

Review Article

Haemovigilance as a quality indicator in transfusion medicine: Pakistan's perspective

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ABSTRACT

In transfusion medicine, the concept of haemovigilance has emerged during the last three decades. It is structured and systematic surveillance of the entire vein-to-vein transfusion chain and a powerful quality tool. Haemovigilance has become an integral component of transfusion medicine. It helps increase safety and improves quality during blood donation and blood transfusion, from the blood donor to recipient of blood and blood components. The haemovigilance can be successfully implemented and maximum benefit obtained if the data analysis and resulting conclusions are mutually shared with the shareholders. Although haemovigilance has proven to be an effective tool to influence policy development, it is not well established in Pakistan. The government's Safe Blood Transfusion Programme has taken key initiatives to introduce, support, and consolidate the haemovigilance system necessitating many changes, in the system, in the institutions, in attitude, and behaviour. The implementation of haemovigilance in Pakistan will require a major paradigm shift. It will be a stepwise or staged approach, starting from institutional to regional/provincial levels and ending at the national level.

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Haemovigilance is a set of processes that brings the entire vein to vein chain of blood transfusion under examination intending to document and avoid any untoward events in the transfusion chain from donor end to the recipient end, thus maximizing the donor recruitment and retention and making the provision of blood transfusion more efficient and safe.

According to the International Haemovigilance Network (IHN), Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components to their provision and transfusion to patients and 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 actions to prevent their occurrence or recurrence'.¹

Haemovigilance, at its core, is purely data record keeping and extrapolating the results to correct any malfunction in the blood transfusion services. The data obtained also forms the basis for renovating systems, revising policies and strategies, refining standards, and practices all adding to the safety of the blood transfusion chain.² The haemovigilance systems were triggered by the terrible experience with transfusion-transmitted HIV nearly four decades ago in the 1980s. The first reporting system was developed by France through a legislation in 1994.^{3,4} Soon after, many other European countries stepped

forward and passed similar legislation in line with the EU directives.⁵

The haemovigilance is no longer limited to patients getting a blood transfusion (recipients) but covers entire vein to vein transfusion chain⁶ including (i) monitoring the frequency of transfusion-transmitted infections in blood donors; (ii) collecting information on adverse events/reactions associated with blood collection (donor vigilance)⁷ or transfusion of blood components (recipient haemovigilance);⁸ and (iii) authenticating the transfusion of blood components to recipients. The haemovigilance reporting can be *hot* if the adverse events or reactions are immediately reported, or it can be *cold*, when the reporting is periodical, e.g. annual reports with data analysis and recommendations.

Haemovigilance is also a critical element of quality control in a blood system, allowing remedial and preventive actions, and for the continuous advancement of the quality and safety of blood, blood components and the transfusion process. Therefore, haemovigilance forms an essential part of quality management in blood transfusion services. Haemovigilance can be compared with the 'check' step of the PDCA cycle (plan – do – check – act), which is a four-step management technique applicable to the control and perpetual improvement of processes.⁹

The haemovigilance can be successfully implemented and maximum benefit obtained if the data analysis and resulting conclusions are mutually shared with the shareholders including hospital transfusion services, blood centre, clinical faculty, quality department, infection control department, nursing department, hospital transfusion committees (HTCs), and blood transfusion authorities (BTAs). The ultimate aim of a strong haemovigilance network is to identify the problem areas as well as successful interventions and connecting the data globally for a more coherent approach in the blood transfusion services.

The haemovigilance system can be centralized or decentralized.¹⁰ For a centralized haemovigilance model, there is a central haemovigilance headquarters that collects data from blood centres and hospitals responsible for managing the adverse event(s) in blood donors or recipients. Reports of the data analysis with feedback and recommendations are made available to all stakeholders nationally. In the decentralized haemovigilance model, there is no central body to gather data instead it may be organized at a lower level, e.g. province-wide or at a

state-level. International experience shows that haemovigilance works best in a centralized way.^{3,11} However, it is pertinent to mention here that regardless of the model adopted by a country, it has to be simple, confidential, and quick.

Haemovigilance has proven to be an effective tool to influence policy development,¹² yet it is mostly underdeveloped. During the last three decades, several countries have established haemovigilance systems to improve blood safety, but there are considerable differences in haemovigilance around the world, in terms of definition, organizational structures, state of development and implementation.¹³ Most of these systems are voluntarily but there are a few where the reporting of the reactions is mandatory as a statutory requirement. In most developed countries, the haemovigilance systems have been established as a hybrid of these two approaches.¹⁴

The World Health Organization (WHO) identifies the significance of haemovigilance as a cornerstone to recognize and prevent occurrence or recurrence of transfusion-related unwanted events, and to increase the safety, efficacy, and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient. Since 1975, WHO has passed several resolutions and decisions concerning blood safety and haemovigilance. WHO organized a global consultation on haemovigilance in 2012, where the Member States agreed on recommendations for establishing national haemovigilance systems.¹⁵ Subsequently WHO developed an aide-memoire¹⁶ on establishing a national haemovigilance system in 2015 and a guide¹⁰ to establishing a national haemovigilance system in 2016. This was followed by a regional consultation¹⁷ on Haemovigilance for the Eastern Mediterranean region States in December 2016 to assess the status, successes, and challenges of establishing and/or strengthening national haemovigilance systems.

Pakistan, a developing country of 220 million inhabitants, is located in the Eastern Mediterranean region of WHO. The country has a demand-driven fragmented blood transfusion system where services are provided by public or private hospital-based blood banks or stand-alone facilities. Blood banks carry out all or some of the processes of the transfusion chain, i.e. blood collection, testing, processing, storage, and distribution. There is generally no functional and spatial separation between manufacturing units (Blood Centres) and ordering units

(Hospital Blood Banks), which significantly affect the organization of services. It is estimated that 2.7 million blood donations are collected in the country annually from approximately 650 blood centres of varying workloads.¹⁸ An estimated one-fourth of the national annual blood collections are transfused to the transfusion dependant thalassaemia, major patients. If effective thalassaemia prevention, management, and control strategies are in place then this additional burden on the system can be curtailed.¹⁹

The hospital blood banks in the country provide 'all-inclusive' services, which tends to foster whole blood approaches, while donor management is largely 'outsourced' to the patient's family, requiring them to make available 'replacement' donors or to obtain blood units from the private sector or civil society organizations with corresponding safety risks. Some public sector (Armed Forces) and civil society organizations (larger NGOs or Blood Donor Organizations [BDOs]) assume initial functions of regional blood centres, while an unknown number of small laboratories provide unregulated and undocumented demand-driven services based on unclear prescription protocols. Principles of rational clinical use of blood still have to be adopted at the operational level. Due to the uneven access to blood in the presence of largely insufficient regulation, exploitation of the patients and families occur and unsafe practices also transpire. In some cases, this involves pilferage of blood, especially from the large public sector blood establishments.²⁰ The legal and regulatory environment under which blood transfusion services are provided is characterized largely by inaction on the part of the sector authorities (BTA) 'notified' but under-resourced. Human resources are not consistently trained and developed, and requirements differ across the provinces. Blood banks are managed alternatively by medical officers or pathologists, as blood bank services are often provided through general pathology laboratories.

Similar to many developing countries,²¹ the haemovigilance system is not well established and is relatively a new concept in Pakistan. Traceability is vulnerable, from donor to recipient and vice-versa, the identification of blood donors, blood donations, blood and blood components, transfused patients, and blood samples, is difficult in most instances. Notification of individual adverse reactions,²² whether in blood donors or transfused recipients is generally not done (only in a few places a notification system is in place, but analysis and

evaluation of available data are very weak and utilization of these data to initiate corrective and/or preventive actions is missing). The reporting of compiled data concerning donations and transfusions is sporadic in the vast majority of institutions. Although a considerable level of sensitization on transfusion-transmitted infections (TTIs) has already brought significant attention from healthcare professionals, still blood donors are not informed about their TTI positive reports and TTIs transmission occurring in patients are not reported thus no significant advances have been made to minimize preventable transfusion errors.

Donor vigilance, if existing at all, is primarily limited to documentation of severe adverse reactions in blood donors. As most donors are replacement, one-time donors, there is no proper mechanism to follow up on donors and delayed complications are likely to escape attention. Moreover, as regards donor vigilance, there are no mechanisms for data compilation and analysis, or necessary corrective and/or preventive actions.

Regarding the patient vigilance, most institutions have some kind of notification of adverse transfusion reactions in recipients, usually to their blood bank which also undertakes investigations, if deemed necessary. There is a dearth of proper training and awareness about the management of transfusion-related adverse reactions among health workers leading to under-reporting of transfusion adverse events. In most instances, these are limited to 'notifications' without proper follow up.

While a centralized, coordinated haemovigilance mechanism is missing, individual institutions are making in this direction, but individually and by their own methodologies. The key institution in hospitals, involved in haemovigilance and auditing the use of blood is the Hospital Transfusion Committees (HTCs). In the majority of settings, however, HTCs are non-existent and even if exist they are not functioning properly.

The concrete design of a haemovigilance system, its structure, flow of information, data analysis, and reporting, however, needs to be worked out. Any model from another country would not necessarily be feasible for Pakistan with its unique set of circumstances, particularly its decentralization of health,²³ the lack of central coordination, diversity of BTS models (centrally coordinated, as in the province of Punjab, versus fragmented) and service providers (public, private, NGOs, BDOs).

As blood safety continues to be among the government's core priorities within the health sector²⁴ and cognizant to the ground realities, the Government of Pakistan launched the nationally coordinated Safe Blood Transfusion Programme (SBTP) through a grant-in-aid by the German government.²⁵ The German support was the driving force and critical to kick-off the reform, develop guidelines and technical standards, and establish the nationwide modern infrastructure. In Phase I of SBTP (2010-16), a network of 10 Regional Blood Centres was established and equipped while 60 attached Hospital Blood Banks were renovated, equipped, and refurbished. Phase II (2017-20), involves additional infrastructure development and refurbishment in different cities (18 Regional Blood Centres).

The SBTP has taken key initiatives during the last decade to introduce, support, and consolidate the haemovigilance system necessitating many changes, in the system, in the institutions, in attitude, and behaviour. According to WHO¹⁰, the two foremost requirements for an effective haemovigilance system are the national blood policy and a legal framework. Keeping abreast of the global strategy, the SBTP, formulated a National Blood Policy and Strategic Framework (2014-20)²⁶ where haemovigilance was incorporated as a priority area to '*develop a comprehensive and nationwide haemovigilance system to monitor, evaluate, and improve clinical transfusion practice*'. This followed a laborious process of revising the blood safety legislation in all confederating units.²⁷ The revised legislative framework, enacted in three provinces so far, included haemovigilance as a pre-requisite for licensing of blood establishment. The central coordination of haemovigilance in each of the confederating units, however, is assigned to the respective Blood Transfusion Authorities (BTAs) who are being strengthened to ensure the implementation of haemovigilance at the provincial and state level.

Likewise, the establishment of the Hospital Transfusion Committee is now mandatory in every hospital and forms an integral part of the regulatory framework of a Blood Transfusion System, as well as a hospital. The law²⁸ enjoins the establishment of a Hospital Transfusion Committee in every hospital and states that '*the hospital administration will ensure rational clinical use of blood and blood components through their Hospital Transfusion Committees in accordance with guidelines adopted and endorsed by the Blood Transfusion Authority*'. Transfusion-related data, especially the types and frequencies of transfusion reactions and events at the

hospital level, are collected by the HTC and communicated to the BTAs.

The SBTP formulated and later updated the National Guidelines for Quality Control in Transfusion Medicine²⁹ in an effort to ensure the maximum safety of all procedures for donors, recipients, and staff in transfusion services. The document includes a chapter on haemovigilance with a basic introduction and key forms to be filled in for reporting an adverse event both in the donors and the recipients. The implementation of the document was made mandatory, through the Islamabad Blood Transfusion Authority, and a prerequisite for licensing in the Islamabad Capital Territory.³⁰

Lack of capacity has been identified as one of the main reasons for the BT sector 'underdevelopment' in Pakistan. Hence, the capacity building remained an incessant priority of SBTP. To sensitize, train and convince the workforce in blood service to understand that haemovigilance is vitally important when it comes to safety and quality, SBTP in collaboration with WHO, organized several capacity building workshops in different cities mostly facilitated by an international expert.³¹⁻³⁴ All such training echoed the basic concept of haemovigilance, i.e. to generate results and allow improvement of quality and safety.

The new blood system introduced by SBTP is gradually replacing and phasing out the current fragmented scattered system which promotes unsafe transfusions. The new system is being implemented not only in the new infrastructure being developed with the support of the German government but also in the existing blood centres. The exciting developments taking place in the Pakistan blood sector are keenly followed and supported by the international blood community. Pakistan received the country membership of the IHN and the collected haemovigilance data will in future be shared with the IHN. Currently, the data generated from individual large centres are presented at regional and international fora including annual congresses of the international society of blood transfusion³⁵ and annual seminars of the IHN.^{36,37} Similarly, SBTP regularly publishes its research work on all aspects of blood safety reforms especially haemovigilance, in reputed international and national research journals.³⁸⁻⁴⁰ The implementation of haemovigilance in Pakistan will require a major paradigm shift. It will be a stepwise or staged approach, starting from institutional to regional/provincial levels and ending at the central level.

Conclusion

The establishment of an effective haemovigilance system is a dire need of Pakistan because substantial risks with regards to blood donation and transfusion of blood and blood components exist and cannot be denied. Haemovigilance can help quantify these risks and also qualify them, leading to changes and improvement of quality and safety all along the blood chain, to the benefit of donors, patients, and staff.

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References

1. Wiersum-Osselton JC, Wood E, Bolton-Maggs PHB, Schipperus MR. Definitions in haemovigilance: guiding principles and current state of development of international reference definitions. *ISBT Science Series* 2014; 9(1): 91–97.
2. de Vries RR, Faber JC, Strengers PF; Board of the International Haemovigilance Network. Haemovigilance: an effective tool for improving transfusion practice. *Vox Sang.* 2011;100(1):60–67.
3. de Vries RR. Haemovigilance: Recent achievements and developments in the near future. *ISBT Sci Ser.* 2009;4:60–62.
4. Noel L, Debeir J, Cosson A. The French haemovigilance system. *Vox Sang.* 1998;74(Suppl 2):441–445.
5. Watson R. EU tightens rules on blood safety. *Br Med J.* 2005;331(7520):800.
6. Faber JC. Hemovigilance: Definition and overview of current hemovigilance systems. *Transfusion Alternatives in Transfusion Medicine* 2003;5(1): 237–245.
7. Jorgensen J, Sorensen BS. Donor vigilance. *ISBT Sci Ser.* 2008;3(1):48–53.
8. Agnihotri N, Agnihotri A. Active Hemovigilance significantly improves reporting of acute non-infectious adverse reactions to blood transfusion. *Indian J Hematol Blood Transfus.* 2016;32(3):335–342.
9. Tague NR. *The quality toolbox.* 2005, 2nd Ed. Cengage Learning. 390–392.
10. World Health Organization. A guide to establishing a national haemovigilance system, 2016. Available from <https://apps.who.int/iris/> [Last accessed 27 Jan 2020].
11. Vasudev R, Sawhney V, Dogra M, Raina TR. Transfusion-related adverse reactions: From institutional hemovigilance effort to National Hemovigilance program. *Asian J Transfus Sci.* 2016;10(1):31–36.
12. Hindawi SI, Badawi MA, Raj ET, Gholam KA, Al-Weail SO, Azher F. The use of transfusion quality indicators as a tool for hemovigilance system implementation at a tertiary care center in Saudi Arabia. *Saudi Med J.* 2016;37(5):538–543.
13. Faber JC. Worldwide overview of existing haemovigilance systems. *Transfus Apheresis Sci.* 2004;31:99/110.
14. Proposed standard definitions for surveillance of non-infectious adverse transfusion reactions. International haemovigilance network 2011. Available from: http://www.isbtweb.org/fileadmin/user_upload/WP_on_Haemovigilance/ISBT_definitions_final_2011_.pdf. [Last accessed 27 Dec 2019].
15. World Health Organization. Global consultation on haemovigilance report, 2012. Available from <https://www.who.int/bloodsafety/haemovigilance/haemovigilance-report.pdf> [Last accessed 24 Dec 2019].
16. World Health Organization. Aide-memoire on establishing a national haemovigilance system, 2015. Available from https://www.who.int/docs/default-source/searo/blt/am-national-haemovigilance-system.pdf?sfvrsn=eb752a58_2 [Last accessed on 27 Feb 2019].
17. WHO events addressing public health priorities: Regional consultation on haemovigilance. *E Mediterr Health J.* 2017;23(8): 581–583.
18. Zaheer HA, Waheed U, Tahir S, Nasir K. National blood banks data collection report (2018). Safe Blood Transfusion Programme, Government of Pakistan. Available from <https://www.sbtg.gov.pk/wp-content/uploads/2019/10/National-Data-Collection-Report-2018.pdf> [Last accessed 5 Jan 2020].
19. Zaheer HA, Waheed U, Abdella YE, Konings F. Thalassemia in Pakistan: A forward-looking solution to a serious health issue. *Glob J Transfus Med* 2020;5(1): 108–110.
20. Zaheer HA, Waheed U, Nasir K, Tahir S. Annual Report Safe Blood Transfusion Programme. 2019. Available from <https://www.sbtg.gov.pk/wp-content/uploads/2020/02/Final-Report-2019.pdf> [Last accessed 27 Jan 2020].
21. Ayob Y. Hemovigilance in developing countries. *Biologicals.* 2010;38(1):91–96.
22. Delaney M, Wendel S, Bercovitz RS, Cid J, Cohn C, Nancy M Dunbar NM, et al. Transfusion reactions: prevention, diagnosis, and treatment. *Lancet.* 2016;388(10061):2825–2836.
23. Nishtar S, Boerma T, Amjad S, et al. Pakistan's health system: performance and prospects after the 18th Constitutional Amendment. *Lancet.* 2013;381(9884): 2193–2206.
24. Pakistan National Health Vision 2016-25. Ministry of National Health Services, Regulations, and Coordination, Government of Pakistan.
25. Zaheer HA, Waheed U. Blood safety system reforms in Pakistan. *Blood Transfus.* 2014; 12(4): 452–457.

26. Safe Blood Transfusion Programme, Government of Pakistan. National Blood Policy and Strategic Framework (2014-20). Available from <http://sbtp.gov.pk/wp-content/uploads/2019/06/nbp-nsf-2014-20-final-2-1.pdf> [Last accessed 27 Jan 2020].
27. Zaheer HA, Waheed U. Legislative reforms of the blood transfusion system in Pakistan. *Transfus Med.* 2014;24(2):117-119.
28. Punjab Blood Transfusion Safety Act 2016, Act XLVI of 2016. Punjab Gazette (Extraordinary). Available at http://punjablaws.gov.pk/laws/2664.html#_ftn1 [Last accessed 20 Dec 2019].
29. Zaheer HA, Ahmed S, Waheed U, Wazeer A, Saba N. National guidelines for quality control in transfusion medicine. 3rd Edition; 2020: Safe Blood Transfusion Programme, Ministry of National Health Services, Pakistan.
30. Waheed U, Hasan SI, Wazeer A, Zaheer HA. The status of blood safety in Islamabad, Pakistan. *Ann. Pak. Inst. Med. Sci.* 2016; 12(4):209- 214.
31. Safe Blood Transfusion Programme, Government of Pakistan. National Consultation on Blood Donor Management Workshop Report, 2017. Available from <https://www.sbtp.gov.pk/publications/seminar-workshop-reports/> [Last accessed 27 Dec 2019].
32. Safe Blood Transfusion Programme, Government of Pakistan. Regulatory and Quality Initiatives in Transfusion Medicine Workshop Report. 2015. Available from <https://www.sbtp.gov.pk/publications/seminar-workshop-reports/> [Last accessed 27 Dec 2019].
33. Safe Blood Transfusion Programme, Government of Pakistan. Quality Management in Blood Transfusion Services Workshop Report, 2014. Available from <https://www.sbtp.gov.pk/publications/seminar-workshop-reports/> [Last accessed 27 Dec 2019].
34. Safe Blood Transfusion Programme, Government of Pakistan. Quality Control and Haemovigilance in Transfusion Medicine Workshop Report, 2016. Available from <https://www.sbtp.gov.pk/publications/seminar-workshop-reports/> [Last accessed 27 Dec 2019].
35. Waheed U, Zaheer HA. Establishment of donor Haemovigilance system in blood banks of Islamabad, Pakistan. *Vox Sanguinis.* 2015; 109 (Suppl. 1):148-149.
36. Waheed U, Zaheer HA. Donor vigilance in blood transfusion services, Pakistan Institute of Medical Sciences, Islamabad, Pakistan. *Blood Transfus.* 2014; 12(Suppl. 2): s457.
37. Bolton-Maggs PHB. Conference report: International haemovigilance seminar and the SHOT annual symposium, 10-12 July 2018. *Transfus Med.* 2019;29(4):247–252.
38. Waheed U, Taimoor M, Naseem L, Zaheer HA. Clinical audit of fresh frozen plasma usage in a tertiary care hospital of Islamabad, Pakistan. *Glob J Transfus Med.* 2016;1(2):61-65.
39. Waheed U, Saba Ne, Wazeer A, Arshad M, Zaheer HA. Epidemiology of syphilis in blood donors in Pakistan. *Glob J Transfus Med.* 2020;5(1):100-101.
40. Waheed U, Zaheer HA. Evaluation of deferral pattern among the blood donors in Islamabad, Pakistan. *Glob J Transfus Med.* 2016;1(2):81-84.