Laboratory Errors n=885 (530 errors and 355 near misses)

14

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Key SHOT messages

- Many of the incidents reported appeared to result from failure to follow correct procedures, inadequate processes, omitting steps or wrong procedure being performed
- Robust root cause analysis using ergonomics/human factors approach should be undertaken to identify quality management systems (QMS) improvements to mitigate these errors
- All laboratory staff must complete annual good manufacturing practice (GMP) training (European Commission 2015)

Key SHOT messages from the 2017 Annual SHOT Report for laboratory staff on knowledge and skills, shared responsibility and information technology (IT) remain pertinent (Bolton-Maggs et al. 2018).

Summary

Laboratory errors in transfusion practice continue to put patients at risk. There were 24 deaths but none directly attributable to component transfusion. However, there were 3 instances of serious harm, 4 ABO-incompatible (ABOi) transfusions (1 red cells (serious harm to patient) and 3 plasma components) and 2 serological crossmatch-incompatible transfusions.

Major morbidity n=3

The 3 cases complicated by major morbidity were all female. One where ABO-incompatible red cells were transfused in the emergency department (as the biomedical scientist (BMS) manually interpreted the group incorrectly, group B when patient was group A), because they were released prior to completion of the serological crossmatch due to the urgency of the situation. A second sample was not tested, the patient remained in resuscitation for observations and fortuitously experienced no further adverse outcome.

The second was in a paediatric patient three weeks post liver transplant who received the wrong ABO group (patient group B, donor group O). The BMS failed to heed patient historical records where the necessary information was available. The patient experienced an acute febrile transfusion reaction and signs of haemolysis and was admitted to the intensive therapy unit (ITU). The hospital does not perform solid organ transplants and rarely admits patients less than 3 months post-transplant; therefore, no robust procedure was in place.

The third case of major morbidity involved a woman of childbearing potential who was sensitised to the Kell antigen when a warning flag on the LIMS was not heeded, and K-negative blood was not selected.

ABO-incompatible transfusions n=4

There were 4 ABOi transfusions (1 red cells (serious harm, described earlier), 2 fresh frozen plasma (FFP) and 1 cryoprecipitate). These were due to component selection errors (2) and testing (interpretation) errors (2).

The cases of serious harm and ABOi transfusions are discussed in further detail in Chapter 8, Incorrect Blood Component Transfused (IBCT).

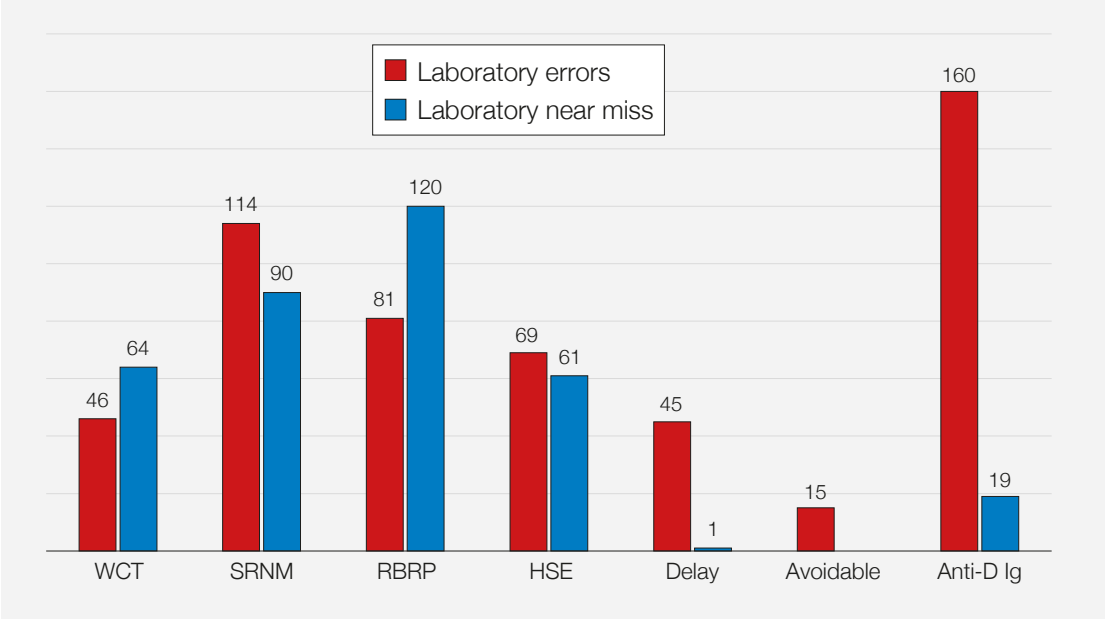
Serological crossmatch-incompatible n=2

There were 2 cases where patients received crossmatch-incompatible components due to failure to follow the correct procedure.

Processes in place need to be detailed and precise to achieve consistent and accurate results for every task undertaken and need to consider any limitations to that procedure. Procedures should be as simple as possible to follow but as complex as they need to be to ensure that staff have all the information necessary to perform and complete tasks accurately. Poor practice should be identified and corrected before it results in errors.

This year there has been an increase in the number of reports to SHOT where the primary error originated in the laboratory. There were 530 cases where a patient was transfused, and a further 355 near miss laboratory incidents. This is compared with 409 transfused cases in 2017 and 331 near miss laboratory incidents. A more thorough breakdown into laboratory errors is given in the remainder of the chapter.

Figure 14.1: Laboratory incidents and near misses by category of outcome n=885



WCT=wrong component transfused; SRNM=specific requirements not met; HSE=handling and storage errors; RBRP=right blood right patient; Ig=immunoglobulin

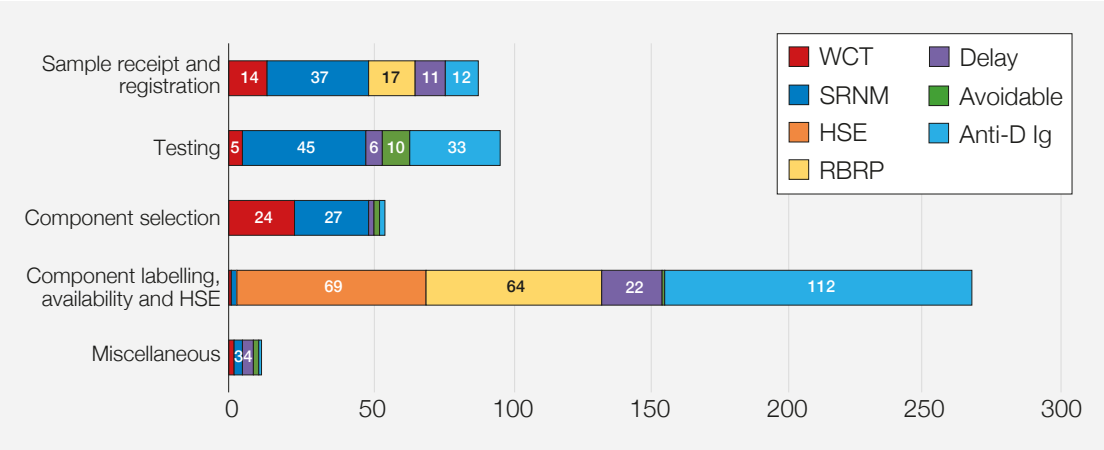


Figure 14.2: SHOT laboratory data (n=530) showing at which stage in the transfusion process the primary error occurred

WCT=wrong component transfused; SRNM=specific requirements not met; HSE=handling and storage errors; RBRP=right blood right patient; Ig=immunoglobulin

Numbers <3 are too small to be annotated on the figure: Component selection: delay=2; avoidable=2, anti-D Ig=2; Component labelling, availability and HSE: WCT=1; SRNM=2; avoidable=1; Miscellaneous: WCT=2, avoidable=2, anti-D Ig=1

Errors with component labelling and availability for anti-D Ig errors are disproportionate as there was 1 case reported where anti-D Ig was stored inappropriately and given to 106 patients which cannot be reported to SHOT as a single incident.

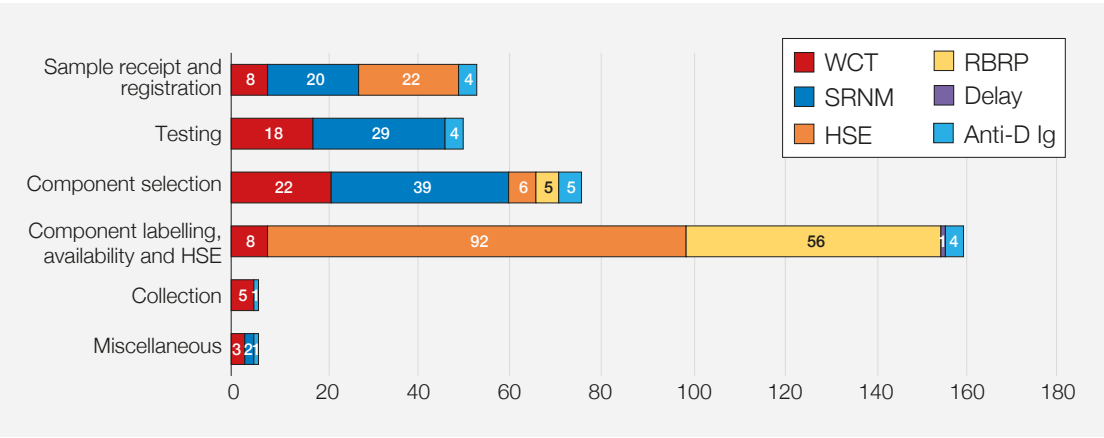


Figure 14.3: SHOT near miss laboratory errors (n=355) showing at which stage in the transfusion process the primary error occurred with outcome

WCT=wrong component transfused; SRNM=specific requirements not met; HSE=handling and storage errors; RBRP=right blood right patient; Ig=immunoglobulin

Sample receipt and registration (SRR) n=145 (including 54 near miss)

Correct sample receipt and registration are essential to ensure that the right investigation is performed for the right patient on the right sample at the right time (dependent on the patient's transfusion history).

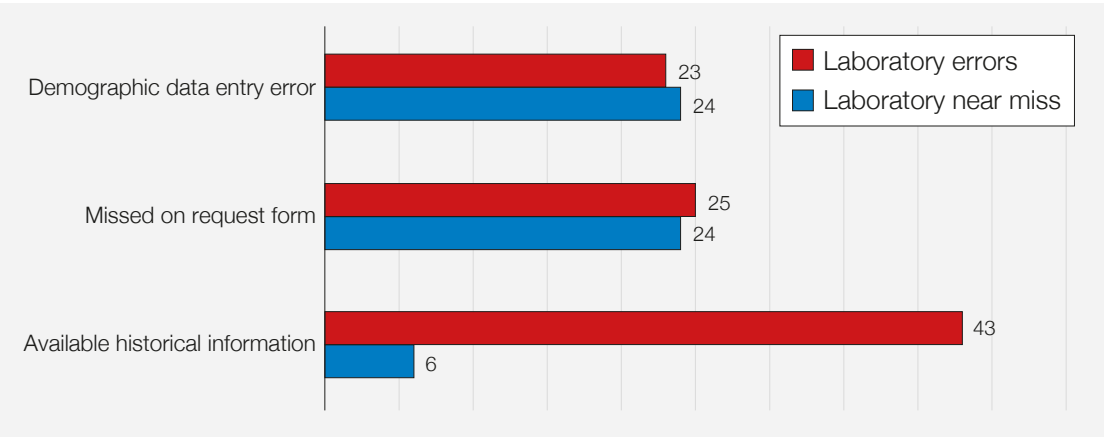


Figure 14.4: Sample receipt and registration errors with outcome n=145

Learning points from sample receipt and registration errors

- **Treatment plans:** A detailed treatment plan for transplant patients, including specific component requirements at different time points, should be shared with the transfusion laboratory prior to transplantation so relevant information is available on the laboratory information management system (LIMS) prior to receiving a request. This treatment plan also needs to be shared with the transfusion laboratory at the hospital the patient is transferred to post transplant
- **Upgrading LIMS:** Laboratory staff need to validate software appropriately and test it against a broad range of scenarios to demonstrate compliance and mitigate errors. It is essential that as much data as possible are captured from the old system into the new. If this is not possible and a legacy system is used for historical data, laboratory staff must check the legacy system for any patient-specific requirements and update and link to the new record in the LIMS before selecting and issuing components. It is also essential that laboratory staff receive in depth, comprehensive training on all aspects of the use of the LIMS and have access to a detailed LIMS standard operating procedure (SOP) to refer to if needed (BSH Jones et al. 2014)
- **Specialist Services electronic reporting using Sunquest's Integrated Clinical Environment (Sp-ICE) access (England only):** Sp-ICE should be accessible to all laboratory staff 24/7 and should be considered as part of the routine practice at sample receipt. All hospitals should have a local policy as to which patients should be looked up on Sp-ICE and that any information found must be documented on the patients record on the LIMS

The learning points for SRR from the 2017 Annual SHOT Report are still valid for heeding patient history and sample acceptance (Bolton-Maggs et al. 2018).

Case 14.1: BMS issued anti-D Ig because the midwife was persistent and did not seek further guidance

A request was received out-of-hours for 500IU anti-D Ig for a patient with a per vaginal (PV) bleed. The BMS informed the clinical area that the patient had an immune anti-D and that prophylaxis was inappropriate, but the midwife was insistent that the patient required anti-D Ig. The BMS issued it without seeking further clinical guidance although the hospital policy clearly stated that anti-D Ig was not to be issued in cases where an immune anti-D was present. Both the BMS and the midwife were aware of this policy stipulation.

There should be clear BMS training and understanding of all component/product types and their specific requirements for release/issue. If there is any uncertainty or question raised that goes against what is thought to be correct, further advice should be sought to confirm the legitimacy of the issue.

Testing n=150 (including 51 near miss)

Correct and accurate analysis of samples is required to ensure the safe provision of blood components for transfusion and should be undertaken with full compliance of local and national guidelines for pre-transfusion testing (BSH Milkins et al. 2013).

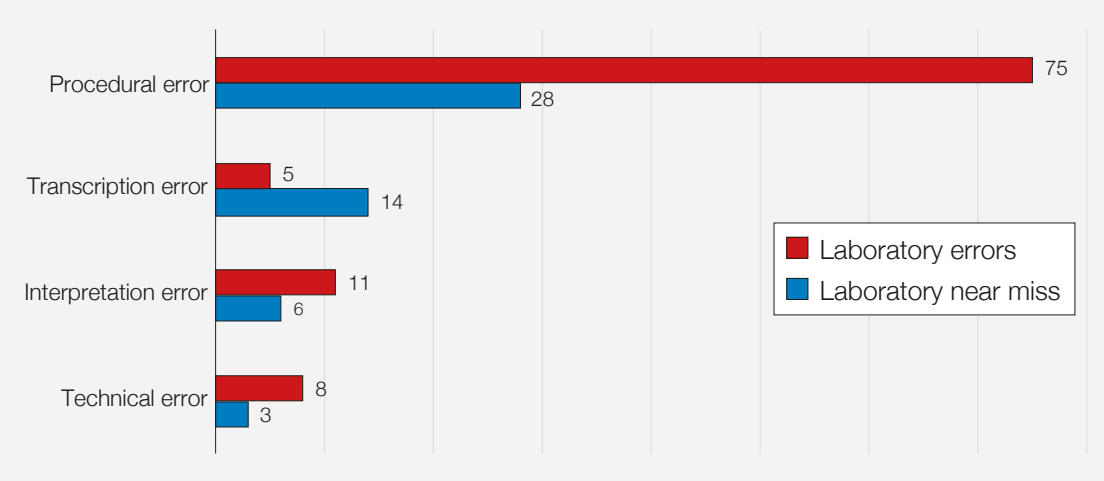


Figure 14.5: Testing errors with outcome n=150

The learning points for testing errors from the 2017 Annual SHOT Report are still valid for lessons surrounding anti-D Ig and failure to follow procedures (Bolton-Maggs et al. 2018). A more detailed and thorough investigation and root cause analysis in these errors could uncover system failures and identify any system improvements.

Case 14.2: Failure to look at Sp-ICE results in a patient receiving incorrectly phenotyped units

Eight units of red cells for a patient with newly diagnosed sickle cell disease (SCD) were requested. The request form identified that the patient had received previous transfusions. The BMS contacted the clinical area to gain a further understanding of these transfusions, but was incorrectly informed the patient had not been previously transfused. Two samples were grouped, and ABO/D/K compatible red cell units were electronically issued. Two months later the laboratory received a sample and the antibody screen was positive, but the identification panel was inconclusive. The BMS then checked with the National Health Service Blood and Transplant (NHSBT) Sp-ICE database which held a record stating that this patient had known antibodies detected 6 years earlier in another hospital. Had this been identified in the first instance the electronic issue (EI) would have been negated and the correct phenotype blood requested.

The NHSBT Sp-ICE database (England only) should be used for new patients with SCD to identify a red cell phenotype and any known antibodies.

Case 14.3: Omission or late administration of anti-D Ig as BMS fails to follow SOP accurately as they had not been trained to issue anti-D Ig

A BMS was checking outstanding work on the LIMS and found the 'anti-D Ig' field was still pending on a patient record. The system was further checked and identified that the anti-D Ig had not been issued. On checking the request form and baby's blood group to see if anti-D Ig had been omitted it was found that >72 hours had elapsed. No follow up call was received from the maternity ward. On investigation it was found that the BMS had not followed the SOP accurately, as they were not fully trained and competent to issue anti-D Ig. The request should have been placed in the appropriate file, to allow anti-D Ig to be issued by another BMS who was trained and competent.

It is inappropriate and potentially dangerous to have any staff working in the transfusion laboratory undertaking tasks they do not understand and are not fully trained and competent to perform. All staff who are not trained/undergoing training require direct supervision and/or all work checked by an experienced and competent member of staff trained in that process.

Component selection (CS) n=134 (including 77 near miss)

The process must ensure that the correct components (together with any specific requirements) are selected to comply with the patient's requirements and the clinical request.

Learning points in component selection

- **Component identification:** Components can sometimes appear to be very similar e.g. fresh frozen plasma (FFP) and cryoprecipitate. Training must include recognising the different component types and their specific storage requirements. Laboratory staff must take care in reading the label to ensure that the correct component is selected (https://www.shotuk.org/resources/current-resources/ SHOT Bite No 9. Component Compatibility)
- **Group-check sample:** A group-check sample policy should be in place and if blood is required on the first sample then group O red cells or group AB/A plasma components should be issued until a second sample is analysed to confirm the patients' blood group (https://www.shotuk.org/resources/current-resources/ SHOT Bite No 9. Component Compatibility and SHOT Bite No 10. Why 2 Samples?)
- **Unrequested specific requirements:** There is an increasing number of incidents for patients born after 01/01/1996 who require pathogen-inactivated plasma components, and this group of patients is getting larger and currently includes people up to the age of 22-23 years. These adults may present to the emergency department (ED) with bleeding from for example, trauma or obstetric causes. The laboratory needs a robust system in place to identify these patients as soon as a sample is booked in so that a flag can be added to the patient's record to ensure the correct blood components are issued, however any delay to transfusion must be avoided in an emergency situation and use of standard plasma components may be necessary

The learning points for CS from the 2017 Annual SHOT Report are still valid for unrecorded specific requirements, multiple specific requirements and compatibility of components (Bolton-Maggs et al. 2018).

Case 14.4: BMS fails to notice a wrong component was selected and continues to not notice even when the alert on the LIMS highlights the error

A haemato-oncology day case patient (group AB D-negative) required transfusion of irradiated red cells. The BMS took two units from the irradiated drawer but failed to notice one was A D-negative and the other A D-positive. The BMS then failed to respond to the alert on the LIMS highlighting the group difference and issued both units. The process failed again during the component labelling as the blood group difference between unit and patient was not noticed. The clinical area did not have any competent staff on duty available to collect the red cells, so the same BMS checked out the components and again failed to notice the group difference. The clinical area did not complete adequate bedside checks before transfusion and also missed the error. This component selection error was discovered on a later sample from this patient, when it was identified that they had developed an anti-D antibody. At the time of this incident the BMS involved had a history of stress and anxiety and the laboratory had an increased workload.

This case report highlights a systemic failure that allows a staff member with a history of stress and anxiety to work in a high pressure situation without adequate support and second checks in place. This also highlights the need for a comprehensive pre-administration bedside checklist to be in place, to include basic group ABO/D compatibilities, to assist clinical staff in spotting this type of error before a unit is transfused (Bolton-Maggs et al. 2018, DH 2017).

Case 14.5: BMS selects wrong component without following SOP or seeking further advice

A request for red cells was received out-of-hours for a leukaemia patient transferred from another centre. Two samples were received and analysed, and both showed a weak mixed field reaction with anti-B in the forward group. No historic group was available on the LIMS. The BMS contacted the clinical area and was informed there had been no previous transfusions or haemopoietic stem cell transplant (HSCT). The BMS believed the sample 'looked' like group B, therefore they crossmatched and issued group B red cells, without checking the SOP (that stated 'to give group O red cells if a clear group cannot be determined') or seeking advice from a senior member of staff working in haematology. The patient was subsequently grouped some time later and did group as B without any mixed field result. This event occurred in the early hours of the morning during a busy time in the laboratory.

This case report demonstrates that staff should never presume in the event of anomalous results. Although here the patient did turn out to be group B it was inappropriate at the time to issue group B red cells. The guidelines state that if a group is unknown then group O red cells or group AB/A plasma should be issued (BSH Milkins et al. 2013).

Component labelling, availability, handling and storage (CL) n=432 (including 161 near miss)

The right component needs to be labelled with the correct four (or five) key patient identifiers; first name, last name, date of birth (DOB), unique patient identifier (and first line of address in Wales) of the intended recipient (BSH Milkins et al. 2013). Components need to be accessible and available for the time required, if this is not attainable then the clinical area need to be informed. The components need to be handled and stored in the correct way as defined in the guidelines (JPAC 2013).

Learning points in component labelling, availability and handling and storage

- **Component storage:** Refrigerators must have their temperature monitored 24/7, with the use of a validated temperature monitoring system that will alert the laboratory if there is a power failure or temperature excursion. If an in-house system is in use, for example, if refrigerators are connected to the building management system, this must alert the transfusion laboratory or the switchboard/ estates team if there is a power failure or temperature excursion. Alerts must be dealt with or escalated immediately, and steps that need to be taken must be included in a robust protocol/ procedure

The learning points for component handling, storage, labelling and availability from the 2017 Annual SHOT Report are still valid for transposed labels, major haemorrhage protocols, storage of components and recovery of components beyond reservation (Bolton-Maggs et al. 2018).

Case 14.6: BMS incorrectly interprets a warning flag as an error on the IT system resulting in expired units being transfused

A unit of red cells was removed from a refrigerator controlled by an electronic blood management system (EBMS) at 00:43 hours. The unit had expired at midnight and the EBMS alerted the nurse collecting the unit with a message that the unit had expired and to contact the laboratory. The out-of-hours BMS incorrectly assumed the EBMS alert was related to an earlier network failure and allowed the clinical staff to take the unit back to the ward. When an attempt was made to receipt the unit in the clinical area, a second alert occurred via the personal digital assistant (PDA) again, explaining that the unit had expired and not to continue. The transfusion was started despite the alerts and pre-transfusion checks at the bedside failed to pick up the error. Within a few minutes the BMS looked into the alerts further and realised their error. The ward was contacted immediately and told to stop the transfusion however, the transfusion had already commenced.

The principle failure in this case report in the laboratory is the assumption that the alert was for another event without checking the alert for the detail. This was compounded when the clinical area got a second alert and, on this occasion, instructed them not to continue which they failed to follow. Consideration needs to be given to working with the EBMS suppliers, to develop software that does not allow the blood issue refrigerator to be accessed in the first instance if components are beyond expiry or reservation.

Case 14.7: Previous patient's compatibility labels still attached on units and transfused to another patient

A major haemorrhage protocol (MHP) was activated for a patient and the appropriate blood components were issued and transfused. The patient was to be transferred to a local specialist unit along with further blood components. The BMS contacted the ward to discuss the transfer of blood components and during this phone call the BMS was informed that the MHP had been activated again and blood was needed urgently. The MHP bleep went off and when the BMS was putting down the phone to switchboard the porter was already in the laboratory looking shaken and visibly panicked. The porter stated they wanted blood urgently and the BMS, knowing the patient was A D-positive, selected two O D-positive units from the refrigerator and boxed up these units even though these two units still had another patient's compatibility labels on them, and they were subsequently transfused. The BMS made a conscious decision due to the clinical urgency of the situation, the ward staff were aware of different patient details but knew units were compatible for the patient in the clinical emergency.

Protocols explaining the issue of components, especially those in urgent situations where uncrossmatched components are issued should be clear, prescriptive and simple to follow. Wrongly selecting components already labelled for a different patient, could have led to the emergency transfusion being delayed causing further harm and then this in turn could have resulted in a delay in the transfusion for the patient that the component was originally issued for.

Collection n=6 (all near misses)

This step ensures that the correct component is collected from the storage site and delivered to the correct clinical area.

All 6 cases were near miss incidents, in 5 of them the wrong component was given to clinical staff (3 for the wrong patient and 2 the wrong component) and 1 involved anti-D Ig given to the clinical area for a woman who had given birth to a D-negative baby. All incidents were detected prior to administration.

Miscellaneous n=18 (including 6 near miss)

This section includes instances where the error has occurred in areas other than the key laboratory steps in the transfusion process detailed above.

The outcome of the 12 miscellaneous cases where patients were transfused are; 2 WCT, 3 SRNM, 1 Anti-D Ig and 6 ADU (4 delayed, 2 avoidable).

- In 4 cases the errors originated in the blood establishment:
  - Information was not passed on correctly and the patient did not receive anti-D Ig in the correct timeframe
  - A wrong component was selected for a patient
  - A patient received a unit of the incorrect specification
  - The final patient endured a delay
- In 3 cases laboratory staff did not update the patient records when instructed leading to:
  - Specific requirements not met (1 irradiated and 1 human leucocyte antigen (HLA)-matched components)
  - Incorrect ABO group to a HSCT patient

- In 2 cases patients received an avoidable and delayed transfusion respectively due to LIMS downtime
- In 2 cases the bleep was not working resulting in a delay in providing emergency components during a major haemorrhage
- In 1 case the BMS gave incorrect information that a sample was available for testing in the laboratory when it was not, resulting in emergency uncrossmatched components being used

The 6 near miss miscellaneous cases could potentially have led to 5 patients having a wrong component transfused and 1 case related to anti-D Ig.

For further cases of avoidable or delayed transfusions see Chapter 10, Avoidable, Delayed or Under/Overtransfusion (ADU).

Medicines and Healthcare products Regulatory Agency (MHRA) / inspectors report

Author: Chris Robbie

The different remits and approaches to incident reporting by the MHRA and SHOT should not be seen as differing, but complementary. Regardless of the type of incidents reviewed; the root causes and analysis of the reports is largely the same in that errors are almost always the result of individuals not performing the task they should have done, or in a way that it should have been done. However, this should not mean the individual was at fault.

It should be noted that the Guide to Good Practice (Council of Europe 2016) is clear that where human error is suspected or identified as the cause of a deviation or non-conformance, this should be justified in the investigation report having taken care to ensure that process, procedural or system-based errors or problems have not been overlooked, if present (section 1.2.13).

Discussions with colleagues from SHOT, UK Transfusion Laboratory Collaborative (UKTLC), National Blood Transfusion Committee (NBTC), Royal College of Pathologists (RCPath), MHRA inspections, visits and discussion with reporters frequently cite that lack of resource, staffing, education of newly qualified staff and loss of experience all have an effect on a laboratory's performance. Improvement in QMS by effective investigation of deviations and non-conformances and implementation of effective corrective and preventive action (CAPA) should improve patient safety.

UK Transfusion Laboratory Collaborative (UKTLC)

Author: Rashmi Rook, Chair UKTLC

Importance of collective knowledge to the transfusion community

Over the last year it has become apparent and of significant concern to the UKTLC that even fewer transfusion laboratory managers (TLM) and senior BMS are attending professional meetings. Reduced participation at this level will adversely affect the *collective knowledge* that resides within this group as many laboratory technical and serological experts have retired, or are due to leave in the next few years. Improvements to patient safety and care relies on the availability of clinical and laboratory experts, so there is an urgent need to build new teams of subject matter experts (SME) to provide support and guidance at local, national and international levels. This will only be achieved by the presence and active participation of TLM and seniors at all meetings including the local transfusion technical user groups - this is shared learning at its best and has contributed to decades of progress and development made in this field.

Collective knowledge: *Knowledge that is possessed by a group or organisation and allows access to SME. For blood, this 'body of knowledge' influences decisions on public health.*

Our laboratory teams must be given adequate resources to develop. This includes time to gain expertise and knowledge of their technical systems, the understanding of serological testing regimes, and quality systems management including human factors. This can only come about once staffing levels in the laboratories are correctly set to enable these activities. When writing staff capacity plans, laboratory workload figures must not be solely based on the number of samples tested and components issued.

The following list identifies concerns raised with UKTLC and can possibly be attributed to the lack of stabilising the workforce to allow the acquisition of the right skill set, depth of knowledge and experience that is impacting on overall profound knowledge at the laboratory level. This can only be to the disadvantage to the transfusion community as a whole but particularly to our patients:

- Sub-optimal equipment and techniques being developed and implemented
- Errors with LIMS implementation, management and incorrect rules applied
- Remote issue and traceability systems being set up incorrectly
- Incorrect testing reagents being used
- Delays to updating or writing new guidelines and standards
- Lack of understanding of complex regulations and guidelines

Over the last year there has been considerable information in the media about the *Infected Blood Inquiry* dating back to the 1980s and 90s. Since these events having occurred the collaboration of laboratory and clinical specialists has helped to create a world-leading National Blood Service and haemovigilance systems that we, as part of this community should be proud of. The focus on blood safety and technology improvements to further enhance patient treatment and care, and the development of new innovative practices relies on all staff being given the right opportunities to fulfil their job roles and actively participate in this incredible community. The importance of having adequate resources to improve this knowledge base, to develop robust laboratory processes and to share information openly and transparently with colleagues across organisations and professions should not be overlooked. We cannot risk another tragedy related to blood events caused by the failure to support our staff and give them the right work conditions and opportunities to succeed at being our new generation of technical experts.

Finally, there is a need for all colleagues regardless of grade or job role to continue with their own learning, and much of this is gained by being actively involved with questioning and discussing at meetings, and respectfully challenging information or to stand up and say when things are unclear. This is the normal process of acquiring knowledge and understanding. As a respected colleague once said, *'The only silly question is the one that's never asked!'*

Updates:

- During 2018 the focus of UKTLC has been to encourage laboratories to ensure that staffing capacity plans are written, with some guidance being developed. UKTLC are also working with NHS Improvement (NHSI) on a more formal way to implement this guidance (Bolton-Maggs et al. 2019)
- UKTLC are looking at ways to incorporate the key requirements of the standards (2014) into the relevant British Society for Haematology (BSH) guidelines as these are updated rather than a full re-write of the standards. This should help to streamline information, but will be reviewed in due course (Chaffe et al. 2014)
- Continuing to promote the sharing of ideas and information on the MHRA Blood Forum http://forums.mhra.gov.uk/forumdisplay.php?60-Blood-Forum

UK National External Quality Assessment Scheme (UK-NEQAS)

Author: Claire Whitham

SHOT errors are shown to be attributable to many factors, including those related to knowledge, training, competency, and to human factors. Results of external quality assessment (EQA) show that these factors also contribute to EQA errors. An error in EQA can be seen as a 'free lesson', as CAPA undertaken in response can allow the underlying causes to be addressed before a similar error occurs in clinical practice.

This report takes into account trends in errors made during EQA exercises between June 2017 and January 2019.

It is widely understood amongst the transfusion community that the current climate in hospital blood transfusion laboratories is one of immense pressure, where increasing workloads coupled with the loss of experienced staff create additional training burdens. This has again been a contributory factor in many EQA errors made during 2017-2018. During three exercises (17E6, 17R8 and 18R8) four laboratories cited these pressures as a direct cause for EQA errors. One laboratory, working under resource and time constraints, made an error in antibody identification, correctly identifying anti-D in a sample, but misidentifying the second specificity, as a result of not following their own protocol for inclusion and exclusion of antibody specificities. Two further laboratories missed incompatible crossmatches, one caused by a failure to add plasma as a result of distraction, and the other, recording their results in a testing grid, rotated these results through 90 degrees during data entry. Another laboratory made an error in phenotyping, recording all three donors as S-negative, suggesting that the antisera being used was either not performing as expected or had not been added to the tests. There are many potential sources of distraction in the busy transfusion laboratory (see Chapter 6, Human Factors in SHOT Error Incidents); it is important to understand the potential effects of distraction and workload pressures, especially when performing critical manual testing.

There is evidence from EQA that some of the errors made are attributable to a lack of knowledge.

A number of laboratories made errors in identifying antibody mixtures in EQA exercises. The risks of misidentifying antibodies can lead to incompatible blood being issued in an urgent clinical situation. In a sample containing anti-c+K, one laboratory obtained a positive reaction with a c- K+ cell, but did not take this into consideration during interpretation, and another recorded anti-Jk^{a} as the second specificity, based on a positive reaction with a single c- Jk(a+) cell without noting that this cell was also K-positive and that anti-K could not be excluded. A further three laboratories recorded anti-S as the second specificity on the basis of a negative reaction in an enzyme technique with a c-negative, S-positive and K-positive cell that had given a positive reaction by indirect antiglobulin test (IAT). For a sample containing anti-c+M, six laboratories correctly identified anti-c but misidentified the second specificity, five recording anti-K and one recording anti-S.

To avoid misidentification, every antibody investigation should include a systematic process for exclusion and positive identification of antibody specificities, and all reactions should be accounted for before a conclusion is reached.

The interpretation of phenotyping results has also revealed knowledge gaps. During 18R2 (Kidd typing), four laboratories recorded the rare phenotype Jk(a-b-) for one or more of the three donors. An apparent 'null' phenotype of this nature should prompt repeat testing to confirm the result.

Errors made due to the transposition of either samples or results during testing, and those made during result transcription continue to be recurring errors made in all elements of testing across the majority of EQA exercises. Although the format of an EQA exercise cannot exactly replicate clinical testing scenarios, performing checks such as sample labelling prior to the commencement of and during any serology testing, and checking results prior to any manual reporting step, could be considered to be routine practice across all laboratories. In seven exercises (17E6, 17R8, 17R10, 18R2, 18E3, 18R5 and

18R8) a number of laboratories made procedural errors which have the potential to occur during routine clinical testing or reporting of patient results, where samples were transposed during testing or recording results of ABO typing, antibody screening and identification, crossmatching and phenotyping. Causes reported include antibody identification panel reactions incorrectly transcribed from an analyser to a paper panel sheet, switching results of phenotyping at data entry, inadvertently testing samples from a previous UK NEQAS exercise, and testing Patient 1 or 3 twice in place of Patient 2.

To reduce the potential for procedural errors, checks are required at critical points in the pre-transfusion process, e.g. sample labelling, performing and interpreting manual tests and transcribing information. Care should be taken to confirm the identity of all samples before testing. For clinical samples, this requires a full check of the patient details to ensure that results are assigned to the correct patient. EQA samples should be subject to the same process with a check of the patient number and exercise code on each sample.

The exercise that produced the highest number of 'unexpected' errors in 2018 was 18R2 where laboratories were asked to perform Kidd phenotyping on the three donor samples supplied. At the end of the exercise, forty-nine laboratories had recorded 54 incorrect phenotypes, 47 of which were false negative Jk^b types for Donor W (Jk(a+b+)). Extensive investigation including testing at the International Blood Group Reference Laboratory (IBGRL) with three different anti-Jk^b reagents and a titration, confirmed that the Donor W cells had normal Jk^b expression. The majority of participants that were contacted regarding phenotyping errors had used the same anti-Jk^b reagent that required use of a 'non-standard' serological tube technique, involving an additional incubation step to '-enhance the reaction strength in typing cells of rare phenotype', if a negative reaction is obtained after the first recommended incubation.

As a part of the investigation, participants were asked to clarify the technique used to test Donor W, and a high proportion of laboratories using the implicated reagent (49%) used methodology that deviated in some way from the manufacturer's instructions. Column agglutination technology (CAT) rather than tube testing was used by 25%, and sixteen laboratories did not include the second incubation, with four of these reporting Donor W as Jk(b-). There were several comments received from participants that suggested some had experienced difficulty in obtaining the product insert, which was not provided with the reagent, and there had been confusion with another reagent for use by CAT previously provided by the same supplier, that may have been contributory factors. Whilst ultimately it is the laboratory's responsibility to use the reagent according to the instructions, the manufacturer also has a responsibility to make the instructions as clear as possible.

Some laboratories obtained negative or weak reactions with Donor W, using the implicated anti-Jk^b reagent in this and in a subsequent EQA exercise (18R8), and the scheme reported this to the MHRA. It was noted in the EQA report for 18R2 that commercial phenotyping reagents generally give 'strong' reactions with antigen-positive cells, and it is advisable to repeat tests and question results where a weaker than expected reaction is obtained with either the positive control or with an individual test. Some of those making Jk^b typing errors in exercises 18R2 and 18R8 indicated that cells with apparent homozygous expression, i.e. Jk(a-b+), had been used as a positive control rather than Jk(a+b+). When performing red cell phenotyping, it is good practice to select a 'positive' control cell with heterozygous expression of the relevant antigen to demonstrate that the weakest normal antigen expression can be detected on the test cells.

Learning point

- It is important that reagents are validated for use, manufacturer's instructions are followed and appropriate cells are selected as controls each time they are used

In most laboratories, reservation of ABO-incompatible red cells is prevented by the LIMS. However, during LIMS downtime or failure, it is important for laboratories to have robust systems and processes for ensuring that ABO-incompatibility is detected. In exercise 18R8, three laboratories, all recording a negative reaction in the IAT crossmatch, missed the incompatibility between Patient 1 (B D-positive) and Donor Y (A D-negative). The IAT crossmatch is not the technique of choice for detection of ABO-

incompatibility and in the rare situation where a serological crossmatch is used without IT support to prevent ABO-incompatibility, it is advisable to also include a crossmatch by direct agglutination at room temperature. One manufacturer of CAT states in the instructions for use for the 'Coombs' card used for compatibility testing, that 'to ensure the ABO compatibility between recipient's and donor's blood, a serological (saline at room temperature with immediate centrifugation)… is recommended'.

During 2018, UK NEQAS blood transfusion laboratory practice (BTLP) distributed a pre-transfusion practice questionnaire to laboratories in the UK and Republic of Ireland. There was little variation in practice since a similar questionnaire was reported in 2016, with the most notable change related to the policy of transfusion laboratories to be sent a 'group-check' sample prior to transfusion. In 2018, 84% of laboratories required a group-check sample (*cf.* 67% of laboratories in 2016) and 12% stated that they supply the tube for the group-check sample direct from the transfusion laboratory. There continues to be an increase in the number of laboratories using the automation for tests other than the 'group and screen', with 73% using automation for antibody identification (*cf.* 64.9% in 2016), 39.4% for crossmatch (*cf.* 34.6%), 51.7% for phenotyping (*cf.* 41.7%) and 63.9% for the direct antiglobulin test (DAT) (*cf.* 56.1%).

Conclusion related to laboratory errors

This year's Annual SHOT Report still demonstrates that staff are working beyond their capability or knowledge and giving out information they are not qualified to give or altering laboratory practice to try and achieve a safe conclusion. Robust SOP must be in place that clearly instruct staff what they should do when events fall outside their understanding or the detail of the processes and procedures being followed. It must be made clear that such events need to be referred to either a more senior/experienced BMS or a clinician with knowledge of transfusion, who can then advise on the appropriate course of action to be taken. The updated BSH administration guidelines (BSH Robinson et al. 2017) state that part of the critical pre-transfusion bedside checks should include knowledge of component compatibility for your patient prior to administering the component. However, the laboratory must also ensure that the component issued is correct for the patient it is issued to by performing essential checks before the components leave the laboratory. The SHOT nine step transfusion process requires all staff working within this process to work as a team, to ensure that the right patient receives the right blood at the right time. This requires communication and accurate handovers between staff, shifts and departments/wards. All of the laboratory key messages and learning points in this report need to be considered 24/7 not just during core hours. As reported last year, laboratory staff must be responsible for keeping their competencies up to date (HCPC 2018). Pathology services all over the UK are constantly under intense pressure and the demands on the workforce are increasing for a workforce that is already stretched and under resourced, making it even more vital that vigilance and duty of care is upheld to ensure transfusion and patient safety. Although errors in laboratory working are highlighted in this chapter, often these errors result from initial errors in clinical area or by portering staff, or laboratory errors are further compounded by additional errors by clinical or portering staff further in the time line. All hospital staff are under pressure from resource and workload issues, but all hospital staff must work together to eliminate errors, not only to improve safety for patients, but to not waste precious resource by making and then having to correct errors.

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