



Hemovigilance: the experience of transfusion reaction reporting in a Teaching Hospital

Hemovigilância: a experiência da notificação de reações transfusionais em Hospital Universitário
Hemovigilancia: la experiencia de la notificación de reacciones transfusionales en Hospital Universitario

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How to cite this article:

Grandi JL, Grell MC, Areco KCN, Barbosa DA. Hemovigilance: the experience of transfusion reaction reporting in a Teaching Hospital. Rev Esc Enferm USP. 2018;52:e03331. DOI: <http://dx.doi.org/10.1590/S1980-220X2017010603331>

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ABSTRACT

Objective: To describe the occurrence of immediate transfusion reactions received by the Risk Management Department of Hospital São Paulo. **Method:** Cross-sectional and retrospective study which analyzed the notification sheets of transfusion reactions that occurred between May 2002 and December 2016 and were included in the Hemovigilance National System. **Results:** One thousand five hundred and forty-eight transfusion reaction notification sheets were analyzed, all of which concerned immediate reactions associated with packed red blood cells (72.5%). The most frequently reported reaction was febrile non-hemolytic transfusion reaction, and among severe and moderate cases, allergic reaction was the most common. The most frequently reported signs and symptoms were hyperthermia, sudoresis, chills, and skin lesions. No differences were observed regarding gender and age, and 90.7% of reactions occurred in patients with Rh+ factor. **Conclusion:** This study allowed for a better assessment and understanding of transfusion reactions, which will help to improve the quality of blood circulation and provide greater safety of patients undergoing transfusion therapy.

DESCRIPTORS

Blood Transfusion; Blood Safety; Health Surveillance of Health Services; Patient Safety.

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Received: 03/09/2017
Approved: 12/31/2017

INTRODUCTION

Blood transfusion is a therapeutic method that is globally accepted and that has been proven effective⁽¹⁾. However, it involves both benefits and risks, even when it is suitable and, despite its indication, proper administration is necessary because reactions may occur.

Hemovigilance is defined as a set of monitoring procedures that includes the whole blood cycle, with the purpose of obtaining information about adverse effects occurring at different stages and making it available, to try to prevent the emergence or recurrence of adverse effects and to improve the safety of both the donor and the receptor⁽¹⁻²⁾.

In the United Kingdom, the hemovigilance system called SHOT (Serious Hazards of Transfusions), which aims to minimize transfusion errors, has reported a significant number of undesirable events related to transfusion and to the use of hemocomponents⁽³⁾. Even in countries with longer experience in hemovigilance such as France, where reports of transfusion events are compulsory⁽⁴⁾, and in England, where data are collected spontaneously⁽³⁾, there is always an incidence bottom line, no matter how good and controlled the hemotherapy system is.

Brazil began to discuss hemovigilance in 2000⁽⁵⁾, and in 2001 the Brazilian Health Regulatory Agency (ANVISA, as per its acronym in Portuguese), in fulfillment of its mission to promote health and protect people from the risks associated with the use of the products and technologies of health services, suggested the creation of the Brazilian Network of Sentinel Hospitals which, among other purposes, would help to integrate the Hemovigilance National System (SNH – *Sistema Nacional de Hemovigilância*).

The SNH is an assessment and warning system that is part of the post-use sanitary surveillance process (VIGIPÓS – *Vigilância Sanitária Pós-uso*) of health products, and its purpose is to collect and analyze information about the unexpected effects of the use of hemocomponents in order to prevent their resurgence or recurrence⁽⁵⁾.

The implementation of the SNH took place mainly within the scope of the Brazilian Network of Sentinel Hospitals, by encouraging spontaneous notifications from participating hospitals, with the purpose of reaching all hemotherapy units and other health services that perform transfusion of blood and its derivatives in Brazil. Data collected in each unit of the Sentinel Network are recurrently consolidated by ANVISA at a national level and in each state.

In Brazil, transfusion reaction notifications had been done spontaneously until 2010, when they became compulsory with the publication of RDC 57/2010⁽⁶⁾. However, despite the efforts made by ANVISA and the Sentinel Network units, transfusion reaction events are still underreported, and this makes it difficult to know the actual frequency of such events, as well as the conditions related to them.

In view of the above and the interest in providing information about hemovigilance through sharing the results of the experience of event notification in a high-complexity University Hospital of the Sentinel Network, the objective of this study is to analyze the occurrences of transfusion

reactions in hospitalized patients, and blood and hemocomponent receptors, by identifying the frequency of the main immediate reactions, their severity, and related factors by means of an analysis of transfusion reactions that occurred and were included in the Hemovigilance National System between May 2002 and December 2016. All notification sheets received by the Hospital Sanitary Risk Management (GRSH – *Gerência de Risco Sanitário Hospitalar*) were included in the Health Surveillance National System (SNVS – *Sistema Nacional de Vigilância Sanitária*).

METHOD

ETHICAL ASPECTS

This study was previously approved by the Research Ethics Committee of the Hospital São Paulo, a university hospital of the Universidade Federal de São Paulo, under number 1794086.

STUDY DESIGN, LOCATION, AND DURATION

This is a retrospective study that used data collected between May 2002 and December 2016. It was carried out in a high-complexity philanthropic university hospital located in São Paulo which has 862 beds. The aforementioned hospital is a reference in teaching and research at national and international levels. It is part of the Brazilian Network of Sentinel Hospitals, and has carried out hemovigilance actions since 2002 by means of the Sanitary Risk Management (GRSH).

POPULATION/SAMPLE

The study sample was composed of 1,548 sheets, out of a total of 1,559, and they contained notifications of transfusion incidents of patients who received blood transfusions and hemocomponents between 2002 and 2016.

INCLUSION CRITERIA

All hemovigilance notification sheets that were properly filled in with reports of transfusion reactions confirmed by a hematologist from the hemotherapy service were included.

EXCLUSION CRITERIA

Late incidents or notifications for which reported signs and symptoms were not related to immediate transfusion reaction were excluded.

STUDY PROTOCOL

Data were collected by means of transfusion incident notification sheets, created and validated by the institution itself to collect data that feed the SNH system, under the responsibility of its GRSH, used for both late and immediate reactions. Data collection and identification of events of interest followed a standardized process within the institution: in the event of clinical manifestations that suggest transfusion reaction, the transfusion is interrupted and peripheral venous blood is collected and sent to the

Transfusion Agency together with the content remaining in the bag, in order to have new immuno-hematological tests performed, so the adverse reaction can be classified in the unit. The diagnosis of transfusion reaction provided by the hematologist follows the recommendations of the Hemovigilance Manual, published by ANVISA in 2015⁽¹⁾. The following variables were collected: age; gender; unit; diagnosis hypothesis at admission; signs and symptoms observed; time of clinical manifestations; reaction severity; ABO system and Rh factor (+); and type and amount of administered hemocomponents. All sheets filled in and received by the GRSH were included in ANVISA's SNVS.

ANALYSIS OF RESULTS AND STATISTICS

Data saved in Excel spreadsheets that were compatible with the sheet structure, and fed and kept by the institution's GRSH, were analyzed with the help of statistical packages *Stata Statistical Software*, by means of descriptive and inferential statistics. The numeric variables were described by measures of central tendency and variability, and tested for adherence to normal distribution on the basis of skewness and kurtosis values (between -2 and +2). The association between categorical variables was analyzed by means of the chi-square test or Fischer's exact test, and for all tests the significance level was 5%.

RESULTS

Between May 2002 and December 2016, Hospital São Paulo (HSP) reported a total of 1,548 immediate transfusion reactions to ANVISA, which corresponded to 99.3% of the total throughout the period.

Among the receptors of blood transfusion, the proportion between men (50.7%) and women (49.3%) was very similar, and corresponded to 785 and 763 individuals, respectively.

The observed proportions by age group were as follows: 13.0% aged 70 years old or over; 14.2% aged between 60 and 69; 16.1% aged between 50 and 59; 13.2% aged between 40 and 49; 14.1% aged between 30 and 39; 17.0% aged between 18 and 29, and 12.4% aged between 0 and 17 years old. Age was normally distributed, with a mean of 44 years, median of 45 years, standard deviation of 22 years, minimum of 0 (under 1 year), and maximum of 96 years.

For men, age varied from 0 to 93 years, with a mean of 44 years, median of 45 years and standard deviation of 21.7 years, whereas for women aged varied from 0 to 96, with mean and median of 45 years and standard deviation of 22 years. Age distribution did not present a statistically significant difference between genders ($p=0.218$).

As for the reporting unit, a higher number of notifications came from cancer treatment wards, with 477 sheets (30.9%), followed by the medical clinic, with 359 (23.2%). Urgency and emergency units accounted for 16.7% (259) of the total notifications. The lowest percentages of notification were found in surgical units (8.1%), in mixed units (7.2%), and in pediatric wards, which represented only 2.3% of the overall total of notifications (Table 1).

Table 1 – Distribution of transfusion reaction events according to the reporting unit – São Paulo, SP, Brazil, 2016.

Reporting Unit	N.º	%
Oncology	477	30.9
Medical Clinic	359	23.2
Urgency and Emergency	259	16.7
Critical and Semi-critical	180	11.6
Surgical and Obstetrics	126	8.1
Mixed	111	7.2
Pediatrics	36	2.3
Total	1,548	100.0

Note: Data from May 2002 to December 2016.

Regarding the clinical manifestations observed for notification purposes, the most frequent ones were body temperature rise of at least 1°C, reported in 853 sheets (27.4%); followed by sudoresis and chills in 558 (17.9%); and skin lesions in 486 sheets (15.6%). Among the symptoms with greater morbidity, we found tachycardia, reported in 301 sheets (9.7%); followed by dyspnea and cough in 244 sheets (7.9%); and cyanosis in only 63 sheets (2%). Among the least frequent symptoms, but with the same morbidity rate, we found hemoglobinuria and changes in consciousness levels, both reported in only five sheets (Table 2).

Table 2 – Distribution of clinical manifestations observed in hemocomponent receptors – São Paulo, SP, Brazil, 2016.

Signs and Symptoms	N.º	%
Body temperature rise	853	27.4
Sudoresis and chills	558	17.9
Skin lesions	486	15.6
Itching	402	12.9
Tachycardia	301	9.7
Dyspnea and cough	244	7.9
Chest and abdominal pain	89	2.9
Blood pressure changes	83	2.7
Extremity cyanosis	63	2
Nausea with or without vomiting	18	0.6
Hemoglobinuria	5	0.2
Changes in consciousness levels	5	0.2
Total	3,107	100.0

Note: Data from May 2002 to December 2016.

As for receptors' typing by the ABO system, the Rh⁽⁺⁾ factor was predominant for all blood types. O+ and A+ blood types corresponded to 43.6% and 31.8% of transfusion reactions, respectively (Table 3).

As for the administered hemocomponent type, a greater number of reactions were related to the therapeutic use of packed red blood cells, with 72.5% of total reactions, followed by platelet concentrate, with 17.2% of the overall total of reactions. The other reactions occurred in transfusions of cryoprecipitate and granulocytes. The other hemocomponents, although widely used in the institution, were not related to transfusion reaction throughout the 14 years covered by this study (Table 4).

Table 3 – Distribution of blood types among hemocomponent receptors who had a transfusion reaction – São Paulo, SP, Brazil, 2016.

Blood type	No.	%
O+	675	43.6
O-	87	5.6
A+	493	31.8
A-	28	1.8
B+	173	11.2
B-	16	1.0
AB+	64	4.1
AB-	12	0.8
Total	1,548	100.0

Note: Data from May 2002 to December 2016.

Table 4 – Distribution of hemocomponent types related to transfusion reaction – São Paulo, SP, Brazil, 2016.

Hemocomponent type	N.º	%
Packed red blood cells	1,122	72.5
Platelet concentrate	267	17.2
Fresh frozen plasma	156	10.1
Others	3	0.2
Total	1,548	100

Note: Data from May 2002 to December 2016.

Regarding severity: 87.3% were mild; 11.3% were moderate; and 1.4% were severe. With regard to the type of reaction reported, febrile non-hemolytic transfusion reaction (FNHTR) represented 56.6% (877/1,548) of analyzed cases, and allergic reactions represented 38.4% (595/1,548), totaling 95% (Table 5).

Table 5 – Distribution of transfusion reaction events according to the reaction severity – São Paulo, SP, Brazil, 2016.

Adverse reactions	Reaction severity							
	Mild		Moderate		Severe		Total	
	No.	%	No.	%	No.	%	No.	%
Main								
Febrile non-hemolytic transfusion reaction (FNHTR)	838	95.6	38	4.3	1	0.1	877	100
Allergic reaction	466	78.3	117	19.7	12	2.0	595	100
Others								
Transfusion-associated circulatory overload (TACO)	20	57.1	10	28.6	5	14.3	35	100
Transfusion-related acute lung injury (TRALI)	5	38.5	6	46.2	2	15.4	13	100
Acute hemolytic transfusion reaction (AHTR)	14	82.4	2	11.8	1	5.9	17	100
Hypotensive transfusion reaction (HTR)	6	75.0	2	25.0	-	-	8	100
Bacterial contamination	3	100.0	-	-	-	-	3	100
Total	1,352	87.3	175	11.3	21	1.4	1,548	100

Note: Data from May 2002 to December 2016.

Considering only the main reactions (FNHTR and allergic) and the three levels of severity (mild, moderate, and severe) presented in Table 5, we see that the frequency of immediate reactions varied according to reaction severity. In FNHTR the frequency of moderate reactions was 4.3% and 0.1% for severe ones. As for allergic reactions, 19.7% were moderate and 2% were severe. This association was statistically significant (chi-square test= 105.544; gl=2; p<0.001). If we add the moderate and severe categories together and compare the proportions between the main reactions (FNHTR and allergic), we can see that mild reactions are more frequent among FNHTR than among allergic reactions (Fischer's exact test; p<0.001), with proportions of 95.6% and 78.3%, respectively.

TACO, TRALI, AHTR, and HTR (Table 5), despite being less frequent reactions, were moderate or severe and accounted for 42.9%, 61.6%, 17.7%, and 25%, respectively.

DISCUSSION

Hemovigilance in the studied institution was officially implemented in Risk Management in 2002, when cases were first reported to SNH. Between May 2002 and December 2016, Hospital São Paulo reported a total of 1,548 confirmed cases of transfusion reaction to ANVISA. Three hundred twenty-five of these (21.4%) were included in the previous system (SINEPS) between 2002 and 2006. In the first year, 33 transfusion reactions (2.4%) were reported in the hospital, which corresponded to 18.7% of the national total of notifications received by SINEPS⁽⁷⁾. When we compare this to the findings of this study, we see that we reported 4.65% of all cases received by NOTIVISA (*Sistema de Notificação em Vigilância Sanitária*) from all institutions of the Sentinel Network between 2002 and 2009^(5,8).

The lowest percentage of transfusion incidents was observed in children and adolescents. The average age of

participants in this study was 44 years, which is similar to that found in a study carried out in northwest India⁽⁹⁾, with an average age of 44.3 years. This is well below that found among Japanese receptors, whose average age was 56.7 years, with 94% of reactions occurring among people aged over 18⁽¹⁰⁾.

Among the patients in this study who had transfusion reactions, we observed a slight difference with regard to gender: 50.7% men and 49.3% women. These findings confirm the national literature⁽⁶⁾, which reports the same distribution pattern for both genders. It is important to note that no statistically significant differences between genders were found in the literature^(9,11-13). Only in two studies there was a significant difference between genders found: in a cohort study, in which men represented 60% of individuals⁽¹⁴⁾, and in another study carried out in an accredited hospital in the state of Ceará, which consisted of 52.5% women⁽¹⁵⁾. It is worth mentioning that our study did not analyze the association between gender and transfusion reactions, because data of transfusions with no reaction were not included in our analysis.

The highest number of notifications was reported by cancer treatment units, followed by medical clinic units and urgency and emergency units. These facts confirm the literature, which reports a higher frequency of transfusion reactions in units with cancer patients^(1,11,16), followed by medical clinic units^(5,8). Some studies reported a greater probability of reactions in receptors with a transfusion history, but they did not mention the underlying disease or the type of reporting unit⁽¹⁷⁾.

The more frequent clinical manifestations in this study were hyperthermia (body temperature rise), sudoresis, and chills, followed by skin lesions. In a study carried out in Ceará⁽¹⁵⁾, which analyzed 45 transfusion reactions, fever was the main symptom, found in 55.6% of reactions. No other studies have been found to compare the frequency of clinical manifestations in transfusion reactions. Among transfusion reactions, the Rh⁽⁺⁾ factor prevailed (90.8%). No other studies have been found to compare this prevalence in transfusions with or without reactions.

Regarding severity of transfusion reactions, most were mild (first degree). Second and third degree reactions were not frequently reported, as with other studies^(9,15).

Hemolytic transfusion reaction, although not frequent, with only 17 cases, 17.7% of which were moderate or severe, is of great interest for its morbidity, due to the destruction of transfused red blood cells as a result of blood incompatibility of both ABO system and Rh factor (+) types, along with human error.

When notifications and hemocomponents are analyzed separately, we can see that the greatest number was related to the therapeutic use of packed red blood cells; results which were similar to those in the literature^(15,17) and to data published by ANVISA^(1-2,6). In our service, the average of annual transfusions per packed red blood cells is around 46.5% of the total of other hemocomponents used, and this can explain the higher frequency of reactions of this hemocomponent among receptors.

The most reported mild reactions were FNHTR and allergic reactions; however, when only moderate and severe reactions are analyzed, allergic reactions were the most reported. These findings are confirmed by both the

national literature, which indicates FNHTR^(1,6,8) as the most reported reaction in NOTIVISA by hospitals of the Sentinel Network, as well as the international literature, which suggests a higher incidence of FNHTR reactions, followed by allergic reactions^(12,16,18-21). When data from NOTIVISA recorded between 2007 and 2015 are analyzed separately, we see that FNHTR and allergic reactions are more prevalent in SNH, with incidence rates of 49% and 37.3%, respectively⁽⁶⁾.

Although severe reactions result in greater morbidity, they were not thoroughly analyzed, similarly to other studies^(16,22), which described most reactions as being of first degree (mild). However, in another study⁽¹¹⁾, most adverse reactions did not present any risk of mortality to patients. Among severe reactions, 57.1% (12/21) were allergic, followed by TACO at 23.8% (5/21). Among those of greater morbidity were TRALI at 9.5% (2/21) and AHTR at 4.8% (1/21)^(8,10,14). TRALI, which is a severe reaction, is not frequently reported by services and this leads some authors to suggest the occurrence of underreporting as a result of the lack of preparation or knowledge within these services^(16,22-23). In a study conducted in Norway, the authors state that such reaction rarely occurs⁽²⁰⁾, whereas in a study conducted in Germany TRALI was the most common cause of death related to transfusion reaction⁽²²⁾.

The profile of data reported by Hospital São Paulo, where 99% of immediate reactions were observed⁽²⁴⁾, is similar to those of NOTIVISA⁽⁶⁾ (97%) and of the state of São Paulo (99.9%)⁽²³⁾. The same occurs with the diagnosis of transfusion reactions, with respectively 49% and 37.3% at a national level⁽⁶⁾; 51% and 40% in the state of São Paulo⁽²³⁾; and 56.6% and 38.4% in Hospital São Paulo. These findings confirm those of the French hemovigilance system⁽⁴⁾, which indicated that 85.2% of events were FNHTR, followed by allergic reactions.

We point out as limitations to this study the possible underreporting of immediate transfusion reactions, but especially of late reactions that take place shortly after transfusion, generally with mild manifestations and which are disregarded by health professionals or are not related to a previous transfusion. Therefore, continuous awareness-raising among health professionals must be fostered so as to encourage notifications and the assessment of events.

CONCLUSION

This study allowed for a better assessment and understanding of transfusion reactions, which will help to improve the quality in blood cycle and greater safety of patients undergoing transfusion therapy.

In view of the above, we suggest that hemotherapy services and health professionals who deal with blood transfusion carefully observe the clinical manifestations that indicate allergic reactions, which can be more severe.

In addition, further studies should be carried out to assess the risk factors involved in transfusion reactions, with the aim to improve the quality of processes and increase the safety of hemocomponent receptors, in addition to strengthening transfusion committees and tackling underreporting, bearing in mind that transfusion reactions also occur in well-structured services.

RESUMO

Objetivo: Descrever a ocorrência das reações transfusionais imediatas recebidas na Gerência de Risco do Hospital São Paulo. **Método:** Estudo transversal retrospectivo, com análises das fichas de notificação de reações transfusionais, no período de maio de 2002 a dezembro de 2016, que foram inseridas no Sistema Nacional de Hemovigilância. **Resultados:** Foram analisadas 1.548 fichas de Reação Transfusional, em sua totalidade reações imediatas, associadas ao Concentrado de Hemácias (72,5%). A mais comum foi a Reação Febril Não Hemolítica Leve, e, entre as graves e moderadas, a Reação Alérgica. Os sinais e sintomas mais notificados foram a hipertermia, a sudorese, os calafrios e as lesões em derme. Não foram observadas diferenças entre sexo e idade, 90,7% das reações ocorreram em pacientes com Fator Rh⁺. **Conclusão:** O estudo permitiu uma melhor avaliação e compreensão das reações transfusionais, o que viabilizará a qualidade no ciclo do sangue e uma maior segurança dos pacientes submetidos à terapia transfusional.

DESCRITORES

Transfusão de Sangue; Vigilância do Sangue; Vigilância Sanitária de Serviços de Saúde; Segurança do Paciente.

RESUMEN

Objetivo: Describir la ocurrencia de las reacciones transfusionales inmediatas recibidas en la Gestión de Riesgo del Hospital São Paulo. **Método:** Estudio transversal retrospectivo, con análisis de las fichas de notificación de reacciones transfusionales, en el período de mayo de 2002 a diciembre de 2016, que fueron introducidas en el Sistema Nacional de Hemovigilancia. **Resultados:** Fueron analizadas 1.548 fichas de Reacción Transfusional, en su totalidad reacciones inmediatas, asociadas con el Concentrado de Hematíes (72,5%). La más común fue la Reacción Febril No Hemolítica Ligera y, entre las severas y moderadas, la Reacción Alérgica. Las señales y los síntomas más notificados fueron la hipertermia, la transpiración, los escalofríos y las lesiones en la dermis. No se observaron diferencias entre sexo y edad, el 90,7% de las reacciones ocurrieron en pacientes con Factor RH⁺. **Conclusión:** El estudio permitió una mejor evaluación y comprensión de las reacciones transfusionales, lo que hará factible la calidad en el ciclo de la sangre y una mayor seguridad de los pacientes sometidos a la terapia transfusional.

DESCRIPTORES

Transfusión Sanguínea; Seguridad de la Sangre; Vigilancia Sanitaria de Servicios de Salud; Seguridad del Paciente.

REFERENCES

1. Brasil. Ministério da Saúde; Agência Nacional de Vigilância Sanitária. Marco conceitual e operacional de hemovigilância: guia para hemovigilância no Brasil. Brasília: ANVISA; 2015
2. Carneiro-Proietti ABF. Haemovigilance: a system to improve the whole transfusion chain. Rev Bras Hematol Hemoter. 2013;35(3):158-9. DOI <http://dx.doi.org/10.5581/1516-8484.2013.0045>
3. Bolton-Maggs PH, Cohen H. Serious Hazards of Transfusion (SHOT) Haemovigilance and progress is improving transfusion safety. Br J Haematol. 2013;163(3):302-14.
4. Agence Nationale de Sécurité du Médicament et des Produits de Santé. Rapport d'activité hémovigilance 2014 [Internet]. Paris: AMSN; 2015 [cited 2017 Oct 10]. Available from: http://ansm.sante.fr/var/ansm_site/storage/original/application/4ee5a6f35365ab8b2ab1ad5eaccb5bd6.pdf
5. Boletim de Hemovigilância. Agência Nacional de Vigilância Sanitária [Internet]. 2010 [citado 2017 fev 22];(3). Disponível em: http://portal.anvisa.gov.br/documents/33868/405222/boletim_hemovigilancia.pdf/83875701-cbaf-4d6e-94b2-5e189660038f
6. Brasil. Ministério da Saúde; Agência Nacional de Vigilância Sanitária. Hemovigilância no Brasil: relatório consolidado 2007-2015. Brasília: ANVISA; 2016.
7. Brasil. Ministério da Saúde; Agência Nacional de Vigilância Sanitária. Boletim Anual de Avaliação Sanitária em Serviços de Hemoterapia. Brasília: ANVISA; 2016.
8. Brasil. Ministério da Saúde; Agência Nacional de Vigilância Sanitária. Boletim Anual de Hemovigilância. Brasília: ANVISA; 2008.
9. Sharma DK, Datta S, Gupta A. Study of acute transfusion reactions in a teaching hospital of Sikkim: a haemovigilance initiative. Indian J Pharmacol [Internet]. 2015 [cited 2017 Oct 10];47(4):370-4. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4527056/>
10. Kato H, Uruma M, Okuyama Y, Fujita H, Handa M, Tomiyama Y, et al. Incidence of transfusion-related adverse reactions per patient reflects the potential risk of transfusion therapy in Japan. Am J Clin Pathol. 2013;140(2):219-24.
11. Freitas JV, Almeida PC, Guedes MVC. Perfil das reações transfusionais em pacientes pediátricos oncológicos. Rev Enferm UFPE [Internet]. 2014 [citado 2017 out. 10];8(9):3030-8. Disponível em: <https://periodicos.ufpe.br/revistas/revistaenfermagem/article/viewFile/10022/10408>
12. Azizi S, Tabary SZ, Soleimani A. Prevalence of acute blood transfusion reactions in Mazandaran Heart Center, Sari, Iran, 2010-2012. Med Arch [Internet]. 2014 [cited 2016 Nov 23];68(2):137-39. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4272498/>
13. Knutson F, Osselaer J, Pierelli L, Lozano M, Cid J, Tardivel R, et al. A prospective, active haemovigilance study with combined cohort analysis of 19 175 transfusions of platelet components prepared with amotosalen-UVA photochemical treatment [Internet]. 2015 [cited 2017 Oct 10];109(4):343-52. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4690512/>
14. Macedo ED, Silveira VMJ, Athayde LA. Índice de reação transfusional em pacientes submetidos a transfusão em um Hemocentro do Norte de Minas Gerais. Rev Bras Pesq Cien Saúde [Internet]. 2015. [citado 2017 out. 10];2(2):54-7. Disponível em: <http://www.icesp.br/revistas-eletronicas/index.php/RBPcCS/article/view/49>
15. Beserra MPP, Portela MP, Monteiro MP, Façanha MC, Adriano LS, Fonteles MMF. Reações transfusionais em um hospital Cearense acreditado: uma abordagem em hemovigilância. Arq Med [Internet]. 2014 [citado 2017 abr. 27];28(4):99-103. Disponível em: http://www.scielo.mec.pt/scielo.php?script=sci_arttext&pid=S0871-34132014000400002
16. Belém LDF, Nogueira RG, Leite TR, Costa LC, Alves LDFP, Carneiro S. Descrição de reações transfusionais imediatas na Fundação Assistencial da Paraíba, Brasil. Rev Baiana Saúde Pública [Internet]. 2010 [citado 2017 abr. 27];34(4):810-7. Disponível em: <http://files.bvs.br/upload/S/0100-0233/2010/v34n4/a2170.pdf>

17. Waller C, Vicariot M, Gunzberger H. Analysis of transfusion incident reports filed at 15 blood transfusion centers and health facilities during 17 months. *Groupe Receveurs de laSFTS. Transfus Clin Biol.* 1997;4(6):541-8.
18. Siegenthaler MA, Schneider P, Vu DH, Tissot JD. Haemovigilance in a general university hospital: need for a more comprehensive classification and a codification of transfusion-related events. *Vox Sang.* 2005;88(1):22-30.
19. Souza Neto AL, Barbosa MH. Analysis of immediate transfusion incidents reported in a regional blood bank. *Rev Bras Hematol Hemoter.* 2011 [cited 2017 Oct 10];33(5):337-41. Available from: <http://www.scielo.br/pdf/rbhh/v33n5/v33n5a08>
20. Michlig C, Vu DH, Wasserfallen JB, Spahn DR, Schneider P, Tissot JD. Three years of haemovigilance in a general university hospital. *Transfus Med.* 2003;13(2):63-72.
21. Steinsvag CT, Espinosa A, Flesland O. Eight years with haemovigilance in Norway. What have we learnt? *Transfus Apher Sci.* 2013;49(3):548-52.
22. Keler-Stanislawski B, Lohmann A, Gunay S, Helden M, Funk B. The German Haemovigilance System-reports of serious adverse transfusion reactions between 1997 and 2007. *Transfus Med.* 2009;19(6):340-9.
23. Boletim de Hemovigilância. São Paulo: Secretaria de Estado da Saúde, Centro de Vigilância Sanitária. 2016;(2).
24. Grandi JL, Grell MC, Barros MO, Chiba A, Barbosa DA. Frequência dos incidentes transfusionais imediatos em receptores de hemocomponentes. *Vigil Sanit Debate* 2017;5(2):93-88. DOI <http://dx.doi/10.22239/2317.269X.000878>



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