%) observation possibilities of the activities for execution of pre-transfusion tests, transfusions procedures and their respective registrations. Nevertheless, there were 10,562 (91.3%) IDs evaluated for conformities, nonconformities and near-misses in the institution, since 922 (8.7%) activities were not observed *in loco*, due to absence of the researchers at the TA. For this reason, these activities were not included in the results of the study. The items represented on Chart 3 and 4 are only those which showed nonconformities and/or near-misses.

Discussion

Evaluation of transfusion complexity

Studies that evaluated the quantity of hemocomponent transfusions in high complexity hemotherapy institutions detected erythrocytes

as the most transfused hemocomponent, followed by plasma and platelets.[17,18] These results corroborate those reported in this study, since the most transfused hemocomponents at the studied TA were erythrocytes as well. The reason for a bigger demand of erythrocyte hemocomponents at the TAs could be related with the complexity of procedures executed in the hospitals, as polytraumatized patients with acute hemorrhages and patients that need to undergo major surgery procedures.[19]

Chart 3 Absolute and percentage results of nonconformities and/or near-misses, obtained from *in loco* observation of the established requirements from biological sample collection to registration of pre-transfusion tests

Pre-analytical phase				Analytical phase			
ID	**C**	**NC**	**NM**	**ID**	**C**	**NC**	**NM**
EAP 01	227 (98.7%)	3 (1.3%)	0 (0%)	AP 08	160 (98.2%)	3 (1.8%)	0 (0%)
EAP 02	227 (98.7%)	3 (1.3%)	0 (0%)	AP 09	155 (95.1%)	8 (4.9%)	0 (0%)
EAP 03	227 (98.7%)	3 (1.3%)	0 (0%)	AP 12	208 (99.0%)	2 (1.0%)	0 (0%)
EAP 04	219 (95.2%)	11 (4.7%)	0 (0%)	AP 13	13 (9.5%)	124 (89.2%)	0 (0%)
EAP 05	224 (98.7%)	3 (1.3%)	0 (0%)				
EAP 06	199 (96.6%)	7 (3.39%)	0 (0%)				
EAP 08	69 (30.1%)	160 (69.9%)	0 (0%)				
EAP 09	185 (80.8%)	44 (19.2%)	0 (0%)				
EAP 10	224 (99.6%)	1 (0.4%)	0 (0%)				
EAP 11	220 (98.7%)	3 (1.3%)	0 (0%)				
EAP 12	227 (99.1%)	0 (0%)	2 (0.87%)				
EAP 13	227 (99.1%)	0 (0%)	2 (0.87%)				
EAP 15	187 (81.3%)	43 (18.7%)	0 (0%)				

Legend: ID: code of legal requirement abbreviated and classified according to the phase of hemotherapy procedure; C, conformity, accordingly with protocols and valid legislation, NC, nonconformity, accordingly with protocols and valid legislation, NM, near-miss detected, accordingly with protocols and valid legislation; EAP, pre-analytical phase; AP, analytical phase

Chart 4 Absolute and percentage results of nonconformities and/or near-misses, obtained from *in loco* observation of the established requirements for execution of transfusion procedures

Pre-analytical phase of transfusion procedure				Analytical phase of transfusion procedure				Post-analytical phase of transfusion procedure			
ID	**C**	**NC**	**NM**	**ID**	**C**	**NC**	**NM**	**ID**	**C**	**NC**	**NM**
EAPTP 01	55 (24.2%)	171 (75.3%)	1 (0.5%)	APTP 01	225 (99.1%)	2 (0.9%)	0 (0%)	TAPTP 01	176 (99.4%)	1 (0.6%)	0 (0%)
EAPTP 02	115 (50.7%)	112 (49.3%)	0 (0%)					TAPTP 02	175 (98.3%)	3 (1.7%)	0 (0%)
EAPTP 03	189 (98.4%)	3 (1.6%)	0 (0%)					TAPTP 03	40 (17.7%)	185 (81.9%)	1 (0.4%)
EAPTP 04	174 (96.7%)	5 (2.7%)	1 (0.6%)					TAPTP 07	221 (99.2%)	1 (0.4%)	1 (0.4%)
EAPTP 05	173 (96.1%)	4 (2.2%)	3 (1.7%)								

Legend ID: code of legal requirement abbreviated and classified according to the phase of hemotherapy procedure; C, conformity, accordingly with protocols and valid legislation, NC, nonconformity, accordingly with protocols and valid legislation, NM, near-miss detected, accordingly with protocols and valid legislation;

EAPTP, pre-analytical phase of transfusion procedure; APTP, Analytical phase of transfusion procedure and TAPTP, post-analytical phase of transfusion procedure

Aside from the quantity and specificity analysis of the blood component to be transfused, it was important to verify and evaluate the period of time used to execute these procedures. During the past time of this study with the researchers *in loco*, the morning shift was the period with more transfusion procedures, followed by night and afternoon. This corroborates national and international protocols and legal recommendations,[2,9,20] since international protocols establish that the main quantity of transfusions should be executed during day shifts to increase patient's transfusion safety.[21,22] Even fulfilling international recommendations of not transfusing during night shifts, 9 ABO-incompatible transfusions occurred on the day shift in Japan between 1995 and 2005, although these occurred on the day shift due to laboratory errors.[23]

From SHOT reports between 1996 and 2003, 30% of "wrong blood" incidents occurred in the laboratory, this elevated number of errors happened out of the high demand shift, in work under pressure conditions, when the staff of professionals in the laboratory is reduced and these could be relatively inexperienced. An inquiry about work overload in a laboratory in the United Kingdom indicated that 20% of pre-transfusion tests occurred out of business hours and 40% of laboratory errors notified to SHOT occur on this schedule. Urgent pre-transfusion tests are unsafe and represent a high potential of misinterpretation and documentation errors. [24]

Evaluation of pre-analytical phase

Concerns about ABO-incompatible transfusions are not recent. Previous studies have already detected that 3 out of 30 fatal transfusions were caused by identification error on the pre-transfusion sample collection.[25] Literature indicates that correct pre-transfusion sample identification as well as positive receiver patients' identification are fundamental pre-analytical procedures to avoid errors in hemocomponent transfusions that result in incompatible transfusions.[26]

Between 1996 and 2003, 226 cases of ABO-incompatible transfusions were reported to SHOT. During this period, 23 million hemocomponents were transfused by hemotherapy services in the United Kingdom, with a total of 2087 notified incidents. Out of these, 1393 (67%) were quoted as "wrong blood transfusion", with a patient receiving hemocomponents designated to another patient or receiving hemocomponents that did not go through procedures, as leukocyte removal, to meet the needs according transfusion prescription.[24]

Aside from countries in the United Kingdom that trace transfusions incidents, Japan performed 2 studies between 1995 and 2005. The first study analyzed 166 incidents from 578 hospitals, between 1995 and 1999, while the second study, executed between 2000 and 2004, identified 60 transfusion incidents in 829 studied hospitals. In both cases the main cause for ABO-incompatible transfusion was identification error between patient and hemocomponent: 91 (55%) in the first and 27 (45%) in the second study. The results showed 9 avoidable deaths in the first and 8 in the second study.[23] In the current study were found important nonconformities that could result in wrong blood in the right tube, as sample permutation or sample mislabeling (EAP 09 e EAP 15). It has been identified that ID EAP 08 (positive patient's identification at the moment of biological sample collection) was not executed in 69.9% of the observations during pre-analytical phase, according to valid legislation recommendation. Through *in loco* analysis during the study it has been inferred that this item was not executed correctly due to lack of knowledge that the execution of this could avoid countless unwanted transfusions, contributing to patient's safety.

Researchers presented that identifying and labeling of pre-transfusion samples are the main nonconformities in the pre-analytical phase.[27] A Brazilian study also demonstrated these nonconformities. In a simulation performed during the study, 76.1% (51/67) of professionals did not notice nor identify that the patient's requisition for hemocomponent transfusion was different than the patient in bed.[28] Other studies demonstrated that the main cause of transfusion incident is wrong blood in the tube.[24,29] The incident could occur when the samples are properly labeled and identified with the patient's data, but the error occurs at the moment of positive patient's identification. Therefore, the wrong blood is collected in the previously labeled tube, which could lead to ABO-incompatible transfusions. Also, mislabeling could occur when the tube is labeled and identified away from patient.[30]

ANVISA (National Sanitary Surveillance Agency) emphasizes that sample identification error remains the major cause of acute hemolytic transfusion reactions, due to permutation of patient's name and/or registration.[12] The current study detected that the most relevant items for correct pre-transfusion sample identification were not adequately executed. Thereby, nonconformities found in items EAP 09 (registration of Irregular Antibodies Test results on book and/or transfusion computerized system), EAP 10 (registration of Compatibility Test results on book and/or transfusion computerized system) and EAP 11 (registration of ABO and RhD Retyping of hemocomponent results on book and/or transfusion computerized system) are corroborated by literature. Through evaluations during execution of phases for transfusion tests, it was observed that numerous times the samples were labeled in the TA at the moment before collecting or when the professional returned to the TA after collecting, away from patient, with no positive identification, only based on requisition issued by the physician, which was printed by the hospital interfaced system. Due to hospital high demand, normally were executed more than one requisition at the time, consequently the professional in charge for sample collection left the TA aiming the execution of more than one collection, increasing even more the chance of occurring a transfusion incident.

In 2010, an audit performed among 8 hospitals in New Zealand indicated that 55% of the transfusion incidents occur in the positive patient's identification. Besides, the authors describe the execution error reasons of the same item evaluated in this study (EAP 08). The authors detected that 53% did not ask for patient's identification, 18% mentioned the name and asked for patient' confirmation, 14% asked for secondary identifications (birthdate), 14% justified the patients were unconscious or intubated, 1% did not execute it, due to the patient being asleep.[22]

With the intention of minimizing errors of pre-transfusion samples and patient's identification, bar code technology is currently utilized as a trace system to improve safeness of transfusion procedures. The application of this technology is recommended for sample collection, compatibility test and blood administration and it includes the use of portable computers which may be interfaced with the hospital system. It is known that patients with chronic transfusion dependency need a more durable than a standard wristband means of identification. The study also recommends in these cases an identification card with a photograph on it as a way to improve identification.[24] It is worth mentioning that the studied TA manually identifies every sample and registers patients' vital signs at the moment of transfusion. When arriving to the TA, after the transfusion procedure, professionals transcribe the information into the computerized system, which increases human interference and consequently provides even more transfusion incidents.

Although with the possibility of near-miss underreporting in the pre-analytical phase of the transfusion procedure, a nonconformities main quantity was detected with emphasis on IDs EAPTP 01 (positive patient's identification at the moment before transfusion) and EAPTP 02 (verification of patient's wristband id with hemocomponent label). These IDs evaluated the positive patient's identification at the moment immediately before transfusion and verification of patient's wristband id with hemocomponent label, according to valid legislation.[2] In Japan, misidentification between patient and hemocomponent occurred in 55% of cases from January 1995 to December 1999. Conversely, from January 2000 to 2004 was registered a decrease of these errors to 45% of cases. Among reported cases there were no technology-based identification systems, with the authors suggesting a simple positive identification method which significantly improves patient's safety through concomitantly utilization of nominal identification and numerated labels. That way, as well as the nominal and active verification of patients in every transfusion it is necessary numerical verification.[2,23] Another Brazilian study that evaluated the nursing staff through questionnaire about the same IDs evaluated in this study, EAPTP 01 and EAPTP 02, indicated that 100% of participants answered they followed this stage of the process.[31] Nonetheless, the present study evaluated professionals *in loco*, at the moment of executing the transfusion procedure, and in this case it was observed discrepancy between results and the way the study was executed, once Brazilian authors evaluated through questionnaires and this study applied *in loco* evaluation.

Evaluation of analytical phase

In Brazil, valid legislation determines that immunohematology tests to be executed in erythrocyte hemocomponents (RBCs) receivers are: ABO/RhD phenotyping, Irregular Antibodies Test (IAT), ABO and RhD Retyping of RBCs and compatibility test[2]. The execution of these tests promotes a safe and high quality transfusion for the patient, on the other hand avoiding the ABO/RhD phenotyping and/or the compatibility test could lead to an ABO-incompatible transfusion.[32,33] In this study, in relation to IAT, that aims detecting clinically significant antibodies from 35 blood systems, among the 36 existing systems,[34] it

was possible identifying the nonconformities in IDs AP 08 (execution of irregular antibodies test) and AP 09 (execution of compatibility test) that evaluated the execution of this test and the compatibility test. Not executing any of these tests is only justified when the patient's clinical status presents the need of an emergency transfusion.[2] In IDs AP 08 and AP 09 were verified the nonconformities since there were no emergency requisitions.

To prevent the nonconformities found in this study, the quality control systems look for more efficient ways that aim transfusion safety. These systems utilize the standardization of every process, improving communication between employees and documentation, allowing every patient's traceability. This way, the quality control system with patient's electronic documentation provides an effective way to reduce analytical errors, through an integrated database, comprising all the data from serological tests to the hemocomponent designed to the patient and also it is possible reducing laboratory errors, through electronic confirmation between blood receiver and compatibility of the selected blood units.[35]

Aside from hemocomponent-receiver integrated digital systems, it is possible preventing ABO-incompatible transfusions through transfusion management systems. These systems need a transfusion committee and a responsible hematologist physician to evaluate existing risks at the hospital unit. Additionally, in large hospitals it is performed a considerable daily amount of hemocomponent transfusions. In view of this, it is important hiring health professionals specialized in hemotherapy.[23] In the present study was observed that the analytic registration mechanisms are manual, performed by health professionals, being only one of them specialized in hemotherapy. However, manual registration hampers laboratory routine of transfusion agencies, mainly in high transfusion demand situations, as well as in emergency assistance situations.

Evaluation of post-analytical phase

Correct registration enables transfusion traceability, since it includes all the data of patients and professionals related to procedures. These registrations simplify traceability in case of transfusion reaction allowing finding main causes that provided the reaction.[1]

Studies have pointed out that transfusion errors occur in the post-analytical phase, mainly in the laboratory report releasing process and wrong transcription of them to the computerized system.[36,37] A study evaluating 578 Japanese people that underwent transfusion procedures between 1995 and 1999 showed that there were typing errors in 25 transfusions, being 17 cases by physicians and the others by laboratory technicians.[38] In another study, although the authors did not present statistical data about the errors, they affirmed that most typing errors occurred on holidays or night shifts and emergency cases.[39]

It is important to emphasize that the TA of the approached institution in this study presented 100% of conformities in Post-analytical IDs. This TA was in accreditation process through the Organization of National Accreditation (ONA) that aims promoting a constant evaluation and improvement process on health services. Besides, the institution participates of the State Program of Hematology Network Qualification (PEQH) from Ministry of Health, which annually executes technical visitations identifying processes, providing technical and scientific consultancies and therefore collaborating with the necessary adjustments according to Brazilian valid legislation. It is believed that the number of conformities in this phase is associated with the ONA accreditation process and the participation on PEQH, since these programs require transfusion procedure traceability. In the study with participation of the researchers *in loco* for a longer process than the ONA and PEQH evaluations, the nonconformities detected in other analytical phases were highlighted due to constant follow-up of transfusion processes, since ONA and PEQH stimulate the continuous improvement and traceability of processes.

It has been possible observing an expressive number of nonconformities, 185 (81.9%) and 1 (0.4%) near-miss in the ID TAPTP 03, which evaluates if the professional remains with the patient within the 10 first minutes of transfusion after installing the blood bag. A study performed in Brazil detected that 42% of professionals execute the ID TAPTP 03 eventually and 25% of them did not describe this activity.[31] Another study revealed that 61.7% of professionals described not utilizing the checklist before sample collection or blood transfusion[28]. Therefore, the present study demonstrates the importance of evaluation from responsible professionals, identifying if the employees are indeed executing the *in loco* patient's follow-up within the initial 10 minutes of transfusion.

Apart from the initial follow-up of patients, it is crucial their monitoring of vital signs.[9,40] Among hospitals in the United Kingdom, even with majority of patients (97.7%) receiving a safe transfusion, it was identified that some of them were exposed to identification errors and/or not experiencing the observed transfusion reaction, due to absence of identification wristband or lack of follow-ups during transfusion (2.3%).[41] The objective of these follow-ups is monitoring of vital signs, since it is common for transfusion reactions to occur in the initial moments of blood infusion, thus this follow-up allows intervention in case of reaction.[9,41,42] In the present study, only 9 (4.9%) nonconformities were identified in the vital signs evaluation in the pre-analytical phase. This low percentage also was verified in the registration of those vital signs with 4 (2.3%) events in the post-analytical phase. Because of the studied TA utilizes manual registrations, all the cited IDs totally relay on human based execution, consequently the errors are a direct effect of human behavior and whether stages are well executed or not.

Evaluation of near-misses

The near-miss is an event that anticipates the act, and which the professional is able to recognize before its execution and consequently damage to the patient, being considered by the researchers difficult to detect in the daily transfusion routine, since there were detected in 7 IDs (EAP 12, EAP 13, EAPTP 04, EAPTP 05, APTP 01, TAPTP 03 and TAPTP 07). The fact of detecting near-misses in these items denotes the attention of this procedure is fundamental to minimize transfusion errors. It is estimated that the low percentage could be underreported in this study, once this report depends on near-miss pointing by the observed employees that executed the procedure. This underreporting effect may be justified if considered that the researchers could not follow *in loco* every transfusion procedure, since the TA had 4 health professionals executing many activities in the evaluated period of time. It is emphasized as well that the researchers following *in loco* the activities for near-misses detection were in minor number than the employees executing procedures. Therefore, an employee that was not being observed could be producing a near-miss without being noted.

Among all the observations in this study, there were a low number of near-misses, totaling 11 (0.10%). This data is inferior to the registered by SHOT (2015) which evaluated 3288 transfusion incidents in 2015. The United Kingdom evaluated that 77.7% out of the 3288 incidents were produced by human errors. SHOT considered only 10% of these as inevitable by lack of mechanisms to detect them. Furthermore, 288 near-miss events were related to wrong blood in tube, which could result in ABO-incompatible transfusions[43]. The near-misses are important for potentially grievous results, and the

risk is bigger than the reports indicate, since many of these events are underreported by professionals and they are difficult to detect. Studies indicate that these events occur by some factors, such as a smaller the than necessary number of professionals or long multitasking shifts, which reflect an increasingly difficult and error-prone work environment.[38,43]

The near-miss experience is as serious as the error itself. Incorrect attitudes and small common error on a daily basis are indication that a bigger error is about to occur.[31,40,43] However, notification rates present a significant variability, especially when referred to near-misses and this fact limits to some extend the quantitative reliability of adverse event and incident reports. Health institutions tend to ignore events such as near-misses.[43]

Utilizing technology to minimize transfusion incidents

Attention of professionals that execute transfusion is something vital for patients. There were admittedly as human errors leading to transfusion reactions 27 (58.7%) out of 46 reports with diagnosis of acute hemolytic transfusion reactions.[44] It is known that human errors could be minimized with continuous training, aiming at exposing to the professionals the importance of developing activities with commitment, showing them every consequence that could possibly occur.[5]

The use of tools and practical improvements, as a checklist application aside of the patient right before transfusion preparation, could minimize errors and near-misses. It is greatly relevant the application of this checklist close to the patient. Although very useful information about transfusion reactions, the main risks remain to be the human factors. The recommendations of reducing errors through a back to basics approach remain relevant nowadays, as cited in the first annual report of SHOT.[43] Even with a proper legislation to follow in the United Kingdom, there are still occurrences of identification far from patients, which indicates the need of improvement in verifying processes through electronic means to reduce even more the chance of incidents.[43,45,46] However, simple changes in the processes could be an effective way to reduce errors in institutions that cannot adopt electronic means for safeness.[28,31,41,45,46]

Final considerations

The continuing education programs are simple and practical measures to reduce transfusion incidents and near-misses. Meanwhile, obtaining efficient results from continuing education becomes a difficult task, due to the accentuated staff turnover in hemotherapy institutions. Another factor that promotes the occurrence of transfusion incidents is the low demand of immunohematology tests, mainly for professionals executing activities with a lower number of transfusions. Thereby, these professionals need to search for information about test execution in standard operating procedures unavailable on electronic media. This search delays patient care or leads to the professional anticipation of processes preventing the accomplishment of stages defined in the operating procedure. Yet, the activity overload as those which require attention and emotional control from professional of the TA also contributes in the increase of transfusion incidents. Therefore, permanent education training and others that involve problem solving under emotional stress abilities are essential for the professional development of activities with attention and safeness towards the patient, minimizing transfusion incidents.

In this study, it has been possible to observe the importance of continuing education in relation to technical procedures that depend exclusively on human attention and aim at reducing errors of pre-transfusion samples collection and hemocomponent installation. The evaluation of abilities for execution of pre-analytical, analytical and post-analytical phases and the transfusion procedure is a fundamental tool in the detection of potential errors caused by employees.

There were no fatalities related to the incidents or near-misses detected in this study, however it was possible asserting that the *in loco* evaluation of activities at the TA is essential for transfusion incident detection. Besides, this *in loco* evaluation is capable of estimating underreport occurring in the hemotherapy service. It is also important emphasizing the role of health professionals' engagement in technical and scientific knowledge in analytical phases of the transfusion procedure, for monitoring of transfusions incidents and near-misses. In this way, the participation of hemotherapy institutions in accreditation or evaluation processes such as PEQH is crucial to minimize underreporting of transfusion errors and near-misses, preventing them to occur.

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Conflict of interest

The authors declare that there is no conflict of interest.

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