

The use of transfusion quality indicators as a tool for hemovigilance system implementation at a tertiary care center in Saudi Arabia

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ABSTRACT

الأهداف: الإبلاغ عن تجربة استخدام لمدة عامين لمؤشرات الجودة المتعلقة بنقل الدم كوسيلة لتفعيل نظام اليقظة في نقل الدم.

الطريقة: تم جمع المعلومات بأثر مستقبلي خلال الفترة ما بين 2012 و 2013م في مستشفى جامعة الملك عبد العزيز بجدة، المملكة العربية السعودية. تضمنت المعلومات ما يلي: المضاعفات التي تعرض لها المتبرعون بالدم، المضاعفات التي تعرض لها المرضى المستقبلون للدم، فاقد البلازما الطازجة المجمدة (FFP) خلال فترة الصلاحية، والأخطاء والحوادث المتعلقة بطلبات الدم والعينات المرتبطة بها. تم جمع المعلومات بشكل مستقبلي ربع سنوي وعرضها على لجنة نقل الدم بالمستشفى (HTC) لمراجعتها.

النتائج: كان عدد المتبرعين بالدم 23,132 متبرعا خلال فترة الدراسة. تم الإبلاغ عن مضاعفات حدثت ل 148 متبرعا، بنسبة مقدارها 0.63%. تم الإبلاغ عن مضاعفات صاحب 84 حالة نقل دم لمرضى. كانت معظم التفاعلات من نوع الحساسية (79.7%). تم الإبلاغ عن أخطاء أو حوادث متعلقة ب 0.3% من مجموع طلبات نقل الدم والعينات المرتبطة بها. كانت نسبة الفاقد من فاقد البلازما الطازجة المجمدة خلال فترة الصلاحية 21.3% من مجموع الفاقد من البلازما الطازجة المجمدة. راجعت لجنة نقل الدم بالمستشفى المعلومات المتعلقة بنظام اليقظة في نقل الدم بانتظام وتم اتخاذ إجراءات لزيادة الإبلاغ وتحسين السلامة.

الخلاصة: أدى استخدام مؤشرات الجودة كوسيلة لبناء و تفعيل نظام اليقظة في نقل الدم إلى فهم أفضل للمناطق التي تحتاج إلى تحسين لرفع مستوى الجودة والسلامة.

Objectives: To report 2-years experience of using transfusion-related quality indicators as a tool in hemovigilance system implementation.

Methods: The study was carried out between 2012 and 2013. Blood transfusion service data were prospectively collected at King Abdulaziz University Hospital, Jeddah, Saudi Arabia. Donor reactions, transfusion reactions,

fresh frozen plasma (FFP) in-date wastage, incidents, and errors pertaining to orders, or requests were collected quarterly and prospectively and forwarded to the Hospital Transfusion Committee (HTC) for review.

Results: Donor population consisted of 23,132 donors. One hundred and forty-eight donor reactions were reported, resulting in a rate of 0.6%. Eighty-four transfusion reactions were reported and most were allergic reactions (79.7%). Errors or incidents were reported with approximately 0.3% of the total number of submitted samples/request forms. The FFP in-date wastage was 21.3% of the total FFP wastage. The HTC regularly reviewed the hemovigilance data and reporting; and safety improvements were implemented.

Conclusion: The use of quality indicators as a tool for developing and implementing a hemovigilance system provided a better understanding of improvement areas for continuous progress in quality and safety, and is expected to enhance these features along the blood transfusion chain.

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The production and transfusion of blood components is a complex process that can be associated with significant risks to blood donors and transfused patients. Tracking the adverse events assists with the planning of methods to reduce these potential

risks. The set of surveillance procedures covering the complete transfusion chain from the collection of blood and its components to the follow up of the recipients is called hemovigilance.¹ Such practice is intended to assess and collect the information on the undesirable and unexpected effects resulting from the collection and use of blood products, and to prevent their occurrence and recurrence.¹ This concept was first coined in 1991 in France.¹

The transfusion of blood components has long been recognized as being associated with significant risks.² In the late 1980s, the transmission of hepatitis C virus and human immunodeficiency virus through transfusions alerted health care professionals to the dire need for systematic surveillance of adverse reactions to transfusions.³ Many different national hemovigilance system models exist, for example, the nationwide scheme implemented in France, where reporting all adverse events despite their severity is mandated by law.⁴ However, the hemovigilance scheme in the United Kingdom, Serious Hazards of Transfusion (SHOT), started as a voluntary system in which only limited errors and serious reactions were reported.⁵ Serious Hazards of Transfusion plays an important role at national and international levels, and many countries consult with SHOT when they are developing their own hemovigilance systems. Currently, most state members of the European Union have established hemovigilance systems at various levels.⁶ After forming the European Hemovigilance Network in 1998, the International Hemovigilance Network (IHN) was formed in 2009.⁷ In February 2013, IHN had 32 members.⁷ However, 57 countries reported having national hemovigilance systems according to the World Health Organization (WHO) Global database on blood safety report in 2008.⁸ Transfusion medicine experts from Arab countries and the Gulf Cooperation Council (GCC) realized the benefits of well-developed hemovigilance systems and are taking further steps to planning and implementation of such systems.^{6,9} In Saudi Arabia, a proposal and plan for developing a national hemovigilance system have been discussed by the National Committee for Blood Transfusion and Bone Marrow Transplant (2014). The Blood Transfusion Service (BTS) at King Abdulaziz University Hospital (KAUH) in Jeddah was one of the first few centers in the

Middle East to implement an effective hemovigilance system. Aside from the mandatory annual reporting of transfusion reactions to the Ministry of Health (MOH) by all hospitals, KAUH BTS also voluntarily collects data on donor complications, as well as errors, and incidents. The use of quality indicators to build the hemovigilance system facilitated the development of such a system and allowed areas requiring improvement to be tracked and identified. This study aims to report the experience of KAUH in using quality indicators as a tool for implementation of the hemovigilance system and to share the rates of reported adverse reactions and incidents for benchmarking purposes, as similar data from the developing world are rare in the literature.

Methods. King Abdulaziz University Hospital, Jeddah, Saudi Arabia is a tertiary care academic center with a 760-bed capacity; it serves a large population of patients with hereditary hemoglobin disorders, as well as other medical, surgical, obstetrics, and pediatrics patients. The services offered by the BTS include collecting whole blood and apheresis blood components, manufacturing labile blood components, pre-transfusion testing, and issuing. Approximately 60% of packed red blood cell units (PRBCs) are leukoreduced and are mainly assigned to patients undergoing chronic transfusion regimens.

Before 2012, the BTS attempted implementing a hemovigilance system with the goal of capturing any adverse events occurring along the transfusion chain. The tool used was a single reporting form. Reporting rates were extremely low, and the procedure was not well utilized. In 2012, BTS started using the data, already being collected as quality indicators, to implement a functioning hemovigilance system. This report summarizes data that were prospectively collected as quality indicators for a 2-year period, between January 2012 and December 2013.

Donor eligibility criteria in our institution are in compliance with the American Association of Blood Banks (AABB) standards. Donors may donate whole-blood or may donate platelets through apheresis. Platelet apheresis donors are required to have had a successful whole-blood collection. In case a donor developed a reaction, hospital staff working in the blood donation area report the complications manually using specific forms (donor reaction forms). Donors are encouraged to report any adverse events to the BTS, particularly those events occurring within the first 24 hours after donation. Donor reactions are categorized according to the international definitions,

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and they are considered to be major reactions if they are linked to fainting or syncope.¹⁰ Donor reactions rates are calculated as the percentage of all adverse occurrences affecting the donors and are associated with the collection of blood and blood components to all donors who were eligible to donate and had the process of collection started, even if not completed.

Hospital policy mandates reporting adverse events of all severities associated with blood transfusions. Adverse transfusion reactions are reported electronically through the hospital information system (HIS) by physicians and nurses working in the clinical areas. The involved physician is required to fill the electronic form that contains a checklist of possible clinical findings. Once a transfusion reaction is reported, the HIS automatically orders a pre-determined list of laboratory tests and the specimen labels are made ready for collection. All reported transfusion reactions are reviewed by the director of BTS. The final comments from BTS director on the classification of the reported reaction and further recommendations appear to the clinical staff in the HIS. In addition, direct communication between the treating physicians and BTS director takes place when deemed necessary. Reactions rates are calculated as the percentage of all reported adverse reactions associated with transfusion, to units of all transfused blood components. Incident reports and fresh-frozen plasma (FFP) wastage is reported manually and electronically by staff working in BTS and clinical areas, and they are eventually collected electronically by the BTS supervisor.

For all parameters, data are analyzed quarterly as quality indicators by the BTS. Reports are presented to the hospital transfusion committee (HTC) and quality management department for analysis and advice for improvement, and they are then presented to the hospital management to act, or implement changes.

All reporting forms can be made available upon communication with the authors. The study was approved for publication by the Research Ethics Committee, Faculty of Medicine, King Abdulaziz University. We used MS-Excel statistics software (Microsoft, Redmond, WA, USA) data analysis.

Results. Donor reactions. The donor population (individuals who were eligible to donate and had the donation procedure initiated even if not completed) during the study period was 23,132 (11,511 donors in 2012 and 11,621 donors in 2013), most of whom (approximately 94%) were males. Donor reaction incidence rate was 1:150 donations (0.63%).

All reported donor reactions were vasovagal in origin. Most reactions were minor. Two donors (females) and 5 donors (4 males and 1 female) experienced major reactions in 2012 and 2013. All donors experiencing major reactions were first-time donors, and all major reactions occurred during (4 donors) or after (3 donors) the whole-blood collection. A single donor reaction was reported after the donor left the blood donation area, but he was still inside the institution. No major reactions occurred in association with platelet apheresis. Donors suffering from major reactions required medical assessment, but none required hospitalization. Donor reaction data are summarized in Table 1.

Transfusion reactions. A total of 39,045 blood components units were transfused in 2012 and 2013 including PRBCs, random platelets, single donor platelets, cryoprecipitate, and FFP. Among the transfusion recipients, adverse transfusion reactions were reported in 84 patients (0.2%). Most reported adverse events were acute: 17.9% of the reactions were febrile reactions and 79.7% were allergic in nature (urticaria and mild to moderate allergic reactions), along with 2.4% of the reactions being non-specific. Table 2 includes details on the transfusion reactions reported within the 2-year period. No transfusion-related mortalities were identified.

Incidents and errors. During the study period, there were 250 incident reports and errors that were recognized before the transfusion. These reports were classified into 3 categories: i) incidents related to component/test request forms: (n=37, 14.8%), including details not specified on the request form and incorrect orders of tests, or blood components. ii) Incidents related to sample collection: (n=198, 79.2%), including errors occurring in the clinical areas at the time of sample collection, such as blood collection in a tube with the wrong additives, hemolyzed samples, and request forms not being accompanied by samples, as well as deficiencies, and errors in identifying data (pre-analytical). iii) Incidents related to testing: (n=15, 6%);

Table 1 - Number of donors and donor reactions of submitted samples/request forms during the study period (2012 and 2013).

Year	Total number of collections	Number of donor reactions	Number of minor donor reactions	Number of major donor reactions
2012	11,511	92	90	2
2013	11,621	56	51	5
Total	23,132	148	141	7

these incidents describe events when current ABO and Rh typing did not match historical records, which was typically the result of pre-analytical or post-analytical errors. The incident and error data are displayed in Table 3.

Fresh-frozen plasma in-date wastage. During the study period, 9,070 units of FFP were transfused out of 9,802 units that were processed for transfusion. The remaining 732 units of FFP were thawed for transfusion, but were not transfused and were wasted in-date. The overall FFP in-date wastage was 21.3% of total FFP wastage. Details of the FFP in-date wastage are presented in Table 4.

Discussion. Transfusing blood components is a complex process that involves many health care team members, in addition to the donor and the recipient. The need to monitor incidents and adverse events occurring through the process is highly encouraged by international organizations, such as the WHO, the IHN, and the International Society of Blood Transfusion (ISBT). This fact was emphasized during a 2012 global forum attended by representatives from many countries. It was apparent that worldwide, hemovigilance systems are at varying levels of development. Many factors appear to impede advances in this area, such as lack of support from authorities, lack of resources, and

difficulty changing cultures to maintain a blame-free environment when adverse events are reported.⁵ The reported systemic donor reaction rates from our institution appears to be lower than similar recently published reports.^{10,11} No phlebotomy related local complications were reported at our institution, likely because of under-recognition or under-reporting. Interestingly, all reactions observed in female donors in our institution were major. The sample size is small, but this observation is worth monitoring, as risk factors may need to be explored.

As with local donor reactions, the phenomenon of under-reporting seems to affect transfusion reactions in our institution. The literature suggests that 1-3% of

Table 4 - Percentage of discarded units of fresh frozen plasma (FFP) in 2012 and 2013 classified according to the reason for discard.

Year	Percentage of discarded units (%)	Percentage of positive transmissible disease testing (%)	Percentage of expired units (%)	Percentage of units wasted in-date (%)
2012	40.25	6.47	23.75	10.03
2013	34.36	6.32	22.04	6
Total	36.3	6.24	22.3	7.74

Denominator for all values is the total number of manufactured FFP units.

Table 2 - Transfusion reactions of submitted samples/request forms during the study period (2012 and 2013).

Year	Number of transfused units	Febrile reactions	Allergic reactions	Non specific reactions	Total number of reactions	Percentage of transfusion reactions*
2012	19,568	6	21	2	29	0.1
2013	19,477	9	46	0	55	0.3
Total	39,045	15	67	2	84	0.2

Denominator is the total number of transfused units. Data are expressed as number.

Table 3 - Incidents and errors of submitted samples/request forms during the study period (2012 and 2013).

Year	Total number of requests and samples	Incidents related to requests	Incidents related to sample collection	Incidents related to testing	Total number of incidents	Percentage of incidents
2012	46,251	14	141	10	165	0.36
2013	35,229	23	57	5	85	0.24
Total	81,480	37	198	15	250	0.31

Denominator is the total number of requests and samples. Data are expressed as number.

transfusions are complicated by allergic reactions. The incidence of non-hemolytic transfusion reactions varies according to the type of component, but febrile non-hemolytic transfusion reactions (FNHTR) are reported to complicate 0.411% of transfused non-leukoreduced red blood cell units.¹²

Multiple potential factors might explain the apparent under-reporting of reportable transfusion reactions at our institution. Human factors include under-recognizing events, recall bias, fear of blame, disciplinary action, or litigation. The nature of the system, the reliance on passive reports, rather than active surveillance, certainly contributes to under-reporting. The phenomenon of under-reporting is not unique to our institution. There are many examples of low event reporting in the first few years of implementing a new hemovigilance system. For example, 65 adverse events were reported in 2008 through the National Hemovigilance Program in Tunisia, which was implemented in 2007.¹³ Approximately 172,000 units were transfused during the time frame.

A number of measures were introduced at our institution between 2012 and 2013 to improve the reporting rates for transfusion reaction, such as updating the hospital electronic patient information system to allow nurses to report transfusion reactions. This change increased the number of reported transfusion reactions from 2012 to 2013. However, it appears that severe transfusion reactions were not reported, likely because of under-recognition, as it may be challenging to identify such reactions in patients suffering from severe underlying illness. Another potential cause of under-reporting is the fear of reporting reactions when human factors (namely, clerical errors) are involved.

The following actions are recommended through HTC to address the issue of under-reporting of transfusion reactions and to improve quality: 1) continuously educating all health care workers working in clinical areas in terms of adverse transfusion reactions, their identification, and management, 2) ensuring that staff members in clinical areas have around-the-clock access to advice from a physician who is knowledgeable in transfusion reactions, 3) adopting a "just culture" in which staff members involved in incidents are only disciplined for intentional errors; more common errors must be handled through education and training, and 4) hiring a dedicated transfusion safety (hemovigilance) officer.

In terms of donor reactions, there has been an improvement in reporting rates over the course of 2 years, although no statistical analysis was performed to detect if that was a statistically significant difference.

Specific steps were taken to improve donor safety, such as encouraging donors to drink water before and after donating blood. Donors were provided with verbal and written messages describing possible adverse symptoms and potential reactions and the need to notify staff in the collection area to obtain further assistance. Fresh-frozen plasma wastage and error rates decreased after quality indicators data were reviewed in 2012, an action plan was implemented for staff training, and staff performance was followed up. Staff education and training is a fundamental part of an effectively functioning hemovigilance system. Monitoring error data and providing feedback to those involved will improve staff awareness on the importance of reporting errors and will help to ensure that the hemovigilance system is fully effective. The reporting of errors and near-misses is also essential to monitor transfusion safety and to help policy makers make informed decisions on the systematic introduction of instruments identifying patients and units of blood components.¹⁴

Study limitations. The retrospective nature of collecting data on reactions is recognized as a cause of under-reporting of events.¹⁵ In addition, no statistical analysis was performed to allow statistically significant changes to be identified. Despite these limitations, we share our experience to encourage other institutions considering implementation of a hemovigilance system and to consider using quality indicators as a useful tool.

In conclusion, reporting and following-up reactions, incidents, and adverse events within the first 2 years of the implementation of a quality-indicator based hemovigilance system led to better tracking of areas requiring improvements. Such improvements are expected to result in enhanced safety and quality. As transfusion professionals become increasingly aware of the need to implement functioning hemovigilance systems, the use of a similar model in other institutions would be a feasible method of initiating such a system. This process would improve the services provided to blood donors and patients.

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