



Review Article

HAEMOVIGILANCE - ROLES AND GLOBAL STATUS IN TRANSFUSION SAFETY: A REVIEW

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ABSTRACT

Blood transfusion plays a key role in improving health and saves many lives. Haemovigilance system is the programme which ensures the transfusion safety by monitoring every step of transfusion process from donor to recipient. This system mainly focused on collection and analysis of data concerned with adverse events/reactions related with transfusion of blood or its components with the aim of identifying their causes and outcomes and prevents their occurrence or recurrence. Thus the ultimate object of haemovigilance system is improving the quality and safety of transfusion therapy.

Key words: Haemovigilance, Blood transfusion, Transfusion safety

INTRODUCTION

Blood is one of the connective tissues provide protection from different problems¹. Blood transfusion saves many lives and plays a key role in improving health. Transfusion is the process having several steps and participation of various professionals such doctors, nurses and laboratory scientists. The donors and recipients of transfusion are also the key participants. There is chance for developing several risk points in transfusion because of its multi step procedure. Mistakes in transfusion may force the patients to life threatening state².

The concept of safe blood transfusion gained attention since 1980s. In 1990s, transfusion related HIV and Hepatitis C virus infection were identified in haemophilia patients in USA, UK, France, Canada and Japan created an immediate need for developing a surveillance system for transfusion safety. Now this surveillance system is commonly known in the name of haemovigilance³.

Haemovigilance – Origin and important definitions

In 1991, the term 'haemovigilance' (he'movigilance in French) was coined in France^{2,4} in analogy to the already existing term 'Pharmacovigilance'.⁴ This term has Latin and Greek roots (Haema-blood; vigilance-paying special attention to).^{4,5,6}

The initial work on haemovigilance was initiated in France in 1994 by creating a monitoring system 'Blood transfusion committee' and establishing a national haemovigilance system. Later in 1995, a resolution was published by European council with the aim of improving the public confidence in safe blood supply. Hence the haemovigilance system came under the governance of legal authorities. Later in 1998, the European haemovigilance network (EHN) was organized. Nowadays, a global system, 'International haemovigilance network' (IHN) is in functioning. The objective of IHN is to organize and maintain

a body concerned with the safety of blood and its components, transfusion medicines and haemovigilance throughout the world. The IHN is working along with 'International society of blood transfusion' (ISBT) to ensure a better service⁷.

Based on the reports of World health organization (WHO), ISBT and IHN, the haemovigilance is defined as a set of surveillance procedures covering the whole transfusion chain from collection of blood and its components up to the follow-up of its recipients intended to collect and assess information on undesirable or unexpected effects resulting from the use of blood products and to prevent their occurrence or recurrence.^{2,6}

In 2005, the guidelines for 'adverse event reporting and learning system' was published by World Health Organization. It describes the need and importance of patients' safety reporting system in the improvement of patients' safety and provides instruction about learning from failures. It also clearly indicates that the success of an adverse event reporting system is not only relied on proper collection of data and its analysis, but also by its use to make recommendations that improve the patient safety. According to this guideline, an adverse event is defined as any undesirable or unintended occurrence before, during or after transfusion of blood or its components that may lead to death or life threatening or disabling condition of patient or which results in, or prolongs, hospitalization or morbidity.^{5,6}

The "European blood directive" gives various definitions regarding with haemovigilance. It defines the serious adverse reaction as an unintended reactions occur in donor or recipient associated with the collection or transfusion of blood or its components that leads to fatal, life threatening, disabling or incapacitating state or which results in or prolongs, hospitalization or morbidity. Some of the definitions were obtained from other areas such as pharmacovigilance etc. The definition about the types of blood components is based on the council of Europe: Guide on preparation, use and quality

assurance of blood components, Recommendation No. R (95) 15, Part C: Blood components. Some other aspects are based on the guidelines of EHN and the council of Europe: Guide on the preparation, use and quality assurance of blood components, Recommendation No. R (95)15, chapter 31 of haemovigilance.

Scoring for severity:

- 0 – No sign;
- 1 – Immediate symptoms without vital risk and complete resolution;
- 2 – Immediate symptoms with vital risk;
- 3 – Prolonged morbidity;
- 4 – Death of the patient.

Scoring for imputability:

- 0 – No relationship;
- 1 – Possible;
- 2 – Likely;
- 3 – Sure

Clinical and biological symptoms

Immediate reaction: haemolysis, non-hemolytic febrile transfusion reaction [NHFTR]; allergic reactions - rash, erythema, urticaria, anaphylaxis, transfusion related acute lung injury (TRALI)

Delayed reaction after transfusion – hemolysis, graft-versus-host disease (GvHD), post-transfusion purpura (PTP),

Microbiological / viral transmission, allo-immunization (against antigens of RBC, WBC, PLT), incorrect blood component transfused (IBCT) and others⁶.

Current global status and recommendations for a better haemovigilance system

At present, the haemovigilance system has been implemented in most of the developed countries to monitor the adverse events/reactions related with donation and transfusion of blood.⁴ Depending upon the country, this system is governed by either regulator (example: France, Germany and Switzerland) medical societies (example: UK and Netherland), public health authorities (example: Canada) or blood manufacturers (example: Japan, Singapore and South Africa).³ In India, on 10th December 2012, the haemovigilance programme of India (HvPI) was implemented throughout the country under the Pharmacovigilance programme of India (PvPI). The Indian pharmacopoeia commission in collaboration with National institute of biological, Noida, U.P has launched this programme⁵.

Haemovigilance monitor every step of transfusion process from donor to recipient (from vein to vein). It covers the whole chain of transfusion with various objects such as monitoring of prevalence and incidence of infectious markers in blood donors, compiling the data of adverse reactions/events including transfusion errors and product related side effects either suspected or confirmed and providing alert/warning procedures, thereby covers the whole transfusion chain and the respective activities.

Some pre requisites are needed for establishing and maintaining a fully functional haemovigilance system. They are

- Legal framework
- Continuous and guaranteed budgeting and finance facility
- Central evaluation centre setup
- Commonly agreed definitions
- Standardized reporting system
- Development of rapid alert/early warning system
- Established culture of professionalism

- Functional hospital transfusion committees
- Introducing the preventive or corrective procedures
- Creating the international cooperation

Different category of participants such as blood centres, hospitals, competent authorities etc are present in this system. However, these key participants should be ready to work in a constructive and coordinated manner to fulfill the overall objectives of haemovigilance system.

Manufacturers of equipments, reagents and disposable materials for blood centers and hospitals should establish the post marketing survey procedures for the collection and processing of data related directly and indirectly with blood transfusion.

Blood banks are the consumers of equipments, reagents and disposable materials but they provide services associated with transfusion and also importantly they produce various types of labile blood components. Thus on one side, they are consumer and on other side they are producers and play an important role in haemovigilance.

Hospital transfusion committee has a prime role in the designing of guidelines, training administration, ensuring the peer review, reports supervision, taking preventive or corrective actions and auditing concerned with haemovigilance. Physicians and paramedical staffs are also playing an important role in haemovigilance.

Competent authorities are essential for the success of haemovigilance system. They play an important role in legislation, inspection, budget designing and ultimately surveying either directly or by delegation. Thus each and every haemovigilance system, whatever form it exists requires the role of competent authorities.

Haemovigilance is a quality process; it needs improvement in the quality and safety of blood transfusion. So that this process focusing on both input (transfusion of a patient or intent to do so) and output (corrective or preventive measures and follow-up on them). Various essential steps involved in the haemovigilance are

- Assessment or recognition of an occurrence
- Reporting by using established criteria and reporting form
- Collection of data
- Compilation by using predefined matrix
- Evaluation as per approved techniques
- Conclusions and feedback to those concerned and published
- Actions either corrective or/and preventive and follow-up on them.

As a quality process, the hemovigilance needs to be deeply embedded into the Quality Management Systems (QMS) of various establishments such as blood centers, manufacturing units, and hospitals. In order to ensure the final result (the efficient and safe blood transfusion to patient) there should be no exception to these rules, at any stage of blood transfusion chain.

Problems associated with the implementation of haemovigilance

Concerned with haemovigilance, several problems exist at different levels, includes institutional, regional, national and international. In fact, these problems could not be solved. Generally, there is a deficit in relation with common definitions, terminology, standardized reporting formalities and uniform matrix. In Europe also there are still various organizational

problems, funding shortages, unclear mandates, undefined responsibilities, low sensitivity, insufficient training and hesitation to move forward by implementing strong actions. In several countries across Europe haemovigilance is really established and working. But a national haemovigilance system is not in place in every European country.

Limitations and recommendations

A strong network in haemovigilance will be vital and also common definitions, standards, forms, exchangeability of information, rapid alerts and early warnings are also playing important role. Mechanisms of corrective and preventive actions at community level will need to be developed. The players in the blood transfusion chain will see their respective roles and their input into the system will quickly grow in importance. The problem of current vigilance systems interfering with blood transfusion needs to be resolved: spinning of or bridging and bundling will be crucial issues when it comes to modern, advanced haemovigilance, especially at the community level⁶.

CONCLUSION

Haemovigilance is a continuous process of data collection and analysis of transfusion-related adverse reactions in order to investigate their causes and outcomes, and prevent their further incidence. The well established haemovigilance systems of various countries have provided insight into various measures based on their data. Such systems would definitely improve blood safety. Haemovigilance is thus a tool to improve the quality of the blood transfusion chain, primarily focusing on safety. However this has to be strengthened further by improved information management or better progress in standardization from one region to the other.

Haemovigilance is the ultimate quality indicator of a transfusion service. There is a continuous need to work on hemovigilance. Even though the laws and tools are in place, there is still the need of establishing the right awareness system in order to ensure that the procedure will be followed so that haemovigilance will aid in preventing undesired reactions to blood donation and during the course of the transfusion chain. The haemovigilance system provides information that facilitates the steps associated with correction and prevention of risks associated with safety and also the quality of processing of blood and its components and their transfusion. Also these informations are helpful for introducing necessary changes in

the policies for improving the standards of systems and processes connected with transfusion safety.

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