Available online on 15 Mar, 2023 at https://ijdra.com/index.php/journal

International Journal of Drug Regulatory Affairs

Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with RAPS & Delhi Pharmaceutical Sciences & Research University

Review Article

Open Access

Haemovigilance Programme of India: A brief Review on Musketeer of safe Blood Transfusion in India

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Abstract

Haemovigilance contributes major importance in regard to safe blood transfusions and ensuring patient safety. With coherently scrutinizing adverse events in the transfusion chain, Haemovigilance aids a safer and effective blood donation and transfusion procedures. These days, adverse event tracking, investigation, and analysis create pertinent data for the quality cycle of blood collection facilities, transfusion laboratories, and transfusion institutions. This review article focuses on the requirement of Haemovigilance, the current status of Haemovigilance in India as well as the Haemovigilance Program of India (HvPI) with respect to blood transfusion.

Keywords: Haemovigilance, Blood Transfusion, Adverse events, Blood transfusion, Haemovigilance Programme of India (HvPI)

Article Info: Received 31 Jan 2023; Review Completed 28 Feb 2023; Accepted 08 Mar 2023

Cite this article as:
Rashmi and Heena. Haemovigilance Programme of India: A brief Review on Musketeer of safe Blood Transfusion in India. Int J Drug Reg Affairs [Internet]. 2023 Mar 15 [cited 2023 Mar 15]; 11(1):24-30. Available from: http://ijdra.com/index.php/journal/article/view/576

DOI: 10.22270/ijdra.v11i1.576
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1. Introduction

In India, there have recently been a number of issues related to inadequacies in transfusion of blood and the delivery of blood products to patients. To lessen and eventually eliminate those unforeseen risks, haemovigilance has been fairly implemented. Haemovigilance can be used to administer and transfuse blood and blood products with increased safety and quality. Stringent guidelines should be put in place for blood products due to the increased risk of microbial contamination in blood from external sources and the fact that blood is collected in blood banks and hospitals without the necessary instrument or depository. In lieu of safer blood transfusions, Haemovigilance Programme of India has been started nationwide.

Planning Background

This review article's primary goal is to provide an overview of the Haemovigilance programme and discuss its significance and what India is doing to achieve so. The regulations pertaining to hemovigilance were introduced in order to establish standards on quality and safety aspects in the procedure for gathering, assessing, storing, as well as distributing human blood and blood-related products, for establishing standards related to specific technical requirements, for making provisions to track and notify severe risk factors, and for offering guidelines with respect to quality management. All these aspects would be briefly reviewed in this article.

2. Blood transfusion

Blood transfusion is a procedure of getting blood or parts of blood through intravenous route for the purpose of replenishing lost blood or lost blood components due to various medical conditions or physical injuries. (1,2)

Blood transfusions have a long history dating back to the 1600s, when British physician William Harvey learned how blood circulates and the first transfusion was undertaken. Richard Lower, an English physician, performed the first successful blood transfusion in1665, keeping a dog alive by giving it blood from other canines. Although many such attempts were done in coming years and human blood transfusions were significantly attempted in the 1900s with many fatalities, the discovery of ABO blood groups by Karl Landsteiner, an Austrian physician in the year 1901 was groundbreaking and brought considerable safety to human blood transfusion. (2,3)

The requirement of safer blood transfusions was realized as early as 1980s-1990s when a lot of hemophilia patients in the USA, UK, Japan, Canada and France contracted HCV and HIV from blood transfusions and factor concentrates, provoking a need of safety measures. This tragic incident in history accentuated the

importance of haemovigilance. The effort on haemovigilance was firstly initiated by France in 1991, with the framework of surveilling institutions by Blood Transfusion Committees followed by the inception of Centre National d`Haemovigilance in 1992. A complete French Haemovigilance System was established by 1994, followed by the Serious Hazards of Transfusion launched by the UK. (4)

2.1 Risks in Blood Transfusions

Any blood transfusion procedure is connected with the following three risk categories:

1. Adverse reactions, like allergic or immuno-suppressing reactions, brought on by the patient interacting with the wrong blood features and components.
2. Manual error by person, such as improper handling, continues to greatly increase the dangers associated with transfusions for patients.
3. Unpreventable adverse reactions like anaphylaxis reactions, which must be taken into account as a viable threat for blood transfusion. (5)

3. Haemovigilance

To monitor any adverse events after blood donation or blood transfusion, there is a need for surveillance in order to achieve safety of donor and more importantly the patient receiving blood. To achieve this, haemovigilance is that stepping stone; an organized scheme to monitor, identify, investigate and analyze adverse reactions and events with respect to blood and blood products. (6) The term 'Haemovigilance' (pronounced he'movigilance in French) had been birthed in France in 1911, analogous to the existing term 'Pharmacovigilance' and is made by amalgamation of Greek word 'haema' meaning blood and a Latin word, 'vigilans' meaning watchful. (4,7-9)

As per the definition by the International Haemovigilance Network (IHN), Haemovigilance is defined as "a set of vigilance procedures that span the entire transfusion process, from the collection of blood and its constituents to the follow-up of recipients, with the goal of gathering data on any unexpected or unfavorable effects of using unstable blood products therapeutically & preventing their frequencies or reappearances.". (8,10)

3.1 Indian Scenario

India, an enormous nation of approximately 1300 million population density, has been reportedly documented to contain 3,840 authorized blood banks as per March, 2022; a considerable lot of them are hospital- grounded. There are total 2,626 operative blood banks, excluding 46, which are army blood banks. These numbers have been stated by the Union Minister of State for Ministry of Health and Family Welfare. The operative 2,626 blood banks make 1,131 National AIDS Control Organization (NACO) assisted blood banks, while the remaining 1,495 makes non-NACO blood banks. A large number of these blood banks i.e., 77% are associated to hospitals, 1% are linked to laboratories, and the remainder 22.1% are autonomous blood banks. (7,11) The NACO's blood safety division helps orchestrate the government's management of the advancement of blood banks in charitable and public healthcare systems. A blood safety action plan had been developed in 2003 following the establishment of the National Blood Policy in 2002. The action plan outlines the growth of a National Haemovigilance Program. However, improvement in blood constituents' formation, expanded blood donation, and training personnel for quality-assured laboratory blood testing are necessary to corroborate the safety of blood & blood components. Through our review article, we made an attempt to accumulate information on the Haemovigilance Programme of India (HvPI), a program devised to increase safety and quality of blood transfusions. (7)

3.2 Steps to Implement Haemovigilance

For implementing a haemovigilance system, a potent & progressive schematic work would be required in order to unveil some of the factors which involve:

- Organizing a formulized blueprint for laying out managerial setup of the institution of the national haemovigilance system.
- To resolute methods to convey any adverse reactions/events to the regulatory bodies.
- Creating methodologies for the purpose of choosing donors who are voluntary and healthy individuals.
- Arranging awareness campaigns and events on the basis of updated problems and obstacles involved in blood transfusion safety.
- Acquiring monetary support in order to carry all the functionalities. (5)

3.3 The Haemovigilance Programme of India

The concept of haemovigilance, which aims to study plus spot out the unfavorable consequences of transfusion to avoid their occurrence and recurrence, was made popular by pharmaco-vigilance. Before haemovigilance became available in India in December 2012, it was a part of the National Blood Policy. (7) A systematic and efficient haemovigilance system was lacking in India. This was primarily caused by an absence in reporting requirement for unfavorable transfusion events. Additionally, the medical staff was seen to underreport. However, numerous institutes as well as centers all over the country have currently published consequential data on adverse transfusion events as a result of the gradual rise in awareness of hemovigilance and blood safety over the past few years. On 10th December 2012, the Indian Pharmacopoeia Commission (IPC) of India and the National Institute of Biologicals (NIB) located at Noida, Uttar Pradesh, started a new initiative dubbed the Haemovigilance Programme of India (HvPI) across the country as part of the Pharmacovigilance Programme of India (PvPI).

(4,8,12) HvPI is a centralized, well-organized program for keeping track of negative effects related to use of the blood and blood products. A designated budgetary allocation of INR 29.36 crore was used to implement the program, which was divided into three phases for the establishment of a haemovigilance programme (initiation phase for the financial year 2012–13, expansion and consolidation phase for the financial year 2013–15, and expansion and maintenance phase for the financial year 2015–17). (13,14) The Communication Centre is the NIB, where the data is gathered, scrutinized, and guidance documents being formulated to report severe blood transfusion adverse effects that includes Transfusion Reaction Reporting Form. (14)

To gather and examine data on hemovigilance across India, a software called Haemo-Vigil was devised. The version 1.0 of the transfusion reaction reporting form (TRRF) had been used to gather hemovigilance data between 2013 and April 2016. A major proposition in the initial report to enhance the level of quality of hemovigilance data led to the launch of the latest version of the Haemo- Vigil software in May 2016 i.e., the TRRF version 2.0. (15,16)

For the purpose of coordinating and putting HvPI into practice, five expert subgroups are responsible: The National Advisory Committee, Core Committee, Quality Panel Signal Review Panel, and Training Panel. (16,17)

The joint recommendation of IPC-NIB has laid out an organogram for the functions of the Haemovigilance programme. In the organizations like medical colleges, hospitals, nursing homes, etc., the technical associate receives information from constitute part of the organogram (Fig.1), i.e., Signal Review Panel, Quality Panel, and Training Panel. (17,18)

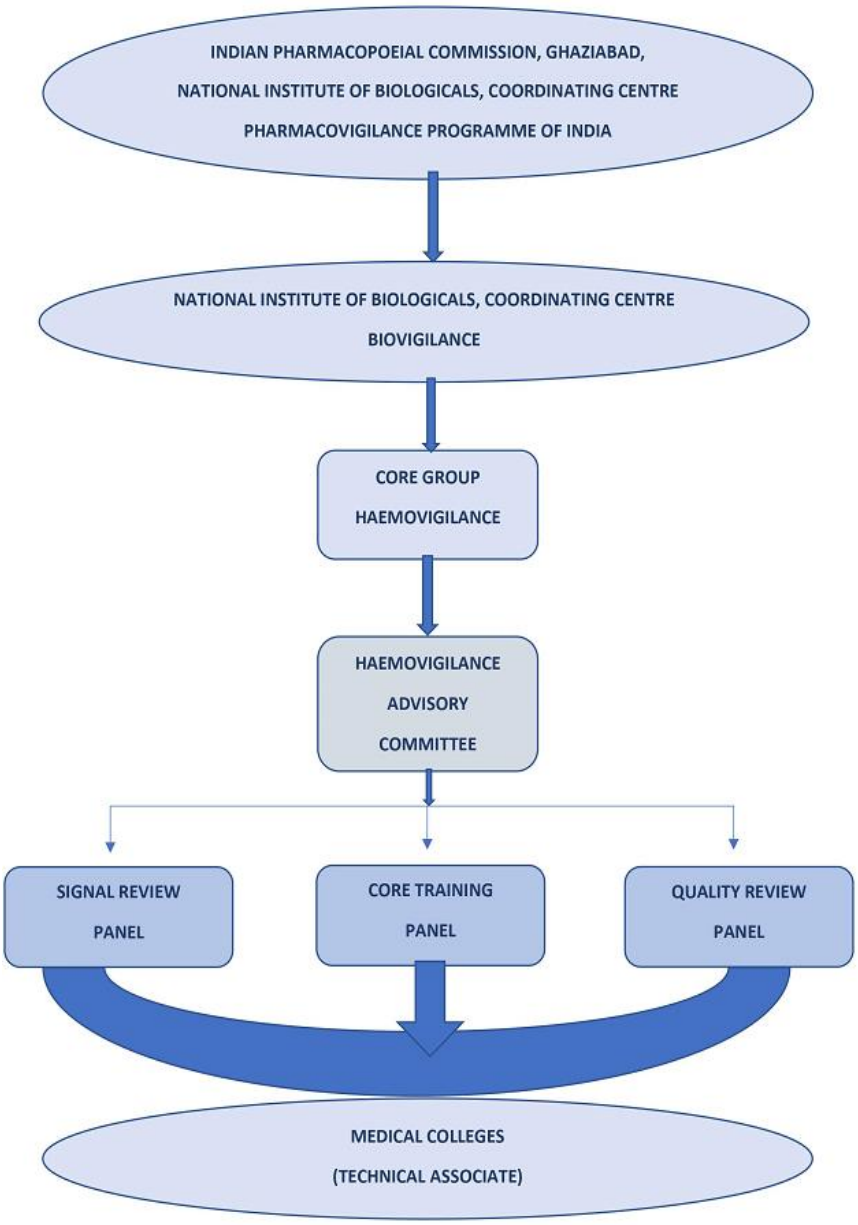

Figure 1. Haemovigilance Organogram (6,18)

3.4 Goals of the Haemovigilance Programme of India

This programme's major goal aims to surveil adverse reactions and occurrences linked to the delivery of blood products and blood transfusions, recognise shifts, and suggest premium implementations and arbitrations needed for enhancing patient care and safety. HvPI's overall target was to join the International Hemovigilance Network (IHN), and in December 2014, this was achieved. India is one among the 33 nations that

are currently members of IHN, which offers a world-wide colloquium to communicate best conventions, as well as comparing and standardizing hemovigilance data. (13,14)

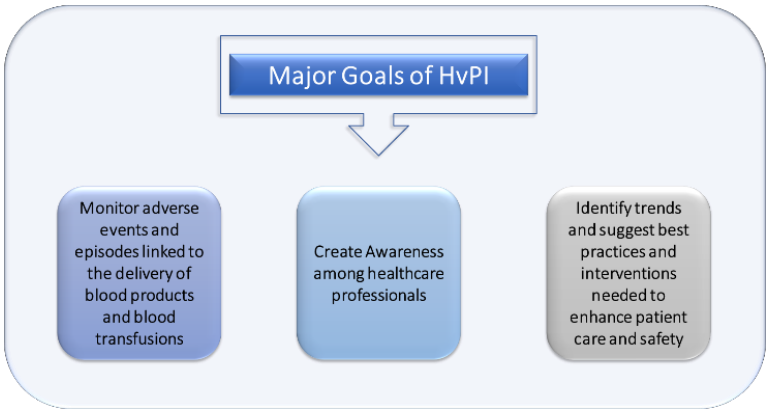

Figure 2. Goals of Haemovigilance of Programme of India (13)

3.5 Objectives of Reporting ADRs related to Transfusion under HvPI

As per the Guidance Documents by NIB for reporting ADRs related to blood transfusion by centres under HvPI, the objectives of reporting are:

- A nationwide reporting system that can be used to assess how far public policy on patient safety has advanced.
- Reporting can pinpoint dangers and hazards as well as reveal where the system is broken.
- By doing this, the risk of future patients being injured can be decreased.
- Timely reporting helps with efficient risk management (6)

Haemovigilance Unit	Role & Responsibility
CDSCO- DCGI	• Develop safety-related regulatory judgements • Notifying stakeholders of decisions on the transfusion safety of blood and blood products • Ensuring 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	• Hand-in recommendations of HV – National Advisory Committee to CDSCO
Reporting Units	• Create transfusion reaction reports • Causality assessment • Submission of a report through HV software

Figure 3. Role & Responsibility of HvPI- CDSCO units (12)

3.6 Documenting and Reporting of Serious ADRs/ Events

Based on the symptomatology, aetiology, and/or timing of the reaction transfusion reactions are further divided in several ways. Based on duration, it is subdivided as acute (< 24 hours after transfusion) and delayed (> 24 hours after transfusion) reactions. As per pathogenetic factors, adverse reactions can be further divided as infectious and non-infectious adverse reactions. Major non-infectious acute reactions include Febrile Non-Haemolytic Transfusion Reactions (FNHTR), Acute Haemolytic Transfusion Reactions (AHTR), allergic reactions including Transfusion Associated Acute Lung Injury (TRALI), anaphylactic reactions, Transfusion Associated Circulatory Overload (TACO), hyperkalaemia and hypotensive reactions. Non-infectious delayed transfusion reactions are Delayed Serological Transfusion Reactions (DSTR),

Delayed Haemolytic Transfusion Reactions (DHTR), Post-Transfusion Purpura (PTP), Transfusion-Associated Graft Versus Host Disease (TAGVHD) and haemosiderosis. (19,20)

In context to documenting and reporting, Transfusion Reaction Reporting Form (TRRF), a reporting format developed by HvPI for the documentation and reporting of transfusion reactions, includes information on the patient, the transfusion reaction particulars, blood parts or blood product particulars, a list of pertinent & important investigations, the nature of the adverse reaction, and an assessment of accreditation has been provided. This TRRF is openly accessible on the website of HvPI. (20) All Indian medical institutions have been urged to sign up for HvPI and submit transfusion-related adverse events using the Haemo-Vigil software after completing the transfusion reaction reporting form. The information gathered via this software would be arranged and investigated to find out the shifts and suggest suitable practices and interventions requisite to optimize patient care and safety. (9)

The guidance documents of IPC-NIB describe a flow chart format (Figure.4) for informing severe adverse reactions to blood transfusions as well as the duties and obligations of the medical and nursing staff on the ward plus the staff in the department of transfusion medicine.

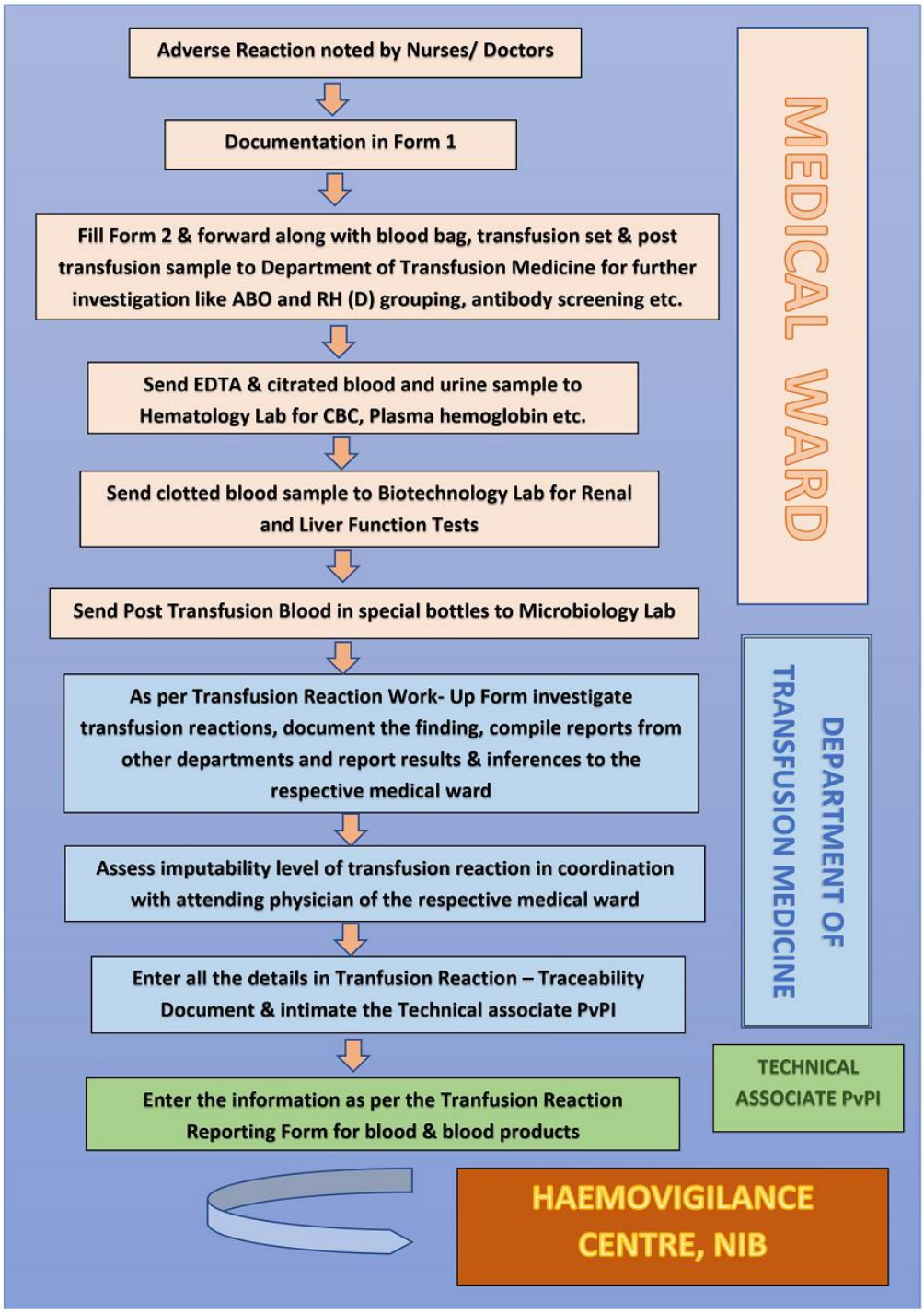

Figure 4. Reporting severe adverse reactions in blood transfusion (Flowchart) (6)

Data regarding adverse transfusion reactions & events that is being retrieved by the "Haemo-Vigil" software is then communicated to the HvPI-NCC, NIB by the transfusion medicine department, blood bank, hospitals, and medical colleges. In order to develop the standard operating procedures, guidance manuals, and communicate suggestions to IPC, HvPI-NCC examines the accuracy and completeness of the data. IPC ultimately sends the Drug Controller General of India (DCGI)-CDSCO body the recommendations of the hemovigilance advisory group. The DCGI-CDSCO develops regulatory decisions pertaining to blood & blood product transfusion safety as well as notifies stakeholders. (12,20)

3.7 Advantages of Haemovigilance in Safe Blood Transfusion

For the blood donor:

- Increased donor safety by lowering blood transfusion-related problems
- Encourages deliberate blood donation.

Blood transfusion service:

- Any relevant deficits could be found right away.
- By presenting safety-related facts, the development process will be accelerated.

Healthcare facility and blood bank affiliated with hospitals:

- Mistakes will be minimized and reported by identifying system problems.
- Accurate & ongoing reporting of negative incidents.
- To assure safety, development plans will be chosen.

By precisely predicting present issues that the patient may experience, hemovigilance systems can increase patient safety as:

- Outlining the primary causes of problems and possible solutions.

Making proposals for improved policy improvements that are supported by evidence (5,20)

Recommendations

- ❖ Updating guidelines and regulations in parallel to World Health Organization.
- ❖ Attending Conferences, Seminars and Webinars organized by IHN and strengthening HvPI objectives alongside IHN.
- ❖ Mandating Healthcare facilities maintaining regular haemovigilance at premises.
- ❖ Safeguarding and updating regulations of blood donation facilities and blood banks.
- ❖ Ensuring safe carry out of Blood Transfusion Process.

4. Conclusion

The Hemovigilance System is a delicate & successful programme that considers risk variables when monitoring, looking into, and evaluating blood transfusions and blood products for assuring the safety & purity of blood. This result in the development of safety & quality components throughout the entire blood transfusion chain, from donors to recipients, by combining the necessary criteria with pertinent evidence-based policies, enhancing standards, offering corrective and preventive actions, and adhering to guidelines. Despite the technical difficulty, Haemovigilance gives patients the assurance they need to feel secure during the blood transfusion procedure.

List of Abbreviations

NIB: National Institute of Biologics

WHO: World Health Organization

CDSCO: Central Drug Standard Control Organization

IHN: International Haemovigilance Network

DCGI: Drug Controller General of India

ADR: Adverse Drug Reaction

IPC: Indian Pharmacopeia Commission

NIC: National Informatics Center

TRRF: Transfusion Reaction Reporting Form

HvPI: Haemovigilance Programme of India

PvPI: Pharmacovigilance Programme of India

AHTR: Acute Haemolytic Transfusion Reactions

TRALI: Transfusion Associated Acute Lung Injury

TACO: Transfusion Associated Circulatory Overload

DHTR: Delayed Haemolytic Transfusion Reactions

FNHTR: Febrile Non-Haemolytic Transfusion Reactions

DSTR: Delayed Serological Transfusion Reactions

PTP: Post-Transfusion Purpura

TAGVHD: Transfusion-Associated Graft Versus Host Disease

Acknowledgements

We would like to express our sincere gratitude to IJDRA Journal for publishing our work.

Financial Disclosure statement: The author received no specific funding for this work.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article

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