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Managing haemovigilance at hospital and national level

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Background The haemovigilance system is an adverse event monitoring system established at the beginning of the last decade (1990s) in Europe. It then became a crucial part in quality system of blood transfusion in developed countries. However, there have been difficulties in taking farther steps in the direction of haemovigilance in developing countries up until now. In each country, a proposal of clear simple plan should be submitted to an official national body responsible of transfusion services in the country to get approval and support. The proposal should include aim and objective of having such system. The aim was to prevent the risk and/or to reduce the severity of adverse events, a written policy and standard to be followed, working group or committee to be responsible for the process of implementation, funds to cover system requirement and the running cost of the system. The decision must be taken to apply the haemovigilance system as voluntary or mandatory process according to the need of the country. At national level, the ministry of health (MOH) or the National Blood Authority (NBA) should ensure that bidirectional traceability is maintained from donor to patient and vice versa. In addition, they should ensure that mechanisms are in place for data collection, monitoring, analysis, reporting, evaluation and assessment.

Conclusion Haemovigilance should be part of quality management systems of blood centres and healthcare institutions and should result in improved policies, procedures and practices in the blood transfusion chain.

Key words: adverse events, haemovigilance system, quality system

Introduction

The term 'haemovigilance' was introduced for the first time in 1991 in France in parallel to the pre-existing word 'pharmacovigilance'. It was originated from the Greek word 'haema' meaning blood and the Latin word 'vigilans' meaning watchfulness. The main purpose of implementing the haemovigilance system was to analyse all undesirable and adverse events of blood transfusion by optimizing their cause in order to prevent occurrence and recurrence [1]. Haemovigilance is a safety concept which refers to a system of set measurements used to collect data on adverse effects of transfusion. It involves a continuous surveillance of all the procedures in the transfusion chain from the blood donor to the recipient of the blood components, in order to improve the safety of both groups [2–5]. In developed countries, the systems of haemovigilance have shown promising outcome in terms of improving the safety of blood transfusion compared with the use of medicinal drugs, and hence, blood components have reached a high safety standard [1]. Haemovigilance is now universally recognized to play an integral part of safety in blood transfusion, and thus, increasing attention is being paid to effectively implement it in many countries. The WHO Global Database on Blood Safety Summary (haemovigilance data for 2011–2012 and 2012–2013 report) indicated that a national haemovigilance system was present in 13% of low-income countries, 30% of middle-income countries and 78% of high-income countries. Therefore, efficient execution of national haemovigilance system is greatly required in order to provide an evidence-based improvement in the safety of blood transfusion practice globally [5–9].

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There are several challenges that can affect and delay in implementation of haemovigilance at hospital or national level such as lack of support from authorities, lack of resources and difficulties in transforming cultures to maintain a blame-free environment when adverse events are reported. In order to overcome these challenges, a basic haemovigilance system is required to be adopted in each facility where blood donation and transfusion are performed. In addition, the successful establishment of haemovigilance systems in developing countries can be facilitated through awareness, education and training programme for all professionals working in blood transfusion [10].

Managing haemovigilance system at national level (NHS)

The aim of haemovigilance was to ensure high quality for blood transfusion by applying methods such as identification of errors, adverse events incidents and reactions used to take corrective measure like inquiry of complaints, traceability systems, alert systems, notification systems and audits of practice. It is crucial to make haemovigilance system more reliable by constantly improving the safety and quality of the blood transfusion process from blood donors to recipient patients and vice versa (bidirectional tracking system). In this regard, the objectives are directed towards receiving and following up of reports from hospitals on adverse events with regard to blood components and providing feedback information confidentially and advising on the follow-up action necessary for the improvement of the process. In other words, observing, recording, reporting and analysing the adverse events and incidents in the blood transfusion chain and making corrective measure from the past learned lessons to take action to avoid repetition or recurrence of such undesirable episode [11]. For this purpose, it is necessary to offer adequate and advanced training to hospital staff and haemovigilance officers under the haemovigilance awareness programmes as well as provide scientific recommendations of adverse reaction reports. Moreover, it is essential to support the developmental and improvement procedures of clinical transfusion guidelines and hospital practice.

Haemovigilance programmes are linked to International Haemovigilance Network (IHN), which presently has 28 members. The member states of the European Union have to implement haemovigilance programmes by reporting to a Central Office as per the commission directive. In most developing countries, except for few countries, which have published their reports on adverse reactions, a well-established haemovigilance system is lacking and there is lack of haemovigilance data.

In order to offer successful implementation and best services, haemovigilance programmes should be under effective leadership to provide competent authority and resources. In addition, dedicated professional team for effective communication, expert advice and recommendations are an indispensible need for greater co-operation towards providing best treatment with blood components or blood alternatives. We have to consider in establishing a haemovigilance systems the confidentiality, information management, training and education. In addition, there must be an effective infrastructure, adequate resources and co-ordination among the involved authority.

Road map for haemovigilance system at national level

In order to implement a haemovigilance system effectively and successfully, there is need to prepare a long-term road map at national level to fully achieve the objectives. This can be obtained through the simple phases as follows:

Phase I

A proposal on a haemovigilance plan should be required to set up through National Blood Transfusion Committee (NBTC) or equivalent body to the National Blood Authority (NBA) in order to get their approval for continuous support and involvement in monitoring the successful implementation of the haemovigilance programme.

Phase II

National Blood Authority should approve and prepare a set of national standards, policies on haemovigilance and clinical guidelines that must be followed strictly by all hospitals at national level.

Phase III

Formulation of a professional body or working group to be responsible for the process of implementation, assess and follow-up data collected from hospitals on adverse events and give recommendation for their improvement and safety measures.

Phase IV

The working group must be involved in arranging awareness; training and educational programmes on haemovigilance frequently for all staff engaged in blood transfusion chain and they must encourage staff in various ways to participate in such programmes. In addition to that, there must be an encouragement for the medical healthcare workers or medical staff who involves in blood

transfusion to support them to deliver correct reporting of errors in case of adverse events and be responsible to acknowledge the errors individually to fully create a blame-free culture [2, 12].

Haemovigilance standards

To implement an effective haemovigilance system, a set of national standards should be developed and followed by all hospitals.

(1) The National Authority for blood transfusion shall set quality and safety standards for the collection, testing, processing, storage and distribution of blood and blood components. The requirement for the so-called vein-to-vein traceability.
(2) Certain definitions related to haemovigilance and adverse events shall be in place by National Authority accordance with international guidelines and definitions of such events.
(3) The person who is responsible for the management of hospital blood bank or the assigned haemovigilance officer should notify to Hospital transfusion Committee with any adverse events related to the testing, storage and distribution of blood or blood components.
(4) Hospital Transfusion Committee (HTC) should be formed in each hospital and will be responsible for reviewing of all abnormal and adverse reactions and preparing recommendations in order to take future preventive measures to avoid such incidents or adverse event.
(5) National Haemovigilance Office should be formulated, and a panel of highly qualified scientific advisory group should be assigned by the National Authority to receive reports from hospital on all adverse events related to the collection, testing, processing, storage and distribution of blood or blood components and to develop the national recommendations and policies that can prove beneficiary in improving the overall quality and safety of blood transfusion in the country [12–13].

Haemovigilance policies

A national policies related to the haemovigilance system should be in place and must be uniformly directed to distribute the guide line to all hospitals for proper implementation. These policies can be developed and reviewed on regular basis through NBA and/or haemovigilance advisory group and may include the following:

(1) All adverse events related to transfusion chain should be collected, documented and reported manually or electronically by hospital staff (physicians and/or nurses) to the haemovigilance officer who will be responsible to report to HTC after analysis and investigation must be accomplished by blood bank authority for such events.
(2) Monthly report of all adverse events will be reviewed by HTC, and recommendation should be in place for improvement of safety and quality of transfusion chain. Serious adverse events or all adverse incidents and episode should be reported to the national haemovigilance office in due time, and moreover, annual haemovigilance reports must be submitted by all hospitals to the National haemovigilance Office (NHO).
(3) The haemovigilance advisory group should analyse and consider the adequate advice and must forward their recommendations for better practice to the all-participating hospitals on regular bases. A yearly anonymous report prepared by the advisory group should be generated to all participant hospitals to encourage reporting and improvement of practice through general recommendations.

Benchmarking and auditing of practice will eventually lead to the improvement of quality and safety of blood transfusion chain resulting into more reliability in hospital services which in turn help in establishing trust among donors and recipients [12].

Managing haemovigilance system at hospital level

A simple and effective haemovigilance system should be designed in order to implement blood transfusion policy and procedure in all hospitals. Management of haemovigilance system at hospital level should be applied through implementation of specific tasks necessary for the surveillance of transfusion therapy as follows:

(1) There must be a formulation of an active and vigilant working Hospital Transfusion Committee.
(2) Clinical guidelines should be formulated and implemented at local level through following the internationally approved guidelines with local experience input in order to be followed by medical staff.
(3) Policies and procedures on haemovigilance and on routine work should be prepared, implemented effectively and must be followed by the concerning staff.
(4) A system of ordering blood products should be developed with standardized forms requests.
(5) Quality indicators should be set up to measure the technical and clinical practice.
(6) The traceability process must be ensured including the confirmation of transfusion/destruction by medical staff.

(7) There must be a regular documentation of all steps involved in transfusion process.
(8) There must be an online system in place to report errors or adverse events or undesirable reactions/incidents.
(9) There must be a recommendation from the local governing body associated with haemovigilance monitoring to organize awareness, training and education programmes frequently for all medical staffs involved in the transfusion chain.
(10) It is crucial to co-ordinate the policies and activities related to haemovigilance at national and hospital level, and hence, the system needs efficient and dedicated leadership and governance.

A successful and effective haemovigilance system relies upon reporting of adverse events and analysing the errors and mistakes occurred during blood transfusion chain [3, 14]. Therefore, it is essential that a haemovigilance system operates in a non-punitive environment and that reporting should be confidential and anonymous. In order to take corrective and preventive measures (CAPA), there must be a clear-cut policy with regard to identifying gaps and mistakes or errors encountered by concerning medical staffs during the procedures. The implementation of this road map at hospital level or national level will eventually provide hospital with evidence-based knowledge for improvement of safety and quality of blood transfusion services.

Discussion

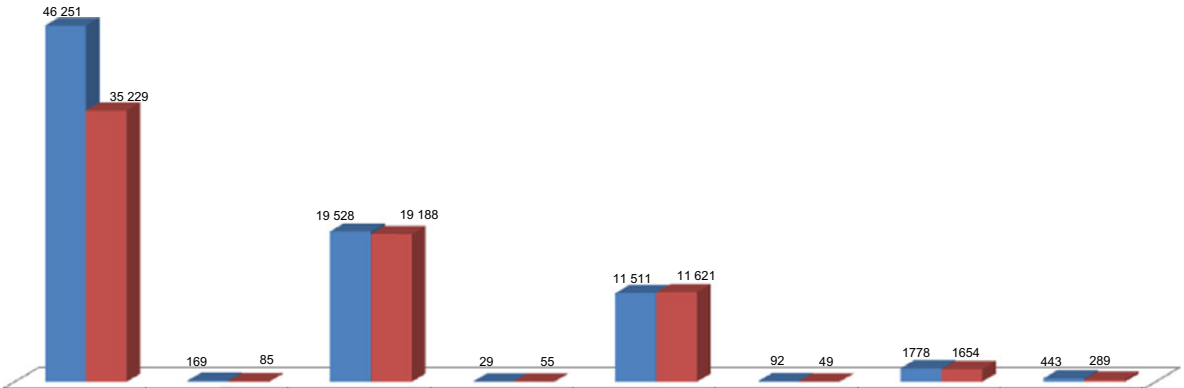
We should not reinvent the wheel but we have to learn from the experience of others. There are numerous haemovigilance systems that have been reported to collect data on complications in blood donors and/or recipient with a view to monitoring and improving blood safety. Many countries have national haemovigilance system in place. The guidelines and the standards for haemovigilance system are published and can be tailored to be suitable to local needs [5, 6, 8, 9].

Therefore, standardized definitions are essential for classifying and comparing data at all levels. In this regard, there are several definitions internationally adopted for haemovigilance that can be used by any blood transfusion centre or at national level with the aim of streamlining the reporting system and collection of data for subsequent analysis and improvement in haemovigilance system. Hence, there must be universally accepted standardized definitions that can be used locally and agreed upon at national level. Some of these definitions are summarized in Table 1 [2, 4].

An established haemovigilance system will have a potential impact on best possible blood usage. In spite of the awareness among medical staffs and apart from vital indications, the effectiveness of blood transfusions is often not determined, not fully established, and hence, it has resulted in a significant decrease in the use of blood products as reported by most of the haemovigilance systems. In order to comprehend this development, the surveillance of proper or optimal use of blood in a more detailed way, for example through the collection of a set of indicators that may be provided easily by most hospital information systems, has to be initiated. At the same time, audit methods should be adapted to measure and analyse critical parameters for optimal blood use, such as compliance with guidelines.

Table 1 Showing the terms and standard definitions on haemovigilance

S. No.	Term	Definition
1	Adverse event	Any unfavourable reaction to the donor or the recipient of blood. It also includes any incident, which can affect the safety of staff, donor, recipients or other patients.
2	Transfusion reaction	It is a serious complication that can occur following a blood transfusion. Such a reaction occurs when red blood cells that were transfused are destroyed by the recipient's immune system.
3	Donor reactions	These are adverse reactions that may occur to the donor during or at the end of blood collection. The donor's reactions may be local or systemic.
4	Near miss	It is an error or deviation from standard procedures that is discovered before the start of actual transfusion.
5	Incident	This term refers to any adverse event that take place in the transfusion chain or process The incident can lead to a harm to the recipient, donor or staff.
6	Rapid alert system	It is a procedure for immediate reporting of any emerging infection or hazard to blood transfusion, which can affect the safety of staff, donors or recipients.
7	Imputability	Assessing the strength relationship between the blood transfusion and adverse reaction following the completion of investigation is called imputability. It can be categorized into various types according to the strength of assessment like definite, probable, possible, doubtful, ruled out and not determined. When imputability is doubtful or ruled out, routine reporting should be avoided (2–5)



	Total no of request/ specimen	Incidents	Total no of transfusion	Transfusion reactions	Total no of donation	Donor reactions	Total wastage(Expired, Serology Pos, Indate wastage)	Indate wastage
2012	46251	169	19 528	29	11 511	92	1778	443
2013	35229	85	19 188	55	11 621	49	1654	289

Fig. 1 Haemovigilance comparison chart of year 2012–2013 at University Hospital, Jeddah.

Nevertheless, it is expected that establishment of a haemovigilance systems and presence of the haemovigilance officers in hospitals will contribute also to the surveillance of optimal blood use.

In the Kingdom of Saudi Arabia, blood transfusion reaction is reported yearly by all hospitals to MOH and recently donor reaction was also reported. Although there is still no proper haemovigilance system nationally, the proposal and plan for having a national haemovigilance system has been discussed in the National Committee for Blood Transfusion and Stem Cell Transplantation and was submitted to higher authority for their approval and support.

At hospital level, the Blood Transfusion Service (BTS) in King Abdulaziz University Hospital (KAUH) in Jeddah was one of the few centres in the Middle East that has initiated the implementation of a haemovigilance system. In addition to the mandatory reporting of transfusion reactions, KAUH Blood Transfusion Services also voluntarily collects data on donor complications and errors or incidents through using quality indicators, as a measure for implementation of haemovigilance system. For example, our surveillance data on haemovigilance for 2012–2013 showed improvement in blood transfusion practice locally through using quality indicators as shown in Fig 1. For errors and incidents in the transfusion chain, further work is necessary to improve comparability of data between haemovigilance systems [14].

In conclusion, haemovigilance system should be an essential part of national health services.

The best approach for those centres that are aiming to develop a haemovigilance system is to start with a simple proposal plan to be implemented locally with the support of the country's National Blood Authority (NBA). Therefore, based on my experience locally, I recommend to start with a simple plan and work on its implementation then move forward and upgrade the system to improve safety and quality of blood transfusion services in the country.

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