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Review on Haemovigilance and Transfusion Safety

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ABSTRACT: This review paper is about Haemovigilance and its transfusion safety. Haemovigilance system is an integral part of quality management in a blood system, triggering corrective and preventive action for the continual improvement of the quality and safety of blood products and the transfusion process. On the basis of this study, it demonstrates the safety of existing transfusion system to population. The transfusion system which creates national and international linkages to improve the patient and product safety. It encompasses all adverse events including reactions and incidents that occurs during the donation, processing and transfusion of blood.

KEYWORDS: Haemovigilance, Transfusion, Blood products

I. 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.[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 after effect of an error or an incident and it may or not effect 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.[3]

Hemovigilance is the set of surveillance procedures covering the entire blood transfusion chain, from the donation and processing of blood and its components, through to their provision and transfusion to patients, and including their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking action to prevent their occurrence or recurrence. The reporting systems play a fundamental role in enhancing patient safety by learning from failures and then putting in place system changes to prevent them in future.

The hemovigilance system should involve all relevant stakeholders and should be coordinated between the blood transfusion service, hospital clinical staff and transfusion laboratories, hospital transfusion committees, the national regulatory agency and national health authorities. The resulting modifications to transfusion policies, standards and guidelines, as well as improvements to processes in blood services and transfusion practices in hospitals, lead to improved patient safety. Transfusion of blood and blood products is not without risks and it can lead to complications. The primary aim of the centralized Haemovigilance programmme is to improve transfusion safety and quality by collecting, collating, analyzing and disseminating information on a commonly agreed upon set of adverse reactions due to to the transfusion of blood and blood products. The primary aim of the centralized Haemovigilance programmme is to improve transfusion safety and quality by collecting, collating, analyzing and disseminating information on a commonly agreed upon set of adverse reactions due to to the transfusion of blood and blood products.

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Information obtained will used to build better and safety systems, efficient use of valuable health resources and ultimately deliver better patient healthcare. The Programme has enrolled various centres including Medical colleges/ Institutes/ Hospitals/ Blood Centers all across the Country and have an oversight by the Haemovigilance Advisory Committee so that it can achieve its goal and objectives. Haemovigilance Programme of India is now a part of the International Haemovigilance Network (IHN) which provides a global form for sharing best practices and benchmark for Haemovigilance.[4]

HAEMOVIGILANCE PROGRAM IN INDIA

A centralized hemovigilance program to assure patient safety and to promote public health has been launched for the first time in India on Dec 10, 2012 in 60 medical colleges in the first phase along with a well-structured program for monitoring adverse reactions associated with blood transfusion and blood product administration. National Institute of Biologicals (NIB)will be the National Coordinating Centre for Hemovigilance. This program will be implemented under overall ambit of Pharmacovigilance Program of India (PvPI), which is being coordinated by Indian Pharmacopoeia Commission (IPC). All medical colleges of the country will be enrolled in this program by the year 2016 in order to have a National Centre of Excellence for Hemovigilance at NIB, which will act as a global knowledge platform. The National Institute of Biologicals (NIB) serves as the HvPI coordinating centre, collecting, combining, and analysing country-wide data on biologicals and haemovigilance across the country. India has become a member of International Haemovigilance Network (IHN) in December 2014. IHN was established in the Year 2009. Presently 33 Countries are members of International Haemovigilance Network including India. [5-8]

NCC- NIB has participated in General Assembly IHN via webinar on 27th March 2015, wherein an update about Haemovigilance Programme was apprised to the General Assembly IHN. Presently, 226 centres, located in Blood Banks, Medical Colleges/Institutions, Govt Private Hospitals are enrolled under this programme. Targets for Haemovigilance program of India which have been distinct into three phases: **Initiation phase [FY 2012-2013]** which includes Develop systems, procedures and software, Enroll participants, Data collection, Zonal workshops**. Expansion and consolidation phase [FY 2013-2015]** which includes continuing Enrollment, zonal workshops, Publication of Newsletter, Application for membership of IHN. [9,10]

HISTORICAL ASPECTS

The pioneering work on hemovigilance started in France in 1994 with the setup of monitoring systems by Blood Transfusion Committees and establishing a national hemovigilance system. Later, in 1995 with an objective to improve public confidence in safe blood supply, the European Council published a resolution. Soon the hemovigilance system became governed by legal authorities. Data from well established hemovigilance systems of various countries such as the United Kingdom (Serious Hazards of Transfusion [SHOT]), Canada (Transfusion Transmitted Injuries Surveillance System [TTISS], Netherlands (Transfusion Reactions in Patients [TRIP]), Japan, Russia, Switzerland, and the United States of America has provided insight into various measures, which can improve blood safety.

Hemovigilance was first introduced in France in 1993 with mandatory reporting and in United Kingdom (UK) with first voluntary reporting system in 1996. Most of the developed countries like Canada, Ireland, Netherlands, and Denmark have a voluntary reporting requirement. Hemovigilance program in these countries is linked to International Haemovigilance Network, which presently has 28 members. Hemovigilance systems, depending upon the country, are governed either by regulators (e.g., France, Germany, Switzerland), blood manufacturers (e.g., Japan, Singapore, South Africa) medical societies (e.g., Netherlands, UK), or public health authorities including regulators. (e.g., Canada). Member states of the European Union have to implement hemovigilance program with reporting to a Central Office as per the commission directive. Among the Asian countries, awell-established hemovigilance system is lacking and there is paucity of data on hemovigilance data except for Japan, which has published a report on adverse reactions. Hemovigilance system is required in the country to have a comprehensive approach to address the issues of adverse reaction following blood transfusion and blood product administration.[11-13]

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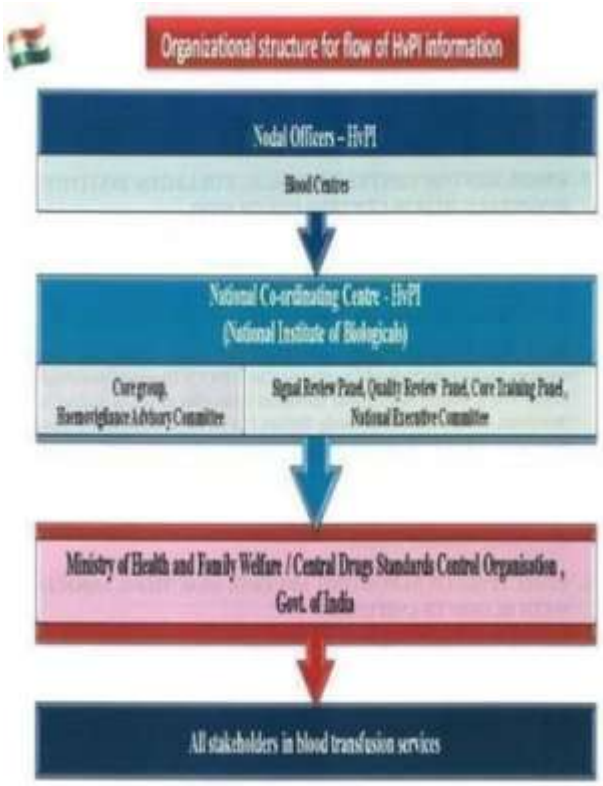

ORGANIZATION OF STRUCTURE OF HvPI

CENTRES UNDER HvPI

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BLOOD TRANSFUSION PROCESS

A blood transfusion provides blood or blood components if you've lost blood due to injury, during surgery or have certain medical conditions that affect blood or its components. The blood typically comes from donors. Blood banks and healthcare providers ensure transfusions are a safe, low risk treatment. Blood transfusions are a relatively common medical procedure, and while typically safe, there are multiple complications that practitioners need to be able to recognize and treat. This activity reviews the indications for blood transfusion, including for special patient populations, the pre- transfusion preparation, and the potential complications of blood transfusions. In addition, this activity highlights the role of the interprofessional team in caring for patients undergoing blood transfusions.[14]

A blood transfusion is a common procedure in which donated blood or blood components are given to you through an intravenous line (IV). A blood transfusion is given to replace blood and blood components that may be too low. Blood transfusion is nessacery in certain medical conditions such as, Anaemia, In certain cancers, Haemophilia, Sickle celldisease or thalassaemia.

Several equipment which had been used for transfusion process. Blood products are transfused through intravenous tubing with filters. The filters, which typically have pore diameters of 170 to 260 microns, are also used to prevent particulate debris from being administered. However, the trapped particulate leads to bacterial growth, and the American Association of Blood Banks (AABB) advises against using a filter for more than four hours. Before transfusion, the tubing should be primed with an isotonic, calcium-free blood- compatible solution, for example, normal saline. Citrate is used as a preservative in packed red blood cells, and clots will form in the intravenous line if there is more calcium than the citrate can buffer. Blood components or whole blood could be provided through various central venous access devices or peripheral intravenous catheters. The following sizes should be considered: 20-22 gauge for routine transfusion in adults, 16-18 gauge for rapid transfusion in adults, 22- 25 gauge for pediatrics and requirements for administration sets might vary such as Blood filters, administration of platelet-poor plasmas, Infusion devices, such as infusion pumps, blood warmers, rapid infusers, and pressure devices can be used to transfuse blood components and blood warmer device is often needed to prevent hypothermia in the rapid administration of cold-blood components, for instance, in trauma settings or operation theatres. Two providers should verify blood products before administering, and patients should bemonitored during transfusion by qualified personnel. Blood transfusions can be carried out by various healthcare providers and other healthcare professionals.

Preparation for blood transfusion involves running pretransfusion testing for compatibility between recipient antibodies and donor red blood cells. This involves obtaining asample of the recipient's blood to send for a type and screen. The type and screen test verifies the recipient's blood type and also determines if the recipient has any "unexpected" (non- ABO) antibodies that might cause reaction. There are multiple methods for running this screen. If the screen is negative, it is very unlikely there will be a reaction. Obtaining blood for the patient should be done rapidly if required. If the screen is positive, many blood banks will crossmatch and hold two units of blood for the patient incase they need a transfusion. Another prerequisite to blood transfusion is to take consent from the patient if possible.[15]

Some of the important steps to follow before proceeding with blood transfusion:

- Find Current Type and Crossmatch
- Obtain Informed Consent and Health History
- Obtain Large-bore Intravenous Access
- Assemble Supplies
- Obtain Baseline Vital Signs
- Obtain Blood from the Blood Bank
- Technique of blood transfusion.

BLOOD TRANSFUSIONS REACTIONS

Transfusion reactions are adverse events associated with the transfusion of whole bloodor one of its components. They range in severity from minor to life-threatening and can occur during a transfusion, termed acute transfusion reactions, or days to weeks later, termed delayed transfusion reactions. Transfusion reactions may be difficult to diagnose as they can present with non-specific, often overlapping symptoms. The most common signs and symptoms include fever, chills, urticaria, and itching. Some symptoms may resolve with little or no treatment. However, respiratory distress, high fever, hypotension, and hemoglobinuria may indicate a more serious reaction.[16]

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Types of transfusion reactions
Immunogenic transfusion reactions

- Acute haemolytic
- Delayed haemolytic
- Febrile nonhemolytic
- Transfusion related acute lung injury
- Allergic (Urticarial)
- Anaphylactic transfusion reactions

Non immunologic transfusion reactions

- Septic infections
- Viral infections
- Circulatory overload
- TRALI (lipids activators ofneutrophil models)
- Post transfusion purpurea
- Transfusion associated graft-versus host
- Transfusion induced hemosiderosis

ABO INCOMPATABILITY REACTIONS

An ABO incompatibility reaction can occur if you receive the wrong type of blood during a blood transfusion. It's a rare but serious and potentially fatal response to incompatible blood by your immune system. Blood group antigens on red blood cell (RBC) surfaces define their immune potential. The different blood groups A, B, AB and O are based on the surface presence of antigen A, antigen B, both antigens or absence of these antigens, respectively. Corresponding to these blood groups, IgM antibodies (anti-A, anti-B) are found in the plasmaof adults lacking the corresponding antigen. Hence, blood group A, B, O, and AB have anti-B, anti-A, both, or none of the isoagglutinins (Rule of Landsteiner).

Apart from these, there are 'minor' aalloantibodies such as anti-D, anti-K, and anti-Jka which are present in varying proportions in the population. .These reactions are extremely rare, because doctors are aware of the danger of using the wrong blood during a transfusion. There are many precautions in place to reduce the chances of a mistake. Compatibility testing pre-transfusion involves blood typing and cross-match to ensure the recipients' blood lacks antibodies that can react with donor antigens and lead to destruction of transfused cells. In spite of compatibility testing, a conglomeration of system and process errors may still lead to transfusion of mismatched blood leading to incompatibility reactions, generally as a clerical or procedural error.[17]

FUTURE PERSPECIVES OF HEMOVIGILANCE

In the future, the use of electronic data sources will likely increase, including bedside transfusion-associated vital parameters of patients undergoing transfusion, more accessible nowadays through the use of bedside scanning as a means of preventing wrong transfusions. New ICT solutions facilitate the logistics for clinicians to improve monitoring and reporting transfusion reactions with more comprehensive data. These parameters can be linked to haemovigilance reports and medication and imaging data. In secured settings allowing anonymised data-based studies, data mining and artificial intelligence can yield information about signals of an impending transfusionreaction.

Continuously recorded peri-transfusion vital parameters using wearables can be employed as study tools and validated, contributing to the development of patient-reported outcome measures to study the benefits of transfusion on patients' quality of life [18]

II. CONCLUSION

Haemovigilance is a cornerstone of transfusion medicine, promoting patient safety, quality improvement, and collaboration within healthcare community. As we move forward, It is essential to prioritize the development and implementation of robust haemovigilance systems, ensuring that blood transfusions remain a safe and medical intervention for patients in need and also contributes to continuous improvement in the quality of blood products and transfusion practices. Transfusion safety is fundamentally about prioritizing the well-being of patients. Every step in the transfusion process, from donor screening to administration, is designed to ensure the safety and efficacy of blood products for recipients.

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