WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 12, Issue 11, 266-275. Review Article ISSN 2277– 7105

HAEMOVIGILANCE IN INDIA: A MILESTONE IN TRANSFUSION SAFETY

Bhagyashri Sudin Jadhav, Kaustubh Sudhakar Pishorkar*

Department of Pharmaceutics, Yash Institute of Pharmacy, Waluj, Chatrapati Sambhajinagar, Maharashtra, India 431001.

Article Received on
10 May 2023,

Revised on 30 May 2023,
Accepted on 20 June 2023

DOI: 10.20959/wjpr202311-28729

***Corresponding Author**
Kaustubh Sudhakar Pishorkar
Department of Pharmaceutics, Yash Institute of Pharmacy, Waluj, Chatrapati Sambhajinagar, Maharashtra, India 431001.

ABSTRACT

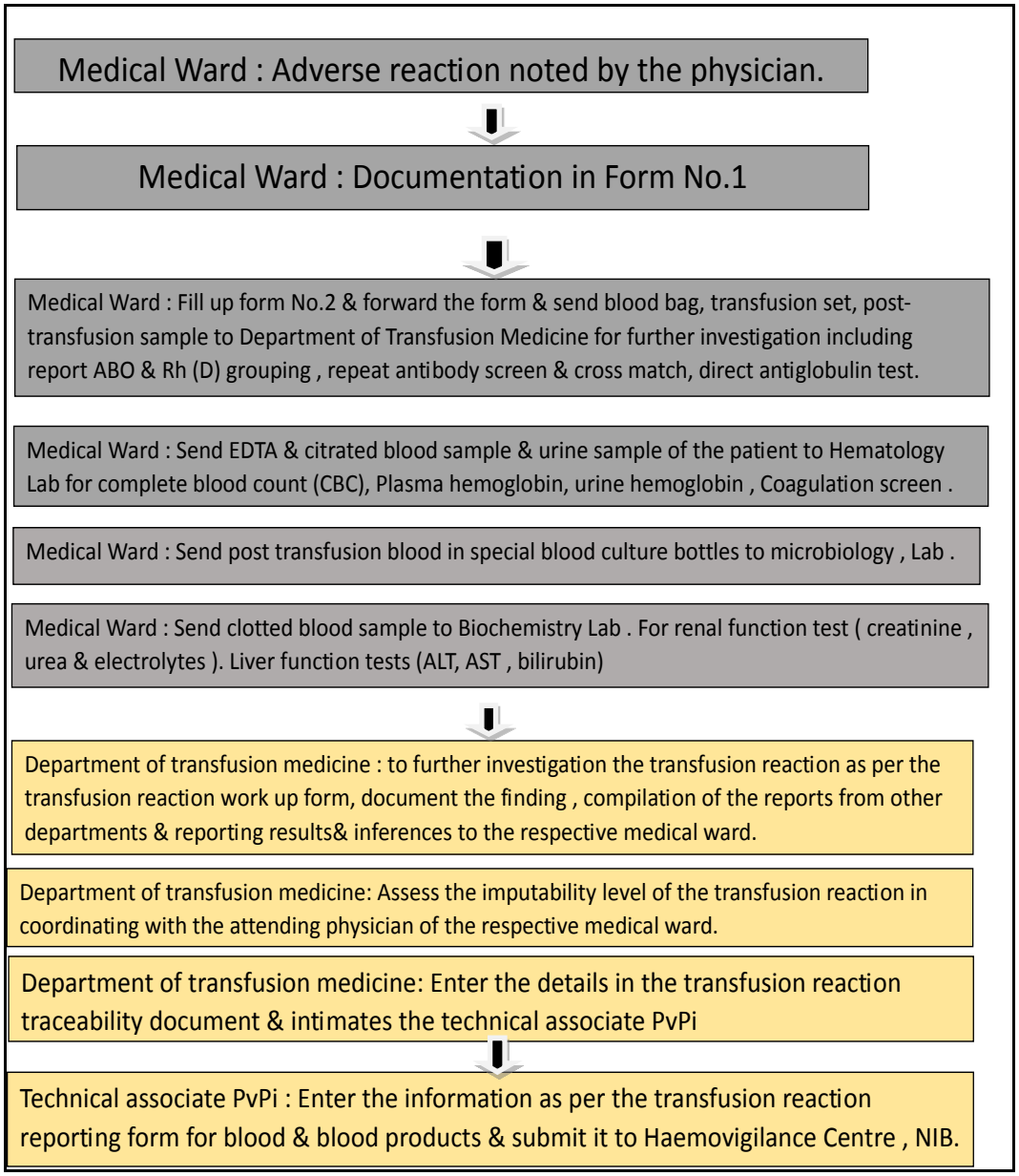
Blood transfusion plays an essential role in the development of health and saves many lives. Hemovigilance system is the program which ensures the transfusion security by monitoring each step of transfusion process from donor to recipient. The ultimate object of hemovigilance system is enhancing the quality and security of transfusion therapy. This article briefly describes about the hemovigilance program of India.

KEYWORDS: Hemovigilance system, Transfusion reaction, Safety management.

INTRODUCTION

Blood transfusion is a frequent and essential life-saving medical technique that is usually viewed as secure when performed exactly. It is a Frequently used therapy among seriously sick patients to cure a problem that is causing significant morbidity or death and cannot be ignored or controlled by other methods. It is a phenomenon that can provide both advantages and disadvantages the recipient. A transfusion response is defined as any adverse event (AE) which finds in an individual during or after the blood transfusion and its elements and for this, no other clarification can be determined. These AEs are mostly non-infectious in origin and might occur instantly. AEs might be slight, average, crucial, or life-threatening, depending on the severity and suitable therapeutic intervention.[1] The International Hemovigilance Network (IHN) defines hemovigilance (Hv) as "a set of surveillance procedures covering the entire transfusion chain (from the sampling of blood and blood products to the follow-up of recipients) intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of

variable blood products, and to prevent their occurrence or recurrence". As the term Hv is derived from the combination of two uniquely found Greek words i.e., 'Haema' which means blood, and a Latin word 'Vigil' which means watchful.[3,4] Hv is examined to be a part of vigilance which contain some analytical procedures that help regulate the quality of blood transfusion including observing, reporting, investigating, and scanning.[5,6] It is not only restricted to processing but it also includes the events related to blood donations, processing while transfusion of blood, and also takes some distinct prevention steps such as the Hv.[7,8] It is considered to be the latest way of transfusion across the world as it possesses indispensable security and quality during blood transfusion.[9] So, Hv can better be defined as the set of collected together surveillance or as an assembly of surveillance strategies that covers all the relevant procedures that relate to severe AE or unpredicted events i.e., from the assembly of blood and its components to the following up of the donors.[10,11] All of these are intended to gather and spread knowledge on unfavorable outcomes associated with the medicinal usage of variable blood transfusions, as well as to avoid its existence and repetition.[12,13] So, Hv is regard to be a surveillance system that is essential in detecting and analyzing the AEs and their associated reactions in the occurring blood transfusion chain by enhancing blood security. As a result, the true objective of a Hv is to increase blood transfusion efficacy. As these are widely accredited across all the analytical procedures that assured the quality of blood and its components regarding the development of health to rescue the patient's life during acute emergencies.[14-16] Figure 1 is appearing the organogram of Hv. Hv is considered to be an advancing field in medical science that support in blood transfusion as its introduction is currently considered to be an integral part of blood protection across the world.[17]



HISTORY

In France, ground-breaking work on Hv began in 1994 with the advancement of governance mechanisms by Blood Transfusion Committees and the upgrade of a nationwide Hv program.[18] Later, in the year 1995, it came intending to upgrade public confidence regarding their security and efficacious blood supply, a resolution was published by the European Council to expand the safety of clinical blood transfusion services in Europe.[19] The scope of the European Hemovigilance Network (EHN) arose as an outcome of the advancement expansion of IHN.[20] IHN aspires to raise and sustain a global collaborative organization applicable to the secure operation of blood and its components, as well as Hv in blood transfusion and transfusion therapy.[21] Through digital distributing of data, workshops, and conferences, the IHN's efforts have made an essential contribution to the top standard of Hv

throughout Europe. In terms of standardization, the IHN and the International Society of Blood Transfusion (ISBT) working party for Hv have presuming two important standardizations[22] i.e., the definitions of adverse reaction (ARs) and AEs in people. So, the main purpose of this introduction Hv system across the country is to search out the right situation of transfusion-related AEs to provide safe transfusion, as well as a reduction in harsh and life-threatening responses.[23]

NATIONAL HAEMOVIGILANCE PROGRAM OF INDIA

Indian Pharmacopoeia Commission (IPC) of India in partnership with the National Institute of Biologicals (NIB) located in Uttar Pradesh has launched a particular program named Hemovigilance Program of India (HvPI) on 10th Dec 2012 across the nation below its Pharmacovigilance Program of India (PvPI).[24,25] It inserts the Core Training Panel, Quality Review Panel, and Signal Review Panel which all together constitute the Hv advisory committee which is a core group of Hv (Figure 2).[26] The main purpose of establishing this program all over the nation is to trace all the Ars or AEs and programs associated while blood transfusing and through blood product directing and also assist recognize the trends that are approved to be the best practices and intervention that are need to enhance the patients care and their safety.[27] In addition, it is also used to compile all those data of ARs or associated AEs adding transfusion errors and QoP-related AEs that are either proved by alerting or caution mechanisms that encompass the full transfusion chain and their definite operations.[28] A particular program called "Haemo-Vigil" has been created to gather and compile data across the country. In India, around 117 Medical Colleges and Hospitals have already engaged in this Program. NIB serves as the HvPI Coordinating Center, accumulating and inspecting data on biologicals and Hv. The ultimate objective of this HvPI is to become a member of the IHN and bestows an international platform for switching best practices and assessing Hv data.[29]

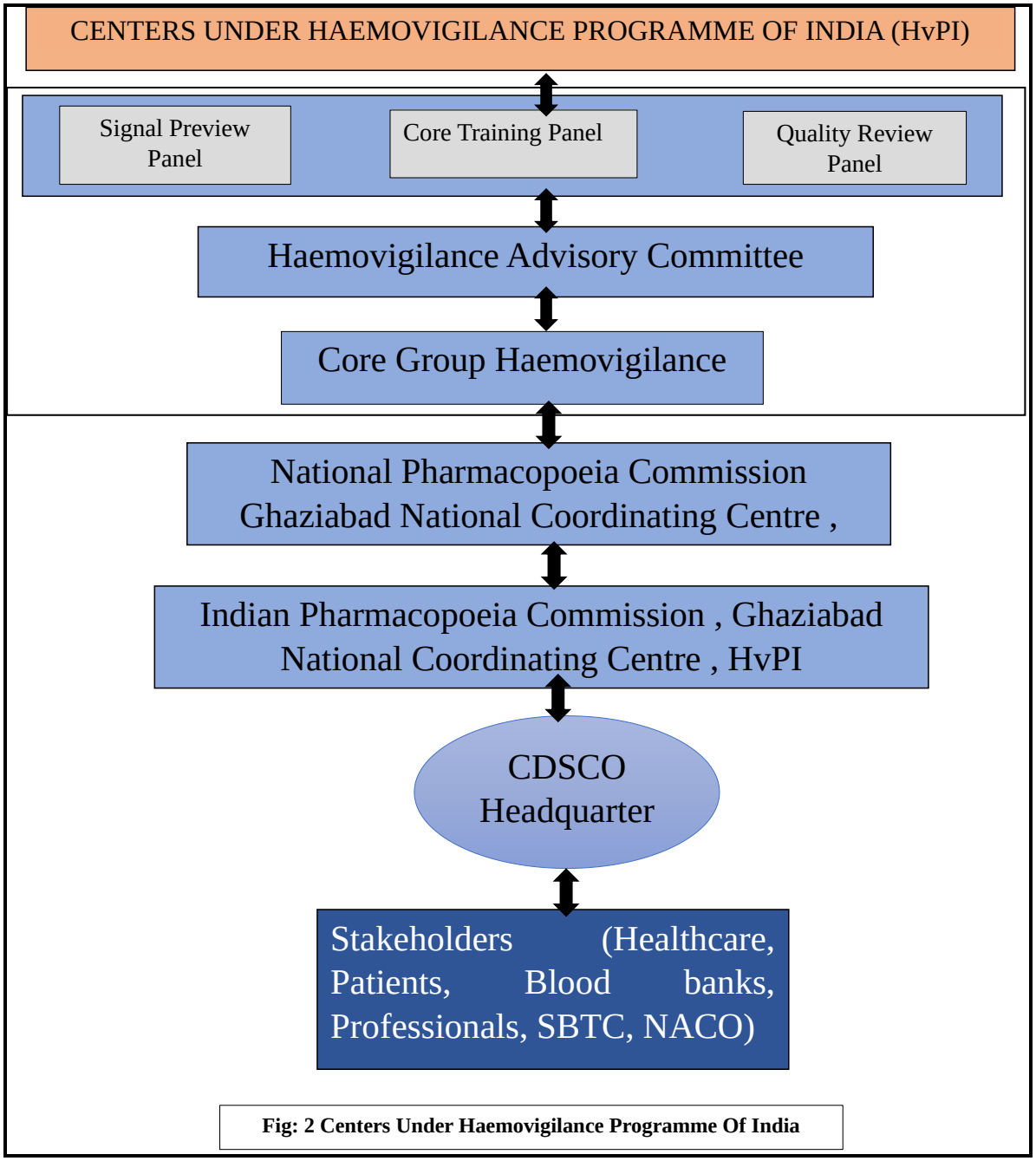


Fig: 2 Centers Under Haemovigilance Programme Of India

ADVANTAGES OF HAEMOVIGILANCE[30]

a) For Blood donors

• Donor security has been increasing by lowering problems in the blood transfusion procedure

• It implants trust in volunteer blood donors

b) Service for blood transfusion:

• On an early basis, any relevant defect can be identified

• By presenting the findings of safety, the development process will be quickened.

c) The hospital-granted blood bank and health-care facility:

• Errors will be reduced and reported as a result of system faults being identified.

• Adverse occurrences must be reported exactly and continuously.

• To guarantee security, development plans will be conceived.

d) Hv systems can enhance patient health safety by:

• Exact forecasting of present concerns impacting the individual.

• Presuming the primary source of problems as well as procedures for correcting and fixing them.

• Providing evidence-based policy suggestions for enhance policy changes.

Risks and factors contributing to transfusion related adverse events[31]

Certain factors accelerate the likelihood of a transfusion related adverse effect and these include:

• Individual patient characteristics

• Blood component

• Equipment

• Concomitant medications and intravenous fluids

Individual patient characteristics

Patients who have formerly been transfused, multiparous women and patients experiencing emergency uncross-matched transfusion are at enhanced risk of instant and retard hemolytic transfusion reactions. Febrile, allergic and anaphylactic reactions happen most frequently in multiparous women and in patients with IgA deficiency and anti-IgA antibodies.

Blood component

Platelet and granulocyte transfusions are related with the elevated rates of febrile non hemolytic transfusion reactions. The occurrence of such reactions can be adapted by changes to the blood component treated by leucodepletion. All red cell and platelet components generated by the blood service are leucodepleted. Platelets, which need storage at 20–24 ºC, are related with higher rates of bacterial infection than red cells, which are regularly refrigerated. All platelets are subject to routine bacterial culture and screening, which permits detection of a bacterial contaminated product. Transfusion of fresh frozen plasma is related with a higher risk of allergic reactions. Some reactions are sensitive, but acute life-

threatening reactions such as anaphylaxis and Transfusion-related acute lung injury (TRALI) may arise.

Equipment

All blood components are dispensed through particularly designed intravenous giving sets, which include a 170–200 micron filter to separate debris and clots that may have gather during storage. All equipment must be particularly designed, and assessed as secure for blood administration and used in granting with the manufacturer‘s operational processes.

Concomitant medications and intravenous fluids

No medication or solutions should be added to or infused through the similar tubing with blood or constituent except 0.9% Sodium Chloride, Injection (BP). ABO-compatible plasma or 4% Albumin or other acceptable plasma expanders may be used with acceptance of the patient‘s physician. Crystalloid and colloid solutions having calcium (e.g., Haemaccel) must never be include to or administered through the similar intravenous line as blood or component collected in an anticoagulant containing citrate because they interfere.

RECOMMENDATION FOR BETTER HAEMOVIGILANCE PROGRAM

- Better national blood quality and security initiatives
- Decreasing or minimizing human errors
- More trained personnel
- Create data standards
- Upgrade reporting cap

CONCLUSION

Hv has been proven to be a component of vigilance, which dispense all of the information by inspecting the problems that must be facilitated to correction and the precautionary actions that must be taken to decrease the threat of associated problems such as safety and quality during blood processing and transfusion, individuals, and linked staffs. Adoption of these problems within the HV system all over the world aids in identifying and reporting instances of under transfusion as a result of inventory, thereby helping in the development of advanced sampling procedures, stock management systems, and implementation of effective policies to promote blood safety and availability. As a result, formulating direction and managing periodic audits through the Hv system in nations with restricted resources may be accomplished more intensively through a gradual deployment.

REFERENCES

1. Somagari DR, Sriram CS, Rachamalla CKV, Dutta UC, Chaliha T, Lahkar M, et al. Haemovigilance study at a tertiary care hospital in the north-east of India. ISBT Science Series, 2015; 10: 61–64.
2. Heuft HG, Taleghani BM. Hemovigilance. Transfusion Medicine and Hemotherapy., 2018; 45: 148–150.
3. Liang WB, Zhang RY, Ye XF, Sun J, Xu J, Tan WB. The haemovigilance: the best quality management system of the transfusion chain? ISBT Science Series, 2012; 1-6.
4. Islam N, Amiruzzaman, Khan MEU, Chakrabarty A, Arifuzzaman M, Hossain MS, et al. Frequency and Nature of Transfusion Related Adverse Reactions in Patients Admitted in A Tertiary Care Hospital. Bangladesh Journal of Medicine, 2021; 33(1): 27–33.
5. Wiersum-Osselton JC(2013). Hemovigilance: is it making a difference to safety in the transfusion chain?..
6. Vries RRP, Faber JC, Strengers PFW. Haemovigilance: an effective tool for improving transfusion practice. Vox Sanguinis, 2011; 100(1): 60-67.
7. Faber JC. Worldwide overview of existing haemovigilance systems. Transfusion and Apheresis Sciences, 2004; 31(2): 99-110.
8. Mukherjee S, Maiti R. Haemovigilance: A Current Update in Indian Perspective. Journal of Clinical and Diagnostic Research, 2016; 10(11): EE05-EE09.
9. Jain A, Kaur R. Hemovigilance and blood safety. Asian Journal of Transfusion Science, 2012; 6(2): 137-138.
10. Wood EM, Ang AL, Bisht A, Bolton-Maggs PH, et al. International haemovigilance: what have we learned and what do we need to do next?. Transfusion Medicine, 2019; 29(4): 221-230.
11. Marwaha N. Haemovigilance – building one from none. ISBT Science Series, 2016; 11(2): 154–158.
12. Ramoa A, Condeço J, Escoval MA, Faber JC, Fdez-Riverola F, Lourenço A. The Evolving Role of Information Technology in Haemovigilance Systems. Journal of Healthcare Engineering, 2018; 2018; 6183468.
13. Gente VK, Basavarajegowda A, Kulkarni R, Basu D. Recipient Hemovigilance at a Tertiary Care Hospital in Southern India: A Cross-Sectional Study. International Journal of Advanced Medical and Health Research, 2018; 5(2): 66-70.

14. Allisabanavar S, Dheemantha P, Jayanthi CR, Reddy RS. A regional hemovigilance study of transfusion-related adverse events at a tertiary care hospital. National Journal of Physiology, Pharmacy and Pharmacology, 2018; 8(12): 1605-1608.
15. Samukange WT, Kluempers V, Porwal M, Mudyiwenyama L, Mutoti K, Aineplan A, et al. Implementation and performance of haemovigilance systems in 10 sub-saharan African countries is sub-optimal. BMC Health Services Research, 2021; 21: 1258.
16. Shivgunde P, Besekar S, Bhojwani K, Bhojwani D. Knowledge, attitude and practice of haemovigilance amongst healthcare professionals in Nashik, Maharashtra, India. IJBCP, 2018; 7: 986-91.
17. Strenger PFW. Is Haemovigilance improving transfusion practice? The European experience. Advances in Transfusion Safety, 2007; 127: 217–24.
18. Hoff HE, Guillemin R. The first experiments on transfusion in France. J Hist Med., 1963; 18: 103-224.
19. Schmidt PJ, Leacock AG. Forgotten transfusion history: John Leacock of Barbados. BMJ., 2002; 325(7378): 1485–1587.
20. Bhattacharya P, Marwaha N, Dhawan HK, Roy P, Sharma RR. Transfusionrelated adverse events at the tertiary care center in North India: An institutional haemovigilance effort. Asian Journal of Transfusion Science, 2011; 5(2): 164-270.
21. Noel L, Debeir J, Cosson A. The French haemovigilance system. Vox Sang, 1998; 74(2): 441–545.
22. Grujic J, Gulan Z, Budakov Z. Importance of haemovigilance and reports on transfusion reaction in blood component therapy. Medicinski Pregled, 2012; 65(1-2): 50-53.
23. Bhattacharya P, Marwaha N, Dhawan HK, Roy P, Sharma RR. Transfusion-related adverse events at the tertiary care center in North India: An institutional hemovigilance effort. Asian Journal of Transfusion Science, 2011; 5(2): 164-170.
24. Wiersum-Osselton JC, Kreek TM, Kort WLAM. Donor Vigilance: What are we doing about it?. Biologicals, May, 2012; 40(3): 176-179.
25. Ayob Y. Haemovigilance in developing countries. Biologicals, 2010; 38(1): 91-96.
26. Sreekumar PK, Kumar TMP, Sarathi GP, Gupta D, Pallavi. Haemovigilance and its significance in transfusion safety. International Journal of Drug Research and Technology, 2016; 6(4): 246—247.
27. Bisht A, Marwaha N, Kaur R, Gupta D, Singh S. Haemovigilance Programme of India: Analysis of transfusion reactions reported from January 2013 to April 2016 and key recommendations for blood safety. Asian Journal of Transfusion Science, 2018; 12: 1-7.

28. Marwaha N, Singh S, Bisht A. Setting up haemovigilancefrom the very first step. The Indian perspective. ISBT Science Series, 2014; 9: 178-183.
29. Busch M, Chanberland M, Epstein J, Kleinman S. Oversight and monitoring of blood safety in the United States. Vox Sanguinis, 1999; 77: 67–76.
30. Sreekumar PK, Kumar TMP, Sarathi GP, Gupta D, Pallavi. Haemovigilance in India - A Milestone in Transfusion Safety. International Journal of Health Sciences and Research, 2017; 7: 310-315.
31. Transfusion risks and factors contributing to adverse events. Australian Red Cross Blood Service. Available from http://www.transfusion.com.au/adverse_events/risks