7 Laboratory Errors

SHOT Laboratory errors n=740 (409 errors and 331 near misses)

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Key SHOT messages for laboratory staff

Knowledge and skills:

- Laboratory staff should have an understanding of all component types, including their storage conditions, but most importantly their compatibility with the patient and specific requirements for certain patient groups e.g. gender, age, pregnancy and taking disease status into consideration (Chaffe et al. 2014)
- Laboratory staff are responsible for maintaining their own continuing professional development (CPD) including competency assessments (https://www.hcpc-uk.org/aboutregistration/standards/cpd/)
- Laboratory staff must understand warning flags, know why they have appeared and acknowledge appropriately. Warning flags should never be overridden by laboratory staff without understanding the reason for them. See information technology (IT) key message below

Shared responsibility and shared care:

- Good communication is paramount between staff in the laboratory, between the laboratory and the clinical area and vice versa
- It is important, when necessary, to look up, understand and maintain patients' historical records and to seek out any further transfusion information that may be available for the patient from a shared care facility e.g. transplant, antibodies, adverse transfusion history. Never assume that something has been done: always double check

Information technology (IT):

- Laboratories should have a contingency procedure for IT downtime/failure and perform a simulated situation competency which renders the laboratory information management systems (LIMS) out of action in order to test that the contingency procedures are robust
- SHOT data continue to highlight many errors caused by overriding warning alerts. It is now time for LIMS suppliers to provide software that requires more than a keystroke to override the warning alert and meet the UK guidelines in transfusion (BSH Milkins et al. 2013, BSH Jones et al. 2014). Consideration could be given to allow the user to record a comment explaining the reason for the override which would certainly focus the mind of the issuing biomedical scientist (positive acknowledgment)

Summary

Laboratory errors continue to occur despite reflective best practice guidance each year in the Annual SHOT Report. Laboratory managers should not be pressurised to put partially-trained/untrained staff (contracted or locum) into positions where they undertake processes outside their competency.

Failures to address long-term resource and staffing problems are being reported by laboratory managers and all the following organisations: SHOT, the UK Transfusion Laboratory Collaborative (UKTLC), the National Blood Transfusion Committee (NBTC), the UK National External Quality Assessments Scheme (UK NEQAS), and the Medicines and Healthcare Products Regulatory Agency (MHRA). It is apparent that staffing levels and numbers of qualified and knowledgeable biomedical scientist (BMS) staff are reducing and vacancies are remaining unfilled for many months (Chaffe et al. 2014, UKTLC 2017). These issues, together with increasing workloads and 24-hour routine working, are not going to be resolved in the short-term and it is imperative that laboratory managers review their processes to ensure that they are robust enough to meet these current challenges and guidelines. As new techniques, technologies and treatments emerge it is essential that robust processes and staff training are developed to mitigate potential errors within these new systems.

Processes need to be carefully planned to achieve consistent and safe outcomes for each task undertaken, and also need to consider when things do not go to plan. Procedures need to be as simple as possible, but as complex as they need to be, to ensure that staff have access to the correct instructions and information at the correct time. Training and education need to cover the situations that staff face on a daily basis. New staff need to be properly trained and supervised while they gain experience in their new working environment. Poor practice should be identified and corrected before it results in errors. The pathology services are under intense pressure in a climate where the workforce is stretched and under-staffed, therefore it is even more vital that vigilance and duty of care are upheld to ensure safe transfusion and patient safety.

A more thorough breakdown into laboratory errors is given in the remainder of the chapter.

Overview

This year there were 740 reports to SHOT where the primary error originated in the laboratory. Actual harm (where the patient was transfused, n=409) was far greater than the potential for harm (near misses where the patient was not transfused, n=331). This indicates key areas of weakness that need more care, attention and knowledge to ensure patient safety (Figures 7.1a and 7.1b). Figure 7.2 illustrates at which stage in the laboratory the error occurred and the outcome.

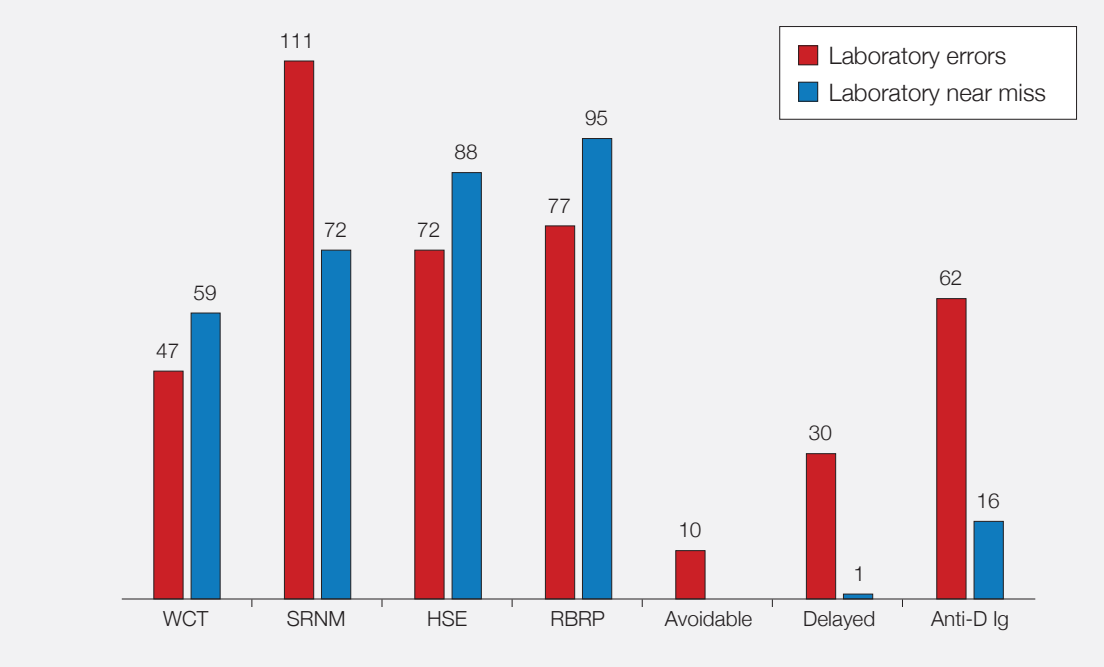


Figure 7.1a: Laboratory incidents and near misses by category of outcome n=740

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

Figure 7.1b: SHOT laboratory data (n=740) showing at which stage in the transfusion process the primary error occurred

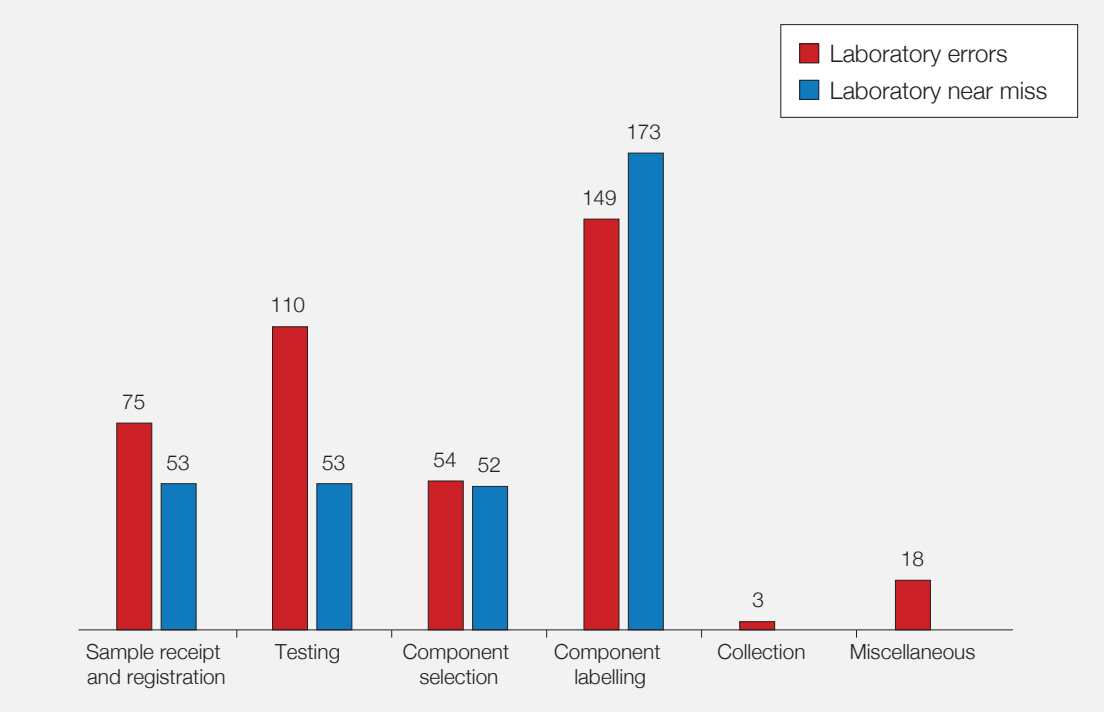


Figure 7.2: SHOT laboratory errors (n=409) showing at which stage in the transfusion process the primary error occurred with outcome

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 errors n=75

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).

Failure to act on the patient's available historical information is the most common error at the sample receipt and registration stage (Figure 7.3).

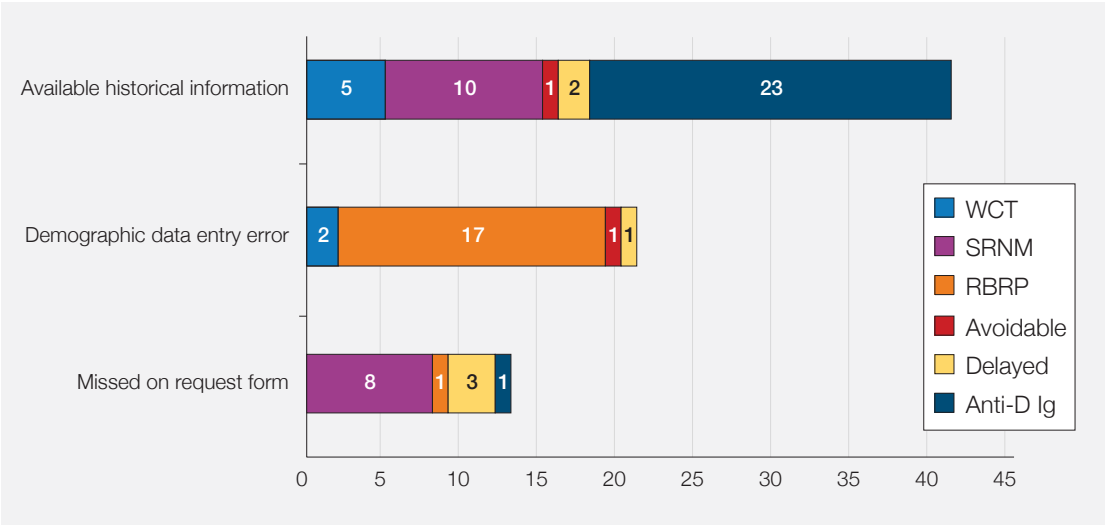


Figure 7.3: Sample receipt and registration errors with outcome n=75

WCT=wrong component transfused; SRNM=specific requirements not met; RBRP=right blood right patient; Ig=immunoglobulin

Learning points for sample receipt and registration errors

- **Heed patient history:** a patient's historical records provide information about the patient's transfusion requirements and should be clear and up to date. Laboratory staff must ensure that this is reviewed thoroughly at sample receipt and prior to testing and component selection. It can also indicate a patient's specific requirement or serological history that may not be given on the clinical request form. If the transfusion history indicates a potential delay in providing a component, then the clinical area needs to be informed
- **Sample acceptance:** adhere to a zero-tolerance policy when accepting samples. The standard operating procedure (SOP) for sample acceptance by the laboratory must define locally agreed minimum acceptable identification criteria and the course of action to be followed when these criteria are not met. These should also comply with the British Society for Haematology (BSH) guidelines (BSH Milkins et al. 2013). Please note: If a sample is rejected, no further testing should be performed and the sample must be discarded. However, if testing is performed once a sample is to be rejected i.e. to confirm an erroneous sample, then this is reportable to SHOT. If the laboratory does not identify an incorrectly labelled sample and proceeds to test it, this is then also reportable to the Medicines and Healthcare Products Regulatory Agency (MHRA) as a failure in the quality management system (QMS) (EU 2016)

Case 7.1: Blood issued and transfused with incorrect spelling of forename

The clinical area notified the laboratory that they had removed, by remote issue, a unit of red cells from the blood refrigerator with an incorrect spelling of the patient's forename. One unit of red cells had already been transfused to the patient with this incorrect spelling. The sample and request form used for crossmatching were labelled with the full first name but the historical record had a shortened version of the same name. This discrepancy had been checked with the electronic patient record at initial input in 2012 and again on the second sample received in 2013. In 2014 the electronic patient record was changed to the full name. When booking in this sample in 2017 the difference in the first name was not noted and it was booked in under the historical record of the short version without updating the forename to the full correct name. Two BMS failed to notice that the forename on the request form and sample were different to that on the historical record. The error was also not detected by ward staff and consequently a unit was transfused with the incorrect patient's forename. At the time of the incident the BMS staff had up-to-date competency assessments.

Good practice: Clinical areas must always use the registered patient name when collecting and requesting pathology samples and should not use familiar or alternative names by which the patient may be known. Laboratory staff must make sure the patient record selected on the LIMS when booking in samples matches the details exactly on the request form and sample received.

Testing n=110

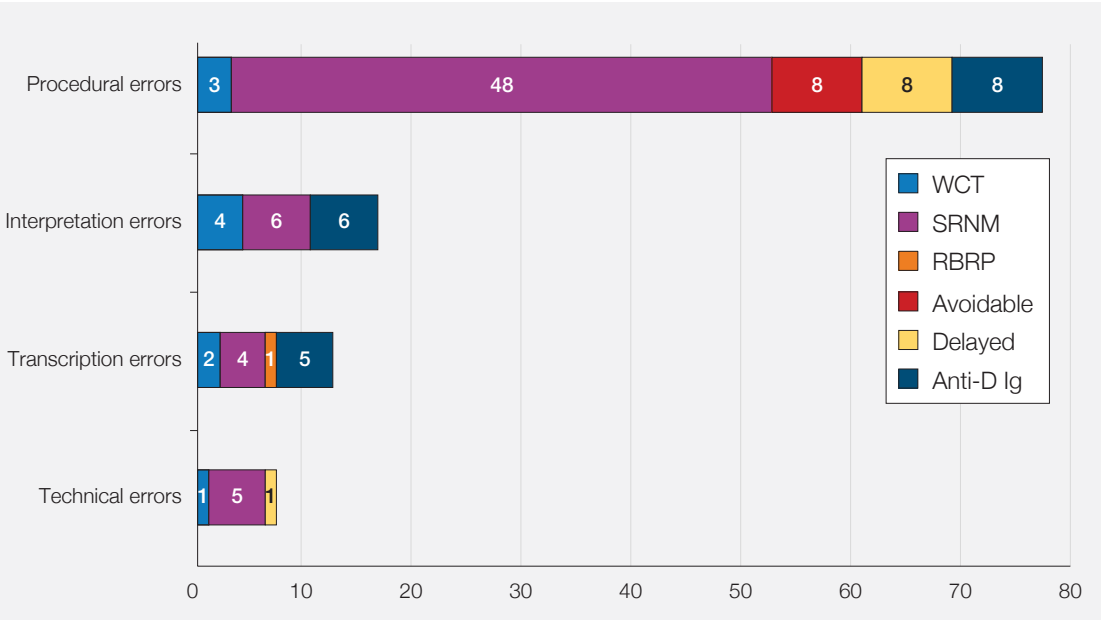
Correct analyses are required to ensure the safe provision of blood components for transfusion and should be undertaken in full compliance with local and national guidelines for pre-transfusion testing (BSH Milkins et al. 2013).

Procedural errors or failures in QMS far outweigh other areas in testing (Figure 7.4). Many of the serious adverse events are due to laboratory staff failing to follow procedure:

- QMS errors i.e. inadequate processes or incorrect procedures
- Procedural errors i.e. wrong procedure performed or procedure performed incorrectly or steps omitted

For further information on these, see the 2016 Annual SHOT Report page 39 (Bolton-Maggs et al. 2017).

Figure 7.4: Testing errors with outcome n=110



WCT=wrong component transfused; SRNM=specific requirements not met; RBRP=right blood right patient; Ig=immunoglobulin

Learning points for testing errors

- **Failure to follow procedures:** all policies and procedures for testing must be robust and strictly adhered to by laboratory staff without deviation. They must be validated and reviewed regularly i.e. review, improve and rewrite
- **Anti-D immunoglobulin (Ig):** the transfusion laboratory should have procedures in place to issue, trace and fate anti-D Ig. It is beneficial if the laboratory information management system (LIMS) can support identifying whether the patient is D-positive or is carrying or has delivered a D-negative baby. If anti-D Ig is issued from the pharmacy, the pharmacist must have access to the blood group of the patient and must understand it. This arrangement is not ideal

See Case 10.1 in Chapter 10, Incorrect Blood Component Transfused (IBCT) and case studies below.

Case 7.2: Preparing units for two patients with the same blood group simultaneously resulted in one patient receiving units intended for the other, 3 errors

Patient 1 received blood crossmatched for Patient 2. The incident involved two 2-unit crossmatches issued within 4 minutes of each other for two patients whose blood groups were both O D-positive with no antibodies detected. The crossmatched units were labelled and issued to the wrong patients. Patient 2's units were labelled with Patient 1's compatibility tag and Patient 1's units were labelled with Patient 2's compatibility tag.

Patient 1 was transfused both units with no adverse events reported. Patient 2 was not transfused and the units were returned.

The error was not detected either at collection or at administration because the compatibility tag was not checked against the component label it was attached to. The error was identified by the medical laboratory assistant (MLA) when fating the units as transfused in the LIMS.

Good practice: Always work with one patient at a time when crossmatching manually or electronically from start to finish, then once blood is issued and safely in the issue refrigerator ready for collection move on to preparation for the next patient.

Case 7.3: Blood issued before compatibility testing was complete

A full indirect antiglobulin test (IAT) crossmatch was set up by BMS 1 during a weekend shift for a patient with a known anti-K antibody which was not detectable at this time. Full testing was incomplete by the end of this shift as the crossmatch had not been interpreted. BMS 1 handed over the patient/testing information to BMS 2 who was starting the next shift, but they ended up working in the haematology section of the laboratory and not in transfusion. BMS 3, who also started on this shift and was covering the transfusion laboratory, assumed testing had been completed for this patient. The red cell unit was labelled, checked and moved from the holding shelf of the testing refrigerator into the issue refrigerator. K-negative red cells had been selected for this patient. The error was not detected until later in the shift when the gel card used for crossmatching was found still in the incubator. BMS 3, realising the error, checked the issue refrigerator however, the unit had been removed and transfused to the patient. The LIMS and report form indicated the units had been compatibility tested.

This incident demonstrates the importance of a robust and clear handover to the person continuing the work.

Case 7.4: Out-of-date LIMS and a manual interpretation error leads to two different blood groups being reported on a patient's record

A new patient was grouped on two separate occasions. Manual interpretation of the results was performed by the BMS. The first result recorded was interpreted as A D-positive and the second result was interpreted as B D-positive. Group O compatible red cells were issued, and one unit was transfused before the error was noted by a second BMS. The laboratory used an out-of-date LIMS which added complication to authorising results and allowed two different blood groups to be reported on the same patient.

Good practice: Validation of a LIMS should challenge all potential areas, especially those surrounding the issue of blood components based on testing results. Systems, including LIMS, should be re-qualified as stated in the European Union (EU) Guidelines for Good Manufacturing Practice (GMP) (EU 2015).

Component selection errors n=54

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

Learning points in component selection

- **Unrecorded specific requirements:** laboratory staff need to have knowledge and understanding about the requirements for key patient demographics including age-restricted requirements (pathogen-inactivated plasma components for patients born after 1 January 1996, K-negative red cells for a person of childbearing potential (BSH Milkins et al. 2013) and, in an emergency where the age is known, D-negative uncrossmatched red cells for males under 18 years of age). These requirements are not usually indicated on the clinical request form and are seldom supported by the laboratory information management system (LIMS)
- **Multiple specific requirements:** if a patient has several specific requirements, laboratory staff may fail to select for all of them as they may be busy focussing on one of them e.g. a pregnant person with lymphoma may get irradiated but not cytomegalovirus (CMV)-screened cellular components. A robust process should be in place to ensure that components with all the correct requirements are selected
- **Compatibility of components:** knowledge about the compatibility of all components is an essential requirement for laboratory staff (see SHOT Bite No. 9: Component Compatibility, www.shotuk.org/resources/current-resources/). Laboratory staff must also remember to take into consideration maternal antibodies when issuing blood components for a neonate, ensuring that the units are compatible with maternal antibodies. When only one group and screen sample has been tested for a patient for whom blood components are required, group O red cells and group AB fresh frozen plasma (FFP) (if AB not available then group A FFP) are the groups of choice until a second sample is received and analysed to confirm the patient's blood group. In an emergency it may be acceptable to issue group-compatible red cells on a first perfectly labelled sample if locally risk-assessed

See Case 10.5 (transfusion of incompatible FFP) in Chapter 10, Incorrect Blood Component Transfused (IBCT) and case studies below.

Case 7.5: Non-irradiated platelet units issued to a <10-year-old patient despite a warning flag, 3 errors

A BMS issued two bags of platelets for a patient who required irradiated cellular components. This specific patient requirement was recorded on the LIMS. BMS 2 was covering for a break during a night shift, and receipted the platelets on arrival from the Blood Service. When BMS 1 returned from their break, they received a handover message that the platelets had been placed on the agitator but required irradiation. This message was taken verbally but not written down. It is usual practice at this hospital for all platelets to be irradiated on arrival from the Blood Service and then placed on the agitator, however in this instance that did not happen. The shift ended and day staff arrived. BMS 3 issued the platelets assuming they had been irradiated. A message flagged up that they had not been irradiated but was overridden. At administration BloodTrack® was used but it did not pick up the need for irradiated platelets, and it was not picked up by the registered nurse administering them and so the patient received the transfusion. The error was noticed during the bedside check for the second unit. The unit was returned to the laboratory and an incident form completed.

There were several assumptions that led to this error. Firstly, staff assumed that the message given verbally would be remembered; it was not written down as part of a handover. This was followed by an assumption that the platelets on the agitator had been irradiated. The clinical staff did not identify that the first unit transfused was not irradiated; this could possibly have been due to reliance on BloodTrack® to alert the staff if there were any discrepancies.

Platelets are irradiated in-house when received from the Blood Service. On this occasion, this was not done. If this laboratory received irradiated platelets direct from the Blood Service this incident would not have occurred because 'irradiation' is included in the product barcode. So, if the patient is flagged as needing irradiated components, the LIMS should not allow issue of non-irradiated units.

Case 7.6: Multiple specific requirements for a patient where the need for K-negative units was overlooked

A telephoned request was taken for red cells for a <10-year-old girl, but full details were not entered onto the telephone request form at the time of request, therefore gender was omitted and this was not obvious from the patient's name. The request was taken by a lone overnight worker who was interrupted by a bleep so did not complete the task by looking up the record on the LIMS. Subsequently the LIMS became unavailable due to a planned downtime. A second BMS later issued the red cells while the LIMS was still unavailable, so the patient was looked up on the in-house specific requirement back-up file which stated that the specific requirements were for CMV-screened and irradiated cellular components. This was then written on the request form. A red cell unit was crossmatched, issued and transfused. When the LIMS was back up and running it was noted that the additional requirement for K-negative units, due to patient gender and age, had been overlooked and a K-positive unit had been transfused.

It is essential to know the age and gender of a patient to determine basic requirements which should form part of the information recorded from a telephoned request. Best practice is always to receive a completed signed request form prior to component release that should have indicated the gender and all specific requirements of the patient. The incident also demonstrates reliance on the LIMS to notify the user of specific requirements. Laboratory staff can rely too much on the LIMS to inform them of component selection and specific requirements that are age- and gender-specific rather than using their knowledge achieved through training and competency assessment.

Case 7.7: Incorrect D-group red cells given following liver transplant (donor D-negative, recipient D-positive)

Following a telephone call from the transplant coordinator to the transfusion laboratory, staff became aware that D-positive blood had been issued and administered to a post-liver transplant patient outside the hospital local protocol. The blood was compatible with the recipient but not with the donor organ, which was D-negative. The error was noticed by ward staff and was quickly rectified and new blood components issued by the transfusion laboratory staff. The previous units were removed to prevent any further components being erroneously transfused. The investigation report noted that sample processing occurred outside normal working hours; this was not unusual for a liver transplant patient and workload was not excessive. The checking process and issuing of blood components had been dealt with by three members of staff and covered two handover periods. The blood sample and request also had arrived towards the end of the shift for one of the staff members.

The root cause of this incident involves both communication and educational factors. Staff failed to identify that the notes they were reading on the LIMS were from a previous transfusion. There was no telephone call from the transplant coordinator (usual practice) which would have triggered laboratory staff to look at the notes on the LIMS. Educational factors: no formal training was in place in relation to blood component transfusion for solid-organ transplantation. Staff involved were working across two different sites with two different policies in relation to living-donor transplantation. There was also wrong information on the child's (recipient) operation record note in relation to the donor group.

Although there is a section for haemopoietic stem cell transplants in the compatibility guidelines (BSH Milkins et al. 2013) there is a lack of guidance with respect to some important aspects of transfusion management in ABO-incompatible and D-mismatched solid organ transplants. In the absence of national guidance centres will devise their own protocols (Aujayeb et al. 2014).

Component labelling, availability and handling and storage errors (HSE) n=149

The correct 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) (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 for labelling and availability

- **Transposed labels:** following component labelling laboratory staff should have a 'stop' moment and check that all paperwork is correct and that the right label is attached to the right unit. It is essential that only one patient's component is labelled at a time
- **Major haemorrhage protocols (MHP)**: one person should be nominated in the clinical area and another in the laboratory and all communication should be channelled through these identified individuals. This will avoid duplication of requests and time-consuming telephone calls during a challenging time (See SHOT Bite No. 8: Massive Haemorrhage – Delays www.shotuk.org/resources/current-resources/)

Case 7.8: Blood issued and transfused related to an incorrectly labelled sample

A patient was admitted to the emergency department (ED) and had their surname recorded on the patient administration system incorrectly with a unique patient number but no DOB was provided. Two samples labelled as above were received and processed by the transfusion laboratory. The following day the patient's central record was updated with the name changed to a different but similar and correct surname and updated with a DOB, but the unique patient number remained unchanged. The transfusion laboratory was not informed that there had been a change to the patient's details. Two days later the laboratory received a request for two units of red cells which was fulfilled using the original samples with the incorrect name and no DOB. A member of staff from the clinical area was sent to collect a unit of red cells for this patient and failed to undertake full patient identification checks. At the time they realised that there was no DOB recorded, that the unique patient number was the same but they did not check the patient's name. On return to the clinical area, the staff member contacted the transfusion laboratory and enquired about the missing DOB. They were informed that the component could be transfused. However, two further samples were now needed by the transfusion laboratory. At administration a two-person check was undertaken at the bedside but no check was performed against the identification band and the unit was then transfused. On investigation the staff member said that they were concerned about the lack of a DOB however, when they telephoned the laboratory they were told that the blood was safe to use.

The DOB is an essential core identifier (BSH Robinson et al. 2018). Routine samples without this information should not be processed. In emergency situations with unknown patients the guidelines recommend 'at least one unique patient identifier', and a guestimate of the age which can inform about potential patient-specific requirements. Hospital transfusion policies should be clear that it is not acceptable, unless in emergency situations, to proceed with transfusion if the core identifiers are missing or incorrect.

Figure 7.5 shows the laboratory-related HSE. For additional HSE, including those in the clinical area, see Chapter 9, Handling and Storage Errors (HSE).

Learning points about handling and storage for laboratory staff

- **Storage of components:** adequate cold chain needs to be maintained to ensure that units out of temperature control are not transfused or returned to the storage unit
- **Recovery of components beyond reservation:** transfusion laboratories must have robust procedures in place for uncollected components that are beyond their reservation date and still in a storage unit to prevent them from being accessed and transfused

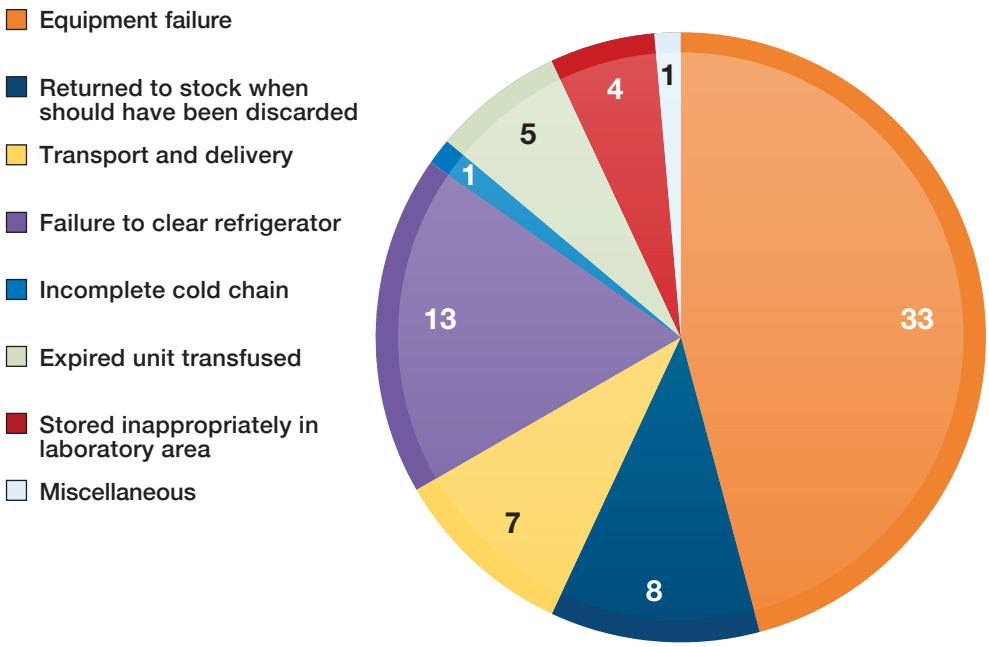


Figure 7.5: Laboratory-related handling and storage errors with outcome n=72

Case 7.9: Transfusion of FFP which had exceeded the post-thaw expiry time

FFP was requested for an elderly patient who was bleeding during a hip replacement. The laboratory keeps stocks of different types of frozen plasmas (methylene blue-treated FFP (MB-FFP), solvent-detergent treated FFP (SD-FFP) and standard FFP) and usually keeps pre-thawed standard FFP for up to 5 days for major trauma only (JPAC 2016).

A BMS selected thawed MB-FFP, which was beyond its permitted 24-hour post-thaw storage period, and issued it for the patient. The error was detected by the transfusion practitioner while following up data collection. The BMS on duty did not notice that the pre-thawed plasma was not suitable for 5-day storage and inappropriate for non-MHP use.

Storage requirements for different types of FFP are complex. To minimise confusion, FFP types should be stored in distinct and clearly-labelled storage locations. This is also applicable for storage of pre-thawed plasma components/products. Pre-thawed FFP for major haemorrhage activations should be labelled 'for MHP use only'. Clear training and competency assessment for BMS staff should be in place. Procedures should also be in place to remove from storage locations and discard components/products that have expired to avoid accidental issue and/or use.

Collection errors n=3

Correct procedure will ensure that the correct component is collected and that it fulfils the clinical request and meets the details on the collection slip.

There were 3 errors in collection where laboratory staff did not hand over the unit of the correct specification to the clinical staff, see Case 10.7 in Chapter 10, Incorrect Blood Component Transfused (IBCT).

Learning point about collection

- **Direct handover**: if laboratory staff are responsible for directly handing over components to a nurse/porter at collection, they need to ensure that all components meet the requirements of the clinical request and the collection slip. Any additional components must be confirmed with a traceable clinical request

Miscellaneous n=18

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

Learning point

- **Blood Service errors:** these are not reportable to SHOT unless they contribute to patient risk or harm. The transfusion laboratory staff should check all patient history and component selection (including components selected by a Blood Service)

Case 7.10: A patient with sickle cell disease received an incorrectly phenotyped component following an error from the Blood Service

A unit of red cells was requested from the Blood Service for a patient with sickle cell disease. The Blood Service crossmatched the unit but it was not matched for Rh and K. Specific requirements for sickle cell patients are that red cell units should be sickle-negative (HbS-), matched for both Rh and K, and <10-days old. The receiving transfusion laboratory failed to identify this omission and made the unit available for the patient. The patient subsequently developed anti-C as they should have received red cells negative for the antigens C, E and S that were also HbS-negative as recommended by the Blood Service expert laboratory report.

BMS should never take for granted that the earlier steps in the transfusion process have been undertaken correctly and should always perform their step in the transfusion process fully and with care. The bedside check is the last step in the process to identify errors made earlier in the transfusion process and staff administering blood components should have a clear understanding of the specific requirements of their patients.

Case 7.11: FFP reconnected and transfused after being disconnected

FFP was being administered to a patient when a problem arose with the cannula. The nurse stopped the transfusion and disconnected the component. The nurse took the component to the laboratory to ask how long FFP can be out the refrigerator and if it could still be given within the allowed timeframe. The BMS advised that the component could be re-connected to finish the transfusion as it was still within time. The nurse (who had received transfusion training) queried this instruction as she would not have done this with red cells but because two BMS told her the same thing she assumed this was correct. The nurse re-connected the unit and completed the transfusion. The nurse was unaware of the correct procedure to follow if a cannula becomes blocked (i.e. to discard remainder of the unit after disconnecting). It was noted that she had relied on inappropriate advice.

Staff should clearly ascertain exactly what is being asked of them and then any advice given should only be within the scope of their training. BMS staff have limited clinical knowledge and should not give clinical advice. This should be referred to a transfusion practitioner or an appropriate clinician.

Case 7.12: Pathology LIMS was down, manual back up of patient data was available but had not been updated for 3 months, so missed the patient's specific requirements

Over time, several hard drives containing the pathology LIMS records failed and eventually the final hard drive failed. The LIMS shut down throughout pathology, which covered three teaching hospitals across two cities, including the blood transfusion department. It was not reinstated until 8 days later and was not in full use until the 9th day following validation. During this period blood requested for a patient had no indication on the request form of any specific requirements or history of alloantibodies. Some patient history was available on an out-dated spreadsheet, including specific requirements and alloantibodies, but this was not consulted before issuing blood. This was because it was time-consuming to do, and staff were very busy because of the increased workload. Education for this important step was not routinely delivered in training.

In addition, the working environment became difficult due to the amount of paper being used for each record and space became compromised due to the amount of manual work that had to be

completed, all of which had to be completed with the existing number of staff. Staff morale was affected by the demands of increased concentration required, user requesting and overall stress of providing a service during this situation.

A manual backup from the LIMS to an Excel spreadsheet which records known alloantibodies was last performed three months before and was only ever done on an ad-hoc basis. Had this been done more frequently, then the potential for missing a specific requirement or alloantibody would have been reduced.

The failure of the clinical areas to inform the laboratory of any specific requirements and/or alloantibodies highlights the lack of understanding in the clinical areas of the importance of serological history and specific requirements. SHOT reports continue to indicate a national, systemic misunderstanding of the importance of this information among clinical and nursing staff. However, the laboratory staff should have sufficient robustness within their contingency planning to be able to access specific requirement data on previously-reported patients. The contingency planning should also ensure that staff are fully supported in managing changes in workload.

Medicines and Healthcare Products Regulatory Agency (MHRA)

Author: Chris Robbie

There are several differences in reporting to both haemovigilance organisations which are described in the 2016 Annual SHOT Report (Bolton-Maggs et al. 2017). Despite the variation in numbers and categorisation the MHRA can confirm that the reflective learning described throughout the SHOT laboratory chapter is similar, therefore this MHRA summary has focused on additional key areas that are only reportable to the MHRA. The full MHRA chapter, Chapter 24, is available online only on the SHOT website (www.shotuk.org).

There are several related themes in the case studies included here. Staff appear to be making assumptions, skipping steps in procedures, multitasking, using uncontrolled forms, giving advice that they are not qualified to give and showing a lack of attention to detail. All these are examples of poor laboratory practice. Collectively these can be addressed by annual GMP training which makes clear the expectations of staff to conduct themselves correctly when working in the laboratory. GMP training should make it clear to staff:

- Do not continue without having the correct information
- Do not work on two tasks at the same time
- Do not use sticky notes to document information
- Do not perform tasks or give advice you have not been trained for
- Check at all stages that the work you have done is correct before you proceed to the next stage

Simple stuff, right?

Not entirely. Analysis of SHOT and serious adverse blood reactions and events (SABRE) reports demonstrates that in many cases staff are already aware of what they should do and how to conduct themselves. MHRA inspectors having assessed compliance, as demonstrated by the blood compliance report, have shown it to be failing. Inspection findings have shown an increase in non-compliances found during inspections. SHOT, UKTLC, NBTC, laboratory managers and the MHRA are also reporting failures to address long-term resource and staffing problems.

These problems are not going to be easy or quick to solve, but a robust QMS can help to alleviate some of them. Processes need to be carefully planned to achieve consistent and safe outcomes for each task undertaken, and also need to consider when things do not go to plan. Procedures need to be as simple as possible, but as complex as they need to be, to ensure that staff have access to the correct instructions and information at the correct time. Training and education need to cover the situations that staff face on a daily basis. New staff need to be properly trained and supervised while they gain

experience in their new working environment. Poor practice should be identified and corrected before this results in errors.

The QMS should not be seen as a time-consuming inconvenience, but as a tool to be used effectively to ensure safety and consistency. It should be used to gather evidence to highlight the pressures laboratory staff face. Staff should never be guilty of making basic GMP errors, but if they are not properly supported by a robust QMS then sometimes they might feel they have no choice. If this is the case, and errors are made, it is their duty to report this so the failings of their QMS can be addressed.

UK National External Quality Assessment Scheme (UK NEQAS)

Authors: Jenny White and Clare Whitham

Following last year's report, UK NEQAS blood transfusion laboratory practice (BTLP) sent out its annual pre-transfusion testing questionnaire to laboratories in the UK and overseas. A relatively low return rate this year has, however, limited data analysis. For the first time, a question was included to collect data on the number of laboratories that use the 'Rh shorthand' notation, e.g. R_1R_1, CDe/CDe, and in what context. The responses show that 60/114 (52.6%) laboratories use the shorthand notation, mainly in conversation with blood transfusion staff, but also for blood ordering and on the LIMS. UK NEQAS (BTLP) currently send one exercise a year assessing phenotyping for Rh antigens, but intend to increase this as part of a scheme redesign. While penalty scoring for Rh phenotyping is based on the reactions recorded rather than the shorthand interpretation, during exercise 17R1, 33/532 sets of correct reactions were assigned an incorrect shorthand interpretation, with 27/33 of these due to not taking the D-type into consideration.

As reported last year, results of BTLP external quality assessment (EQA) exercises have shown some continuing issues with laboratories failing to either adhere to or understand recommendations made by the manufacturers of their chosen technology. In 2016 (exercise 16R9, D-positive cells coated with anti-D) and again in 2017, in exercise 17R5, red cells of one of the patients (D-negative) were coated with anti-c to give a 2+ positive DAT. This caused a positive reaction in the control well of BioVue grouping cassettes, invalidating the D-typing results. The majority of laboratories using BioVue either reported an interpretation of uninterpretable (UI) or undertook repeat testing with a second technique enabling them to make an interpretation of D-negative. However, eight laboratories reporting positive reactions versus anti-D reagent(s) and/or the reagent control went on to make an interpretation of D-positive or D-variant.

Ortho BioVue instructions for use for ABO-Rh/Reverse Grouping Cassette recommend that '*all weak Rh(D) positive typing results of 2+ or less be confirmed by an alternative method'* and that *'invalid test results due to spontaneous agglutination may occur on rare occasions with the Anti-D reagent when testing red blood cells heavily coated with antibodies*.' It is important that all users are aware of the limitations of technology that is used for any application in the blood transfusion laboratory, and that manufacturers' instructions are understood and followed. Laboratories should have clear policies for defining and investigating anomalous ABO/D typing results, and all staff undertaking testing and reporting should have the knowledge required to recognise potential sources of error, including those specific to the technology in use.

Further issues related to lack of adherence to or misunderstanding manufacturer recommendations included one laboratory, experiencing supply problems with the panel provided for their column agglutination technology (CAT) technology, substituted this panel with one designed for a different CAT technology, causing insensitivity in the IAT. This resulted in a false negative reaction which contributed to misinterpretation of an antibody mixture. Each CAT system employs a diluent with a specific ionic strength, designed along with the volume of plasma required to give the optimal ionic strength of the final mixture of reactants.

In an exercise containing a weak anti-E, three laboratories made errors in antibody screening, despite having obtained weak positive reactions in the initial screen. One made a decision to discount a weak positive reaction with one screening cell in view of a field safety notice warning of occasional non-specific reactions with quality control (QC) samples. Two other laboratories repeated the testing on their

respective analysers, obtained negative results and reported a negative screen. One of these laboratories made a decision to report the screen as negative in the context of on-going problems with occasional false positive reactions versus screening cells with clinical samples, and the other did not follow their protocol for investigation of equivocal reactions in the screen. Knowledge of current issues or problems related to different technologies or current testing environments can influence interpretation of antibody screening results. Bearing this in mind, it is important that laboratories have clear protocols for dealing with inconsistent, non-reproducible or weak reactions in antibody screening or identification panels.

In the current climate of increasing workload, loss of experienced staff due to retirement and falling staff numbers, resource and time constraints are contributory factors for errors made in EQA exercises (UKTLC 2017). A laboratory, working under such constraints, identified an anti-D in an EQA sample but misidentified a second specificity as a result of not following their own protocol for inclusion and exclusion of antibody specificities. Loss of staff knowledge and experience are further contributory factors. In an exercise with a sample containing anti-Fy^a+K, two laboratories identified anti-Fy^a, but misidentified the second specificity and did not record the potential presence of anti-K. 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. In all cases, a process of exclusion/positive identification was not undertaken.

As for last year, data analysis of EQA exercises repeatedly shows transcription and transposition errors made either during testing or reporting of results. Some of these are caused or exacerbated by the fact that processing and reporting of EQA samples is not identical to that for clinical samples. However, manual testing is vulnerable to transcription and interpretation errors and must include checks at critical points. In one exercise, an error was made when manually transcribing results from an analyser, leading to misidentification of the antibody, and in another, an error occurred during interpretation of a manual ABO/D group undertaken in accordance with the laboratory's policy for patients requiring a crossmatch, and this manual result was reported rather than the routine automated ABO/D group. Even laboratories with full automation will on occasion be required to undertake manual grouping and should have a back-up process in place that is useable 24/7.

Welsh Assessment of Serological Proficiency Scheme (WASPS)

Author: Gareth Nottage

The Welsh Assessment of Serological Proficiency scheme (WASPS) is based on a simulated compatibility test that is performed by individual members of staff using manual serological techniques. Sufficient material is provided to each laboratory so that all members of staff, including on-call and multidisciplinary staff, are able to participate. The 2012 Annual SHOT Report (published in 2013) recommended that 'Regular practice and competency assessment of infrequently used manual techniques is important'.

Performance scores are based on the comparison of individual results to the overall modal results within technique. Laboratories are classified as persistent unsatisfactory performers (PUP) when they incur an unsatisfactory performance score in two consecutive exercises. During the period 2005-2013 no laboratories were identified as such, however, one laboratory was identified in 2014 and two identified in both 2016 and 2017.

In the first instance in 2014 five different individuals failed to detect seven weak incompatibilities over two exercises (W10/13 and W01/14).

In the first of the two laboratories identified during 2016 three individuals recorded three missed incompatibilities, in the second laboratory identified, four individuals recorded ten missed incompatibilities. In the first of the two laboratories identified during 2017 nine individuals recorded 15 missed incompatibilities, the second laboratory identified two individuals who recorded three missed incompatibilities. Where these missed incompatibilities have been recorded it has been noted that other individuals, who either tested on the same day or at a later date, completed the exercise correctly.

UK Transfusion Laboratory Collaborative Update

Author: Rashmi Rook

Capacity planning – safer staffing

The UKTLC standards (Chaffe et al. 2014) are regarded as *industry standards,* and laboratories should strive towards meeting these requirements. The standards were devised based on historical knowledge of transfusion processes and years of analysing laboratory error data by the SHOT and MHRA teams, which identified the factors that contributed to these errors.

Transfusion teams are strongly advised to plan their staffing levels and skill mix to ensure that all aspects of service provision are met and continually assessed through their local governance structures. A simple template for capacity planning and review was released on the MHRA blood forum and can also be located at the foot of the SHOT current resources web page (under UK transfusion laboratory collaborative resources, https://www.shotuk.org/resources/current-resources/); the sole aim for this process is to have:

- Right staffing levels
- Right skill mix
- Right knowledge
- Right supervision
- Right equipment
- Right procedures
- Right resources

Considerations when capacity planning:

- The senior and lead BMS should be excluded from the shift rotas if this impacts on core-hours availability
- If it is necessary to use the senior team for out-of-hours provision, then additional staffing resource must be built into the plan, i.e. if a senior member of staff is on a full shift and their core-hour availability (09:00-17:00) is 0.7 whole time equivalent (WTE), then additional 0.3 WTE staffing resource is needed
- There must be staff available to support the transfusion laboratory manager with the following service aspects:
  - Supervision
  - Training
  - Equipment management
  - Error management, audit, improvements, validation and changes
  - Traceability
  - Haemovigilance
- Consider using permanent MLA staff to support the functions of traceability and some training functions such as stock entry, sample, and stock management
- Ensure that time is built in to enable staff to be released to meet training commitments
- Allow staff opportunities to attend courses and external transfusion meetings to build on their interest and knowledge
- To allow for continued stability of the department it is essential that any changes to working patterns

of shared rotational staff are assessed through a formal change-management process to review the impact on the transfusion department, and the potential to undermine adherence to the regulations

- Any deviations from the required staffing levels should be managed via the hospital risk governance procedures (risk register), for full visibility and planning improvements
- A simple way to work out what staffing is needed is to look at the tasks *not achieved* both in the laboratory and QMS activities, and to identify what the service needs are to meet the standards, and thereby comply with the Blood Safety and Quality Regulations (BSQR) (BSQR 2005):
  - Documents past review dates
  - Training delays
  - Delays with annual competencies
  - Overdue audits
  - Overdue equipment cleaning/planned preventative maintenance (PPM)/or reviews not performed to schedules
  - Overdue error investigations
  - Processes/equipment/tests not re-qualified within timescales
  - Pre-acceptance testing not performed
  - Staff not reading/signing standard operating procedure (SOP)
  - Staff unable to be released to attend professional meetings

The transfusion team must ensure that the QMS is embedded as part of their normal working practice, and not considered to be the sole responsibility of quality personnel, as the knowledge of errors, and the improvements needed reside with the expertise of the transfusion team.

As previously mentioned, we all come to work intending to do a good job. It is faulty systems and processes that let us down and place our staff in situations where they are more likely make an error that may result in patient harm, as well as affecting their own confidence. It is time to build a resilient workforce and give staff the right tools and capabilities to succeed via the capacity planning process, so that errors of the past are not repeated. The workforce can then be developed and encouraged, and we can bring back the pleasure and pride in our working environment.

Updating current standards

The UKTLC standards (Chaffe et al. 2014) are under review. There will be some guidance on demonstrating equivalence to the qualification requirements.

Conclusions relating to laboratory errors

Cases in this Annual SHOT Report have demonstrated that staff are stepping beyond their capability or knowledge and giving out information they are not qualified to give or incorrectly modifying laboratory practice to try and achieve a safe conclusion. There should be robust SOP that indicate what staff should do when events fall outside their understanding or the detail of the SOP. It should be made clear that these events need to be referred to either a more senior/experienced BMS or a clinician with a knowledge of transfusion to advise on the appropriate course of action to be taken. Where additional laboratory procedures may cause delay in provision of suitable components the clinical staff should be informed as soon as practicably possible.

The BSH administration guidelines have been updated and highlight that clinical staff are required to perform the critical bedside checks including knowledge of compatibility prior to administering the component (BSH Robinson et al. 2018). However, the laboratory staff must perform essential checks in the transfusion laboratory to ensure that the component is correct for the patient prior to it leaving the laboratory. The transfusion process requires all staff working in blood transfusion to work as a

team, and not only within their key areas, to ensure patient safety. This requires communication and effective handovers between staff. The key laboratory messages and learning points above need to be considered for both routine and out-of-hours service. Laboratory staff must be responsible for keeping their competencies up to date (https://www.hcpc-uk.org/aboutregistration/standards/cpd/). The pathology services are under intense pressures and demands in a climate where workforce is stretched and under-staffed, therefore it is even more vital that vigilance and duty of care is upheld to ensure safe transfusion and patient safety.

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