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Haemovigilance and its Significance in Transfusion Safety and its Adverse Effect

Sachin Vinchurkar, Vaibhav Patil, Junaid Pinjari, Sonia Sevlani
Students, Department of Pharmacy
P.G. College of Pharmceutical Science and Research, Nandurbar, Maharashtra, India
svsachin1999@gmail.com and vaibhavpatil20600@gmail.com

Abstract: *Blood transfusion saves lives and improves health, but many patients requiring transfusion do not have timely access to safe blood. Blood transfusion is always associated with some level of risk. Haemovigilance is a continuous process of data collection and analysis of transfusion-related adverse reactions/events in order to investigate their causes and outcomes, and prevent their occurrence or recurrence. It is a risk monitoring system integral to the practice of transfusion medicine whose ultimate purpose is to improve the quality and safety of transfusion Blood transfusion has certain risks, and any unfavorable event occurring in a patient during or after transfusion, for which no other reason can be found, is called a transfusion reaction. These untoward effects vary from being relatively mild to severe and require rapid recognition and management. Transfusion services rely on transfusion reaction reporting to provide patient care and protect the blood supply. Unnecessary discontinuation of blood is a major wastage of scarce blood, as well as man, hours, and funds. Although strict procedures are applied during blood donations preparations and transfusions, errors in transfusion and infection complications still serve a problem in clinical practice. Hemovigilance is intended for the detection and analyzing all untoward effects of blood transfusion to correct their cause and prevent recurrence. In this review, we will discuss hemovigilance and transfusion Safety and its adverse effect.*

Keywords: Adverse event, blood donor, blood donation, Haemovigilance, Transfusion safety

I. INTRODUCTION

Blood and blood plasma transfusion are a life-saving therapy. The transfusion of blood and blood products to patients, as well as the donation of blood and its components, involve risks of adverse effects. Adverse responses, occurrences, near-misses, mistakes, departures from best practises, and accidents related to blood donation and transfusion are all considered adverse events. The implementation of steps to improve the quality, safety, effectiveness, and affordability of blood and blood products as well as of the donation and transfusion procedures can be driven by learning from bad events and identifying system flaws.[1]

1.1 What is Haemovigilance?

A set of surveillance practises known as haemovigilance monitors every step of the transfusion process, from the donation and processing of blood and its constituent parts to their provision and transfusion to patients and their subsequent monitoring. It involves keeping track of, recording, examining into, and analysing any negative events connected to blood donation, processing, and transfusion, as well as taking steps to prevent them from reoccurring again.[2]

II. ORIGIN OF HAEMOVIGILANCE

The term "haemovigilance" (he'movigilance in French) was created in France in 19911.[3], as a relation to the term "Pharmacovigilance," which was already in used.[5]The words "haemovigilance" are derived from Latin and Greek (Haema-blood; vigilance-paying special attention to). The haemovigilance was first developed as a safety concept in the 1990s. The initial work on haemovigilance was originated in France in 1994 by developing a national haemovigilance system and a monitoring system called the "Blood transfusion committee." Later in 1995, the European Council published a resolution with the purpose of increasing trust of the people in a reliable blood supply. As a result, the

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haemovigilance system was put under the control of the judicial system. The European Haemovigilance Network (EHN) was established later in 1998. Currently, the "International haemovigilance network" (IHN) is a functioning global system.IHN's mission is to establish and sustain a global organisation dedicated to ensuring the safety of blood and its constituent parts, transfusion medications, and hemovigilance. To ensure better service, the IHN collaborates with the "International society of blood transfusion" (ISBT).[4]

III. BENEFITS OF HAEMOVIGILANCE

Table shows ways in which haemovigilance can have a positive impact on many stakeholders throughout the blood transfusion chain.[2]

Stakeholder	Impact/outcome
Blood donor	• Improved donor safety with a reduction in the frequency and severity of donor complications • Greater confidence in the blood donation process
Blood transfusion service	• Improved donor retention and return • Early detection of deficiencies and weaknesses • Continuous improvement in the quality of the services and products • Improved public confidence and trust in the blood transfusion service system
Hospital blood bank and health care facility	• Reduction in errors, omissions and system failures • Systematic and consistent reporting of all adverse events • Development of skills and expertise in the area of total quality management • Reduction in adverse events • Better health care outcomes • Less medico-legal action with an overall improvement of the community's regard of a particular facility
Patients receiving transfusion therapy	• Reduced risk of harm due to adverse events • Greater confidence in the blood transfusion process
Physicians and other health care professionals	• Identification and mitigation of transfusion-associated risks • Identification and quantification of unavoidable complications • Feedback leading to improved practice
Regional and national health authorities, regulatory and health agencies	• Early detection of emerging pathogens and the implementation of measures to mitigate the associated risks • Identification and mitigation of noninfective risks • Identification of trends in adverse events and opportunity for timely corrective action
Community	• Better care and stewardship of the gift of blood donation • improved donor and patient confidence and trust in the blood system
International bodies, societies, organizations	• Benchmarking, developing best practice and creating awareness

IV. RECOMMENDATIONS FOR A BETTER HAEMOVIGILANCE SYSTEM

Establishing and maintaining a completely working hemovigilance system requires a few prerequisites. They are

- A legal framework
- An ongoing, secure budgeting and financing system;
- Establishing a central evaluation centre, common definitions, a standard reporting system, a quick alert/early warning system, a professional culture, and functional hospital transfusion committees.
- Establishing preventative or countermeasures
- Encouraging global cooperation In this system, there are a great variety of participants, includes blood banks, hospitals, and relevant authorities.

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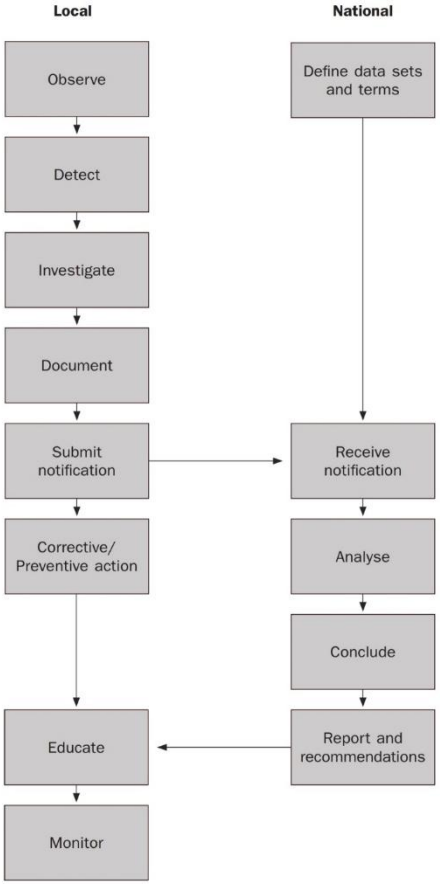
- To achieve the overall goals of the hemovigilance system, these significant indicators must be prepared to coordinate in a positive way.[6] [7] [9]

4.1 National Haemovigilance Activity

A national haemovigilance office's roles and responsibilities within a national framework include.

- Establishing mechanisms for data collection, validation, and analysis.
- Publishing and disseminating reports.
- Developing recommendations; and monitoring implementation. •Receiving adverse event reports from blood transfusion services and hospitals.
- Reviewing reports to ensure the accuracy of reporting.
- Identifying trends and investigating underlying causes
- Developing ways to improve the transfusion chain
- Increasing the awareness of hemovigilance.
- Generating an annual report on national hemovigilance
- The potential creation of a quick alert and early warning platform to exchange information.
- Interconnection and link with other pertinent national systems, regional programmes, and multinational activities.
- Regular analyses of the hemovigilance system's performance. The ministry of health may oversee this national activity directly, or a third party, such as a professional organisation, may administer it. There are many different models, but effective leadership is important. To ensure the greatest advice and quality development, participation with national and international experts and professional associations should be encouraged. [9]

V. FLOW CHART OF HAEMOVIGILANCE DATA



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VI. MONITORING, EVALUATION AND OUTCOMES

The ability of the system to adapt over time to changing conditions and surroundings is highly dependant on monitoring and evaluation. A strategy should be created to regularly assess the haemovigilance system's impact and track its progress. Regular evaluation is essential for the viability of the programme and offers unbiased proof in favour of its continuation. No matter how well they have been implemented, haemovigilance systems all have some limits. Low involvement is one of the potential downsides and restrictions.

- Insufficient reporting.
- Omitted information.
- Terminologies and definitions that differ.
- Failure to identify transfusion link, particularly when events (such as some infections) aren't discovered until after the transfusion occurrence.
- The "culture" of the institution or healthcare system's compliance, process improvement, and reporting. To monitor planned haemovigilance operations and evaluate the haemovigilance system's effectiveness and success, process and result indicators should be created. The haemovigilance system should be actively researched if issues are found, and appropriate action should be taken to further the system's aims. The haemovigilance system's ability to influence changes in policies and procedures regarding donation, processing, and transfusion depends on its linkages to organisations charged with developing rules and guidelines, such as:
- Regional and national committees for transfusions.
- Organisations for professionals (in medicine, nursing, technology, and science).
- Healthcare facilities like hospitals.
- Health ministry.
- Regulatory agencies. Therefore, when evaluating the haemovigilance system, it is important to consider how well these connections work and how much they are used to advance donation and transfusion safety.[2]

VII.HAEMOVIGILANCE IN INDIA

The India Haemovigilance Program (HvPI) was introduced on December 10th, 2012. It is a centralised, well-organized procedure for keeping track of adverse reactions related to blood transfusions and the administration of blood products.. It was launched by Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Government of India in collaboration with National Institute of Biologicals (NIB), Noida, Ministry of Health & Family Welfare, Government of India.[11] [12]

HvPI was implemented across the country under the Pharmacovigilance Programme of India (PvPI) in 90 medical colleges in the first phase. At present more than two hundred centres are covered under this programme. The national coordinating centre (NCC) for HvPI is at NIB, Noida. The International Haemovigilance Network now includes HvPI as a member (IHN).Thetargets of HvPI are grouped into three phases –initiation phase, expansion & consolidation phase and expansion & maintenance phase. The initiation phase (From the year 2012 to 2013) was focused on the development of systems and procedures and software development. It also gave attention in the enrollment of participants and startup of data collection. During this phase, it was also planned to organise zonal workshops and publish the Haemovigilance newsletter to raise awareness. From 2013 through 2015, the second phase, known as the expansion and consolidation phase, had a number of goals, including maintaining enrollment levels, holding zonal workshops, and publishing a newsletter. This phase also focused on training of staffs and took effort for the membership in IHN. The third one, expansion & maintenance phase (From the year 2015 to 2017) have various aims to achieve. It comprises maintaining and system and procedure optimization, gap analysis, scheduling suitable trainings, determining the viability of donor vigilance, and developing rapid alert systems. Epidemiological surveillance for Transfusion-transmissible infections (TTI) are also planned to develop in this phase.[13] [14]

VIII. NATIONAL HAEMOVIGILANCE PROGRAMME OF INDIA (HVPI)

HvPI was launched on 10th December 2012 by Indian Pharmacopoeia Commission in association with National Institute of Biologicals, Noida, Uttar Pradesh, across the country under its Pharmacovigilance Programme of India. Hemovigilance program has been launched with the following aims:

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- To monitor transfusion reaction .
- To create awareness among health-care professionals.
- To generate evidence-based recommendation.
- To communicate findings to all key stakeholders.
- To create national and international linkages.
- Providing Central Drug Standard Control Organization with regulatory safety advice.

Hemovigil, a software programme, was created to gather and compile data related to the overall country. In India, 117 medical colleges and hospitals have already signed up for the programme. The National Institute of Biologicals, which collects and examines details relating to biological and hemovigilance, serves as the HvPI's coordination centre. In this context, a core group and advisory committee have already been established; the advisory committee's first meeting, to conclude Haemovigilance, took place on November 29, 2012. Transfusion Reaction Reporting Form and Guidance Document. The ultimate goal of this HvPI is to be a part of the IHN, which presently has 28 countries as its members and provide a global forum for sharing best practices and benchmark of hemovigilance data[15]

8.1 Possible Risks of Blood Transfusion

A. Acute hemolytic transfusion reactions (AHTRs)

AHTRs is one in which symptoms and clinical or laboratory signs of increased red cell destruction are produced by transfusion. In AHTRs symptoms appear within minutes after starting the transfusion, common laboratory features are hemoglobinemia, hemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinemia, increased lactate dehydrogenase and serum glutamic-oxaloacetic transaminase levels, and decreased hemoglobin. The immunologic basis for AHTRs is the interaction of preformed antibodies from the recipient with red cell antigens from the donor, which results in the rapid death of the transfused red cells. Rarely, hemolysis of the patient's red blood cells can result from the transfusion of ABO-incompatible plasma (such as ABO mismatch platelet transfusion) especially if donors have high titers of ABO antibodies.According to reports, AHTRs and accompanying mortality happen in about 1 in 76,000 and 1 in 1.8 million transfused units, respectively.[17]

B. Febrile non-hemolytic transfusion reactions (FNHTRs)

FNHTRs are characterized by an otherwise unexplained rise in temperature of at least 1°C during or shortly after transfusion. The chills and rigours, which are brought on by a cytokine-mediated systemic inflammatory response, can be disguised by antipyretic pre-medications, but they typically do not prevent them. Before confirming a diagnosis of FNHTR, other causes of fever should be ruled investigated.. FNHTRs are seen more often after transfusion of platelets (up to 30% of platelet transfusions) Compared to red blood cells (RBCs), platelets are more susceptible to cytokine buildup and leukocyte activation because they are maintained at ambient temperature. patients at risk or who have experienced febrile reactions for them are usually given blood productare leukoreducedThis shows that filters or other techniques were used to eradicate the white blood cells.[18]

C. Allergic Reactions

After the transfusion begins, symptoms may start to appear immediately or may take several hours to appear. This is the most common reaction. The body reacts to plasma proteins or other components in the donor blood during the transfusion. Usually, the only symptoms are hives and itching, which can be treated with antihistamines such as diphenhydramine.[18]

D. Urticaria

The mildest allergic reaction, known as urticaria, can arise unexpectedly, itch, and linger for several days or even hours before going away. More extensive cases may be accompanied by angioedema. The incidence of uticaria is 1–3%.Once the symptoms subside, the transfusion may be resumed. Methylprednisolone (125 mg intravenously) or prednisone(50 mg orally) may be used to treat severe responses. [18]

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E. Anaphylaxis

Anaphylaxis is a more severe form of an allergic reaction with an incidence of 1:20,000–1:50,000 transfusions,in which severe hypotension, shock, and loss of consciousness may occur.Anaphylaxis is commonly antibodies against donor IgA, which is why it is detected in recipients with low levels of IgA.. Patient antibodies against the C4 determinant of complement, ethylene oxide, and haptoglobin penicillin have all been linked to the reason. For responses that have symptoms resembling anaphylaxis but are not IgE-mediated, the term "anaphylactoid" is used. Adrenaline injections can be administered intravenously while the patient's heart is being monitored if they are unconscious or in shock.[19]

IX. RISKS AND FACTORS CONTRIBUTING TO TRANSFUSION RELATED ADVERSE EVENTS [20]

Certain factors may increase the likelihood of a transfusion related adverse effect and these include:

- Individual patient characteristics
- Blood component
- Equipment
- Concomitant medications and intravenous fluids

9.1 Individual Patient Characteristics

Prior transfusion recipients, multiple pregnancies, and patients receiving emergency uncross-matched transfusions are more likely to experience both immediate and delayed hemolytic transfusion responses.. Patients with IgA deficiency and anti-IgA antibodies, as well as multiparous women, are more likely to experience febrile, allergic, and anaphylactic reactions.

9.2 Blood Component

Platelet and granulocyte transfusions are associated with the highest rates of febrile nonhaemolytic transfusion reactions. The incidence of such reactions can be modified by changes to the blood component processed by leucodepletion. All red cell and platelet components produced by the blood service are leucodepleted. Platelets, which require storage at 20–24 ºC, are associated with higher rates of bacterial contamination than red cells, which are routinely refrigerated. All platelets are subject to routine bacterial culture and screening, which allows detection of a bacterial contaminated product. Transfusion of fresh frozen plasma is associated with a higher risk of allergic reactions. Although some reactions are minor, some can be severe and life-threatening, including anaphylaxis and transfusion-related acute lung injury (TRALI).

9.3 Equipment

All blood components are delivered using specially created intravenous giving sets that have a 170-200 micron filter built in to get rid of any debris or clots that may have collected during storage. Everything that is used to provide blood must be specifically designed for that purpose, have their safety reviewed, and follow the operational guidelines provided by the manufacturer.

9.4 Concomitant Medications and Intravenous Fluids

No medication or solutions should be added to or infused through the same tubing with blood or components except 0.9% Sodium Chloride, Injection (BP). ABO-compatible plasma or 4% Albumin or other suitable plasma expanders may be used with approval of the patient‘s physician. Never combine blood or a component collected in an anticoagulant containing citrate with crystalloid and colloid solutions containing calcium (such as Haemaccel), since they can interfere with the anticoagulant's function and induce clotting.

X. CONCLUSION

The information gained from the haemovigilance and analyses facilitate corrective and preventive actions to be taken to minimize the potential risks associated with safety and quality in blood processing and transfusion for donors, patients and staff. 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. There is a continuous need to work on haemovigilance and also establishing a right awareness system. It is just a beginning, a long way to go...

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REFERENCES

[1]. World Health Organization; WHO Guidelines for Adverse Event Reporting and Learning Systems. WHO/EIP/SPO/QPS/05.3/2005
[2]. World Health Organization are available on the WHO website (http://www.who.int)
[3]. Paula, HB Bolton-Maggs and Hannah, Cohen (2013), "Serious Hazards of Transfusion (SHOT) haemovigilance and progress is improving transfusion safety", British Journal of Haematology, Vol. 163(3), 303-314.
[4]. Ashish, Jain and Ravneet, Kaur (2012), "Hemovigilance and blood safety", Asian J Transfus Sci, Vol. 6(2), 137–138.
[5]. Amit, P Date; Anjali, A Date; Amruta, V Dashputra and Archana, S Borkar (2016), "Knowledge, attitude and practice of haemovigilance among doctors in tertiary care hospital in Nagpur, Maharashtra, India", Int J Basic Clin Pharmacol, Vol. 5(3), 788-793.
[6]. Paula, HB Bolton-Maggs and Hannah, Cohen (2013), "Serious Hazards of Transfusion (SHOT) haemovigilance and progress is improving transfusion safety", British Journal of Haematology, Vol. 163(3), 303-314.
[7]. Ashish, Jain and Ravneet, Kaur (2012), "Hemovigilance and blood safety", Asian J Transfus Sci, Vol. 6(2), 137–138.
[8]. Amit, P Date; Anjali, A Date; Amruta, V Dashputra and Archana, S Borkar (2016), "Knowledge, attitude and practice of haemovigilance among doctors in tertiary care hospital in Nagpur, Maharashtra, India", Int J Basic Clin Pharmacol, Vol. 5(3), 788-793.
[9]. Sukanta, Sen; Pankaj, Gupta; Satwika, Sinha and Pawan, Bhambani (2014), "Haemovigilance and transfusion safety: A Review", Sch. J. App. Med. Sci, Vol, 2(1A), 85-90.
[10]. Jean-Claude Faber (2003), "Hemovigilance: Definition and overview of current hemovigilance systems",
[11]. .Jaspreet Kaur Boparai, Surjit Singh. Haemovigilance: A new beginning in India. Int J App Basic Med Res. 2015; 5(3): 200-202. http://dx.doi.org/ 10.4103/2229-516X.165379
[12]. 12.Satyajeet Singh, Akanksha Bisht, Surinder Singh, Kalaiselvan, Varun Chopra, Pallavi Kumari, Ruchi Rao. Review on haemovigilance practice in India. World Journal of Pharmacy and Pharmaceutical Sciences 2015; 4(12): 350-357.
[13]. Haemovigilance Newsletter (Haemovigilance Programme of India) 2015; 3(6): 1-16. http://www.nib.gov.in
[14]. Akanksha Bisht. Haemovigilance programme of India (HvPI)-organizational structure. IHS; 7th March 2014; Barcelona, Spain. p. 1-19. http://www.ihn-org.com/wp-content/uploads/2014/01/Haemovigilance-Programme-of-India-by-Akanksha-Bisht.pdf
[15]. Haemovigilance Programme; National Institute of Biologicals and Indian Pharmacopoeia Commission Collaboration. Available from: http://www.nib.gov.in/ haemovigilance.html. [Last accessed on 2016 Mar 02].
[16]. Guavin F, Lacroix J, Robillard P, Lapointe H, Hume H. Acute transfusion reactions in the pediatric intensive care unit. Transfusion 2006;46:1899-908.
[17]. Mazzei CA, Popovsky MA, Kopko PM. Non-infectious complications of blood transfusion. In: Roback JD, Combs MR, Grossman BJ, Hillyer CD, editors. Technical Manual. 16th ed. Bethesda, MD: American Association of Blood Banks; 2008. p. 715-49.
[18]. Sahu S, H, Verma A. Adverse events related to blood transfusion. Indian J Anaesth 2014;58:543-51.
[19]. Ellis AK, Day JH. Diagnosis and management of anaphylaxis. Can Med Assoc J 2003;169:307-11.
[20]. Transfusion risks and factors contributing to adverse events. Australian Red Cross Blood Service. Available

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from http://www.transfusion.com.au/adverse_events /risks.