

Healthcare EXECUTIVE

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UNDER THE LENS

An initiative for Blood Safety

The Haemovigilance Programme of India strives to assure the public health system of safe blood transfusion, writes **Akanksha Bisht**

Haemovigilance 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 an important tool for improving safe blood transfusion practices in a country. Haemovigilance system was first set up in France in 1993, with provision for mandatory reporting in response to threat of transfusion transmitted infections. Today, International Haemovigilance Network comprises more than 28 countries, including Singapore and Japan.

There are 2545 licences blood banks in India, out of which 996 are in public health sector; and 1549 are either in private hospitals, charitable or voluntary organizations. They collect on an average 7-8 million units of blood per annum. The Department of AIDS Control has laid down the standard for blood banks and blood transfusion services in the country to ensure better quality control system on collection, storage, testing and distribution of blood and its components. The development of National Haemovigilance Programme has been stated as an objective of National Blood Policy’s action plan for blood safety

A haemovigilance programme at the national level was launched in 2012 by National Institute of Biologicals Ministry of Health & Family Welfare, Government of India as the National Coordinating Centre (NCC) in collaboration with Indian Pharmacopoeia Commission

(IPC), Ghaziabad, Ministry of Health & Family Welfare, Government of India, in 90 medical institutions within the country. The objectives of the Programme are to:

- Monitor transfusion reactions
- Create awareness amongst health care professionals
- Generate evidence-based recommendations
- Advise Central Drugs Standard Control Organization (CDSCO) for safety related regulatory decisions
- Communicate findings to all key stakeholders
- Create national & international linkages

Currently, 153 centres, located in blood banks, medical colleges/institutions, government/private hospitals, are enrolled under this programme. Reporting is voluntary and limited to information related to adverse transfusion reactions in recipients. Data in transfusion reaction reporting form (TRRF) from these centres is being collected through a software – Haemo-Vigil developed by IT division of NIB. The activities of this programme are coordinated by a core group, haemovigilance advisory committee, quality, training and signal review panels. Ministry of Health & Family Welfare, Government of India allocated Rs. 29.63 crores for this program during the 12th Fifth Year plan.

The first point of contact with Haemovigilance programme of India is through submission of transfusion reaction report via Haemo-Vigil Software by Department of Transfusion Medicine/ Blood Bank. Awareness about haemovigilance programme is being created through haemovigilance newsletter and by providing

updated information on the website of NIB). Further, series of CMEs and workshops for healthcare professionals from, both, the field of transfusion medicine and clinical practice, are being organized to enable them to uplink the data in TRRF for onward transmission to the national coordinating centre via Haemo-Vigil software.

The major challenge for implementation of HvPI was to have an indigenous software to facilitate collection and collation of data in TRRF from various centres across the country and to transmit this data to NCC at NIB. The development of this software entailed its validation, verification, operationalization and hands-on training to end users. The IT division of NIB developed the Haemo-Vigil software and obtained the Security Audit and Compliance Audit through National Informatics Centre (NIC), Government of India. The adverse transfusion reaction data collected from the centres enrolled under the programme is secured in the NIC Server. The software is available online at NIB website and is password protected. The user ID & password for the software is issued only to the head of transfusion medicine department / in-charge of blood banks of the centres under HvPI by National Coordinating Centre- HvPI, NIB.

A five year roadmap i.e. year 2012-17 with three phases i.e. Initiation Phase (year 2012-13); Expansion and Consolidation Phase (year 2013-15); Expansion and Maintenance Phase (year 2015-17); has been prepared for implementation of this programme. The targets for initiation phase have been successfully accomplished with development of systems & proce-

dures for the programme, launch of Haemo-Vigil software, enrolling of Medical colleges, Institutes Blood banks, hospitals under this programme, facilitation of data collection from these centres under HvPI, organizing awareness programme / CMES and publication of haemovigilance newsletter. The targets for year 2013-15 i.e. Expansion and Consolidation Phase is to continue enrolment of centres under the Programme, organizing awareness programme / CMES and publication of the newsletter. NIB is in continuous process of enrolling centres under HvPI. NCC, NIB has organized 15 CMEs all across India besides publishing 3 haemovigilance newsletters as on date. During this phase, it also aims to become a member of International Haemovigilance Network (IHN).

Moving forward

The targets for the Year 2015-17 are maintenance and optimisation of the programme, identifying gaps and addressing them through appropriate measures, include donor vigilance, initiate Rapid alerts systems and Epidemiological surveillance for Transfusion Transmitted Infections.

Haemovigilance programme of India will benefit public health system by assuring donor and recipient safety, promote safe blood transfusion and blood product administration practices and assure overseas patients seeking medical interventions in India about safe blood transfusion practices.



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