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An Overview on Haemovigilance: Part of Pharmacovigilance

Devesh U. Kapoor[1,], Diwakar Dadarwal[2], Ruchi B Vyas[1], Chaitali Lad[1] and Manish Patel[1]*

[1]Dr. Dayaram Patel Pharmacy College, Sardar baug, Station Road, Bardoli, Surat, Gujarat-394601, India
[2]Sanjeevani College of Pharmaceutical Sciences, Rajota, Khetri, Rajasthan, India

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*Corresponding author: Dr. Devesh U. Kapoor, Dr. Dayaram Patel Pharmacy College, Sardar baug, Station Road, Bardoli, Surat, Gujarat-394601, India;
E-mail: dev7200@gmail.com

Abstract

Haemovigilance plays an indispensable role in confirming patient safety with regard to blood transfusions. Haemovigilance is a structured scheme of observing, identifying, reporting, investigating and analysing adverse events and reactions pertinent to transfusion and manufacturing blood products. This system is also a rudimentary part of quality control in a blood system, bringing about counteractive and preventive measures, and for the perpetual advancement of the quality and safety of blood products and the transfusion process. The data generated through the haemovigilance system helps in framing important changes in the whole blood transfusion process which are useful for better patient safety. This article momentarily reveals the history of haemovigilance, necessity of haemovigilance and also explain about the Haemovigilance program of India.

Keywords: PvPI; Blood transfusion; Adverse drug reaction; CDSCO.

Introduction

The word "Haemovigilance" is derived from the Greek word "haema" which means blood and the Latin word "vigilans" which means watchful. Haemovigilance as defined by Faber is "a set of surveillance procedures covering the whole transfusion chain (from the donation of blood and its components to the follow-up of recipients of transfusion), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent the occurrence or recurrence of such incidents [1,2]. The aim of haemovigilance is to identify and analyse all untoward effects of blood transfusion in order to correct their cause and to prevent recurrence, thus improving the safety of blood transfusion. Haemovigilance is a significant part of the quality system for blood transfusion. It implies methods for identifying errors, adverse events and reactions including alert systems, investigation of complaints, traceability systems, notification systems and audits of practice. Haemovigilance is defined as 'a set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the follow-up of its recipients, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence [3,4].

Haemovigilance at two levels:

Haemovigilance systems exist basically at two levels:

(1) In the blood establishment and the hospital comprising the blood transfusion chain and

(2) At a regional, national and international level.

History [5,6]

The need for safe blood transfusion was felt as early as 1980's and 1990's when many hemophilia patients in the UK, France, Canada, Japan, and USA contracted HCV and HIV from blood transfusions and factor concentrates. This heartbreaking example in history emphasized the need for haemovigilance. The work on

haemovigilance was first initiated in France in 1991, with the setup of monitoring systems by Blood Transfusion Committees followed by the inception of Centre National Haemovigilance in 1992. A complete French Haemovigilance System was in place by 1994, followed by the Serious Hazards of Transfusion launched by the UK. A similar voluntary scheme called the Transfusion Transmitted Injuries Surveillance System was introduced by the Public Health Agency of Canada. Currently, on a global scale an International Haemovigilance Network (IHN) is functional, which evolved from the European Haemovigilance Network established in 1998.

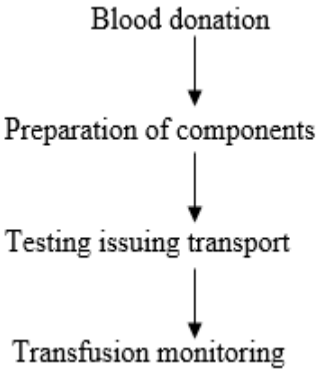

Figure 1: The blood transfusion chain.

To further augment the safety of blood transfusion an international database - International Surveillance of Transfusion Associated Reactions and Events has been formed to share haemovigilance data across the globe. Blood transfusion safety systems may be managed either by regulators (e.g. France, Germany, and Switzerland), blood manufacturers (e.g. Japan, Singapore, and South Africa), medical societies (e.g. Netherlands, UK) or public health authorities (e.g. Canada). Haemovigilance has evolved from pharmacovigilance, which aims to collect and assess information related to medicinal products, most importantly adverse drug reactions in human beings. Pharmacovigilance in transfusion medicine deals with plasma derivatives: Clotting factor concentrates immunoglobulin's, albumin, and other fractionated products. Haemovigilance, as the name suggests, is responsible for blood components: Whole blood, erythrocytes concentrates, thrombocytes concentrates, and fresh frozen plasma. The information obtained through haemovigilance is imperative to make necessary changes in transfusion policies, for amendments in transfusion practices in hospitals and blood services, to enhance transfusion standards, to help in formulating transfusion guidelines and to improve quality and safety of entire transfusion process. The ultimate goal is to improve the overall safety of blood transfusion by detecting and analyzing all untoward effects of blood transfusion to correct their cause and to prevent recurrence. As per the Ministry of Health and Family Welfare, Government of India, there are 2545 authorized blood banks in India which emphasise the need of a centralized haemovigilance system in India.

Haemovigilance Program in India

Haemovigilance Program of India was launched at the national level on 10th December 2012, as a basic element of the Pharmacovigilance Program of India (PvPI). The haemovigilance program is purposeful through a core group and an advisory committee, which harmonize the activities of haemovigilance between medical colleges and the National Coordinating Centre and also offer a connoisseur opinion for investigation of the information generated. The advisory committee also provides insights helpful in linking Haemovigilance Program of India with the IHN. The Transfusion Reaction Reporting Form (TRRF) and the software (Haemovigil) for reporting were also designed under the guidance of the advisory committee. Haemovigil software was uplinked on National Institute of Biologicals website on January 24th January 2013 and can be accessed from http://nib.gov.in/haephp/haemovigilance_login.php. The TRRF can be downloaded from these websites: www.nib.gov.in, www.ipc.gov.in and www.cdsco.nic.in.

This program is being implemented under the ambit of the PvPI. It is launched by the NIB in collaboration with the Indian Pharmacopoeia Commission (IPC). Currently, 154 centers have been enrolled in this program. The data from the medical colleges (Department of Transfusion Medicine or the blood bank) in case of any adverse reaction related to blood transfusion or blood product administration is collected. Information obtained is filled in the TRRF and forwarded to the National Coordinating Centre at NIB through Hemovigil software. The recommendations based on the collected data will be forwarded to the National coordinating Centre IPC for further transmission to Drugs Controller General (India), Central Drugs Standard Control Organization. The safety regulatory guidelines will be formulated and modified from time to time by CDSCO based on the inputs from TRRF, which will be implemented by health care professionals and blood banks for the benefit of patients [7].

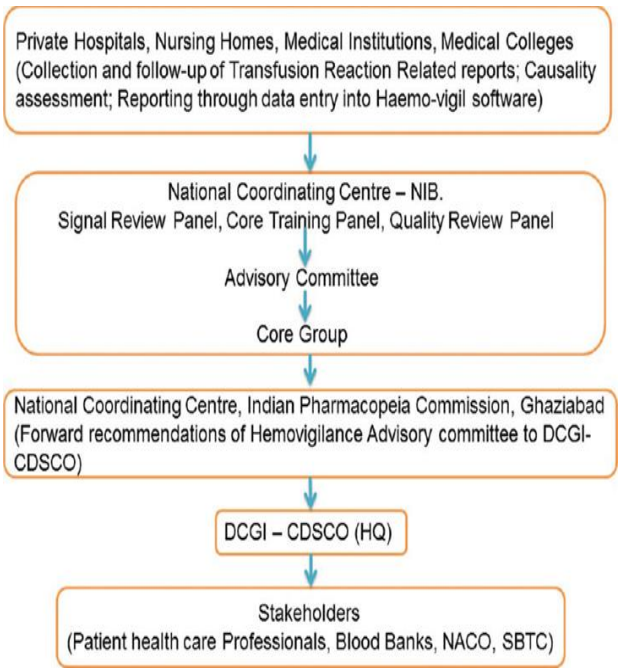

Figure 1: Flow chart of transfer of information under haemovigilance program of India.

This data communication process has been illustrated in figure 2.

Map of haemovigilance program of India (2012-2017):

1. Initiation phase (2012-2013):

- Develop systems and procedures for reporting
- Develop software
- Enrol participants
- Start Data Collection
- Zonal workshops for awareness
- Publication of HV Newsletter
- Standard Definitions of Adverse Transfusion Reactions (ISBT–WP on haemovigilance and IHN)
- Finalisation of Transfusion Reaction Reporting Form (TRRF)
- Development of indigenous Software, (Haemo-Vigil)
- Ensure Security and Confidentiality of Data
- Conduct Awareness and Training CMEs/workshops
- Develop methods for Analysis of Data

2. Expansion and consolidation phase (2013-2015):

- Continue enrolment
- Awareness and Training of staff
- Continue Zonal Workshops
- Publication of Newsletter
- Application for membership of IHN

3. Expansion and maintenance phase (2015-2017):

- Identify gaps and address appropriately
- Reasons for not reporting (questionnaire already circulated)
- Review and improve quality of data
- Assess feasibility of donor vigilance
- Feasibility of Rapid alerts and Near Miss events
- Epidemiological surveillance for TTIs
- Publication of the Haemovigilance Report with recommendations

Further Plan:

- Launch of dedicated website for HvPI
- Public domain
- Restricted domain
- Implementation of revised TRRF
- State Working Groups on Haemovigilance
- Appreciation certificates for participants
- Publishing the annual haemovigilance report
- Making use of HV data for specific recommendations
- Sharing information with international experts

Objective of reporting adverse reactions in transfusion in National Haemovigilance Programme: [8]

- A national reporting system can usefully be regarded as a tool to advance public policy concerning patient safety.
- Reporting can help identify hazards and risks and make available information as to where the system is breaking down.
- This can help target improvement efforts and systems changes to shrink the likelihood of damage to future patients.
- Reporting of suspected adverse reactions in a timely manner facilitates effectual risk management.
- Reporting means for obtaining information which can be used to perk up the product safety.

Role of medical and nursing staff of the adverse drug reaction monitoring centres: [9]

Physicians and nurses attending to patients having suspected transfusion complications should execute the following documentation and reporting functions:

- Maintain records of the complication in the patient's medical record, including the report of the investigation completed by the Department of Transfusion Medicine
- Document the details of the patient as well as the implicated units/ products in the Form and retain in the patient's file.
- Send the details of the transfusion reaction to the Department Transfusion Medicine in the Form
- Attending nursing staff should report suspected transfusion reaction immediately to the attending physician
- Assess the imputability levels of the adverse reactions in coordination with the Department of Transfusion Medicine

Roles and responsibilities of CDSCO

The data on adverse transfusion reactions and events are entered into the "haemovigil" software from the transfusion medicine department/blood bank/hospitals/medical colleges and transmitted program must integrate better national blood quality and safety initiatives, reducing or minimizing human errors, recruiting more trained personnel, generate data standard and enhanced reporting capacity [10]

Conclusion

Haemovigilance is an indispensable component of quality management in a blood system and is needed for the persistent augmentation of quality and safety of blood products and transfusion process by monitoring and safeguarding the undesirable events associated with the use of blood products. Haemovigilance will have a chief brunt on optimal blood usage. The consciousness that, apart from crucial indications, the effectiveness of blood transfusions is often unidentified, not recognized or even negative, has resulted in a noteworthy diminution of the use of blood products as acknowledged by many, In order to comprehend this progress, the observation of suitable or best possible blood use in a more exhaustive way, e.g. through the assortment of a set of indicators that may be provided simply by most hospital information systems, has to be started. On the same time, assessment methods should be more adapted to measure and analyse critical parameters for optimal blood use, such as acquiescence with guidelines (see http://www.optimalblooduse.eu). Nevertheless, it is expected that active haemovigilance systems including the haemovigilance officers in hospitals will contribute in the near future also to the supervision of optimal blood use. Finally, haemovigilance systems will be a contender to make sure vigilance and surveillance of other human products that are transplanted, such as cells and tissues and, at a later stage, organs for transplantation.

Conflict of Interest

None declared.

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