HAEMOVIGILANCE: A SYSTEM TO IMPROVE SAFETY IN BLOOD TRANSFUSION PROCESS

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ABSTRACT

Haemovigilance is a system that governs the safety surveillance of the whole transfusion chain i.e. from the collection of blood and its components to the follow-up of recipients. It includes collection and assessment of information on emergent or inexpedient adverse events resulting from the therapeutic use of labile blood products, and to avoid their occurrence or recurrence, prioritizing the safety of the process. The issues associated with safety reporting in blood transfusion process are lack of clarity on roles and responsibilities of personnel involved, lack of tools or procedure of data collection, lack of reliable data on blood transfusion, insufficient knowledge regarding blood transfusion system, carelessness during blood transfusion procedure and absence of a central regulating structure for haemovigilance. The blood transfusion process involves more than 70 steps and each of these may be subjected to error. It is essential to establish standard protocols for the administration of blood so as to minimize the potential for errors. The cases of adverse events related to blood transfusion all over the world are increasing. The aim of haemovigilance programme must be to set standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. The approach should be to produce quality, rather than controlling it. Therefore, on the regulatory aspect, it is essential to introduce and implement centralized regulatory guidance, which can assure safe and quality blood transfusion process.

Keywords: Haemovigilance, blood transfusion, issues, regulatory guidelines, standard protocols.
INTRODUCTION
Haemovigilance is a set of surveillance rules which envelops the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), purporting to collect and assess information on emergent or inexpedient effects resulting from the therapeutic use of labile blood products, and to avoid their occurrence or recurrence. [1] The major requirement of any transfusion medicine is ‘zero risk’ to the recipient, as the aftermaths of any error during transfusion is huge. The potential risks associated with blood transfusion are HIV, hepatitis, sepsis from bacterial contamination and trauma. [2] Hence there is a need for a haemovigilance system which can assure patient safety and promote public health. Haemovigilance is a mode to reform the virtue of the blood transfusion chain, prioritizing the safety of the process. The products which are under surveillance in haemovigilance system are mainly blood components. Plasma derivatives are also foreseen under haemovigilance in some countries. A system of haemovigilance is incumbent on: traceability of blood and blood products from donors to recipients; spontaneous reports of transfusion adverse events; and adamant management of acquaintance related to the transfusion process. The information obtained through this system is a key to: introduce required changes in the transfusion policies; reform transfusion standards; follow up in the formulation of transfusion guidelines; and to enhance the safety and quality of the whole transfusion process. Haemovigilance have a significant part to play in optimal blood usage and patient blood management initiatives, key areas for the ‘Blood Service’.

PURPOSE
This review article confers to various risks emanating from blood transfusion process, the need of a vigilance system that can provide for elimination or minimization of these risks, and role of haemovigilance system in ensuring safety of transfusion patient. It also discusses the various case reports of haemovigilance around the world.

BACKGROUND
A blood transfusion process cab broadly be summarized as a procedure in which blood or its component(s) is received through an intravenous (IV) line inserted into one of the blood vessels. Blood transfusions are used to replace blood lost during any surgery or a serious bunt. A transfusion also might be done if body fails to make blood properly because of an illness. [3] The responsibility of blood banks is to collect, test and store blood. Then they carefully screen all donated blood so the right blood type should be available for transfusion.
Most of the blood transfusion procedures go very smoothly. However, sometimes mild problems and, very rarely, serious problems can be encountered if the process of blood transfusion go wrong at any step. The risk which can be experienced after unsafe blood transfusion procedures are

- Allergic reactions
- Viruses and Infectious Diseases
- Acute Immune Hemolytic Diseases
- Delayed Hemolytic reaction
- Graft-Versus-Host Disease
- Sepsis from bacterial contamination
- Trauma
- Hepatitis B and C
- Human Immunodeficiency Virus

Since the magnitude of the risks associated with blood transfusion process are huge, so a vigilance system is needed which can ensure that the patients’ safety is not compromised at any stage of the transfusion process. Also, there should be measure put in place which can ensure risk minimization.

Thus a system of haemovigilance was introduced which is required to identify and prevent occurrence and recurrence of transfusion related unwanted events, to increase the safety, efficacy and efficiency of the blood transfusion process. This system covers all the activities of the transfusion chain from donor to recipient. The responsibility of the haemovigilance system is monitoring, identification, reporting investigation and analysis of adverse events near misses and reactions related to blood transfusion and manufacturing.

**RISK AND ISSUES ASSOCIATED WITH BLOOD TRANSFUSION PROCESS: CURRENT SCENARIO**

There are three risk categories associated with any blood transfusion process:

1. Adverse reactions such as allergic or immunological reactions which arise from the interaction of patient and blood component characteristics
2. Human errors, which continue to contribute significantly to transfusion-related risks to patients.
3. Certain adverse reactions such as anaphylactic reactions often are not avoidable and therefore have to be considered as an inherent risk of blood transfusion.\textsuperscript{[6]}

There are a number of reasons and issues which contribute to these risks. Various issues, related to blood transfusion process, being encountered are\textsuperscript{[7]}:

- Lack of clarity on roles and responsibilities, channel of communication: The responsibility of reporting, what to report, how to report, when to report and where to report is not assigned. Even the collected data management was one of the issues.
- Lack of tools or procedure of data collection: Only few data were analyzed and little action was taken based on data analyzed.
- Lack of reliable data on blood transfusion.
- The feedback mechanism to the concerned was not developed
- Insufficient knowledge regarding blood transfusion system
- Carelessness during blood transfusion procedure
- Absence of central regulating structure
- Inadequacy of the texts organizing and regulating blood transfusion and haemovigilance

RESPONSIBILITY OF THE HAEMOVIGILANCE PRACTITIONER

Physicians and other healthcare professionals must immediately report the Blood Transfusion Institute or a Blood Transfusion Centre or a hospital blood bank for any severe adverse reactions that they observe and that could be associated with the quality and safety of blood and blood components, using the form for reporting.\textsuperscript{[8]} The roles of haemovigilance practitioner are

- Assuring patient safety and quality improvement
- Act as Interface between blood bank and clinical areas.
- Access and manage associated risk.
- Reporting Incident and investigating the incident.
- Monitor adequacy of transfusion and of waste.
- Act as information resource
- Educate all those who are involved in the blood transfusion process.

The blood transfusion process involves more than 70 steps and each of these may be subjected to error. It is essential to establish standard protocols for the administration of
blood so as to minimize the potential for errors. The protocols must be in place in each institution and must conform to standard practice.⁹

**WORLD WIDE ADVERSE EVENT REPORTS RELATED TO HAEMOVIGILANCE**

<table>
<thead>
<tr>
<th>Country</th>
<th>No. of Serious Adverse Reactions cases related to blood transfusion</th>
<th>Special Note</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>913 (year 2009-2011)</td>
<td>Increase in no. of cases till 2013</td>
<td>Australian National Haemovigilance Programme</td>
</tr>
<tr>
<td>Europe</td>
<td>527 (year 2012)</td>
<td>60% increase in severe adverse reaction since 2010.</td>
<td>Surveillance of Adverse Reactions/Events (STARE)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>3545 (year 2012)</td>
<td>3.2% increase as compared with report of 2011</td>
<td>Serious Hazards Of Transfusion (SHOT)</td>
</tr>
<tr>
<td>United States of America</td>
<td>Transfusion related acute lung injury TRALI (35%); ABO blood group hemolytic transfusion reactions (22%); non-ABO hemolytic transfusion reaction (15%); microbial infection (15%) and transfusion associated circulatory volumes overload (TACO) (7%; year 2008)</td>
<td>Transfusion-related acute lung injury has been the most frequent cause of transfusion-associated mortality in the United States for the past several years.</td>
<td>U.S. Food and Drug Administration.</td>
</tr>
<tr>
<td>India</td>
<td>105 (year 2002-2003)</td>
<td></td>
<td>Transfusion-related adverse events at the tertiary care center in North India: An institutional hemovigilance effort. <em>Asian Journal of</em></td>
</tr>
</tbody>
</table>
### PROPOSED SETTLEMENTS FOR RELATED ISSUES

1. **Ensuring “Universal Access to Safe Blood Transfusion” for the whole country**
   - Reforming availability of safe blood through the country;
   - Alignment of regulation on transfusion and haemovigilance systems;
   - Reinforcement of unification of haemovigilance to quality system\(^{10}\)

2. **Haemovigilance should be the “business” of everyone**
   - The Health authorities must be sensitized on the ponderability of haemovigilance in blood transfusion safety;
   - All the staffs of health structures must be enamored in haemovigilance;

3. **Reinforce competences of the staffs of health organizations**
   - Reinforcement of blood transfusion education in the schedule of health teaching schools;
   - Stated recycling sessions for hospital staffs;
   - Regular supportive tending of transfusion and haemovigilance stager.

4. **Well-implication of health authorities for more regulation, control and financing of blood transfusion dispensation;**\(^{11}\)

5. **Collaboration at regional level between regional health associations and the regional blood transfusion center;**\(^{12}\)

6. **At the local level, reclamation of hospital transfusion committees’ function and training of stager.**

7. **Installing a substantial information system in blood transfusion services, permitting a regional exchange of data and their regional elaboration and diffusion.**

8. **Reporting to the regulator might prevent some institutions to report errors**

The aim of haemovigilance programme must be to set standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. The approach should be to produce quality, rather than controlling it. Haemovigilance is essential for improving transfusion safety and highlights those areas which require action.
REGULATIONS RELATED TO HAEMOVIGILANCE
The regulations related to haemovigilance were introduced so as to: [13], [14]
- set standard of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.
- set standard related to certain technical requirements for blood and blood components.
- set requirements for traceability and notification of serious adverse reactions and events.
- set standard regarding community and specifications relating to a quality system for blood establishment.

The guidelines for the blood transfusion process and adverse event reporting are: [15], [16], [17]
1. Patient information should be noted with detailed documentation of medical information in a clear language. Name, gender, age and all basic information should be written along with the type of treatment that the patient is undergoing.
2. The blood and blood components should be issued on physician prescription after analysis of the patient and figuring out that whether blood transfusion is essential or not.
3. It is essential to identify correct blood transfusion process for correct patient. Positive patient identification is essential so as to provide with the best treatment.
4. The pre-transfusion sampling is essential so as to identify the blood for its quality and so as to prevent any adverse event during transfusion.
5. The blood issued should be documented and registers should be maintained so as to write each issued blood record.
6. The pre-transfusion testing of blood is as much important so as to make sure that blood is free from any types of infectious substance.
7. The storage of blood components should be in a clean and in appropriate conditions so as to maintain the quality of the blood and its components.
8. The collection of blood or the components from the hospital transfusion laboratory should be carried out under the supervision of trained personnel.
9. The administration of blood component should be at optimal time and at optimal infusion rate depending upon patient’s need.
10. The blood administration sets/equipments should be clean and free from infectious substances which could harm the patient and hinder the process of blood transfusion.
11. Monitoring for adverse event after blood transfusion process is essential so as to take immediate action to save the life of patient.
12. The documentation and traceability of blood transfusion process is essential so as to figure out that where the process went wrong if adverse event is reported.

13. It is necessary to develop the information technique according to requirements and recent advances in system so as to use the best tool to minimize errors in data.

14. The transfusion committee should be there who could monitor blood transfusion process and make decisions accordingly.

15. The staff involved in transfusion process should be given education and training session according to recent advances in the techniques.

16. There should be a hospital based haemovigilance programme so as to carry out “zero risk” transfusion process and wipe out the chances of adverse event.

**CONCLUSION**

On the clinical side, transfusion medicine urgently solicits the highest degree of professional attention and educational care. [18] An active transfusion committee should be introduced, which can control the process to correct protocols and practices when deficiencies are identified, and which also participate in local and regional audits and in the national haemovigilance programmes. The haemovigilance program should be in a place which can work in collaboration with local committees to collect on a national basis the data on transfusion related adverse reactions. A transfusion reaction is unfavorable event occurring in a patient while or after blood transfusion [20]. About 0.5–3% of all transfusions show some adverse events, but the majority of them are minor reactions with no significant clinical consequences [21]. Although haemovigilance can be appropriately conceived as a precious mode for improvement of the transfusion system, it is in the interest of the community that the system to be “vigilated” should be already originally based on criteria based on quality management. Therefore, on the regulatory aspect, it is essential to introduce and implement centralized regulatory guidance, which can assure safe and quality blood transfusion process. [22]

**REFERENCE**


