

The Indian Hemovigilance System: The Challenges Ahead

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The term "Hemovigilance" has become widely used over the past decade to describe the systematic surveillance of adverse transfusion reactions and events, encompassing the whole transfusion chain and aimed at improving the safety of the transfusion process, from donor to recipient, "vein to vein." (1) Various hemovigilance programs have been developed and implemented in several countries including Canada, United Kingdom and France; and they publish their annual reports of adverse events associated with blood transfusion. The aim of these programmes is to have a system of surveillance and thus lower the risks associated with transfusion. (2,3,4)

Blood Transfusion Services in India: In India, authorities concerned with the organization and administration of blood transfusion services include Central, State, and Autonomous Government Institutions, Municipal Corporations, Cantonment Boards, Railway Services, Armed Forces, Red Cross Society, private and non-government organizations. The licensing of blood banks is under the dual authority of the State and Central Governments. The State Licensing Authority issues the license after getting its approval from Drug Controller General, India which acts as Central License Approving Authority.

Haemovigilance Programme in India: Unfortunately, there has been no National Hemovigilance program in India and the reporting of transfusion hazards is not mandatory. Also there is under reporting by the medical staff and thus most of the minor adverse events do not come to attention and therefore the exact incidence of various types of transfusion reactions is not known. Understanding the magnitude of problem a National hemovigilance program as an integral part of pharmacovigilance program of India at a national level has been launched on December 10, 2012. Initially, 60 medical colleges that are already enrolled under pharmacovigilance program of India have been brought under the ambit of this program. The Medical Colleges enrolled under hemovigilance program will collect data in respect of adverse reactions associated with blood transfusion and blood product administration in Transfusion Reaction Reporting Form (TRRF). The information collected will be used to formulate recommendation and guidelines that will be communicated to various stake holders (5).

Challenges ahead in implementing the Haemovigilance Program in India: Though the

Haemovigilance programme already stands launched in our country on 10th of December, 2012, there seem to be many problems/hurdles in implementing this programme fully at the ground level which need to be tackled at the appropriate levels. Following seem to be the challenges ahead in implementing Haemovigilance programme in India. Inadequate knowledge / Ignorance among the blood bank staff/personals and the blood Users:- There is an urgent need of providing them the awareness about Haemovigilance which could be in the form of CMEs, Awareness Lectures, Seminars, and Symposium etc.

Confidentiality: Confidentiality in respect of Health Care Institution, Health Care Worker involved and especially the patient should be maintained so as to achieve success in the implementation of the Haemovigilance program.

Hospital Transfusion Committees: The constitution and functioning of hospital transfusion Committees needs to be strengthened across the country to encourage coordination between the blood users and blood providers.

Inadequate maintenance of Blood Transfusion Reactions records in the Blood Bank/Blood Centre:- As per Drug and Cosmetic Act it is mandatory to maintain a record of all adverse transfusion reactions in a more efficient manner but majority of Blood Banks do not strictly adhere to this policy. Learning from the countries who have already implemented the Haemovigilance programme: We should also seek guidance from the countries where this program has already been implemented successfully but at the same time local conditions of the area be kept in mind before the start of this program.

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