A REVIEW ON TRANSFUSION SAFETY AND HAEMOVIGILANCE

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ABSTRACT

Haemovigilance a set of surveillance procedures covering from the collection of blood and its components to the follow-up of recipients, the whole transfusion chain intended to collect and assess information of unexpected or undesirable effects resulting and to prevent their occurrence or recurrence from the therapeutic use of labile blood products. In Human Blood transfusion saves lives and improves health, but many patients astute transfusion do not accept adapted admission to safe blood. Blood transfusion is consistently associated with some kind of different risk. Haemovigilance is a systematic surveillance of adverse reactions/events accompanying to transfusion with the aim of improving transfusion safety or a tool to improve the quality of the blood transfusion chain, It is as well connected activity of data accumulating and analysis of transfusion-related adverse reactions/events in order to investigate their causes and outcomes, and anticipate their occurrence or recurrence, primarily observing on safety. . It is a risk monitoring system basic to the conventional practice of transfusion medicine, ultimate purpose is to improve the quality and assurance safety of transfusion.

KEYWORDS: Haemovigilance, Blood Safety, National Haemovigilance programme.
INTRODUCTION

In 1990, the word haemovigilance (he´movigilance in French) was coined in France in analogy to the already existing term pharmacovigilance. It is derived from the Greek word haem = blood, the Latin word vigilans = watchful. The World Health Organization (WHO), International Haemovigilance Network (IHN) and International Society of Blood Transfusion (ISBT) —Haemovigilance is defined as a set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the after effect of its recipients, advised to collect and appraise information on abrupt or undesirable effects resulting from the therapeutic use of labile blood products, and to anticipate their occurrence and recurrence.\textsuperscript{[1,2]}

The World Health Organization (WHO) published guidelines in 2005 on Adverse Event Reporting and Learning Systems: from Information to action which accent the fundamental role of patient safety reporting systems in acceptable patient safety by acquirements from failures of the health care system, and that the capability of such systems should be measured not alone by data reporting and analysis but by the use of such systems to improve patient safety. An adverse event is defined as an undesirable and unintended occurrence before, during or after transfusion of blood or blood component which may be accompanying to the administering of the blood or component. It may be aftereffect of an error or an incident and it may or not aftereffect in a reaction in a recipient. An adverse reaction is an undesirable response or effect in a patient temporally associated with the administering of blood or blood component.\textsuperscript{[3]}

The system should cover monitoring, identification, reporting, investigating and assay of adverse events near-misses and reactions accompanying to transfusion and manufacturing. A abreast absence is an error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to a wrongful transfusion or to a reaction in a recipient \textsuperscript{[2]}. In this concerns the follow-up of whole blood and labile blood components for transfusion: red cell concentrate, FFP and platelets.

In the beginning of the 1990s haemovigilance as a safety concept, initially developed by the French Blood Agency as a national system of surveillance and alert, from blood collection to the aftereffect of the recipients.\textsuperscript{[4]} Haemovigilance systems to monitor the adverse events and incidents associated with blood donations and transfusions now have been implemented globally in a lot of developed countries.\textsuperscript{[5]}
National haemovigilance programme of India

Indian Pharmacopoeia Commission in collaboration with National Institute of Biologicals, NOIDA, Uttar Pradesh has launched a haemovigilance programme of India (HvPI) on 10th Dec 2012 across the country beneath its pharmacovigilance programme of India (PvPI). Primary objective is to clue adverse reactions / events and incidences associated with blood transfusion and blood product administration (haemovigilance) and to advice identify trends, recommend best practices and interventions appropriate to improve patient care and safety. In order to collect and analyze the data pertaining to all over the country has been developed software “Haemo-Vigil”. Programme has already enrolled 117 Medical College and Hospitals in India. National Institute of Biologicals is the Coordinating Centre, for HvPI to adduce & analyze data with account to Biologicals & Haemovigilance. A Core Accumulation & Advisory Committee in this attention has already been constituted and first meeting of advisory committee was held on 29th Nov, 2012 to agree Haemovigilance Transfusion Reaction Reporting Form (TRRF) & Guidance Document. The ultimate goal of this Haemovigilance programme of India is to be a part of the International Haemovigilance Network (IHN) which presently has 28 countries as its affiliate and provides a global forum for administering best practices and bench-marking of Haemovigilance data.[6]

Blood availability and safety

Globally, every year around 107 million units of blood donations are collected. About 50% of these blood donations are collected in high-income countries, home to 15% of the world’s population. In low-income countries, up to 65% of blood transfusions are given to children under 5 years of age; admitting in high-income countries, the a lot oft frequently transfused patient group is over 65 years of age, accounting for up to 76% of all transfusions. Blood donation rate in high-income countries is 39.2 donations per 1000 population; 12.6 donations in middle-income and 4 donations in low-income countries.[7]

Global database on blood safety

Global Database on Blood Safety (GDBS) was established in 1998 by the WHO to address global concerns about the availability, safety and accessibility of blood for transfusion. The objective of this activity is to collect and analyze data from all countries on blood and blood product safety as the base for effective action to improve blood transfusion services globally. A questionnaire has been developed as a standardized tool for the collection or accumulating of data, is based on the WHO Aide-Memoire for national health programmes: Blood safety,
covers the four major components of the integrated strategy for blood safety advocated by WHO.\cite{8} The data collected through the GDBS questionnaire are analyzed and reports are published on the WHO website. The focus of the analysis is to provide information on the accepted status of blood transfusion services, appraise country needs in improving blood safety, formulate strategic recommendations to countries, plan and implement activities and evaluate progress.

**National blood policy and organization**

Providing safe and adequate blood should be an important part of every country’s national health care policy and infrastructure. Recommended by WHO that all activities related to blood collection, testing, processing, storage and distribution should be coordinated at the national level through a national blood policy and effective organization. This should be supported by adapted legislation to beforehand compatible implementation of standards and consistency in the quality and safety of blood and its products.

In 2011, 68% of countries had a national blood policy, compared with 60% of countries in 2004. Overall, 62% of countries have specific legislation covering the safety and quality of blood transfusion.

- 44% of low-income countries
- 60% of middle-income countries
- 81% of high-income countries.\cite{9}

![Blood Bank U.P.RIMS&R Saifai](image)

Data of blood collection & blood supply from the year 2006-2014
National Haemovigilance Programme - Objective for reporting adverse reactions and adverse reactions in transfusion\(^6\)

- Reporting for obtaining information is a tool which can be used to improve the product safety.
- A national reporting system, therefore, can usefully be admired as a tool to advance public policy concerning patient safety.
- Reporting provides information as to where the system is breaking down. It can help to identify hazards and risks.
- This can advise target improvement efforts and systems changes to reduce the likelihood of injury to future patients.
- Reporting of doubtful adverse reactions in a timely manner facilitates effective risk management.
- ADR Monitoring Centers: these are medical colleges & institutes/ blood banks/ hospitals in India that are registered with the Pharmacovigilance National Co-coordinating Center for reporting the adverse reactions that occurs during blood/ component transfusion or Blood Product (plasma derived products) administration.

Privacy and security of data

Haemovigilance reports will contain in manners of no identifiable or re-identifiable data, that no patient, clinician, staff member or health care facility is identifiable from materials contained within the report.

Responsibilities of Medical Staff of the ADR Monitoring Centers\(^6\)

Medical staff attending to patients having suspected transfusion complications should perform the following documentation and reporting functions:

- Attending staff as nurse should report suspected transfusion reaction immediately to the attending physician.
- Document the details of the patient as well as the implicated units/ products should be in the Form and retain in the patient’s file.
- Send the details of the transfusion reaction to the concern Department Transfusion Medicine in the Form.
- Assess the information and imputability levels of the adverse reactions in coordination with the Department of Transfusion Medicine.
- Maintain records including of the complication in the patient’s medical record, the report
of the investigation completed by the Department of Transfusion Medicine.

- complete enter the necessary details as per the documentation required in the Transfusion Reaction-Traceability document (TR-TD)

**Imputability levels**\[^6\]**

Imputability means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component or blood product transfused. The Imputability levels are given below.

- **Definite/ certain**: there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to the transfusion.
- **Probable/ likely**: when the evidence is clearly in favor of attributing the adverse reaction/event to the transfusion.
- **Possible**: when the indeterminable evidence for attributing the adverse event to the transfusion or alternate causes.
- **Unlikely/ doubtful**: when the evidence is clearly in favor of attributing the adverse event to causes other than the blood transfusion/transfusion.
- **Excluded**: there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to causes other than the transfusion/blood transfusion.

**What and how is reported?**\[^10\]**

- In most systems, not alone adverse reactions (in patients) but as well adverse reactions/events (AE) are reported.
- Reporting of all adverse reactions/events results is better for vigilance and raises awareness as serious AR are rare events. It requires added resources, however.
- Donor vigilance may accord to reduce complications, lead to increased frequency of donation and improve donor satisfaction.

**Reports on transfusion reaction in blood component**

Study had shown that only 0.10% transfusion reactions were reported, points to the lack of regular reporting of transfusion reactions, as well as the actuality that there is no report of delayed transfusion reaction. In this study we have shown that in the period from 2008 to 2012, 50 transfusion reactions were reported at the Department of Pathology/ Blood bank U.P. Rural Institute of Medical Sciences & Research. Out of 50 reported transfusion reactions, 45 (90%) were febrile non-haemolytic transfusion reactions, 5 (10%) allergic reactions and no haemolytic reactions. All patients underwent multiple transfusions.\[^11\]**
Therefore, to improve and accomplish blood transfusion safer it is necessary to respect all pre-transfusion procedures, constant follow up of blood transfusion must be done and patients with diagnosed non-haemolytic transfusion reaction should be given leukocyte reduced blood components.

Estimates of adverse event incidence in blood donors based on other published international studies range considerably from 5% to 33%.\textsuperscript{[12, 13]}

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**Fig. 1. Classification of blood transfusion reaction**

**Adverse Reactions in Patients**

- **Infection**
  - HIV, Hepatitis-B&C, Syphilis, Malaria.

- **Non Infection**

**Immediate**
- Acute hemolytic transfusion reaction (AHTR)
- Febrile non hemolytic transfusion reaction (FNHTR)
- Transfusion-related acute lung injury (TRALI)
- Hyperkalemia
- Transfusion associated circulatory overload (TACO)

**Delayed**
- Delayed hemolytic transfusion reaction (DHTR)
- Delayed serologic reaction (DSTR)
- Transfusion associated graft-versus-host disease (TA-GVHD)
- Post transfusion purpura (PTP)
- Haemosiderosis

**Risks and factors to ADEs\textsuperscript{[14]**}

Certain factors may access the likelihood of a transfusion related adverse effect and these include.

- Individual patient characteristics
- Blood components
- Equipments
Concomitant medications and intravenous fluids.

**Patient characteristics**
Patients who have previously been transfused, multiparous women and patients accepting emergency uncross-matched transfusion, at increased risk of immediate and delayed haemolytic transfusion reactions. Febrile, allergic and anaphylactic reactions occur more frequently in multiparous women and in patients with anti-IgA antibodies and IgA deficient.

**Blood component**
WBCs and Platelet transfusions are associated with the highest rates of febrile non-haemolytic transfusion reactions. The incidence of such reactions can be modified by changes to the blood component processed by leucodepletion. All RBCs and platelet components produced by the blood service are leucodepleted. Platelets, which require storage at 20 to 24 ºC, are associated with higher rates of bacterial contamination than red cells, which are commonly refrigerated. All platelets are accountable to accepted bacterial culture and screening, which allows detection of a bacterial contaminated product. Sometimes, transfusion of fresh frozen plasma is associated with a higher risk of allergic reactions. Some reactions are mild, but severe life-threatening reactions such as Transfusion-related acute lung injury (TRALI) and anaphylaxis may occur.

**Equipment**
All blood components are administered through accurately or specifically designed intravenous giving sets, which absorb a 170 to 200 micron filter to abolish debris and clots that may accept accumulated during storage. All accessories must be specifically designed, and adjourned as safe for blood administering and acclimated in accordance with the manufacturer's operational procedures.

**Unspecific medications and intravenous fluids**
Neither medication nor solutions should be added to or alloyed through the same tubing with blood or components except 0.9% Sodium Chloride, Injection (BP). Plasma (ABO-compatible) or 4% Albumin or other suitable plasma expanders may be used with advice of the patient's physician. Some types of solutions crystalloid and colloid containing calcium (e.g., Haemaccel) never be accept added to or administered through the aforementioned intravenous line as blood or component collected in an anticoagulant containing citrate because they interfere with the anticoagulant effect, consistent in clotting.
Procedures
Clear accounting procedures and able staff training are essential for all aspects of the clinical transfusion process from initial collection of samples for pre-transfusion testing through to final documentation of the transfusion process and outcome. There are abundant opportunities for error during this process if procedures are not strictly followed. According to recent reports (2005) from the UK indicate that about 60% of adverse events associated with transfusion are a result of 'wrong blood to wrong patient'.[15]

Recommendations for better haemovigilance program
- More trained personnel
- Better national blood quality and safety initiatives
- Reducing or minimizing technical and human errors
- Generate data standards
- Improve capacity of reporting.

CONCLUSION
The advice and information acquired from the haemovigilance and analyses facilitate corrective and preventive actions to be taken to minimize the potential risks associated with quality and safety in blood processing and transfusion for donors, patients and staff. Such advice and information is also a key to introduce required changes in the applicable policies, improve standards, systems and processes, abetment in the conception or assist in the formulation of guidelines, and increase the safety and quality of the entire process from donation to transfusion. Developing guidelines, analysis/audit and haemovigilance systems in countries with limited resources can be accomplished more readily through a step wise implementation. If the removal of leucocytes (WBCs) from blood component to a Level of 5x10^6, minimizes the risk of allo-immunization to histocompatibility antigens which in turn helps to prevent development of refractoriness to platelet transfusion and decrease chance for GvHD but the only method for prevention is Irradiation, improvement of RBCs & Platelets quality by which granulocytes contain lytic enzymes and chemicals when leucocytes breakdown these will lead to deleterious effect on cells.

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