Research Article • DOI: http://dx.doi.org/10.2478/medu-2018-0008 Medical University • 1(1) • 2018

Medical University

ESTABLISHMENT OF THE HEMOVIGILANCE SYSTEM IN AN ONCOLOGY-BASED HOSPITAL OF NEPAL: A NEW STARTING IN THE FIELD OF BLOOD TRANSFUSION IN LIMITED RESOURCE SETTINGS

A. Shrestha[1], R. M. Shrestha[2,3], S. Shrestha[4,5], S. Shrestha[6]

[1]Consultant Clinical Hematologist, Hematology Unit, Nepal Cancer Hospital and Research Center Pvt. Ltd, Harisiddhi, Lalitpur, Nepal
[2]Senior Consultant Pathologist, National Public Health Laboratory, Teku, Nepal
[3]Coordinator, National Bureau of Blood Transfusion Services, Teku, Nepal
[4]Clinical Pharmacist and Research Associate, Department of Pharmacy, Nepal Cancer Hospital and Research Center Pvt. Ltd, Harisiddhi, Lalitpur, Nepal
[5]Lecturer, Department of Biochemistry, Nobel College, Sinamangal, Nepal
[6]Senior Consultant Medical Oncologist, Department of Medical Oncology, Nepal Cancer Hospital and Research Center Pvt. Ltd, Harisiddhi, Lalitpur, Nepal

Abstract

An access to adequate and safe blood transfusion services is an essential measure of basic healthcare systems. The main purpose of hemovigilance is to enhance the quality and safety of the blood transfusion chains, which are implemented for improving the quality of the blood transfusion chain processes, especially focusing on blood safety. Globally, the framework of hemovigilance is extending as one of the key escalations to the group of the human services administrations, recognizing restructured blood transfusions administrations.

The core objective of this review article is to highlight the objectives of the hemovigilance framework, historical aspects of the hemovigilance framework around the world and the scenario of Nepal. Furthermore, it likewise features the scopes and strategies for implementation of hemovigilance at a hospital. An acceptance and incorporation of the hemovigilance system in an oncology hospital or in any tertiary care hospitals in Nepal can avert the incidence or reappearance of adverse events due to the transfusion identified with the whole transfusion chain process. Globally, including the least developed country like Nepal, the hemovigilance framework must be incorporated and systematized for upgrading transfusion and general society certainty additionally regarding blood and its products. Different strategies must be made for the successful implementation and strengthening the hemovigilance system.

In conclusion, there is an interminable and endless necessity for the effort on hemovigilance; although the rules, regulations, and tools are in place. With the end goal to have a productive hemovigilance framework in the least developed countries like Nepal, an extensive methodology and enormous ideas are required.

Keywords

hemovigilance • adverse reactions • blood safety • Nepal • transfusion

Introduction

An essential measure of any basic health care system is to have an access to the adequate and safe facilities for blood transfusion services, which remain often life savers on the road to critically ill patients. For the development of every healthcare system, the important factor to be considered is a safe and enough supply of the blood. On the other hand, blood transfusion is also intrinsically accompanied by the risks that vary in severity, from negligible to life frightening occasions [1]. Today, even in developed nations, the greatest hazard to the patient lies in non-irresistible issues of blood transfusions that cause sickness and demise [2]. Defending threats which is linked with transfusion, beneficiaries have remained a global public health urgency with the appearance of human immunodeficiency virus (HIV) in 1980, which is the root of HIV contagion and over time acquired immunodeficiency syndrome (AIDS) resulting from blood transfusions as a threat to blood transfusion safety [3]. As the hazard of acquiring infectious diseases, the clinical threat of transfusions is asserted basically [4, 5].

Corresponding Author: Sunil Shrestha
ORCID: 0000-0002-9174-7120
E-mail: sunilcresta@gmail.com

sciendo

With a resemblance to the previously existing term "Pharmacovigilance", the word "Hemovigilance" was invented in France in1990. It is derived from the Greek word "*haema*" which means blood and the Latin word "*vigilans*" which means watchful/ paying special attention to/ keep watching. As the term enlightens the aforementioned, the purpose of hemovigilance is to enhance the quality and safety of the blood transfusion chain, first and foremost focusing on the blood safety [6]. As defined by Faber, hemovigilance is "a set of surveillance procedures covering the whole transfusion chain (from the donation of blood and its components to the follow-up of recipients of transfusion), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent the occurrence or recurrence of such incidents" [7]. In developed countries, similar to quality systems, reviews and audits, hemovigilance has turned into a vital piece of the Blood Transfusion Service (BTS). Being an important part of the modern health care system, the latter has added astoundingly to the development of the services related to blood and blood transfusion [8].

Globally, the hemovigilance system is evolving as a vital addition to the human facilities care team fetching almost enriched patient care. Starting with the blood donors and blood donation, hemovigilance is one of the continuous and standardized systems for gathering of the data and its analysis and disseminating the outcomes and effects among clinical and public health decision makers [9]. The gathering of information that can be generated on responses taking place during the blood donation, or after the donation of blood, as well as determinations of blood donors to evade the occasion/rehash of such scenes, should be acceptable.

Objectives of the hemovigilance system

The objective of the hemovigilance framework is to monitor transfusion reactions, to identify risks, to make blood transfusions additional secure, more effective and more proficient, to create awareness among the healthcare professionals, to exhibit the safety of the current system in blood transfusion to the population, to present the risks and advantages of this treatment, to generate evidence-based recommendations, and to show that the issues are outstanding and viably tended to attempt to increase blood safety [10]. In contrast to clinical and epidemiological research on labile blood products, this framework has unexpected objectives [6]. The other objectives are to create linkages at national and international levels.

The ethical aspects of hemovigilance consider benefits identified by keeping away from malpractice, recklessness, and carelessness, blood donor awareness and giving data to both healthcare specialists. The healthcare specialists including medical doctors, nurses, lab technicians, and pharmacists/clinical pharmacists and even the patients are comprised. The ethical aspects of hemovigilance are valuable to the safety of patients and give data on wellbeing as a preventive measure in conceivable instances of the contact [11].

History of Hemovigilance

Intending to have an arrangement of blood surveillance and hence to bring down the threats related to the transfusion, several hemovigilance systems have been produced and executed in many nations. In 1993, France became the first country to present hemovigilance as a national program with compulsory reporting including surveillance activities incorporating the entire process of transfusion [12]. In 1996, the United Kingdom (UK) presented the first voluntary reporting framework which was a non-dependent, professionally directed hemovigilance system concentrated on learning from adverse events [13]. Even though the hemovigilance systems of France and the UK are different from each other. Many developed nations like Canada and European nations like the Netherlands, Ireland, and Denmark have a prerequisite of voluntary reporting [8]. Afterward, in 1995 the European Council distributed a determination through an objective on the way to enhance open trust in the harmless supply of the blood. Soon the hemovigilance framework progressed toward becoming represented by the legal specialists [9,11]. In other countries, hemovigilance is known by another name. In the United Kingdom (UK), Canada and the Netherlands, hemovigilance systems are known as Serious Hazards of Transfusion (SHOT), Transfusion Transmitted Injuries Surveillance System (TTISS), and Transfusion Reactions in Patients (TRIP), respectively. The Norwegian Haemovigilance System is known as a Troll. It was introduced in the year 2003 as a voluntary and confidential reporting system. The information from entrenched hemovigilance frameworks of different nations, for example, the UK, the Netherlands, Japan, Russia, Switzerland, and the United States of America (USA) has assumed appreciative understanding keen on diverse processes which can be beneficial in an improvement of the blood safety [8]. In the USA, in order to accomplish obligatory reporting requirements or a portion of the safety of patient improvement initiatives, hospital transfusion services report all the different hemovigilance

happenings to federal, state, and non-governmental organizations (NGOs) [14, 15]. In 2004, The Norwegian hemovigilance system initiated a system of reporting which is directed to professional and voluntary systems. In 2007, haemovigilance turned out to be the duty of an expert, according to the European Union (EU) blood instruction, and recording of serious adverse reactions (SARS) and serious adverse events (SAEs) grew into being obligatory [16].

Excluding Japan, which has disseminated the information about antagonistic responses, there is a nonexistence of established hemovigilance framework and inadequacy of hemovigilance information between the Asian countries [8]. One of the essential in the nation is the hemovigilance framework to have an exhaustive way to deal with the addressed matters of antagonistic response succeeding transfusion of blood and its products.

In 2004, South Korea introduced the Korean Hemovigilance Systems for starting the activities for the additional enhancement of safety measures in blood transfusion [17]. In 2012, the neighboring country of Nepal in South Asia, India has launched a hemovigilance program, which is known as Haemovigilance Programme of India and makes a significant portion of a pharmacovigilance program at a nationwide level. With a roadmap of five years with four phases of hemovigilance, i.e., the phase of launching, the phase of expanding and partnership, the phase of development and conservation, and the phase of optimizing, it is an all-inclusive, integrated, and well-structured method [18].

Scope of Hemovigilance

Due to the regulations in the variety of reporting, the scope of assorted hemovigilance frameworks from the diverse countries reveals an inconsistency, i.e., reporting of adverse reactions versus reporting of adverse events, reporting of all versus reporting serious adverse reactions only; reporting only incidents in recipients or also in donors; reporting all adverse events or only the SARs in recipients [6]. Superlatively, the hemovigilance system needs to buffer strategies wherever all through the entire transfusion chain, from the preliminary donation of blood, passing out of blood, and blood transfusion to patients for the spotting, recording, and exploration of adverse events and responses, and proximate failures or errors identified with the blood transfusion. It ought to be very much fit between the blood transfusion office, hospital's staff (clinical),and transfusion research or laboratories, hospital transfusion boards and the administrative office [19].

The Hemovigilance Program in the developing country of Nepal

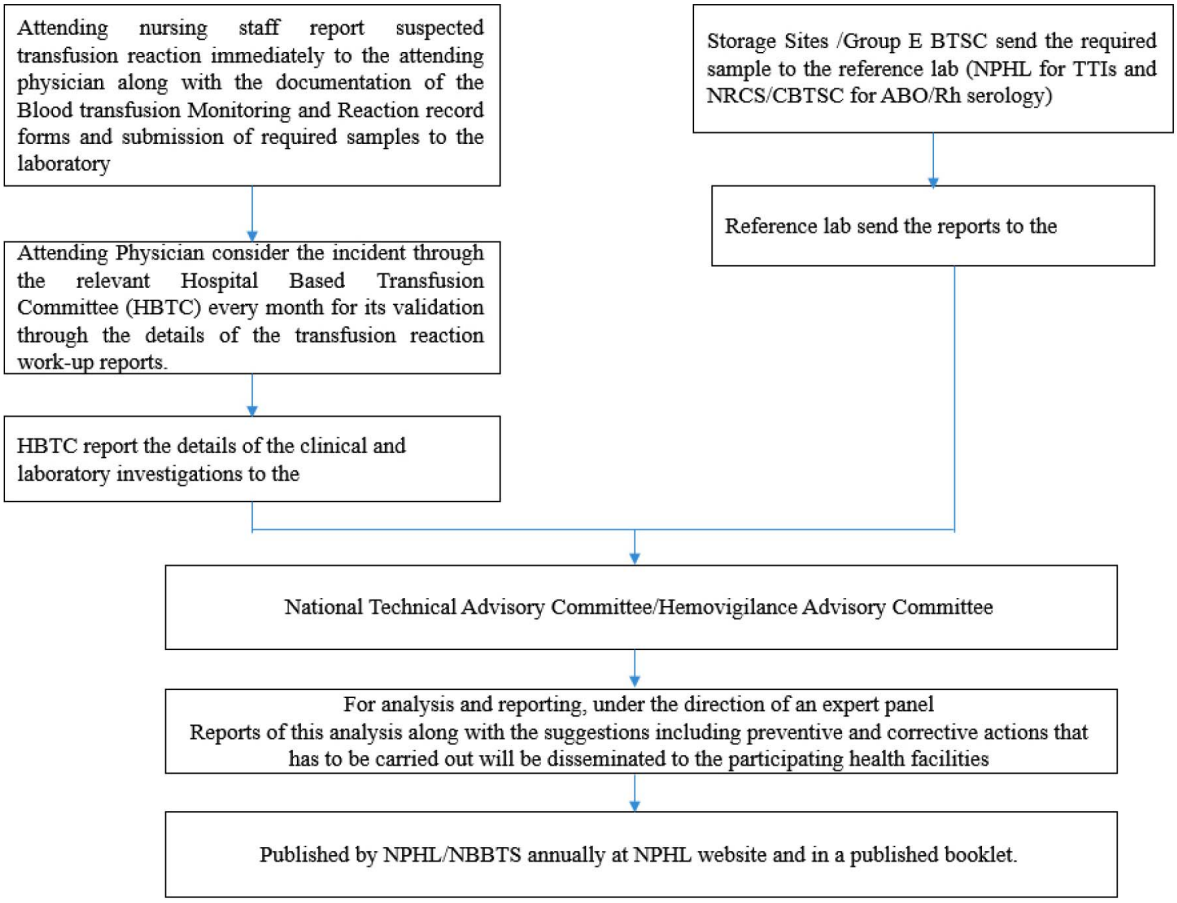
Following this international development in hemovigilance, National Hemovigilance Reporting Guideline in Nepal was developed in 2017 by the Government of Nepal (GoN) through the National Bureau for Blood Transfusion Service (NBBTS) as a focal point for blood safety on behalf of the Ministry of Health and Population which provides the instructions on procedures covering the entire transfusion chain, their provision for transfusion to patients and their follow-up. The established Hemovigilance Program of Nepal is based on a non-punitive and anonymized approach. For the implementation of the Hemovigilance Program in Nepal, currently four hospitals (two government hospitals and two private hospitals) of Nepal are nominated. One of the nominated hospitals is the Nepal Cancer Hospital and Research Center which is an oncology-based hospital of Nepal. After the pilot study, it will be increased accordingly for the next year. The ultimate goal of the Hemovigilance Program of Nepal is to become a part of the international hemovigilance network. However, the concept of hemovigilance is not well developed in Nepal, the least developed country in South Asia.

Hemovigilance setup at Nepal Cancer Hospital and Research Center (NCHRC)

An acceptance of the hemovigilance system in an oncology hospital or in any hospitals in Nepal or globally can inhibit the occurrence or recurrence of adverse events related to the entire transfusion chain. Nepal Cancer Hospital and Research Center (NCHRC) which is an oncology based hospital in Nepal follows National Hemovigilance Reporting Guideline in Nepal (2017). All the serious adverse reactions (SARs) are reported that comprise immunological haemolysis due to ABO incompatibility and other alloantibody, non-immunological haemolysis, transfusion-transmitted bacterial infection, anaphylaxis/ hypersensitivity, transfusion-related acute lung injury (TRALI), transfusion-transmitted viral infections (HBV,HCV,HIV ½ and others), transfusion-transmitted parasitical infection (malaria), post-transfusion purpura, graft versus host disease, transfusion-associated circulatory overload (TACO), and febrile non hemolytic transfusion reactions (FNHTR). All these SARs are reported via Form 1of Blood Transfusion Monitoring Record and Form 2 of Blood Transfusion Reaction Record (Appendix I and II) once the blood is ordered from the blood bank.

According to Form 1 conditions of the patient (general appearance of the patient, temperature, pulse, blood pressure, respiration) are monitored before and during the blood transfusion, before

Figure 1 The organogram of the Nepal Hemovigilance System



the beginning of the transfusion and as soon as the transfusion is in progress every next fifteen minutes. After that every hour up to 4 hours, monitoring of blood transfusion is performed. According to Form 2, different types of the transfusion reaction (fever, chills, rigors or urticaria, pruritis, flushing or hypotension, anxiety, oliguria, renal failure, anaphylaxis, shock, dyspnea, orthopnea, cough, tachycardia and delayed transfusion reactions like fever, decreasing hemoglobin) are noted before beginning the transfusion, as soon as the transfusion is started and after fifteen minutes after the transfusion. After that every hour up to four hours, monitoring of blood transfusion is performed.

The attending nursing staff of the hospital reports the suspected transfusion reaction immediately to the attending physician along with the documentation of the blood transfusion monitoring and reaction record forms and submission of required samples to the laboratory. The attending physician considers the incident through the relevant Hospital Based Transfusion Committee (HBTC) every month for its validation through the details of the transfusion reaction work-up reports. HBTC reports the details of the clinical and laboratory investigations to the National Technical Advisory Committee/Hemovigilance Advisory Committee for analysis and reporting, under the direction of an expert panel. Reports of this analysis along with the suggestions including preventive and corrective actions that have to be carried out will be disseminated to the participating health facilities. Finally, they will be published by National Public Health Laboratory (NPHL) / NBBTS annually at NPHL website and in a published booklet for public and concerned stakeholders.

Strategies for implementing hemovigilance at the hospital

There are strategies for the successful implementation of hemovigilance at the hospital which include awareness, education, and training. They are very important to every characteristic of blood safety. Education on hemovigilance can be given in the form of Continue Medical Educations (CME), awareness, lectures, seminars, and symposium, etc. for health care professionals including medical oncologists, doctors, pharmacists, nurses, and even patients. Additionally,

it is necessary to develop a committee on hemovigilance within a hospital to encourage synchronization between the blood users and blood providers. Adequate maintenance of blood transfusion reactions records in the hospital should be done. Learning from the other countries which have already successfully implemented the hemovigilance system in their countries and taking guidance from the countries where this program has already been implemented successfully, but at the same time before the start of this program, we should keep in mind the local conditions of the area.

Conclusion

In healthcare settings, hemovigilance is considered as a new system which is essential and which has been following by a numerous nation, especially in an emerging country like Nepal. The incorporation of the hemovigilance system in a hospital can improve the patient care, the blood-related safety, and blood transfusions. Hemovigilance is a surveillance procedure for recognized adverse events and also sentinel recording and documenting of unpredicted adverse events which occur during or after the transfusions. Working as a bridge, Hemovigilance develops the safety through benchmarking to encourage superlative practices and by empowering brisk reactions to new threats regarding blood transfusions [21]. However, these days, blood transfusions are particularly harmless, yet obligatory vigilance is required for ensuring appropriate safety use of blood and blood products [11].

In conclusion, there is an interminable and endless necessity for the effort on hemovigilance; although the rules, regulations, and tools are in place, but there is still the prerequisite of beginning the spot-on awareness and alertness system in order to make certain that the measures will be followed and that hemovigilance will help to prevent undesired reactions related to entire blood transfusion chains. With the end goal to have a productive hemovigilance framework globally, an extensive methodology and enormous idea are required. A simplified tool for data collection using standardized instruments at the hospital level and with a good coordination at the national level can bring up effective hemovigilance system within a country. The data and information from that standardized tools can be utilized as a quality marker to screen blood security and furthermore contribute essentially to evidence-based medicine as well as help to bring together different related stakeholders and /or get access to the prevailing blood policies. At the worldwide level, the hemovigilance framework must be encouraged and institutionalized to improve transfusion safety and the public confidence as well. Furthermore, more researches should be conducted in this hemovigilance framework to create a national and international database.

Abbreviations

AIDS: Acquired Immunodeficiency Syndrome
BTS: Blood Transfusion Service
CBTSC: Central Blood Transfusion Service Center
EU: European Union
GoN: Government of Nepal
HBTC: Hospital-Based Transfusion Committee
HIV: Human Immunodeficiency Virus
MOHP: Ministry of Health and Population
NBBTS: National Bureau for Blood Transfusion Service
NGOs: Non-Governmental Organizations
NPHL: National Public Health Laboratory
NRCS: Nepal Red Cross Society
SARS: Serious Adverse Reactions
SHOT: Serious Hazards of Transfusion
TACO: Transfusion-associated circulatory overload
TRALI: Transfusion-related acute lung injury
TTIs: Transfusion Transmissible Infections
TTISS: Transfusion Transmitted Injuries Surveillance System
UK: United Kingdom
USA: United States of America

Declarations

Ethics approval and consent to participate Not Applicable
Consent for publication Not Applicable
Availability of data and material Not Applicable
Competing interests None
Funding The author(s) received no financial support for the research, authorship, and/or publication of this article.

Authors' contributions

AS and SS (a) visualized the concept and were responsible for writing the manuscript. AS and RMS provided the information regarding Nepal issues. SS (b) reviewed the manuscript and added further information regarding historical aspects. All authors contributed to and approved the final version of the manuscript.

Conflict of Interest Statement

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

References

1. Sahu S, Hemlata, Verma A. Adverse events related to blood transfusion. Indian J Anaesth. 2014;58(5):543-51. https://doi.org/10.4103/0019-5049.144650
2. Hendrickson JE, Hillyer CD. Noninfectious serious hazards of transfusion. Anesth Analg. 2009;108(3):759-69. https://doi.org/10.1213/ane.0b013e3181930a6e
3. Robillard P, Nawej KI, Jochem K. The Quebec hemovigilance system: description and results from the first two years. Transfus Apher Sci. 2004;31(2):111-22. https://doi.org/10.1016/j.transci.2004.07.005
4. Giampaolo A, Piccinini V, Catalano L, Abbonizio F, Hassan HJ. The first data from the haemovigilance system in Italy. Blood Transfus. 2007;5(2):66-74. https://doi.org/10.2450/2007.0001-07
5. Kleinman SH, Busch MP. The risks of transfusion-transmitted infection: direct estimation and mathematical modelling. Baillieres Best Pract Res Clin Haematol. 2000;13(4):631-49. https://doi.org/10.1053/beha.2000.0104
6. de Vries RR, Faber JC, Strengers PF. Haemovigilance: an effective tool for improving transfusion practice. Vox Sang. 2011;100(1):60-7. https://doi.org/10.1111/j.1423-0410.2010.01442.x
7. Faber JC. Haemovigilance procedure in transfusion medicine. Hematol J. 2004;5(Suppl 3):S74-82. https://doi.org/10.1038/sj.thj.6200427
8. Ayob Y. Hemovigilance in developing countries. Biologicals. 2010;38(1):91-96. https://doi.org/10.1016/j.biologicals.2009.10.002
9. Salmi LR. [Epidemiological support in blood surveillance]. Transfus Clin Biol. 1994;1(6):421-4.
10. Callum JL, Merkley LL, Coovadia AS, Lima AP, Kaplan HS. Experience with the medical event reporting system for transfusion medicine (MERS-TM) at three hospitals. Transfus Apher Sci. 2004;31(2):133-43. https://doi.org/10.1016/j.transci.2004.07.007
11. Williamson LM, Lowe S, Love EM, Cohen H, Soldan K, McClelland DB, et al. Serious hazards of transfusion (SHOT) initiative: analysis of the first two annual reports. BMJ. 1999;319(7201):16-9.
12. Andreu G, Morel P, Forestier F, Debeir J, Rebibo D, Janvier G, et al. Hemovigilance network in France: organization and analysis of immediate transfusion incident reports from 1994 to 1998. Transfusion. 2002;42(10):1356-64.
13. Stainsby D, Jones H, Asher D, Atterbury C, Boncinelli A, Brant L, et al., Serious hazards of transfusion: a decade of hemovigilance in the UK. Transfus Med Rev. 2006;20(4):273-82. https://doi.org/10.1016/j.tmrv.2006.05.002
14. Linden JV, Wagner K, Voytovich AE, Sheehan J. Transfusion errors in New York State: an analysis of 10 years' experience. Transfusion. 2000;40(10):1207-13.
15. Chung KW, Harvey A, Basavaraju SV, Kuehnert MJ. How do hospitals participate in national recipient hemovigilance in the United States? Transfusion. 2015;55(4):703-7. https://doi.org/10.1111/trf.12980
16. Steinsvag CT, Espinosa A, Flesland O. Eight years with haemovigilance in Norway. What have we learnt? Transfus Apher Sci. 2013;49(3):548-52. https://doi.org/10.1016/j.transci.2013.09.013
17. Kim S, Kim HO, Kim MJ, Lee SW, Shin YH, Choi YS, et al. Performance review of the National Blood Safety Improvement Project in Korea (2004-2009). Blood Res. 2013;48(2):139-44. https://doi.org/10.5045/br.2013.48.2.139
18. Bisht A, Singh S, Marwaha N. Hemovigilance Program–India. Asian J Transfus Sci. 2013;7(1):73-4. https://doi.org/10.4103/0973-6247.106744
19. Jain A, Kaur R. Hemovigilance and blood safety. Asian J Transfus Sci. 2012;6(2):137-8. https://doi.org/10.4103/0973-6247.98911
20. National Bureau for Blood Transfusion Service. National Hemovigilance Reporting Guideline in Nepal. Kathmandu : Department of Health Services; 2017.
21. Epstein JS. Alternative strategies in assuring blood safety: An overview. Biologicals. 2010;38(1):31-5. https://doi.org/10.1016/j.biologicals.2009.10.009

Appendix I

FORM 1: BLOOD TRANSFUSION MONITORING RECORD

Name of the hospital and address, Fax No. and E-mail address

Blood Transfusion Record

Name of patient: Age/Sex: Ward/Bed:

Inpatient No.: Patient's ABO & Rh: Donor No.:

Donor ABO & Rh: Date of transfusion: Bag No.:

Transfusion started by: Time of transfusion: Hosp. code No:

Type of blood product transfused: WB ☐, PRC ☐, PRP ☐, FFP ☐, Cryoprecipitate ☐

Conditions of the patient to be monitored before and during the blood transfusion	Before starting the transfusion	As soon as the transfusion is started	After Fifteen minutes	Hourly Monitoring of blood transfusion			
				First	Second	Third	Four
The general appearance of the patient							
Temperature (°F)							
Pulse (/min)							
Blood pressure (mmHg)							
Respiration (/min)							

The first few minutes of a blood transfusion are crucial. Therefore, continuous attention needs to be given at least for fifteen minutes and if any reaction is suspected immediately stop the flow, start IV drip, inform BTS Centre, complete the transfusion reaction form, and **follow instructions as given in the next page**.

....

Signature of Physician Signature of Nursing In charge

Appendix II

FORM 2: BLOOD TRANSFUSION REACTION RECORD

Name of the hospital and address, Fax No. and E-mail address

Blood transfusion records

Name of patient:	Age/Sex:	Ward/Bed:
Inpatient No.:	Patient's ABO & Rh:	Donor No.:
Donor's ABO& Rh:	Date of transfusion:	Bag No.:
Transfusion started by:	Time of transfusion:	Hosp. code No:

Type of blood product transfused: WB ☐, WRC ☐, PRP ☐, FFP ☐, Cryo ☐

Type of transfusion reaction	Before starting the transfusion	As soon as the transfusion is started	Fifteen minutes after the transfusion	Hourly Monitoring of blood transfusion			
				First	Second	Third	Four
• Fever, chills, rigors							
• Urticaria, pruritis, flushing							
• Hypotension, anxiety, oliguria, renal failure							
• Anaphylaxis/Shock							
• Dyspnea, orthopnea, cough, tachycardia							
• Delayed: fever, decreasing Hb							

**In case of a reaction, a comment from the physician:

Signature of the physician

Instructions to the staff:

The moment reaction occurs, first stop further transfusion of blood, complete the transfusion reaction report form, and take the following samples, and send with the report to the BTSC for laboratory investigations:

1. For immediate post-transfusion blood samples (1 clotted and 1 anti-coagulated) from the vein opposite the infusion site.
2. Blood culture from a blood bag
3. The blood unit and transfusion set containing residual blood
4. The first specimen of the patient's urine following the reaction
5. Additional samples depending on the patient's condition.

To be printed on the Reverse of Blood Transfusion Monitoring Record Form
Please do attach Lab Investigations Report along with the sample