

HEMOVIGILANCE OF IMMEDIATE TRANSFUSION REACTIONS: OCCURRENCES, DEMAND AND CARE CAPACITY

HEMOVIGILÂNCIA DAS REAÇÕES TRANSFUSIONAIS IMEDIATAS: OCORRÊNCIAS, DEMANDA E CAPACIDADE DE ATENDIMENTO

HEMOVIGILANCE DE REACCIONES TRANSFUSIONALES INMEDIATAS: OCURRENCIAS, DEMANDA Y CAPACIDAD DE ATENCIÓN

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Objetivo: identificar e discutir a ocorrência de reações transfusionais imediatas, considerando o tipo de hemocomponente transfundido, demanda e capacidade de atendimento em um Hospital Universitário do estado da Bahia, Brasil. **Método:** estudo de caso, retrospectivo, quantitativo, realizado por meio de levantamento de registros e documentos. Análise descritiva das frequências e percentuais das ocorrências e tipologias das Reações Transfusionais, bem como da demanda e capacidade de atendimento da unidade de hemoterapia deste hospital. **Resultados:** frequência de 6,43% de Reações Transfusionais imediatas/1.000 hemocomponentes transfundidos. A Reação Febril Não Hemolítica e a Reação Alérgica foram as que mais ocorreram. Maior número de Reações Transfusionais foram do grau I (97,5%); os concentrados de hemácias (44,1%) e de plaquetas (41,9%) foram os hemocomponentes envolvidos na maioria das Reações Transfusionais. **Conclusão:** a unidade estudada mostrou capacidade de atendimento à demanda, com notificação das reações transfusionais e destaque de tais ações para contínuo aperfeiçoamento da qualidade.

Descritores: Segurança do Sangue. Reação Transfusional. Notificação. Sistemas de Informação. Serviço de Hemoterapia.

Objective: to identify and discuss the occurrence of immediate transfusion reactions, considering the type of transfused blood component, demand and care capacity in a University Hospital in the state of Bahia, Brazil. Method: case, retrospective, quantitative study, performed through the collection of records and documents. Descriptive analysis of the frequencies and percentages of occurrences and typologies of Transfusion Reactions, as well as the demand and capacity of the hemotherapy unit of this hospital. Results: frequency of 6.43% of immediate Transfusion Reactions/1,000 transfused blood components. The Nonhemolytic Febrile Reaction and Allergic Reaction were the ones that most occurred. The highest number of Transfusion Reactions were grade I (97.5%); red blood cell concentrates (44.1%) and platelets (41.9%) were the blood components involved in most Transfusion Reactions. Conclusion: the

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unit studied showed capacity to meet the demand, with notification of transfusion reactions and highlighting such actions for continuous quality improvement.

Descriptors: Blood Safety. Transfusion Reaction. Notification. Information Systems. Hemotherapy Service.

Objetivo: identificar y discutir la aparición de reacciones transfusionales inmediatas, considerando el tipo de componente sanguíneo transfundido, la demanda y la capacidad de atención en un Hospital Universitario en el estado de Bahía, Brasil. Método: estudio de caso práctico, retrospectivo, cuantitativo, realizado a través de la recopilación de registros y documentos. Análisis descriptivo de las frecuencias y porcentajes de ocurrencias y tipologías de reacciones transfusiones, así como la demanda y capacidad de la unidad de hemoterapia de este hospital. Resultados: frecuencia del 6,43% de las reacciones transfusiones inmediatas/1.000 componentes sanguíneos transfundidos. La Reacción Febril No-hemolítica y la Reacción Alérgica fueron las que más ocurrieron. El mayor número de reacciones transfusionales fue el grado I (97,5%); los concentrados de glóbulos rojos (44,1%) y plaquetas (41,9%) fueron los componentes sanguíneos involucrados en la mayoría de las reacciones transfusiones. Conclusión: la unidad estudiada mostró capacidad para satisfacer la demanda, con notificación de reacciones transfusiones y destacando tales acciones para la mejora continua de la calidad.

Descritores: Seguridad de la Sangre. Reacción Transfusional. Notificación. Sistemas de Información. Servicio de Hemoterapia.

Introduction

Transfusion safety and the quality of blood components have become a concern and a focus of concern for hemotherapy since the 1980s, due to the emergence of AIDS and Hepatitis C. Since then, transfusion safety has become a worldwide need and is based on processes in order to eliminate or reduce risks⁽¹⁾. There is a mobilization on the part of the public sector to improve practices, through the evaluation and continuous improvement in the work processes and the adoption of measures capable of monitoring and evaluating the quality of its products and services⁽²⁾.

Brazilian Hemosurveillance stands out for a set of surveillance methods that involve the blood cycle, aiming to include and ensure information on adverse events that occur during the blood cycle, with the purpose of “[...] preventing its manifestation or recurrence, improving the quality of processes and/or products, reducing risks in the hemotherapeutic process, increasing the transfusion safety of the donor and host”^(3:3).

In Brazil, from 2015, through the National Hemosurveillance System (NHS), the scope of hemosurveillance was expanded, including adverse events throughout the blood cycle, in hosts and donors, and not only those related to

transfusion, following international guidelines and trends⁽⁴⁾.

In order to expand the knowledge about the existing scientific production on Hemosurveillance and Transfusion Reactions (TR), a search was conducted at Lilacs, SciELO and MEDLINE, databases, based on selected descriptors – “Blood Safety” and “Transfusion Reaction” – and other terms – “*Hemovigilância*” and “*Incidentes transfusionais*” – used alone and with the following combination: “Blood Safety AND Transfusion Reactions”, “*Hemovigilância* AND Transfusion Reaction”, considering a recent 5-year time frame (2013 to 2017), returning 147 articles. After applying the exclusion criteria, 39 articles from 11 countries were selected. In this set, some studies that evaluate the frequency of transfusion reactions by type of blood components, associated with demographic data (age, gender, race) and signs and symptoms stand out⁽⁵⁻¹⁵⁾.

In Brazil, the absolute frequency of transfusion reactions notifications in the years 2002 through 2015 increased from 160 to 12,841 notifications/year. The increase in registrations from 2010 was due to the mandatory notification of TR. However, the number of underreporting is still very high. International parameters state that

the estimated percentage of TR underreporting is 15%, but according to Anvisa, the national parameter is not known⁽¹⁶⁾.

The transfusion act is not without risks, despite all the knowledge gathered and used thus far. The international literature shows that immediate transfusion reactions are predominant, although the proportion is different from that verified in the Brazilian reality. The notification of transfusion reactions has become a primordial instrument for the continuous improvement of the quality of blood and its products, as well as the safety of the transfusion act, which makes the Hemosurveillance System indispensable in this process.

This article aims to identify and discuss the occurrence of immediate TR, considering the type of transfused blood component, demand and care capacity in a University Hospital in the state of Bahia, Brazil.

Method

This is a retrospective, descriptive, quantitative study that adopts the case study as a research strategy.

The field of this study is characterized as a hospital and outpatient unit, classified as a university hospital (UH), one of which integrates and serves the UHS Network, being a reference in the state of Bahia. The Hemotherapy Unit (HU) that integrates this hospital is a transfusion agency (TA) that assists patients throughout the hospital complex, upon request for transfusion requested by a doctor. For the operation of this TA, the managers of the University and the Coordinating Hemocenter of Bahia, the Foundation of Hematology and Hemotherapy of Bahia (Hemoba), signed an agreement, through a contract, in which the HU team is responsible, from the management of blood components, in the hospital, to the traceability of use.

For the collection of secondary data, carried out between December 2018 and April 2019, records of 84 monthly HU productivity reports (referring to the years 2012 through 2018) were used, in addition to 405 notification forms of transfusion reactions (TR) that feed

the Health Surveillance Notification System (Notivisa) and data from the National Registry of Establishments (CNES). Documents were also consulted, including: Hospital management report, Clinical Epidemiology Center report and hemotherapy unit report. Other documents were also made available by the field, such as the University-HEMOBA contract, technical health inspection report, visit report, case books and operational procedures, as well as others of public access.

The selection of data and documents met the following inclusion criteria: data and production records from 2012 to 2018; documents and reports reporting to the organization and procedures for the production of HU and related to the notification and follow-up of transfusion reactions.

Microsoft Excel software was used for the organization and systematization of the data collected in the notification forms and in the monthly productivity reports. Next, graphs and tables containing the number of hospital beds for the period under analysis and data on hosts were produced, such as: ABO Rh group, age, gender, color, type of blood components used, hospital unit where transfusion occurred, frequency and type of immediate transfusion reaction occurred, severity of reaction, signs and symptoms evidenced. Thus, a descriptive analysis of the frequencies and percentages of occurrences and typologies of TR was carried out, as well as the demand and capacity to meet this HU.

It is noteworthy that the reference to *transfusions performed* refers, in this study, to the number of times a transfusion was performed, whether of red blood cell concentrate, platelet pool, fresh plasma or cryoprecipitate pool. The number of *transfused blood components* refers to the unit number of each blood component in each transfusion, and not to the pool that was produced.

This study was developed in accordance with Resolution n. 466/2012 of the National Health Council. The project was submitted to the Research Ethics Committee (REC) of the Institute of Collective Health of the Universidade Federal da Bahia (UFBA), Certificate of

Presentation for Ethical Appreciation (CAAE) n. 01605218.5.0000.5030, and approved by Opinion n. 3.003.450. It was also appreciated by the Ethics Committee of the University Hospital (UH) surveyed, as a co-participant institution, under protocol number CAAE 01605218.5.3001.0049 and Approval Opinion n. 3.100.746.

Results

The results are presented in two subsections entitled “Immediate transfusion reactions: notifications, profile of the affected population and its relationship with transfused blood components” and “Demand and care capacity of the HU”.

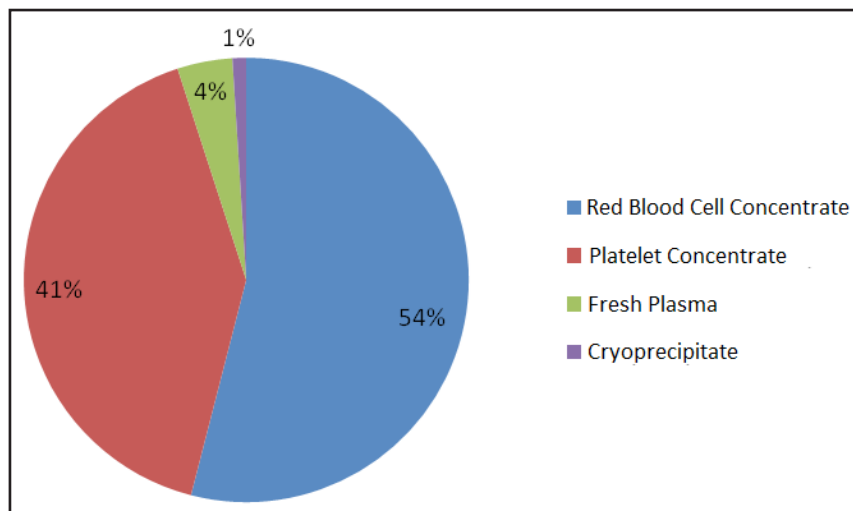
Immediate transfusion reactions: notifications, profile of the affected population and its relationship with transfused blood components

Of the 62,968 blood components transfused in this hospital from 2012 to 2018, 405 immediate

TRs were notified to Anvisa. The blood components most involved in these reactions were: 219 Red Blood Cell Concentrate (RBCC), 165 Platelet Concentrate (PC), 16 Fresh Frozen Plasma (FFP), 5 Cryoprecipitate.

Graph 1 shows the frequency of TRs reported by blood components during the study period. The blood component most involved in transfusion reactions was red blood cell concentrate, followed by platelet concentrate. These two blood components were involved in 95% of the reported transfusion reaction reports. The data presented in the graph were extracted from the 405 service forms. The most reported immediate transfusion reactions to Anvisa were: 261 Nonhemolytic Febrile Reactions (NHFR), followed by Allergic Reaction (AR) with 135 cases, 8 notifications such as Volume Overload (VO) and 1 reported case of Transfusion Related Acute Lung Injury (TRALI). During this period, hemolytic reaction (HR) was not observation.

Graph 1 – Frequency of blood component involved in immediate transfusion reactions at a University Hospital. Bahia, Brazil – 2012-2018

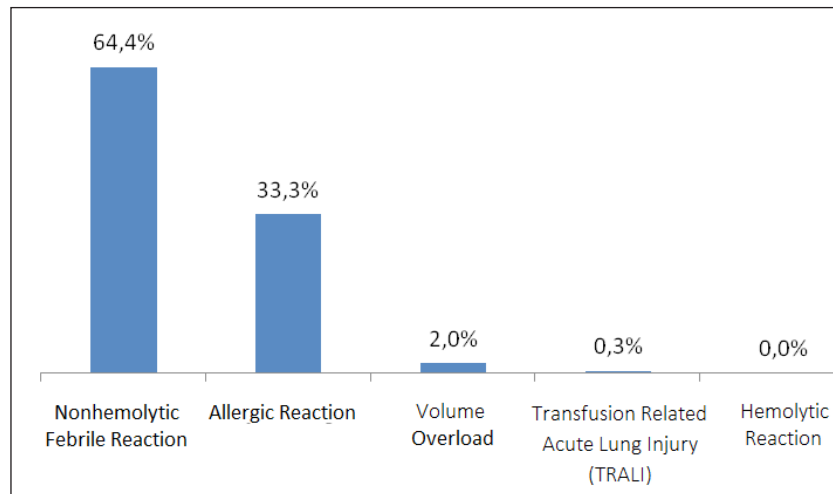


Source: Created by the authors.

Graph 2 shows the most frequent transfusion reactions, according to the notifications, with the Nonhemolytic Febrile Reaction (NHFR) as the most notified, followed by Allergic Reaction

(AR). These two types of transfusion reaction represented, together, 97.7% of the total. The data shown in the chart corresponds to the information from the 405 notification forms.

Graph 2 – Frequency of Transfusion Reactions notified at the University Hospital. Bahia, Brazil – 2012-2018



Source: Created by the authors.

Table 1 shows the frequency, in absolute and relative numbers, regarding the sociodemographic data of age group, gender, race/color of transfusion hosts, notified to

Hemosurveillance as those who reported and/or in which transfusion reaction was observed, in addition to the severity with which the TR presented.

Table 1 – Characterization of notifications sent by the University Hospital to Anvisa. Bahia, Brazil – 2012-2018. (N=405)

Variables	n	%
Age Group		
0 - 9 years	9	2.2
10 - 19 years	42	10.4
20 - 29 years	72	17.8
30 - 39 years	71	17.5
40 - 49 years	66	16.3
50 - 59 years	65	16.1
60 - 69 years	43	10.6
70 years or +	37	9.1
Sex		
Female	210	51.9
Male	195	48.1
Race/Color (1)		
Brown	275	67.9
Black	64	15.8
White	62	15.3
Yellow	1	0.2
Uninformed	3	0.8
Severity (2)		
Grade I	395	97.5
Grade II	6	1.5
Grade III	4	1
Total	405	100

Source: Created by the authors.

(1) In the race-color variable, there was no notification of Transfusion Reaction in indigenous women in the analyzed period.

(2) In the severity variable, there was no record of Grade IV Transfusion Reaction in the analyzed period.

There was no expressive concentration in any age group. Moreover, the lowest age of a patient whose TR was reported was 1 month of life, and the oldest, 86 years. Regarding the gender variable, there was no prevalence of transfusion reaction; concerning self-reported race/color, brown color prevailed. As to severity, TRs with grade I were the most notified. There were no grade IV reports, the one in which death can be attributed to adverse reactions.

During the period of this study, the infirmaries/units where transfusion reactions were evidenced were: hematology ward and outpatient clinic, with 233 records; Medical Clinic, with 66 notifications; Intensive Care Unit

(ICU), with 62 reactions; followed by Surgical Clinic, with 32 records; and, finally, Pediatric Clinic, with 12 notifications. There was no notification of immediate transfusion reaction, by spontaneous demand or active search, in patients in the Surgical Center.

Different signs and symptoms were grouped into 29 distinct groups, being reported 611 times in 405 patient recipients. Table 2 lists the 10 most frequently pointed out. It is worth mentioning that symptoms were identified that suggested a worsening of the clinical picture, such as bronchospasm (2 cases), acute pulmonary edema (1 case), convulsion (1 case), crepitus in lung basis (1 case).

Table 2 – Signs and symptoms perceived and reported in hosts who had an immediate transfusion reaction at the University Hospital. Bahia, Brazil – 2012-2018. (N=611)

N.	Signs/symptoms	Year								Total	%
		2012	2013	2014	2015	2016	2017	2018			
1	Fever	65	95	28	24	15	15	20	262	42.9	
2	Erythematous plaques/ Skin plaques/ Skin rash/ Burning in the face/ Papules in the face and body	8	17	5	6	24	32	22	114	18.7	
3	Hives/ Itching	9	10	4	14	17	18	21	93	15.2	
4	Dyspnea/ Respiratory distress/ Tachypnea/ Orthopnea	4	1	2	4	10	6	5	32	5.2	
5	Chill	6	3	1	4	4	2	6	26	4.2	
6	Eyelid edema / Lips edema / Ocular/ Periorbital region	-	-	1	-	5	5	7	18	2.9	
7	Shivering	4	3	-	4	1	1	3	16	2.6	
8	Cough/ Throat discomfort	1	-	-	-	2	3	2	8	1.3	
9	Hypertension	1	-	-	2	2	-	3	8	1.3	
10	Nausea/ Vomiting	-	5	1	1	-	-	-	7	1.1	

Source: Created by the authors.

Note: Conventional sign used:

- Numerical data equal to zero not resulting from rounding.

Demand and care capacity of the Hemotherapy Unit

HU receives from the Hemoba Foundation concentrated red blood cells, random platelet concentrate, platelet pool and platelets by apheresis, frozen plasma concentrate and cryoprecipitate.

From January 2012 to December 2018, 39,310 transfusions of 62,968 blood components were performed in 6,477 patients (hosts).

The most frequent distribution by ABO Rh group of blood component hosts in the HU was the group with “Rh positive”. Among the patients who received transfusion, most were from the O(+) group, followed by group A(+). The least

frequent groups regarding the blood typing of the hosts were those belonging to the “Rh negative”, with fewer recipient patients of group AB(-), followed by group B(-).

Regarding the number of transfusions by type of blood component, among the 62,968 blood transfusions, there was a higher number of RBCC transfusions, corresponding to 44.1% of the transfusions performed, followed by PC transfusion, with a quantity of 41.9% of infusions; subsequently, the most used blood component was the FPC, with 12.6% and, finally, 1.4% of the transfusions was cryoprecipitate.

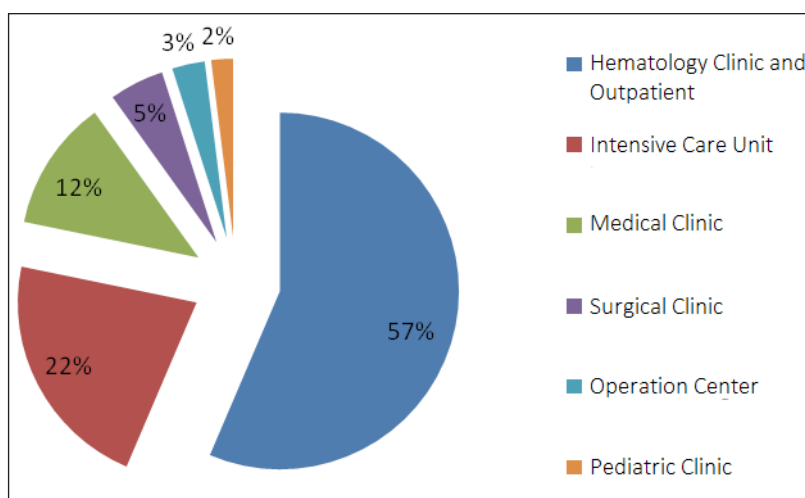
Transfusions occurred in all units/wards of the hospital. In this period, specifically, the quantities and places to which blood components were referred and transfused corresponded to: 36,165, in the infirmary and in the hematology outpatient clinic; 13,649 in ICUs; 7,222, in the specialty wards of Medical Clinics; 1,001, in the

Pediatric Clinic wards; 3,137, in Surgical Clinics; and 1,794 in the Operating Room.

The number of hematology, clinical, surgical and pediatric beds of the hospital, during the study period, ranged from 200 to 289; the number of ICU beds was between 10 and 20, according to data from the Epidemiology Center of the Hospital.

Graph 3 shows the frequency of transfusions performed per blood component unit, distributed by the units/infirmaries of hospitalization during the study period. Over half of the transfusions performed in this hospital occurred in the infirmary and outpatient clinic of hematology and bone marrow transplantation, followed by the ICU. The Pediatric Clinic was the place where there was a lower number of transfusions. The data shown in the graph correspond to the information of the 39,310 transfusions that occurred.

Graph 3 – Transfusion of blood components according to the care unit at the University Hospital. Bahia, Brazil – 2012-2018



Source: Created by the authors.

Discussion

Anvisa's Risk Monitoring Management hypothesized that the TR rate in the country is closer to 5 TR in 1,000 blood components, while the French Hemosurveillance system points to an expected incidence of three transfusion reactions in 1,000 transfused blood components⁽¹⁷⁾.

The case studied reported the frequency of 6.43 immediate TRs/1,000 transfused blood components. Other studies⁽¹⁸⁻¹⁹⁾ indicate variety in transfusion incidence rates of 1.7 and 3.9 per 1,000 transfused blood components, respectively.

Regarding the profile of such occurrences in the UH surveyed, regarding the gender variable, 51.9% of the immediate TRs occurred

in women and 48.2%, in men. The 2010 Anvisa Hemosurveillance Report⁽¹⁶⁾ generally notes a slight predominance of females. However, the differences between the sexes presented in studies^(14,20) did not exceed 3%, with the majority being female. The percentage distribution was the same for the sexes in a study⁽²¹⁾ that described the acute transfusion reaction in a Brazilian transfusion service, while, in a study on the epidemiology of immediate transfusion reactions⁽²²⁾, on the contrary, most TR were reported in males. Regarding the race/color variable, the most self-declared color was brown, followed by white and black color.

Transfusion reactions can be classified according to the time of onset, severity, correlation with transfusion (imputability) and diagnosis⁽³⁾. The NHFR and AR were the two immediate TRs most notified to Notivisa in the period from 2012 to 2018, reaching 97.7% of the total reactions, agreeing with what is disclosed in the reports of the Ministry of Health⁽¹⁶⁾. In Anvisa's Hemosurveillance Bulletin, there are reports of occurrence of NHFR and AR as the most prevalent, with accumulated rates of 48% and 36%, respectively, in the period 2013 and 2014⁽¹⁷⁾. Regarding the typology of transfusion reactions, immediate reactions totaled almost all reports of reactions (97%), against 3% of late reactions⁽²³⁾.

Specifically regarding the type of immediate TR, the data presented in this study differ from those found in studies^(20,22) that report the occurrence of a higher percentage of AR and then the NHFR. However, a study on transfusion reactions in a university hospital⁽²⁴⁾ reports that the TR that most occurred was the NHFR followed by AR.

There might be underreporting of cases of TRALI, as it is not always well differentiated from volume overload or congestive heart failure. Due to the similarity of the symptomatic picture with other adverse reactions, TRALI may often have been mistakenly reported, in some cases, as volume overload or as bacterial contamination, because the latter presents the same symptom: chills⁽²⁵⁾.

Regarding the type and severity of immediate TRs, the results of this study are similar to what is observed by the Ministry of Health⁽¹⁶⁾, with NHFR and AR as the most notified. They are also similar to that found in a study conducted in a university hospital⁽²⁴⁾. In the analysis of notifications of reactions by type of severity for 2014, Anvisa⁽¹⁷⁾ found that, in Brazil, mild severity represented 82.6%; moderate, 14.3%; severe, 2.8%; and death, 0.3%.

In relation to the units/infirmaries where the immediate TRs occurred, this study showed that 57.5% were notified in the hematology outpatient and infirmary, after medical clinics, followed by ICUs. For this fact, this may have occurred because the greatest number of transfusions was performed in those clinics instead of in ICUs. In 2016, there was a higher prevalence of TRs reported in a medical clinic, followed by the ICU/ICC and transfusion outpatient clinic⁽¹⁶⁾. It is similar to the one identified in a study⁽²⁴⁾ that reports the Oncology Unit as the one where TR was most reported, followed by the Medical Clinic and by critical and semi-critical units. The lowest percentages are also similar to those in this study, with surgical and pediatric clinics as the least notified. These results differ from the one found in a study⁽²²⁾ that identified the highest number of notifications in the Medical Clinic, followed by the Pediatric Clinic, Surgical Clinic and, only later, in the ICU.

Based on this study, fever, erythema plaques and pruritus were the most frequent signs/symptoms, even more evident in these reactions (NHFR and AR). Such evidence coincides with those found in a study⁽²⁰⁾ that brings, as the three most reported main signs/symptoms: hives, chills and fever. Research⁽¹⁴⁾ reports that the most perceived signs were fever, dyspnea and hives. Another study⁽²⁴⁾ reports fever, chills and/or sweating and dermis lesions as the most present signs in the notifications.

When verifying the data of this study, the blood components most involved in immediate TR were red blood cells concentrate, followed by platelet concentrate and fresh frozen plasma and, finally, cryoprecipitate. This frequency of

transfusions is similar to that found in a study developed in Northern Minas Gerais⁽²⁰⁾. RBCC was also identified as the most transfused blood component, but the second most transfused blood component was fresh plasma concentrate and not platelet concentrate and, finally, cryoprecipitate^(14,22).

An important limitation of the study was the availability of data only in printed version, which required more time for collection and may hinder other studies that require bigger time cutoff information.

The results are expected to support the development of new studies on adverse events presented by blood recipients, contributing to Public Health, since reflection and discussion on transfusion safety may potentially produce effects for improving the quality of care provided in institutions that perform transfusion therapy, in addition to adding new knowledge to health professionals working in this area.

Conclusion

This study aimed to identify and discuss the occurrence of immediate TRs, considering the type of transfused blood component, demand and care capacity in a University Hospital in the state of Bahia, Brazil.

The transfused blood components were red blood cells concentrate, platelet pool, fresh plasma or cryoprecipitate pool; the immediate TRs most notified to Anvisa were Nonhemolytic Febrile Reactions (NHRF), followed by Allergic Reaction (AR), notifications such as Volume Overload (VO) and Noncardiogenic Pulmonary Injury. The hospital studied presented the capacity to meet the transfusion demand.

The results and reflections presented here may stimulate new studies that allow better evaluating and understanding transfusion reactions, as well as stimulating/ensuring practices that promote greater safety of patients undergoing transfusion therapy.

It is worth highlighting the importance of computerization of the data, since the recording only in printed form limits the rapid access, as

well as may prevent studies that want greater period for analysis, since it will require more time for collection.

Collaborations:

1 – conception, design, analysis and interpretation of data: Marta Suzin Cercato and Mariluce Karla Bomfim de Souza;

2 – writing of the article and relevant critical review of the intellectual content: Marta Suzin Cercato and Mariluce Karla Bomfim de Souza;

3 – final approval of the version to be published: Marta Suzin Cercato and Mariluce Karla Bomfim de Souza.

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