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HAEMOVIGILANCE: STEPPING STONE TOWARDS BLOOD SAFETY- INDIAN SCENARIO

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ABSTRACT: Blood transfusion is an important part of various treatment protocols. Blood should be transfused with certain precautions like drug because blood and its constituents have the propensity to cause effects like introduction of donor antigens within the recipient, transfusion reactions or exposure to numerous transfusion-transmitted diseases. Thereby, it is important for the clinicians to remember those potential risks to the recipient of blood and blood components as well as donors. Haemovigilance system includes monitoring, identification, reporting, investigation, and analysis of adverse reactions associated with transfusion. The data gained from the investigation and analysis facilitates corrective and preventive action to be taken to attenuate the potential risks related to safety and quality of blood donation and transfusion for donors and patients. Forever the developed countries have taken the lead within the haemovigilance. However, developing Asian countries like India lacks a well-established system for haemovigilance program. In this review we have compiled the various haemovigilance and blood safety studies conducted in India to know the current update of haemovigilance program in our country.

INTRODUCTION: The blood is essential for transporting nutrients, oxygen, and more other substances throughout the body. Blood transfusion is an essential component of health care system, and it saves millions of lives each year, as it is a key life-saving intervention. Mostly the medical world is in the need of blood for surgery, trauma, severe anemia or complications of pregnancy [1]. Blood is classified as a 'drug' according to the Drugs and Cosmetics Act, 1940 and blood banking services and Ministry of Health and Family Welfare, Government of India are regulated by the rules therein, amended once in a while [2, 3].

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Blood transfusion is a process with human participation, so the human error is inevitable throughout the process [4, 5]. Nearly one-third of transfusions resulted in adverse reactions and death, before the discovery of antigens in blood groups by Karl Landsteiner 1901.[6] After that blood transfusion therapy in humans changed from a dangerous proposition to a comparatively safe procedure. The new laboratory testing modalities have lowered the occurrence of infectious and non-infectious transfusion reactions to minimum. Phenomena's like alloimmunization, ABO incompatibility, bacterial contamination, adverse effects/events due to human errors remains as a matter of concern [7].

India is a huge nation with a population of nearly 130 crores. There are 2760 authorized blood banks; a large portion of these are hospital-based [8]. The assessment exercise identified 2,626 functional blood banks across the country excluding 46 military blood banks. Of the 2,626 blood banks,

1,131(43%) were supported by National AIDS Control Organization (NACO), Ministry of Health and Family Welfare, Government of India and the remaining 57%(1,495) were Non-NACO blood banks. The majority of the blood banks, 77% (1919) were attached to hospitals, 1% (23) was attached to laboratories, and the remaining 22.1% (551) were standalone blood banks [9]. The modernization of blood banks in charitable and public healthcare systems was managed by the government through the blood safety division of National AIDS Control Organization. The National Blood Policy was figured in 2002 with an action plan on blood safety in 2003.

The action plan expressed the advancement of a National Program of Haemovigilance. However, the safety of blood and blood components needs considerations in upgrading blood component preparations, enhancing voluntary blood donation, training manpower and quality assured laboratory blood testing [10]. In this review, we attempted to gather most of the studies led in India about haemovigilance and blood safety to illustrate HvPI, which will increase safety and quality of blood transfusions.

Haemovigilance: Blood transfusion can be lifesaving intervention and which can be fatal sometimes so that transfusion of blood and blood products should be used cautiously. Even in the medical literatures regarding the use of blood and blood products, always there has been a concern and debate [11]. The evidence of the pros and cons of blood and blood products transfusion is limited throughout the world [12]. The awareness about types of transfusion reactions **Table 1** will help in taking adequate measures to prevent and also in their early identification and management. The lack of awareness about haemovigilance and proper documentation of transfusion reactions in our country made difficulty in determining the incidence of transfusion reactions [13].

Hemovigilance is a moderately on-going expansion to the idea of blood safety. It is a surveillance procedure covering the entire blood transfusion (BT) chain from accumulation of blood and components to the recipients. One of the fundamental points is to recognize inclines in adverse events and reactions to blood transfusions are with the goal that awareness in regards to transfusion effects can be expanded and improved blood transfusion services. The milestone haemovigilance plan of the United Kingdom-Serious Hazards of Transfusion (SHOT) has incited numerous noteworthy changes in BT practices more than 17 years of its reality [14]. A haemovigilance program was initiated in India in the year of 2012 and this program is still in its early stages [15]. The main purpose of haemovigilance is to improve reporting of transfusion events and blood transfusion practices. It is defined as the collection and analysis of information on the difficulties of blood transfusion practice [16].

TABLE 1: SIGNS AND SYMPTOMS OF TRANSFUSION REACTIONS

Possible Transfusion Reactions	Signs & Symptoms
Acute Haemolytic Transfusion Reactions (AcHTR)	Hemoglobinuria, rigors fever, jaundice, lumbar pain, hypotension, pallor, acute renal failure
Febrile Non-Hemolytic Transfusion Reactions (FNHTR)	Chills, rigors, fever, hypotension, vomiting, myalgia, cough
Allergic reactions	Rash, pruritus, periorbital edema, wheals, cough, chills, vomiting
Anaphylactic Reactions/Anaphylactoid Reactions	Rash, hypotension, respiratory distress, flushes, fever, rigors
Bacterial Sepsis	Fever, rigors, hypotension, oliguria
Hypervolemia	Acute respiratory distress, cyanosis, orthopnoea, frothy cough, gallop sound on auscultation
Hypocalcemia	Bradycardia and twitching, cardiac arrest, hypocalcemia
Transfusion Related Acute Lung Injury(TRALI)	Respiratory distress, Cyanosis, chest X-ray-bilateral pulmonary edema
Transfusion Associated Circulatory Overload(TACO)	Cyanosis, orthopnoea, hypertension, headache, tachycardia, acute respiratory distress
Delayed Hemolytic Transfusion Reaction (DHTR)	Jaundice, unconjugated, hyperbilirubinemia
Transfusion-associated graft versus host disease (TAGVHD)	Erythematous rash, Loose stools, unconjugated, hyperbilirubinemia
Mixed reactions	Allergic reactions (Rash, pruritus, *etc.* Jaundice with hyperbilirubinemia)
Unclassified	Urticaria, rash, wheels

Clinical case reporting of transfusion reactions and workup of adverse effects related to transfusion will determine the risks of allogeneic transfusion. The limitations in case reporting should be overcome by the monitoring of adverse effects that could have been caused by transfusion. Mild and non- specific reactions are less likely to be reported especially when it occurs after a long time of transfusion [7]. Underreporting can be improved by haemovigilance system. Reporting of transfusion reactions, adequate and skilled manpower, and continuous medical education to all health care professionals involved in transfusion chain, proper functioning of hospital transfusion committee will definitely help in reinforcing haemovigilance system.

Clinical errors caused adverse reactions lies a concern because it may question the efficacy, knowledge, and service of skilled professionals as well as the ability of administration. The head of transfusion service should be investigator and also vigilant to know the root cause of transfusion reactions and which will help in rectifying it. The whole health care professionals involved in the transfusion chain should understand the importance of reporting all transfusion events whether it is a major or minor, to the transfusion medicine service. This can be achieved by establishing a haemovigilance system which can promote the goal of safe transfusion. Promoting the safety and quality of blood transfusion is the main goal of haemovigilance. To reduce the incidence of transfusion reactions, identification of these reactions as well as appropriate steps to avoid them will make the blood transfusion service safe [13].

History of Haemovigilance: "Hemovigilance" is derived from a Greek word "haema" which implies blood and the Latin word "vigilans" which implies watchful [17]. Hemovigilance has characterized by Faber may be "a set of surveillance procedures covering the whole transfusion chain, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent the occurrence or recurrence of such incidents [18, 19].

Haemovigilance was introduced as mandatory surveillance programme in France in 1993 while the very first voluntary reporting system was introduced in 1996. The developed countries have taken a lead in the Haemovigilance[18]; however developing Asian countries like India, initiated a haemovigilance program. The main objectives of this program are to monitor adverse reactions associated with blood and component transfusions and to create awareness among health care professionals [15, 16].

Haemovigilance Program of India: Pharmaco-vigilance made the emergence of haemovigilance concept, which is aimed to analyze and detect the untoward effects of transfusion to prevent their occurrence and recurrence. In India, before the implementation of haemovigilance in December 2012, it was included in the National Blood Policy[7].

Hemovigilance Program of India (HvPI) was introduced at the national level as a basic segment of the Pharmacovigilance Program of India (PvPI) in collaboration with National Institute of Biologicals (NIB) with an initial road map for 5 years. The haemovigilance program is utilitarian through a core group, and an advisory committee, which facilitates the exercises of haemovigilance between medical colleges and the National Coordinating Center (NCC) and furthermore gives an expert opinion for the examination of the data created. The advisory board additionally gives experiences supportive in connecting Hemo-vigilance Program of India with the IHN (International Haemovigilance Network). The software "Hemovigil" and the Transfusion Reaction Reporting Form (TRRF) for reporting were likewise composed under the direction of the advisory committee. 'Hemovigil' programming was uplinked on NIB site and can be surveyed [15].

As of now, 368 centers have been enlisted in Haemovigilance program [20]. The information from the Medical Colleges (Blood Bank or Department of Transfusion Medicine) in the event of any untoward response identified with blood transfusion or blood component is gathered. Data is filled in the TRRF and sent to the National Coordinating Center at National Institute of Biologicals through 'Hemovigil' software. The recommendations based on the gathered information will be sent to the National Coordinating Center at Indian Pharmacopoeia

Commission (IPC) for further transmission to Drugs Controller General (India), and Central Drugs Standard Control Organization (CDSCO). The regulatory guidelines for safety will be modified and formulated once in a while by CDSCO mainly based on the contributions from TRRF, which will be executed by blood banks and health care professionals to assist patients [21]. The transfer of data has been represented in **Fig. 1**. This information will be used to construct guidelines and recommendations that will be circulated to various stakeholders.

An initial literature search for this review was done through Pubmed, Pubmed Central, Google Scholar and Science direct databases using keywords 'Haemovigilance', 'Blood safety' and 'India', additional hand search and cross-reference were used to find out number of studies conducted in India. We found 21 studies (Nine-Retrospective, Ten- Prospective, One- Prospective and Retrospective, One- Cross-sectional) conducted in Indian Scenario to describe the present situation of haemovigilance and blood safety in India.

We categorized these studies into three, comprising studies investigating haemovigilance and transfusion reactions **Table 2**, studies with the aim of blood safety **Table 3** and studies for the improvement of transfusion practice **Table 4**.

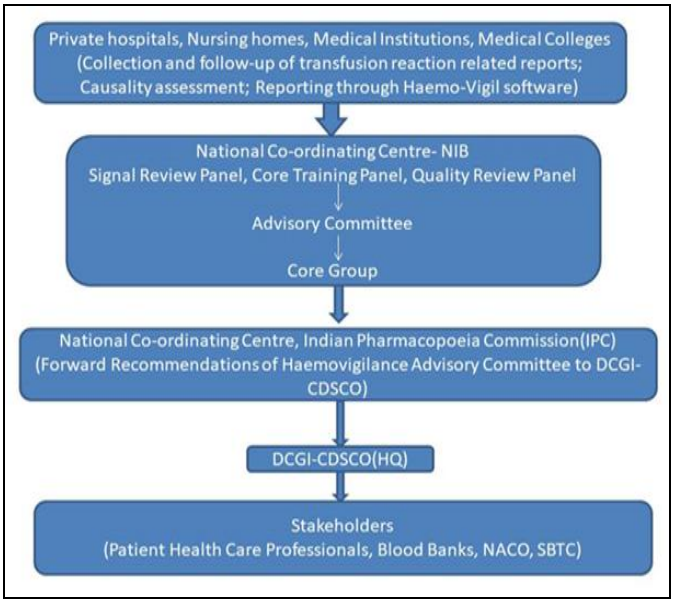

FIG. 1: FLOW CHART OF TRANSFER OF INFORMATION UNDER HAEMOVIGILANCE PROGRAM OF INDIA

TABLE 2A: SUMMARY OF INDIAN STUDIES INVESTIGATING ON TRANSFUSION REACTIONS AND HAEMOVIGILANCE

Author	Study type	Duration of study	Patients in the study/ units of blood	Type of transfusion reactions
Pahuja S *et al.*, 2017 (48)	Retrospective	9 years	1,60,973 blood/blood components	FNHTR, Allergic Reactions Anaphylactic/Anaphylactoid reactions TRALI, TACO, AcHTR
Vasudev R *et al*., 2016 (43)	Prospective	1 year	45812 blood/blood components	AcHTR, FNHTR, Allergic reactions, anaphylactic/anaphylactoid reactions, hypervolemia, hypocalcemia, TRALI, DHTR, Unclassified reactions
Sharma DK *et al*., 2015 (49)	Retrospective	20 months	3455 units of blood/blood components	anaphylactic reactions, FNHTR, allergic reactions, pulmonary embolism
Kumar R *et al*., 2014 (50)	Retrospective	2 years	21,971 blood components	FNHTR, allergic, hemolytic reactions, Transfusion-related sepsis, TRALI, Non-specific reactions
Bhattacharya P *et al*., 2014 (7)	Prospective	1 year	56,503 units of blood & blood component to 29,720 patients	AcHTR, FNHTR, allergic reactions, anaphylactoid reactions, bacterial sepsis, hypervolemia, hypocalcemia, TRALI, DHTR,N TAGVHD, mixed reactions, unclassified reactions
Kumar P *et al.*, 2013 (13)	Retrospective	4 years & 4 months	3,80,658 units of blood and blood components	FNHTR, allergic reactions, anaphylactoid reactions, acute non-immune hemolytic, transfusion reactions, circulatory overload, TRALI
Venkata-chalapathy TS, 2012 (51)	Prospective	6 months	1453 units of blood/blood component for 696 patients	FNHTR allergic, anaphylactic

TABLE 2B: SUMMARY OF INDIAN STUDIES INVESTIGATING ON TRANSFUSION REACTIONS AND HAEMOVIGILANCE

No of transfusion reactions	Product transfused	Departments reporting transfusion reactions	Purpose of study
314	WB, RCC, Buffy coat depleted, RBC, Leukodepleted RBC, PC/PRP	Not mentioned	To analyze the data on adverse events related to blood transfusion
84	WB, PRBC, FFP, Platelets	Medical Oncology, Medicine Surgery Gynecology& Obstetrics	To evaluate the various transfusion reactions occurring, as a pilot institutional effort towards Haemovigilance program
32	WB, PRBC, FFP, Platelet, Cryoprecipitate, CPP	Dialysis, Medicine, Surgery, OBG	To analyze the frequency and nature of transfusion reaction reported to the blood bank of a remote northeast Indian teaching hospital.
225	PRBC, FFP, Platelet concentrate	Emergency ICU, Medical ICU, Surgical ICU, Cardiac ICU, Paediatric ICU	To analyze the incidence and spectrum of transfusion reactions occurring in critically ill patients
105	WB, PRBC, Platelet concentrate, FFP, Cryoprecipitate	Surgical, Oncology, NICU, OBG, Emergency	Detect and analyze transfusion related adverse events.
196 (0.05%)	Leucodepleted PRBC, RDP, FFP, SDP, Cryoprecipitate	Surgical, Obstetric, Neonatal, Hemato-oncological, Medical, Emergency	To determine the frequency and type of transfusion reactions
48	WB, FFP, Packed Cells, Platelet Concentrate, Fresh Whole blood	Medicine, Surgery, OBG, Orthopedics, NICU/Pediatrics, Psychiatry	To define the problems associated with blood transfusion in the light of its risks and benefits as a drug

FNHTR- Febrile non-hemolytic Transfusion Reactions, WB- Whole Blood, PRBC- Packed Red blood Cells, FFP- Fresh Frozen Plasma, CPP- Cryoprecipitate Poor Plasma, RDP- Random Donor Platelet, CRYO- Cryoprecipitate, SDP- Single Donor Platelet, AcHTR- Acute Hemolytic Transfusion Reactions, TRALI- Transfusion Related Acute Lung Injury, DHTR- Delayed Hemolytic Transfusion Reactions, TAGVHD- Transfusion Associated Graft Versus Host Disease, NICU- Neonatal Intensive Care Unit, OBG- Obstetrics and Gynecology, TACO- Transfusion Associated Circulatory Overload, RCC- Red Cell Concentrate, PC/PRP- Platelet Concentrate/Platelet Rich Plasma, RBC- Red Blood Cells.

TABLE 3: SUMMARY OF STUDIES WITH THE AIM OF BLOOD SAFETY

Author	Year	Study type	Duration of study	Purpose of the study	Findings of the study
Makroo RN *et al.*, (5)	2017	Retrospective	6 years	To assess the role of delta checks in improving transfusion practice	Delta checks proved to be an effective tool for detecting blood group errors and prevention of accidental mismatched blood transfusions
Tiwari AK *et al.*, (52)	2017	Prospective Longitudinal	3 months	To study the safety and effectiveness of IS(Immediate Spin) crossmatch in comparison to conventional AHG(Anti-Human Globulin) in antibody screening negative patients.	In AS negative patients, IS crossmatch is as safe as conventional AHG crossmatch
Naidu NK *et al.*, (53)	2016	Retrospective	5 years	To study the prudence of universal NAT testing in India.	Strict implementation of the quality management system, development of well-defined testing strategies and strong haemovigilance system could take as a step in right direction
Gupta A *et al.*, (54)	2016	Retrospective	2 years	To study the usefulness of monitoring of the National Accreditation Board for	Monitoring of NABH core indicators results in the enhancement of quality and

				hospital and healthcare provides core indicators in blood transfusion and in the maintenance of haemovigilance	safety in blood transfusion services
Gajjar M *et al.,* (55)	2016	Prospective	2 years	To evaluate the frequency of Rh & Kell phenotype of voluntary donors in Gujarat State	Phenotype and probable genotype showed wide range of variations in different races and religion. Reliable population-based frequency data of Rh & Kell antigens has vital role in population genetic study in resolving medico-legal issues and in transfusion practice
Sidhu M *et al.,* (56)	2016	Prospective	1 year	To analyze the errors that threaten patients' transfusion safety and serious adverse events that occurred in patients.	Sample labeling, Inappropriate request, and sample were the high-risk errors
Kumar R *et al.,* (31)	2015	Prospective	1 year	To assess the impact of the introduction of ID-NAT for HIV-1, HCV and HBV and its role in further improving blood safety	ID-NAT testing can tremendously improve the efficacy of screening for protecting blood recipient from TTIs

TABLE 4: SUMMARY OF STUDIES FOR THE IMPROVEMENT OF TRANSFUSION PRACTICE

Author	Year	Study type	Duration of study	Purpose of study	Findings
Date AP *et al.,* (57)	2016	Cross-sectional Questionnaire-based study	6 months	To know the knowledge, attitude, and practice (KAP) of haemovigilance among doctors	Awareness of Haemovigilance among doctors and training on reporting transfusion reactions would likely improve reporting and help to strengthen the blood transfusion system
Kulkarni RG *et al.,* (58)	2016	Prospective	1 year & 5 months	To find out the prevalence of Gilberts syndrome in healthy blood donors & review the literature about the feasibility of utilizing blood components from Gilbert syndrome (GS) donors	Blood components can be used by donors suffering from GS. There should be introspection and proper guidelines about the use and discarding of blood components in donors with GS
Mittal M *et al.,* (59)	2016	Retrospective	6 months	To analyze the utilization of different blood components	Regular audits, Continuous medical educational programs are must which will help to decrease irrational use of blood
Mandal R *et al.,* (27)	2015	Retrospective	3 years	To assess the prevalence of TTI s within blood donors at a sub –Himalayan rural tertiary care institution.	Immaculate eligibility criteria should be adopted while selecting blood donors to minimize TTIs
Kumar A *et al.,* (60)	2014	Prospective	19 months	To find out the reasons for discarding blood bags which could be utilized judiciously with minimal wasting	A properly conducted donor interview, notification of permanently deferred donors, and properly implemented blood transfusion policies will help in discarding less number of blood bags
Ramani KV *et al.,* (61)	2009	Retrospective and Prospective	-	To understand the existing systems of blood transfusion services in India, focusing on Maharashtra and Gujarat states	There are many managerial challenges in blood transfusion service which should be strengthened, planned and monitored
Makroo RN *et al.,* (62)	2007	Prospective	4 months	To define the appropriateness of use of FFP in the light of its risks and benefits	Regular audits, appropriate training of medical staff, conducting regular CMEs is the measures being incorporated to rationalize the use of blood components

National Blood Donor Vigilance Programme: The increase in voluntary non-remunerated donations in South-East Asia was mainly contributed by India, which reported collecting 8.5 million donations from voluntary non- remunerated blood donors, an 85% increase from the reported 4.6 million in 2008 according to World Health Organization (WHO), Global Database on Blood Safety (GDBS) 2016. [22] Furthermore, low and middle-income countries still lack enough voluntary non- remunerated blood donors, with low blood donation rates accompanied by high rates of discard. Ten countries declare for 65% of blood collections worldwide, and India is in the third position following United States and China. WHO targets 100% of voluntary donations by the year 2010, and India is expected to head on this target [23].

Since 1930 transfusion medicine has been the cornerstone of several medico-surgical therapies [24]. There are voluntary/unpaid, family/replacement and paid donors [25]. Voluntary donor donates blood without any remuneration whereas the replacement donor is requested to donate by the patient or his/her associates [26, 27]. In India voluntary donors constitute only 55% of all blood donors while in most developed countries, most donors are repeat voluntary donors. It has found that the major population of Indian voluntary donors being first time voluntary donors may not be safer than replacement donors [28].

The recipient's transfusion reactions/events were under the Haemovigilance Program of India [29]. According to the guidelines of the HvPI, vigilance in donors, *i.e*., revealing adverse reactions related to a donation of blood was intended to be started by 2017. Although with the accomplishment of the HvPI it was chosen to undertake donor vigilance program by this year itself. Consequently, a National Blood Donor Vigilance Program (NBDVP) was initiated on June 14, 2015 on the World Blood Donor Day at Science City Kolkata, West Bengal, India [30].

Transfusion Transmissible Infections (TTI's): In an era of modern health facilities, blood transfusion is a lifesaving intervention. Healthy donor is the mainstay of transfusion medicine. Therefore, provision for the criterion in recruitment and deferral of blood donors, especially spotlighting Transfusion Transmissible Infections (TTIs) may improve transfusion practice [27]. One of the biggest threats to blood transfusion safety is Transfusion Transmitted infections (TTIs). To reduce this risk of TTIs, many countries have been implemented Nucleic Acid Testing (NAT) in blood donor screening [31]. In India with a population of more than 1.3 billion, blood safety will be a challenging task, including more than 2.5 million, 15 million, 43 million cases of human immunodeficiency virus (HIV), hepatitis C virus (HCV) and hepatitis B (HBV) respectively [32, 33]. Blood donors have a seroprevalence of 0.5, 0.4 and 1.4% for HIV, HCV, and HBV respectively [34], compared to 0.0097, 0.3 and 0.07% in the US blood donors [35].

Blood transfusion inflames the risk of TTIs like Human Immunodeficiency Virus (HIV), Hepatitis C (HCV), Hepatitis B (HBV), syphilis and malaria and less frequently to Brucellosis, Toxoplasmosis and other viral infections [36]. Capitulate to a prevalence of 0.3%, India stands third on earth, in numeral terms of HIV diagnosed people [37]. As of 2009, almost 2.5 million Indians were infected with HIV. Prevalence of hepatitis B surface antigen (HBSAg) varies between 0.02 and 8.5% [38].

In spite of the fact that there are early reports in the medical history that tried to treat patients with human or animal blood and blood products, transfusion medicine is a moderately youthful field that has grown just since the second half of the last century. Rapidly, in any case, it turned out to be evident that these therapeutic approaches additionally conveyed their issues, for example, the incompatibility of red platelets and plasma among donors and recipients, and the likelihood of transfusion-transmitted diseases [39, 40].

While previously, the danger of transfusion-transmitted infections (TTI) was acknowledged by patients and doctors as unavoidable, low-risk blood supply is normal today. Since the mid-nineteen sixties, blood donation centers, and in addition plasma fabricating businesses, have forcefully sought after techniques to decrease the dangers of TTI. Specifically, donor deferral criteria, for example, a past medical history of hepatitis or transfusions in the last six months have been set up since at an early stage. Today, laboratory screening tests, donor assessment, and pathogen inactivation

techniques are viewed as significant methods to diminish the danger of TTI, however don't totally take out all hazard. In the meantime these advances have moved transfusion medication towards progressively more secure items, at relentlessly heightening expenses and subsequently prompting real contrasts in transfusion item wellbeing among poor and wealthy nations [41]. Although, the blood screening practices with new serological tests with a distinction on sensitivities, a danger of transfusion transmittable infections still remains. Various recently contaminated blood donors are neglected to relate to TTIs even with abbreviated pre-seroconversion window period containing serological tests [42].

Since the decrease in the incidence of transfusion-transmitted diseases with advances of technology, other adverse events in transfusion appeared, which were due to ABO incompatibility, bacterial contamination, human errors and immuno-modulation remain as a matter of concern. But the reporting of transfusion events in India is voluntary. So there are chances for under-reporting of transfusion reactions and the actual incidence of reactions is not known [43]. There are emerging and re-emerging infections, so it is necessary to take safety measures in the form of revised risk assessment history and introduction of new donor selection criteria and screening tests.

Problems Associated with Haemovigilance: In haemovigilance, a few issues exist at various dimensions, incorporates institutional, local, national and worldwide. Truth be told, these issues couldn't be comprehended. By and large, there is a deficit in connection with basic definitions, standardized reporting formalities, terminology, and uniform network [44].

The major problems arising in haemovigilance are underreporting of adverse events/effects due to fear of retribution and punishment, late reporting, use of different channels of reporting, incomplete information on incident sheets and failure to report investigation findings and reports the health authority, difficulties in communicating with blood banks in both governmental and private sectors and in motivating hospitals to notify events and to have functional transfusion committees, fragmented blood transfusion systems, lack of understanding or awareness, lack of culture of reporting adverse events, lack of regulatory framework for haemovigilance, lack of computerized management system, lack of transparency in government agencies and absence of well-defined haemo-vigilance structure and protocol, lack of trained manpower, lack of training and no standardized single system common to two blood services and no development of evidence-based guidelines, lack of computerisation and use of "Hemovigil" software makes the transfusion reactions underreported [45]. A functional haemovigilance system can act as a backbone to monitor the transfusion practices and be accountable for appropriate documentation, reporting, and investigation of transfusion reaction [46].

Future Perspectives: A system in haemovigilance will be essential and furthermore normal definitions, forms, measures, exchangeability of data, quick and early alerts are additionally giving vital job. Systems of preventive and corrective activities at the community level should be produced.

The players involved in the blood transfusion chain will see their individual roles and their contribution to the framework will rapidly develop insignificance. The issue of current vigilance frameworks meddling with blood transfusion should be settled: bridging or spinning and bundling will be vital issues with regards to present-day, advanced haemovigilance, particularly at the community level [47].

There are many factors like good inventory management, clerical checks, leukodepletion, betterment in blood storage conditions other than blood banks, more vigilant donor screening, complete monitoring of transfusion and documentation of transfusion reactions may decrease these events in future. The whole transfusion chain will be safe and effective if there is good coordination between transfusion medicine specialists and other clinical specialties. All the transfusion reactions or events will be known if there is a haemovigilance program at the national level which includes the policies formulated to minimize the risks associated with transfusion services [43].

CONCLUSION: Haemovigilance is a continuous process of analysis of transfusion reactions and data collection in order to investigate their causes and outcomes and prevent their incidence. The objective of a sheltered and moderate blood supply that can meet the developing worldwide requests might come by the organized streamlining and progression in the transfusion chain, including the monitoring of donor eligibility criteria, reporting of transfusion reactions, adherence to thorough guidelines, the ideal execution of accessible screening tests, the utilization of reasonable pathogen inactivation techniques lastly the watchfulness of judicious doctors, who assess the need of every transfusion. Haemovigilance is a key with regards to well-being and nature of blood transfusions. In connection to haemovigilance frameworks, huge contrasts right now exist in the nations around the globe, as far as definition, a condition of improvement, effect and productivity, organizational schemes, participation, and so forth. Every nation ought to have a built-up framework with the national scope.

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