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Review article

Hemovigilance and transfusion safety: A review on the hemovigilance systems across various countries

Author affiliations: Anila Mani [1] , I S Chaitanya Kumar [2] , Anand G Bodade [3] , Amol Khade [4]

1. Senior Resident, Department of Transfusion Medicine & Hemotherapy, All India Institute of Medical Sciences, Mangalagiri, Pin – 522503 Email: dranilamani@gmail.com

2. Associate Professor, Department of Transfusion Medicine & Hemotherapy, All India Institute of Medical Sciences, Mangalagiri, Pin - 522503
Email: ischaitanyakumar@gmail.com

3. Assistant Professor, Department of Transfusion Medicine & Hemotherapy, All India Institute of Medical Sciences, Mangalagiri, Pin - 522503
Email: anandbodade5@rediffmail.com

4. Assistant Professor, Department of Physical Medicine and Rehabilitation, All India Institute of Medical Sciences, Mangalagiri, Pin - 522503
Email: dramol.pmr@aiimsmangalagiri.edu.in

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Correspondence to:

I S Chaitanya Kumar

Associate Professor

Department of Transfusion Medicine & Hemotherapy,

All India Institute of Medical Sciences, Mangalagiri, Pin - 522503

Email: ischaitanyakumar@gmail.com

Abstract

Hemovigilance terminology is entitled to the surveillance of adverse reactions that could be encountered by blood donors and untoward effects of blood transfusion in a recipient [1]. This is a broad-spectrum aspect of blood transfusion services (BTS) as it begins from the collection of blood to the transfusion of the same to a recipient. There are a number of quality steps involving various sections of blood banking while a unit of blood is collected for the purpose of blood transfusion. Hemovigilance programmes are currently in place in a vast majority of countries to monitor donor and transfusion reaction in the view of prevention of future occurrences. This article aims to review the various hemovigilance systems across the world.

Keywords

Hemovigilance, blood donor, blood transfusion, recipient

Introduction

Hemovigilance is a set of surveillance procedures that covers the whole transfusion chain from the collection of blood from the blood donor and its components to the follow-up of its

recipients. Hemovigilance is defined to collect and analyse information on unexpected or undesirable events resulting from the therapeutic use of labile blood products and to prevent its future occurrence and recurrence [2]. Proper analysis of donor complications and transfusion reactions, incidents and events are essential to identify contributing factors. Hemovigilance is an essential tool to understand the clinical consequences of transfusion of blood and blood components, and to develop and implement actions to prevent further recurrence.

History

The word 'hemovigilance' was coined in France and is derived from the Greek word 'haema' (means blood) and the Latin word 'vigilans' (means watchful) [1].The first blood transfusion attempts in the 17th century were attempts to transfuse humans with blood of animals for all kinds of illnesses. However, in 18th century the French King Louis XIV forbade the transfusion of animal blood to humans by law because it was considered to be too dangerous [3]. In the 19th century, Henri Leacock and James Blundell pioneered human-human transfusion as a lifesaving therapy for severe blood loss [4]. Towards the end of the 1980s, the transmission of infections by blood created the need for a greater awareness on the safety of blood and pioneer work on hemovigilance started in France in 1992 with the set-up of monitoring systems by Blood Transfusion Committees, resulting in a national hemovigilance network in 1994 [5].

Hemovigilance programmes of various countries

Initial hemovigilance programmes came into existence primarily to improve patient safety because of the fact that blood transfusion was identified as one of the major causes for transmissible infections. Later on, there was better understanding that the causes of transfusion related untoward effects may be found at all levels, from blood donor selection to the blood transfusion. The international hazard surrounding the infection of the blood components by Human Immunodeficiency Virus (HIV) in the 1980s, together with the increasing risk of transfusion associated Hepatitis C Virus (HCV) led to the development of hemovigilance across many countries [6].

Japan

In Japan, the Japanese Red Cross Society (JRCS) founded an established hemovigilance system in 1993 [7]. Japanese Red Cross Society (JRCS) is the sole provider of labile blood products, and controls collection, processing and supply of blood products [8] and manages adverse reactions and infectious diseases [9]. The results of information gathered on reported cases are provided to medical institutions in order to help treating physicians to make accurate diagnosis and thereby improving quality and safety of blood products [9].

France

The "Agence Francaise du Sang" **(**AFS) was in charge of haemovigilance system, from 1994 onwards. The aim of AFS was to pick up and analyse all untoward effects of blood transfusion to prevent further recurrence [5]. Transfusion Incidents Reports (TIR) were centralised at the AFS level and the reporting is mandatory. In French Hemovigilance system, the blood centre physicians in every hospital performing transfusions were enrolled to

ISSN 2515-8260 Volume 09, Issue 07, 2022

responsibility of collection of transfusion reaction reports and report them to the local health authorities. Local authorities had to report to the AFS centralized hemovigilance cell.

United Kingdom (UK)

In United Kingdom (UK), Serious Hazards of Transfusion (SHOT) scheme was established in 1996 for reporting adverse events among patients. SHOT scheme is voluntary [10] and encompassed of all labile blood components issued by the four UK blood transfusion services namely National Blood Service [NBS] in England, Scottish National Blood Transfusion Service, Northern Ireland Blood Transfusion Service and the Welsh Blood Service [11].Participation in SHOT scheme is voluntary and strict confidentiality was assured for donors, recipients and reporters. SHOT scheme introduced an evidence-based strategy to improve patient safety via a proper reporting system. Increased adverse reaction reporting would improve standards of hospital transfusion practice, formulation of clinical transfusion guidelines, and training of rational use of blood among clinicians.

Netherlands

In 1996, hemovigilance was established in Netherlands. Transfusion Reactions in Patients (TRIP) was an independent foundation that aimed to collect, register, analyze and report on adverse effects of blood transfusion. This was a voluntary reporting system for transfusion safety and the prevention of untoward events [12].

America

The American Red Cross (ARC) has got an established hemovigilance system to report and analyze donor reactions [13]. The ARC has laid down its own surveillance programme that covers the hospitals served under ARC.

United States (US):

Blood Transfusion Services are constituted by various organisations like the American Red Cross (ARC), the Council of Community Blood Centers (CCBC) and America's Blood Centers (ABC). The Food and Drug Administration (FDA) takes care of the issues with regard to blood products and establishments. About 50% of all hospitals in the US are under ARC.

North America

Canada:

Two organisations are in place to take care of the activities related to blood transfusion: Canadian Blood Services (CBS) and Hema-Quebec (HQ). A core group would deal with the haemovigilance software issues and input into the software is hospital based [14].

Quebec

Quebec in the year 1998 passed a law creating Hema-Quebec, which is an independent establishment for the manufacture and distribution of blood products. Quebec hemovigilance system was established and participation was not mandatory [14].The hemovigilance system monitors adverse transfusion reactions, transfusion related incidents such as ‘‘incorrect blood component transfused’’ (IBCT), with or without adverse effects, and near-miss events. Data from the Quebec hemovigilance system proved to sensitize hospitals to the importance of reporting adverse transfusion events and thereby prevention [14].

Massachusetts

The National Healthcare Safety Network (NHSN) is a voluntary, Web-based surveillance system to report patient safety information in Massachusetts. Hospital based transfusion

centres can share their data they enter with external agencies to meet reporting requirements [15].

Ecuador:

BTS is handled by the Ecuadorian Red Cross Soceity, with government blood banks, communities and the Army. Ecuador has got more than 35 blood banks currently and some are hospital attached. Immense efforts are being carried out to establish a national hemovigilance system, but the progress is slow [2].

Brazil:

In 1999, the blood surveillance system was implemented by the National Health Service with the aim to ensure donor and patient safety [16]. The information gathered was used to identify risk factors, to improve the quality of blood products and manufacturing processes.

Europe

According to European Directives, Hemovigilance is considered as a surveillance tool and a quality measure to ensure transfusion safety [17].

Denmark

In 1998, the Danish Society of Clinical Immunology (DSKI) initiated the Danish Registration of Transfusion Risks (DART). DART system was organized as a voluntary system and all hospitals could report their adverse events with assured confidentiality [18].

Belgium

The organization of hemovigilance was under Federal Agency for Medicines and Health Products (FAMHP) in Belgium. Reporting to hemovigilance system was mandatory [19] and have showed a clear reduction of errors in connection with prescription and sampling leading to cases of incorrect blood component transfusion (IBCT) in three years of reporting. This was definitely the result of the wide implementation of the procedure of pre-transfusion blood grouping with comparison of blood samples of two different blood takings , thereby reduction of Wrong Blood in Tube (WBIT) [19].

Germany

In Germany, the Hemovigilance System into force in the year 1997. Rapid identification of serious adverse events of blood transfusion were identified at both local and national levels via hemovigilance systems. Germany has reached high standards in the` safety of blood products after the introduction of hemovigilance system [20].

Australia:

The Australian Red Cross Blood Service (ARCBS) has got a centralized national voluntary hemovigilance system. Data reporting would be in accordance with the National Blood Authority (NBA) and NBA would analyse and publish the results [2].

Hemovigilance programmes in developing countries

India

Hemovigilance program as an integral part of Pharmacovigilance Program of India (PvPI) at a national level has been launched on December 10, 2012. The four phases of Hemovigilance Programme of India (HvPI) were - initiation phase, expansion and consolidation phase, expansion and maintenance phase, and optimization phase [21]. Hemovigilance includes the proper identification, reporting, investigation and analysis of adverse reactions and events in

recipients and blood donors. The system also looks into the aspects of manufacturing processes and eventually errors and "near-miss events".

Centres under HvPI are blood centres located in Medical Colleges/ Institutes/ District Hospitals/ Private Hospitals and Stand-alone Blood Centres in India that are registered with the National Coordinating Centre (NCC). Haemo-vigil is the software indigenously developed by National Institute of Biologicals (NIB) for hemovigilance reporting & was officially launched on 24thJan, 2013 [22]. Haemo-vigil software has got separate portals to report donor reactions and transfusion reactions. Currently, infectious diseases are not included in HvPI.

China:

The first guideline on hemovigilance in China was released by Chinese Society of Blood Transfusion (CSBT) in the year 2013. In 2017, the working party on haemovigilance of CSBT was formed, for formulating policies to define standards and guidelines and to establish a national hemovigilance system[2].

Vietnam:

A National Blood Authority was formed in December 2001 for the centralization of adverse reaction reporting and thereby a national hemovigilance system [2].

Thailand:

The Red Cross society takes care of blood banking services in Thailand. They could achieve significant progress in the surveillance of the whole blood transfusion chain after introduction of hemovigilance reporting into blood transfusion services [2].

Malaysia

The hemovigilance program of Malaysia was launched in 2003 which is a voluntary system and is centralized. All adverse events, errors and near misses would be reported into the reporting portal[2].

South Africa:

Collection of adverse reaction data is in terms with the surveillance system having common elements with the UK- SHOT system. Currently, the reporting system in South Africa is voluntary [2].

Tunisia

The National Hemovigilance Program was started in 2007 and is mandatory that all adverse events needed to be reported [2].

International hemovigilance Network (IHN)

The IHN in association with International Society of Blood Transfusion (ISBT) Working Party on hemovigilance proposed standard definitions for hemovigilance system in the year 2011 [23].To further improve the safety of donors and recipients, an international database-International surveillance of transfusion associated reactions and events (ISTARE) has been created. The main goal of ISTARE is to capture all adverse reactions and incidents in recipients of blood and blood products that can certainly, probably, or possibly be attributed to blood transfusion. It also records adverse events in blood donors [24]. ISTARE helps to share the hemovigilance data across the whole world.

ISSN 2515-8260 Volume 09, Issue 07, 2022

Discussion

Among developing countries, some emerging economies are making good advancements in developing a structured and well-organized blood transfusion services. Some countries are making attempts to establish a national hemovigilance program. A few countries like South Africa, Malaysia, Thailand and Tunisia have already established hemovigilance program modeled similar to the developed world. Various types of models are formulated and implemented to suit the needs of various nations [25].

There are countries with mandatory reporting systems and voluntary systems as well. Mandatory system of reporting will make sure the incidence of transfusion reactions in a consistent manner whereas voluntary reporting systems will help to assess the enrolment of new participants in the reporting platforms. Voluntary reporting systems will suit more for developing countries as there may not always exist a centralised co-ordinated system of patient care services.

Hemovigilance systems of some countries includes only adverse transfusion reactions, whereas some has included donor reactions and infectious risk of transfusions reactions. As the working group of hemovigilance expands, more and more countries would come up with national or Red Cross-based reporting platforms.

Developing countries like India has presently achieved a well-established hemovigilance system which involves both donor reactions and transfusion reactions. Hemovigilance started in India with the enrolment of 90 blood centres in 2017 and this has risen up to 615 blood centres in the year 2017 [26]. This indicates the increasing awareness on hemovigilance reporting systems among the various blood centres across the nation. Being a voluntary reporting system, India could enumerate a good number of blood centres with active hemovigilance training programmes.

An effective hemovigilance programme would target to reduce the incidence of donor reactions, clerical and technical errors, laboratory side and bed side errors. Transfusion chain begins from the veins of blood donor and hence, changes should commence from the donor part itself to reinforce bed side transfusion practices.

There should be strategies to improve the awareness on the importance of hemovigilance among developing countries and countries with scarce resources. Hemovigilance is one of the various quality assessment tools in routine blood banking. It helps to gather individual institutional based information on a nationwide basis. The data thereby, analysed on an international basis via IHN; would provide recommendations to prevent the future occurrence of any untoward events.

Conclusion

Hemovigilance reporting systems have enhanced the transfusion safety incorporating both blood donor as well as transfusion recipient safety. Improved reporting system after implementation of an active surveillance would help to make necessary modifications in the blood component preparation and also to minimize clerical and technical errors at both laboratory side and patient side.

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