Laboratory Errors n=573 (389 transfused errors and 184 near miss)

14

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Abbreviations used in this chapter

AAA	Abdominal aortic aneurysm
ABOi	ABO-incompatible
AML	Acute myeloid leukaemia
BMS	Biomedical scientist
BSQR	Blood Safety and Quality Regulations
CAPA	Corrective and preventative action
CL	Component labelling, availability and handling and storage
EQA	External quality assessment
Hb	Haemoglobin
HSE	Handling and storage errors
LIMS	Laboratory information management system
MHP	Major haemorrhage protocol
MHRA	Medicines and Healthcare products Regulatory Agency
QMS	Quality management system
RCA	Root cause analysis
SOP	Standard operating procedure
SRNM	Specific requirements not met
SRR	Sample receipt and registration
UKAS	United Kingdom Accreditation Service
UKNEQAS	UK National External Quality Assessment Scheme
UKTLC	UK Transfusion Laboratory Collaborative

Key SHOT messages

- Final checking of the unit before issuing is important. The use of label verification in LIMS or electronic blood-tracking systems helps to optimise safety
- LIMS alerts should be relevant, appropriate, not easily overridden and have an audit trail
- Communication between clinical teams and the laboratory, and between clinical teams in shared care patients is vital to ensure provision of appropriate blood components
- Manual input of patient information and blood grouping results is prone to error. Independent checking processes should be in place where IT solutions are not available
- Release of red cells in a major haemorrhage situation should not be delayed whilst awaiting Hb results, or where recent Hb is within normal limits

Recommendations

- Laboratories should have training programmes and regular competency-assessments that ensure staff have the appropriate knowledge and skills commensurate to their role
- Laboratories should have a schedule for regular LIMS upgrades in accordance with manufacturers recommendations and contractual requirements. The operational LIMS should include all available functionality to support safe practice, where deficiencies are noted a roadmap for upgrade and/or development should be in place and regularly reviewed by the laboratory management and the LIMS supplier
- The LIMS should be used to its full potential to support transfusion safety, transfusion service managers should work with the LIMS supplier to ensure that all functionality is available and operational to support safe laboratory transfusion practice
- Laboratories should have capacity plans in place that include all aspects of transfusion practice. These should be reviewed regularly and have appropriate escalation processes when safe staffing levels are not met
- Interoperability between patient administration systems and LIMS reduces the risk of errors in manual registration of patient information. Transfusion service managers should work with the LIMS supplier and IT departments to explore options for interfacing

Action: Transfusion laboratory managers, pathology leads

Introduction

The number of events involving laboratory errors and near misses decreased by 10.3% to 573 of 3161 total reports from 639 in 2020. Reported laboratory errors have been reducing since 2018 which may reflect improvements in laboratory processes. Conversely, this could be due to under-reporting as a result of staffing issues during the COVID-19 pandemic. There were 389 laboratory errors where a component was transfused, and 184 near misses.

In 2021, the highest proportion of errors occurred within the component labelling, availability, handling, and storage steps, 122/389 (31.4%), followed by testing, 114/389 (29.3%) and component selection, 91/389 (23.4%) categories. This highlights key areas of weakness that need more care, attention, and knowledge to ensure safe transfusions. Figures 14.1 and 14.2 illustrate at which stage in the laboratory the error occurred.

In 99/389 (25.4%) of laboratory error reports, the error occurred where staff were lone working. Adequate, appropriate training and support must be given to staff before beginning lone working.

Process instructions within SOP must be clear and concise to ensure they can be followed correctly.

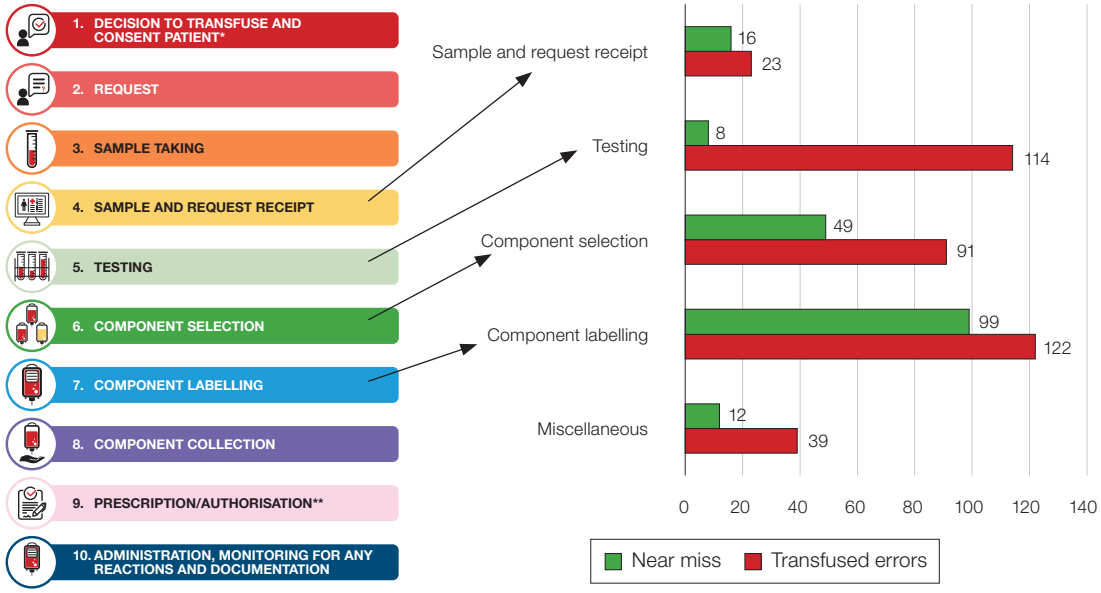


Figure 14.1: Laboratory errors (events and NM) related to the 10 steps

Of the 39 miscellaneous laboratory errors reported 29/39 were related to anti-D Ig errors and 10/39 were due to delays in provision of blood components. The anti-D Ig errors were reportedly due to cffDNA results not being checked, communication failures, incorrect advice from the laboratory to the clinical area and LIMS flags being missed by laboratory staff. The delays were reportedly due to laboratory communication errors and equipment failures.

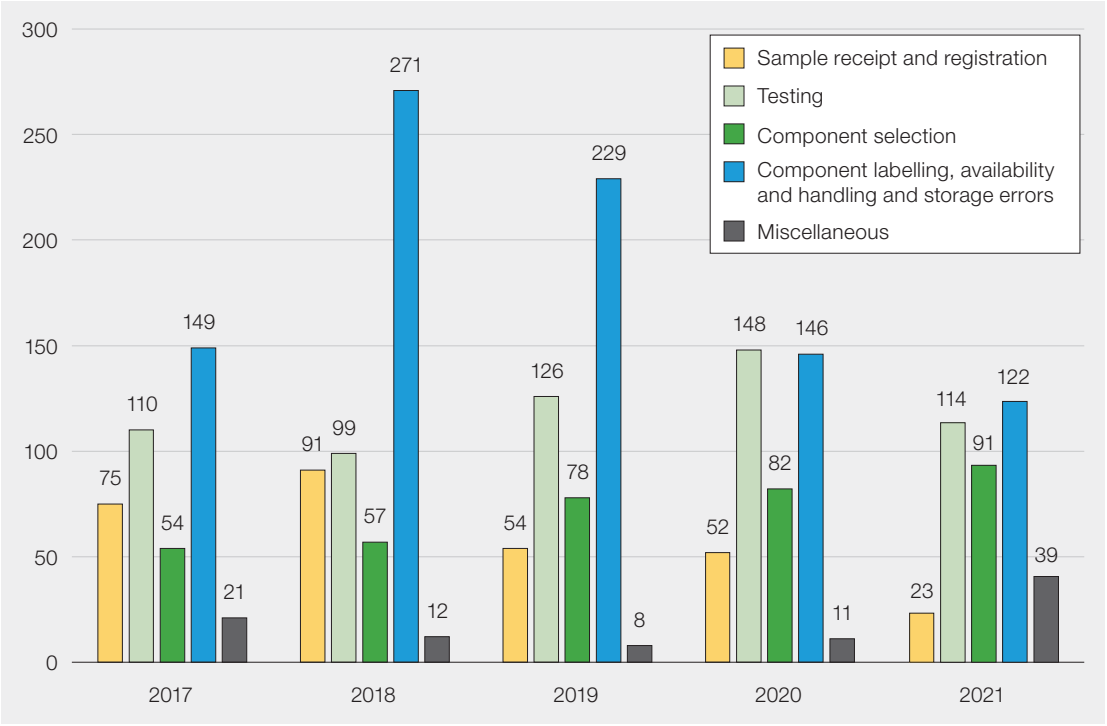


Figure 14.2: Laboratory errors 2017–2021 categorised by step where the error occurred

Deaths related to transfusion n=0

There were no deaths reported relating to laboratory errors.

Major morbidity n=6

There were 6 cases of major morbidity related to laboratory errors; 3 cases of sensitisation to anti-K in females of childbearing potential and 3 errors which resulted in avoidable transfusion delays.

There were 3 cases of preventable alloimmunisation of anti-K to women of childbearing potential following transfusion of K-positive units. In 2/3 cases, reports stated that the LIMS alerted the BMS to the requirement for K-negative, but these were overridden. Females of childbearing potential (<50 years) should receive K-negative red cells unless they are unavailable in an emergency (BSH Milkins et al. 2012). Laboratories should take all steps possible (including the application of LIMS flags which are not easily overridden) to prevent sensitisation to the K antigen and so prevent increased risk for the fetus in future pregnancies.

Case 14.1: Transfusion of K-positive red cells resulted in antibody formation

A female patient in her 20s was transfused two red cell units post miscarriage, one of which was K-positive. The LIMS alerted the BMS to the requirement for K-negative units, but alerts were not heeded and were overridden, with the LIMS allowing users to skip past alerts. This incident occurred towards the end of a night shift. This patient became pregnant again, with anti-K titre of 128, where the partner was Kk. cffDNA results indicated the fetus was K-negative.

Decision fatigue can lead to errors that result in patient harm.

Case 14.2: Lack of provision of emergency stock red cell units

An elderly patient in his 80s was admitted with Hb 110g/L, which had fallen to 92g/L the following day. The patient became hypotensive with rapid deterioration, and an arterial blood gas result indicated the Hb had fallen further to 70g/L. One unit of emergency O D-negative red cells was requested urgently, but the BMS refused the request as they felt this was not appropriate given that there were no obvious signs of blood loss. The BMS suggested to contact the consultant haematologist, which did not happen. By the time the BMS had a confirmed Hb result of 50g/L and contacted the ward to state group specific red cells could be released, the patient had already died. Post-mortem results identified the patient died due to a bleeding duodenal ulcer.

This case highlights that covert bleeding cannot be quantified and transfusion support must be guided by the patient's clinical status. Gastrointestinal bleeding can be deceptive, the severity is often masked, diagnosis may be delayed; hypotension and tachycardia are important clinical signals. Transfusion delays must be avoided. Haematocrit and haemoglobin levels in bleeding patients are not reliable indicators of blood loss (BSH Hunt et al. 2015), and red cells should be readily available for immediate use for life-threatening bleeding.

ABOi cases

There were 3 ABOi cases reported in 2021, all of which were laboratory errors related to selection of plasma components. In all 3 cases group O plasma was issued and transfused to group A patients. In 2/3 cases the LIMS alerted the laboratory staff to the incompatibility, but this was overridden. These cases are discussed in detail in Chapter 9, Incorrect Blood Component Transfused (IBCT) Cases 9.1, 9.2 and 9.3.

Transplant cases

For further details of laboratory errors in patients who had received a transplant, please see Chapter 24, Transfusion Errors in Transplant Cases.

Trends in error reports

The highest proportion of errors occurred within the IBCT-SRNM category, 94/389 (24.2%), which is similar to previous years. The highest proportion of near miss events involved RBRP events, 84/184 (45.7%).

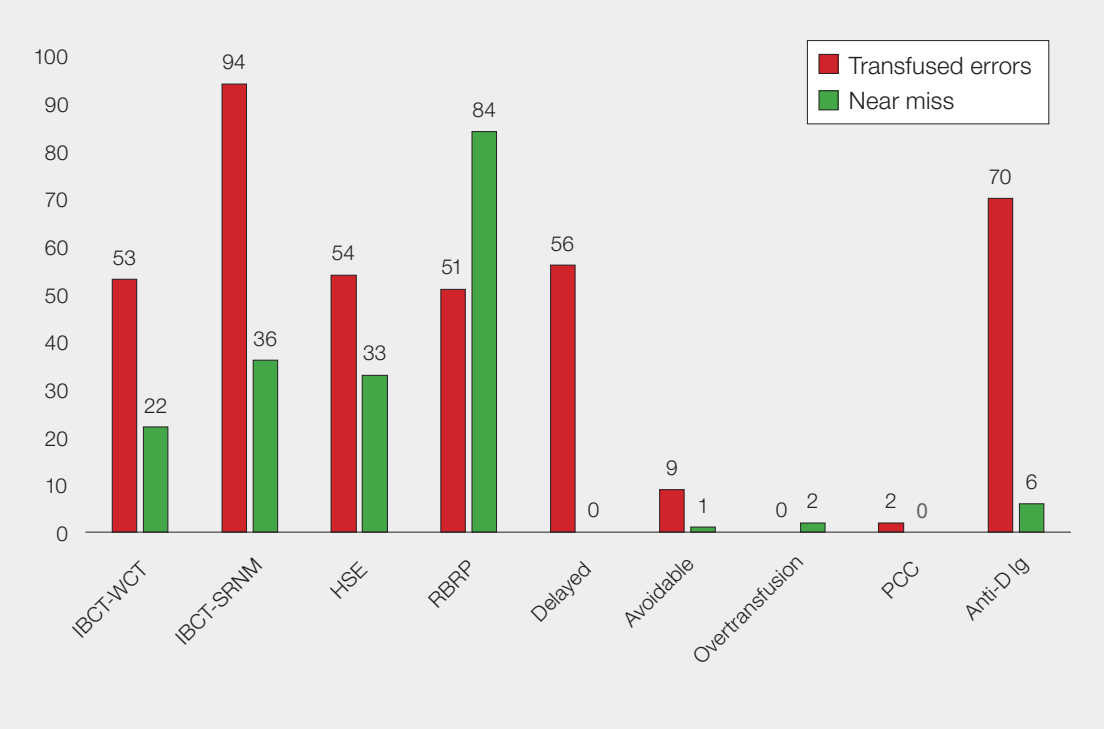


Figure 14.3: Laboratory incidents and near misses by category of outcome (n=573)

IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; HSE=handling and storage errors; RBRP=right blood right patient; PCC=prothrombin complex concentrate; Ig=immunoglobulin

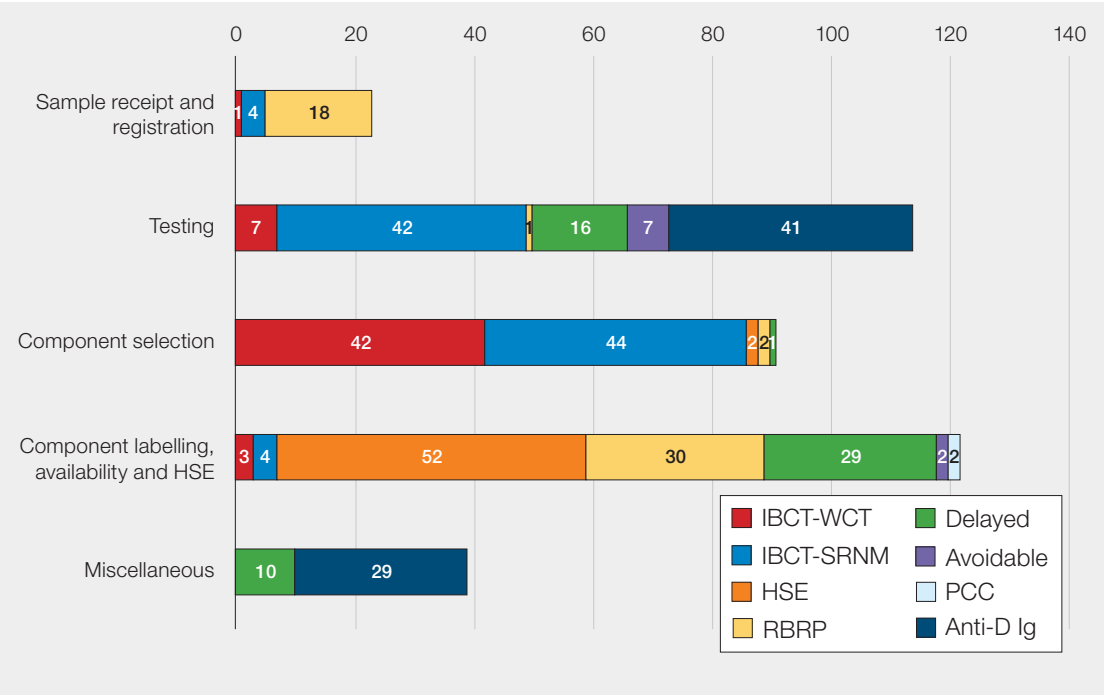


Figure 14.4: SHOT laboratory data showing at which stage in the transfusion process the primary error occurred (n=389)

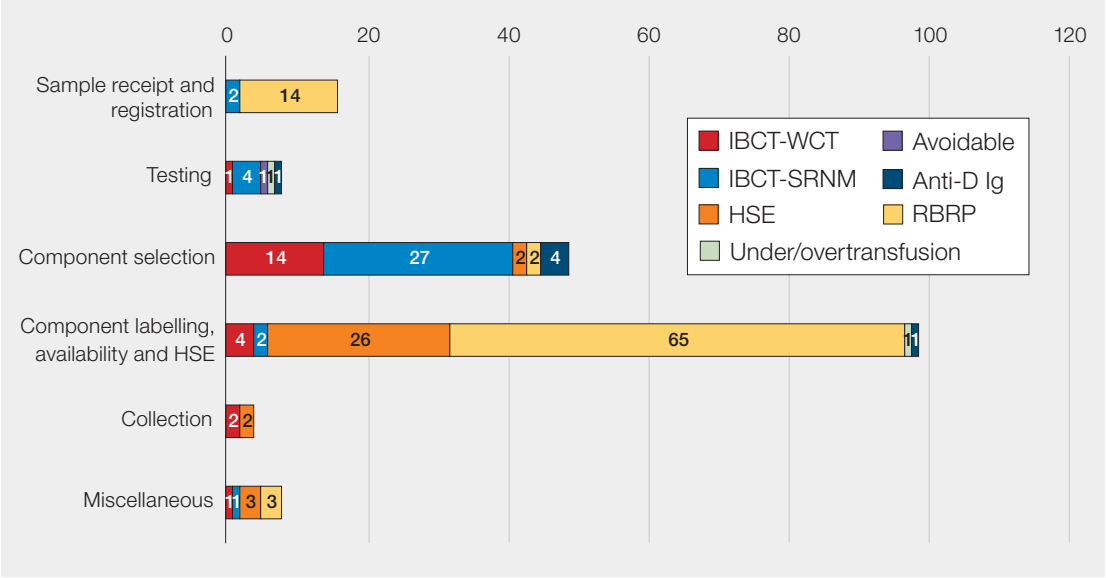
IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; HSE=handling and storage errors; RBRP=right blood right patient; PCC=prothrombin complex concentrate; Ig=immunoglobulin

It is concerning that similar patterns and themes are observed in laboratory reports, and sustained improvements have not been made to laboratory practices. A safety-II approach to incident investigation and review of laboratory procedures could help identify potential gaps which can be rectified, and also areas of good practice which may be able to be applied elsewhere (Hollnagel et al. 2015).

Near miss cases n=184

There has been a decrease in NM laboratory errors since 2020, from 200 to 184. The pattern of laboratory near miss errors is consistently highest at the component labelling, availability, handling and storage stages, 99/184 (53.8%), and component selection stage, 49/184 (26.6%).

Figure 14.5: SHOT near miss laboratory errors showing at which stage in the transfusion process the primary error occurred with outcome (n=184)



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

The largest group of single errors occurred in the RBRP category, 84/184 (45.7%) of which 56/84 (66.7%) were related to labelling errors. Of these 31/56 (55.4%) were reports of transposed labels between units. Where possible label verification systems should be implemented to prevent release of units with labelling errors. The recent SCRIPT survey indicated that 100% of UK LIMS suppliers had a label verification process available (see 'Recommended resources').

In 14/84 (16.7%) RBRP NM events, the error occurred at the sample receipt and registration stage, with 12/14 due to demographic data entry error, leading to incorrect details present on compatibility labels at issue. Where there is manual processing of transfusion requests, steps should be taken to verify that the details on the sample/request form and LIMS concur before authorisation of results and issue of units.

There were 49/184 (26.6%) laboratory NM events that occurred at the component selection stage with IBCT-SRNM, 27/49 (55.1%) and IBCT-WCT, 14/49 (28.6%) being the largest categories. Component selection errors consisted of 18 reports not meeting irradiated requirements and 6 reports not meeting CMV requirements for pregnant females. Not heeding LIMS alerts (14/49), not updating LIMS to reflect specific requirements (4/49), and LIMS unable to prevent inappropriate issue (3/49) reiterates the importance of LIMS in preventing incorrect component selection. Triggering a LIMS alert means a component selection error has already occurred, and efforts must be made to minimise these errors at the point of selection by the BMS.

The laboratory NM error was detected at the administration stage in 127/184 (69.0%) of cases. There were 96/127 (75.6%) that had a pre-administration check, which indicates the importance of safety checklists in detecting transfusion errors.

In 126/184 (68.5%) of laboratory NM errors, the reports stated that the event occurred due to failure to follow policy. Whilst policies and procedures are critical aspects for safe laboratory practice, fail safes and barriers to poor practice should be embedded in the system to actively reduce the risk of error. Investigation of near miss events provides opportunities for laboratories to identify effective corrective and preventative actions that can be implemented to support good practice. Near misses are sometimes referred to as 'good catches' as an actual error was prevented. A review of the 'good practice' that prevented an actual error may present an improvement action that can be embedded into the system.

Errors by step in the transfusion process in the laboratory

Sample receipt and registration (SRR) n=39 (23 transfused errors and 16 near misses)

The majority of SRR events occurred when demographic data was incorrectly entered onto LIMS. Electronic transfer of patient information from central patient administration systems to LIMS avoids the requirement for manual registration in the laboratory. Transfusion service managers should collaborate with local IT departments to ensure that electronic transfer of patient data to the LIMS is implemented wherever possible. Where manual registration is necessary staff performing this role should be protected from distractions and second checking systems should be in place, which may be incorporated at later stages in the process.

Case 14.3: Incorrect inputting of surname for patient who later required MHP activation

A group and screen sample was received in the transfusion laboratory for female in her 50s. The name was inputted incorrectly into the LIMS, but the error was not detected during processing checking points. The MHP was activated for the patient and red cells, platelets and FFP were all issued with incorrect details on the labelling. The error was not detected at administration checking, and units were transfused.

Although second checking processes used in the laboratory for manual processes often identify errors in patient data, this case is an important reminder that independent checks can fail to highlight discrepancies. Transfusion service managers should strive to ensure that processes are in place to 'get it right first time', utilising IT systems wherever possible.

Getting it right first time (GIRFT) is a national programme designed to improve the treatment and care of patients through the in-depth review of NHS services, which are used to support change. The GIRFT national pathology report, published in September 2021 (GIRFT 2021), aims to improve patient care by ensuring the right test is carried out at the right time, with the right answer for each patient. To help achieve this GIRFT have developed The Clean Framework, designed to help laboratories to widen their diagnostic pathways into an end-to-end service which includes 'Clean in' (pre-analytical stage), 'Clean through' (the analytical stage) and 'Clean out' (post-analytical stage).

The Clean Framework for pathology is designed to improve quality, develop data interoperability between NHS systems and maximise efficiency to improve the diagnostic service delivery.

Learning points

- Staff responsible for receipt and registration of samples must confirm patient identification match on the sample, request form (if relevant) and LIMS
- Staff responsible for sample receipt and registration should be protected from distractions
- There should be independent checks of sample ID against LIMS prior to authorisation of results and again prior to issue of components

Testing n=122 (114 transfused errors and 8 near misses)

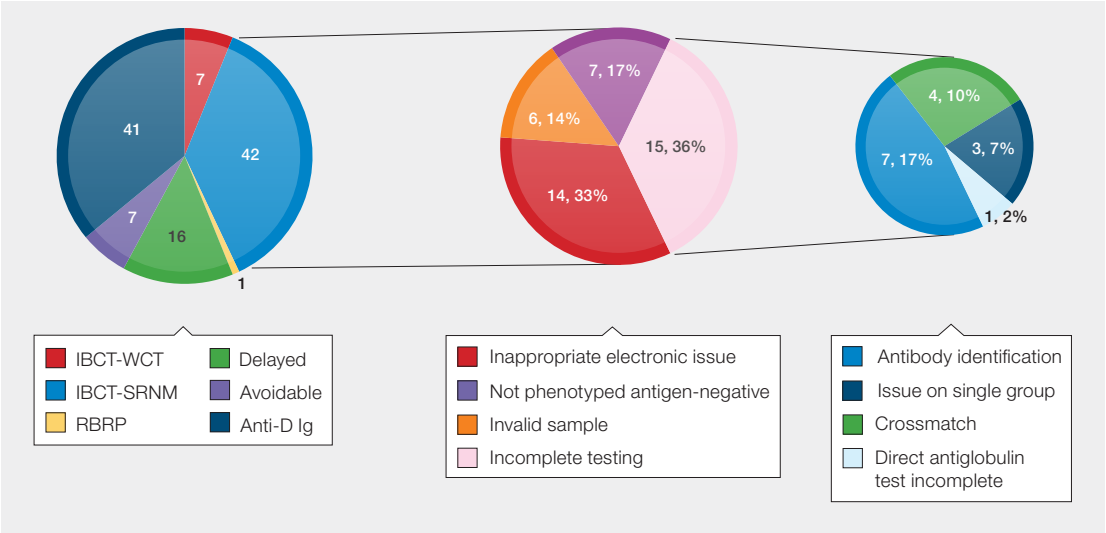
Laboratory testing errors increased significantly in 2020 compared to previous years, but encouragingly have reduced by 26.5% from 166 in 2020 to 122 in 2021. The majority of these adverse events were procedural errors in the categories IBCT-SRNM (42/114) and anti-D Ig (41/114). IBCT-SRNM errors were largely due to inappropriate electronic issue of red cells (15/42) and issue of components with incomplete testing (16/42). There were 4/114 cases where neonatal and maternal sample testing was not completed prior to issue of components.

Of the 67 ADU laboratory error reports, testing was stated as the main fault in 23 reports which led to 7/23 avoidable, and 16/23 delays. The errors contributing to reported transfusion delays were related to laboratory equipment failure, or incorrect or delayed haematology laboratory results being reported on LIMS.

There were 4 cases reported where neonatal testing and crossmatching with maternal sample were not completed appropriately.

During the first 4 months of life ABO antigens may be poorly expressed on red cells and the corresponding ABO antibodies may not have yet developed, making confirmation by 'reverse grouping' unreliable. Maternal IgG ABO antibodies may be detected in neonatal plasma. Wherever possible, samples from both the mother and infant should be tested for ABO and D grouping, an antibody screen should be performed on the larger maternal sample, and a direct antiglobulin test (DAT) on the infant's sample. Because of the significant risk of 'wrong blood in tube' errors due to misidentification, the infant's blood group should be verified on two separate samples (one of which can be a cord blood sample) as recommended for adult patients, providing this does not delay the emergency issue of blood. If there are no atypical maternal antibodies and the infant's DAT is negative, top-up transfusions can be given without further testing during the first 4 months of life (BSH New et al. 2016).

Figure 14.6: Laboratory testing errors by reporting category (n=114) and SRNM testing errors by subcategory (n=42)



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

IBCT-SRNM testing errors n=42/114

Case 14.4: Error inputting group into LIMS

A group and screen sample was received for a female in her 70s. The patient could not be positively identified (unconscious and unable to communicate) and so was given an unknown patient ID. The sample was processed, and the patient had a forward group A, but no reverse group to confirm, therefore the LIMS required a manual overall ABO D interpretation. The BMS entered the group as A D-positive, when in fact the patient was A D-negative. There was no information available as to whether a manual confirmation of group was carried out. The patient was transfused D-positive red cells. The patient was subsequently discovered to require irradiated cellular components, but this was not identified prior to administration.

Manual input of test results into the LIMS should include a verification process that crosschecks the reaction patterns for the assay against the interpretation of the result.

Case 14.5: Neonatal crossmatch without antibody screen

Neonatal red cells were requested for a newborn infant. The BMS checked the LIMS and confirmed that the mother had a negative antibody screen and units were issued and transfused. It was subsequently detected that the maternal antibody screen was 5 days old, and therefore did not meet BSH 2016 guidelines (BSH New et al. 2016) requiring a sample to be ±72 hours from delivery.

Anti-D testing errors n=41/114

Anti-D Ig errors accounts for 41/114 of testing errors, with 16/41 errors related to cffDNA testing. Of these cases, 15/16 were errors related to prediction of fetal D-type, with 10/16 cases cffDNA testing incorrectly predicted D-positive, and 5/16 cases incorrectly predicted D-negative.

Case 14.6: Postnatal patient incorrectly given anti-D Ig after BMS used cffDNA result from previous pregnancy to determine newborn's blood group

A D-negative postnatal patient was transfused anti-D Ig following delivery of a D-negative infant after the BMS used the cffDNA result from a previous pregnancy to confirm the infant's D group, rather than the current cord group result. The EDD date of this pregnancy was exactly 1 year from the EDD of the most recent previous pregnancy.

Care must be taken to ensure the cffDNA result for the current pregnancy is being used to determine suitability for anti-D Ig.

Case 14.7: Miscalculation of FMH post delivery resulted in excessive anti-D Ig administration

A BMS tested a post-natal maternal sample for FMH, but during the calculation entered an incorrect FMH value and the bleed estimate was tenfold larger than the actual value. The actual bleed was 6.4mL, but the estimated bleed was 64mL. The BMS issued 9000IU anti-D Ig to cover this bleed.

Learning points

- Inappropriate electronic issue can be reduced by implementing appropriate LIMS rules
- Where neonatal blood components are required mother and/or baby samples must meet guidelines for antibody screen testing ±72 hours of delivery
- Ensure cffDNA results are for the current pregnancy, and available results should be entered into the LIMS in a timely manner to avoid unnecessary anti-D Ig issue
- Laboratories should have contingency plans in place for equipment failure to avoid delays in the provision of blood components

Component selection n=140 (91 transfused errors and 49 near misses)

Errors related to component selection mainly involved IBCT-SRNM (44/91, 48.4%) and IBCT-WCT (43/91, 47.3%).

Component selection errors in IBCT-SRNM included issuing units which were not antigen-negative as per patient requirement (14/44), K-positive red cells to patients of childbearing potential (8/44) of which 3/8 patients have subsequently developed anti-K, units not tested seronegative for CMV (8/44) and non-irradiated blood components where required (8/44).

Component selection errors in IBCT-WCT included issuing components of the wrong ABO/D group (30/43), of which 17/30 were errors related to patients post HSCT. Other component selection errors included wrong component type (9/43), units issued to the wrong patient (2/43) and incorrectly selecting units which were not crossmatched (1/43).

Component selection should be appropriately controlled by a robust LIMS system where specific requirements based on patient characteristics including age, sex, antibody status and clinical status are incorporated into IT rules and alerts, which are not easily overridden.

There were 8 cases of K-positive units to women of childbearing potential in 2021 in total, with 3 women who went on to develop anti-K.

Learning points

- Understanding of ABO compatibility for red cells and plasma components should be included in training and regular competency-assessment for BMS staff
- LIMS functionality should include decision support for appropriate selection of blood components based on patient characteristics including ABO/D type, age, sex, antigen, and antibody status
- LIMS alerts should be relevant, appropriate, and not easily overridden
- Transfusion laboratory staff should have a good understanding of grouping serology and how this applies to component selection

Case 14.8: Incorrect D group issued to patient – multiple influencing factors

A confirmed B D-negative patient was issued two B D-positive red cells via electronic issue. The BMS selected the incorrect D group red cells and proceeded to assign them to the patient record on the LIMS. The LIMS alerted the user to the D-incompatibility, but this was overridden. The BMS signed a laboratory issue checklist to say the units had been checked as compatible. Theatre staff waiting in the transfusion department were pressurising the BMS to prepare the units urgently. The units were collected and transfused in theatre without checking the D-status of the units and the patient.

Component labelling, availability and HSE n=220 (122 transfused errors and 98 near misses)

The component labelling, availability and handling and storage stage are the final steps in the transfusion process before the units are issued for the patient, and therefore the final stage where errors and discrepancies can be identified.

Handling and storage errors accounted for 52/122 transfused errors, with 27/52 related to cold chain errors including 12/27 refrigerator failures, 7/27 inappropriate return to stock episodes, and 4/27 inappropriate storage events. There were 16/52 errors where the dereservation period (time a component is reserved for a patient) was exceeded at the point of transfusion. In 24/122 cases, errors were related to compatibility labelling, and 29/122 due to delays. The source of delays included communication errors between clinical and laboratory staff, and misidentification of the urgency of the transfusion request.

Case 14.9: Red cell units out of temperature-controlled environment not quarantined correctly and mistakenly returned to stock and issued

Two red cell units were placed into a temperature monitored cool box for a MHP and were returned unused to the laboratory after 5 hours 21 minutes. These units should have been discarded but were instead quarantined in the laboratory refrigerator, without clear handover to next staff member. These units were returned into routine stock, issued, and transfused to other patients with no patient harm occurring.

Learning points

- Laboratory staff should pause, and review the compatibility label at the point of labelling
- There must be clear instructions for both clinical and laboratory staff to follow where the cold chain of the blood components has not been maintained

PAUSE

An overview of the laboratory data indicates that final checks of the units before they leave the laboratory could prevent errors and NM events. SHOT is introducing the PAUSE concept, encouraging laboratory staff to pause and recheck at this final critical step before the component is released for transfusion, this will help ensure that that all previous steps have been completed correctly and that unit is safe for issue to the clinical area.

At the point of unit release laboratory staff should ask themselves:

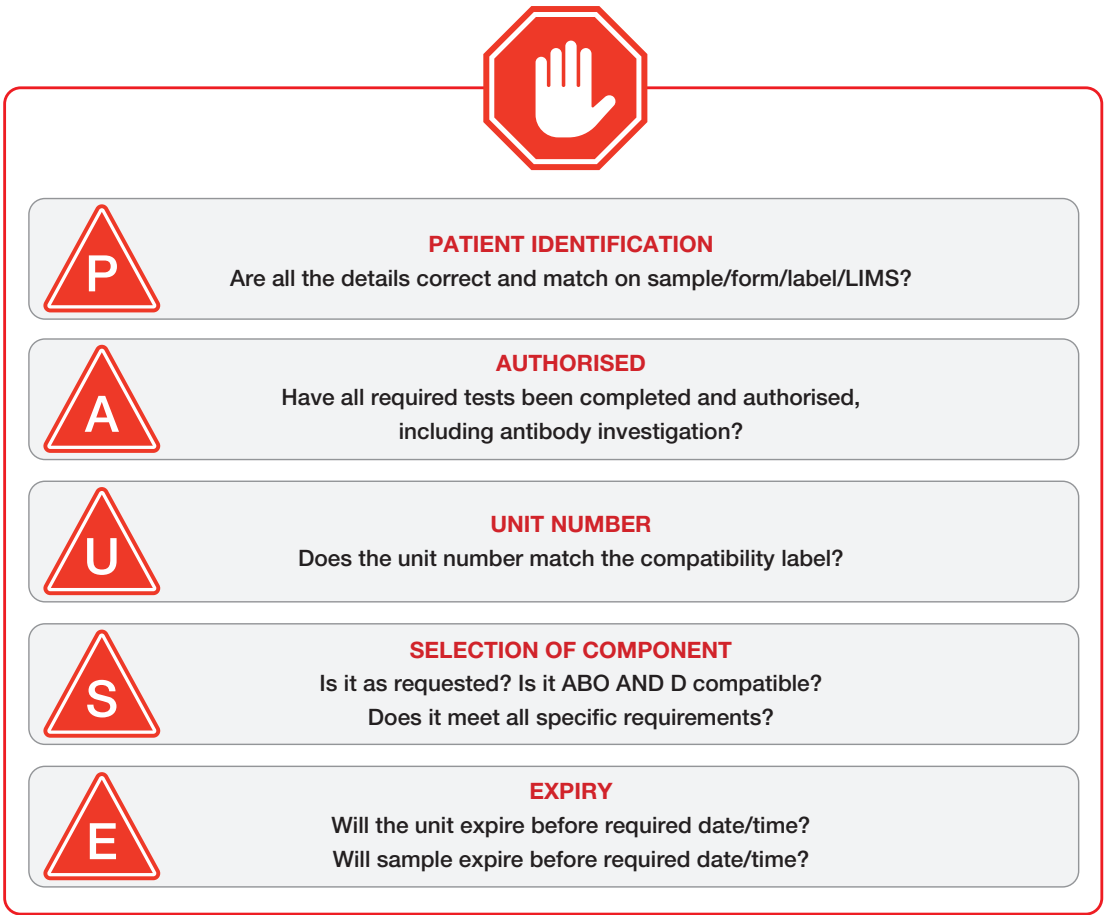


Figure 14.7: The PAUSE checklist prior to release of blood components from the transfusion laboratory

Further laboratory learning

Importance of structured handovers in the transfusion laboratories

Effective transfer of information relating to patient care helps ensure safe patient care. While a formal handover is an established and well reported process in the clinical setting, it is not so well established in transfusion laboratories. Blood transfusions occur within many hospital specialities and across clinical and laboratory staff shifts, making robust handover critical for safe practice.

Failure to adequately transfer information relating to pending or ongoing provision of blood components during shift handover in the laboratory can have an adverse impact on patient care.

Between 2015-2020, laboratory incidents involving handover were mainly associated with IBCT-SRNM and delays in provision of blood components for transfusion, with 16.6% of these cases involving major haemorrhage situations. Handover was found to be insufficient in most cases, no handover was completed in 29.5% of cases, inadequate written handover accounted for 14.8% cases, and inadequate verbal handover for 5.7% of cases (Tuckley et al. 2022).

Lack of clear communication and comprehensive handover has been shown to be causative of, or contributory to laboratory errors, particularly delays. Information vital for safe transfusion is missed in a high proportion of urgent cases where there is increased pressure and communication may not be ideal. Handover should be considered a task that is built into routine laboratory practices, ensuring effective transfer of information and appropriate follow up actions are taken. SHOT have created a handover template which can be adopted in laboratories to formalise this process (See 'Recommended resources').

Case 14.10: Transfusion delays due to lack of handover by laboratory staff

An elderly male had a delay of over 24 hours for his transfusion due to lack of handover within the transfusion laboratory regarding this patient's red cell units requiring transport to the satellite refrigerator. The BMS forgot to add the need to organise transport for these units on the laboratory handover log.

Handover is a safety critical point in the working day. Transfusion laboratories should implement a written handover log to support clear communication, as recommended in the 2020 Annual SHOT Report (Narayan et al. 2021).

Cognitive bias as a source of error in transfusion laboratories

Cognitive biases are flaws or distortions in judgment and decision-making (Tversky et al.1974). These are inconsistently reported and therefore challenging to quantify but cognitive biases are increasingly recognised as contributors to patient safety events. Whilst the contribution of cognitive biases to errors has not been systematically captured or analysed, cases reviewed have highlighted that these are under-recognised and need addressing to reduce errors (O'Sullivan et al. 2018). The following cases highlight the importance of recognising and mitigating impact of cognitive bias in day-to-day transfusion practice.

All staff need to be aware of the potential for such biases, and be trained to recognise, and if possible, prevent them through simple interventions. These include formally 'slowing down', using checklists, use of flowcharts and 'metacognition' (considering alternatives). Such strategies help mitigate the effect of cognitive bias in healthcare and improve patient safety.

Alert fatigue in transfusion laboratories

IT has become integral to day-to-day working in the laboratory. LIMS alerts are designed to ensure transfusion safety and accuracy of transfusion decisions. However, it is important to recognise that laboratory transfusion staff can get overwhelmed by multiple alerts resulting in 'alert fatigue' i.e., users inundated with constant reminders that are meant to be helpful but are more of a nuisance. This results in staff tendency to ignore notifications when they become too frequent with the potential for errors and impact on transfusion safety. Staff can overcome alert fatigue, identify, and respond to critical issues in real time, and reduce risk continuously over time if these alerts can be transformed into relevant and actionable intelligence.

Between 2016-19 over 10% of SHOT reports stated the source of error was overriding alerts (Swarbrick et al. 2022).

A structured, proactive approach is suggested to address this by using the following practices:

1. Regularly review and reduce redundant alerts

2. Make all alerts contextual and actionable

3. Ensure appropriate escalation and that correct individuals and teams are notified

4. Apply human factors principles when designing alerts (e.g., format, content, legibility, and colour of alerts). Consider having tiered alerts according to severity, consistently throughout laboratories, so that attention is drawn to those more clinically consequential thus allowing staff to maintain situational awareness and responsiveness

5. Improve the culture of safety in transfusion by creating a shared sense of responsibility between users and developers, paying careful attention to safe IT implementation, and engaging leadership in IT planning, implementation, and evaluation

LIMS alerts should be driven by evidence, well-designed logic, ensuring that an alert will only be triggered appropriately and only provides recommendations that are relevant to the laboratory staff decision at that point. Ultimately, when it comes to LIMS alerts, less is often more.

COVID-19 pandemic

COVID-19 was mentioned as a contributory factor in 9 cases and included: reduced staffing levels, additional pressures on remaining staff and staff recovering from COVID-19, pressures on ability to effectively train staff, redeployment of staff into unfamiliar areas and reorganisation of workspaces which all contributed to errors.

Pre-existing staffing issues were highlighted in the key findings of the 2019 UKTLC transfusion laboratory survey, which also detailed the high level of inexperienced staff who require training, and the overall increased level of vacancies (Bolton-Maggs et al. 2019).

Conclusion

Transfusion laboratories have a crucial role in ensuring safe and timely provision of suitable blood components for patients. A trained, competency-assessed workforce with the right skill mix is vital to support the needs of patients across all clinical disciplines. Training in human factors and understanding of cognitive bias will help improve process-based safety.

Multiple UKTLC surveys have highlighted staffing challenges, lack of appropriately trained scientists, increasing out-of-hours' workload which need to be addressed urgently to ensure transfusion safety.

The COVID-19 pandemic has worsened pressures on scientific and technical staff, requiring staffing shortages to be urgently addressed.

Effective, clear communication at multiple levels of the multidisciplinary, interprofessional team caring for patients is critical for this life-saving therapy to be effective and safe for patients.

It is also important to embed a learning culture in healthcare organisations - to support learning at an individual and organisational level, organisations need to create an environment that embeds learning into the way they do things and to continually adapt and transform. This will ensure that learning is optimised from all experiences, adverse events, and instances of excellent care.

Use of IT supports safe transfusions, but it must be set up and used correctly to be safe.

UKTLC update

Haemovigilance reporting continues to show laboratory-based errors with 389 transfused errors and 184 near misses reported this year (639 in 2020). Of the 389 transfused errors 56.3% involved IT. Laboratory errors have shown a decrease and the UKTLC aims to support the reduction of laboratory-based errors with supporting materials. The UKTLC standards from 2014 (Chaffe et al. 2014) are being updated and a 2022 revision is due to be released to provide laboratories with guidance for staffing, education, culture and IT. Further resources to support implementation of the standards and capacity plan examples will be available later this year on the UKTLC page of the SHOT website.

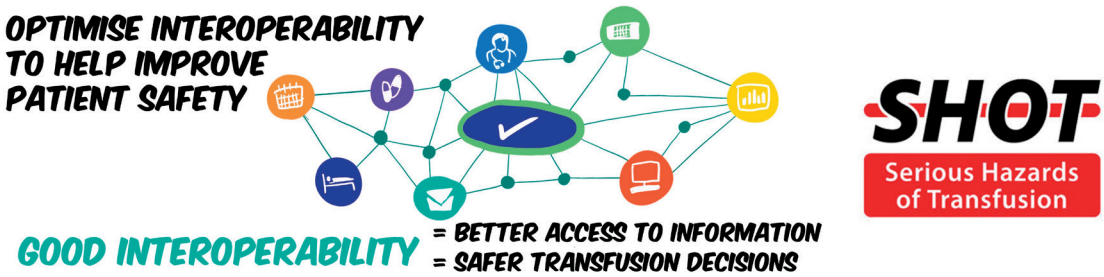
UK NEQAS update

Participation in EQA offers the chance to learn from errors. The errors made in EQA exercises can be viewed as 'free lessons', as appropriate corrective action can be taken before the error occurs with a clinical sample.

As in other years, errors caused by sample or result transposition, and/or data transcription into the UK NEQAS website continue to be the leading cause of penalty during EQA exercises. Participants made many of these such errors in nine out of the ten pre-transfusion testing exercises distributed during 2021. In exercise 21E6, a laboratory submitted a reaction pattern which did not match the anti-S present in the sample but appeared to match the pattern for anti-S if using a previous batch of screen and panel antigrams. In exercise 21R10, a participant submitted results identical to those in the previous exercise, and upon enquiry, it was confirmed that the samples from 21R8 had been used erroneously. When testing samples, or entering data for EQA samples, it is important to check that the data is being recorded and transcribed against the correct patient or donor; this also applies to the data entry of results of manual testing of clinical samples into a LIMS, or in the event of LIMS downtime.

During two exercises, 21R2 (Patient 3 anti-K+Fy^{a}) and 21E6 (Patient 3 anti-c+K), several laboratories excluded the presence of anti-K on the basis of negative reactions with K-positive cells in an enzyme panel. Whilst the K antigen is generally resistant to enzyme treatment, not all examples of anti-K react with enzyme treated red cells in a standard two-stage enzyme test, and anti-K should not be excluded on a negative reaction with a K-positive cell using this test alone. However, anti-K that is detectable by IAT will react in an enzyme IAT, and this technique can be useful in differentiating between anti-K and specificities where the corresponding antigen is denatured by enzyme treatment.

The results of EQA exercises also continue to show laboratories missing clinically relevant antibodies in the 'patient' plasma samples and also, conversely, recording confirmed specificities for antibodies not present in the samples. In exercise 21E3, one participant did not notice that the analyser had flagged an 'incorrect liquid level' and had not dispensed plasma into the test well; the participant missed the anti-D in two patient plasma samples as a result. A second participant in this exercise did not record the presence of anti-E for Patient 2 (anti-D+E), and a third recorded the presence of anti-C^{w} as a confirmed specificity for Patient 1 (anti-D). To avoid misidentification, every antibody investigation should include a systematic process for exclusion and positive identification of antibody specificities, and all positive reactions should be accounted for before a conclusion is reached. BSH guidance for inclusion of antibody specificities requires that 'the plasma is reactive with at least two examples of reagent red cells expressing the antigen and non-reactive with at least two examples of reagent red cells lacking the antigen. In a sample already containing anti-D, two examples of very rare D-negative C^{w} positive cells would be required to confirm the presence of anti-C^{w}. These are just two examples of antibody specificities either overlooked or confirmed when not present in the sample; the first instance having the potential to cause a haemolytic transfusion reaction, and the second possibly causing delays to transfusion where further testing of patients or donors is carried out unnecessarily.



Recommended resources

SCRIPT user and supplier report summaries
https://www.shotuk.org/resources/current-resources/script/

SHOT Bite No. 12: Cognitive Bias
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Video: ABO-incompatible transfusion events
SHOT Video: Learning from transfusion laboratory errors
https://www.shotuk.org/resources/current-resources/videos/

The UKTLC capacity plan guidance
https://www.shotuk.org/resources/current-resources/uktlc/

An example handover document
https://www.shotuk.org/shot-reports/report-summary-and-supplement-2020/

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