



ISSN (E): 2277-7695
ISSN (P): 2349-8242
NAAS Rating: 5.23
TPI 2023; 12(4): 1824-1827
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www.thepharmajournal.com

Received: 08-01-2023

Accepted: 13-02-2023

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Hemovigilance: A step to safe blood transfusion

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Abstract

Hemovigilance is projected for the recognition and studying all inconvenient possessions of blood transfusion to accurate their basis and foil reappearance. Transfusion services trust on transfusion response reportage to offer patient care and shield the blood stock. Redundant withdrawal of blood is a major depletion of unusual blood, as well as man, hours, and reserves. Although strict measures are pragmatic during blood contributions arrangements and transfusions, errors in transfusion and infection snags serve a problem in clinical practice. The monitoring, investigation and analysis of hostile measures creates applicable data for the eminence set of these systems, pouring continuous upgrading in blood transfusion practice. Endorsements based on findings have led to variations in clinical strategies and plans. Despite the advancement further developments are still needed. Current challenges are low resource settings, the international coordination of descriptions and the preclusion of underreporting. In count, the connecting affiliation between the transfusion and the reaction is often uncertain. Biomarkers may help in the imputability assessment and their role in the analysis of blood transfusion reactions needs to be more explored.

Keywords: Hemovigilance, safe blood transfusion, biovigilance

Introduction

Biovigilance extends the term hemovigilance beyond blood to incorporate monitoring of adverse events associated with other medical products of human origin, such as tissue, organs, and cells used for transplantation. Vigilance has a broader role, beyond that of blood and blood products, in the public health and health care service of a country. In addition, surveillance for adverse events associated with medications is referred to as pharmacovigilance [Chisakuta *et al.*, 2001] [1]. The scheme encompassing haemovigilance, biovigilance, pharmacovigilance and other health care-associated vigilance programmes may differ depending on the structure of public health and health care delivery in the country. There may be overlap between biovigilance and pharmacovigilance. For instance, plasma products are sometimes included in either haemovigilance or pharmacovigilance. Where pharmacovigilance systems, patient safety agencies, or offices for health care standards are active within the same jurisdiction, haemovigilance systems should interact with these agencies for the purposes of leveraging efficiencies of operation

Hemovigilance is derived from the blend of the greek word haema, or “blood”, and the latin word vigilans, or “alert”. The basic unit of hemovigilance is the blood transfusion chain. Initially Japan and France first specialized and structured national surveillance systems for blood transfusions as a reaction to the HIV contaminated blood transfusion [6].

Denmark, Ireland, Netherland, and Canada have a unpaid reportage requirement, which are connected to International Haemovigilance Network (IHN) International Haemovigilance Network (IHN) has covered the entire surveillance procedures casing the whole transfusion chain, from the collection of blood and its components to the track of recipients. It also collect information on undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their recurrence [Haemovigilance Programme, 2016] [7].

The World Health Organization (WHO) has described the goal of hemovigilance as the continuous quality improvement of the transfusion chain through improved donor and patient safety, improve transfusion suitability and reduce depletion. The transmission of infectious diseases through contaminated blood products became a recognized adverse complication of transfusion.

Aim of hemovigilance

The main objective of hemovigilance is unremitting quality improvement of the blood transfusion through corrective and preventive measures imparting patient safety and preventing adverse reactions during blood transfusion. This system resembles any continuous quality improvement cycle and shows the same elements and activities.

Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up. Haemovigilance includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, as well as the development and implementation of recommendations to prevent their occurrence or recurrence. [Mukherjee & Maiti 2016] ^[8] The ultimate goal of haemovigilance is continuous quality improvement of the transfusion chain through corrective and preventive actions to improve patient safety and outcomes, enhance donor safety and reduce wastage. Haemovigilance should be fully integrated into the quality systems of all institutions involved in the donation and provision of blood and blood products, including processing, inventory management, storage and distribution, and in clinical transfusion. The organization of a haemovigilance system is largely determined by the structure of the national blood system and the health system. A system of haemovigilance is dependent on the traceability of blood and blood products from donors to recipients and vice versa, and on the monitoring, reporting, investigation and analysis of adverse events Procedure followed for compliance of hemovigilance [Bolton & Watt 2020]. ^[9]

Hemovigilance should be fully unified into the quality systems of all institutions involved with the blood and blood products supply chain, including donation, testing, processing, inventory management, storage and distribution, and clinical transfusion, to ensure donor and patient safety at all levels. The administration should secretly approach towards the development of a coordinated approach to the continuous improvement of the safety, availability and appropriate use of blood and blood products and related activities across all organizations involved in the transfusion chain. Donor and patient confidentiality is maintained and to this end donor- or patient-identifiable information should not be recorded in hemovigilance reports. [Whitaker *et al.*, 2019] ^[10]

International Society of Blood Transfusion (ISBT) has put forward adverse reactions as unwanted responses or effects in patients temporally related with the administration of blood or blood components, and range in severity from minor reactions to reactions with a fatal outcome. Haemovigilance systems initially engrossed the risk of transfusion-transmitted infectious diseases and the focus expanded to other infectious and non-infectious adverse reactions. Errors, deviations from standard operating procedures (SOPs) and failures, adverse reactions and the adverse effects of delay, or the risk of harm stands as a major factor during the entire procedure. [Vossoughi *et al.* 2018] ^[11]

In order to augment transfusion safety, it is crucial to expand the scope of hemovigilance beyond that of the safety of blood or blood components. In count to the analyses of occurrences that led to damage, haemovigilance has grown to incorporate the search of events where there was a peril of harm but this did not happen. Such near errors fact to weak or helpless steps

in the transfusion chain. Analysis of near errors can recognize basic causes in waged means that should be reformed to foil future illegal blood transfusion events, adding influence to proactive enhancements of transfusion protection and the prevention of transfusion reactions. [Hauser *et al.*, 2019] ^[12] Finally, the thought of monitoring of usefulness and efficacy of the transfusion chain can be considered as part of haemovigilance in its wide-ranging sense. By monitoring optimal blood use, not only the healing outcome of transfusions is under scrutiny, but also under- and overtreatment and the wastage of resources by outdated, over-ordering or ill-timing between the collation and the definite start of transfusion. The surveillance of efficacy and efficiency of transfusions is currently not incorporated in most of the national level haemovigilance systems. While strongly dependent on the presence of evidence-based practice and adherence to guidelines, the monitoring of efficacy and efficiency of transfusion constitutes a domain haemovigilance can progress into. [Roubinian *et al.*, 2020] ^[13]

An adequate hemovigilance system must be able to account for and monitor all processes that lead to patient blood transfusion. The intertwined and reliant on steps in this chain include: the process of blood collection, together with donor monitoring and safety, blood component preparation blood testing for quality and infectious diseases, blood issuing from the donor center to the hospital and from the hospital transfusion provision to the patient, blood carriage from the contributor service to the hospital and from the hospital transfusion service to the patient, blood administration and monitoring, and hospital physician verdict construction. [Edgren & Hjalgrim 2019] ^[14]

Hemovigilance is an important portion of a eminence management system in healthcare. It exists at three levels: 1) the blood stake and sickbay, 2) regional or coast-to-coast levels, and 3) global levels. At all 3 levels, the system is designed to notice, record, report, and explore anything that goes wrong in the blood transfusion chain. Perhaps more pointedly, the system is only effective when it can use the instructions educated to take feat to circumvent forthcoming complications.

Obstacles in Hemovigilance

In all hemovigilance systems, there is a need on the donor hubs or hospital systems to properly record data into a chief record source. Consequently, systems such as these are all resisted to dazed a number of foottraces to be edifying and effective. It is important to realize that hemovigilance systems are often limited by substantial intermissions in the strategy and coverage of scheme data, inadequate seized aspect regarding described hostile events, an inability of the system to be stretchy sufficient to arrest new or growing problems, data entry faults, limited institutional contribution, and limited resources (financial or staffing), such that the system cannot feasibly capture and report what is anticipated. [Tonino *et al.*, 2019] ^[15]

Contempt being dynamic, there is general underreporting of adverse reactions connected with blood transfusion. WHO acknowledged that the scrappy blood transfusion systems, lack of government obligation, lack of considerate among clinicians, lack of ethos of reporting, distress of punishment, lack of skill and regulatory framework on hemovigilance, nonexistence of computerized management system might be challenges for the execution of hemovigilance package in the

world [18]. Backers in governing authorities (CDSCO) and supporter hemovigilance programs need to toil together to upsurge the input of blood centers and ensure extensiveness of data in this program for more mark based blood donation safety measures.[Bisht 2021] [2]

Solutions to the Challenges:

The possessions of blood alarms should be judged using SWOT (strengths, weaknesses, opportunities, threats) investigation. HPV's strengths are its central skills and properties for effective HPV. Feebleness is an part of unmapped accomplishment. [Van den, Detmer] [3,4] Prospects are the probable for novel or pioneering innovations that could meaningfully inflate that outlook. The hazard could be a troublemaking new expertise for HvPI. The needling is to understand not only the feedback of the internet, but even the sociology of human webs. Ensuring the reliability, sensitivity, and comment of each alert is also important. Hemovigilance is a significant area of PvPI and ADR should be conveyed and logged after blood transfusion / blood products. [Vasudev *et al.*, 2016] [5] One of the main tasks of hemovigilance is ADR, which qualms legal and monitoring implications for blood bank staff and doctors. Despite these trials, it is now well-accepted that nationwide hemovigilance plans can and do influence patient defense. One of the best instances of this comes from the UK's Stern Hazards of Transfusion (SHOT) program. Precisely, a successive assessment of stated cases of transfusion-related severe lung injury (TRALI) from 1996 to 2003 demonstrated that the peril was utmost after getting plasma-rich blood components. They surely found that there was a 7-8 fold amplified danger for transfusion linked acute lung injury when receiving plasma or platelets, which is often packed in essentially 100% plasma, related to red cells. Moreover, female contributors were more often caught up in these cases. Because of these remarks, Blood Services in the UK make known to risk-reducing approaches, such as the transfer to all-male donors for fresh frozen plasma in 2003, and the fortunate conscription of male apheresis platelet funders. These donors were also screened for antibodies to human leukocyte antigens, and human neutrophil antigens, and retested later incubations. With the overview of these strategies, the number of testified transfusion-related severe lung injury cases were shown to decline from a peak of 36 suspected cases, and seven deaths, in 2003 to 11 suspected cases, and no deaths, in 2012. [Land *et al.*, 2018] [16]

Conclusion

Hemovigilance plays a perilous quality function at both limited and general levels. National hemovigilance efforts, in particular, can be unbelievably helpful to public health. Unfortunately, US national hemovigilance exertions has wrapped behind other countries, and even nowadays, consists of a makeshift of unequal national reportage courses. A key task for these systems poignant onward is increasing the number of voluntary participant's and improving awareness regarding the critical importance of these systems. The data apprehended in these systems are growing each year, and are beginning to produce important data that can inform future domestic transfusion initiatives to improve blood safety.

The transfusion of blood and blood products is a life-saving intervention. However, there are risks of adverse events associated with the donation of blood and its components, and with the transfusion of blood and blood products to patients. Adverse events include all reactions, incidents, near misses,

errors, deviations from standard operating procedures and accidents associated with blood donation and transfusion. Learning from adverse events and identifying systems problems can drive the introduction of measures to enhance the quality, safety, efficacy, and cost-effectiveness of blood and blood products as well as the donation and transfusion processes. The rigorous management of information generated through this system is key to introducing amendments in blood policies and guidelines that lead to changes in processes and practices in donation and transfusion. The establishment of a haemovigilance system involves coordination and collaboration among all stakeholders, including the ministry of health, blood transfusion services, hospitals, professional bodies, public health institutions and regulatory agencies, as well as patient and donor groups.

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