Original Article

Report on errors in pretransfusion testing from a tertiary care center: A step toward transfusion safety

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Abstract:

Introduction: Errors in the process of pretransfusion testing for blood transfusion can occur at any stage from collection of the sample to administration of the blood component. The present study was conducted to analyze the errors that threaten patients' transfusion safety and actual harm/serious adverse events that occurred to the patients due to these errors. **Materials and Methods:** The prospective study was conducted in the Department Of Transfusion Medicine, Shri Maharaja Gulab Singh Hospital, Government Medical College, Jammu, India from January 2014 to December 2014 for a period of 1 year. Errors were defined as any deviation from established policies and standard operating procedures. A near-miss event was defined as those errors, which did not reach the patient. Location and time of occurrence of the events/errors were also noted. **Results:** A total of 32,672 requisitions for the transfusion of blood and blood components were received for typing and cross-matching. Out of these, 26,683 products were issued to the various clinical departments. A total of 2,229 errors were detected over a period of 1 year. Near-miss events constituted 53% of the errors and actual harmful events due to errors occurred in 0.26% of the patients. Sample labeling errors were 2.4%, inappropriate request for blood components 2%, and information on requisition forms not matching with that on the sample 1.5% of all the requisitions received were the most frequent errors in clinical services. In transfusion services, the most common event was accepting sample in error with the frequency of 0.5% of all requisitions. ABO incompatible hemolytic reactions were the most frequent harmful event with the frequency of 2.2/10,000 transfusions. **Conclusion:** Sample labeling, inappropriate request, and sample received in error were the most frequent high-risk errors.

Key words:

Pretransfusion testing, errors, labeling, ABO incompatibility

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Introduction

Safety of the transfusion practices depends on a series of processes starting from the decision to administer a suitable blood component, sample collection, labeling, transportation and handling, pretransfusion testing, and finally administration of the relevant blood component to the patient. Errors made at any step in these processes may assign wrong blood to the patient, which can have serious consequences on the recipient.[1] Various national hemovigilance programs document that transfusion of blood of the incorrect type remains a significant problem worldwide in transfusion safety.[2,3] In the United Kingdom and Ireland, 366 reports of death or major complications of transfusion were reported as part of serious hazards of the transfusion initiative. The most common adverse event (52%) was giving wrong blood to the patients.[3] Transfusion safety has not received the same recognition as blood safety. Errors in the process of transfusion of blood to a patient are unfortunately too common.[4] The relevance of near-miss events in analyzing system errors is their ability to show weaknesses in the system and how individuals recover from these errors to prevent harm to the patients. The present study was conducted to analyze the errors that threaten the patients' transfusion safety, and actual harm/serious adverse events that occur to patients due to these errors.

Materials and Methods

The present study was conducted in the Department Of Transfusion Medicine, Shri Maharaja Gulab Singh Hospital, Government Medical College, Jammu, India from January 2014 to December 2014 for a period of 1 year. Errors were defined as

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any deviation from established policies and standard operating procedures. A near-miss event is defined as the error, which did not reach the patient. An actual harmful event is an error, the effect of which reaches the patient and causes harm. And actual no-harm event is the event, which reaches the patient, but causes no harmful event.[4]

Errors were categorized as preanalytical, analytical, and postanalytical and also, according to the place of occurrence, i.e., whether it has occurred in the clinical department or in blood transfusion services. The errors were explained in detail to the technical staff and they were asked to report all the errors and any adverse event associated with it to the person in charge. Only type and cross-match samples were included in the study.

During the 1-year study period, it was explained to the staff that error collection would be nonpunitive and the main aim was to determine the weaknesses in the whole chain of pretransfusion testing and strengthen the transfusion safety.

Results

A total of 32,672 requisitions for type and cross-match for transfusion of blood and blood components were received. Out of these 26,683 patients were transfused with blood components in various clinical departments. A total of 2,229 events/errors were detected with the median of 182 per month and the mean of 185.3 per month, i.e., 6/day. Actual harmful events due to errors occurred in 12 (0.26%) patients. There were 2,202/2,229 errors in the preanalytical phase of pretransfusion testing accounting for 98.7% of all the errors, 6/2,229 (0.2%) in the analytical phase and postanalytical errors were 21/2,229 (0.9%). Errors related to sample collection and labeling of samples that comprised 793 (35.5%) were the most common of all errors in the preanalytical phase, whereas in the postanalytical phase issuance of wrong blood component to the patient was the most common error, which occurred in 11/21 (0.49%) instances [Table 1].

Errors in clinical services were 2,030/2,229 (90.9%). Among these, the most common errors were sample collection and labeling errors which constituted 793/2,030 (39%) followed by inappropriate request for component transfusion which were 511/2,030 (25%). Errors in transfusion services were 199/2,229 (9.1%). Error in accepting of samples was the most frequent [174/199 (87.4%)] error in transfusion services [Table 2].

Near-miss events constituted 1185/2229 (53%) of all errors. Errors related to sample collection were the most frequent constituting 1,007/1185 (85%). All were recognized before the analysis of the samples. Out of all the inappropriate requests, i.e., 155/680 were recognized, whereas in 425 blood components were issued, which resulted in six harmful events and 419 in no-harm events. Four out of six analytical errors were near-miss events detected before the issuance of blood and two resulted in harmful events. Nine out of 11 issuance errors were detected in clinical departments before administration; two errors led to harmful events. Blood bags before issuance were labeled with color coded labels for each group, along with donor unit number, date of collection, and expiry. Transfusion services have a policy of documenting the patient's name and central registration number (CR No.) on the label. There were 8 errors of labeling of the blood bags; six were detected before issuing these components by the issuing staff and two led to ABO incompatible adverse events.

Adverse transfusion reactions or harmful events occurred in 12/2,229 (0.53%) due to errors in the pretransfusion testing chain. Details of adverse transfusion reactions are summarized in Table 3. ABO incompatible reactions were the most common harmful event that comprised 7/12 (58.3%) and occurred mainly due to nontechnical errors in 6/7 (85%) [Table 4]. Exchange transfusion was performed with 1 unit of O-negative whole blood in B-positive neonate having ABO incompatible hyperbilirubinemia, who developed increase in serum bilirubin levels, increase in reticulocyte count, and fever. Further exchange transfusions were performed using O-negative packed cell in AB plasma, and the patient recovered. This was probably due to high titers of hemolysins present in the previous O-negative unit. However, titration for hemolysins could not be performed.

Frequency of actual harmful events in the present study was 4.4 per 10.000 transfusions [Table 5].

Table 1: Types of errors in various phases of pretransfusion testing

Types of errors	No. and % of errors (No. 2229)	Frequency of errors* (%)
Preanalytical errors	2,202 (98.7)	6.7
Requisition, labeling, and sample collection errors	1348 (60.5)	4.03
Labeling errors	793 (35.5)	2.4
Unlabeled or incompletely labeled samples for two key identifiers, i.e., name and CR No.†	755	2.3
Mislabeled samples, i.e., patient's blood labeled with another patient's name	38	0.11
Wrong blood in tube (WBIT)	14 (0.62)	0.04
Information on requisition form not matching with that on sample, i.e., CR No. or name not matching	511 (22.9)	1.5
Requisition form and sample are from two different patients	30 (1.3)	0.09
Inappropriate blood component request by the physician	680 (30.5)	2.0
Sample accepted in error by the staff	174 (7.8)	0.53
Analytical errors	6 (0.26)	0.018
Postanalytical errors	21 (0.9)	0.06
Inappropriate blood bag labeling	8 (0.35)	0.24
Issuance of wrong blood to the patient	11 (0.49)	0.03
Transfusing wrong blood to patients	2 (0.08)	0.006

*Denominator is total no of requisitions received, †CR No.: Central registration number

Discussion

The hemovigilance program in India was started in December 2012 in collaboration with the National Institute of Biologicals under its Pharmacovigilance Programme of India coordinated by the Indian Pharmacopoeia Commission to assure transfusion safety and public health, where mostly data of adverse reactions due to blood transfusion are recorded nationwide from the various medical colleges registered with it.[5] However, reporting of errors, which can cause reactions and near-miss errors are not being reported. Errors in the transfusion chain have the potential to cause untoward events in the patients.

In the present study, 2,229 errors with the median of 182 per month were recorded over a period of 1 year, whereas studies from the West reported the median of 51 events[6] and 215 errors per month.[4] Out of these, 82% were near-miss errors.[6] In a study from Lucknow, 271 near-miss events were reported over a period of 1 year and 33% of these were sample collection errors.[7] Sharma *et al*.,[8] reported 123 preventable errors over a period of 1 year, 73 of which were sample labeling errors. Events related to sample collection such as unlabeled or mislabeled samples were the most common events in our study, constituting 35.5% of all the errors as reported by others.[4,6,7] Sample collection error was the most common error detected by Maskens *et al*.[5] All the samples were labeled manually in our study. A multicenter study on sample collection reported that the frequency of unacceptable samples ranged from 1 in 3 to 1 in >60,000 samples.[1] Wrong blood in tube (WBIT) is a serious error in critical safety process. It was detected by the discrepancy in the sample results from the prior results.[9] Frequency of WBIT was 0.04% of all the cross-match samples in the present study and all the cases were identified during testing. Jain *et al*.[10] reported 0.27% of WBIT. The biomedical excellence for safer transfusion group reported that wrong blood in the tube occurred 1 in every 1,986 samples.[1] Another study showed WBIT in 1 in 2,283 in type and screen samples and 1 in 1,108 in type and cross-match samples and had caused ABO incompatible reaction in one patient.[9] Strict attention to sample accepting criteria is also an important line of defense within blood transfusion laboratory and other laboratory disciplines.[11] "Silent WBIT" is undetectable because the ABO type in the WBIT matches with that of the patient because the underlying frequency distribution of ABO group in the population determines the chance frequency of silent WBIT.[1] The rate of mislabeled specimen was 1.12% and WBIT was 1 in 2,500 samples in Q-Probes study.[12] All the WBIT samples were recognized in the present study because of departmental policy of repeating two more samples from the patient one for type and screen and the other for type and cross-match to resolve such discrepancies. Errors in the sample collection can be reduced by the use of innovative technologies including use of an automated patient and sample identification system,[13] adherence to the British Committee for Standards in Hematology guidelines that recommend not using preprinted patient identification card labels[14] and using the barcode wanding system.[15] Labeling errors are derived from how labeling devices are used rather than devices themselves. Periodic analysis of mislabeled and miscollected samples by the hospitals should be performed to track the performance of the sample collection process over time.[1]

A recently published study from Chandigarh, India reported 2.76% requisition errors, out of which 75% were contributed by CR No. discrepancy (40.5%) and the patient's name different on form and sample (14.76%), incomplete patient information (19.83%).[10] Similarly, in our study requisition and sample labeling/collection errors comprised 4.03% of all the requisitions received and 60% of the preanalytical errors, comprising mainly sample labeling errors (35.5%) and discrepancy in CR No. and patient's name (24.2%). These are high-risk errors with the potential to cause a harmful event to the patient if not detected well in time.

Inappropriate request for components comprised 30.5% of all the errors, approximately 2-3 per day, similar to the studies by Callum[6] and Masken *et al*.[4] who also reported a high frequency of inappropriate request. It has led to six harmful events in the present study. Interventions to change physician's behaviour, such as audit plus feedback and/or transfusion guidelines, have been shown to improve transfusion practices. Reduction in the inappropriate use

Table 2: Location of error

Location of error	Number and % of error (*n* = 2229)
Clinical services	2,030 (90.9)
Transfusion services	199 (10.1)

Table 3: Details of the adverse reactions occurred due to errors

Error type	Harmful event
Inappropriate request	Patient with chronic renal failure Hb□ 4.3 g% transfused 3 units of whole blood in two days developed TACO§ Dengue patient with Hb 12.7 m%, platelet count 8,000/cumm transfused with 2 units of fresh whole blood developed in 3 h developed TACO. Carcinoma breast patient with platelet count of 65,000 cumm transfused random donor platelet developed severe dyspnea, ARDS†-like features. Patient died. Probably due to ?TRALI, ?TACO, could not be diagnosed properly. Exchange transfusion was performed with one unit of O-negative whole blood in B-positive neonate markedly raised the bilirubin and reticulocyte count. Two obstetric patients with Hb <6 g/dL having h/o FNHTR‡ earlier with whole blood transfusion were transfused again whole blood developed FNHTR with severe hypotension needing ICU□ admission.
Labeling errors	Exchange of labels after cross matching resulted in mild to moderate ABO incompatible transfusion reactions in two patients
Sample testing errors	One analytical error where reverse grouping was not done during emergency duty hours resulted in ABO incompatible hemolytic reaction
Issuance Errors	Wrong blood issued to two patient developed mild hemolytic reactions. Error recognized after 50-60 mL blood transfused
Error at the bedside transfusion	Blood unit got exchanged in two patients with similar name in the labor room. Patients' details on cross-matching report and label not checked before transfusion. One patient developed ABO incompatible reaction.

□Hb: Hemoglobin, §TACO: Transfusion-associated cardiac overload, #TRALI: Transfusion-related acute lung injury, †ARDS: Acute respiratory distress syndrome, ‡FNHTR: Febrile nonhemolytic transfusion reaction, □ICU: Intensive care unit

Table 4: Errors leading to adverse events

Type of adverse event	Errors causing event
ABO incompatible reactions (7/12)	Nonanalytical errors (85%)
	Labeling of blood bags 2/8
	Issuance of wrong blood 2/11
	Inappropriate request 1/680
	Transfusion of wrong blood 1/2
	Analytical error 1/6 (15%)
TACO[§] (2/12)	Inappropriate request
FNHTR[†] (2/12)	Inappropriate request
?TACO, ?TRALI[‡] (1/12)	Inappropriate request

[§]TACO: Transfusion-associated cardiac overload, [†]FNTHR: Febrile nonhemolytic transfusion reaction, [‡]TRALI: Transfusion-related acute lung injury

Table 5: Frequency of actual harmful events (denominator is no of transfusions)

Actual event (12/26,683)	Frequency (4.4/10,000)
ABO incompatible hemolytic reactions	2.2 per 10,000 transfusions
TACO[†]	0.7 per 10,000 transfusions
FNHTR[‡]	0.7 per 10,000 transfusions

[†]TACO: Transfusion-associated cardiac overload, [‡]FNHTR: Febrile nonhemolytic transfusion reaction

of blood is most successful with active enforcement of hospital transfusion guidelines.[16]

The frequency of accepting sample in error was 7.5% of all errors occurring in transfusion services. All the samples accepted in error were detected before or during testing. Maskens *et al*., who reported 0.5% samples accepted in error and in 0.2% final check before issuing was not done.[6] Analytical errors have the high potential of causing ABO incompatible harmful events, comprising 0.018% of all the samples tested and 0.2% of all errors comparable to another study.[4] These occurred in transfusion services despite the presence of trained staff on duty, which may have been due to fatigue, inattention, and heavy workload as compared to manpower in transfusion services.

Most of the errors are occurring in the clinical services comprising nearly 90.9% and 10.1% in transfusion services findings are similar to Sharma *et al*.,[8] who also reported 87% errors occurring outside the blood bank and most of these were preventable. Nine of their patients received the incorrect blood or blood components owing to nonuniform identification numbers, and this resulted in serious morbidity in two patients.

ABO incompatible transfusion reactions were the commonest harmful event due to errors occurred with the frequency of 2 per 10,000 transfusions; 85% of these were due to nontechnical errors, whereas Linden *et al*. reported 1 per 14,000 mistransfusions.[17] Transfusion-associated cardiac overload (TACO), hemolytic reaction in one, transfusion-related acute lung injury (TRALI) in one, and febrile nonhemolytic transfusion reaction (FNHTR) occurred due to inappropriate request for transfusion. The Serious Hazards of Transfusion (SHOT) group 2010-2012 reported that TACO was the most common reaction leading to the patient's death (http:/shotuk.org, Sept-Oct 2014). Twenty out of 23 harmful events occurred in a study from Canada due to inappropriate request. TACO was the most common adverse event reported.[6] Narick *et al*.[18] reported TACO in 4.8% of plasma recipients. The rate of transfusion and the patients' underlying ability to deal with volume are risk factors for TACO. Thus, associated comorbidities need to be addressed before transfusion. One case of hemolysis occurred due to insistence by the clinician to transfuse O-negative whole blood for exchange transfusion in B-positive neonate. Attention to transfusion-related errors has been drawn by Serious Hazards of Transfusion Hemovigilance Programme. In the 2011 annual report from SHOT, there were 247 incorrect blood components transfused, 149 inappropriate and unnecessary transfusions, 325 handling and storage errors, 249 anti-D events, and 1,080 near-miss events with the potential for wrong blood or product transfused (http:/www.shot uk.org, Sept-Oct 2014).

The present data suggest that errors are much more frequent than actual events. Thus, implementing error reporting in transfusion services will help in determining the problematic areas and making effective policies to deal with them, thus improving the transfusion safety. The most common errors in the present study were inappropriate sample collection, inappropriate ordering of blood components, and sample accepted in error. The most common adverse events reported were ABO incompatible reactions due to clerical errors followed by TACO. There may be underreporting of errors in the present study mainly during emergency hours when the staff is less as compared to the workload and unattentive attitude. Larger and elaborate studies are required to know errors, near-misses, and actual events in the transfusion chain.

Conclusion

To conclude, error reporting is critical to the transfusion safety as the data generated can be utilized for identifying the weaker areas and further strengthening it by taking corrective action. The frequency of errors related to pretransfusion testing is very high in the present study but tracking of events will help us in formulating stringent policies and hospital-based guidelines such as bedside labeling for sample collection, making the clinicians aware of the rational use of blood components and getting them implemented through the Hospital Transfusion Committee to improve services.

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Conflicts of interest

There are no conflicts of interest.

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