

Review Article

Haemovigilance for Safer Blood Transfusion Process

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ABSTRACT

Haemovigilance is a surveillance program aimed at identifying and preventing the occurrence and reoccurrence of transfusion related adverse reactions and events and to increase the safety and efficiency of transfusion process. It surveys a chain of events from the collection of blood and its products to the follow up of the recipient. It is a continuous process of data collection and analysis of the adverse events related to blood and its products transfusion. The blood and its product transfusion carry with it a risk of acute or late adverse reaction. The adverse events may range from fever, chills to delayed haemolytic reactions. Some may even develop transfusion induced acute lung injury, bacterial contamination etc. Blood transfusion is a complex process involving more than 70 steps and error may occur in any step and will lead to adverse events. The lack of a clear idea about the roles and responsibility of the individuals involved, the lack of proper tools or procedure for the data collection, the incomplete knowledge about blood transfusions, the lack of necessary data of the transfusion, the carelessness during blood transfusion are the factors that lead to increase in adverse events in blood transfusion process. The main aim of Haemovigilance program is to set guidelines for improving the quality of blood collection, testing, processing, storage and distribution and to follow up the recipient for providing better safety. Therefore it is important to have a standard protocol for guidance and to improve the safety and quality of blood transfusion process.

Keywords: Haemovigilance, Adverse events, Blood transfusion, Standard protocol, Guidelines



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INTRODUCTION

Haemovigilance is a set of chain events and process of data collection and analysis on transfusion related adverse events so as to find its causes and consequences and thereby preventing its occurrence. Haemovigilance is very important to improve the quality and increase the safety of transfusion of blood and its products as the data collected allows corrective as well as preventive actions to be taken to reduce the risk associated

with transfusion process [1,2]. A Haemovigilance program is an integral part of pharmacovigilance and it was launched in India at a national level on 10th December 2012. A transfusion process should ensure that there is no risk to the recipient as some of the risk can be life threatening. Hence Haemovigilance program is needed to ensure the safety of patient and public health [1,4,5].

Adverse Events Associated With Transfusion

1. Immediate adverse effects

- Febrile reactions
- Allergic reactions
- Anaphylactic reactions
- Haemolytic reactions
- Bacterial contamination
- Transfusion induced acute lung injury
- Hypothermia
- Volume overload

2. Delayed and long term effects

- Delayed haemolysis
- Graft versus host disease
- Iron accumulation
- Immunomodulation
- Transmission of infectious disease[6,7].

Risk Factors Associated With Transfusion

- Lack of clarity regarding the roles and responsibilities of individuals involved and lack of proper communication between them.
- Lack of proper tools and procedure for the collection of data.
- Inadequate reliable data on the transfusion process.
- Inadequate knowledge on blood transfusion system.
- Careless attitude of the individuals involved in the transfusion process.
- Lack of a proper central regulating system.

Thus a haemovigilance system was established which was important for identifying the problems related to transfusion process and to prevent the adverse events to ensure safer transfusion of blood and its products. This system surveys all the events in transfusion process starting from the donor to the follow up of the recipient.[5,8,9].

Objectives of Haemovigilance Program

The haemovigilance program have the responsibility of monitoring of transfusion, identification of problem, reporting of the investigation carried out, and analysis of the various adverse events and reactions associated with transfusion of blood and its products and its manufacturing. The objectives of the program are as follows:[4,8,10].

- monitoring of various transfusion related adverse events
- Creating awareness among all the health care professionals
- Generating evidence based recommendations for improving the transfusion process
- Setting up of rules and regulations to improve the safety and quality of transfusion
- Advising the Central Drugs Standard control

organization on safety related regulatory decisions

Responsibility of the Haemovigilance Practitioner

All the health care professionals should be a part of haemovigilance. The adverse event that occur during the transfusion process which may compromise its quality and safety should be immediately reported by the physician or other health care professional using a adverse event reporting form. The responsibilities of an haemovigilance practitioner are as follows:[11].

- Should assure the safety of the patient and improvement in the quality of transfusion
- Should act as an interface between the blood bank and other clinical areas
- Should assess the risk associated with transfusion and should manage it
- Should monitor the adequacy and efficiency of the transfusion process
- Should act as an resource for information
- Should educate and guide all the individuals involved in the transfusion process

Regulations and Guidelines of Haemovigilance

The blood transfusion is a very lengthy and complicated process involving more than 70 steps and any of these can be subjected to error. Therefore it is very important to establish a standard protocol for minimizing the potential for mistakes.[12].

The regulations of the haemovigilance were introduced to;

- Set a standard for the quality and safety for the various steps involved in transfusion like collection of blood, teasing and its processing, storing and its distribution.
- Set the standard for the various technical requirements needed during transfusion process.
- Set standards for the traceability of any transfusion related adverse event and its notification.
- Set standard regarding the community and quality system for the blood establishment.

The following are the guidelines for the transfusion process and for reporting of adverse event related to transfusion process[10,12].

- All the basic information of the patient should be documented along with the current type of treatment the patient is undergoing in a clear language.
- The issuing of blood and its components should be done only under physicians prescription after analyzing whether the patient requires transfusion or not.
- It is very essential to identify the correct

transfusion process for the patient so as to provide the best treatment.

- The pre-transfusion sampling is very important to check the quality and to prevent adverse events.
- A proper register should be maintained to document each issuing of blood and its components.
- The blood and its components should be stored in a clean place under appropriate conditions to maintain its quality and the transfusion set should be clean and free from harmful substance.
- The blood component should be administered at optimal rate and for optimal duration according to the patient's requirement.
- The patient should be monitored during and after the transfusion process for any adverse reaction.
- If an adverse event has been reported the traceability of the transfusion process is important to find where the error has occurred.
- The individuals involved in the transfusion process should be educated and trained properly and made aware about the recent advancement in the system to minimize the chances of error.

CONCLUSION

Transfusion process on the clinical side requires high professional attention and care so as to avoid the occurrence of any adverse event. Haemovigilance as an integral part of the pharmacovigilance program controls the transfusion process by collecting data and analyzing them so as to prevent the occurrence and reoccurrence of any adverse event. The program introduced a standard protocol and guidelines for the transfusion process which is aimed at reducing the risk associated with transfusion process. Thus the haemovigilance program assures the quality of the transfusion process and increases the patient safety.

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