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Review Article

Hemovigilance: a momentous step to blood safety

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ABSTRACT

Hemovigilance is a series of monitoring procedures that cover the entire transfusion chain, from blood and its component collection to recipient follow-up, collecting and collecting information about unexpected or adverse effects resulting from the therapeutic use of unstable blood products. It is designed to be evaluated, and to prevent their occurrence and recurrence. The Haemovigilance program in developed countries is associated with IHN and has voluntary reporting requirements. In France, Germany and Switzerland, the hemodynamic system is regulated by supervisors. It is one of the blood manufacturers in Japan, Singapore and South Africa. In the Netherlands and the United Kingdom within the Medical Society; in Canada, regulated by health authorities. Intensive blood exercise program to ensure patient safety and promote public health begins on December 10, 2012 in Phase 1 in collaboration with National Institute of Biological Sciences under MOHFW for the first time in India it was done. HvPI is responding very well, as most medical colleges and laboratories have already registered and are beginning to provide data on side effects. The HvPI Unit produces educational materials in the form of publishing the Haemovigilance newsletter, information, education and communication (IEC) literature, and conducts an academic CME and awareness program on Haemovigilance throughout the year in India. The provocation is to understand not only the feedback of the internet, but even the sociology of human networks. Guaranteeing the reliability, responsiveness, and feedback of each alert is also important. Blood products are an important area of PvPI for reporting and recording post-transfusion ADRs of blood / blood products. To work efficiently, a lean mechanism and proper coordination with standardized tools at all levels is needed.

Keywords: Haemovigilance, Blood transfusion reactions, Adverse drug reactions, PVPI, Pharmacovigilance

INTRODUCTION

Hemovigilance is a set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the follow up of its recipients intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent their occurrence and recurrence. It is a vital tool for improving safe blood transfusion practices.[1] Haemovigilance, the term derived by amalgamation of Greek word `haema` means blood and a Latin word, `vigil` means watchful. In India, it was launched in 2012 under PvPI in collaboration with National Institute of Biologicals, Noida, UP under Ministry of Health and Family Welfare (MOHFW) in order to track the ADR related to blood and blood products thus contributing to improvement of patient safety.[2] Hemovigilance as defined by Faber is "a set of surveillance procedures covering the whole transfusion chain (from the donation of blood and its components to the follow up of recipients of transfusion), 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."[3]

NEED FOR HEMOVIGILANCE

In the 20th century, due to discovery of ABO blood groups and evolution of cross-matching technique and anti-coagulation used in the blood, blood transfusion became an accepted treatment modality.[4] At the end of the 1980s, the transmission of infections by blood prompted the need for a greater awareness on the safety of blood and pioneer work on hemovigilance started in France in 1991 with the setup of monitoring systems by blood transfusion committees, resulting in a national hemovigilance network in 1994.[5,6] The work on hemovigilance was first initiated in France in 1991, with the setup of monitoring systems by Blood Transfusion Committees followed by the inception of Centre National hemovigilance in 1992.[7] A complete French Hemovigilance System was in place by 1994. Currently, on a global scale an International Hemovigilance Network (IHN) is functional. Haemovigilance program in the developed countries is linked to IHN and have a voluntary reporting requirement. At France, Germany, Switzerland, hemovigilance system is governed by regulators; in Japan, Singapore, South Africa, it is under blood manufacturers; in Netherlands and UK, it is under medical societies; and in Canada it is regulated by public health authorities. Well established hemovigilance systems are inadequate or lacking among Asian countries and there is lack of hemovigilance data also.[8-11]

THE HEMOVIGILANCE PROGRAM OF INDIA

A centralized hemovigilance program to assure patient safety and to promote public health was launched for the first time in India on December 10, 2012 in the first phase along in collaboration with National Institute of Biologicals, Noida, UP under MOHFW. It was a well-structured program for monitoring adverse reactions associated with blood transfusion and blood product administration named as the Hemovigilance Program of India. (Figure 1)

It is an independent program primarily for the voluntary reporting of serious adverse reaction in recipients. Fundamental aim of this program is to trail adverse reactions and episodes related to blood transfusion and blood product administration and to help recommend best practices or policies required to improve patient care and safety. A software -"Haemo-Vigil" has been developed to collect and analyse the data related to hemovigilance all over the country. Hemovigil software was uplinked on National Institute of Biologicals (NIB). The Transfusion Reaction Reporting Form (TRRF) can be downloaded from websites.[1]

Blood donor adverse reaction reporting has 6 sections i.e. donor information, details of blood collected, type of complications, outcomes, immutability (causality) followed by reporter details. The other is Transfusion Reaction Reporting Form (TRRF) for Blood and Blood Components' to be filled by HCP. This has patient information, transfusion product details, nature of adverse reactions, outcome, reporter details and causality assessment.[2]

HvPI-NCC reviews completeness of data quality, prepare sops, guidance documents and communicate these recommendations to Indian Pharmacopoeia Commission (IPC). IPC finally forwards recommendations of hemovigilance advisory committee to Drug Controller General of India (DCGI)-CDSCO body. It is the DCGI-CDSCO who formulates blood and blood product transfusion safety related regulatory decisions and communicate to stakeholders. The table below outlines the flowchart for reporting adverse reactions related to blood and blood products.[13] (Figure 2)

HvPI is responding very well, as most medical colleges and laboratories have already registered and are beginning to provide data on side effects. However, less attention has been paid to the hemodynamics of the donor. Then, on June 14, 2015, the National Blood Donor Alert Program (NBDVP) was launched.[14,15] Systematic monitoring of adverse events or adverse events in the first part of the transfusion chain. The process of collecting blood is called donor blood movement. The goal of donor surveillance is to ensure and improve the quality and safety of both donors and recipients throughout the year in India.[16]

With one of Bisht et al. study conducted, DAR (Donor Adverse Reaction) was reported under this program in early 2016 and early 2017. The participation of blood centers in both recipient and donor monitoring was a positive step. Young, first-time, and female donors have been found to be more susceptible to DAR than older, repetitive, and male donors. After analyzing the data, the following recommendations were made: This can be improved by updating the reporting form and conducting regular continuous medical education (CME) at participating blood centers.[17]

HURDLES IN HEMOVIGILANCE

There is still a deficit in relation to hemovigilance and materiovigilance when it comes to common definitions, terminology, standardized reporting and uniform matrix. Despite being active, there is overall underreporting of adverse reactions associated with blood transfusion. WHO identified that the fragmented blood transfusion systems, lack of government commitment, lack of understanding among clinicians, lack of culture of reporting, fear of punishment, lack of expertise and regulatory framework on hemovigilance, lack of computerized management system might be challenges for the implementation of hemovigilance program in the world.[18] Stakeholders in regulatory authorities (CDSCO) and donor hemovigilance programs need to work together to increase the participation of blood centers and ensure completeness of

data in this program for more evidence based blood donation safety measures.[16]

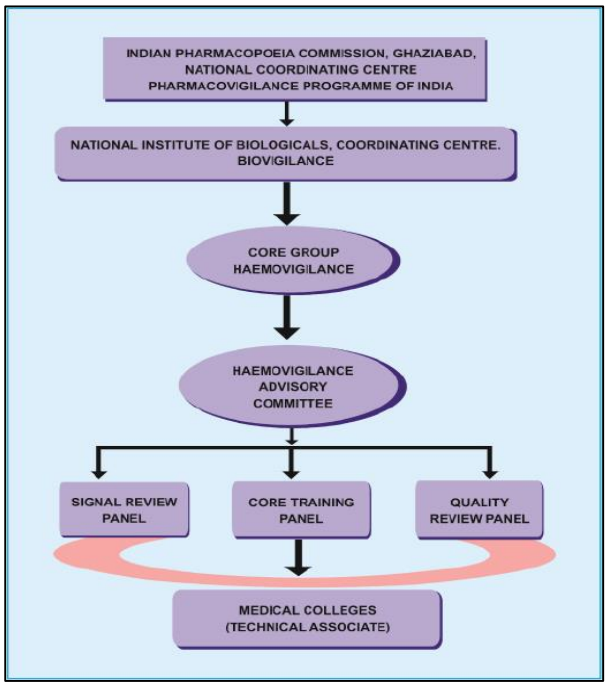

Figure 1: Hemovigilance organogram.[12]

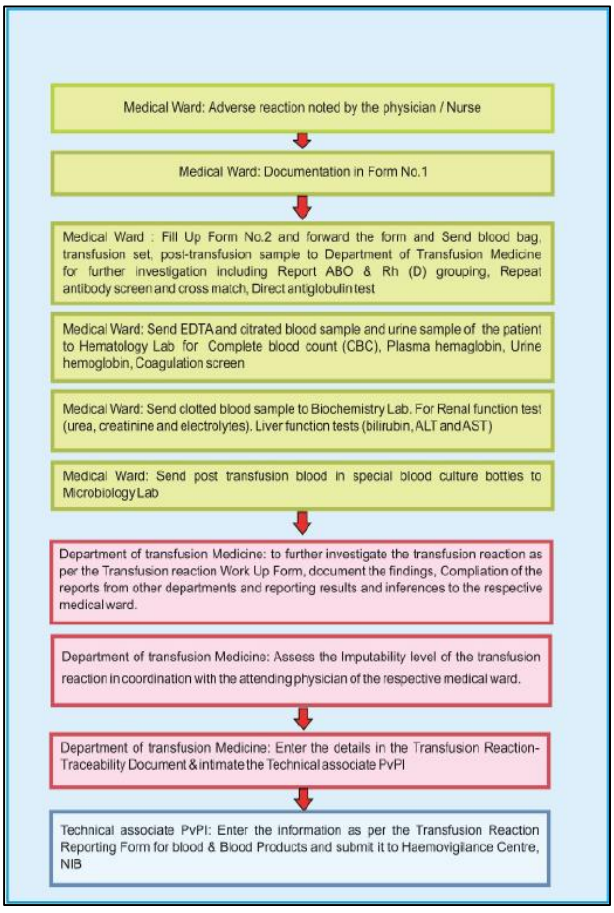

Figure 2: Flowchart for reporting adverse reactions related to blood and blood products.

The present scenario of healthcare system in India foregrounds the need for stern surveillance to safeguard the health and safety of patients. The patient safety requires continual enhancement of quality and safety of related materials and the blood products for the transfusion process by monitoring and safeguarding the adverse event associated with the use of materials and blood products. In this regard, hemovigilance has proved to be essential components of quality management in healthcare community.[19]

HOW TO OVERCOME THESE CHALLENGES: SWOT ANALYSIS

The effects of blood alerts should be assessed using SWOT (strengths, weaknesses, opportunities, threats) analysis. HPV's strengths are its core competencies and resources for operating HPV. Weakness is an area of unexplored achievement.[20,21] Opportunities are the potential for new or innovative breakthroughs that could significantly expand that outlook. The threat could be a disruptive new technology for HvPI. The provocation is to understand not only the feedback of the internet, but even the sociology of human networks. Guaranteeing the reliability, responsiveness, and feedback of each alert is also important. Hemovigilance is an important area of PvPI and ADR should be reported and recorded after transfusion of blood / blood products.[22,23] One of the main challenges of hemovigilance is ADR, which fears legal and regulatory implications for blood bank staff and physicians.

CONCLUSION

Hemovigilance is an integral part of India's Pharmacovigilance program, which reviews, accelerates, corrects and takes precautions to minimize potential safety and quality risks in blood treatment and transfusion for donors, patients and healthcare professionals. Resources-constrained countries will need to implement phased policies in order to develop policies and develop large-scale blood monitoring systems. This also has a significant impact on optimal blood use. Efficient functionality requires a lean mechanism and proper coordination with standardized tools at all levels. Therefore, hemodynamics should be carefully monitored from the perspective of patient safety as the primary goal.

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