2019 Annual SHOT Report – Supplementary information

Chapter 14: Laboratory Errors

This supplementary data contains additional illustrative cases demonstrating errors at each step in the laboratory process.

Sample receipt and registration

Case 14.4: Untrained staff supporting lone worker causes sample labelling error to go unidentified

A unit of red cells was transfused overnight to a patient in his 60s. The following morning it was discovered that the sample used for crossmatching had an incorrect date of birth written on it. This had not been picked up by the biomedical scientist (BMS) during processing. A second check was not performed before analysis of the sample due to staffing issues, which should have picked up the discrepant date of birth.

The laboratory information management system (LIMS) had the correct date of birth, which meant that the blood unit compatibility paperwork was correct and the error would not be picked up at collection or administration. An additional unit of red cells which had been issued was recalled, and replacement units were issued on a correctly labelled sample once received and processed. The incident occurred following increased pressure on a lone working BMS, who was not adequately supported by the medical laboratory assistant (MLA) on duty. The MLA later stated that they were not confident to work in the transfusion laboratory and required further training.

Whilst responsibility for correct patient identification and labelling of samples lies with clinical staff, this incident could have been avoided if proper staff support and training had been provided in the laboratory. It is unacceptable to have any staff working in the transfusion laboratory undertaking tasks they are not fully trained and competent to perform. In particular, further problems can be created if untrained staff members are expected to support a lone BMS as this then causes undue pressure on that BMS, who is essentially working unsupported.

Case 14.5: Patient post autologous haemopoietic stem cell transplant (HSCT) transfused with non-irradiated blood

The LIMS contained two records for a patient in her 50s who had undergone a HSCT, however only one record had an alert flag for irradiated blood components recorded against it. A sample for group and screen was received and booked in against the patient record with no alert flag. A verbal request was later received for red cells, and non-irradiated red cells were selected and transfused.

The duplication of records was not identified by the laboratory. Irradiated blood requirements were not identified from clinical details provided with previous samples. There was no indication that irradiated blood was required on the group and screen request form or the transfusion prescription chart. Staff performing the bedside checks not aware that the patient required irradiated components.

Communication between clinical area and the laboratory is paramount to avoid these errors. Robust procedures need to be in place within the laboratories when patients are transferred from another hospital to ensure that any specific requirements and/or transfusion history are passed on.

Medicines and Healthcare products Regulatory Agency (MHRA) regulatory comment

The laboratory must have processes in place to create records that avoid duplication. There must also be processes to merge records appropriately. Where a laboratory has access to data regarding the specific requirements of a patient, these records may be held in various databases in both electronic and hard copy. If merging these records is not possible, there must be a defined and documented process to identify multiple and duplicate records.

Testing

Case 14.6: Specific requirements not met due to incorrect antibody identification

The red cell immunohaematology (RCI) laboratory contacted the hospital transfusion laboratory regarding a sample that had been sent to them in October for confirmation of anti-Fy^a identification. RCI said that they could not find anti-Fy^a, but they had identified anti-M, anti-K and anti-Kp^a and that the patient themselves was Fy^a positive.

On investigation the previous testing in the hospital laboratory in April had identified anti-Fy^a because the antibody identification worksheet used had an expiry date of 28th March, so this red cell panel was no longer in use. The antibodies which should have been detected using the correct worksheet was anti-M and anti-Kp^a. The transfusion dependant chronic kidney disease patient in her 80s had been transfused with a unit of red cells that was negative for Fy^a and K but unknown to M in October. It is assumed that the unit was M negative as the crossmatch was compatible. There were no reported adverse events for the patient during or after the transfusion.

Laboratories must ensure that a robust process is in place when changing batch of reagents and cells, so that all documentation for the old batch is discarded and replaced with documentation for the new batch. It is also the responsibility of laboratory staff to check that all documentation, reagents and cells being used are in date.

Case 14.7: Neonate transfused a unit of red cells that was not antigen-negative for a maternal alloantibody

A neonate was transfused a unit of red cells that was not compatible with the maternal specific requirements. The mother of the neonate was known to have Anti-M of IgG sub-class. One unit of red cells was requested for transfusion and an O D-negative paediatric pack unit was selected from stock. This was then crossmatched by indirect antiglobulin test (IAT) against both the maternal plasma and also the neonate's plasma. The neonate's plasma by IAT was compatible and the unit was issued and transfused. It was later noticed by a second BMS during the second check performed on all manual compatibility tests, that the IAT maternal plasma crossmatch was incompatible. The transfused unit was confirmed as being M positive.

On investigation the maternal IAT crossmatch had not been documented on the manual crossmatch worksheet. The 'family link' had not been made on the laboratory information management system between mother and baby, therefore, maternal flags were not seen and the

alert flag to indicate maternal antibodies was not added onto the babies record. It was also found that the standard operating procedure (SOP) required clarification, as there was some confusion over the crossmatch method and what sample should be used for the IAT crossmatch. This led to the unnecessary set-up of both the baby and maternal IAT crossmatches.

It is essential that SOP provide clarity and guidance for the standards that should be adhered to for best safe practice. SOP that are unclear could leave room for misinterpretation as was the case here. Laboratory staff ideally, should not be distracted during crossmatching, especially during lone working, as this can lead to errors and mistakes.

Case 14.8: Transcription error results in specific requirement not being met

A patient in her 70s with a history of anti-Jk^{b} required a one-unit red cell transfusion. The BMS checked the patient records and noted the history of the patient and specific requirements but wrote anti-Jk^{a} on the request form instead of anti-Jk^{b}. The BMS then selected a Jk^{a}-negative unit and crossmatched it alongside a manual group and antibody screen on the patient. The antibody screen was negative and the crossmatch was compatible. The unit was then issued to the patient on the LIMS and subsequently transfused.

When issuing the unit to the patient on the LIMS, a warning flag was displayed notifying the BMS that the special requirements were not met. The BMS did not take heed of the warning, accepted it and carried on.

The error was identified when a further request for one unit was sent 2 days later. The antibody screen was negative and direct antiglobulin test negative. The patient was monitored and no symptoms of delayed transfusion reaction were observed.

It is important that laboratory staff take heed of any warning alert messages the LIMS provides to avoid selection and transfusion of units that do not meet specific requirements. Being able to override alerts with no action needs to be addressed by the LIMS providers.

Case 14.9: Incorrect blood group manually entered on to the LIMS

A patient in her 80s requiring a two-unit transfusion was grouped manually due to persistent analyser maintenance failures. The blood group result was as O D-negative; however, it was transcribed onto the LIMS as O D-positive. Two O D-positive units were issued. The sample should then have been put on to the analyser for processing, but there was a delay to the maintenance of the analyser and the sample was not processed until later that day. The analyser grouped the sample as O D-negative and flagged the discrepancy, but the error was not picked up in time and both units were transfused.

There were no adverse clinical consequences for the patient. This error highlights the issues with manual inputting of blood groups in to the LIMS. If this needs to be done a ‘stop’ moment is needed to check that what has been entered is correct, ideally by a different member of staff, before finally authorising the result.

Case 14.10: Patient transfused platelets unnecessarily

A patient in her 80s was bleeding and was prescribed two units of platelets following a reported low platelet count. During transfusion of the second unit the patient experienced a suspected transfusion reaction. They developed a fever of 39.2^{0}C, rigors, increased respiratory rate of 24, normal O_2 saturations of 98% on air, with no change to blood pressure but heart rate did increase to 100 beats per minute.

The patient had a history of platelet aggregates. The platelet count of 29x10^{9}/L was reported while a blood film was being made and looked at. The film confirmed the presence of platelet aggregates and this was written on the report, however the count was not removed from the LIMS. The incorrect platelet count was seen and acted upon by medical staff who prescribed two units of platelets for the patient. The patient went on to have a transfusion reaction during transfusion of the second unit of platelets.

It was during the investigation of the transfusion reaction that this error was identified.

This is a good example of where an error within another laboratory can result in unnecessary transfusion of blood components, which in this case resulted in a transfusion reaction. It is vital that if a haematology result is thought to be incorrect that these results are not reported and removed from the LIMS pending confirmation and communicated to the clinical area.

Case 14.11: Delayed transfusion for a patient on monoclonal antibody therapy

A transfusion dependant myeloma patient in his 60s on monoclonal antibody therapy, had a crossmatch sample taken and sent to the laboratory on a Friday morning for booked transfusion on the following Monday in the day case ward. This patient's sample needed to be sent to the RCI laboratory for testing due to pan-reactivity caused by the anti-CD38 drug they were on. The hospital laboratory did not send the sample until 11:00 on the Sunday and also did not let RCI know that it was being sent to them. The hospital laboratory contacted RCI at 08:45 on the Monday chasing up the crossmatched blood as the patient was attending that day for transfusion. RCI informed the laboratory that they were not aware of the sample until that morning and the results would not be available until that afternoon. The crossmatched blood was received from RCI and issued by the hospital laboratory on Tuesday afternoon at 15:17. This resulted in a 2-day delay in the blood transfusion to this patient. There were no adverse effects reported.

On investigation the SOP needed more clarification on sending samples to RCI for investigation, especially at weekends and that RCI require at least 24 hours to work on samples from patients on monoclonal antibody therapies.

This incident highlights the importance of taking heed of information given by the clinical area on their requests for transfusion. This request stated that the patient was on monoclonal antibody therapy and when blood was required for, but was not dealt with correctly. It also highlights the importance of communication between the hospital laboratory and Blood Service laboratory, to ensure that testing is performed in a timely fashion, and thus ensuring transfusions are not delayed.

Component selection

Case 14.12: Specific requirement not met for a patient of childbearing potential

A patient in her 30s, with per vaginal bleeding following miscarriage, was transfused three units of red cells in April 2018. Antenatal booking bloods were received and analysed in February 2019. The patient now had a positive antibody screen and the antibody was identified as being anti-K. On investigation one of the three units transfused in 2018 was K-positive. The BMS who issued the units failed to select a K-negative unit, as per requirements for a patient was of child bearing potential. The LIMS had a flag alerting of the need for K-negative units for this group of patients but this was not adhered to.

Sensitisation to the K antigen in a patient of childbearing potential is a defined cause of major morbidity, posing a threat the all subsequent K-positive pregnancies.

It is important that lab staff take head of any warning alert messages the LIMS provides. Being able to override alerts with no action needs to be addressed by the LIMS providers.

Case 14.13: Group O FFP selected for a group A patient

A patient in her 70s attended the emergency department with a catastrophic intra-abdominal bleed after suffering a fall onto her left side while in the nursing home.

The group and screen sample was being analysed when the massive haemorrhage protocol was activated. The blood group results showed a forward group of A but the reverse group had no reactions with A or B cells. The blood group was later confirmed as group A D-positive.
While the BMS was waiting to confirm the blood group, O D-negative red cells and four group O fresh frozen plasma (FFP) were issued. The patient was taken to theatre and during the procedure was transfused all four units of FFP.

This ABO-incompatible transfusion was only detected when an incident relating to a delay in blood component provision was being investigated. It was then noted that group O FFP had been transfused. The patient was on the intensive care unit (ICU) postoperative for 7 days and was monitored more closely for any signs of a transfusion reaction.

On investigation it was found that the BMS had issued group O red cells to the patient then proceeded to incorrectly select group O FFP instead of group AB or A as emergency issue. The BMS failed to take head of the alerts to ABO-mismatch on the LIMS before accepting and issuing the incompatible units.

It is important that laboratory staff take heed of any warning alert messages the LIMS provides. Being able to override alerts with no action needs to be addressed by the LIMS providers. This also highlights a gap in knowledge of the clinical staff with regard to ABO-compatibilities which was highlighted in the 2017 Annual SHOT Report and a pre-administration bedside checklist including ABO/D-compatibilities recommended.

Component labelling, availability and handling and storage

Case 14.14: Test tube labelled with incorrect barcode

Retrospective crossmatching of two units of red cells, which were issued and transfused in an emergency situation, showed an error in the labelling of the test tubes containing cells from the units.

Both test tubes had been labelled with the barcoded donation number for unit A. It was later discovered that the blood units had both been labelled with the barcoded donation number for unit B on the traceability tags. The error on test tubes was discovered when they were put on the analyser for crossmatching against the patient's sample. The analyser would not perform the crossmatch because the tubes were labelled exactly the same.

The SOP had not been adhered to; printing the barcodes for the donor units twice, labelling the test tubes with one barcode and the second left to place on the traceability tags before labelling the units. This resulted in the both test tubes being labelled as donor unit A and the blood units both being labelled as donor unit B.

This highlights the importance of following processes and procedures as detailed, because making deviations or cutting corners can produce errors such as this.

Case 14.15: Unit of red cells transfused to a patient after the sample used for testing had expired

A member of clinical staff rang the laboratory enquiring about blood for a patient, as a unit had been collected earlier that morning but on return to the refrigerator the other units had been removed. The units had been returned to the laboratory at 10:20 that morning, but should have been returned at 09:00 when the reservation expiry was reached. The laboratory staff were too busy to get down to the theatre refrigerator at 09:00. This meant that at 10:00 a unit was collected by clinical staff and transfused.

The blood track collection competency did not cover the checking of the reservation expiry on the blood bag and label but it is clearly stated in the policy.

Training and competencies should cover all critical aspects of the procedure to which they apply. Electronic tracking systems should not allow the removal of units which have reached their reservation expiry, or to at least provide an alert to the user to prevent removal.

Case 14.16: Transfusion of a blood component that was out of temperature control

A request was made to the laboratory at 02:00 four units of FFP and two units of cryoprecipitate (cryo) for a patient in his 30s with disseminated intravascular coagulation (DIC). The request had been discussed with consultant haematologist who advised to correct the coagulopathy. All units of FFP and cryo were thawed and then issued to the patient at around 03:00. The units were sent to the ward at 05:45. The first unit was connected at 06:00 and an attempt was made to run the component through the giving set; however, the component was not fluid enough to get through the filter and continue through the giving set to port end. The laboratory was contacted immediately by nursing staff; they were advised to discard the component that had been spiked by the giving set and to warm the second component to room temperature prior to transfusion. As a blood

warmer was not available this was achieved by placing in the pocket of one of the nursing staff, delaying transfusion of cryo by 20 minutes.

On investigation it was discovered that once thawed, the FFP and cryo were all placed in the refrigerator until needed. This storage error was realised by the BMS when the above call was received from the ward, which is why nursing staff were instructed to warm up the second unit of cryo before transfusing.

The following day the patient had further blood components and the coagulopathy was corrected but unfortunately they did not survive.

It is important that all laboratory staff are clear about the correct handling and storage requirements of blood components. If there is any discrepancy raised by the clinical area about this the clinical staff must be advised to return components immediately back to the laboratory so that any errors can be corrected and suitable replacement components issued.

Near miss

Case 14.17: Incorrect sample used for crossmatching detected prior to transfusion – systemic factors addressed

Four units of blood were requested for a patient, these were manually crossmatched and issued to the patient during the night shift, and subsequently collected by clinical staff. At 09:30 the next day more units were requested, however on looking for the sample to test and allocate the additional units, the sample in the position for this laboratory number belonged to another patient. The laboratory number label had been placed on another patient's sample and this sample used to crossmatch the four units of red cells. However, the label on the request form was for the correct patient. The ward was contacted to inform them of the error and the units retrieved.

This error could have been identified at five points in the laboratory processes and was missed by two members of staff. Staff members recorded excessive tiredness and stress due to increased workload on the shift. The department has introduced several corrective measures to ensure resilience in the shift system, such as a training rota to ensure cross cover between departments, shortening of night shifts and additional staff being allocated.

This case demonstrates the influence cognitive bias in the members of staff assuming the laboratory number had been affixed to the correct specimen, and failing to undertake additional checks due to the stressful environment. The corrective actions implemented by the hospital should be commended as tackling the systemic factors involved in the incident.