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STRENGTHENING THE TRANSFUSION CHAIN: A COMPREHENSIVE REVIEW OF HEMOVIGILANCE AND SAFETY PROTOCOLS

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ABSTRACT

Hemovigilance serves as a critical, continuous surveillance framework designed to safeguard the entire transfusion chain, from initial donor selection to post-transfusion recipient follow-up. This review evaluates current hemovigilance frameworks, clinical indications for specific blood components, and the systematic management of adverse events, with a particular focus on regional data provided by the Haemovigilance Programme of India (HvPI). Through a systematic analysis of donor screening protocols, strict storage requirements, and Root Cause Analysis (RCA) methodologies—including the "Five Whys" and fishbone diagrams—this study examines the factors that influence product integrity and patient safety. Clinical data synthesized from reports between 2013 and 2017 indicate that while surveillance systems effectively track thousands of incidents, preventable errors such as ABO incompatibility due to mislabeling and non-immunological hemolysis remain significant challenges. The review concludes that a comprehensive hemovigilance system, supported by proactive safety cultures and standardized digital reporting, is indispensable for minimizing transfusion-related morbidity and maintaining public trust in the healthcare system.

KEYWORDS: Hemovigilance, Blood Transfusion, Patient Safety, Adverse Events, Root Cause Analysis, Quality Assurance.

1. INTRODUCTION

Hemovigilance is defined as a set of surveillance procedures intended to collect and assess information on unexpected effects resulting from the therapeutic use of blood products.[1,4] First developed in France in the 1994, it has evolved into a global public health strategy supported by national regulatory agencies.[2,5] Its primary goal is to identify risks and implement corrective actions to prevent the recurrence of transfusion-related incidents. Beyond mere reporting, it promotes collaboration between blood banks, regulators, and clinicians to ensure the ongoing quality and effectiveness of transfusion medicine.[1,3] Today, it functions as a global public health strategy fostering accountability and continuous quality improvement.

2. CLINICAL INDICATIONS AND PRODUCT INTEGRITY

Modern transfusion medicine relies on component therapy rather than whole blood, which is now largely reserved for massive hemorrhage or severe shock. Safe transfusion practice relies on the appropriate clinical indication for specific blood components.[6,7]

Product	Key indications	Haemovigilance Focus
Red Blood Cells	Anemia (Hb <7-8 g/dL), acute blood loss	Monitoring hemolytic reactions and iron overload
Platelets	Thrombocytopenia, prevention of bleeding	Bacterial contamination risk and GVHD
Plasma	Coagulation deficiencies, liver disease.	Tracking TRALI and allergic responses.
Cryoprecipitate	Fibrinogen deficiency, severe bleeding.	Storage conditions and TRALI risk

3. THE DONOR-TO-RECIPIENT CONTINUUM: ENSURING QUALITY AND SAFETY

3.1. Clinical Protocols for Donor Vigilance

The integrity of the transfusion chain is predicated on a rigorous donor selection process. This begins with stringent screening protocols designed to evaluate medical history, lifestyle indicators, and the presence of transfusion-transmissible infections (TTIs), including Syphilis and Human Immunodeficiency Virus (HIV). Such measures serve as a primary prophylactic barrier against the introduction of pathogens into the blood supply.[8,9]

3.2. Technological Advancements in Blood Collection

Modern transfusion medicine increasingly utilizes apheresis—a sophisticated automated technology that allows for the selective extraction of specific blood components, such as platelets or double red cell units. This method is highly efficient, as it returns the remaining blood constituents to the donor's circulation, thereby reducing donor recovery time and increasing the therapeutic yield per donation.[10,11]

3.3. Monitoring Adverse Donor Events

Donor safety is further reinforced through dedicated vigilance modules, such as those integrated into the Haemovigilance Programme of India (HvPI). These frameworks are essential for tracking and analyzing adverse donor reactions, ranging from common vasovagal episodes to citrate-induced reactions associated with apheresis. By documenting these events, healthcare institutions can implement corrective strategies to enhance donor retention and maintain the ethical standards of the blood transfusion service.[10,12]

4. STORAGE AND TRACEABILITY

The blood components must be stored under strictly controlled environmental conditions, to maintain product integrity and ensure patient safety. Failure to adhere to these standards can lead to bacterial proliferation or the loss of therapeutic efficacy.[19]

- Red Blood Cells (RBCs): These are maintained at a temperature range of 2°C to 6°C. Under these conditions, they typically have a shelf life of up to 42 days, depending on the preservative solution used.
- Platelets: Unlike other components, platelets must be stored at room temperature (20°C to 24°C) to preserve their functional capacity. They require continuous agitation to prevent aggregation and are generally viable for 5 to 7 days.
- Fresh Frozen Plasma (FFP): Plasma is stored in a frozen state at -18°C or lower, which allows it to remain therapeutically active for up to one year.

Traceability Protocols

Traceability is the ability to track every single unit of blood from the initial donor collection through processing and testing, and finally to the end recipient or final disposition. This "vein-to-vein" tracking is essential for:

1. Recall Procedures: Quickly identifying and retrieving units if a donor later tests positive for an infectious disease.
2. Look-back Investigations: Tracing the history of a unit if a recipient develops a transfusion-transmitted infection.
3. Accountability: Reducing the risk of "wrong blood to patient" errors by ensuring a rigorous documentation trail at every hand-off point in the clinical setting.[19,20]

5. CLASSIFICATION OF ADVERSE TRANSFUSION EVENTS

Adverse events are categorized into infectious and non-infectious reactions.[13,14]

- **Acute Immune Reactions:** Occurring within 24 hours, these include Acute Hemolytic Transfusion Reactions (AHTR) often caused by ABO incompatibility, and Febrile Non-Hemolytic Reactions (FNHTR).[9,15]
- **TRALI:** A severe reaction triggered by donor antibodies reacting with recipient white blood cells, remaining a leading cause of transfusion-related death.[16,17]
- **Delayed Reactions:** These include Delayed Hemolytic Transfusion Reactions (DHTR) occurring days or weeks after transfusion.[15,18]

6. ROOT CAUSE ANALYSIS (RCA)

Adverse reactions are categorized into acute (within 24 hours) and delayed events.[4,19] TRALI remains a leading cause of mortality, triggered by donor antibodies reacting with recipient white blood cells.[16,20] Rather than focusing on individual error, RCA utilizes tools like the "Five Whys"(Essential for investigating the 22 cases of ABO incompatibility to find the "root" reason for the labeling error) to identify systemic weaknesses in labeling, storage, or training.[19,21]

7. NATIONAL SAFETY DATA EVALUATION

Analysis of regional safety data from 2013–2017 revealed 8,162 reported adverse reactions across 104 centres.[22] Key findings included 22 cases of ABO incompatibility linked to preventable labeling errors/ sampling error, 84 cases of non-immunological hemolysis attributed to improper storage or warming techniques and 18 cases of transfusion-transmitted infections.[23,24] Despite its infrastructure, the program faces significant hurdles including underreporting, incomplete data entry, and limited awareness among frontline healthcare personnel.

8. CONCLUSION

A comprehensive hemovigilance system is indispensable for safeguarding public trust in healthcare. Achieving zero-harm requires continuous staff education, standardized reporting, and strict adherence to good transfusion practices from the moment of donation to the point of care.

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