

Hemovigilance: a system to improve the whole transfusion chain

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Hemovigilance is used to track and reduce the occurrence of adverse events associated with blood donations⁽¹⁾. Hemovigilance programs have now been in existence for about 20 years after being developed in 1993 in France. Although it has emerged as a tool to improve transfusion safety, many countries and centers are still in the development stage and have not yet established functioning hemovigilance systems with adequate notification.

Hemovigilance is one of the most important activities of professionals in the field of blood transfusion. All professionals who deal with transfusions are involved in blood safety, from the blood bank director to quality managers, donor physicians, nurses, phlebotomists, laboratory technicians, transfusing physicians and hospital nurses. In transfusion medicine, quality starts with the process of attracting, recruiting and informing blood donor candidates and extends through all the transfusion chain to the transfused patient. Even with precise indication and correct administration, blood transfusion procedures have inherent biological risks related to health with the potential of transfusion incidents (TI), whether immediate or delayed. TI are defined as injuries occurring during or after blood transfusion that are related to the procedure. All professionals involved in prescribing and administering blood products must be trained to identify and manage TI and to establish measures to prevent future incidents. Thus, the notification of immediate and delayed TI is essential to minimize risk⁽²⁾.

The safety of blood products from their source, the blood donor, until their use in the recipient is of the utmost importance. Today, the field of hemovigilance is very extensive covering blood components, tissues and cell preparations including donor vigilance, material vigilance and the safety of the patient. While hemovigilance is well known to those who work in the field of transfusion medicine, there are important differences between countries when it comes to the implementation of national hemovigilance programs. In Brazil, the blood-surveillance system was implemented by the National Health Service in 1999⁽³⁻⁵⁾. Resolution number 57 of the Brazilian National Surveillance Agency, 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”. And follows: “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”⁽⁴⁾.

Although regulations and laws are in place, there is a concern about underreporting undesired reactions to blood and blood products. This is still a common problem in Brazil, which shows reporting rates much lower than in countries such as France and the United Kingdom where the systems are consolidated⁽²⁾.

There is an international effort to establish common definitions and in bringing together the different national policies. These are pooled by diverse international and national associations that make a concentrated effort to standardize definitions and measures around the world⁽⁶⁾.

The paper on hemovigilance in the current issue of the *Revista Brasileira de Hematologia e Hemoterapia* illustrates how local attempts to evaluate information on adverse and unexpected reactions in the use of blood products may function in order to prevent the onset or recurrence of reactions⁽⁷⁾. It shows that after initial resistance, there was a growing trend in the number of hemovigilance processes opened followed by a downward trend, a variation that is explained by statistical analysis. Human immunodeficiency viruses (HIV), Hepatitis B virus (HBV) and Hepatitis C virus (HCV) seroconversion cases in donors were tracked and associated to infection in the blood recipient. These cases are not dealt with unless there is an active hemovigilance system in place which shows the importance of this instrument in increasing transfusion safety.

There are currently technologies that capture and analyze donor reaction information, focusing on donor hemovigilance, including monitoring, analyzing and investigating the risks involving donors at the time of blood donation or following the blood donation event. Some enable users to track the different reaction rates, provide baseline metrics and help analyze the trends and changes in reaction rates over time, thereby giving clues to the

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factors that affect reaction rates. They may facilitate the ability to hypothesize, design and analyze interventions, as well as to assess their impacts with the goal of improving donor and donation safety.

In conclusion, there is a continuous need to work on hemovigilance; the laws and tools are in place, but there is still the need of establishing the correct awareness system in order to ensure that the procedures will be followed and that hemovigilance will help to prevent undesired reactions to blood transfusions.

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