



## Transfusion reactions: a challenge in hemovigilance

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### ABSTRACT

Hemovigilance is the set of surveillance procedures that covers the entire blood cycle, in order to obtain and make available information on adverse events occurring at different stages to prevent their occurrence or recurrence, improve the quality of processes and products and increase the safety of the donor and recipient. Objetivo: conhecer o perfil das reações transfusionais ocorridas entre os anos de 2002 a 2015. Methodology: The data available in the Ministry of Health publications from 2002 to 2015 on transfusion reactions and their characteristics were analyzed. Discussion: The rational

use of blood products for therapeutic purposes is the effect of a historical development, in which curiosity and the instinct of the human being's need for investigation were subjugating the obstacles of knowledge, making admissible a transfusion practice currently selective, but that in the beginning of the last century, went through trials often empirical, well or badly occurred, which harmonized the advanced scientific knowledge in the area of Hemotherapy Conclusion: Although we have compiled data, there is a need for periodic updating so that a quantitative analysis is carried out that permeates the number of transfusions and transfusion reactions notified in order to estimate underreporting and stimulate the permanent training of professionals who work in care.

**Keywords:** blood products, hemovigilance, transfusion reactions.

## 1 INTRODUCTION

Hemotherapy composes a therapy that aims to maintain the ability to conduct oxygen, sustain blood volume and hemostasis. Thus, blood and its derivatives are employed as support in the treatment of numerous pathologies, transplants, chemotherapies, and surgeries (GRANDI; GRELL; ARECO; BARBOSA, 2018).

When a patient exhibits an undesirable effect or response to the transfusion process and with the administration of blood or blood component, this is conceptualized as a Transfusion Reaction (RT). A RT may be the result of an incident during the blood cycle or from the recipient's interaction with and response to the donated blood, blood component, or a biologically active product. These complications are emergency occurrences and bring serious risks to transfusion recipients, including fatal (SOBRAL; GÖTTEMS; SANTANA, 2020).

*Transfusion reactions are graded by severity. Grade I*

- Mild, it does not offer risk to the life of the individual, whereas the grade II - moderate, can lead to long-term morbidity, as a result of the adverse event there may be the need to prolong the hospitalization process, in the same way it can cause persistent and significant disability or inability being imperative medical or surgical intervention to avoid permanent damage or direct impairment of an organ (or system) or functions; The degree III - severe, threatens the individual's life and may lead to death; and the degree IV - leads the patient to death (ALMEIDA; BORGES; LIMA, 2021).



## General procedures for the care of immediate transfusion reactions

1. Stop the transfusion;
2. Maintain venous access with 0.9% saline solution;
3. Check at the bedside that the blood component was correctly administered to the intended patient;
4. Check vital signs;
5. Report it to the patient's physician;
6. Notify the reaction to the hemotherapy service through a specific form;
7. Send the recipient's samples, when indicated, the blood component and its container to the hemotherapy service;
8. When indicated, send blood and/or urine samples from the recipient to the laboratory;
9. Record it in the medical record.

(FEDERAL)

REACTION	SIGNS/SYMPTOMS	EXAMS	ETIOLOGY/ INCIDENCE	MANAGEMENT AND TREATMENT	PREVENTION
<b>Acute hemolytic</b>	Restlessness, anxiety (feeling of imminent death) Sickness (thorax, fusion floor, abdomen, flanks) Severe hypotension Fever Chills Hemoglobinuria Hemoglobinemia	ABO/Rh D retype of the component and the recipient Pre and post-transfusion recipient FATHER of the pre and post-transfusion of the receiver. Direct antiglobulin post-transfusion test Prothrombin time Visual inspection of the patient's chest and urine	Incompatibility of the ABO system, more often. Antirhesus, anti-P1, anti-Lea with thermal amplitude, most rarely. Incidence: 1:70,000 - 1:38.000	Institution of intravenous and support measures Administer active vessels Maintain diuresis of 100 mL/h.	Attention at the stages related to the transfer of sample. Infusion rate in the first 50 ml.
<b>Febrile non-hemolytic</b>	Chills / shivering, Temperature increase (>1°C) Headache Nausea Vomiting  Pre-medicate with an antipyretic 30 to 60 minutes before the transfusion.	No aplasia (diagnóstico clínico de exclusão) Opção: do sag em o f antirhesus An ti-HLA and/or cytokinetic sag em.	Antirhesus contra leucócitos e doador Incidence: Pharmacy Concentrate: 1:200 - 1:17 (0,5-6%) Powder-filter < 0.5% Plasma concentrate: 1:100 - 1:3 (1-38%)	Antipyretic (avoid acetylsalicylic acid) For persistent chills: meperidine	DESLEUKOCYTE PRODUCTS FOR RECURRENT CASES



<p><b>Allergic</b></p>	<p>Pruritus Urticaria Erythema Papules Cough Rough skin</p>	<p>Not applicable (clinical diagnosis)</p>	<p>Anticoagulant prophylaxis Antihistamine Incidence: 1:100 - 1:33 (1-3%)</p>	<p>Most reactions are benign and can cease without treatment</p>	<p>ANTI-HISTAMINE 1st severe reaction: medicate before the next transfusions and/or wash the surrounding haemorrhages. After 2 or more reactions, wash the blood components.</p>
<p><b>Anaphylactic</b></p>	<p>Respiratory failure Wheezing Laryngeal edema Nausea/vomiting Hypotension Shock Usually the symptoms begin immediately after the start of the transfusion.</p>	<p>Dosage of IgA and/or antibody anti-Ig A</p>	<p>Anti-Ig A antibody Incidence: 1:50,000 - 1:20.000</p>	<p>Instituting intensive and - supportive measures Epinephrine Diphenhydramine Corticoid</p>	<p>Diphenhydramine 1 hour before transfusion Corticosteroid 2 to 6 hours before transfusion Autologous transfusion Washed blood components Blood components from IgA-deficient donors, if appropriate</p>
<p><b>Volume overload</b></p>	<p>Dyspnea, orthopnea, cyanosis, jugular distension, tachycardia, hypertension, peripheral edema, and dry cough. Pulmonary auscultation usually reveals gurgling.</p>	<p>Clinical diagnosis Chest X-ray Elevated BNP can help</p>	<p>Excess volume Incidence &lt; 1%</p>	<p>O2 SUPPORT Diuretics</p>	<p>Infusion rate and volume control Fractionating the bag for infusing smaller volumes</p>
<p><b>Bacterial contamination</b></p>	<p>Tremors Chills Fever Hypotension Nausea Vomiting Shock</p>	<p>Hemoculture of the component and the recipient</p>	<p>Contaminated blood component Incidence: Platelet concentrate: 1:38,000 - 1:3000 RBC concentrate: 1:172.000 - 1:25.000</p>	<p>Instituting intensive and - supportive measures Administer appropriate broad-spectrum antibiotics</p>	<p>Care in the steps of the blood cycle, regarding the reduction of bacterial contamination risks.</p>
<p><b>Transfusion-related lung injury - TRALI</b></p>	<p>Hypoxemia, dyspnea, respiratory insufficiency, FEVER, BILATERAL PULMONARY EDEMA</p>	<p>Discard hemolysis; search for anti-wBC antibodies in the donor and in the patient; Chest x-ray; Low O2 concentration</p>	<p>Antileukocyte antibodies in donor (sometimes in patient), possibly immunological Incidence: Unknown, but reported from 1/5,000 to 1/190,000 transfusions</p>	<p>Respiratory support Refuse related donors</p>	<p>There is no unanimity. Do not use plasma from involved donor in case of TRALI.</p>
<p><b>Hypotensive reaction</b></p>	<p>Drop in BP, anxiety, malaise, and sudoresis, in the absence of fever, chills or shaking</p>	<p>Not applicable (clinical diagnosis) Incidence: unknown</p>	<p>PATIENTS ON ECA USE USE OF FILTERS AT THE BEDSIDE READ O</p>	<p>Hold in Trendelenburg position Infuse 0.9% saline solution</p>	<p>The use of bench filters for leukocyte removal is recommended.</p>



<b>Non-Immune Hemolysis</b>	Oligosymptomatic Attention to the presence of hemoglobinuria and hemoglobinemia	Visual inspection of the patient's plasma and urine	Cell destruction before transfusion in general due to the action of chemical or mechanical agents Incidence: rare.	Patient observation and renal function monitoring Stimulate diuresis until the mel-time of the condition hemoglobinemia and hemoglobinuria	REVIEW OF PROCESSES AND CORRECTION OF CAUSES
<b>Metabolic disorders Hipopocalcemia</b>	Paresthesia, tetany, arrhythmias	Serum calcium ion levels Electrocardiogram	Rapid or excessive citrate infusion (transfusion massive, late citrate metabolism) The incidence depends on the clinical situation Etiology unknown (use of a bench filter? anti-HLA? antibody) Incidence: 1:4,500	Slow calcium replacement with periodic monitoring of serum levels	Monitoring calcium ion levels in patients receiving massive transfusions
<b>Acute pain related to transfusion</b>	Short acute pain duration in region LUMBAR, THORACIC, AND UPPER LIMBS, NOT ASSOCIATED WITH OTHER SIGNS AND SYMPTOMS.	Not applicable (clinical diagnosis of exclusion)	Etiology unknown (use of a bench filter? anti-HLA? antibody) Incidence: 1:4,500	Analgesics	There are no pre-emption methods
<b>Hyperemolysis syndrome</b>	Fever and/or hemoglobinuria and/or DOLOROSA crisis.	Search and identification of irregular antibody Direct antiglobulin test Hemolysis tests Incidence: 1:25 (4%) in sickle cell patients	Production of alloantico rpo or autoantico rpo antieritro c i - tary (including the HLA system), against plasma proteins or against a component triggering binding antigen-a n tic orpo e  complement activation .	Intravenous corticoid and/or immune globulin Immediately after reaction, blood transfusions should be avoided and reserved for life-threatening anemia situations and should ALWAYS BE PREVENTED from medication.	Transfusions respecting antigens D, E, e, C, c, K, whenever possible.



One form of RT prevention is the use of a special blood component, which is altered by washing, irradiation, or leukoreduction. In the washing process, the packed red blood cells (PRBC) and platelet concentrate (PC) are submitted to an isotonic solution of sterile sodium chloride to eliminate as much plasma as possible, then centrifuged and the NaCl is removed. Gamma rays are used in the irradiation, which do not allow the multiplication of lymphocytes. Leukoreduction removes the WBCs through a special filter, resulting in a quantity of less than  $5 \times 10^6$  WBCs per unit of CH, and can be performed pre-storage or post-storage (near the time of transfusion). WBCs can be leukoreduced by plasmapheresis (DA SILVA; TROVÃO, 2021).

Hemovigilance is the set of health surveillance procedures that includes the analysis of the entire blood circuit, aiming to obtain and make available data on adverse events arising from the different phases in order to prevent the manifestation or recurrence of RT, improving the quality of methodologies and products and, consequently, increasing the safety of the blood donor and transfusion recipient (FERREIRA; SANTOS; DA SILVA et al., 2021).

The research process is a post-use evaluation of the blood and its components, with the perspective of incorporating information for a more consistent analysis of the results and promote the appropriate measures for the improvement of the hemotherapy process. The implementation of the SNH began, within the sentinel hospitals network, with the proposal to progressively reach all hemotherapy services and health services that perform transfusion in the country (DE SOUZA; CERQUEIRA, 2019).

## **2 GOALS**

### **2.1 GENERAL OBJECTIVE**

To know the profile of transfusion reactions that occurred between the years 2002 and 2015.

### **2.2 SPECIFIC GOAL**

To verify the peculiarities in the profile of transfusion reactions notified between the years 2002 to 2015.

## **3 METHODOLOGY**

The data available in the publications of the Ministry of Health from 2002 to 2015 were analyzed. The justification for choosing this period is because the information became public after the release of the Consolidated Report 2007-2015. The National System of Hemovigilance (SNH), created in 2001, is an evaluation and alert system, inserted in the process of post-use sanitary surveillance of products under sanitary surveillance - Vigipós, and organized with the purpose of collecting and



evaluating information on the undesirable and/or unexpected effects of the use of blood products in order to prevent their appearance or recurrence.

After the data analysis, the following analyses were performed:

- a- Absolute frequency of transfusion reaction notifications, according to year of notification and year of occurrence. Brazil, 2002 to 2015;
- b- Absolute frequency of transfusion reaction notifications by region and Federation Unit, according to year of notification. Brazil, 2002 to 2015;
- c- Absolute frequency of health services notifying transfusion reactions, according to year of notification. Brazil, 2002 to 2015;
- d- Frequency of notifying services in the period and percentage of notifiers in 2015, by Federal State. Brazil, 2007 to 2015;
- e- Absolute frequency of transfusion reactions notifications, according to participation or not of the service in the Rede Sentinela. Brazil, 2013 and 2015;
- f- Relative frequency of transfusion reactions notifications, by sector of occurrence. Brazil, 2007 to 2015.
- g- Absolute (f) and relative (%) frequencies of transfusion reactions reported, according to the blood components associated with the reactions. Brazil, 2007 to 2015;
- h- Absolute frequency of notifications, by year of occurrence of transfusion reactions, according to sex and age group. Brazil, 2007 to 2015.
- i- Relative frequency of notifications of transfusion reactions, according to age group and year of occurrence. Brazil, 2007 to 2015.

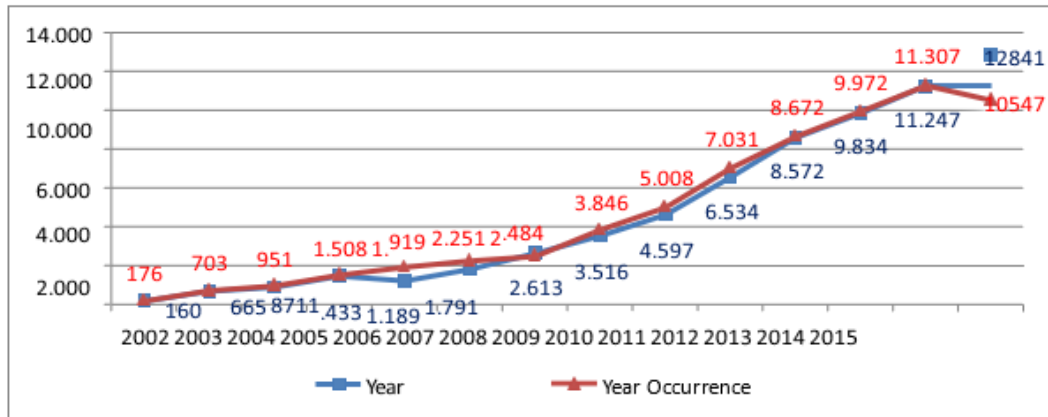
#### **4 RESULTS AND DISCUSSION**

The rational use of blood components for therapeutic purposes is the effect of a historical development, in which curiosity and the instinct of the human being's need for investigation were subduing the obstacles of knowledge, making admissible a transfusion practice that is currently selective, but that, at the beginning of the last century, went through trials that were often empirical, well or badly occurred, which harmonized the advanced scientific knowledge in the area of Hemotherapy. Today, transfusion is considered proven effective, when well employed, and relatively safe (GONÇALVES, 2018).

Chart 1 shows the frequency curves of transfusion reactions (RTs) by year of notification and year of occurrence, with ascending characteristics since 2002. Between 2013 and 2015, the average increase in the number of notifications was 14.0% (Chart 1).



Graph 1. Absolute frequency of transfusion reaction notifications, according to year of notification and year of occurrence. Brazil, 2002 to 2015;



Source: Sineps (data from 2002 to 2006, plus frequencies in Notivisa) and Notivisa (data from 2007 to 2015).

Table 1 presents the frequency of notifications for each Federal Government since 2002, by year of notification, and charts 2.1 to 2.5 show the evolutions in the notifications from the UFs for each region.

Table 1: Absolute frequency of transfusion reactions notifications, by region and UF, according to year of notification. Brazil, 2002 to 2015.

UF	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
DF	0	0	0	0	0	0	0	1	60	115	385	209	222	239
GO	0	0	1	0	0	9	13	6	3	17	81	112	186	240
MS	0	0	0	6	7	0	0	26	46	26	38	69	39	45
MT	0	0	0	0	0	0	0	0	0	13	29	14	22	28
Midwest	0	0	1	6	7	9	13	33	109	171	533	404	469	552
AL	0	16	7	8	4	9	11	44	28	30	57	77	51	72
BA	28	50	34	69	86	83	150	226	367	353	421	496	477	538
CE	1	54	24	32	76	217	113	107	359	565	413	415	574	661
MA	0	0	0	4	3	25	31	41	67	35	185	145	139	115
PB	0	3	0	0	0	0	17	22	108	138	124	97	105	111
PE	0	0	12	6	0	5	43	91	57	155	110	205	334	383
PI	0	0	0	0	0	0	0	0	0	1	59	55	45	68
RN	0	1	0	0	0	0	0	3	6	6	33	41	29	21
IF	0	0	0	0	0	0	0	0	0	12	22	37	37	93
Northeast	29	124	77	119	169	339	365	534	992	1295	1424	1568	1791	2062
AC	4	10	6	9	5	1	3	6	22	22	20	27	32	26
AP	0	0	0	0	0	0	4	0	0	0	0	0	6	0
AM	0	0	0	0	0	40	31	33	9	30	101	77	96	115
PA	0	7	3	12	6	11	67	35	104	366	254	181	169	139
RO	0	0	0	0	0	8	30	12	6	17	29	58	67	114
RR	0	0	0	0	0	0	0	0	1	0	0	0	28	56
TO	0	0	0	0	0	0	0	2	0	13	14	2	40	31
North	4	17	9	21	11	60	135	88	142	448	418	345	438	481
ES	0	0	0	0	0	0	32	23	21	50	159	197	289	357
MG	2	4	17	0	0	26	53	93	61	173	188	315	312	729
RJ	59	54	57	140	118	157	270	247	293	512	861	1173	1178	1126
SP	24	98	438	777	585	806	1212	1603	1845	2536	3306	3831	4424	4852
Southeast	85	156	512	917	703	989	1567	1966	2220	3271	4514	5516	6203	7064
PR	41	173	186	171	204	120	246	341	326	382	558	658	734	976
RS	1	184	57	60	20	133	212	338	466	661	715	871	1071	1062
SC	0	11	29	139	75	141	75	216	342	306	410	472	541	644
South	42	368	272	370	299	394	533	895	1134	1349	1683	2001	2346	2682
Brazil	160	665	871	1433	1189	1791	2613	3516	4597	6534	8572	9834	11247	12841

Source: Sineps (data from 2002 to 2006) and Notivisa (data from 2007 to 2015).

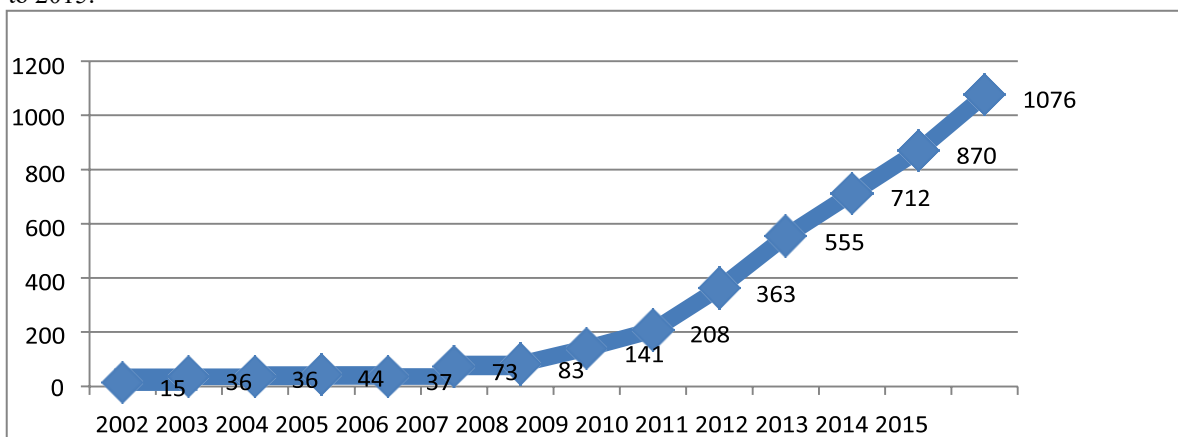


Chart 2 below shows the evolution of the frequency of health services that notify since 2002, noting that between 2002 and 2006, the notifying services were only those participating in the Rede Sentinela. Since 2007, with the implementation of Notivisa, all services that perform transfusions can notify.

In this graph, it can be seen that the curve becomes progressively upward from 2007, with the introduction of Notivisa, which reveals the contribution of this system to facilitate and expand the notifications. In December

In 2010, with the publication of the RDC 57, replaced by RDC 34/2014, it was established the obligation to notify RTs, contributing to the increase observed in the respective curves.

Graph 2. Absolute frequency of health services notifying transfusion reactions, according to year of notification. Brazil, 2002 to 2015.



Source: Sineps (data from 2002 to 2006) and Notivisa (data from 2007 to 2015).

Table 2 presents the frequency of services that notified year by year from 2007 to 2015 in each Federation Unit and the percentage of notifying services, by Federal Government for the year 2015. The percentage was built considering the estimated number of health services with complexity to perform blood transfusion registered in the CNES in each UF. It is observed the low density of notifying services in all states - none of them reaches 50% of notification. The UF with the highest percentage of services that notified in 2015 is the Federal District, with 42.6%. The state of Minas Gerais went from 6.3% of notifying services in 2014 to 19.7% in 2015, showing an important notification effort. Amapá is the UF that represents the greatest concern in this set because it was silent for most of the period analyzed, but other UFs such as Tocantins, Maranhão, Mato Grosso, and Mato Grosso do Sul also reveal weaknesses in local health surveillance action.

Even with the annual increase in the percentage of services that notify in the country, as shown in graph 3, they represented only 15.6% in 2015. As there is no information nationwide on the frequency of transfusions per health service, it is not possible to assess whether the services that report are those with the highest volume of transfusions.





Table 2: Frequency of notifying services in the period and percentage of notifiers in 2015, by Federal State. Brazil, 2007 to 2015.

Region/UF	Frequency of notifying services/ Year									% in 2015
	2007	2008	2009	2010	2011	2012	2013	2014	2015	
Federal District	0	0	1	3	8	33	29	30	29	<b>42,6</b>
Goiás	2	1	1	2	4	19	35	46	48	<b>10,6</b>
Mato Grosso do Sul	0	0	2	1	2	5	6	5	4	<b>3,0</b>
Mato Grosso	0	0	0	1	3	3	3	7	7	<b>3,7</b>
<b>C. West</b>	<b>2</b>	<b>1</b>	<b>4</b>	<b>7</b>	<b>17</b>	<b>60</b>	<b>73</b>	<b>88</b>	<b>88</b>	<b>10,5</b>
Alagoas	3	2	3	4	6	6	6	5	4	<b>5,3</b>
Bahia	4	3	8	22	22	26	33	42	46	<b>8,0</b>
Ceará	5	5	5	8	18	18	37	30	35	<b>12,5</b>
Maranhão	2	2	2	2	1	3	3	5	4	<b>1,6</b>
Paraíba	0	1	2	7	9	8	13	11	14	<b>8,8</b>
Pernambuco	3	3	4	2	8	9	19	37	33	<b>12,5</b>
Piauí	0	0	0	0	0	6	9	8	7	<b>5,5</b>
Rio Grande do Norte	0	0	1	1	2	8	12	9	6	<b>5,4</b>
Sergipe	0	0	0	0	4	6	8	9	9	<b>17,0</b>
<b>Northeast</b>	<b>17</b>	<b>16</b>	<b>25</b>	<b>46</b>	<b>70</b>	<b>90</b>	<b>140</b>	<b>156</b>	<b>158</b>	<b>8,3</b>
Acre	1	1	1	1	3	3	2	4	3	<b>12,5</b>
Amapá	0	2	0	0	0	0	0	1	0	<b>0,0</b>
Amazon	1	1	1	0	1	6	14	13	15	<b>14,0</b>
Pará	1	4	5	17	52	47	35	34	24	<b>9,8</b>
Rondônia	1	2	2	1	2	3	5	8	18	<b>20,7</b>
Roraima	0	0	0	0	0	0	0	2	4	<b>30,8</b>
Tocantins	0	0	1	0	2	1	1	3	2	<b>2,9</b>
<b>North</b>	<b>4</b>	<b>10</b>	<b>10</b>	<b>19</b>	<b>60</b>	<b>60</b>	<b>57</b>	<b>65</b>	<b>66</b>	<b>11,9</b>
Holy Spirit	0	2	2	2	5	20	28	34	38	<b>32,8</b>
Minas Gerais	3	3	3	5	17	22	31	42	137	<b>19,7</b>
Rio de Janeiro	10	10	19	23	54	90	115	127	140	<b>24,8</b>
São Paulo	24	24	49	63	89	118	160	224	285	<b>25,3</b>
<b>Southeast</b>	<b>37</b>	<b>39</b>	<b>73</b>	<b>93</b>	<b>165</b>	<b>250</b>	<b>334</b>	<b>427</b>	<b>600</b>	<b>24,0</b>
Paraná	4	5	9	11	10	27	37	58	65	<b>12,8</b>
Rio Grande do Sul	4	7	7	11	24	37	43	46	57	<b>15,4</b>
Santa Catarina	5	5	13	21	17	31	28	30	42	<b>17,8</b>
<b>South</b>	<b>13</b>	<b>17</b>	<b>29</b>	<b>43</b>	<b>51</b>	<b>95</b>	<b>108</b>	<b>134</b>	<b>164</b>	<b>14,7</b>
<b>Brazil</b>	<b>73</b>	<b>83</b>	<b>141</b>	<b>208</b>	<b>363</b>	<b>555</b>	<b>712</b>	<b>870</b>	<b>1076</b>	<b>15,6</b>

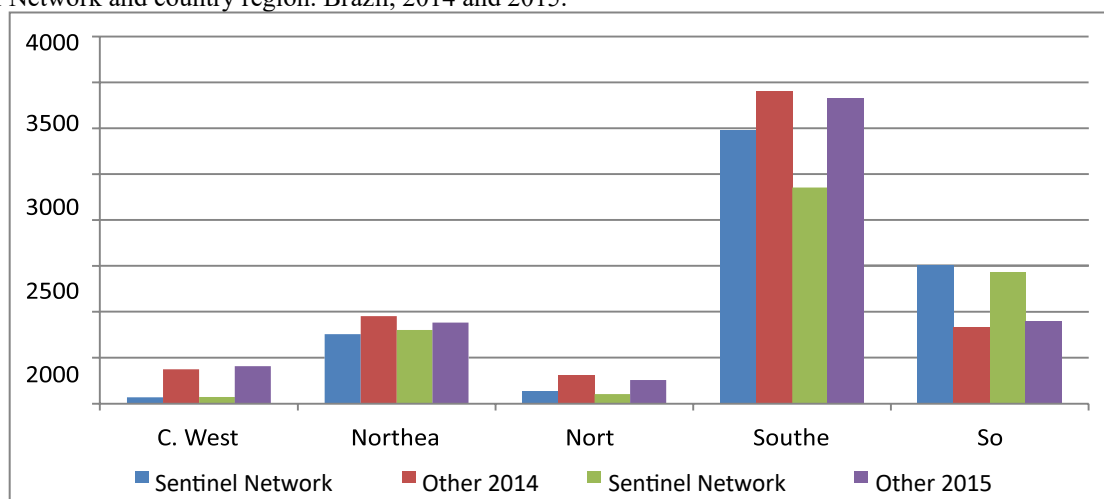
Source: Ministry of Health (Cadastro Nacional de Estabelecimentos de Saúde, competence December 2015, and Cadernode Informação: Sangue e Hemoderivados); Anvisa (Notivisa).

With regard to the participation of the Sentinel Network services in transfusion notifications, in 2014 there was a change in the criteria for accreditation to the Network, with the disaccreditation of some services and the accreditation of others.

Thus, Chart 3, shows this difference in participation in the notification of services participating or not in the Sentinel Network, by region of the country. The Sentinel Network services totaled 219 services in December 2015. Considering that in Brazil there are about 7,500 health services with complexity to perform blood transfusions, we can infer the importance of the Sentinel Network in the notifications of transfusion reactions.



Graph 3. Absolute frequency of transfusion reaction notifications, according to participation or not of the service in the Sentinel Network and country region. Brazil, 2014 and 2015.



Source: Ministry of Health (Cadastro Nacional de Estabelecimentos de Saúde, competence December 2015, and Cadernode Informação: Sangue e Hemoderivados); Anvisa (Notivisa), 2015.

As 2007 was the year of the effective implementation of Notivisa, the other analyses will be presented with the historical series starting in that year. Furthermore, the information presented will be based on the notification data by year of occurrence.

Table 3 shows the relative frequency of notifications, according to the sector of occurrence of transfusion reactions for the period measured. In this series, the sector with the highest prevalence of reported RTs is the medical clinic, followed by the ICU/ICU and transfusion outpatient clinic. Perhaps because they are the most prevalent transfusions, but not for the risk of reactions, since the denominator, that is, the frequency of transfusions performed in these sectors in the same period, is not known.

Table 3: Relative frequency of transfusion reactions notifications, by sector of occurrence. Brazil, 2007 to 2015.

Sector	Year	2007	2008	2009	2010	2011	2012	2013	2014	2015
Medical Clinic		37,4	34,1	32,4	34,9	35,0	34,9	34,4	35,4	34,6
Clinical Surgery		8,6	9,2	8,3	9,1	8,9	8,4	8,2	7,6	6,8
Pediatric Clinic		5,3	6,6	6,8	6,7	6,7	7,0	6,6	5,2	5,5
Gyneco-Obstetrics		2,7	3,3	2,8	3,0	2,6	2,6	2,1	2,4	2,3
Surgical Center		1,9	1,4	2,2	2,2	1,5	1,6	1,7	1,9	1,9
Obstetric Center		1,4	1,3	0,8	0,7	0,9	0,8	0,7	0,8	0,7
ICU/CICU		9,3	9,3	10,3	11,9	11,2	13,3	14,5	13,8	15,3
Emergency/PS		7,3	8,2	8,0	8,7	9,5	9,4	9,1	10,0	11,1
Transfusion Clinic		11,0	14,7	12,7	11,2	13,7	14,2	14,0	13,6	12,7
Home Transfusion		0,0	0,0	0,0	0,1	0,1	0,0	0,1	0,1	0,0
Dialysis Clinic		1,0	1,3	1,3	1,2	1,5	1,6	1,1	1,3	1,1
Cl. TMO		4,8	4,3	5,0	3,8	3,2	4,1	5,6	5,8	5,4
Not Informed		9,3	6,4	9,4	6,4	5,3	2,0	1,9	2,1	2,6

Source: Ministry of Health (Cadastro Nacional de Estabelecimentos de Saúde, competence December 2015, and Cadernode Informação: Sangue e Hemoderivados); Anvisa (Notivisa).



Table 4 presents the absolute and relative frequencies of the notifications of transfusion reactions, according to the type of blood component transfused and the year of occurrence of the reaction. The packed red blood cells is the blood component most associated with the reported RTs in the years of the series. The risk of this blood component is presented in item 7 of this report.

In Brazil, the RT notification system is compulsory since 2010, according to the RDC 57/2010, but even after many years of the creation of this RDC, it is verified that the notifications are still little performed. The underreporting of RT can be linked to several reasons, such as absence of information about the transfusion act and the route, failures of systematic monitoring of the transfusion; insecurity of the health team to correlate the clinical manifestations to the use of blood products or lack of knowledge of the specific propedeutics for each RT. Still in this sense, a study conducted in the United States of America in 2015 showed that the lack of notification and information from the sectors about the possibility of RT to the Transfusion Agency can reach up to 75% of the events (GEHRIE; HENDRICKSON; TORMEY, 2015).



Table 4: Absolute (f) and relative (%) frequencies of transfusion reactions reported, according to the blood components associated with the reactions. Brazil, 2007 to 2015.

	2007		2008		2009		2010		2011		2012		2013		2014		2015	
	F	%	F	%	F	%	F	%	F	%	F	%	F	%	F	%	F	%
RBC Concentrate	1.554	69,0	1.722	69,3	2.605	67,7	3.560	71,1	4.993	71,0	6.002	69,2	6.835	68,5	7.875	69,6	7.233	68,6
Platelet Concentrate	489	21,7	553	22,3	867	22,5	1035	20,7	1404	20,0	1929	22,2	2341	23,5	2611	23,1	2520	23,9
Fresh Frozen Plasma	174	7,7	175	7,0	328	8,5	348	6,9	541	7,7	617	7,1	717	7,2	720	6,4	667	6,3
Platelets Other Type	10	0,4	5	0,2	4	0,1	13	0,3	11	0,2	13	0,1	6	0,1	12	0,1	12	0,1
Granulocyte Concentrate		0,0	3	0,1	3	0,1	2	0,0		0,0	6	0,1	7	0,1	1	0,0		0,0
Cryoprecipitate	3	0,1	6	0,2	11	0,3	5	0,1	16	0,2	18	0,2	18	0,2	28	0,2	23	0,2
Whole Blood	1	0,0	1	0,0		0,0	4	0,1	1	0,0	2	0,0	2	0,0	2	0,0	1	0,0
Reconstituted whole blood		0,0		0,0	1	0,0	2	0,0		0,0		0,0		0,0		0,0	2	0,0
Another	20	0,9	19	0,8	27	0,7	39	0,8	65	0,9	85	1,0	46	0,5	58	0,5	89	0,8
Multicomponent	10	0,4	34	1,4	49	1,3	52	1,0	75	1,1	109	1,3	151	1,5	157	1,4	124	1,2
<b>Total</b>	<b>2.261</b>		<b>2.518</b>		<b>3.895</b>		<b>5.060</b>		<b>7.106</b>		<b>8.781</b>		<b>10.123</b>		<b>11.464</b>		<b>10.671</b>	

Source: Ministry of Health (Cadastro Nacional de Estabelecimentos de Saúde, competence December 2015, and Cadernode Informação: Sangue e Hemoderivados); Anvisa (Notivisa).

Table 5 shows the frequencies of notifications, according to the type of transfusion and the year of occurrence of the transfusion reaction, from 2007 to 2015. The prevalence of notifications related to allogeneic transfusions tends to 100% in all years of the series.

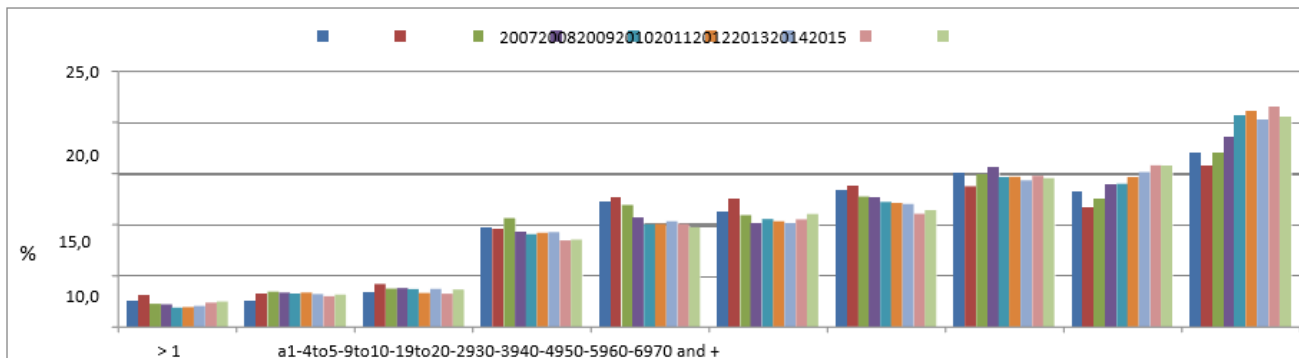
Table 5: Absolute frequency of notifications, by year of occurrence of transfusion reactions, according to sex and age group. Brazil, 2007 to 2015.

Age Group	2007		2008		2009		2010		2011		2012		2013		2014		2015	
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
< 1 year	38	18	42	35	44	42	60	48	64	67	85	78	114	86	139	123	147	109
1 to 4 years	32	25	50	31	69	62	96	69	132	96	173	114	189	128	162	171	192	136
5 to 9 years old	45	32	59	44	76	67	119	68	135	123	170	113	211	155	209	152	230	151
10 to 19 years old	113	106	134	103	231	177	226	235	327	310	420	372	495	423	518	429	481	410
20 to 29 years old	126	149	142	171	210	247	262	274	318	387	401	465	503	522	523	605	471	548
30 to 39 years old	110	141	130	179	175	244	209	299	303	438	338	550	436	571	463	715	442	712
40 to 49 years old	129	171	130	212	191	298	270	365	353	505	418	626	498	695	497	742	487	706
50 to 59 years old	176	162	137	203	288	285	352	428	447	583	576	687	688	734	815	841	700	821
60 to 69 years old	145	151	137	152	244	239	311	387	495	489	632	630	737	766	843	931	806	844
70 years and +	184	197	180	211	300	354	384	541	610	842	772	1047	853	1161	1075	1345	933	1220
<b>Total</b>	<b>1098</b>	<b>1152</b>	<b>1141</b>	<b>1341</b>	<b>1828</b>	<b>2015</b>	<b>2289</b>	<b>2714</b>	<b>3184</b>	<b>3840</b>	<b>3985</b>	<b>4682</b>	<b>4724</b>	<b>5241</b>	<b>5244</b>	<b>6054</b>	<b>4889</b>	<b>5657</b>

Source: Notivisa Note: In the respective years of the series, the frequencies of notifications with ignored gender were disregarded: 2007 =1; 2008=2; 2009=3; 2010=5; 2011=7; 2012=5; 2013=7; 2014=9; 2015=1



Graph 5: Relative frequency of transfusion reaction notifications, according to age group and year of occurrence. Brazil, 2007 to 2015.



Source: Ministry of Health (Cadastro Nacional de Estabelecimentos de Saúde, competence December 2015, and Cadernode Informação: Sangue e Hemoderivados); Anvisa (Notivisa).

## 5 CONCLUSION

Despite scientific advances in hemotherapy, the transfusion of blood products still exposes the patient to risks inherent to the process, because blood is a biological material, obtained by donation, which depends on the altruism of the donor and on specialized services for its collection.

The issue of underreporting of transfusion reactions, besides being evidenced in recent ANVISA data, can be perceived in descriptive studies carried out in Blood Services, where the incidence coefficient of transfusion reaction is evaluated by active search.

Computerization may have been a significant factor in the increase of notifications.

The "Internal Medicine" specialty, due to its intense connection with hematology and hemotherapy, is the one that registers more cases of transfusion reactions, since it is the one that requests more hemotherapeutic procedures, and it should therefore be more careful in the management of RT.

The southeastern region is the territory that reports the most transfusion reactions.

The diversity of hemovigilance services around the world, disparate nomenclatures and information evaluation configurations, indicative of adverse event underreporting; expansion of hemovigilance in Brazil, with standardization of meanings, and the universal apprehension about transfusion safety are factors that encourage new studies.

Although we have compiled data, there is a need for periodic updates so that a quantitative analysis can be carried out that permeates the number of transfusions and transfusion reactions reported in order to estimate underreporting and stimulate the permanent training of professionals who work in the care.



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