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Review Article

Haemovigilance in India - A Milestone in Transfusion Safety

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ABSTRACT

Blood transfusion plays an important role in the improvement of health and saves many lives. Haemovigilance system is the programme which ensures the transfusion safety by monitoring every step of transfusion process from donor to recipient. The ultimate object of haemovigilance system is improving the quality and safety of transfusion therapy. This article briefly describes about the haemovigilance programme of India.

Key words: Transfusion safety, Haemovigilance, Haemovigilance in India.

INTRODUCTION

Blood transfusion saves many lives and plays a key role in improving health. As such there is no substitute for human blood and its components. The concept of safe blood transfusion gained attention since 1980s. In 1990s, transfusion related HIV and Hepatitis C virus infection were identified in haemophilia patients in USA, UK, France, Canada and Japan created an immediate need for developing a surveillance system for transfusion safety. Now this surveillance system is commonly known in the name of haemovigilance. [1]

The term 'haemovigilance' (he'movigilance in French) was coined in France in 1991 in analogy to the already existing term 'Pharmacovigilance'. The term 'haemovigilance' has Latin and Greek roots (Haema-blood; vigilance-paying special attention to). [2, 3] The initial work on haemovigilance was initiated in France in 1994 by creating a monitoring system 'Blood transfusion committee' and establishing a national haemovigilance system. Later in 1995, a resolution was published by European council with the aim of improving the public confidence in safe blood supply. Hence the haemovigilance system came under the governance of legal authorities. Later in 1998, the European haemovigilance network (EHN) was organized. Nowadays, a global system, 'International haemovigilance network' (IHN) is in functioning. The objective of IHN is to organize and maintain a body concerned with the safety of blood and its components, transfusion medicines and haemovigilance throughout the world. The IHN is working along with 'International society of blood transfusion' (ISBT) to ensure a better service. [4]

Based on the reports of World health organization (WHO), ISBT and IHN, the

haemovigilance is defined as a set of surveillance procedures covering the whole transfusion chain from collection of blood and its components up to the follow-up of its recipients intended to collect and assess information on adverse effects resulting from the use of blood products and to prevent their occurrence or recurrence. [5, 6]

At present, most of the developed countries in the world have haemovigilance program which is known in different names in different countries. For example, in U.K, it is known as Serious Hazards of Transfusion (SHOT), in Netherlands, it is known as 'Transfusion Reactions in Patients' (TRIP), in Canada it is known as Transfusion Transmitted Injuries Surveillance System (TTISS). [3, 4]

Depending upon the country, this system is governed by either regulator (example: France, Germany and Switzerland) medical societies (example: UK and Netherland), public health authorities (example: Canada) or blood manufacturers (example: Japan, Singapore and South Africa). [1, 6]

HAEMOVIGILANCE IN INDIA

Haemovigilance programme of India (HvPI) was launched on 10th December 2012. It is a centralized, well structured programme for monitoring adverse reactions associated with transfusion of blood and administration of blood products. It was launched by Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Government of India in collaboration with National Institute of Biologicals (NIB), Noida, Ministry of Health & Family Welfare, Government of India. [1, 2]

HvPI was implemented across the country under the Pharmacovigilance Programme of India (PvPI) in 90 medical colleges in the first phase. At present more than two hundred centres are covered under this programme. The national coordinating centre (NCC) for HvPI is at NIB, Noida. Now HvPI is a member of International Haemovigilance Network (IHN). [7] The targets of HvPI are grouped into three phases – initiation phase, expansion & consolidation phase and expansion & maintenance phase. The initiation phase (From the year 2012 to 2013) was focused on the development of systems and procedures and software development. It also gave attention in the enrollment of participants and startup of data collection. Organizing the zonal workshops and publication of haemovigilance newsletter for awareness were also planned in this phase. The second one, expansion & consolidation phase (From the year 2013 to 2015) had various objects such as continuation of enrollment, organizing of zonal workshops and publication of news letter. This phase also focused on training of staffs and took effort for the membership in IHN. The third one, expansion & maintenance phase (From the year 2015 to 2017) have various aims to achieve. It includes maintenance and optimization of system and procedures, identification of gaps, planning of appropriate trainings, assessing the feasibility of donor vigilance and rapid alert system development. Epidemiological surveillance for Transfusion-transmissible infections (TTI) are also planned to develop in this phase. [8] Some important events and developments associated with HvPI are presented in Figure 1.

Objectives of HvPI

To collect, combine and analyze the data of reactions associated with transfusion of blood and its components. (The term blood and its components include homologus and autologous whole blood, red blood cells, fresh frozen plasma, plasma derivatives, platelets, cryoprecipitate etc.)

- To promote awareness among the healthcare professionals to participate in this programme
- To develop evidence based recommendations and assist the Central Drugs Standards Control Organization (CDSCO) in regulatory decision making regarding with transfusion safety

- ❖ To communicate relevant information to stake holders
- ❖ To create national and international contacts

Figure 1: Some important events and developments associated with HvPI

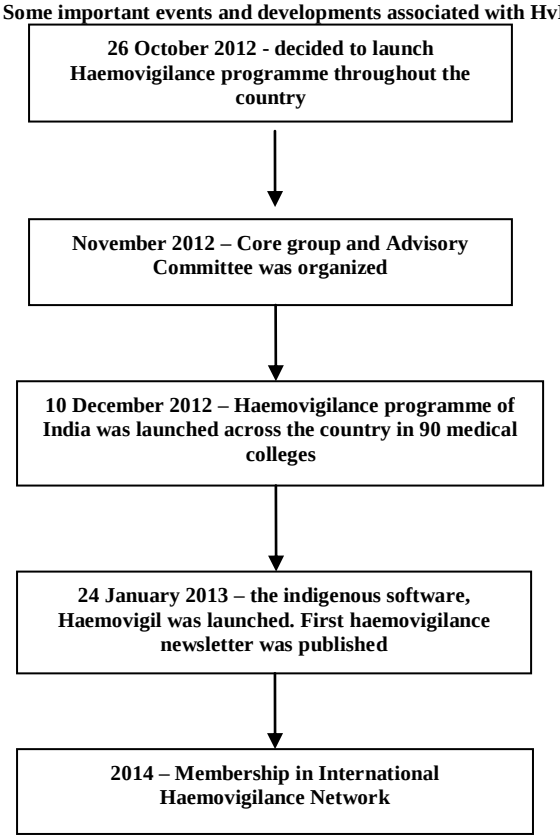
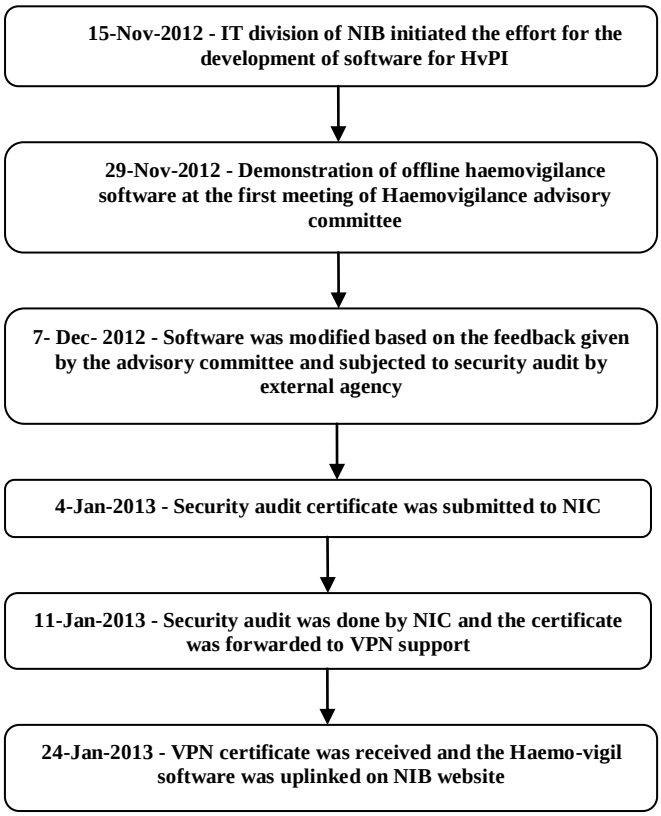


Figure 2: Important events in the development of Haemo-vigil software



Functional units of HvPI and their responsibilities [2]

Healthcare professionals (Medical and Nursing staff)

- ❖ Department of haematology and transfusion medicine
- ❖ Hospital transfusion committee
- ❖ National coordinating centre of haemovigilance
- ❖ CDSCO

In HvPI, to facilitate the reporting of transfusion reactions, a software known as Haemo-vigil was developed. Some important events in the development of this software are represented in figure 2.

Procedure for enrollment in HvPI

Medical colleges / Institutes/ Hospitals / Blood banks in India can enroll in this programme. Head / In charge of Transfusion Medicine Department / Blood bank can apply by submitting a duly filled enrolment form to NCC-HvPI, at NIB by post or through E. mail to NCC at haemovigilance@nib.gov.in

NCC verifies the details submitted by the applicant. After verification, NCC issues the user ID and password to the applicant to assess the Haemo-vigil software for reporting the transfusion reactions to NCC.

HvPI – Aim and important definitions associated with transfusion

HvPI has been designed and developed to find out, collect, combine and examine the adverse reactions / events associated with transfusion of blood or its components with the aim of identifying the trends, suggesting suitable practices and interventions needed to improve the patient care and safety and providing suggestions to the authorities to make the changes in policy for improving transfusion safety.

The adverse event reporting and learning system published by WHO in 2005 clearly defined the adverse event is any undesirable or unintended occurrence before, during or after transfusion of blood or its components that may lead to death or life threatening or disabling condition of patient or which results in, or prolongs, hospitalization or morbidity. [4, 5] The "European blood directive" defines the serious adverse reaction as an unintended reactions occur in donor or recipient associated with the collection or transfusion of blood or its components that leads to fatal, life threatening, disabling or incapacitating state or which results in or prolongs, hospitalization or morbidity. In HvPI, an internationally accepted grading system has been used to describe the severity and attributability of the adverse event. It includes

Grade – 1 (non severe), Grade – 2 (severe), Grade – 3 (life threatening), Grade – 4 (death).

In case of grade – 1 adverse event, medical intervention such as symptomatic treatment may needed to the recipient but lack of such a treatment would not lead to permanent impairment or damage to the body function. But in case of grade – 2, the recipient need in-patient hospitalization and may need medical or surgical intervention to prevent permanent impairment or damage to the body function. In grade – 3 adverse events, the recipient should require a major medical intervention to prevent death. But in case of last one, the grade – 4 adverse events leads to the death of the recipient. [2]

Imputability means the possibility that an adverse event / reaction in a recipient may be attributed to transfusion. Various levels of imputability include

- ➢ Definite (Certain): When there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to the transfusion.
- ➢ Probable (Likely): When the evidence is clearly in favour of attributing the adverse event to the transfusion.
- ➢ Possible: When the evidence is indeterminate for attributing the adverse event to the transfusion or an alternate cause.
- ➢ Unlikely (Doubtful): When the evidence is clearly in favour of attributing the

adverse event to causes other than the transfusion.

- Excluded: When there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to causes other than the transfusion. [2, 5]

Types of adverse reactions possible with transfusion

Transfusion associated adverse reactions are broadly grouped in to two categories, infectious and non infectious. The noninfectious category is further subdivided in to acute and delayed type reactions. Acute type include various reactions such as acute haemolytic transfusion reaction, febrile non-haemolytic transfusion reaction, transfusion associated acute lung injury, hyper kalemia etc.

Some other reactions such as delayed haemolytic transfusion reaction, delayed serological transfusion reaction, post transfusion purpura, transfusion associated graft versus host disease, haemosiderosis etc are come under delayed type transfusion reaction. In case of infection type transfusion reaction, the examples are Hepatitis B, C, HIV and Malaria. [2]

Responsibilities of medical and nursing staffs in a haemovigilance centre

- The medical and nursing staffs working in a haemovigilance centre is responsible for documenting and reporting the functions of that centre. It include if any transfusion reaction is suspected, the concerned nursing staff should report it immediately to the concerned physician.
- Details such as patient and product/implicated units related information should document properly.
- Document the transfusion reaction details and submit it to the Dept. of Immunohaematology and transfusion medicine.
- Assess the imputability level in co-ordination with the Dept of Transfusion Medicine.
- Keep the details of complications and also investigation report from Dept of Transfusion medicine in patient's medical record. [2, 5]

Processing procedure of report submitted to HvPI

- The TRR form submitted to NCC-HvPI is subjected to initial assessment for correctness and completeness.
- After the initial assessment, the core group forwards it to the Quality Review Panel for the evaluation of its quality. After that, the data reaches Signal Review Panel for the further statistical analysis.
- Recommendations of these two panels are forwarded to the core group and Haemovigilance advisory committee.
- Then the recommendations of Haemovigilance advisory committee are forwarded to IPC by core group. Then the IPC forward it to CDSCO.
- The CDSCO takes regulatory decisions and forwarded them to the stakeholders such as patients, health care professionals, blood banks, NACO and SBTC. [2]

National blood donor vigilance programme (NBDVP)

National blood donor vigilance programme was launched under haemovigilance programme of India with the objectives of

- Improving the safety and satisfaction of donor through monitoring and analyzing the adverse events
- Analyzing the associated risk factors, implementing and evaluating the preventive measures
- Providing evidence based assistance for the improvement of blood donation process
- Increasing the donation frequency and reducing the frequency of adverse events.

For the effective implementation of this programme, a software was developed for the communication of data regarding with the adverse events developed in donors at the time of blood donation by blood banks to NCC. A mobile application was also developed for the use of blood donors

to uplink the adverse events if any developed to NCC. Moreover, a toll free help line number was launched to enable the blood donors to collect the details regarding with blood donation and adverse reactions. **[7, 9]**

CONCLUSION

Haemovigilance programme is an important part of quality management in blood transfusion chain. There is a continuous need to work on haemovigilance and also establishing a right awareness system. It is just a beginning, a long way to go...

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REFERENCES

1. Jaspreet Kaur Boparai, Surjit Singh. Haemovigilance: A new beginning in India. Int J App Basic Med Res. 2015; 5(3): 200-202. http://dx.doi.org/ 10.4103/2229-516X.165379
2. Satyajeet Singh, Akanksha Bisht, Surinder Singh, Kalaiselvan, Varun Chopra, Pallavi Kumari, Ruchi Rao. Review on haemovigilance practice in India. World Journal of Pharmacy and Pharmaceutical Sciences 2015; 4(12): 350-357.
3. Jean-Claude Faber. Hemovigilance: Definition and overview of current hemovigilance systems. Transfusion Alternatives in Transfusion Medicine (2003); 5(1): 237-245
4. Ashish Jain, Ravneet Kaur. Hemovigilance and blood safety. Asian J Transfus Sci. (2012); 6(2): 137–138. http://dx.doi.org/10.4103/0973-6247.98911
5. Sukanta Sen, Pankaj Gupta, Satwika Sinha, Pawan Bhambani. Haemovigilance and transfusion safety: A Review. Scholars Journal of Applied Medical Sciences 2014; 2(1A): 85-90.
6. Amit P. Date, Anjali A. Date, Amruta V. Dashputra, Archana S. Borkar. Knowledge, attitude and practice of haemovigilance among doctors in tertiary care hospital in Nagpur, Maharashtra, India. International Journal of Basic & Clinical Pharmacology 2016; 5(3): 788-793. http://dx.doi.org/10.18203/2319-2003.ijbcp20161520
7. Haemovigilance Newsletter (Haemovigilance Programme of India) 2015; 3(6): 1-16. http://www.nib.gov.in
8. Akanksha Bisht. Haemovigilance programme of India (HvPI)-organizational structure. IHS; 7th March 2014; Barcelona, Spain. p. 1-19. http://www.ihn-org.com/wp-content/uploads/2014/01/Haemovigilance-Programme-of-India-by-Akanksha-Bisht.pdf
9. Akanksha Bisht, Surinder Singh, Neelam Marwaha. National blood donor vigilance programme: India. Asian J Transfus Sci 2016; 10(1): 1-2.

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