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Introduction to Hemovigilance as a Component of Pharmacovigilance

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Abstract

Haemovigilance is critical in ensuring patient safety when receiving blood transfusions. Haemovigilance is a systematic approach of watching, recognising, reporting, investigating, and analysing adverse occurrences and reactions related to blood transfusion and blood product manufacture. This system is also a fundamental component of blood system quality control, bringing about counteractive and preventative actions, as well as the continuous improvement of the quality and safety of blood products and the transfusion process. The data supplied by the haemovigilance system aids in the formulation of significant modifications in the entire blood transfusion process that are beneficial to patient safety. This page briefly explains the history of haemovigilance, the importance of haemovigilance, and the Indian Haemovigilance programme.

Keywords*: - CDSCO, PvPI, Blood transfusion, Adverse drug reaction.*

INTRODUCTION

The term "Haemovigilance" comes from the Greek word "haema," which means "blood," and the Latin word "vigilans," which means "vigilance." According to Faber, haemovigilance is "a set of surveillance procedures covering the entire transfusion chain (from blood donation and its components to transfusion recipient follow-up), 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." The goal of haemovigilance is to identify and analyse any adverse effects of blood transfusion in order to fix the source and avoid recurrence, hence enhancing blood transfusion safety. Haemovigilance is an important component of the blood transfusion quality system. It entails mechanisms for detecting mistakes, undesirable occurrences, and reactions, including as alert systems, complaint inquiry, traceability systems, notification systems, and practise audits.

Haemovigilance is defined as "a set of surveillance procedures covering the entire transfusion chain, from the collection of blood and its components to the follow-up of its recipients, with the goal of collecting and assessing information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and preventing their occurrence and recurrence.

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

Many haemophilia patients in the United Kingdom, France, Canada, Japan, and the United States developed HCV and HIV via blood transfusions and factor concentrates as early as the 1980s and 1990s. This terrible historical event underscored the importance of haemovigilance. The work on haemovigilance began in France in 1991, with the establishment of monitoring systems by Blood Transfusion Committees, followed by the establishment of the Centre National Haemovigilance in 1992.

By 1994, the French Haemovigilance System had been fully implemented, and the UK had established the Serious Hazards of Transfusion.

The Public Health Agency of Canada created a similar voluntary approach called the Transfusion Transmitted Injuries Surveillance System. On a worldwide basis, the International Haemovigilance Network (IHN), which grew from the European Haemovigilance Network created in 1998, is now operational.

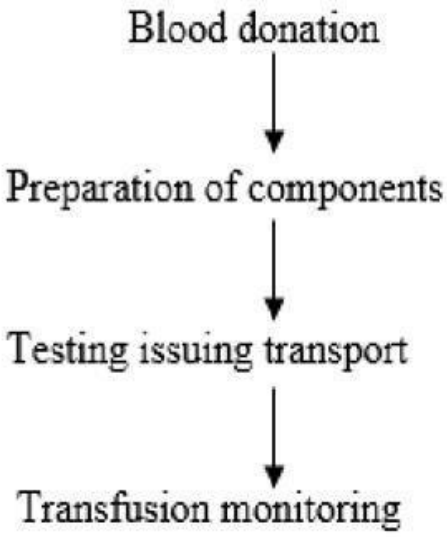

Figure 1: The blood transfusion chain

To improve blood transfusion safety, an international database - International Surveillance of Transfusion Associated Reactions and Events - was established to disseminate haemovigilance data globally. Blood transfusion safety systems can be administered by regulators (such as France, Germany, and Switzerland), blood producers (such as Japan, Singapore, and South Africa), medical societies (such as the Netherlands and the United Kingdom), or public health agencies (e.g. Canada). Haemovigilance originated from pharmacovigilance, which tries to collect and analyse information on pharmaceutical goods, particularly adverse drug reactions in humans. In transfusion medicine, pharmacovigilance is concerned with plasma derivatives: Immunoglobulins, albumin, and other fractionated products are concentrated by clotting factor. As the name implies, haemovigilance is in charge of blood components such as whole blood, erythrocyte concentrates, thrombocyte concentrates, and fresh frozen plasma. The information obtained through haemovigilance is critical for making necessary changes in transfusion policies, amending transfusion practises in hospitals and blood services, improving transfusion standards, assisting in the formulation of transfusion guidelines, and improving the overall quality and safety of the transfusion process. The ultimate objective is to enhance the overall safety of blood transfusion by identifying and evaluating all adverse effects of blood transfusion in order to identify the source and avoid recurrence. According to the Ministry of Health and Family Welfare of the

Government of India, there are 2545 recognised blood banks in India, highlighting the need for a centralised haemovigilance system in India.

Haemovigilance Program in India

On December 10, 2012, the Haemovigilance Program of India was inaugurated at the national level as a core component of the Pharmacovigilance Program of India (PvPI). The haemovigilance programme serves a function through a core group and an advisory committee that coordinate haemovigilance operations between medical schools and the National Coordinating Centre and also provide expert advice for analysis of the information provided.

The advisory council also gives ideas that are useful in connecting India's Haemovigilance Program with the IHN. The advisory group also helped create the Transfusion Reaction Reporting Form (TRRF) and reporting software (Haemovigil). On January 24, 2013, the National Institute of Biologicals website was updated with the Haemovigil software, which can be viewed at http://nib.gov.in/haephp/haemovigilance login.php.The TRRF is available for download at the following websites: www.nib.gov.in, www.ipc.gov.in, and www.cdsco.nic.in.

This initiative is being carried out under the auspices of the PvPI. The NIB has launched it in conjunction with the Indian Pharmacopoeia Commission (IPC). This programme currently has 154 centres enrolled. In the event of an adverse reaction to blood transfusion or blood product administration, data from medical colleges (Department of Transfusion Medicine or blood bank) is collected. The information gathered is entered into the TRRF and transmitted to the National Coordinating Centre at NIB through Hemovigil software.

The suggestions would be conveyed to the National Coordinating Centre IPC for onward transmission to the Drugs Controller General (India), Central Drugs Standard Control Organization. CDSCO will formulate and modify safety regulatory guidelines based on TRRF inputs, which will be implemented by health care professionals and blood banks for the benefit of patients.

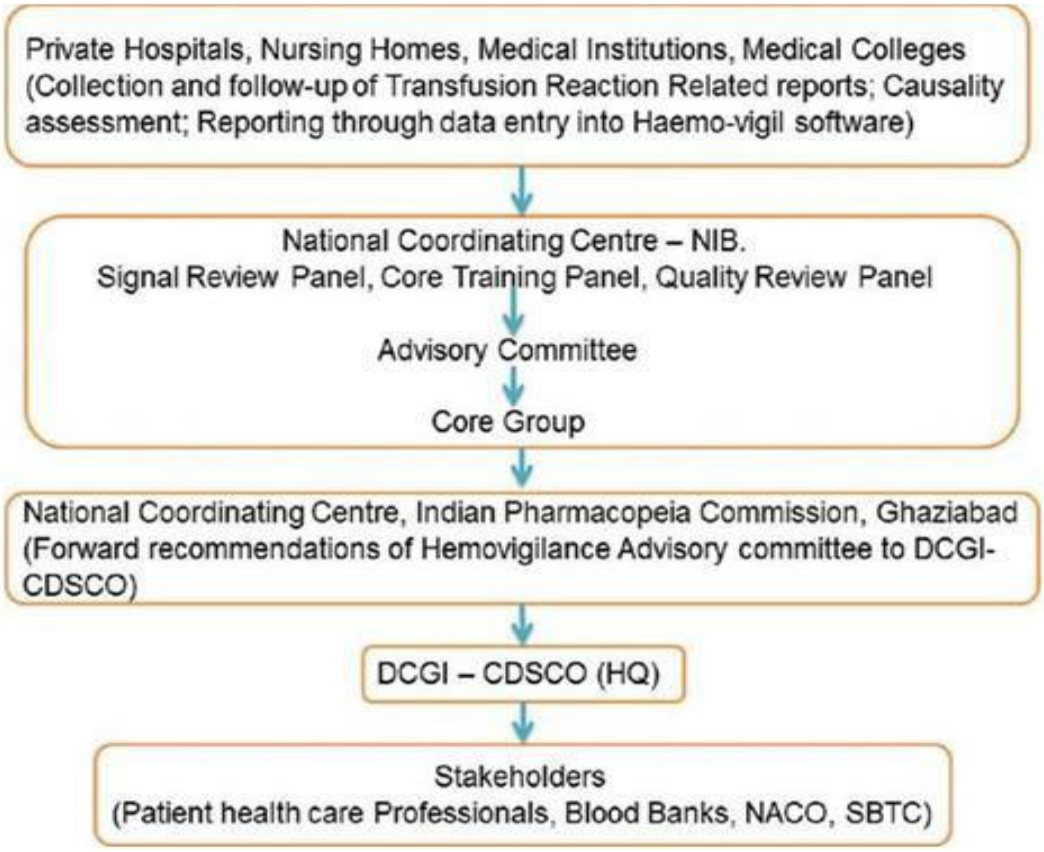

Figure 1: Flow chart of transfer of information under haemovigilance program of India

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:

- 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:

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

Data on adverse transfusion reactions and events are entered into "haemovigil" software from transfusion medicine departments/blood banks/hospitals/medical colleges and transmitted programme must integrate better national blood quality and safety initiatives, reducing or minimising human errors, recruiting more trained personnel, generating data standards, and enhanced reporting capacity.

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.

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