Editorial

Hemovigilance and blood safety

Ashish Jain, Ravneet Kaur[1]

Department of Transfusion Medicine, PGIMER, and [1]GMCH, Chandigarh, India

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Correspondence to:
Dr. Ashish Jain,
Department of Transfusion Medicine, PGIMER, Chandigarh – 160 012, India.
E-mail: ashishjain16@gmail.com

The term hemovigilance is derived from the Greek word 'hema' = blood and the Latin word 'vigilans' = watchful. Hemovigilance is defined as a set of surveillance procedures covering whole transfusion chain from the collection of blood and its components to the follow up of its recipients, intended to collect and access information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence.[1] Thus, the ultimate goal of a hemovigilance system is to improve the safety of blood transfusion.

Historical aspects

The pioneering work on hemovigilance started in France in 1994 with the set up of monitoring systems by Blood Transfusion Committees and establishing a national hemovigilance system.[2] Later, in 1995 with an objective to improve public confidence in safe blood supply, the European Council published a resolution. Soon the hemovigilance system became governed by legal authorities.[3,4] Data from well established hemovigilance systems of various countries such as the United Kingdom (Serious Hazards of Transfusion [SHOT]), Canada (Transfusion Transmitted Injuries Surveillance System [TTISS]), Netherlands (Transfusion Reactions in Patients [TRIP]), Japan, Russia, Switzerland, and the United States of America has provided insight into various measures, which can improve blood safety.

At present, on global scale an International Hemovigilance Network (IHN) is functioning which evolved from European Hemovigilance Network (EHN—founded in 1998). The aim of IHN is to develop and maintain a joint structure relating to the safety of blood and blood components and of hemovigilance in blood transfusion and transfusion medicine throughout the world. The IHN in coordination with International Society of Blood Transfusion (ISBT) working party on hemovigilance proposed standard definition for hemovigilance system (2011).[5]

To further maximize the safety of donors and recipients, an international database-International survilliance of transfusion associated reactions and events (ISTARE) has been developed (http://www.ihn-org.com/haemovigilance-databases/istare-2/), where the hemovigilance data can be shared across the world. The main aim of ISTARE is to capture all adverse reactions and incidents (events) in recipients of blood and blood products that can certainly, probably, or possibly be imputed to blood transfusion. It also records adverse events in blood donors.

Scope of Hemovigilance

Scope of different hemovigilance systems varies due to differences in spectrum of reporting, that is, reporting of adverse reaction versus adverse events, all versus serious adverse reactions only; only incidents in recipients or also in donors; all adverse events or only the serious adverse reactions in recipients.[1] Ideally, the hemovigilance system should cover processes throughout the entire transfusion chain, from blood donation, processing, and transfusion to patients for the monitoring, reporting, and investigation of adverse events and reactions and near misses related to blood transfusion. It should be well coordinated between the blood transfusion service, hospital clinical staff and transfusion laboratories, hospital transfusion committees, regulatory agency, and national health authorities.

Recipient hemovigilance

The 'severity' of an adverse event is graded according to an internationally accepted scale. The imputability, that is, the likelihood be attributed to the blood component transfused is also significant. The ISBT has laid down criteria for 'severity' and 'imputability' of transfusion reactions.[6] The transfusion reactions in a recipient are generally subdivided as acute (within 24 hours) or delayed (after hours of transfusion) reaction.

Hemovigilance related to blood donors

The donor hemovigilance should include reporting of unexpected adverse events in whole blood and component donors and the action taken as a result.

These events may be adverse reactions or complications resulting from donation, selection, and management of donors, which may directly harm the donor or influence the quality of the product, thereby putting the recipient at risk.[6] A joint working group from the ISBT and EHN has proposed a classification and a set of definitions of complications related to blood donation.[6]

In this issue of Asian Journal of Transfusion Science, there are interesting manuscripts focusing on different aspects of hemovigilance. Jeongeun *et al*., in their paper on code development of national hemovigilance system, concluded that few major categories could be added to the blood transfusion safety stages. Through their study, they could suggest expansion strategies of hemovigilance systems for hospital blood banks. In yet another manuscript by Agnihotri *et al*., there is an analysis of adverse events and predisposing factors in whole blood donors. They also concluded that analysis of adverse events helps in identifying the blood donors at risk of donor reactions and adopting appropriate donor motivational strategies.

Among the Asian countries, a well established hemovigilance system is lacking and there is paucity of data on hemovigilance except for Japan, which has published report on adverse reaction and infectious diseases (http://www.jrc.or.jp/vcms_lf/haemovigilanceannualreport1993-2001.pdf). The goal of establishing hemovigilance system in India is already in place under the National Blood Policy.[7] National Blood Transfusion Council will take a lead in developing the program with assistance of Technical Resource Group and a monitoring committee.

In order to have a well organized hemovigilance system in developing countries like India, a comprehensive approach is required. A streamlined mechanism for data collection using standardized tools at hospital level and good coordination at the national level can bring up effective hemovigilance system in a country. A functional hospital transfusion committee can act as backbone for this by developing policies for transfusion practices, appropriate documentation, reporting and investigation of transfusion reaction. In addition the draft recommendation on hemovigilance system by World Health Organization (WHO) may help in developing an efficient system in developing countries (http://www.bloodtransfusion.it/articoli/47/en/Doi%200010.pdf). The data from a well functioning hemovigilance system can be used as quality indicator for monitoring the blood transfusion safety, and also contribute significantly to evidence-based transfusion medicine.

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Upcoming Events

- 32nd International Congress of International Society of Blood Transfusion, Cancun, Mexico. July 7-12, 2012
- TRANSCOM 37th Annual National Conference of Indian Society of Blood Transfusion and Immunohematology, Chennai, September 14-16, 2012. (http://www.isbtitn.org/)
- TRANSMEDCON 1st Conference of Indian Society of Transfusion Medicine, Jaipur. November 23-25, 2012. (http://www.transmedcon2012.com/)
- AABB annual meeting & CTTXPO, Boston. October 6-9, 2012. (http://www.isbtweb.org/mexico)