



Improvement in Blood Transfusion Safety: Using Root Cause Analysis

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Abstract

Objectives: This research aimed at analyzing the adverse events reported related to blood transfusion in one of the large vice-chancellors of Iran University of Medical Sciences in spring 2018.

Methods: This descriptive study was performed based on the eight stages of the root cause analysis (RCA) of healthcare events by the National Authority for Health. For classification of the considered concerns, the "classifying nursing errors in clinical management (NECM)" model, failure classification, approved by the UK National Health System, and also a creative problem-solving technique were used for determining the improvement solutions.

Results: Based on the results, 70% of states of blood transfusion error and blood products were placed in the category of care errors, 10% in the communication category, 20% in the category of implementation errors, and 0% in the category of knowledge and skill errors. A total of 38 influencing factors were identified for adverse events of blood transfusion, the most cause of the error was associated with organizational factors (18.4%), and the least reasons for failure were equipment and resource factors (5.3%).

Conclusions: The establishment of advanced systems for the automatic transmission of blood and blood products, due to the lack of proper infrastructure in Iran, is not economically feasible. Therefore, at the level of this deputy, the guideline for managing blood transfusion and blood products in the two areas of "measures required before, during, and after blood transfusion and blood products" and "hemovigilance for physicians" were developed.

Keywords: Root Cause Analysis, Patient Safety, Health Service, Blood Transfusion, Never Events

1. Background

Preventing errors and patients' safety in transfusion medicine have been serious problems (1). Although there are systems for checking the quality as well as electronic information processing machines, near-miss transfusion events are certain concerns in blood transfusion medicine, which are threatening for patients' lives and impose a remarkable cost on the health care system (1). Transfusion errors occur at five phases: wrist-banding of the patient, collecting samples, laboratory assessment, blood products issuing, and transfusion time (2).

Over 650,000 patients annually are affected by one of such preventable errors resulting in needless pain, trauma, and even death (3). According to statistics from the Joint Commission on Accreditation of Healthcare Organization (JCAHO), blood transfusion errors (2.9%) were pri-

ority adverse events in all hospital departments in America in 2008 (4). Also, recent reports on serious hazards of transfusion (SHOT) estimated a frequency of incorrect blood component transfusion as high as 70% of total transfusion errors (5). In addition, according to annual reports, more than 13 million units of blood are collected and injected into 4 million patients; 10% of these people may be affected by complications of blood transfusion (6). Also, according to Pahuja et al., the incidence rate of immediate blood transfusion complications in one hospital in India from 2005 to 2013 was reported to be 0.19% (7). In addition, according to Karim et al., the incidence rate of blood transfusion complications in one hospital in the south of Pakistan from 2012-2016, was reported as 1.16 per 1000 blood products (8).

In February 2018, the Accreditation Organization of

Iran, in accordance with the National Quality Forum Committee, has developed the “Never Events” framework for immediate investigating and reporting for detecting as well as root cause analysis (RCA) of these incidents. Life-threatening adverse events in the treatment of patients in Iran are classified into 28 categories, one of which (item 14) is related to death or severe disability relevant to hemolytic reaction as a result of quite incompatible blood or blood products. Based on this system, in case one of these occurs, hospitals should report the incident within 24 hours by fax to the vice-chancellor’s office for treatment of the university. Besides, the vice-chancellor of the university is obliged to investigate the issue within the maximum period of 24 hours and upload it to never event system of the Ministry of Health and Medical Education (9). For obtaining their goals, identifying the risks as well as implementing plans for managing such risk factors are needed to be done by organizations (10). Several strategies have been suggested for clinical risk management for ensuring the health care service quality and safety of the patients, of which RCA is a valid method. It is effective to analyze the system failures and find potential solutions to eliminate and/or reduce the errors (11). In the process of RCA of the events, we are not looking for putting the blame on those making the error but also identification and correction of the likelihood of similar adverse events through the therapy and healthcare organizations are considered (12).

In general, one of the priority programs in the field of medical treatment at the medical universities of Iran from 2017-2018 was to improve the reporting system of vital life events of the patients (13). Moreover, RCA has been shown as a structured method for risk assessment and decrease and it has been confirmed as a central approach used in learning from errors and in risk reduction (14). On the other hand, blood transfusion and the control of its complications have always been a cause for concern for blood transfusion centers; and the blood transfusion organizations have always attempted to reduce these complications and manage patients’ blood (15).

2. Objectives

The present research aimed at evaluating the RCA of the adverse events relevant to blood transfusion reported by one of the major vice-chancellor’s offices of the university of medical sciences in Iran, in spring 2018.

3. Methods

This research was done according to the retrospective-qualitative method via achieving the benefits of RCA approach. The study protocol was approved by the Research

Ethics Committee of Shahid Beheshti University of Medical sciences. Prior to the study, written informed consent was obtained from the patients or parents of patients.

This research follows the eight following phases introduced for RCA of the healthcare events by the National Authority for Health (16). It should be noted that some modifications were considered to implement the eight-stage model.

1- Defining the Sentinel Events:

In this phase, a short explanation, the type, time, impact, and severity of adverse events related to blood transfusion were explained.

2- Selecting a Multidisciplinary Team to Perform RCA:

The permanent members of the vice-chancellors for treatment, after receiving the immediate report, attended the place of occurrence within 24 hours and examined all clinical and non-clinical documentation of the patient, and conducted interviews with people involved in the incident.

3- Gathering Information:

In this phase, following group discussion meetings, semi-structured interviews with the affected people, evaluating the patient’s documents, as well as collecting other related files, and observation of the event scene, data associated with the incident were gathered. Next, narrative chronology and timeline or table timeline related to the sentinel incidents were organized by the RCA team.

4- Identifying Problems:

In this stage, the defect and the deficiency available through the service delivery process were accurately classified into two main classes, including care delivery problems and service delivery problems. They were categorized according to the “classifying nursing errors in clinical management (NECM)” approach (17). through group discussion meetings and semi-structured interviews.

5- Identifying Causal Factors:

In this stage, factors that influence the performance and lead to the delivery of unsafe services, resulting in the occurrence of an incident or an event were classified into two general sets of influential factors and causal factors by taking advantage of cause and effect analysis sessions and via copying the lead of the approved model by the UK national health system.

6- Identifying Solutions:

In this phase, enhancement solutions to omit/ reduce the mistake’s concerns and reasons were presented in team meetings by “an innovative problem-solving theory” (18). followed by classifying based on the suggested pattern “classification of the medical errors preventive strategies” (19, 20)

7- Prioritizing and Implementing Solutions:

In this phase, according to the results of the study, the instructions for the management of blood transfusion blood products were formulated by the experts' recommendations in team meetings.

4. Results

Table 1 reports the narrative description of adverse events relevant to incompatible blood and blood transfusion and issues relevant to care or service.

Based on the results of (Table 1), 70% of errors were in the category of care errors, 10% in the category of communication errors, 20% in the category of administrative errors, and 0% in the category of knowledge and skill errors; the categories were proposed by the association of NECM. In total, 38 reasons were detected for the adverse events of incompatible blood and blood transfusion in group discussion sessions. Table 2 represents the contribution of each factor with respect to 9 groups of contributing factors based on the UK National Health System model.

Table 3 represents proposed the classification of strategies and preventive measures of adverse events.

Given that in the present study, most strategies were related to the provision of instructions for the proper administration of blood transfusion process, and periodic training for the staff and because the introduction of advanced systems for the automatic transfusion of blood and blood products, such as an intelligent system for identification of the patients, is not economically feasible due to the lack of appropriate infrastructure in Iran; therefore, at the level of vice-chancellor for treatment, the instructions for transfusion management of blood and blood products in the two areas of "necessary measures before, during and after the transfusion of blood and blood products" and "the practice of haemovigilance among doctors" were compiled by the experts' recommendation and was given to all subordinate units in order to prevent similar incidents (Figure 1).

5. Discussion

RCA is a structured approach to identify causes and determine the vulnerability of the systems (21). In this study, RCA techniques were used to analyze the adverse events related to blood and blood products and corrective measures taken to reduce similar events.

In a study by Tran et al., the highest errors were in the category of care (66%), communication (22%), administrative (6%), and knowledge (5%), respectively, which is in line with our findings (17). In addition, in a study by Molavi-Taleghani, which was carried out at an emergency department in one of the hospitals in Iran, the results showed

that 62.3% of errors were in the category of care services, 13.8% in the category of communication, 15.7% in the category of administrative errors, and 8.1% in the category of knowledge and skill mistakes that is in line with our outcomes (22). On the other hand, in the present study, the greatest number of transfusion errors was related to a domain other than error analysis. This result is supported by the findings of a study in New York as well as a research done by the Commission on Accreditation of National Patient Safety (23).

In this study, the most common causes of error were organizational factors (18.4%), educational factors (13.2%), and duty factors (13.2%). The high rate of organizational factors suggests that in the incidence of adverse events, we cannot blame only the individuals because the weakness in the organization can also disrupt various work systems (24). Meanwhile, task problems are the guidelines, policies, and procedures that are absent, inaccessible, or un-revised (25). In the study by Sorra et al., the commonest reason for mistakes in blood transfusion was associated with the delay in service delivery (51%) and the disproportion between the delivery methods and instructions (49%), and given that the disproportion between delivery methods and instructions has been subordinate to duty factor in the model approved by the national organization of England, the results are consistent with of the present study (26). Considering the educational factors, it is important to note that due to the complex and competitive environment of today's organizations, the managers of organizations and human resources should have a comprehensive understanding in this regard and try to reduce the errors related to educational factor through the empowerment of human resources. In their study, Butlers and Shi considered the inadequate knowledge of trainees and their insufficient education as potential causes of harm to patients (27).

Organizations often deal with issues by short-term solutions rather than deep-rooted analysis. Dependence on quick-fix solutions makes the organization's resources repeat a specific mistake over and over again due to improper detection. The focus of the organizations on quick-fix solutions does not create profits but hinders the growth and prosperity of the organization. In the present study, most guidelines in the provision of instructions are related to the proper administration of the blood transfusion process and to the periodic training on blood and blood products. Linden et al. well documented the incidence of adverse events of the blood transfusion in the majority of health centers, and only educational programs as haemovigilance courses for the treatment staff and periodic training courses to promote the knowledge of the personnel about the management of blood products to pre-

Table 1. Narrative Description of Adverse Events and Distribution of delivery problem to Care or Service

Brief Description	Problems Related to Service Delivery Problems(SDP)	Problems Related to Care Delivery Problems(CDP)
For a 34-year-old woman, the anesthesiologist used the previous patient's medical record for blood transfusion, and the transfusion of 2 units of packed cells with A+ blood type was mistakenly applied for the patient with O+ blood type, and subsequently, it resulted in hematuria, and the patient was kept under intensive care.	Inadequate management in sending the medical record	The patient's identification wristband had not been checked
		Error in the delivery
		Inadequate management in the implementation of surgical safety by the treatment staff
		Inadequate provision of safe care
A 58-year-old patient was hospitalized because of hematuria. Packed cell with A+ blood type injected to the patient with O+ blood type by a nurse with 3 years of clinical experience in nephrology.	Deficiency in implementation of safe systems regarding the maintenance and surveillance	The patient's identification wristband had not been checked
A 24-year-old patient who identified with thalassemia, without the nurse's permission, took another patient's blood bag from the refrigerator mistakenly and injected himself.	Lack of medical records for outpatients	The nursing team had no control over the treatment room
	Deficiency in implementation of safe environment standards	

Table 2. Frequency of contributing Factors in Adverse Events Related to Incompatible Blood Transfusion and Blood Products

Contributing Factors	Frequency (%)
Organization	7 (18.4)
Task	5 (13.2)
Patient	3 (7.9)
Individual	4 (10.5)
Communication	4 (10.5)
Team	4 (10.5)
Education and training	5(13.2)
Equipment and resource	2 (5.2)
Working condition	4 (10.5)
Total	38 (100)

Table 3. Classification of Strategies and Preventive Measures for the Causes of Adverse Events

Strategy Classification	Frequency (%)
Human resources management	7 (23)
Installation of the electronic prescribing system	1 (3.3)
Making people accountable to patient's safety	1 (3.3)
Process standardization	1 (3.3)
Improvement of the patient identification process	3 (10)
Making clear policies	4 (13.3)
Availability of suitable technology	1 (3.3)
Continuous training	1 (3.3)
Participating patients in the treatment process	1 (3.3)
Monitoring suitable changes in clinical processes	4 (13.3)
Promotion of communication	2 (6.6)
Team work	4 (13.3)
Total	30

vent adverse events were reported necessary (23). Moreover, the accreditation commission has determined the instructions for correct verification of the patient in blood transfusion as their primary goal in the patient safety program (28) that is in line with our findings.

5.1. Conclusions

Generally, the incidence of similar adverse events in the future can be avoided by launching a mandatory error reporting system for the detection of system defects and the development and sharing of measures to improve system safety. Educating as well as investigating are needed

Transfusion Consent Form

- Complete registration of the patient's personal information: patient's personal information that must be carefully written in the request form include: birth date, file number or national code, record of transfusion history, review of medical prescription on drug use before transfusion, cause of request or transfusion of blood, to record the type of blood product requested, the purpose of the request, to record the laboratory testing request, doctor's seal and signature, phlebotomist's name and family name.
- In all forms, the specified sections for nurses, physician and phlebotomist must be completed and sealed and signed by the person in charge.
- It is necessary to use appropriate bag (separate bag for each product is mandatory).

Before Blood Transfusion

- Patient identity verification: a. to verify the name, family name, date of birth, and file number of the patient with the information in the blood product request form
- Provision of necessary conditions before receiving blood products from the blood bank: a. using a standard filter for blood transfusion, b. providing medicines such as antihistamines, epinephrine, and normal saline. Moreover, all medications that the patient should use after blood transfusion should also be available in the department.
- Visual inspection of the submitted product: to verify the blood bag number and the blood type on the surveillance form of transfusions of blood and blood products with the blood type on the blood bag label and to check the transferred and received time.
- Checking the blood bag: any clot or hemolysis, any leakage or damage in the bag, abnormal color (purple, violet), turbidity, unhealthy label, if expiration date has passed, if there is gas in the bag, if the product mismatch the type of product requested by the physician
- The items mentioned above should be checked by two people, and in case any of the above items is observed, blood transfusions should not be carried out and the blood bag must be sent back to the blood bank

During Blood Transfusion

- To record patient's vital signs immediately before the transfusion in the surveillance form for blood and blood product transfusion; preparing blood transfusion set (filling the transfusion set by the product itself for evacuation of air bubbles); adjusting transfusion rate of blood product containing red blood cells (the whole blood, packed cells, leukoreduced red blood cells, washed red blood cells, irradiated red blood cells); first 15 minutes of transfusion should be done slowly (2ml or 30 drops per minute), then if no problem arises, according to doctor recommendation, the rate of blood transfusion can be adjusted to non-emergency status.
- The following are required for the registration forms: transfusion start time, transfusion end time form, transfusion volume, the order of products transfusion, transfusion of blood products should be done within 30 minutes after the withdrawal from the blood bank refrigerator otherwise it should be kept in the blood bank refrigerator available in the department.
- It is better to conduct transfusion of a RBC product within 2 hours and transfusion of platelet or plasma within 30-60 minutes.
- Normal sterile saline solution is the only solution that can be given together with blood products and be transfused via a blood transfusion set. The use of ringer and 5% dextrose solution is prohibited.
- To use 1 filter for transfusion of multiple units of packed cells is not recommended in most filters and conditions.

After Blood Transfusion

- Available documentation report of complications and root-causes analysis of complications and errors in the blood transfusion medicine committee during the first or second six months of the year; available blood and blood products for monthly transfusion during the first or second six months of the year
- Necessary measures should be taken when in case of incidence of complications caused by transfusion***rapid stopping of infusion by the nurse***keeping the intravenous route open using normal saline***checking the patient's vital signs***cross-matching transfused blood bag with new sample of the patient blood***sending the blood bag and transfusion set to the blood bank for microbial culture***sending a new sample of the patient's blood and urine to the blood bank
- The documentation that is relevant to report form of complications should be recorded in full: patient file number/diagnosis of the disease/history of the disease/ history of transfusion and the following complication type of transfused product/patient's blood type before transfusion/ patient's blood type after transfusion/blood type of the blood bag before transfusion/result of cross-matching before transfusion/result of cross-matching after transfusion/time between start-time of transfusion and the onset of complication/transfused volume/the occurrence of symptoms in the patient at the time of transfusion done by the nurse and physician/completing the patient's vital signs table before and after transfusion/completing and recording the results of other tests in the form/completing the complication form with the coordination of the physician within 24 hours after the onset of complication/sending the report form of the complication to the blood bank within 48 hours

Figure 1. Instructions for transfusion management of blood and blood products

to be applied as two critical instruments in optimizing the blood transfusion process. Finally, it should be noted that the systematic and constant application of risk management strategies plus the managers' commitment and also studying the organizations' policies are effective to ensure the beneficial effects of these activities.

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Footnotes

Authors' Contribution: All authors contributed to this project and article equally. Mirhashemi and Hashemi conceived of the presented idea. Vahidi and Molavi Taleghani developed the theory and performed the computations. Molavi verified the analytical methods. All authors discussed the results and contributed to the final manuscript. All authors read and approved the final manuscript.

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