WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 13, Issue 6, 913-923. Research Article ISSN 2277– 7105

# HAEMOVIGILANCE AND SAFETY OF BLOOD TRANSFUSIONS

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Article Received on
05 February 2024,

Revised on 25 Feb. 2024,
Accepted on 15 March 2024

DOI: 10. 20959/wjpr20246-31547

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## ABSTRACT

To boost the safety and effectiveness of administering blood transfusions and blood products, the nation urgently needs hemovigilance to recognize and prevent the incidence or recurrence of transfusion-related adverse events. Haemovigilance is a systematic approach of monitoring, identifying, reporting, looking into, and analyzing adverse occurrences and reactions related to the production of blood products and transfusions. As a result, the information gathered will make it easier to take corrective and proactive measures to reduce any potential dangers related to the collection, processing, and transfusion of patient blood. In collaboration with the National Institute of Biologicals (NIB), Noida, Uttar Pradesh, and the Ministry of Health and Family Welfare of the Government of India, the Indian Pharmacopoeia Commission launched the Haemovigilance Program of India (HvPI) in 2012. The primary goal of the Indian government's program is to monitor incidents, adverse responses, and occurrences related to the administration of blood products and transfusions. This article's primary goal is to provide a quick overview of the system that tracks the transfusion reaction at every stage.

**KEYWORDS:** Blood Transfusion reaction, haemovigilance, blood safety, Haemovigilance programme in India.

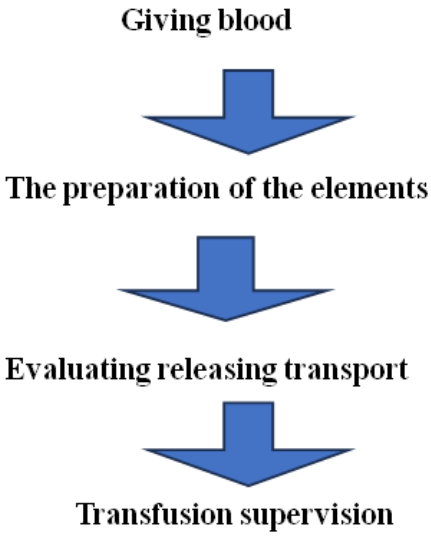
## INTRODUCTION

The Greek word haema means blood and vigilance derived from the Latin word vigilans means watchful. Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from donation and processing of blood and it’s components, to their provision and transfusion to patients and their follow -up. It includes the collection and assess the information on uses, adverse effects of blood and blood products and to The Greek term haema, which

means blood, and the Latin word vigilans, which means watchful, are the roots of the words heamovigilance and vigilance, respectively. Haemovigilance is a set of monitoring techniques that covers every step of the transfusion process, from blood donation and processing to providing patients with the blood and its components and monitoring their recovery. It includes gathering and evaluating data on the harmful consequences of blood and blood products, as well as ways to stop them from happening again.

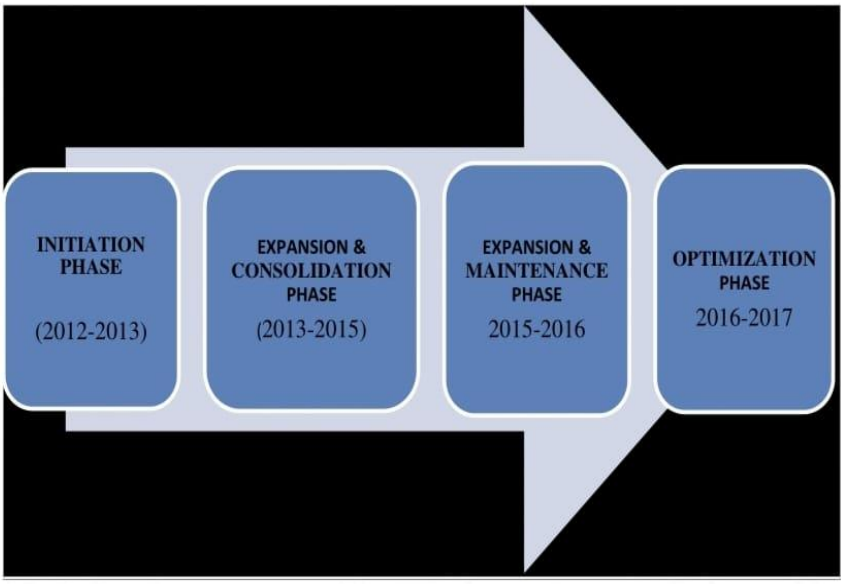
In 1990, the French government introduced the idea of hemovigilance, which shares the same goals and objectives as pharmacovigilance. On December 10th, 2012, the Haemovigilance Program of India (HvPI) went into effect. The blood transfusion quality system includes hemovigilance.[1,2]

**Blood transfusion chain**




**Goal of Haemovigilance**

- By taking corrective and preventative measures, the transfusion chain's quality is continuously being improved to increase donor and patient safety. Boosts the process of blood transfusions' credibility
- increases transfusion accuracy and decreases boosts the process of blood transfusions' credibility
- Services for blood transfusion an increase in public trust and confidence in the blood transfusion service system.[3]




**Transfusion Practices and Haemovigilance in Developing Countries**

Despite the fact that transfusion medicine specialists have already given transfusion transmitted diseases a great deal of attention, there have been no notable improvements achieved to reduce dangerous transfusion errors in developing nations. Health professionals are underreporting transfusion mishaps due to a lack of awareness and adequate training about the management of transfusion-related adverse effects. Few data on transfusion occurrences in Africa are available, and many African nations lack functional hemovigilance systems. As it is not required to record adverse transfusion events, India lacks a standardized and efficient hemovigilance system. Additionally, the medical community underreports, which prevents many negative effects from being noticed.

However, numerous institutes and centers all over India have recently released significant data on adverse transfusion events due to the progressive rise in awareness of hemovigilance and blood safety over the past few years. Consequently, in light of the severity of the issue, a national haemovigilance program was introduced on December 10, 2012, as a fundamental component of the PvPI at the national level. The WHO has taken steps to strengthen and assist the hemovigilance program in countries with limited resources. These programs seek to improve and broaden national systems for data collecting and management, risk assessment, surveillance and vigilance for policy decisions, and program planning for safe blood transfusions. For countries creating hemovigilance systems, the WHO has published norms, standards, recommendations, guidelines, materials, tools, and training materials. This will aid in the national blood program's assessment, monitoring, and evaluation. A Global

Haemovigilance Network is now being established by WHO, expanding on previous initiatives and in partnership with IHN, ISBT, and the Federal Government of Canada (Public Health Agency of Canada and Health Canada). In addition to examining the potential for global data and information sharing, this program will concentrate on the needs of underdeveloped nations in creating hemovigilance systems. In Dubai, United Arab Emirates, in November 2012, WHO convened a global consultation in collaboration with IHN and ISBT and provided suggestions on current advancements in hemovigilance.[7,8,9,10,11,12]

**Haemovigilance for Recipients**

The'severity' of a recipient's unfavorable reaction is rated using a universally recognized scale. It is crucial to ascertain whether or not a blood component was involved in the adverse reaction in order to estimate the likelihood of an adverse reaction or imputability. The ISBT has established criteria for 'severity' and 'imputability' of transfusion responses. In order to share information and compare data, the IHN-ISBT working committee group has created internationally recognized terminology for adverse reactions in recipients.[4,5]

**Haemovigilance for Donars**

As far as adverse reactions or events after whole blood or component donation are concerned, blood donor attention is also crucial. Because its origin differs from that of the receiver, an adverse reaction in the donor is referred to be a complication. These unfavorable effects could be the result of the donation, selection, and management of donors, which could directly hurt the donor or affect the product's quality, which would then affect the recipient. A joint working group from the ISBT and EHN has developed a taxonomy and a list of definitions for complications. They are categorized into general reactions (vasovagal immediate and delayed type), local reactions (vessel injuries, nerve injuries, other), and other significant consequences.[4,6]

**National Haemovigilance Program of India**

The National Institute of Biologicals, Noida, Uttar Pradesh, and the Indian Pharmacopoeia Commission established a HvPI on December 10, 2012, under the PvPI program of the Ministry of Health and Family Welfare of the Government of India. With a dedicated budgetary allocation of Rs 29.36 crore over the course of the 12th Five Year Plan (2012–2017), this program has been implemented under the broad purview of PvPI and divided into three phases (initiation phase for the financial year 2012–13, expansion and consolidation phase for the financial year 2013–15, and expansion and maintenance phase for the financial

year 2015–17) for the establishment of a hemovigilance program. This independent initiative is mostly limited to recipients' voluntary reporting of serious adverse reactions. This program's primary goal is to track adverse reactions and incidents linked to the delivery of blood products and blood transfusions in order to identify trends, suggest best practices and policies, and suggest interventions needed to enhance patient care and safety. To gather and analyze data on hemovigilance across the nation, "Haemo-Vigil" software has been created. The National Institute of Biologicals is serving as the co-ordinating center for HvPI to collect and analyze data related to biologicals and haemovigilance. The ultimate objective of this HvPI is to join the IHN, which currently has 28 countries as members and offers a global forum for sharing best practices and benchmarking of haemovigilance data. The Indian Pharmacopoeia Commission and National Institute of Biologicals' (IPC-NIB) combined recommendation has defined an organogram outlining the functions of the hemovigilance program.[18]

**Objective of Reporting Adverse Reactions and in Transfusion in National Haemovigilance Program**

With the primary goal of gathering data that can be utilized to increase transfusion safety, the advisory committee's core group has already created a guidance document on transfusion reaction reporting .a nationwide reporting system that can be used to assess how far public policy on patient safety has advanced.

- Reporting can pinpoint dangers and hazards as well as reveal where the system is broken.
- By doing this, the risk of future patients being hurt can be decreased.
- Timely reporting helps with efficient risk management.

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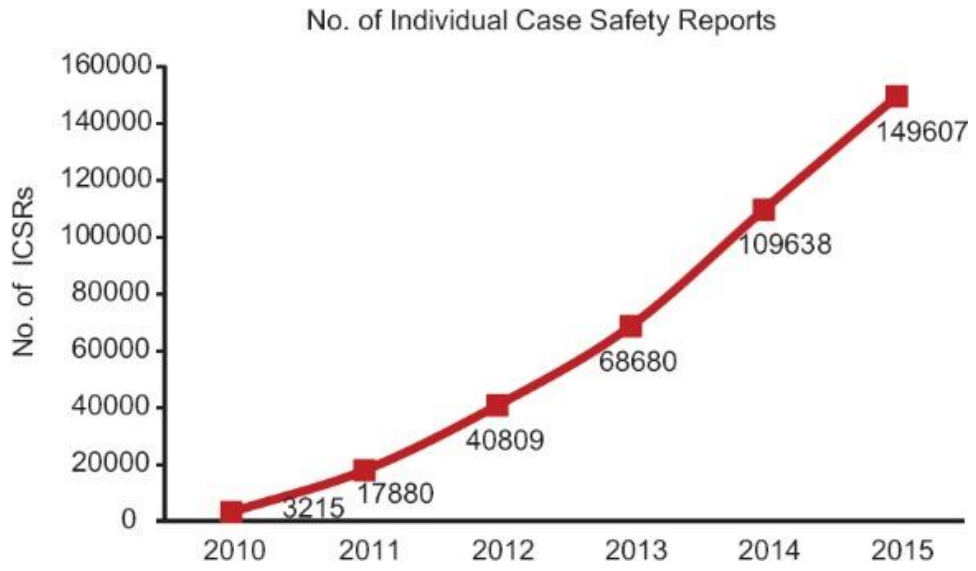


**The benefits of hemovigilance**

a) For blood donors: • It improves donor safety by reducing issues with The blood transfusion process • It fosters trust among willing blood donors

b) Blood transfusion service

• Any relevant problems can be found early;

• The development process will be sped up by presenting

The safety results;

c) The medical facility and blood bank that are connected to a hospital: As systemFlaws are discovered, errors will be reduced and reported; adverse events must be accurately and Continually recorded; and development plans will be created to ensure safety.

D) Hv systems can Increase patient health safety by: • Accurately predicting current concerns affecting the person • Providing the root causes of issues and solutions for fixing them.[17]

**Complications with hemovigilance**

The main issues in hemovigilance are the following: underreporting of adverse events/effects due to Fear of retaliation and punishment, late reporting, use of multiple channels of reporting, incompleteInformation on incident sheets, failure to report investigation findings, challenges in communicating. With blood banks in the public and private sectors and in encouraging hospitals to notify events and Have functional transfusion committees, fragmented blood transfusion records.[16]

## RESULTS, OBSERVATION, AND EVALUATION

In order to make sure that the system is functioning properly, monitoring and evaluation. Effective, capable of adapting over time to new situations, and Environments. It is necessary to create a strategy to keep track of the Regularly assess the effectiveness of the hemovigilance system. Additionally, evaluation offers impartial proof in support of the program's Is essential for its viability and continuation. Regardless of how well they have performed, hemovigilance systems All have restrictions when they are applied. Potential issues and downsides.

Include: Minimal engagement; Inaccurate reporting; Omitted information; Different terminologies and definitions;

Failure to recognize transfusion link, particularly with non-transfusion-related. There are a number of limits to hemovigilance, which is the monitoring and reporting of adverse events associated with blood transfusion, which can be covered in a review paper. Here are some important things to think about

1. Underreporting: For a variety of reasons, such as healthcare providers' hesitation or ignorance, many adverse events associated to blood transfusion may go undetected. This may result in an inaccurate impression of the dangers associated with blood transfusions.
2. Data Quality: It can be difficult to conduct reliable studies because to the variable quality of data gathered by hemovigilance systems. The detection of trends and patterns might be hampered by data that is erroneous or incomplete.
3. Reporting Bias: There might be a tendency to underreport major or fatal adverse events, which could skew the statistics in favor of more serious outcome.
4. Definitional Variability: Because different nations and organizations may use different definitions and standards for reporting adverse occurrences, it can be difficult to compare data globally correctly.
5. Non-Standardized Reporting: The inability to aggregate and analyze data in a consistent manner can make it challenging to get actionable insights from hemovigilance data.
6. Limited Long-Term Follow-Up: Haemovigilance systems frequently concentrate on short-term adverse outcomes, whereas potential long-term transfusion-related effects, such as immunological reactions or infections transferred through transfusions, may not be appropriately documented.

7. Resource Constraints: Numerous healthcare systems may fail to provide enough funding for hemovigilance initiatives, which restricts their capacity to gather extensive data and carry out in-depth analysis.
8. Patient Reporting: Patients are a valuable source of information about adverse events connected to transfusions, yet haemovigilance initiatives may miss their viewpoints.
9. Rare Events: Because some severe transfusion-related adverse events are uncommon, it might be difficult to identify and interpret them in haemovigilance data, especially in smaller-scale systems.
10. Generalizability: The generalizability of research findings is constrained by the fact that results from hemovigilance systems in one region or healthcare setting may not always be applicable to other contexts.[15]

## CONCLUSION

The data from the hemovigilance and analyses enable corrective and preventative measures. preventative measures can be made to reduce the possibility hazards connected to blood quality and safety for donors, patients, and transfusion recipients, processing staff. Such details are essential to provide the necessary alterations to the relevant policies, higher standards, systems and processes support the development of guidelines, improve the security and standard of the from donation to transfusion: the full process. Developing standards, audit, and health monitoring systems in More can be accomplished in countries with low resources. quickly thanks to a step-by-step implementation.

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