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Administration Safety of Blood Products – Lessons Learned from a National Registry for Transfusion and Hemotherapy Practice

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Ammendment

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Amendment

Case#1: Transfusion to the Wrong Recipient with the Same Blood Group

Reporting text: The incident happened during resuscitation for postoperative hemorrhage in an ICU patient X, that recently had been admitted from the OR together with the blood products ordered for him. There are dedicated storage facilities for blood units in the OR and sometimes also in ICU. Since anemia was moderate to considerable but blood pressure drop significant, the ward physician in charge considered transfusion of the blood bags coming along with the patient (they were laying on the bed). He performed a bed side test of the patient's blood group (A; B; 0), and compared it with the blood group of the attached cross match document and administered both units of red cells. The transfusion period was uneventful.

Later, the packed red cells for a patient Y in the OR were missed and in parallel, the originally prepared units for the patient X were found in the OR blood subdepot and delivered to the ICU by the recovery nurse. The mix- up was detected but the administration process of both units to patient x had been completed. The name on the cross match documentation sheet had not been compared with the patients ID, only the blood group and the number. (explanation by the authors: Apparently, in this institution, the cross match result is not labeled to the blood unit directly but attached to the blood unit as a separate sheet of paper. It also shows the blood group but mainly testifies the compatibility of the donors blood with the recipient (name and birth dates of the expected recipient are given too). The patient did not have any clinical signs of transfusion reaction and the result of a repeated cross match showed that the blood was compatible.

Problem analysis:

This is a case of wrong blood for the right patient. The initial mix up of cross-matched packed red cells appeared while leaving the OR for ICU. This is a busy period since many people are moving the patient, his/her documents, monitors, ventilator (if still intubated) cables and iv-lines. In addition, when there is quite a distance to the ICU or the ICU is equipped with an own blood subdepot refrigerator for red cells, then the blood is sometimes transported with or without special cooler bags to the ICU. It is assumed that someone in this situation took the wrong blood units out of the fridge in the OR and gave it along with the patient, usually by placing the products on the bed of the transferred patient. ICU staff assumed the correctness of combined delivery of a patient accompanied by ('his') blood. The risk of this incident was twofold: (1) A special antibody constellation even with compatible major blood group formula potentially can harm the non-cross-matched recipient X. Antibodies against the allogeneic blood cells or plasma might cause hemolysis, fever, thrombosis up to organ dysfunction and death. (2) Unavailability of the blood units dedicated to the second patient Y in the OR might delay a necessary transfusion, especially when cross match is not easy and compatible units not at hand.

The second error was an identification error prior to administration: It is obligatory to complete comparison of not only the bed side test with the blood group formula on the bag but to also check the cross match sheet and the ID of the recipient with the blood that was tested. This matching might be difficult in stressful and busy clinical situations but must always be done carefully by the responsible physician.

In addition, a 'common' problem is that the administration of red cells is not in congruence with guidelines. The indication was that the hemoglobin level of the patient. Hemoglobin levels vary a lot in the perioperative situation. The volume status of the patient remained unchecked upon arrival in the ICU. The assumption that patients usually are getting delivered hypovolemic to the ICU might be true for most of patients in that institution but transfusion indication should be restrictive and according to existing transfusion guidelines. Red cells aren't adequate

volume replacements. The reporter did not tell the exact hemoglobin level but anemia was not severe. The blood pressure drop was interpreted as caused by ischemia but also could be hypovolemia or heart failure. A quick and reliable Trendelenburg test, a quick ultrasound of the vena cava, echocardiography, or other volume status measurement would be preferable in that situation.

The fourth error was to give two units without a reassessment of the clinical situation and symptoms after the first unit. This practice usually causes overtransfusion. Administration of more than one unit is in congruence with guidelines only for severe anemia and uncontrolled ongoing bleeding.

The fifth error was the delivery without a suitable transport bag. Sometimes, especially when the distance to the ICU is short, the temperature of the blood units do not change during a short period. However, for hygienic reasons and as preparation for longer transports i.e. to CT diagnostics, temperature bags should be used even for short transports.

Recommendations of the expert committee:

To avoid the risks and errors mentioned above, the following recommendations should be considered by the reporting institution:

Improvement of process quality:

Introduction of a routine two person double check procedure before administration of a blood unit / 4 eye procedure strongly is recommended in addition to the BST

For better recognition of the intended recipient's name and birth date use bigger font or other color on the document/label on the compatibility sheet

Fixation of each crossmatch test result to the respective unit

Education of the staff involved in the processes at the OR gate

High alertness for the correct assignment of blood products out of the sub-depot fridge is necessary.

Educate staff accordingly about blood administration and ID check.

Educate physicians about the risks of overtransfusion, transfusion reactions and allo-immunization.

Educate physicians about cross sectional guidelines for the administration of blood with focus on diagnosis of hypovolemia and ischemia as well as indication for perioperative red cell transfusion.

Consider a combined sub-depot or no sub-depot for ICU and OR to avoid future mismatches. Also, the waste of blood units by getting lost or being outdated when detected together with the transport problems could be avoided.

Consider an electronic order form for each single blood unit to avoid double unit transfusion in stable patients

Report to the institutional transfusion committee.

Improvement of structure quality:

Blood storage facility/refrigerator should have clear labeled sections for each OR table or patient to minimize the risk of confusion during take-off.

Consider establishing electronic control, match and documentation of administration process of blood units (i.e. bed side patient data monitoring system PDMS) by barcoding patient ID, blood unit and crossmatch test.

Consider a feedback system to the guideline conformity of blood orders such as a clinical decision support (for example for double unit administration in stable patients).

Consider cooled transport of blood units in special containers to improve handling, eventually with RFID label for temperature monitoring or tracing.

Case#2 Delay of Readiness of Compatible Blood Supply due to Irregular Antibodies

Reporting text: A revision of a femur osteosynthesis was started in a 55year old male patient under general anesthesia. Preoperative hemoglobin content was 12.5g/dl. The WHO check list for the patient's entry in the operation theatre was still not completed. Immediately after skin incision, the surgeon asked for a 'pause': At its performance the team detects that nobody did double check if blood was typed and screened for the patient. A call to the blood bank resulted in the need for a re-cross-match since the ward missed requesting it the day before. The ward nurse detected the prepared and labelled but still empty tubes on the desk. The anesthesiologist sent blood to the laboratory and after a little while got the information that compatible units could not be easily reserved since antibodies were detected. Patient did get autologous cell saver blood. In recovery, hemoglobin content was 8.5 g/dl.

Problem analysis: There are several problems to recognize: The WHO checklist (published by the WHO in 2008) was done after induction of anesthesia and skin incision. This schedule together with the team time out ('pause') intends to improve patient surgical safety by ensuring that all pre-requirements have been met as long as the patient is able to confirm them. A check for the right patient and site of surgery is identified, existent allergies, risk of blood loss and accessibility of blood is ensured, written consent documented and more. The late work on the schedule following skin incision detects a few of errors but clearly is a misuse of this safety instrument.

Furthermore, obviously in that institution, the ward is responsible for preparation and the organization of the type and screen blood delivery to the laboratory. It is not clear why the blood withdrawal was missed. Possible explanations are, that there has been no call to a physician in charge to take the blood, that the call was too late or during night shift, that there is no dedicated physician in charge of that task, no time slot during the shift for that person, the task forgotten etc..

The risk of blood loss in that procedure together with the borderline anemia in this male patient justifies the cross-matching and typing of blood. Perioperative anemia can and should be addressed prior to an elective surgery case. In this patient, the low hemoglobin content was assumed to be due to status post primary femur surgery. Preoperative iron therapy could have been potentially effective.

Furthermore, it is not known if the detected antibodies were new or previously known, or if the patient was transfused with the primary osteosynthesis or for some other reasons. If this had have been known before operation due to a thorough anemia history assessment or the patient's security card, this problem might have been addressed differently. However, cell saver use clearly was effective since from the hemoglobin drop of >4g/dl in an adult indicates a blood loss of round 2 l. Allogeneic transfusion however was still necessary in this patient.

Recommendations:

Process quality:

SOP/Education: Correct use of WHO checklist and Team Time Out for patient safety

SOP- Type and Screen blood probe withdrawal: Organization and responsibility should be defined during any shift of day.

SOP- Transfusion history prior to blood loss surgery is mandatory.

SOP/Education: Patient Blood Management program should be established and the diagnosis and treatment of preoperative anemia implemented.

SOP/Education: Relevance and impact of known or new detected allo-antibodies for preoperative blood supply and scheduling of elective cases. Since the cross and type testing in Germany is possible and valid minimal 3 but maximal 4 days prior to surgery, in patients with known antibodies or higher risk for the development of antibodies should be tested earlier than the day before surgery.

Report to the local transfusion committee for discussion and change management.

Structural quality:

Use electronic help: The software for OR management could do a plausibility check for high risk procedures, if blood units have been requested and successfully retrieved/reserved. A pre-requirement for this, would be the communication of the blood banking/laboratory software with the OR management and hospital data management system/patient data file.

Use electronic help: A nation-wide central database for patients with existent antibodies would have indicated the type and screen request as difficult in case antibodies were present before. This data base is not existent in Germany due to data safety reasons. This case is one of many, in our opinion a reason to reconsider the necessity despite data safety restrictions.

Use electronic help: The German patient's insurance card is equipped with a RFID chip that contains a basic data set. In this set, allergies, blood group and detected antibodies should be included. They would have indicated the presence of a difficult blood supply at admission and would potentially alert the caring surgeons.

The implementation of a structure for a Patient Blood Management program for handling, diagnosis and treatment of preoperative anemia would have prepared all participants in this scenario.

A thorough investigation of the reasons why blood probe was not taken might detect some structural improvements concerning the paging system, shift model, staffing, communication, task reminder, backup system for unfulfilled tasks, etc.

Case#3 Erroneous Hemoglobin Content in Blood Gas Sample

Reporting text: An elderly patient for brain tumor resection/debulking received multiple units of red cells during the long procedure. The transfusion trigger was assessed and estimated blood loss and hemoglobin content measured using blood gas analyses. Almost at the end of surgery, the anesthesia nurse took a blood sample from the A-line and sent it via pneumatic delivery to ICU where the blood gas analyzer is located. She informed ICU staff by telephone. She got the information that at that moment a calibration process was running and analysis delayed. After 25 min, the anesthesiologist asked for the result and ICU was called again and the sample was still not analyzed, since it had been forgotten. After analysis, the result was sent to the OR, presenting a very low hemoglobin, indicating transfusion. The anesthesiologist requested a redo: The final analysis had much higher hemoglobin content – no transfusion necessary.

Problem analysis:

The calibration process of a blood gas analyzer delayed the immediate injection by the ICU nurse. Since the analysis was not urgent, the calibration process was not interrupted. Instead, blood was deposited next to the machine at room temperature. Since the sample is deposited and apparently not gently remixed prior to injection, the measured hemoglobin content was too low. Blood gas analyzers vary in the way they receive blood. Some models take injected blood, others aspirate with or without an extended needle. However, with all methods, if the mixing process is not done correctly for the measurement of hemoglobin content, a falsely high or low content can be measured depending which part of the sample is analyzed. Whereas hemoglobin analysis only requires exact mixing after longer storage to be accurate, for the gas analysis itself a longer storage time also changes the result of pH, pO_2, and pCO_2. Obviously, that had been forgotten. If the anesthesiologist had not doubted the plausibility of the result, the low hemoglobin content in that situation might have induced both blood transfusion and re-opening of the skull. Both was avoided by the detection of the error in time.

Furthermore, another problem seems to be that there is no blood gas analyzer in the OR despite the undertaking of complex and major neurosurgery cases. Neurosurgery procedures frequently require tight control for CO_2 and glucose for the avoidance of hyperventilation and hyperglycemia. The staff on ICU are frequently busy with other cases; thus, tasks that are not directly involved or connected to their treatment might be worked on with

lesser attention. The pneumatic delivery to ICU is producing an interface problem as is here demonstrated in this case. For coagulation tests and blood integrity, transport by dedicated personal is preferable.

In addition, remember that volume loss is not reflected by the hemoglobin content. Even if the patient exsanguinates, the hemoglobin content does not change much without volume substitution.

Recommendations:

Process quality:

SOP for users of blood gas analyzers: For handling and analysis of blood samples – if an immediate analysis is not possible – make a note of the sampling time and ensure that the sample is mixed gently and thoroughly before starting the analysis. Another possibility would be the interruption of the calibration mode, wait for the ready mode and inject immediately.

SOP for anesthesiologists in the OR – use alternative Point of Care (POC) method at the bedside for double check and for delayed results: Haemocue, noninvasive HB-oximetry Massimo continuous Radical 7, intermittent Pronto7, IStat, etc. That way, no intermittent blood gas and additional blood loss is necessary.

SOP for anesthesiologists/ Education: Volume measurement in major surgery and invisible blood loss: Assessment for transfusion necessity and monitoring of hemoglobin content not solely by blood gas analysis but also diagnosis of volume deficits by noninvasive cardiac output monitor and stroke variation index or pH, BE, lactate etc..

SOP anesthesia department: BGA-withdrawal and analysis should be done by one person only- if possible and the blood gas analyzer not too far away.

Structure quality:

Recommended for that institution is the provision of a second back up blood gas analyzer in the OR section! Since it is important for CO_2 and pH status, electrolytes, glucose and lactate, the better availability should improve the monitoring quality of neurosurgical patients.

Introduction and use of alternative techniques and machines (Haemocue, Massimo Radical 7, IStAT, etc.) for double checks of implausible results or continuous monitoring should be considered.

Another possibility of improving the monitoring is the equipment and supervision of the anesthesia staff with and in noninvasive measurements of volume status: noninvasive CO-monitors and stroke volume variation index.

Consider other ways to transport blood.