The role of hemovigilance as a mechanism to increase transfusion safety

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The complexity of healthcare organizations involves interdisciplinary professional practice, whose common goal is to provide quality products and services that satisfy the customer's and society's expectations. One of the services that comprise this structure is transfusion medicine, which is an essential specialty in the treatment of hematologic malignancies and numerous other clinical and surgical conditions.[1]

In transfusion medicine, quality starts with the process of attracting donors and extends to the transfused patient, by ensuring traceability of blood components and derivatives. Despite major advances, transfusion, even with precise indication and correct administration, involves risk to health with the potential of transfusion incidents (TI), whether immediate or delayed. TI are defined as injuries occurring during or after and related to blood transfusion.[2]

The professionals involved in prescribing and administrating blood products must be trained to identify signs and symptoms of TI, to manage them and to establish measures to prevent future incidents. Thus, the notification of immediate and delayed TI is essential to minimize these risks.[3]

Immediate TI (within 24 hours of transfusion) are the most commonly observed, with an overall occurrence which varies in different services and countries of between 0.5 and 3%; febrile non-hemolytic and allergic reactions are the most frequent. However, health risks, in order of severity, are: acute hemolytic reaction, TRALI, bacterial contamination and volumetric overload.[4]

Hemovigilance, developed in the early 1990s in France, has emerged as a tool to improve transfusion safety.

In Brazil, a blood-surveillance system was implanted during the restructuring of the National Health Service in 1999 and the goal of the project: "Blood with a guaranteed quality in all its process until 2003" became a reality in 2001.[5]

Resolution number 57 of the Agência Nacional de Vigilância Sanitária (ANVISA) defines hemovigilance as "a set of surveillance procedures covering the cycle of blood, from the donation to the transfusion, generating information about adverse events resulting from the donation and the therapeutic use of blood and blood components. This information is used to identify risks, improve the quality of products and processes and increase the donor and patient safety by preventing the occurrence or reoccurrence of these events."

Article # 152 stipulates that "Any adverse event that occurs in recipients of blood and blood products should be investigated and reported officially to the responsible authorities using the NOTIVISA system."[6]

However, on analyzing the annex of decree 1353 of 13/06/2011 of the Brazilian Ministry of Health, we found that only Article 137, when it addresses late complications, in section IV of the 3rd paragraph, determines that adverse events must be reported to the appropriate health authority, not including early ones.[7]

We believe that the two laws should be standardized urgently if we are to move forward with the system of national hemovigilance improving transfusion safety. Even because, as recorded in the *Hemovigilance Bulletin* number 3 in 2009 the rate of underreporting for all TI in the country is extremely high (69.5%), ranging between 60.5% in the southeast to 99.2% in the Midwest; of the 3348 TI that were documented (0.9 per 1000 transfusions when 10,975 or 3/1000 TI were expected) only 1.5% were delayed reactions with no record of transmissible disease and only 199 TI classified in the group of severe reactions (0.054/1000).[8]

Despite the large difference to developed countries, such as France, United Kingdom, Netherlands, Switzerland, the United States and Canada, where hemovigilance has been consolidated for several years, underreporting is still a common problem. In France and the Netherlands, where all TI must be reported, the rates are 2.8 and 2.9 per 1000 transfusions, respectively (3 times the rate of Brazil). In the UK, where only the serious TI are reported, 0.2 events per 1000 transfusions are recorded which is also 3.7 times higher than in Brazil.[9]

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In the article under review,[10] the index record of immediate TI was 2.4/1000 transfusions and serious events represented 0.17/1000. The results, although lower than expected, are significantly higher than those registered in Brazil as a whole and differ little from those recorded in France (2.8/1000), demonstrating that the Transfusion Committee of this hemotherapy center, although still nascent, is developing a good job.

I consider that similar studies should be encouraged in order to reinforce the importance of transfusion committees and especially of records of TI. These are essential conditions to improve transfusion safety as demonstrated in countries such as France and UK. I do not agree, however, with the authors' conclusions that TI are more frequent in transfusions of packed red blood cells. I think the mistake occurred because they did not include the numbers of transfused blood components in the first table which would permit a calculation of the true occurrence of TI. However, if we consider the information that packed red blood cells account for 64.6% of transfusions (with 1.97 TI per 1000 transfusions) and the platelets were less than 30%, the rate of TI for platelets should be higher than that of red blood cells, which makes the findings of this study in agreement with several reports in the literature.

In summary, except for this consideration, the study is very current, pertinent, and the increase in notifications over the period, as observed in other countries such as France, is a demonstration of the team's commitment and the effectiveness of the transfusion committee, which surely will increase transfusion safety.

References

1. Haddad R. Sistemas de acreditação em serviços de hemoterapia. In: Covas DT, Langhi Júnior DM, Bordin JO. Hemoterapia: fundamentos e prática. São Paulo: Atheneu; 2007. p. 551-5.
2. Atterbury C, Wilkinson J. Blood transfusion. Nursing Stand. 2000;14(34):47-52. Comment in: Nurs Stand. 2001;15 (24):26.
3. Proietti AB, Cioffi JG. Hemovigilância: verificação final da qualidade da transfusão? Rev Bras Hematol Hemoter. 2008;30 (3):173-6.
4. Fry JL, Arnold DM, Clase CM, Crowther MA, Holbrook AM, Traore AN, et al. Transfusion premedication to prevent acute transfusion reactions: a retrospective observational study to assess current practices. Transfusion. 2010;50(8):1722-30.
5. Agência Nacional de Vigilância Sanitária. Hemovigilância. Manual técnico de hemovigilância - investigação das reações transfusionais imediatas e tardias não infecciosas [Internet]. Brasília: ANVISA; 2007. [cited 2010 Jun 27]. Available from: http://www.uel.br/hu/hemocentro/pages/arquivos/manual_tecnico_ hemovigilancia_08112007.pdf
6. Agência Nacional de Vigilância Sanitária. Resolução -RDC 57, de 16 de dezembro de 2010. Determina o regulamento sanitário para serviços que desenvolvem atividades relacionadas ao ciclo produtivo do sangue humano e componentes e procedimentos transfusionais [Internet]. Brasília: ANVISA, 2010. [cited 2011 Sept 15]. Available from: http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2010/res0057_16_12_2010.html
7. Brasil. Ministério da Saúde. Portaria n° 1.353/MS de 13 de junho de 2011. Aprova o Regulamento Técnico de procedimentos hemoterápicos [Internet]. Brasília: Ministério da Saúde, 2011. [cited 2011 Sep 15] Available from: http://anfipdatalegis.inf.br/view/xao.php?KEY&WORD&TIPO=POR&NUMERO=00001353&SEQ=000&ANO=2011&ORGAO=MS&TIPITEM &DESITEM
8. Agência Nacional de Vigilância Sanitária. Hemovigilância-Notifique!. Bole Hemovigilância [Internet]. 2010 [cited 2011 Sep 15];3. Available from: http://www.anvisa.gov.br/hotsite/notivisa/index. htm
9. Daurat G. Le signalement et la déclaration des incidents graves de la chaîne Transfusionnelle. [Reporting and notification of transfusion serious adverse events in France]. Transfus Clin Biol. 2010;17(5-6):362-5. French.
10. Sousa Neto AL, Barbosa MH. Analysis of immediate transfusion incidents reported in a regional center hemotherapy. Rev Bras Hematol Hemoter. 2011;33(5):337-41.

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