

# Hemovigilance and Blood Safety A Review

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## ABSTRACT

**Hemovigilance is a set of surveillance procedures covering the entire blood transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients. It includes monitoring, reporting, investigating and analyzing adverse events related to the donation, processing and transfusion of blood. The aim of hemovigilance is to detect all adverse events of blood transfusion in order to know their cause and to prevent recurrence, and to improve safety of blood transfusion.**

**Key words: Hemovigilance, Adverse events, Blood transfusion.**

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## INTRODUCTION

The term hemovigilance was derived from the Greek word (Haema-blood) and the Latin word (Vigilance-paying special attention to)[1]. Blood transfusion saves many lives and plays a key role in improving health of an individual, As there is no substitute for human blood and its components. The concept of blood transfusion gained attention since 1980s [2].

The initial work on hemovigilance was initiated in France in the year 1994 by creating a monitoring system called 'Blood transfusion committee' and establishing a national hemovigilance system. Later in 1995, a resolution was published by the European council with the aim of improving the public confidence in safe blood transfusion. Hence the hemovigilance system came under the control of legal authorities. Later in 1998, the European hemovigilance network (EHN) was established. Nowadays a global system, 'International hemovigilance 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 hemovigilance throughout the world. The IHN is working in collaboration with 'International society of blood transfusion' (ISBT) to ensure a better service.[3]

## HISTORY OF BLOOD TRANSFUSION AND NEED FOR HEMOVIGILANCE

In the 17<sup>th</sup> century, the first blood transfusion were attempted to transfuse humans with animal blood for all types of ailments. Later in the 18<sup>th</sup> century, the French king Louis XIV legally banned the transfusion of animal blood to human because it was considered unsafe and deadly [4]. In the 19<sup>th</sup> century, Henri Leacock and James Blundell first explored inter-human transfusion as a lifesaving remedy for severe blood loss. Later it failed, because the procedure was also risky [5]. However in 20<sup>th</sup> century, due to discovery of ABO blood groups and evolution of cross matching technique and anti-coagulation used in the blood, blood transfusion becomes more easy and an accepted treatment modality [6].

## SCOPE OF HEMOVIGILANCE

Scope of different hemovigilance system varies due to differences in spectrum of reporting, i.e. reporting of adverse reaction versus adverse events (In both recipients and donors). Ideally, the hemovigilance system should cover processes throughout the entire transfusion chain, from blood donation, processing, and transfusion to patients for the monitoring, reporting and investigation of adverse events and reactions and near misses related to blood transfusion [7].

## HEMOVIGILANCE FOR RECIPIENTS AND DONORS

An internationally accepted scale is used to grade the 'severity' of an adverse reaction in recipient. The likelihood for adverse reaction or immutability can be attributed to the blood components transfused and it is also important to

determine whether blood component has been involved or not. Blood donor hemovigilance is also equally important as far as adverse reaction or event during whole blood or component donation is concerned. Adverse reaction in donor is complicated as the etiology is different from those in the recipient. These adverse reactions may be due to donation, selection, and management of donors, which may directly affect the donor or impact the quality of the product, which ultimately influence the recipient. The recipient's transfusion reactions/events were under the hemovigilance program of India. According to the guidelines of the HVPI, vigilance in donors, i.e., revealing adverse reactions related to a donation of blood was intended to be started by 2017. Although with the accomplishment of the HVPI it was chosen to undertake donor vigilance program. Consequently, a national Blood Donor Vigilance Program (NBDVP) was initiated on June 14, 2015 on the world Blood Donor Day at science city Kolkata and West Bengal. The increase in voluntary non-remunerated donations in South-East Asia was mainly contributed by India, with a reported collection of 8.5 million donations from voluntary non-remunerated blood donors, an 85% increase from the reported 4.6 million in 2008 according to World Health Organization (WHO), Global Database on Blood Safety (GDBS) 2016. Low and middle-income countries still lack enough voluntary non-remunerated blood donors, with low blood donation rates accompanied by high rates of discard. Ten countries declare for 65% of blood collections worldwide, and India is in the third position[8].

### **NATIONAL HEMOVIGILANCE PROGRAM OF INDIA**

Indian Pharmacopoeia Commission in collaboration with National Institute of Biologics, Noida, Uttar Pradesh launched Hemovigilance program of India (HVPI) on December 10, 2012 across the country as an integral part of PVPI, under Ministry of Health and Family Welfare, Government of India. It is a centralized, well-structured program for monitoring adverse reactions associated with transfusion of blood and administration of blood products. This program was implemented with a dedicated budgetary provision of INR 29.36 crore for a five year roadmap plan (2012-2017) and divided into three phases for establishment of hemovigilance program. The main aim of this program was to track adverse reactions and episodes related to blood transfusion and blood product administration and to help determine the trend and recommended best practices and analyze the data related to hemovigilance all over India. For HVPI, National Institute of Biologics is acting as the coordinating center. The ultimate goal of this HVPI was to be a part of the International Hemovigilance Network (IHN) and the same was achieved in December 2014. Currently IHN is having 33 countries as its member including India and provides a global forum for sharing best practices and benchmarking of hemovigilance data[9,10]

### **PROBLEMS ASSOCIATED WITH HEMOVIGILANCE**

The major problems arising in hemovigilance are under reporting of adverse events/effects due to fear of retribution and punishment, late reporting, use of different channels of reporting, incomplete information on incident sheets and failure to report investigation findings, difficulties in communicating with blood banks in both governmental and private sectors and in motivating hospitals to notify events and to have functional transfusion committees, fragmented blood transfusion systems, lack of understanding or awareness, lack of culture of reporting adverse events, lack of computerized management system, lack of transparency in government agencies and absence of well-defined hemovigilance structure and protocol, lack of trained manpower, lack of training and no standardized single system common to two blood services and no development of evidence based guidelines, lack of computerization and use of "Haemo-vigil" software makes the transfusion reactions underreported[11].

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### **CONCLUSION**

Hemovigilance is a continuous process of analysis of transfusion reactions and data collection in order to investigate their causes and outcomes and prevent their incidence. The objective of a sheltered and moderate blood supply that can meet the developing worldwide requests might come by the organized streamlining and progression in the transfusion chain, including the monitoring of donor eligibility criteria, reporting of transfusion reactions adherence to thorough guidelines, the ideal execution of accessible screening tests, the utilization of reasonable pathogen inactivation techniques lastly the watchfulness of judicious doctors, who assess the need of every transfusion. Hemovigilance is a key with regards to well-being and nature of blood transfusions. In connection to hemovigilance frameworks, huge contrasts right now exist in the nations around the globe, as far as definition, a condition of improvement, effect and productivity, organizational schemes, participation, and so forth. Every nation ought to have a built-up framework with the national scope.

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