Volume 20 Issue 53
Originally issued as K11

Global Journal of Medical Research: K
Interdisciplinary
Volume 20 Issue 11 Version 1.0 Year 2020
Type: Double Blind Peer Reviewed International Research Journal
Publisher: Global Journals
Online ISSN: 2249-4618 & Print ISSN: 0975-5888

Reporting and Monitoring of Transfusion Reactions in a Tertiary Care Medical College Hospital: A Prospective Study

By Dr. Nagalakshmi Narayana-Swamy, Dr. Shubha Praveen & Dr. Gramle Amol

Abstract- *Introduction:* Blood transfusions are one of the common procedures encountered in medical practice. A lifesaving intervention although associated with variable degree of risk. The present study was done to assess the effectiveness of haemovigilance in transfusion practice and to emphasise upon the need of transfusion safety.

Methods: This was a prospective study conducted at Sapthagiri Institute of Medical Sciences, Bangalore, India. Pamphlets were distributed in order to create awareness and initiate act of reporting. The adverse events reported were documented in terms of nature, outcome, severity of the event and causality assessment.

Results: A total of 14 (0.77%) suspected transfusion adverse events were reported by the haemovigilance and surveillance system established as part of the design during the study period. The incidence of transfusion events during this period was estimated at 7.6% per 1,000 blood components distributed. The majority of the patients who experienced a transfusion-related adverse event were females (n=11, 78.57%).

Keywords: *hemovigilance; blood transfusion reaction; leucoreduction; TRALI.*

GJMR-K Classification: *NLMC Code: WW 475*

REPORTINGANDMONITORINGOFTRANSFUSIONREACTIONSINATERTIARYCAREMEDICALCOLLEGEHOSPITALAPROSPECTIVESTUDY

Strictly as per the compliance and regulations of:

© 2020. Dr. Nagalakshmi Narayana-Swamy, Dr. Shubha Praveen & Dr. Gramle Amol. This is a research/review paper, distributed under the terms of the Creative Commons Attribution-Noncommercial 3.0 Unported License http://creativecommons.org/licenses/by-nc/3.0/), permitting all non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

Reporting and Monitoring of Transfusion Reactions in a Tertiary Care Medical College Hospital: A Prospective Study

Dr. Nagalakshmi Narayana-Swamy [α], Dr. Shubha Praveen [σ] & Dr. Gramle Amol [ρ]

Abstract- ***Introduction:*** Blood transfusions are one of the common procedures encountered in medical practice. A lifesaving intervention although associated with variable degree of risk. The present study was done to assess the effectiveness of haemovigilance in transfusion practice and to emphasise upon the need of transfusion safety.

Methods: This was a prospective study conducted at Sapthagiri Institute of Medical Sciences, Bangalore, India. Pamphlets were distributed in order to create awareness and initiate act of reporting. The adverse events reported were documented in terms of nature, outcome, severity of the event and causality assessment.

Results: A total of 14 (0.77%) suspected transfusion adverse events were reported by the haemovigilance and surveillance system established as part of the design during the study period. The incidence of transfusion events during this period was estimated at 7.6% per 1,000 blood components distributed. The majority of the patients who experienced a transfusion-related adverse event were females (n=11, 78.57%). The median age was 25 years (with a range of, 8–45 years). The majority of the adverse events occurred due to transfusion with packed red cells (64.29%) followed by transfusion due to platelets (35.71%).

Conclusion: Hemovigilance serves as an effective tool for safe transfusion practice. Its implementation and enabling awareness among physicians, patients about the need for transfusion safety is at need.

Keywords: hemovigilance; blood transfusion reaction; leucoreduction; TRALI.

I. Introduction

Blood is a sparse resource which improves health and is lifesaving. Blood transfusion services are critical for the treatment of medical conditions ranging from life threatening acute haemorrhage to recalcitrant anaemia. It is crucial to replace the lost components of blood expeditiously for reviving the health.

The first intra human blood transfusion was done in the 19th century. Since then, blood transfusion has been a lifesaving therapeutic option.[1] Practice of whole blood transfusion has been subsequently decreased and use of different components of blood specific to each of the conditions has been practiced according to the clinical need and requirement. However, it can occasionally be unsafe and result in a spectrum of adverse events.

Acute Transfusion Reactions (ATRs) occur within 24 hours of transfusion administration, although majority occur during or within four hours of transfusion.[2, 3] They can be immunologic and non-immunologic reactions.[4] Blood transfusion reactions occur as a result of ineffective donor selection, contamination with infectious agents and presence of irregular antibodies which may not be detected by pre-transfusion tests.[5]

The incidence of transfusion-transmitted diseases has decreased to minimum on account of effective screening procedure. However, the incidence of adverse events due to ABO incompatibility, human errors, alloimmunization, immunomodulation phenomena and bacterial contamination remain a matter of concern. Age and the type of blood component are also associated with a specific type of blood transfusion reaction.[6] The routine use of pretransfusion medications has helped in preventing certain transfusion reactions but there are no well controlled trials to support this evidence.

The concept of Transfusion related Cardiac-Overload (TRCO), Transfusion related Acute Lung Injury (TRALI) account for most common causes for morbidity and mortality. TRALI is now the leading cause of mortality after blood transfusion and the risk factors are known to be female sex, previous history of pregnancy and presence of anti-leukocytes antibodies in blood products.[7] The exact mechanism of TRCO is not known.

Any unfavourable event occurring in a patient during or after transfusion of blood and blood components and for which no other reason can be found is labelled as a transfusion reaction. These untoward effects vary from being relatively mild to severe.

Improved donor selection and antibody screening has definitely guaranteed a safe blood supply, still a variety of transfusion reactions are encountered. These reactions are mainly non-infectious in nature and may be acute or delayed in onset. Depending on their severity, causality assessment and

Corresponding Author α: PG Resident Ophthalmology, Vydehi institute of medical sciences and research center, Bengaluru.
e-mail: anushkanarayan5@gmail.com
Author σ: Professor and Head of Pharmacology, Akash institute of medical sciences and research center, Bengaluru.

© 2020 Global Journals

appropriate clinical response, acute reactions can be mild, moderate and severe or life threatening.

Haemovigilance is a systematic process of monitoring the transfusion related adverse events and adverse reactions throughout the transfusion process and aimed at ensuring transfusion safety.[8] It includes series of events ranging from monitoring, identification, and analysis of untoward adverse events in relation to blood transfusion.[9] It also helps to determine the trends of transfusion transmitted infections and need for surveillance of emerging infections.[10]

The purpose of this work is to show haemovigilance as an effective tool to improve transfusion safety by minimization of risks and to shed light upon the need for awareness regarding the process of blood transfusion.

II. Methods

A prospective study was conducted at Sapthagiri Institute of Medical Science and Research Centre, a Tertiary health care teaching Hospital, Bangalore. The study was carried out between June and July, after obtaining permission from the Institutional Ethical Committee.

Hospital personnel involved with dispensing and administering blood units were trained to give relevant information regarding the possible transfusion reactions related with blood transfusion. A Validated information pamphlet was distributed to the patient relatives/bystanders at the time of procuring the blood components from the blood bank. In addition, the telephone number of the person procuring the blood was also noted for future contact by the staff in charge.

The details in the pamphlet included information regarding transfusion process, possibility of adverse transfusion reactions, patient responsibility (to report adverse transfusion reactions to doctor) was provided in the pamphlet which will be bilingual (English and Kannada). Those who did not know these two languages were provided with a pamphlet in Hindi. The pamphlet also included the contact numbers of the student investigator and the Guide.

Patient/relatives and the staff in charge (treating doctor/nursing staff) were instructed to contact in-charge person immediately when any adverse reactions is noticed. Patients contacted after discharge and any missed /neglected adverse reactions were noted down.
Transfusion reactions that occurred were reported in the Transfusion Reaction Reporting Form (TRRF) for Blood and Blood products provided by IPC (Indian Pharmacopoeia Commission) under Pharmacovigilance Programme of India. The original copies of Transfusion Reaction Reporting Forms were sent to National Pharmacovigilance Centre and photo copies of the same were documented.

Patient information, transfusion product details, nature of adverse reactions, outcomes of the adverse reactions, severity of the event and causality assessment was documented.

Statistical analysis: Using Microsoft EXCEL

Inclusion criteria: All patients of either sex undergoing blood transfusion, irrespective of the disease.

Exclusion criteria: Reports not consistent with the definition shall be excluded.

Causality assessment according to a graded scale: [11]

a) Grade 4: death during or after transfusion
b) Grade 3: life threatening adverse reaction
c) Grade 2: long-term(transfusion transmitted infection and allo-immunisation)
d) Grade 1: minor adverse reaction
e) Grade 0: inappropriate transfusion of a labile blood product consecutive to one or several dysfunctions, without any clinical or biological consequence for the recipient

All 1830 reports that met the inclusion criteria were subjected to a quality evaluation to establish the completeness of all the information required. Microbiological investigations we're not done on any of the suspected blood components. Pre-transfusion haemoglobin values were reported in all the cases whilst post-transfusion haemoglobin values were not reported in seven (0.4%) cases.

III. Results

A total of 1830 blood components were distributed during the study period from 1st of June 2015 to 31st of July 2015, giving an average monthly/weekly distribution of 915/229 components. Of these blood components 664 (36.28%) were distributed as packed red blood cells, 25 (1.37%) as whole blood, 169 (9.23%) as fresh-frozen plasma and 972 (53.11%) as platelet concentrates as projected in Figure 1. There were no cryoprecipitate and paediatric packs dispatched.

© 2020 Global Journals

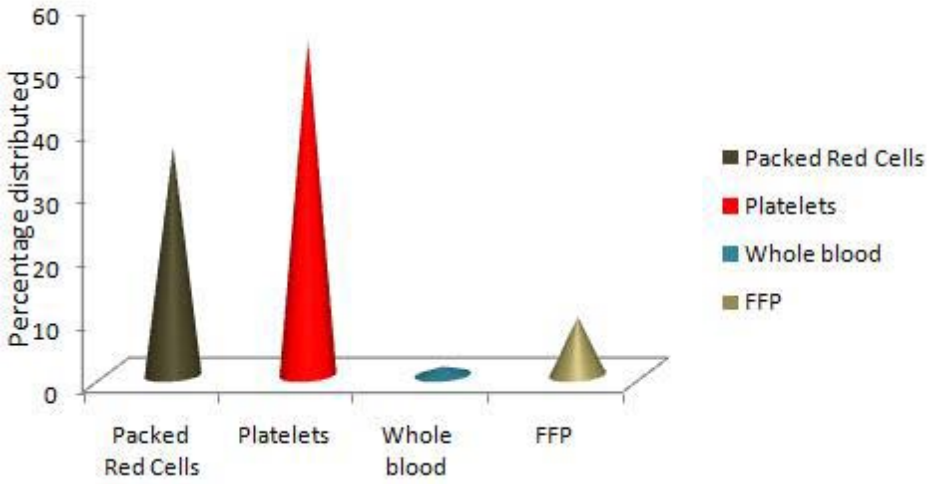


Figure 1: Graphical representation of different blood components distributed in study period

A total of 14 (0.77%) suspected transfusion adverse events were reported by the haemovigilance and surveillance system established as part of the design during the study period. On account of effective training of the reporting personnel all the reports met the inclusion criteria and were included in the analysis. The incidence of transfusion events for this period was estimated at 7.6% per 1,000 blood components distributed. The number of reports varied between 06cases in the month of June and 08 cases in the month of July. The majority of the patients who experienced a transfusion-related adverse event were females (n=11, 78.57%). The median age was 25 years (range, 8–45 years). The majority of the adverse events occurred due to transfusion with packed red cells (64.29%) followed by transfusion due to platelets (35.71%). The frequencies and incidences of transfusion adverse events by each category are shown in Table 1 and Figure 2.

Table 1: Summary of Transfusion Reactions during the study period

Transfusion Reaction	Frequency (%)
Acute Transfusion Reaction (FNHTR)	4 (28.57%)
Hypersensitivity	3 (21.43%)
Unclassified	7 (50%)

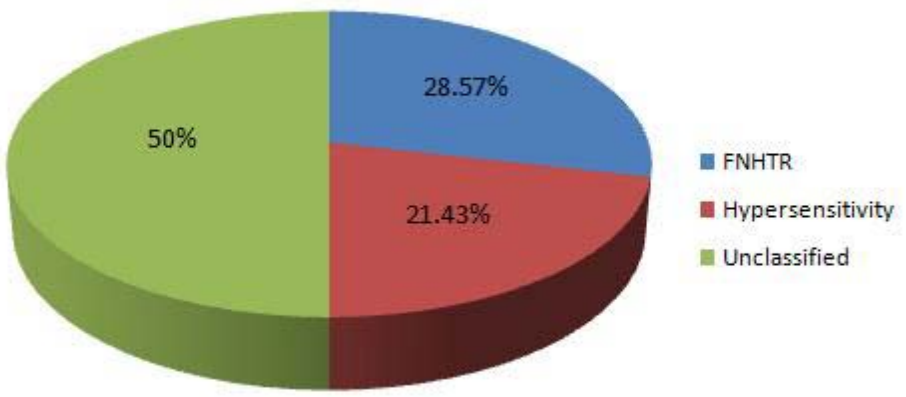


Figure 2: Graphical representation of the type of Transfusion reactions.

© 2020 Global Journals

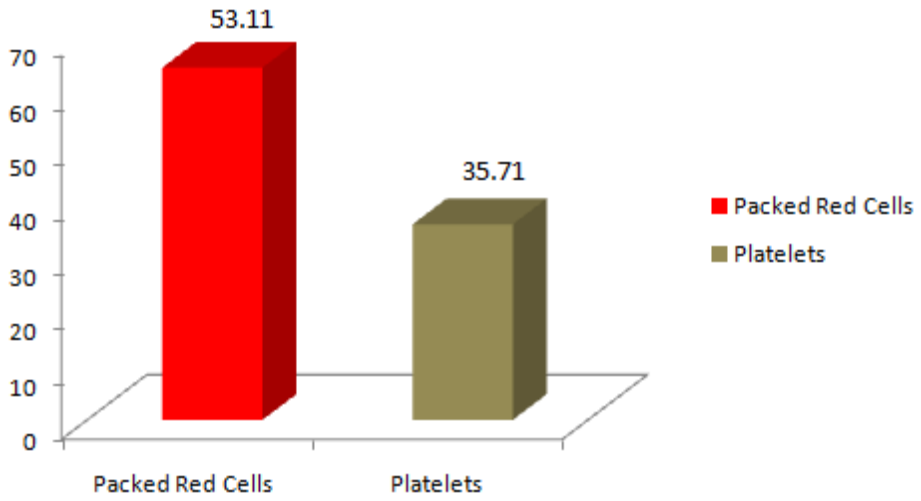


Figure 3: Graphical representation of percentage of transfusion reactions based on blood Components

The symptoms of acute transfusion reactions included pyrexia, rigors, lumbar pain and headache. No further confirmatory tests were conducted to identify the reasons. No cases of overt and dangerous hypotension reported in any of the cases. Seven of the cases(50%) were documented as unclassified due to the failure of analysis into the respective classes mentioned in the list.

Inadequate laboratory and clinical information to classify them further could also be a reason for the unclassified reports. They could probably be allergic or nonspecific reactions. It thus provides a scope for effective skill up-gradation programme for classification of the transfusion reactions.

The major blood component transfused in the study period was the platelet concentrate (n=972, 53.11%). The possible reason was the increase in Dengue cases coinciding with the monsoon season. However, the number of adverse reactions reported was less with platelets which strikes differently from other studies.

No cases of suspected bacterial contamination or fatalities were reported during the study period. The causality assessment of all the reactions was grade 1 i.e. minor adverse reaction as per the graded scale. Additionally, all the reaction occurred despite giving pre-medications except two reactions where pre-transfusion medications were not administered.

IV. Discussion

Blood transfusion is very safe and effective when used appropriately. Additionally, it is a complex multistep process involving members of several different professional groups, nurses, doctors, laboratory scientists as well as the donors and recipients. It therefore results in several risk points mandating requirement of a surveillance system for monitoring, detecting and reporting these events in the best interests of the patients overall wellbeing. There is also a scope for a national level audit programme for improving and scaling up the vigilance activities.

During the brief period of our study, a total of 1830 blood components were transfused. There is a paucity of studies available in the Indian context on Haemovigilance. However, in a study conducted by Gupta M et al, [12] 45 092 blood components were issued resulting in 190 transfusion reactions (0.42%) as against 0.77% reported in our study. The most frequent reaction reported were febrile non-haemolytic transfusion reactions (54.2%) as against 28.57% of FNHTR in our study.

FNHTR as the most commonly reported transfusion reaction. Febrile non-haemolytic transfusion reactions (FNHTRs) are defined as an unexplained rise in temperature by 1° C or more within 4 hours following transfusion and subside gradually after 48 hours with no Identifiable cause.[13] FNHTRs are noted commonly with transfusion of platelets (up to 30% of platelet transfusions) than red blood cells (RBCs) as platelets are stored at room temperature, which promotes leucocyte activation and cytokine accumulation. [14]

Additionally, there have also been studies on single transfusion reactions. As per a study by Kato H et al,[15] it was observed that First transfusion ATRs to RBCs, FFP and PCs were 1.08%, 2.84% and 3.34%, respectively. These are higher than ATR incidences to RBCs (0.69%), FFP (1.91%) and PCs (2.75%) on subsequent transfusions. Specifically, first transfusion incidences of febrile non-haemolytic transfusion reactions (FNHTRs) to RBCs (0.43%) and allergic reactions to FFP (2.51%) were higher than on subsequent transfusions (RBCs: 0.23%, FFP: 1.65%). However, first transfusion reaction events were not documented in our study but most of the events were observed in patients with subsequent history of transfusions.

© 2020 Global Journals

WHO has laid down guidelines for and managing accordingly for acute transfusion reactions where it has been considered under three categories.

1. Category I which can be recognised by mild symptoms like localized cutaneous reaction which includes urticaria, rash pruritis (itching).
2. Category II includes moderately severe reactions like flushing, urticaria, rigors, fever restlessness, tachycardia, anxiety, pruritis, palpitation, mild dyspnoea and headache
3. Category III where life-threatening reactions like hypotension, tachycardia, haemoglobinuria, unexplained bleeding, anxiety and chest pain are included which needs transfusion to be stopped immediately.[16]

Most common cause of the preventable adverse reactions is due to clerical errors.[17] It is less difficult to identify the adverse effects within a short time of transfusion event. However, the longer the time of events to occur after the transfusion, the less likely they are to be reported (especially if they are mild and nonspecific). Transfusion reactions include infectious hazards and non-infectious hazards. Infectious hazards commonly include sepsis from bacterial contamination, which can be minimized by donor screening and infectious disease markers. Emphasis should be laid on vigilance for emerging infectious dieases (EID) like chikungunya Virus, dengue, malaria etc.[18] One of the major risk factors which are observed to be responsible for acute haemolysis is the unmonitored storage conditions. Majority of acute hemolytic reactions are due to improper storage conditions. Additionally, inappropriate storage conditions in refrigerators outside the leads to deterioration of red cell units. Therefore, awareness among the healthcare professionals is essential to reduce the risk of transfusion reactions. [19]

Haemovigilance is the term derived from Latin, where Heame means “Blood” and vigilans means “watchful”.[20] Haemovigilance is about 20 years old and was previously a part of Pharmacovigilance activities. High incidence of infections like HIV, HCV were counteracted between 1980s and 1990 due to transfusion. This disastrous incidents lead to the need for monitoring of transfusion safety in countries like UK.[21]

Haemovigilance is concerned with reactions occurring due to blood components like whole blood, packed cells, platelets and fresh frozen plasma whereas Pharmacovigilance intransfusion medicine also includes components of plasma like clotting factor concentrates immunoglobulin, albumin and other fractionated products.[22]

First work on monitoring of transfusion reaction was started in 1991 in France.[23] Later a serious hazard of transfusion scheme (SHOT) was started in 1996. Hospitals registered with the UK National External Quality Assurance Scheme (UK NEQAS) for blood transfusion laboratory practice were invited to participate and the scheme was widely advertised at meetings and with a leading article in the British Medical Journal.[24]

This scheme was a success as it leads to reduction in bacterial infections, transfusion related acute lung injury(TRALI), and transfusion related Reduction in transfusion-associated graft - versus – host disease (TAGvHD) and post-transfusion purpura (PTP).

Haemovigilance is a complete system which aids in collection, recording and evaluation of blood transfusion reactions. This system of haemovigilance functions with variability among various countries. Haemovigilance is aimed to detect and analyse all untoward effects of blood transfusion in order to correct their cause and prevent recurrence. Many countries in the developed world have established National Haemovigilance systems and a few developing countries are setting it up.

With the concept of universal leukoreduction there is dramatic risk reduction for FNHTR. The most common quoted rate for FNHTR is 0.5-1% among the general populations of patients with red cell transfusion. A comparative study on incidence of FNHTR in leukoreduced vs. nonleukoreduced blood components showed that the incidence is 0.047%% in nonleukoreduced and 0.411% in leukoreduced blood.[25]

A study by Chowdury FS et al has shown that blood transfusion reactions depend upon the frequency and unit of blood transfusion and few recommendations to reduce the incidence of blood transfusion reaction has been elucidated.[26]

In a descriptive study Sobia Nawaz et al conducted at a teaching hospital among pregnant women similar procedure as our study was adopted. The study was undertaken to determine the frequency and types of blood transfusion reactions conducted over a period of 12 months. 20.9% of cases with post transfusion reaction were noted among which 4.9% of haemolytic reactions, non haemolytic reactions in 4.2% and febrile reactions in 11.7%. The study concludes that blood transfusion should be reserved for patients who are haemodynamically unstable patients and blood bank providing the blood products should have adequate cross matching and storage facilities to ensure transfusion safety. [27]

A step to minimize the transfusion risks has been implemented in most of the developed countries. Implementation of an effective system to monitor these transfusion risks is still a challenge in developing countries. In one such report adverse events were evaluated retrospectively i.e. the data on different blood components distributed was collected the post transfusion sequelae was evaluated based on SHOT (Serious Hazards of Transfusion) classification. Such a method would be helpful in missing the cases although establishment of causal relationship in certain case was impossible. [28]

© 2020 Global Journals

The incidence of allergic reactions to blood components vary greatly in literature and there are a few supporting figures on incidence of allergic reactions on well-designed studies in the general patient population.

Each transfusion has to be monitored carefully with prompt recognition and treatment of acute transfusion reactions to decrease transfusion-related morbidity and mortality. Data from a well-functioning haemovigilance system can be used as a quality indicator for monitoring blood transfusion safety and contribute to evidence-based transfusion medicine.

Hence careful monitoring of transfusion process will lead to early detection and reduction of severity of the reaction which can lead to reduction in morbidity and mortality. Thus haemovigilance serves as an ultimate safety tool to ensure safe transfusion process which every country needs to implement. Haemovigilance must be made an integral and a critical component in all the blood transfusion settings. Additionally, heightened awareness about various clinical features of acute transfusion reactions with an ability to assess the serious reactions on time can lead to a better prognosis. The most important concerns with the Haemovigilance is the dependence on the awareness of physicians and other health care workers to look for adverse effects and their reporting determine whether the effects could have been caused by transfusion.[29]

Observation and monitoring are required throughout the transfusion episode, more so for within first 15 min. Delayed reactions must also not be missed. There should be standard operating procedure containing the details for documentation, reporting, evaluation, and follow-up of all adverse reactions. Moreover, a "Conservative approach" of blood transfusion to reduce the number of unwanted transfusions must also be practised.

Acknowledgments: Our sincere gratitude to Indian Council of Medical Research for giving an opportunity to carry out this research work as a part of Short term Studentship-2015. We also thank the staff of Blood Bank Unit, Sapthagiri Institute of Medical Sciences and Research Center for helping us through the research and lastly the patients and their Bystanders for reporting of transfusion related events and their cooperation.

References Références Referencias

1. Karim F et al. "Root cause analysis of non-infectious transfusion complications and the lessons learnt". Transf Apheres Sci (2013).
2. World Health Organization. Global data base on blood safety—report 2001-02.Geneva: World Health Organization; 2004. p. 5–17.
3. NACO Report 2013-2014.
4. Deborah T. Firestone, Christine P. Adverse effects of blood transfusion in Textbook of blood banking and transfusion medicine. 2nd ed. Elsevier; 2005. p. 400–7.
5. Freitas JV de, Almeida PC de, Guedes MVC et al. J Nurs UFPE on line Recife 2014 Sep; 8(7):3030-8.
6. Anna K K V, Franscisco J.M., Luiza D, Grace M.D.j.Pediatr. (Rio J) 2013 Jul/Aug; 89(4).
7. Chasse et al.Systematic reviews 2014;3:(28)
8. World Health Organisation. Aide memoire for national blood programmes. Geneva Switzerland 2002.
9. Hidefumi K,Matoaki U,Yoshiki O,Hiroshi F,Makota H et al. Incidence of Transfusion-Related Adverse Reactions per Patient Reflects the Potential Risk of Transfusion Therapy in Japan. AJCP 2013; 140: 219-224.
10. Paramajit K,Basu S.Transfusion-transmitted infections: Existing and emerging pathogens. Jpgm 2005; 51(2)146-151.
11. Haemovigilance in France: annual report (2004). Available from: http://ansm.sante.fr/var/ansm_site/storage/original/application/00f1b5ffdf75fd3d83c8c62f9f1cd960.pdf. [Last cited 2015 Oct 9}
12. Gupta M, Kumar R, Gupta S, Kaur A, Acute transfusion reactions encountered in patients at a tertiary care centre in Punjab. Natl Med J India. 2015 Jan-Feb; 28(1):8-11.
13. Volker K.Reactions Induced By Platelet Transfusions. Transfus Med Hemother 2008 Oct; 35(5):354-358.
14. Heddle NM, Klama L, Meyer R, Walker I, Boshkov L, Roberts R, et al. A randomized controlled trial comparing plasma removal with white cell reduction to prevent reactions to platelets. Transfusion 1999; 39:231–8.
15. Kato H et al, A retrospective observational study to assess adverse transfusion reactions of patients with and without prior transfusion history, Vox Sang. 2015 Apr; 108(3): 243-50.
16. WHO. Manual of Clinical Use of Blood in Surgery and Anaesthesia. [Last accessed on 2015 Jun 25]. Available from: http://www.who.int/bloodsafety/clinicaluse/en/manual-EN.pdf.
17. de Vries RR, Faber JC, Strengers PF; Board of the International Haemovigilance Network. Haemovigilance: An effective tool for improving transfusion practice. Vox Sang 2011; 100:60-7.
18. Sunelle Engelbrecht, Erica M Wood and Merrole F Cole-Sinclair. Clinical transfusion practice update: haemovigilance, complications, patient blood management and national standards. Med J Aust 2013; 199 (6): 397-401.
19. Sahu S, Hemlata, Verma A. Adverse events related to blood transfusion. Indian Journal of Anaesthesia 2014; 58(5):543-551.
20. Sukant S, Pankaj G, Satwika S and Pawan B. Haemovigilance and Transfusion Safety: A review article: Sch. J. App. Med. Sci.2014;2(1A):85-90.

© 2020 Global Journals

21. Bolton-Maggs PHB, Cohen H. Serious Hazards of Transfusion (SHOT) haemovigilance and progress is improving transfusion safety. British journal of Hematology.2013; 163(3):303-314.
22. Strengers PF.Hemovigilance Why? 102-109.
23. Paulo R J M, Raquel A M, Valdirene F B, Gilberto A P, Helio M S et al. The importance of hemovigilance in the transmission of infectious diseases. Rev Bras Hematol Hemoter. 2013; 35(3):180-4.
24. Cruz J R, Harmening D M, Nance S J. Summary of Caribbean Regional Workshop on quality in immunohematology, a collaborative effort to improve international blood transfusion services. immunohematology 2008.24(1).
25. Argiros E,Elias K,Georgios K N,Marlene S,Stefanos B. Blood Transfus.2015 Apr;12(2):232-237.
26. Chowdury F S,Biswas J,Siddiqui M A E,Hoque M M,Adnan S K.Transfusion Reaction among the blood reciepient- A study of 120 cases. J Dhaka Med Coll 2008;17(2).
27. Sobia N,Nadeem I,Sadaf T,Maliha S,Shagufta SS.Blood transfusion reactions during preganancy. Journal of Rawalpindi Medical College 2013;17(2): 240-242.
28. Nyashadzaishe M,Star K, Marinus van H.Incidence and Pattern of 12 years of Reported Transfusion Adverse Events in Zimbabwe: A Retrospective Analysis. Blood Transfus 2014 Jul;12(3):362-367.
29. Manvi G, Rajesh Kumar, Sonia G, Amarjit K. Acute transfusion reactions encountered in patients at a tertiary care center in Punjab. The Natioanal Medical Journal of India 2015; 28(1)

© 2020 Global Journals