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Serious hazards of transfusion: Evaluating the dangers of a wrong patient autologous salvaged blood in cardiac surgery

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Case Report

Keywords: patient safety, root cause analysis, human factors, autologous-salvaged blood, transfusion, wrong patient, medical error

Posted Date: May 4th, 2022

DOI: https://doi.org/10.21203/rs.3.rs-1605146/v1

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Abstract

Background: Intraoperative cell salvage is widely used, but the risk of incorrect administration remains underappreciated. We report on a case in which blood collected from a patient with lung cancer was mistakenly administered to a patient undergoing cardiac surgery who should have received his own collected blood. The initial investigation found that violations of procedures by field personnel were the cause. However, a detailed investigation revealed that not only violations were the cause, but also that the underlying causes included organizational policies, communication, workload and staffing deficiencies, human factors and cultural challenges.

Case presentation: A 72-year-old male patient requiring dialysis due to chronic renal failure was admitted to our hospital for angina pectoris and multi-vessel coronary artery disease; cardiac surgery was performed using the autologous salvaged blood system with autologous blood collection, with no major problems other than prolonged operative time. A drop in blood pressure that night led to administering the patient's previously stored blood. The nurse took a blood bag from the ICU refrigerator and administered it to the patient. In doing so, neither the physician nor the nurse performed the requisite verification procedures. However, the blood administered was blood from another patient that had been collected the day before from another surgery. The ABO-mismatch transfusion had occurred and the patient was diagnosed with DIC. The patient recovered and was discharged 65 days later. An accident investigation committee was convened, root cause analysis was conducted, and measures to prevent recurrence were developed.

Conclusion: This adverse event occurred because the protocol for intraoperative blood salvage management was not clearly defined, and the procedure was different from the for standard transfusion practices. There were unexpected events, such as the presence of salvaged blood from other patients as well as inadequate and ambiguous information-sharing among the parties involved. We developed a systemic improvement strategy in which intraoperative blood collection would be administered before the patient leaves the operating room to completely prevent recurrence, instead of simply requiring front-line staff to do double-check. Implementing strong systems processes can reduce the risk of errors in blood transfusions and ensure that patients receive the correct blood products.

Background

Autotransfusion of patient blood has been widely used in various surgeries since the early 1970s[1]. One method of blood salvage is to collect it from the operative field and store it intraoperatively[2]. Intraoperative cell salvage is effective for the conservation of red blood cells[3]. Although technical errors in intraoperative cell salvage have been reported, there have been no reported cases of blood transfusion to a wrong patient, a never event[4]. In this report, we describe a wrong patient blood infusion case in which a patient was administered another patient’s blood, which was collected as autologous-salvaged blood (ASB) during cardiac surgery. We investigated the causes of this event by root cause analysis (RCA) from the perspective of patient safety, in order to prevent similar incidents again.

Case Presentation

A 72-year-old patient with a history of congestive heart failure and chronic atrial fibrillation, required dialysis for chronic renal failure due to nephrosclerosis, was admitted to our hospital because of angina pectoris and multi vessel coronary artery disease. His home medications included warfarin potassium (1 mg), clopidogrel sulfate (50 mg), amiodarone hydrochloride (100 mg), and bisoprolol fumarate (1.25 mg). His blood type was O, Rhesus (Rh) D-positive. Blood was collected by the ASB system and the coronary artery bypass surgery was successfully completed. The surgery was prolonged due to re-anastomosis on one of the three-vessel cardiac grafts. The operative time was 8 hours 19 minutes, intraoperative blood loss was 790 ml, and no autologous or allogeneic blood transfusions were performed. was performed. Cardiovascular surgeons at our hospital usually stock the collected blood in the intensive care unit (ICU) if the case does not require urgent use of the collected blood. Depending on the patient's condition, the surgeon usually decides whether to transfuse the blood back to the patient or discard it 24 hours after the operation.

On the night after the operation, a physician in charge decided to administer the salvaged blood of the patient due to a decrease in systolic blood pressure. As the patient was not bleeding, not in shock, and had no abnormalities in cardiac function, blood gases, or electrocardiogram, the low blood pressure was attributed to dehydration. The physician instructed the nurse to bring the patient’s blood from the refrigerator. Because the nurse was engaged in the care of another patient, she requested that another nurse “Bring it to me.” The other nurse went to the refrigerator and picked up a blood bag. However, the bag retrieved by the nurse was not that of the cardiac patient, but was collected from another patient with lung cancer who had undergone thoracic surgery the day before. The blood type of the patient with lung cancer was A, RhD-negative. When stored in the refrigerator, a note with the patient's name and identification (ID) number was supposed to be put on the basket, but this was not present at the time of the incident. The name was written on the pack, but the nurse did not check this because she was in a hurry. The nurse believed that the blood in her hand was that of the patient, and handed it directly to the original nurse, who then connected it to the patient's IV line and started the infusion without further ascertainment. For a typical blood transfusion, the doctor uses a logged-in Personal digital assistant (PDA) for verification, but the salvaged blood bag does not have a barcode and is not verified by the PDA.

The patient became hypotensive with blood pressures in the range of 50 to 60 mmHg systolic pressure range and vasopressors were initiated. Seven minutes after the transfusion began, the patient's blood pressure dropped further, with a systolic pressure in the low 50s. The blood transfusion was stopped considering the possibility of transfusion side effects. The volume of blood administered was estimated to be approximately 50 mL. The blood bag was removed from the venous line and hung on the bedside infusion table. The transfusion was interrupted, Albumin and noradrenaline drop were administered, and 18 minutes later, the patient’s systolic blood pressure increased to 130 mmHg range. There were no physical findings suggestive of an allergic reaction or hemolytic urine. The surgeon thought that the cause of the hypotension was a low circulating blood volume. One hour later, the patient’s serum hemoglobin level decreased to 9.2 g/dl from 11.4 g/dl preoperatively. The nurse was instructed to restart

the transfusion. The nurse connected the blood that was hung on the bedside infusion table to the patient and restarted its transfusion. All residual blood was transfused into the patient. A decrease was noted in the number of platelets the next morning, and the patient was diagnosed with disseminated intravascular coagulation syndrome.

During a regular safety check of the refrigerator by the nurse leader, it was discovered that the ASB, which should have already been administered, was still stored. This revealed that the blood administered to this patient was that of another. The patient was successfully resuscitated and was discharged from the ICU on day 8. The patient was finally discharged home with no complications on day 65 due to persistent pleural effusion and positive CRP, and delayed rehabilitation due to severe back pain.

Adverse incident aftermath: Apology and Disclosure

An hour after the accident the concerned parties gathered to discuss the best course of action. Three and a half hours after the accident, the surgeon in charge and staff of the patient safety department disclosed the facts of the event to the family and apologized to the patient's family[5]. Nine hours later, a second disclosure and apology were made to the patient's family. From day 12 to 60 day after the accident, several meetings and e-mail conferences were held involving the investigation committee, chaired by an external committee member to analyze the causes of the incident and compile measures to prevent a recurrence. The investigation report was submitted to the hospital President, who accepted the recommendations to change the procedures. A periodic audit of blood transfusion indicated that the all the recommended changes in ABS were implemented and no other adverse events have occurred.

Discussion And Conclusions

We describe a completely preventable wrong patient blood transfusion in which a patient was administered another patient's blood, collected as autologous-salvaged blood (ASB) during cardiac surgery. We review the root cause investigation (RCA) and highlight the systems issues that emerged and the corrective actions implemented in our hospital to prevent similar adverse incidents.

Transfusion Safety

The history of blood supply is one of early, sobering frequency of disease transmission but also remarkable improvement in systems safety in terms of correct blood transitions that is free of infectious agents. Blood product safety has been an improving area of focus for many countries over recent decades[6]. Several methods have been employed to reduce the risk of blood transfusions and improve blood product administration safety[7]. The entire blood harvesting and transfusion process has been redesigned from before blood donation collection through post-procedure follow-up of blood product recipients. There have been improvements made in the collection, storage, management, distribution, utilization, and monitoring of transfusions.

Transfusion System Infrastructure

The clinical laboratory is one of the most highly regulated services in the hospital, and the transfusion service is one of the most highly regulated services within the clinical laboratory. The pathway of blood delivery is inherently complex because multiple patient care areas are involved. The goal of the blood delivery pathway is to deliver the right product to the correct patient[8]. The pathway can be summarized by three simple steps:

1) Identify the patient with two unique identifiers (ID).

2) Connect the patient identifiers to all prepared lab samples, tests, and blood products.

3) Deliver the right blood product to the right patient at the right time, confirming patient ID again.

These three simple steps comprise numerous processes, each with its risk of failure. The highest rates of failure are associated with processes outside of the clinical laboratory.

Risk of ABO-Incompatible Transfusions and Hemolytic Reactions

The risk of fatality due to an ABO-mismatched red blood cell transfusion could therefore be estimated at 1 to 4 per 10,000,000 for each red blood cell unit transfused[9]. But fatal reactions represent the 'tip of the iceberg' as most ABO-incompatible near miss transfusions involve small volumes due to early clinical signs/symptoms and often patients survive[10].

The risks of a lethal hemolytic transfusion reaction were estimated at 1 per 550,000 units transfused for the time period 1976–1985 in the US[11]. Not all hemolytic reactions are ABO-related and not all wrong transfusion events result in adverse clinical outcomes. Others have estimated that 1 in every 19,000 units of red blood cells is transfused to the wrong patient each year, 1 in 76,000 transfusions results in an acute hemolytic reaction, and 1 in 1.8 million units of transfused red blood cell units results in death due to acute hemolytic reaction[12].

When estimating risk, the best information available indicates that most transfusions to the wrong patient occur as a result of potentially avoidable system failures[13]. The most frequent error leading to transfusion of ABO-incompatible blood occurs during patient identification/verification at the bedside; as a result, although the blood is labeled appropriately, it is transfused to someone other than the correct recipient.

Root Cause Analysis of this Case

A linkage diagram (Fig. 1) and root cause analysis of events (Table 1) were developed to link a problem statement to conditions and actions.

Table 1

Root cause analysis of events and its application to understanding this case.

Root cause	Application to the case
Communication problems	The blood salvaged during operation of patient Y was not shared within the Cardiovascular Surgery department, Thoracic surgery department and among the nurses. Most of them were unaware that patient Y's blood was being stored postoperatively. Errors occurred in perception and cognition.
	Patient Y's blood was not discarded on 1 POD as policies dictate, nor was its presence shared among the nurses or even within the Cardiovascular Surgery department.
Inadequate information flow	Instructions for blood salvaging were not clearly communicated through either verbally or in writing. Nurses did not communicate with other nurses or physicans about their concerns regarding Patient Y's condition and questions regarding blood salvage protocols.
Human factors problems	Since collected blood devices was not equipped with a dedicated label, the patient's name was written directly on the red transfusion bag with black magic marker. In addition to this, Nurse D could not recognize that the blood was from the wrong patient because the intensive care unit in the evening was dimly lit and the visibility was poor. Nurse D, who was requested by Nurse C, the nurse in charge of Patient X, to retrieve the blood in the cold storage, was in a hurry because the patient's condition was unstable.
Patient-related issues	The patient was transferred to the ICU after a lengthy surgery, and his blood pressure was unstable.
Organizational transfer of knowledge	Nurse D did not know that the Intensive Care Unit had two cold fridges for storing blood.
Staffing patterns/worl flow	The reason for this is that the intensive care unit was always busy, and the duties of the lead nurse were shared among several staff members. The division of duties was the reason why labels were not applied, blood was not checked per hospital policies, and entries were not made in the logbook, nor was their absence noticed**.** However, in the patient were stable, and providers could have taken more time to check the blood for correct identify and follow hospital policy. Multiple healthcare provider teams were involved in the care of the patients, also contributing to communication challenges.
Technical failures	Both the physicians and nurses on site assumed that the only blood collected was that of patient X. They did not know that patient Y's blood was stored. Therefore, they connected the blood to IV line, and administered it to the patient without doing the necessary checks.
Inadequate policies and procedures	The Surgery department did not issue an order to discard the blood on the following day. This was due to the lack of a written procedure and the unfamiliarity of the Thoracic surgeons.
	Intraoperative salvaged blood should have been placed in a dedicated basket with a note attached with the patient's name and ID, and placed in cold storage. However, this was not attached.
	The blood in the cold storage was supposed to be checked twice a day by the lead nurse and recorded in the management log. However, there was no record of these activities.

	It is against hospital policy to salvage blood products in cold storage where the temperature is controlled by the Blood Transfusion Service.
	The Blood Transfusion Service was unaware that intraoperative blood collections were kept away from patients and stored in cold storage. Therefore, the operating room and ICU were unable to question the blood collection procedure of the operating room and intensive care unit.
	The transfusion department could not question the blood salvage procedures in the operating room and intensive care unit because they were unaware that intraoperative salvaged blood was kept away from the patient and stored in cold storage.
	The central operating department and intensive care units were in a position to correct such misuse, but they did not have written procedures for handling intraoperative blood collection and did not exercise proper governance.
	The basket containing Patient Y's blood did not have a note attached with the name and ID, the pack did not have a dedicated label.

Table legend:

Patient X: Patient underwent cardiac surgery. Blood type was O, Rhesus (Rh) D-positive.

Patient Y: Patient underwent lung surgery. Blood type was A, Rhesus (Rh) D-negative.

POD: Postoperative day

ICU: Intensive Care Unit

ID: Identification

These charts identified a number of factors that predisposed the system to errors and revealed multiple contributing factors, including communication problems, human factors problems, inadequate policies and procedures, cultural problems, etc[14]. The downstream effects of the errors lead to the wrong blood reaching the patient's bedside and serious patient outcome.

Initially, the cause of this accident appears to have been a simple case of rule violation, as the blood was administered by a nurse without checking the name against the blood bag label[15]. However, identifying this as the cause and taking measures to prevent recurrence, such as double-checking the patient details, may not improve the system[16–18] and could leave the possibility of recurrence in the future. Therefore, the investigation committee searched for system errors at a deeper level.

Nurse B's action in "administering the wrong infusion" was considered a possible cause of human error, which was investigated using an RCA (see below). Human error is defined as the failure of planned actions to achieve their desired ends without the intervention of some unforeseeable events, and it is not the cause of the accident; it is the factor that causes the human to make the error that is the cause of the accident[19]. Human behavior is the result of a combination of human and environmental factors, known as the *Lewin's Eq. 2*[0] or *the SHELL model*[21]. This could also be considered via the accident analysis.

Figure 1 shows an extract from the RCA. Two factors, human and environmental factors, are involved in Nurse C's behavior. The unique actions of Nurse C are shown on the bottom, and the environmental factors are shown on the top.

First, we consider the human factors[22]. We explored the reasons why Nurse C believed that the blood bag in her hand belonged to Patient X. The probable background factors were that the: 1) fact that autologous salvaged blood from multiple patients were stored in a single refrigerator in the ICU and that this information was not shared among the staff; 2) patient's ID and name were handwritten on the bag after collection, not labeled; and 3) barcode matching system was not applied to the salvaged blood as it was not managed by the Blood Transfusion Service.

Next, the environmental factors were discussed. The cause of Patient Y's blood being passed into the hands of Nurse C as Patient X's blood was discussed. The probable background factors for how Patient Y's blood was in the hands of Nurse C were as follows: 1) the blood collected from multiple patients was stored in multiple refrigerators in the ICU; 2) the patient's name and other information were not written on the basket as required when storing the blood bag in the refrigerator; and 3) the thoracic surgeon who salvaged the blood from Patient Y was not familiar with blood salvage protocols and did not make a decision within 24 hours to use or discard the blood. Due to these factors, Nurse C administered the blood, believing that the blook in her hand belonged to Patient X, when in fact it belonged to Patient Y. The investigation committee determined that the "intraoperative salvaged blood, without starting to administer before leaving theatre, and bringing the bag to the ICU," was the root cause of this event.

Corrective and Preventative Action Plan

The investigation committee believed that measures addressing violations of the confirmation process by the staff, background factors such as lack of information sharing, and compliance failures in storage and destruction of bags, while critical, would not have completely prevented this from recurring. Therefore, measures to prevent a recurrence were focused on the upstream root causes, which included how intraoperative salvaged blood was managed. Transfuse salvaged blood is generally recommended to be given in the operating room but it is not prohibited to given it outside the operating room. However, to prevent mix-ups, it is necessary to start the administration in the operating room. The draft guidelines for the Implementation of Transfusion of Autologous Salvaged Blood (2020) by the Japanese Society for Autologous Blood Transfusion indicates that "in principle," administration should be started in the operating room[23]. At our hospital, we decided to go one step further and require starting all ASB administration in the operating room without exception. Additionally, regulations have been established regarding the recording of blood salvage, labeling of bags, and instructions for administration and disposal, which have been casual and not clearly stated. These regulations will be managed by the Blood Transfusion Service of the hospital.

In conclusion, we investigated a serious adverse incident in which intraoperatively salvaged blood was transfused to another patient with a different blood type. This unfortunate event occurred because the protocol for the management of intraoperatively salvaged blood was not clearly defined, and the

procedure was different from that of standard transfusion products. There were some unexpected events, such as the presence of the salvaged blood from other patients at the same time, as well as inadequate and ambiguous information sharing among the parties involved. We developed a system improvement strategy in which intraoperative blood collection would be administered before the patient leaves the operating room in order to completely prevent a recurrence, instead of simply requiring front-line staff to check or double-check the blood compatibility.

Abbreviations

ASB Autologous Salvaged Blood

RCA Root Cause Analysis

Rh Rhesus

ICU Intensive Care Unit

ID Identification

PDA Personal Digital Assistant

Declarations

Ethics approval and consent to participate

The Tokyo Medical University Institutional Review Boardpermits case reports with the following requirements for permission: comprehensive consent at the time of admission to be the subject of a report at conference or journal, and the patient's written consent for the submission to journals. In this case, in addition to obtaining comprehensive consent at the time of admission, written consent was also obtained for publication.

Consent for publication

Attach a written consent in the patient's own handwriting to the instructions written in the native language.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request after approval by our Ethics Committee.

Competing interests

The authors declare no conflicts of interest associated with this manuscript.

Funding

No funding was received to write the paper.

Authors'contributions

MU, SM, TM were responsible for study design and writing. MU, HM, SM, KA participated in the analysis and creation of preventive measures as members of the accident investigation committee. MU, HM and PB clarified the educational and medical safety implications and led the drafting of the English text. HM, MT and WJ supervised the investigation and analysis.All authors read and approved the final manuscript.

Acknowledgements

We would like to thank the doctors, nurses, and all of care team members, as well as all participants in the accident investigation committee.

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Figures

Figure 1

Figure title: The linkage diagram.

Figure legend: The linkage diagram provides a visual depiction of the contributory factors and underlying causes leading to an adverse event in this case. Two factors, human and environmental factors, are involved in Nurse C's behavior. The unique actions of Nurse C are shown on the bottom, and the environmental factors are shown on the top.