

# Root-Cause Analysis of a Potentially Sentinel Transfusion Event: Lessons for Improvement of Patient Safety

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**Abstract-** Errors prevention and patient safety in transfusion medicine are a serious concern. Errors can occur at any step in transfusion and evaluation of their root causes can be helpful for preventive measures. Root cause analysis as a structured and systematic approach can be used for identification of underlying causes of adverse events. To specify system vulnerabilities and illustrate the potential of such an approach, we describe the root cause analysis of a case of transfusion error in emergency ward that could have been fatal. After reporting of the mentioned event, through reviewing records and interviews with the responsible personnel, the details of the incident were elaborated. Then, an expert panel meeting was held to define event timeline and the care and service delivery problems and discuss their underlying causes, safeguards and preventive measures. Root cause analysis of the mentioned event demonstrated that certain defects of the system and the ensuing errors were main causes of the event. It also points out systematic corrective actions. It can be concluded that health care organizations should endeavor to provide opportunities to discuss errors and adverse events and introduce preventive measures to find areas where resources need to be allocated to improve patient safety.

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## Introduction

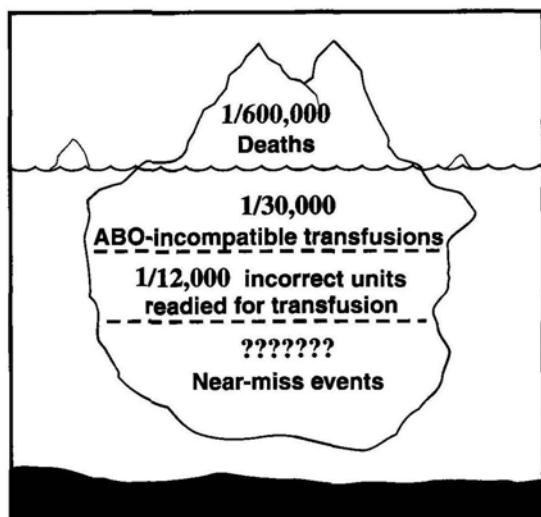
Errors prevention and patient safety in transfusion medicine are a serious concern (1). The incidence and consequences of errors in transfusion processes have been examined in multiple studies (2). The Joint Commission emphasizes at accuracy of patient identification as first Goal in National Patient Safety program (3). Additionally, the National Quality Forum has identified incompatible blood transfusions as “never events,” category and so, incompatible blood transfusions must be reported to the Department of Public Health (4,5). Fortunately, only a small number of such errors result in serious or even fatal effects (6). Errors can occur at any step in transfusion and its root cause can be one or more of the following things: mistakes in patient identification or blood sample giving for type and screen/cross match, errors in

laboratory including, specimen collection and labeling, screening or cross-matching, faults in selection and labeling of the appropriate blood product, and errors in identification of the product recipient patient or pretransfusion bedside checks (7). The population-based Harvard Medical Practice Study showed that Adverse events occurred in nearly 4 percent of the hospitalizations that prolonged their stay or resulted in measurable disability (8,9). Fourteen percent of these injuries were fatal. Other study has found that The median overall incidence of in-hospital adverse events was 9.2%, whose 43.5% were preventable. More than half (56.3%) of patients experienced no or minor disability, whereas 7.4% of events were fatal (10). Often, transfusion-error incidents involve compound errors (6). The iceberg model (Figure 1) based on the report of Linden *et al.* study shows the data about transfusion incidents in near-miss reporting system (6).

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**Figure 1.** Iceberg model showing transfusion error rates extrapolated from New York State Department of Health data.

A “near-miss” event can be defined as an accident that almost happened but was prevented (7). Near-miss events are more common than real adverse events four times (12). Safety studies have shown that the underlying causes of near misses are alike to other events. Thus evaluation of near-miss events can prepare useful information for prevention and safety programs (7). In a systems approach, corrective actions should be focused that address system vulnerabilities, rather than emphasis on disciplinary actions against individual employees (2).

Health and safety researches have made known that systems should eradicate the underlying causes of minor incidents to reduce the frequency of major incidents (13). Root cause analysis as a structured and systematic approach can be used for identifying underlying causes of adverse events especially key system level factors that contribute to the occurrence of events (14). To specify system vulnerabilities and illustrate the potential of such an approach, we describe the root cause analysis of a case of transfusion error in emergency ward that could have been fatal.

## Materials and Methods

We implemented a voluntary adverse event reporting system in the hospital and staff was required to record and report such events in two different varieties, filling the adverse event reporting forms and returning them,

and recording the data in an adverse event register. Moreover, fatal and serious events should be reported to clinical governance department and patient safety office by the head nurse to be analyzed and followed up. The process of root cause analysis and framework of contributory factors were taken from the London protocol of NHS, consist of identification and decision to investigate, organizing team, organization and data gathering, identifying care delivery problems, determining incident chronology, identifying contributory factors, and making recommendations and developing action plans.

The mentioned event was both recorded in the adverse register and was reported to the head nurse of the emergency ward. Following the report, primary intervention measures were conducted in order to shed some light on the detail of the incident; and also, thorough interviews were conducted with the responsible personnel. After collection of the required data, a meeting was organized and held by a committee of experts in the field; and, using conventional root cause analysis techniques, the event was thoroughly analyzed. In this meeting, in addition to the manager of clinical governance office and patient safety staff, the head, manager, supervisor and head nurse of the emergency ward, blood bank and laboratory moderator and metron of the hospital were present. The assembly group defined a timeline for the event, and using brain storming method and the fishbone diagram, discussed and determinate the care and service delivery problems and safeguards and preventive measures. The conclusion of the meeting was then reported to senior managers and related departments of the hospital as well as the Medicare Management Deputy of the University. It is noteworthy that follow up of implementation of the preventive measures is the duty of clinical governance office with the support of senior managers of the hospital.

## Chronology and outcome

The timeline of the incident is depicted in table 1. Fortunately, a few minutes after initiation of transfusion, the emergency ward medical officer noticed that a bag of blood was being infused to a wrong patient. In close collaboration with the nursing staff, the infusion was discontinued and preliminary interventions were initiated urgently. In a few hours, the patient was carried to the operation theatre and the appendectomy was performed. He was then transferred to the ICU and was eventually discharged without any considerable consequence.

## Root-cause analysis of a potentially sentinel transfusion event

**Table 1.** Timeline of the event

Event: transfusion error

Time	21 o'clock	22 o'clock	22,30 o'clock
Incident	The emergency night shift was handed over to 7 nurses instead of 9 which should have taken the shift. As the ward was overcrowded, a relief nurse was summoned from the neonatal ward by the supervisor	2 patients with partial similarity in names were admitted in ward. One for gastrointestinal hemorrhage and indication for transfusion, the other one with blood reserve for a potentially eminent appendectomy.	When blood bag was delivered to the ward, the responsible nurse recorded bag code and gave it to the relief one to infuse it to the patient. He assigned the patient's name erroneously and the relief nurse transfused the blood to the wrong patient without checking bedside controls.
Additional information	Through of whole shift, the emergency staff contested of high workload and shortage of personnel.	As the relief nurse was inexperienced, she was employed in admission unit.	
Missed information			The patient identification and bedside controls and generally, transfusion protocol were ignored.
Correct actions			Fortunately, in the next follow up of patients, this error (transfusion to a wrong patient) was detected and the infusion was discontinued.
Care or service delivery problems	1. Employment of unskilled staff in the emergency ward		2. Poor adherence to transfusion protocols 3. Incomplete information on the blood bag label 4. Assignment of blood transfusion to a relief nurse

### Service and care delivery problem

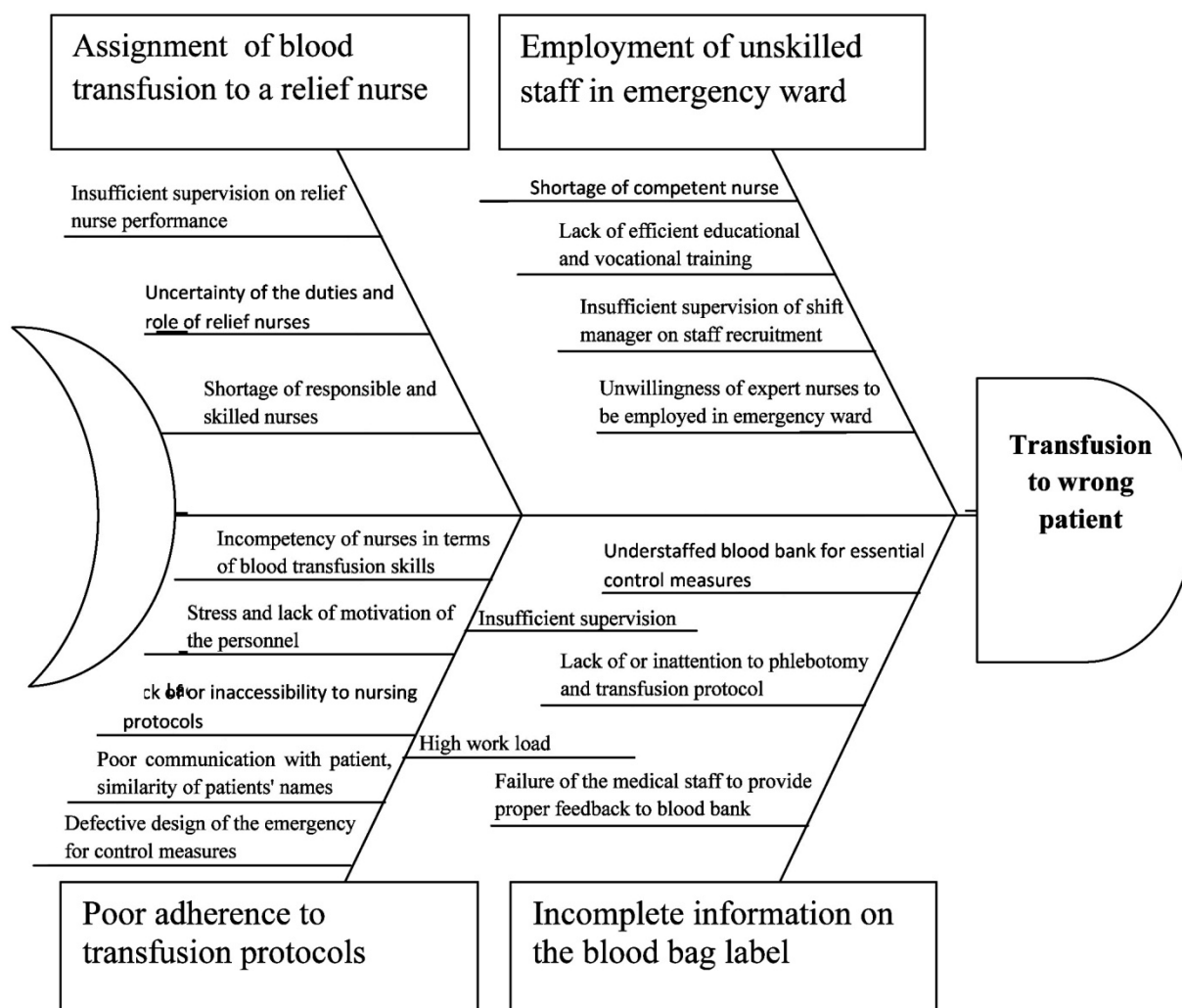
The Fishbone diagram in Figure (2) demonstrates care and service delivery problems as well as predisposing factors and fundamental causes of the event. The understaffed ward and employment of incompetent personnel in emergency, poor adherence to published protocols for blood transfusion, using relief nursing staff for blood transfusion which is considered as a critical procedure and incomplete information on the blood bag label are diagnosed as main problems in service delivery system by the expert panel.

Generally, several recruitment and employment causal factors are considered to be responsible in different accidents and adverse events in the emergency ward. They are: shortage of competent nursing staff in teaching governmental hospitals, lack of efficient planning and shortage of educational and vocational training courses, and insufficient supervision of shift manager in different stages of staff recruitment and performance. Moreover, unwillingness of experienced nurses to be employed in emergency ward for different

reasons such as low wages, insufficient benefits, job stress and high level of responsibility was suggested as the underlying cause of failure to recruit and employ competent nurses in the emergency ward of the hospital.

Regarding the defects and failure of the transfusion process, several contributing factors were claimed to be influential such as: incompetency of nurses in terms of blood transfusion skills, insufficient supervision, high work load, stress and lack of motivation of the personnel, Poor communication with patient and similarity of patients names, lack of or inaccessibility to nursing protocols and procedures, and defective design of the emergency wards which limited proper access to different parts for surveillance of personnel and patients.

The expert group mentioned that failure of the medical staff to provide proper feedback to blood bank, lack of phlebotomy, patient identification and matching protocol and the understaffed blood bank for essential control measures on blood bags to be delivered to the ward, was seen as underlying causes of problem of inadequate information on blood bags.



**Figure 2.** The Fishbone diagram of care and service delivery problems and underlying causes of the event

The expert group strongly criticized assignment of a relief or temporary nurse for transfusion process. Crammed emergency ward, shortage of responsible and skilled nurses, insufficient supervision, uncertainty and not enough briefing of relief nurses about their duties and the role they should play in high loading situations were highlighted as responsible for this problem.

### Corrective action

With the view of provision of an acceptable patient to nurse ratio in critical hospital wards, especially in emergency ward, a practical instruction for defining up to standard nurse/patient ration was codified and it was decided that nursing office and emergency ward supervisors monitor its implementation. Moreover, the hospital senior managers were committed to support this plan so that in no circumstances the number of emergency ward personnel lessens from a minimum essential number and moreover the shift and emergency

supervisor have the authority to recruit nurses from other wards of the hospital or summon the on-call nurses to compensate for the lack of sufficient staff.

One of the main contributory factors of all service delivery problems in mentioned event is the lack of proper supervision of shift managers and ambiguity of their role and responsibilities. With this view, the position of shift supervisor in controlling the emergency ward was reestablished and with clear definition for the role of shift supervisor, it was decided that the supervisor should not be overworked so that to be able to perform the supervisory responsibilities in a proper way. In this framework, the patient care duties were to be divided between other shift personnel.

In order to motivate emergency ward personnel and encourage experienced nurses to work in the emergency ward, establishment of a flexible schedule and payment of bonuses were considered.

## Root-cause analysis of a potentially sentinel transfusion event

In order to maintain and update essential skills of the personnel and ensure in-service and new employee education, the nursing office was obliged to design and implement of educational need assessment programs and proper vocational training courses and establish a set that criteria for ongoing assessment of professional performance of personnel especially in emergency ward.

Moreover, it was decided that practical guidelines for critical procedures such as blood and components transfusion be printed and installed at different wards of the hospital.

One of the main solutions to deal with the shortage of personnel when the emergency ward is crammed is recruiting temporary relief personnel from other wards of the hospital. Considering the fact that relief nurse may not be well-oriented and might be even confused, it was decided that proficient nurses from different wards of the hospital be elected and qualified so that they can be the first priority nurses that recruited as relief. Moreover, it was decided that responsibilities and functions which can be transferred to relief staff should be well defined and the needed information for the job is provided for them. The shift supervisor will be assigned for supervision and co-ordination of relief staff duties.

In the end, it was agreed that the laboratory and blood bank should revise the transfusion protocol of whole process of documenting, phlebotomy, matching tests, labeling, transferring, and delivering blood bags. This was mainly done to address the issue of confusion in different stages of transfusion.

## Discussion

The project of implementation of a competent risk management infrastructure and Adverse Event Reporting System at a teaching hospital aimed to present and implement a risk management system and template specifically according to World Health Organization guidelines and recommendations. Moreover, it aimed to collect information needed for in depth analysis of adverse events for design necessary measures to control. This reported critical adverse event and its root cause analysis illustrates the usefulness of adverse event reporting and learning system in hospitals to draw attention to human and system errors that may otherwise go unnoticed and to identify where resources need to be targeted for patient safety improvement. For tracking accidents associated with blood transfusion Myhre and McRuer recommend that system must be designed to accept this fact of human errors are inevitable and prevent as many errors as possible with gathering,

collating, analyzing, system revision and publishing data in a no fear and blame culture (23). Staff appear to be less likely to report events if they catch and repair a problem before patient harm. With defining importance of learning from studying deviations and events without harm or near misses, staff could be changed their reporting habits. Easy reporting process, providing feedback to staff, and just and non-punitive culture are required for having successful adverse event reporting system (2). In a study in French hospitals, findings showed that the incidence of ABO discrepancies was 1 per 3400 likely to rates reported by Dzik *et al.* 11, 0.33 per 1000 and Lumadue *et al.* 12, 0.9 per 1000 that is 10 times higher than the previous observed number of ABO-mismatched transfusions (13). The main root causes of the ABO discrepancies in this study were sample collection from the wrong patient (phlebotomy error) in 58% of cases, patient misidentification accounting for 36% and transmission of erroneous blood cards (right name with wrong ABO group) in 6% (7). Most errors result from human actions especially when multiple tasks occupy the attention of busy staff, like in emergency department, blood bank, or operating rooms and accordingly these errors may be preventable. In transfusion medicine the majority of events (50%) happen outside the blood banks which necessitate urgent wide preventive actions in hospitals (6).

Callum *et al.* have shown the ineffectiveness of didactic small-group educational sessions, as found in a metaanalysis of randomized trials of continuing medical education, and have emphasized that education, in itself, is insufficient to reduce the frequency and severity of events (12). In addition some other authors have recommended that continuing professional education cannot get better performance. A training curriculum must be considered that could be effective in improving knowledge and changing practice (15). According to some report on low and moderate level of knowledge about blood transfusion in majority of health care workers, there is a need for a curriculum to promote their knowledge. The effectiveness of education in changing nurses' practice patterns is linked to participants impetus to change and the type of training as targeted at nurses' needs and integrated into the work environment (16).

In case of our study, the aforesaid relief or temporary nurse had weak or lowest level of knowledge about transfusion principles. Even so evidences have emphasized on educational subjects that result in practice changes, we moreover think that proper vocational training courses and in-service trainings of

nurses are required to guarantee nurses' knowledge, qualifications and essential skills. In addition, if well-located access to standard transfusion instructions in ward had been provided, it can be influential in prevention of event.

Fastman And Kaplan reported that as many as 40% of transfusion errors happen in the post-analytic phase, often failures occur in the final check of the right blood and the right patient at the bedside, so Bar-code labels, radiofrequency identification tags, and even palm vein-scanning technology are increasingly suggested (17). Stainsby *et al.* in analysis of Incorrect Blood Component Transfused events have revealed that, in about 50% of cases, more than 1 error contributes to an adverse outcome, and that roughly 70% of errors occur in clinical areas, the most frequent error being failure of the bedside patient identification (18). Our results also revealed more than one error involved in happening of the event which emphasizes on priority and importance of considering in depth evaluation of adverse outcomes especially in clinical areas.

In October 1999, California introduced landmark legislation that made it the first US state to mandate safe licensed nurse-to-patient ratios in all acute care units. Safe Staffing Bill mandates ratios based on patients' needs rather than budgets (19). Ellis and Clements emphasize at the importance of the number of nurses working in the system and the right mix of skills, education and experience (20). Employ of a unit leader to provide patient to nurse ratios appears to provide the most complete and accurate labor data (21). The flexible approaches such as nurse staffing on patient acuity or nurse-sensitive outcomes, seem more appropriate than patient to nurse ratios, given the complexity and flexibility in the delivery of hospital care and as a result, hospital nurses can play a more direct role in staffing decisions, which may improve these nurses' job satisfaction and retention (22). In addition, job stress, management style and job satisfaction are associated with a better quality of nursing care (15). Under regulations issued 24 March 2002, hospitals are required to establish committees to develop nurse staffing plans and to use data on nurse-sensitive patient outcomes to assess and adjust staffing plans (22). In safety researches immediate supervisors play a key role in improvement of safety culture and procedures. The most transfusion service staff have positive attitudes on the safety expectations and actions of their immediate supervisors (2). However, emergency room staff encounter high workload in routine practice, and within working shift which aforementioned event occurred, two nurses were

missing the shift that resulted in increase in workload by 30%; so the importance of nurse/patient ratio must primarily be considered.

It seems one of the issues in most cases because of work overloud is the supervisor forget his character and start practicing as a nurse practitioner. For solving this problem, first of all, supervisor position should have been defined in nursing team as a manager and leader. Secondly he must be had the authority to determine and afford required emergency nursing team and open the work environment in such a way that each team member can come to a decision what role he wants to play. Following this way, we expect staff take more responsibility and satisfaction. Thirdly he has to supervise and evaluate the staff professional standard performance.

In report of Linden *et al.*, one a most commonly identified contributory causes in transfusion errors was similarity in patient names (6). They believed that systems must be redesigned to allow minor fluctuations in human performance, especially in routine tasks, simple retraining is not enough, and job aids for prevention specific errors may be helpful. Some other recommended options include: convenient access to standard operating procedure instructions in work areas, a blood-component lock system that should be matched with patient wristband, and computerized inventory control that must be equal with written request. Ultimately, automation throughout the system may be the best solution. (6). Aslani *et al.* have recommended that hospitals activate the blood transfusion committees to enhance the quality of common procedures and prevent side effects by in-service trainings of nurses (24). education and audit as the two main tools in possession of hospital transfusion Committees can optimize blood use (4). Audit is a continuous process aimed at ensuring best practice equal to best evidence (25). Improving professional training, establishing professional standards, spreading guidelines, and revitalizing the Hospital Committees for the Good Use of Blood have been suggested by Italian Society of Transfusion Medicine and Immunohematology to prevent medical errors (26).

We believe that transfusion safety is one of the main priorities of patient safety and hospital risk management system. It can audit transfusion process and comprehensively analyze the distribution of serious errors and guide corrective actions with the systematic approach emphasizing at procedure amendment and interdisciplinary coordination. As well the hospital-based Transfusion Safety Officer that is working outside

the laboratory can improve patient safety regarding transfusion as Dzik *et al.* in new solution for transfusion safety emphasized (27).

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