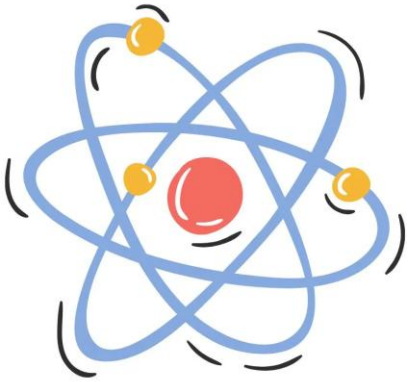

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A COMPREHENSIVE STUDY ON HEMOVIGILANCE SYSTEMS: PRINCIPLES, TYPES, IMPLEMENTATION, AND FUTURE DIRECTIONS IN TRANSFUSION MEDICINE

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Abstract: *Hemovigilance includes an organized overview of monitoring and managing any negative outcomes of blood transfusion along with safeguarding the donors and recipients of blood transfusions. This study articulates systematically the theory, types and ways of putting the hemovigilance systems into practice in micro and macro health institutions. It discusses the role of structured, streamlined, and controlled transfusion safety reporting along with databases and feedback systems. It encompasses the systems of primary donor and recipient hemovigilance, operational and laboratory monitoring, near and other systems for other countries. It analyses current constraints to reporting, definitional inconsistencies, and digital resource deficits, while proposing system effectiveness improvements. It emphasizes system strengthening improvements to artificial intelligence, automatic electronic reporting, donor-recipient system feedback, and definitional globalization, particularly in resource constrained environments. It emphasizes the necessity of improved structured systems to promote transfusion medicine safety and efficient practice globally.*

Keywords: *Hemovigilance, Blood Transfusion Safety, Donor Monitoring, Recipient Reactions, Transfusion Medicine, Surveillance Systems, Artificial Intelligence, Near-Miss Events.*

1. Introduction

Hemovigilance is defined as a systemic, organized methodology which monitors, records, and assesses the transfusion chain of custody; including the selection of the donor, collection of the blood, preparation of components, testing, storage, distribution, and the transfusion of blood products. Hemovigilance is a necessary tool of public health; it ensures the safety, effectiveness, and transfusion safety of blood products according to the standards of the highest international quality (de Jonge et al., 2022). Hemovigilance started in France in the early 1990s and began as a response to the public health crises resulting from blood transfusion controversies. Structured and

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organized systems of monitoring the transfusion chain grew out of a need to restore public trust. Over the years, transfusion systems in many countries in Europe and North America created transfusion safety systems; these countries formed the International Haemovigilance Network (IHN) which is active to this day (Katz et al., 2022). In India, the Hemovigilance Programme of India (HvPI) in collaboration with the National Institute of Biologicals (NIB), Ministry of Health and Family Welfare, was a landmark development in transfusion safety on a national level as it was the first initiative of its kind in India (Vuk et al., 2023). The increase of transfusion related adverse events, which include hemolytic, TRALI, TACO, and allergic reactions, related to blood transfusions, demonstrates a need for greater monitoring, reporting, and analysis of adverse events. Such events proactive and systematic tracking of transfusion adverse reactions would prevent morbidity and mortality (Roudsari et al., 2021).

Entities such as the WHO, ISBT, and other national bodies develop and disseminate objectives, standard definitions and criteria, and reporting systems to ensure consistency in the practice of hemovigilance across the globe (Hamid et al., 2024). They also attempt to build capacity, develop policies, and advocate for the implementation of transfusion safety policies targeted for optimal safety. Hence, this review will attempt to detail the different aspects of hemovigilance and its fundamental concepts, types and strategies of implementation and innovations to enhance understanding of hemovigilance (Rossi & Simon, 2022). Moreover, the review will analyze the gaps in hemovigilance in different health systems and the opportunities to enhance the safety of transfusion practices. The objectives of this study are to synthesize the global perspectives on transfusion safety, identify and describe the best practices, and provide analytical thinking to improve transfusion practices.

2. Principles of Hemovigilance

Quality management across the total transfusion process encourages systematic surveillance, honest reporting, and ongoing development in the scientific field known as hemovigilance. As part of scientific hemovigilance, the monitoring and recording of adverse events in the donation and transfusion process is primarily the responsibility of hospitals. This process begins with the selection of a donor, who is the primary and most important candidate in the event a recipient is lined up (Yadav et al., 2024). Donors are as important as recipients, and following the selection

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process, blood donations are taken in the sterile blood collection process. After blood collection, specimen testing is required. After receiving the blood, blood components are separated, compartmentalized, preserved and then delivered. Each stored, transfused components is then retained for the temporary post transfusion observing period (Prax et al., 2019). Hemovigilance prevents the transfusion process errors during the transfusion by controlling the process and by providing other actions and appropriate responses for the negative effects of each process. Reporting is another important aspect of hemovigilance. Reporting systems assist healthcare providers with documenting adverse transfusion reactions, donor adverse events, and near misses in a systematic way (Schneider & Jackups, 2021). Reporting also aims to enhance the learning process on a systematic basis. This also includes the establishment of major databases to assist with developing national policies. Ethics play a central role in the application of hemovigilance. This relates to confidentiality, the non-doctoring of the transfusion process, equity, and the monitoring of recipients and donors. Donors, their welfare must be prioritized, as must the majority of standards relating to recipient blood component collection and the safety and quality of the transfusion process (Waheed et al., 2020).

SOPs as well as well-structured quality assurance systems are also very important. SOPs secures consistency in blood collection, testing, labeling, compatibility, and transfusion procedures. QA programs including internal audits, external QA, competency assessments and QA programs identify deficiencies and help ensure compliance with national and international standards (Sohrabi et al., 2021). Another important element in transfusion in the collection and analysis of data. Quality, complete and accurate data record is necessary in monitoring quality of data, in determining quality of data, in determining of data and determining the data (Talukdar & Bhattacharya, 2025). Quality data serve as the determining data in monitoring data, in determining of data and evaluating the data. Quality data serve as the determining factor in monitoring data, in determining of data and evaluating the data. Primary goal of the hemovigilance system is to prevent and not simply respond to transfusion safety issues. Integrating surveillance, ethics, quality systems, and data driven decision making fosters a culture of vigilance and accountability. Substantive improvements to the blood transfusion system and enhanced patient safety is the result of this system (Won, 2024).

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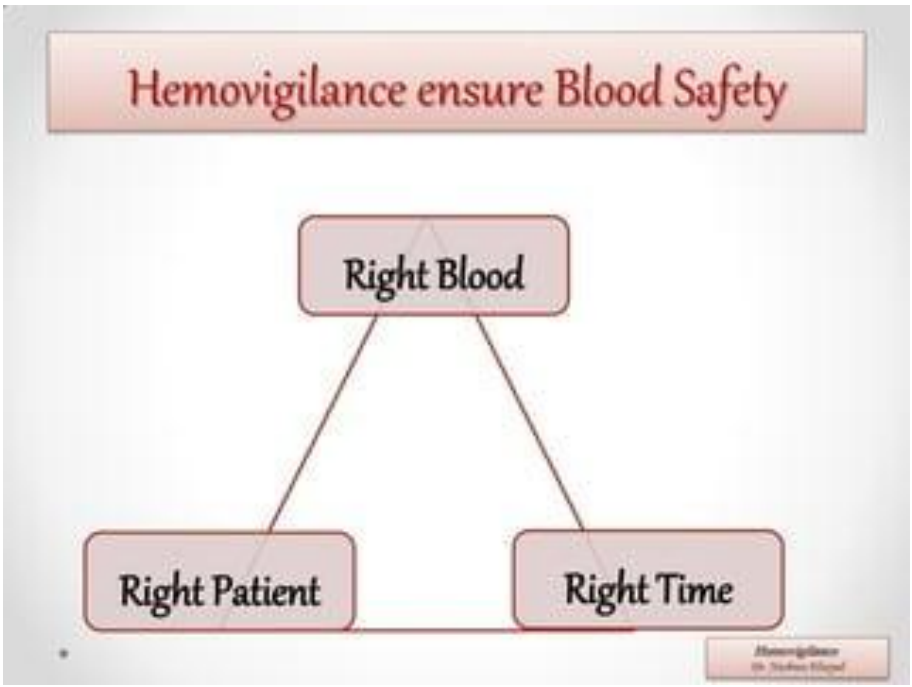

Figure 1: The Blood Transfusion Safety Chain in Hemovigilance

3. Types of Hemovigilance

3.1 Donor Hemovigilance

Unlike other forms of hemovigilance, which analyze the blood donation process, donor hemovigilance attempts to alleviate the health risks and complications experienced by blood donors by monitoring, documenting, and performing analysis at the systemic and clinical levels (Uzun et al., 2024). The goal of hemovigilance is to protect the health of blood donors by finding and noticing the potential health risks and complications, such as vasovagal reactions, hematomas, arterial punctures, nerve injuries, allergic reactions, and citrate toxicity during the apheresis donation process. Blood banks are able to develop corrective action plans and determine the appropriate focus of their action plans (ShojaeiBaghini et al., 2025). The effectiveness of hemovigilance relies on the absence of a punitive culture around reporting. The promotion of preventative actions is required to reduce the likelihood of the risk/problems occurring. The preventative actions include, but are not limited to, reviewing the apheresis donation process donation with the blood donor, ensuring the blood donor is properly hydrated, has the required hemoglobin levels, and has their vital signs assessed, as well as ensuring the blood donor meets

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all the required criteria (Gammon et al., 2021). Experienced phlebotomists employing correct needle positioning along with distraction techniques are the best methods to ensure complications are avoided. After completing the donation the blood donor should be rested with refreshments and given thorough after care instructions to reduce the risk of complications (Simon et al., 2022). Prioritizing the safety and comfort of blood donors is the best way to ensure hemovigilance fosters the safety and longevity of blood donation programs, thereby sustaining the voluntary donor base. The donor is hemovigilance is the clinical and ethical requirement of every transfusion system.

3.2 Recipient Hemovigilance

The systematic process of monitoring, identifying, documenting, and assessing adverse occurrences in patients post-transfusion of blood and blood components is called “recipient hemovigilance”. Its main goal is to safeguard patients by recognizing transfusion complications, and is designed to track complications on an ongoing basis (hemovigilance). Complications can be both immediate or delayed in nature. The adverse reactions can be: transfusion-associated circulatory overload (TACO), caused by rapid transfusion which can result in hypertensive respiratory distress (DUSHIME, 2023). Also, extreme and potentially fatal reactions can occur which consist of transfusion-related acute lung injury (TRALI), non-cardiogenic pulmonary edema of great severity; febrile non-hemolytic transfusion reactions (FNHTRs), which happen frequently as result of the recipient’s antibodies reacting to the donor’s leukocytes or cytokines; allergic which can vary in degree from simple itching, and urticaria to anaphylactic shock (Al-Riyami et al., 2021). Some of these hemolytic transfusion reactions, which can also be acute from ABO incompatibility, are also delayed and pose an extreme threat for the patient as renal failure and shock are also complications which can arise. The effectiveness of recipient hemovigilance is based on monitoring indicated by the presence of the reporting forms and electronic transfusion reaction databases, the signs and symptoms recognition, and the classrooms of bedside monitoring (vigilance) (Lopes et al., 2023). This enables collective data to be utilized for root-cause correction, actions to be taken, and reforms to transfusion procedures. The timely detection and response to transfusion reactions bolster recipient hemovigilance and improve clinical outcomes, improve confidence among patients, and facilitate the creation of safer, more evidence-based practices in transfusion medicine (Mano & Kumar, 2020).

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Table 1: Common Recipient Transfusion Reactions and Their Characteristics

Reaction Type	Onset	Key Features	Severity	Preventive Measures
TACO	Acute	Hypertension, dyspnea, fluid overload	Moderate–Severe	Slow transfusion, monitor volume
TRALI	Acute	Hypoxia, pulmonary infiltrates	Severe	Avoid high-risk plasma donors
FNHTR	Acute	Fever, chills	Mild–Moderate	Leukoreduced components
Allergic Reactions	Acute	Urticaria to anaphylaxis	Mild–Severe	Antihistamine premedication
Hemolytic Reactions	Acute/Delayed	Back pain, hemoglobinuria	Severe/Life-threatening	Strict compatibility testing

3.3 Laboratory/Process Hemovigilance

Most laboratory or process hemovigilance is concerned with tracking and attempting to mitigate or eliminate the risks associated with the technical aspects of blood sampling, testing, processing, and component preparation. Because laboratory procedures are perhaps the most crucial component of transfusion safety, any incurring errors, no matter how inconsequential they might seem, have the potential to cause irreparable harm, clinically speaking (Quadros & Paliwal, 2025). Errors can occur, and have occurred in 3 particular sets of activities. The first of these is the pre-analytical phase which contains such activities as sample collection, labeling, patient identification, and sample transport. Next we have the analytical phase (Schijman et al., 2024). This is where blood grouping and typing, cross-matching, reagents and equipment are all accounting for proper testing and standard operating procedures being taken. Finally we have the post-analytical phase which is where result transcribing, reporting, laboratory and clinical communication are involved (Sibinga, 2024). Process hemovigilance is concerned with integrating such activities to derive the causes of errors in order to implement preventative measures. In laboratory errors, the most common cause of such errors is the lack of Standard Operating

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Procedures in place, and while those may be in place, the post-analytical phase activities are the most common place for human errors to be made (Regassa, 2024). The cumulative effect of all these elements is the ability to radically decrease the number of avoidable transfusion risks as well as the blood system overall (Allard et al., 2021). Having accurate and consistent procedures to follow is what ultimately gives hemovigilance the ability to ensure safety with the transfusion system.

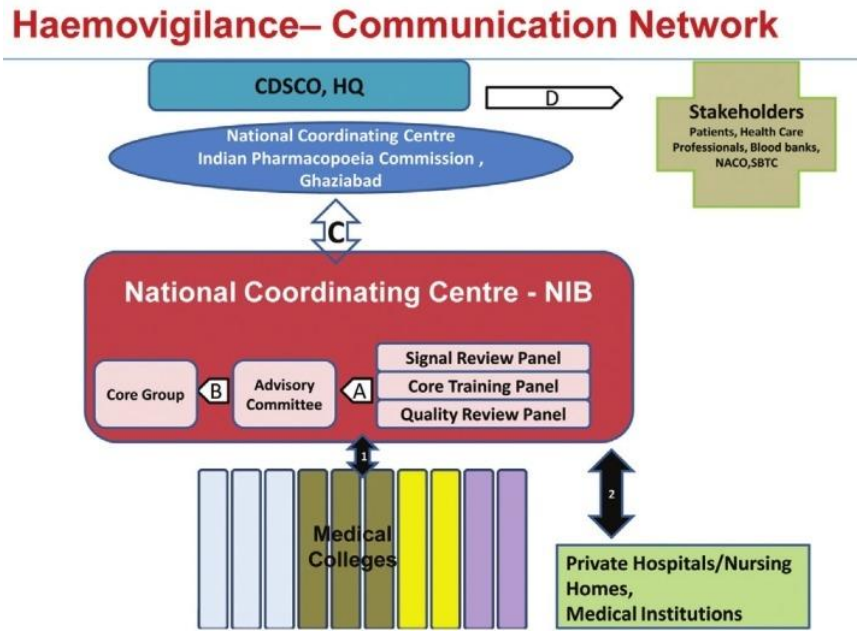

Figure 1: Hemovigilance communication network

3.4 Near-Miss Event Surveillance

Surveillance of near-miss cases encompasses the near-miss detection, documenting, and analysis of occurrences where events during a transfusion process could lead to adverse transfusion reactions, but were successfully intercepted prior to affecting the patient. Examples of these near miss events include, but are not limited to, inadvertent collection of blood products, errors in blood sample labeling or collection, selection of incompatible blood components, administration of incompatible blood units, and discrepancies in documentation that could result in a high volume transfusion error (de Jonge et al., 2022). While these events do not render any clinical harm from transfusion themselves, they do signify oversights, as well as weaknesses and near miss vulnerabilities that remain inactive in the transfusion system. Healthcare systems that possess near-

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miss transfusion surveillance systems acquire the ability to detect and assess prospective patterns and identify specific system steps that correlate with elevated incidence of adverse events, allowing for the preemptive closure of process vulnerabilities and near miss transfusion events and negative transfusion reactions (Sibinga, 2021). Ongoing transfusion medicine quality enhancement is the utilization of near miss transfusion surveillance to alter system weaknesses where SOPs `are insufficient and where verification controls have to be augmented and training of pertinent personnel should be increased (Vuk et al., 2023). Near-miss reporting systems allow for the analysis and enhancement of error reporting systems without the fear of reprisal from the error maker. The application of near miss surveillance systems to hemovigilance systems reduces the transfusion system gap, decreasing the potential for adverse transfusion reactions, and improving system dependability (Bolcato et al., 2020).

Table 2 : Common Near-Miss Events and Preventive Strategies

Near-Miss Event	**Stage of Occurrence**	**Potential Risk**	**Preventive / Corrective Measures**
Wrong patient identification	Pre-transfusion	Incompatible transfusion	Barcode systems, double-check protocols
Sample mislabeling	Pre-analytical	ABO mismatch	Bedside labeling, staff training
Incorrect blood component selection	Storage / Issue	Hemolytic reaction	Electronic cross-match, SOP compliance
Documentation errors	Post-analytical	Traceability failure	Standardized forms, digital records
Delayed reaction reporting	Post-transfusion	Missed adverse trend detection	Awareness programs, non-punitive reporting culture

4. Implementation of Hemovigilance Systems

4.1 Healthcare Facility Level

The first step in a healthcare institution is the establishment of the Hospital Transfusion Committees (HTC). These Committees form the highest level of authority within the institution

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pertaining to transfusion supervision (Falakdami et al., 2024). These Committees are accountable to supervision of transfusion compliance, review and control of transfusion supervision adverse outcomes, as well as documentation of corrective actions and preventive actions (Abdallah et al., 2021). The safety in transfusion is approached from all angles owing to the multidisciplinary composition of the Committees which is made of physicians, nurses, transfusion specialists and quality assurance managers. Capacitated personnel and training are fundamental in the establishment of effective hemovigilance (Hamid et al., 2024). Health care personnel involved in the transfusion chains should have the capacity to recognize transfusion reactions in a timely manner, be made aware of reporting mechanisms and the relevant standard operating procedures, and know the actions to be taken to mitigate the risks of adverse outcomes. Increased participation of the staff in training programs, simulation exercises, refresher courses, and competency evaluations contributes to heightened readiness of the staff and decreases the likelihood of a complication (Rajkumar et al., 2025). The establishment of an effective hemovigilance system is dependent on complete and accurate recording of the transfusion as well as the procedures, outcomes, and adverse events of transfusion. Recording donor information, blood component, and transfusion as well as patient outcomes facilitate accountability and support the establishment of quality assurance processes (McQuilten et al., 2022). Where there is an adverse outcome, structured root cause analysis (RCA) is used to determine underlying system errors or procedural omissions. The analysis of the system errors directs targeted action to curb these system failures, including the development of new standard operating procedures, training of personnel, or the addition of procedures to automate system functions (Yadav et al., 2024). Healthcare facilities can improve transfusion safety outcomes with the implementation of evidence-based transfusion safety initiatives and the generation of transfusion safety outcomes data which can then be used to support the national hemovigilance programs.

4.2 National Level

The effective practice of hemovigilance on a larger scale needs the development of a seamless system of unified reporting that permits regional and national data collection from donor centres, blood banks, and hospital transfusion services (Salamanca-Pachon et al., 2023). This tiered reporting system allows for comprehensive data collection for national authorities, and enables them to trend, evaluate the transfusion-related risk burden, and develop policies for related risk

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mitigation. A national policy initiative that elaborates clear and concrete mechanisms for definitions, timelines for mandatory reporting, event classification, fortified protocols for investigation and corrective actions, is indispensable (Waheed et al., 2020). More developed countries in the practice of hemovigilance are beginning to incorporate the data from hemovigilance into the national public health surveillance system. This system allows for the enhanced monitoring of the safety of biologicals and other medical products (Mammen et al., 2021). The convergence of systems—hemovigilance and pharmacovigilance—has become more important, especially since there are safety issues related to blood components and other therapeutics. The convergence of these systems allows for improved reporting and resource practices, as well as the increased reporting of unified, coordinated national safety practices (Talukdar & Bhattacharya, 2025). The convergence of systems developed in different countries strengthens the safety of transfusion practices and also enhances the development of national guidelines that promote the standardization and accountability of practices in the country.

4.3 Barriers and Challenges

While hemovigilance systems have obvious value, they are still remarkably difficult to integrate. The greatest impediments are fear, unawareness, and/or excessive workloads when it comes to reporting as well as underreporting. Lack of reporting, as well as adverse reaction reporting and near misses, are systemic reporting gaps across numerous health facilities (Shrivastava et al., 2022). When it comes to the variables sustaining the differences between facilities and the cutoffs to enable comparisons, of data, resulting in the inability to perform valid comparisons, there are systemic differences between facilities when it comes to data definitions and data classification (Won, 2024). Data definitional and classification systems gaps leave multiple health facilities unable to perform valid cross national and cross global comparisons when they are able to perform advanced data analytics. The real time reporting of data gaps systems in developing countries due to the reliance on manual systems and fragmented automated systems (Gammon et al., 2024). Weak gaps systems in data reporting due to limited human and financial resources, high staff turnover, and no reporting culture have systemic reporting gaps.

4.4 Solutions and Best Practices

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To mitigate these drawbacks, as a start, standardization, digitalization, and capacity strengthening should form the basis of a multipronged approach. Using standard reporting templates allows for uniform recording of transfusion reactions and also near miss and deviations of processes across all units. Digital hemovigilance—web-based, mobile and automated reporting systems—improves reporting and closes gaps and delays and facilitates reporting and ongoing surveillance. Stand-alone clinical decision support systems integrated with electronic medical records (EMRs) and laboratory information systems (LIS) strengthens clinical decisions by alerting providers of incompatible transfusions, ABO mismatches, or other threats (Simon et al., 2022). Reporting ongoing staff activity is essential. Encouraging participation through supportive commissioning and strengthening a non-punitive culture around reporting is advantageous. These approaches enhance credibility and enable healthcare systems to handle accountability and continuous system improvements. These systems can then respond to the national hemovigilance systems (Ozawa et al., 2023).

Table 3: Key Solutions and Their Expected Impact on Hemovigilance

Solution	Description	Expected Impact
Standardised Reporting Formats	Uniform forms & definitions	Reduced errors, better data comparison
Digital Hemovigilance Systems	Online portals, automated alerts	Faster reporting, real-time monitoring
Decision-Support Software	Integration with LIS/EMR	Early detection of risks
Staff Training Programs	Workshops, competency tests	Improved recognition & reporting
National Policies & SOPs	Harmonized frameworks	Consistency and accountability

5. Future Perspectives

Emerging technologies and global health obligations will reap benefits in transfusion safety and, thus, the future of hemovigilance. One key development to help improve the reliable prediction of transfusion-related risks, adverse reactions, and clinical decision support is in the use of hemovigilance and transfusion-related AI and predictive analytics. AI algorithms could monitor transfusion events in real time and flag instances of high risk. In time, the field is expected

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automation of comprehensive reporting systems of hemovigilance and transfusion-related systems that will totally eliminate manual reporting (DUSHIME, 2023). These systems will improve reporting accuracy, decrease reporting delays, and enhance system interoperability, especially at the hospital level but across networks, including national health systems. Automated and interconnected donor and recipient systems will strengthen health outcome surveillance along with donor retention, and adverse event signal detection to further improve hemovigilance systems and practice (Schäfer et al., 2025). The integration of hemovigilance with other systems to monitor health technologies, particularly biovigilance and pharmacovigilance, is expected to strengthen unified safety surveillance that incorporates blood components. Cross-border collaborations in transfusion safety initiatives will be bolstered by the development of globally standardized definitions, harmonization of reporting systems, and protocols to enable valid comparisons of data from different countries. Discrepancies in healthcare infrastructures are acknowledged (Schijman et al., 2024). Consequently, the emphasis on addressing the limitations on hemovigilance in low-resourced countries, such as building capacity, cheap digital tools, and collaboration across borders, is essential for the worldwide equity in transfusion-associated safety. Improving the future hemovigilance systems, customized transfusion medicine which entails the recipient's immune and genetic composition, the transfusion thresholds, adaptive component therapy, and optimal matched cross-donation, will unarguably reduce the negative consequences associated with transfusion and enhance the outcomes (Booth et al., 2025). These transfusion medicine future prospects advocate for the implementation of the most creative, flexible, and complex systems of hemovigilance on a global scale.

Table 4: Emerging Technologies and their role in Hemovigilance

Technology	Role in Hemovigilance
Artificial Intelligence (AI)	Predicts transfusion reaction and enable early Identification of at -risk patients.
Big Data Analytics	Analyzes transfusion reaction trends to support improved surveillance and data-driven decisions.
EMR–LIS Integration	Automates capture and reporting of transfusion events, reducing underreporting and improving data accuracy.

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Clinical Decision Support Systems (CDSS)	Provides alerts for blood incompatibility, enhancing patient safety and clinical decision-making.

6. Conclusion

Hemovigilance is the most important component of transfusion medicine that allows for measuring the safety, quality, and the overall efficacy of the transfusion practices within any and all healthcare organizations. This paper sets out to cover the aspects of the principles of hemovigilance, the various types of surveillance functions, and the major determinants requirement for the successful execution and functioning of hemovigilance both at the institutional and national levels. This detailed review study demonstrated that in order to eliminate or reduce the risks, as well as enhance the overall safety of the transfusion practices, systematic surveillance of donor reaction, transfusion event, transfusion laboratory, and near miss surveillance is needed. As there are still potential transfusion-related adverse events that go unnoticed and are still clinically important, continuous surveillance of transfusion practices is very important. The impact of adverse events related to transfusion practices is tremendous, but the ultimate challenge is to implement adequate surveillance of transfusion practices ADC. The need for strong, efficient, and comprehensive hemovigilance systems in transfusion medicine is especially pressing. The shift in surveillance systems to preventative and predictive systems is both unprecedented and feasible. Enhanced digital infrastructures, coupled with international protocol harmonization, will optimize hemovigilance and transfusion practices. surveillance of transfusion practices.

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