

Review Article

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Mini-Review on Haemovigilance: an Indian Perspective

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ABSTRACT

Haemovigilance is considered to be the collection of monitoring measures that encompass the entire transfusions process ranging from monitoring of blood to the prevention of blood-related disease. The term hemovigilance originated from the word pharmacovigilance, which comprises operations and methods to gather intelligence valuable in overseeing pharmaceutical goods, particularly adverse drug responses in humans, and to scientifically assess such data. This follows the reporting system which includes the enhancement of patient safety. It also includes learning from failures that result in certain system changes and thus prevents the associated errors. It also includes all key parties and organizes numerous operations among blood banks, transfusion facilities, and hospital caregivers. The majority of affluent nations now use Haemovigilance to track adverse responses and occurrences connected with blood donation and transfusion. This mini-review sheds the light on an overview of haemovigilance from an Indian perspective.

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Abbreviations

Adverse event (AE)
International Haemovigilance Network (IHN)
Haemovigilance (Hv)
European Haemovigilance Network (EHN)
International Society of Blood Transfusion (ISBT)
Adverse reaction (ARs)
Quality of Product (QoP)
Indian Pharmacopoeia Commission (IPC)
National Institute of Biologicals (NIB)
Haemovigilance Programme of India (HvPI)
Pharmacovigilance Programme of India (PvPI)
Central Drugs Standards Control Organization (CDSCO)

Introduction

Blood transfusion is a common and necessary life-saving medical technique that is usually viewed as safe when performed correctly. It is a commonly used therapy among critically sick patients to treat a problem that is causing significant morbidity or death and cannot be avoided or controlled by other methods. It is an occurrence that can provide both advantages and hazards to the recipient. A transfusion response is defined as any adverse event (AE) which occurs in an individual during or after the blood transfusion and its elements and for this, no other explanation can be determined. These AEs are mostly non-infectious in origin and might occur suddenly or gradually. AEs might be minor, moderate, severe, or life-threatening, depending on the severity and proper therapeutic intervention [1].

The International Haemovigilance Network (IHN) defines haemovigilance (Hv) as “a set of surveillance procedures covering

the entire transfusion chain (from the sampling of blood and blood products to the follow-up of recipients) intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence” [2].

As the term Hv is derived from the consolidation of two uniquely found Greek words i.e., ‘Haema’ which means blood, and a Latin word ‘Vigil’ which means watchful [3,4]. Hv is considered to be a part of vigilance which include several analytical procedures that help determine the quality of blood transfusion including monitoring, reporting, investigating, and analysis [5,6]. It is not only limited to processing but it also involves the events related to blood donations, processing while transfusion of blood, and also takes some special prevention steps such as the Hv [7,8]. It is considered to be the newest way of transfusion across the world as it possesses indispensable safety and quality during blood transfusion [9].

So, Hv can better be defined as the set of organized surveillance or as an assembly of surveillance strategies that covers all the relevant procedures that relate to serious AE or unexpected events i.e., from the collection of blood and its components to the following up of the donors [10,11]. All of these are meant to gather and distribute knowledge on unanticipated or unfavorable outcomes associated with the medicinal usage of labile blood transfusions, as well as to avoid its existence and repetition [12,13]. So, Hv is considered to be a surveillance system that is useful in detecting and analyzing the AEs and their associated reactions in the ongoing blood transfusion chain by improving blood safety. As a result, the true objective of a Hv is to increase blood transfusion efficiency. As these are widely accredited across all the analytical procedures that assured the quality of blood and its components regarding

the improvement of health to save the patient's life during acute emergencies [14-16]. Figure 1 is showing the organogram of Hv. Hv is considered to be a developing field in medical science that helps in blood transfusion as its introduction is currently considered to be an integral part of blood safety across the world [17].

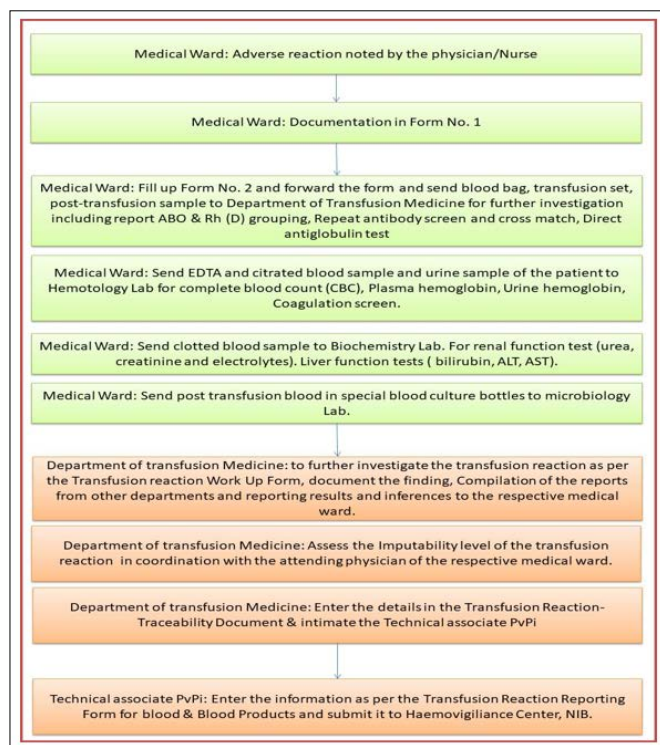


Figure 1: Haemovigilance Organogram

History

In France, ground-breaking work on Hv began in 1994 with the development of governance mechanisms by Blood Transfusion Committees and the development of a nationwide Hv program [18]. Later, in the year 1995, it came intending to improve public confidence regarding their safe and efficacious blood supply, a resolution was published by the European Council to increase the safety of clinical blood transfusion services in Europe [19]. The scope of the European Haemovigilance Network (EHN) arose as a result of the progressive expansion of IHN [20]. IHN aspires to build and maintain a global collaborative organization relevant to the safe operation of blood and its components, as well as Hv in blood transfusion and transfusion therapy [21]. Through digital sharing of data, workshops, and conferences, the IHN's efforts have made a vital contribution to the top standard of Hv throughout Europe. In terms of standardization, the IHN and the International Society of Blood Transfusion (ISBT) working party for Hv have provided two significant standardizations [22] i.e., the definitions of adverse reaction (ARs) and AEs in people. So, the main goal of this introduction Hv system across the country is to find out the actual situation of transfusion-related AEs to provide safer transfusion, as well as a reduction in severe and life-threatening responses [23].

Scope of HvPI

The Hv structure should preferably encompass all metrics and procedures used throughout the transfusion process, from blood donation to monitoring, reporting, and analysis of AEs and ARs [24,25]. Because of variances in the reporting spectrum, the extent of distinct Hv systems differs:

- Reporting of AR versus AE.
- Serious ARs only occur in recipients or also in donors.
- Ideally, the Hv system should oversee procedures across the transfusion chain, from donating blood to processing and transfusion to recipients.
- Following up on AEs, ARs, and near misses connected with blood donation.
- There should be good communication between the blood transfusion department, hospital personnel and transfusion laboratories, hospital transfusion committees, regulatory bodies, and national health authorities.

Recipients and Donor

Donor Hv should involve the reporting of unexpected AEs in blood and component donors, as well as the actions performed as a result. These might be ARs or difficulties related to donor donation, management, and selection, which could damage the donor or affect the quality of the product (QoP), placing the receiver at risk [26]. A collaborative work of the EHN and ISBT has developed a categorization and set of definitions for blood donation problems.

Haemovigilance for Recipients

The internationally recognized scale for grading the severity of an AR in the receiver. These are often seen as the AR or imputability that can be ascribed to blood component transfusion, and they are also a crucial aspect in determining whether or not blood components are implicated [27]. Some complications may occur, for example, as a result of the production of new RBC alloantibodies, which is one of the most common ARs following an RBC transfusion [28].

Haemovigilance for Donors

The donor of blood Hv is also essential in terms of AR or AE after whole blood or component donation. Because the etiology of AR in the donor differs from that of the recipient, it is referred to be a complication. These ARs may be the result of donor contribution, selection, and management, which may directly affect the donor or impair the QoP, influencing the receiver [29]. As a result, a specific vigilance team is linked with it, known as donor vigilance, whose purpose is to systemically monitor ARs and their occurrences related to blood donor care, as well as to keep an eye on the improvement in quality and safety for blood donors [30].

National Haemovigilance Programme of India

Indian Pharmacopoeia Commission (IPC) of India in collaboration with the National Institute of Biologicals (NIB) situated in Uttar Pradesh has launched a special program named Haemovigilance Programme of India (HvPI) on 10th Dec 2012 across the nation under its Pharmacovigilance Programme of India (PvPI) [31,32]. It includes the Core Training Panel, Quality Review Panel, and Signal Review Panel which altogether constitute the Hv advisory committee which is a core group of Hv (Figure 2) [33]. The main objective of introducing this program across the nation is to track all the ARs or AEs and incidents associated while blood transfusing and during blood product administration and also helps identify the trends that are recommended to be the best practices and intervention that are required to improve the patients care and their safety [34]. In addition, it is also used to compile all those data of ARs or associated AEs including transfusion errors and QoP-related AEs that are either assumed or verified by alerting or caution mechanisms that encompass the full transfusion chain and their separate operations [35].

A specific program called “Haemo-Vigil” has been created to gather and combine data across the country. In India, around 117 Medical Colleges and Hospitals have already engaged in this Program. NIB serves as the HvPI Coordinating Center, collecting and analyzing data on biologicals and Hv. The ultimate objective of this HvPI is to become a member of the IHN and bestows an international platform for exchanging best practices and evaluating Hv data [36].

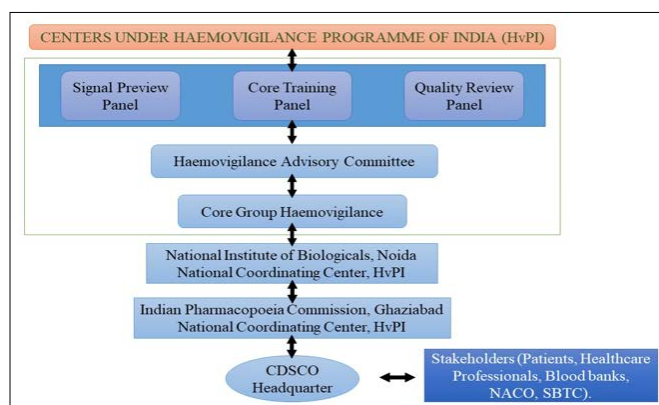


Figure 2: Haemovigilance Programme of India

Objectives of HvPI

- Collect, consolidate, and evaluate data on responses linked with blood transfusion and its components
- Raise awareness among healthcare professionals about the importance of participating in this initiative.
- To generate evidence-based recommendations and support the Central Drugs Standards Control Organization (CDSCO) in transfusion safety regulatory decision-making
- To transmit essential information to stakeholders
- Establishing national and international relationships [37].

Table 1: Roles and responsibilities of functional units of HvPI

SERIAL NUMBER	HV UNITS	ROLES & RESPONSIBILITIES
	CDSCO–DCGI	Formulate safety-related regulatory decisions Communication of blood and blood products transfusion-safety-related decisions to stakeholders To monitor compliance
	National Co-ordinating Centre – HvPI	Review quality and completeness of data Collation and analysis Preparation of guidance documents Training and awareness programs Feedback to reporting units Recommendations for blood safety to NCC – PvPI at IPC
	National Co-ordinating Centre PvPI	Forward recommendations of HV – National Advisory Committee to CDSCO
	Reporting units	Generate transfusion reaction reports Causality assessment Submit a report through HV software

CDSCO-Central Drugs Standards Control Organization; DCGI-Drug Controller General India; HvPI-Haemovigilance Programme of India; IPC-Indian Pharmacopoeia Commission; PvPI-Pharmacovigilance Programme of India.

Advantages of Haemovigilance

- For Blood donors:
 - Donor safety has been enhanced by lowering problems in the blood transfusion procedure
 - It instills trust in volunteer blood donors
- Service for blood transfusion:
 - On an early basis, any relevant flaws can be identified
 - By presenting the findings of safety, the development process will be accelerated
- The hospital-affiliated blood bank and health-care facility:
 - Errors will be decreased and reported as a result of system faults being detected
 - Adverse occurrences must be reported precisely and continuously
 - To guarantee safety, development plans will be devised
- Hv systems can improve patient health safety by:
 - Exact forecasting of present concerns affecting the individual
 - Providing the primary causes of problems as well as methods for correcting and repairing them
 - Providing evidence-based policy suggestions for improved policy changes [38].

Problems

The main problems concerned with Hv are found at different subsequent levels. Usually, there is a deficit within the common definition, terminology, and standardized reporting formalities with a uniform matrix [39]. In Europe there are still numerous organizational problems arose due to a shortage in funding, mandates unclear, undefined responsibilities, low sensitivity with insufficient training, and hesitation to move forward by executing strong actions [40]. In several European countries, HvPs are well established and working but few countries lack the HvPs [41].

Although regulations and laws are in place, there is a concern about underreporting undesired reactions to blood and blood products. This is still a common problem in Brazil, which shows reporting rates much lower than in countries such as France and the United Kingdom where the systems are consolidated [42]. There are numerous opportunities for error during this process if procedures are not strictly followed due to untoward occurrences associated with the collection, testing, processing, storage, and distribution of blood or blood components that might lead to death or life-threatening [43]. Reports from the UK (2005) indicate that nearly 60% of adverse events associated with transfusion are a result of ‘wrong blood to the wrong patient [44]. The majority of these errors are the result of failure to follow procedures, or inadequate or unclear procedures [45,46].

Conclusion

Hv has been proven to be a component of vigilance, which provides all of the information by analyzing the problems that must be facilitated to correction and the preventive actions that must be taken to minimize the risk of associated problems such as safety and quality during blood processing and transfusion, individuals, and related staffs. Adoption of these issues within the HV system around the world aids in recognizing and reporting instances of under transfusion as a result of inventory, thereby assisting in the development of advanced sampling procedures, stock management systems, and implementation of effective policies to promote blood safety and availability. As a result,

formulating recommendations and conducting frequent audits through the Hv system in nations with limited resources may be accomplished more intensively through a gradual deployment.

Conflict of Interest

The authors declare that there is no conflict of interest.

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