REVIEW ON HAEMOVIGILANCE PRACTICE IN INDIA

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ABSTRACT

Haemovigilance is a continuous process of data collection and analysis of transfusion-related adverse reactions/events in order to investigate their causes and outcomes, and prevent their occurrence or recurrence. It includes the identification, reporting, investigation and analysis of adverse reactions and events in recipients and blood donors as well as incidents in manufacturing processes and eventually errors. It is a risk monitoring system integral to the practice of transfusion medicine whose ultimate purpose is to improve the quality and safety of transfusion therapy.

KEYWORDS: Haemovigilance, Haemovigilance Programme, Blood Safety.

INTRODUCTION

The word ‘haemovigilance’ (he’movigilance in French) was coined in France in 1991 in analogy to the already existing term ‘pharmacovigilance’. It is derived from the Greek word ‘haema’ = blood and the Latin word ‘vigilans’ = watchful. The aim of haemovigilance is to detect and analyse all untoward effects of transfusion of blood and blood components in order to correct their cause and prevent recurrence, thus improving their safety.

Haemovigilance is an important component of the quality system for blood transfusion. It implies methods for identifying errors, adverse events and reactions including alert systems for 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. In other words haemovigilance is close monitoring, recording, reporting and analyzing adverse event occurring in the blood transfusion chain and undertaking action plan to avoid its occurrence.

History of Haemovigilance
The first blood transfusions in the 17th century were attempts to transfuse humans with blood of animals (innocent lambs were favorite) for all kinds of illnesses. In the 18th century, however, the French King Louis XIV forbade the transfusion of animal blood to people by law because it was dangerous. In the 19th century, Henri Leacock and James Blundell pioneered inter-human transfusion as a life saving therapy for severe blood loss. However, Blundell warned to apply this therapy only as ultimo refuge because it was also dangerous. Subsequently, due to cross matching of blood and use of anti-coagulant for blood transfusion became less dangerous in the 20th century and was accepted as life saving therapy. However, soon it was realized that transfusion was certainly not without risk, data was lacking about the actual risk associated with blood transfusion. At the end of the 1980s, the transmission of various infections by blood created the need for a greater awareness on the safety of blood and pioneer work on haemovigilance was started in France in 1991 with setting up of monitoring systems by Blood Transfusion Committees, resulting in a National Haemovigilance Network in 1994.

Haemovigilance Programme of India (HvPI)
A centralized and structured Haemovigilance Programme has been launched in India on 10th December 2012. It is an independent programme under the broad ambit of Pharmacovigilance Programme of India (PvPI), which was initiated in July 2010 with the objective of assuring patient safety and promoting public health. The PvPI is being executed by the Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare (MOHFW), Govt. of India. The data is being collected through Adverse Drug Reaction (ADR) monitoring centers set up in 150 medical institutions in the country. Trained staff-the technical associates has been recruited for these ADRs for data collection and submission. After the successful launch of PvPI, the Haemovigilance Programme has been started.
National Institute of Biologicals (NIB) an autonomous institute under the MOHFW, Govt. of India is a National Co-ordinating Centre for Haemovigilance Programme of India. At Present 236 Centers are enrolled under Haemovigilance Programme of India and adverse reaction are being report to NIB via Haemo-vigil software, an indigenous software prepare by NIB.

**Objectives of the programme**

(i) to collect, collate and analyse data related to transfusion reactions of blood and its components( Blood include homologus and autologous whole blood, fresh frozen plasma, red blood cells, platelets, cryoprecipitate, plasma derivatives etc.)

(ii) to create awareness amongst healthcare professionals in the country for participation in the programme,

(iii) to generate evidence based recommendations and assist Central Drugs Standards Control Organization (CDSCO) for undertaking blood safety related regulatory decisions,

(iv) to communicate relevant information to all key stakeholders and

(v) to create national and international linkages.

Currently the reporting is voluntary.

**Functional Units For Haemovigilance**

- Medical and nursing staff
- Department of Immunohematology and blood transfusion medicine
- Hospital Transfusion Committee
- Haemovigilance center , NIB
- CDSCO

The entire programme has been structured to track, collect, collate and analyze adverse reactions/events associated with blood transfusion and blood components administration, to identify trends, recommend best practices and interventions required to improve patient care and safety and for making recommendations to the Regulators to make policy changes for improving blood safety.
Table 1: Critical areas for errors in blood transfusion process

<table>
<thead>
<tr>
<th>Location</th>
<th>Critical point</th>
<th>Health care professionals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood donor centre</td>
<td>Assessment of donor for safety</td>
<td>Donation session staff</td>
</tr>
<tr>
<td>Blood bank</td>
<td>Processing and issue</td>
<td>Blood bank staff</td>
</tr>
<tr>
<td>Ward or outpatient clinic</td>
<td>Assessment of recipient and decision to transfuse</td>
<td>Medical and nursing staff</td>
</tr>
<tr>
<td>Ward</td>
<td>Prescription request form</td>
<td>Medical staff</td>
</tr>
<tr>
<td>Ward or phlebotomy clinic</td>
<td>Sample for pre transfusion testing</td>
<td>Doctors, nurses, phlebotomist</td>
</tr>
<tr>
<td>Laboratory</td>
<td>Reception, Testing, allocation of component, labeling and issue</td>
<td>Laboratory assistant, Biomedical scientist</td>
</tr>
<tr>
<td>Blood refrigerator</td>
<td>Collection from storage site</td>
<td>Porter, nursing staff</td>
</tr>
<tr>
<td>Ward, operation theater, emergency department</td>
<td>Bed side administration check, monitoring or adverse incidents</td>
<td>Nurses, doctors, operative department staff</td>
</tr>
</tbody>
</table>

Adverse reaction in recipient
An adverse event should be described according to its severity and attributability. A grading system according to an internationally accepted scale has been developed.

Grade 1 (Non-Severe): The recipient may have required medical intervention (e.g. symptomatic treatment) but lack of such would not result in permanent damage or impairment of a body function.

Grade 2 (Severe): The recipient required in-patient hospitalization or prolongation of hospitalization directly attributable to the event and/or the adverse event resulted in persistent or significant disability or incapacity; or the adverse event necessitated medical or surgical intervention to preclude permanent damage or impairment of a body function.

Grade 3 (Life-threatening): The recipient required major intervention following the transfusion (vasopressors, intubation, transfer to intensive care) to prevent death.

Grade 4 (Death): The recipient died following an adverse transfusion reaction. The attributability or causality means the likelihood that an adverse reaction in a recipient can be due to the blood component transfused.

Causality/Attributability Category
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 favor 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 favor 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.

Types Of Blood Transfusion Reactions
There are many different types of transfusion reactions, which can be subdivided in several ways according to their occurrence, pathogenesis and symptomatology. (Fig.1)

![Figure 1: Classification of blood transfusion reaction](image)

Details Of Procedure to Enrolment under HvPI
i) Who can enrol?
Medical Colleges/ Institutes/ Hospitals/ Blood Banks of India

ii) How to enrol?
1) Head / Incharge of Transfusion Medicine Department / Blood Bank provides the necessary details to the National Coordinating Centre (NCC) - Haemovigilance Programme of India (HvPI) by sending the duly filled Enrolment Form either to NCC at National Institute of
2) NCC verifies the details provided by the Center.

3) After verification, NCC issues the User Id and Password to the Head / Incharge of Transfusion Medicine Department / Blood Bank to access the Haemo - Vigil Software for onward transmission of Transfusion Reactions Reports to NCC.

iii) What happens to submitted report?

- The TRR Form submitted to National Coordinating Center –HvPI, is assessed by HvPI Personnel for completeness and correctness.

- Once the data is assessed Core Group forward it to the Quality Review Panel for the quality check. Then the data is further forwarded to the Signal Review Panel for the statistical analysis and also for the detection of “Signal”. Quality Review Panel and Signal Review Panel in turn provide their recommendations to the Core Group which further forwarded to the Haemovigilance Advisory Committee.

- The recommendations from the Haemovigilance Advisory Committee is forwarded by the Core Group of HvPI to the Indian Pharmacopoeia Commission (IPC), Ghaziabad.

- Indian Pharmacopoeia Commission (IPC), Ghaziabad then forward the same to CDSCO, Headquarter and CDSCO further takes regulatory decisions and forward them to the Stakeholders (Patients, Healthcare Professionals, Blood Banks, NACO, SBTC etc.).

Role and Responsibilities of Medical and Nursing Staff of the Haemovigilance Centers

Physicians and nurses attending patients with suspected transfusion complications should perform the following documentation and reporting functions:

- Attending nursing staff should report suspected transfusion reaction immediately to the attending physician

- Document the details of the patient as well as the implicated units/ products in the form and retain in the patient’s file

- Document the details of the transfusion reaction and submit the form to the Department of Immunohematology and Transfusion Medicine

- Assess the imputability (causality) levels of the adverse reactions in co-ordination with the Department of Transfusion Medicine

- Maintain the records of the complication in the patient’s medical record, including the report of the investigation completed by the Department of Transfusion Medicine.
CONCLUSION
Haemovigilance programme is an integral part of a quality system in blood transfusion chain of a healthcare organization. It covers the donor, transfusion process and recipient of blood transfusion and its component. It is a comprehensive and a well-structured approach to collect, collate, and analyze data to address the issues of adverse reactions associated with blood transfusion and blood product administration by generating evidence-based information and to undertake policy decisions to provide high standards of care and ensure transfusion safety. A functional haemovigilance system can act as a backbone to monitor the transfusion practices and be accountable to appropriate documentation, reporting and investigation of transfusion reaction.

REFERENCES
3. Serious Adverse Blood Reactions and Events (SABRE) User guide for mandatory haemovigilance reporting in the UK Published by the MHRA, the UK competent authority for blood safety and quality December 2010.