7 Laboratory Errors

SHOT laboratory errors n=678 (378 laboratory and 300 laboratory near miss)

Medicines and Healthcare Products Regulatory Agency (MHRA) serious adverse events (SAE) n=1027

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Key SHOT messages

- Understaffing and poor knowledge and skills featured in many reports in 2016: 10.0% (103/1027) of SAE reported to the MHRA result from errors made when the workload was considered to be too high or staffing too low. This was also reflected in SHOT reports. This confirms the findings in the UK transfusion laboratory collaborative (UKTLC) survey 2015 (UKTLC 2015). Staffing gaps may be filled with staff who are not transfusion-competent and lacking knowledge in transfusion. Laboratories should always have adequate staffing at the appropriate grade to support those that require training (Chaffe et al. 2014)
- Appropriate use and management of laboratory information management systems (LIMS) are essential for patient safety
- Gap analyses should be performed against national transfusion guidelines (e.g. BSH Harris et al. 2017, BSH Milkins et al. 2013, BSH Jones et al. 2014) and standard operating procedures (SOP) amended to correct deficiencies and to identify any necessary alterations to laboratory procedures

Introduction

From October 2015 all errors and near misses have been reported without the need to specify to which organisation the incident should be reported. Both SHOT and the MHRA can now review all haemovigilance incidents. The MHRA has been able to select SAE that meet the Blood Safety and Quality Regulations 2005 (BSQR) reporting requirements.

When comparing the number of SAE and reports to SHOT there are significant recognised differences, therefore the incidents are classified here under 3 main headings:

- Both SHOT- and MHRA-reportable
- Reportable to SHOT only
- Reportable to MHRA only

These **differences** in reporting between the 2 haemovigilance organisations include, but are not limited to the following issues:

MHRA reporting:

- Includes all SAE reports where a confirmation report was submitted in 2016 and reports where the notification report may have been submitted in a different year prior to 2016. Any report where a confirmation report has not been submitted is not included. Therefore SHOT may have a completed report that the MHRA cannot include in its 2016 assessment and vice versa
- Is based on reports made strictly under the BSQR. Excluded reports may include laboratory errors that were not reportable under BSQR (e.g. not related to the potential issue of a component, or related to other laboratories such as haematology, etc). Incidents may not involve the laboratory, but would still be reportable under the BSQR (e.g. storage errors in a clinical area)

- Does not include errors in clinical practice and administration of blood, e.g. wrong blood in tube (WBIT), inappropriate or wrong transfusions where there is no serious reaction in the patient and errors in anti-D immunoglobulin (Ig) issue and administration
- Does not include reactions to blood products which are classified as medicines rather than blood components such as Octaplas® (solvent-detergent fresh frozen plasma (SD-FFP)) and immunoglobulins (both anti-D Ig and intravenous Ig). The MHRA issue data also do not include these products
- Excludes some incidents reported to the MHRA as serious adverse reactions (SAR) where the reaction may have resulted from a SAE that originated in the laboratory. These are counted in the SHOT reports as incorrect blood component transfused (IBCT) because SHOT categorises these as errors whether or not they lead to a reaction

SHOT reporting:

- Does not include cases where the component does not leave the laboratory, e.g. expired components left in the refrigerator, unless these were missed during a routine stock check
- Does not include cases where there was failed recall of a blood component, unless this resulted in a transfusion reaction, which would be reported as a SAR
- Each report is linked to a specific patient, therefore if an incident has multiple patients associated with it SHOT will duplicate the incident for each patient but it will remain a single case for the MHRA

Laboratory staff are encouraged to focus on the key messages and learning points that are highlighted by both organisations.

Serious adverse events (SAE)

Definition:

Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

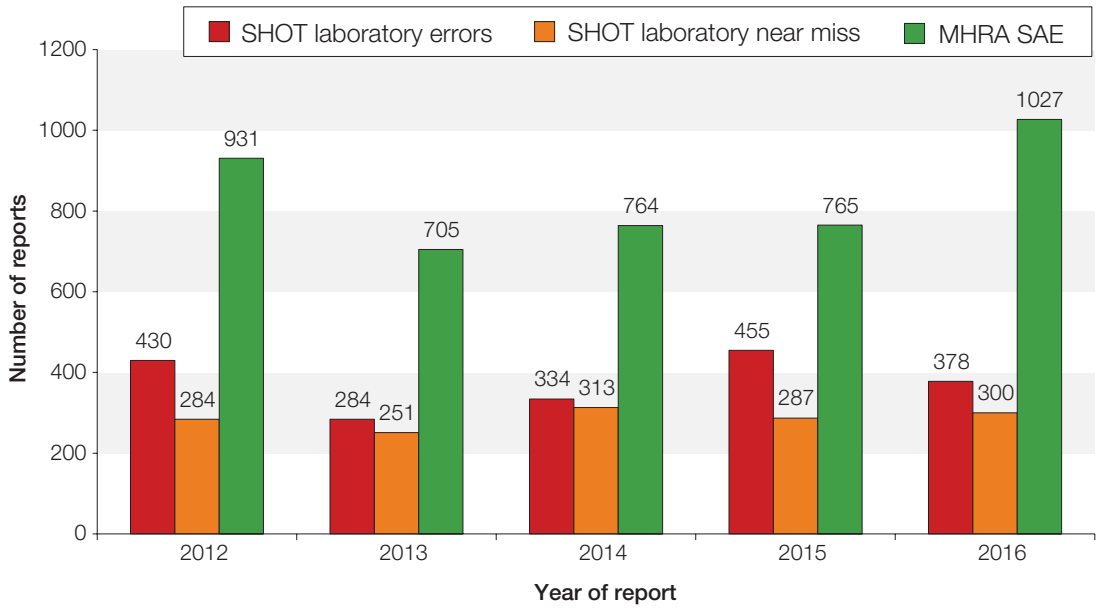


Figure 7.1: A comparison of the numbers of laboratory-related reports to SHOT and the MHRA over a 5-year period

There were 300 near miss laboratory cases reported to SHOT which are also reportable to the MHRA as there was potential for harm. These are included in Table 7.2.

Table 7.1: Categories of SHOT laboratory errors

Laboratory categories	Total	%	Outcome					
			IBCT	SRNM	HSE	RBRP	Anti-D Ig	ADU
Sample receipt and registration	94	24.9%	9	40	0	35	4	6
Testing	99	26.2%	11	53	0	0	16	19
Component selection	50	13.2%	18	23	2	0	3	4
Component labelling, availability, handling and storage	116	30.7%	3	5	44	55	1	8
Miscellaneous	19	5.0%	4	4	0	0	4	7
Total	**378**	**100%**	**45**	**125**	**46**	**90**	**28**	**44**

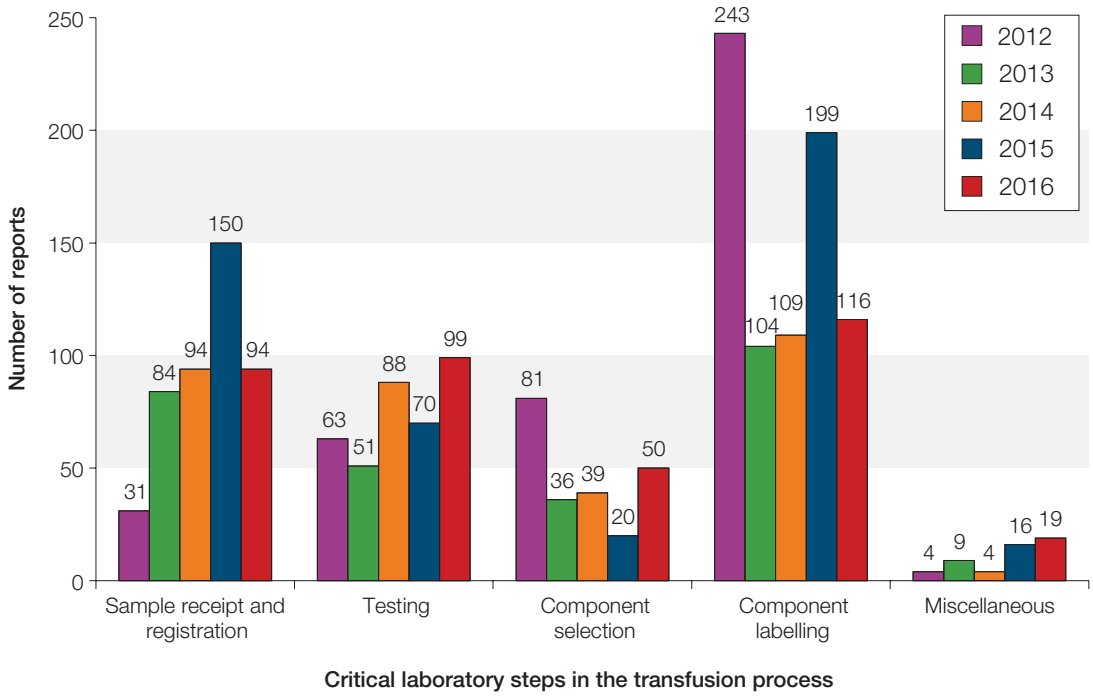
**IBCT=incorrect blood component transfused; SRNM=specific requirements not met; HSE=handling and storage errors; RBRP=right blood right patient; Anti-D Ig=anti-D immunoglobulin (Ig) errors; ADU=avoidable, delayed and undertransfused*

Table 7.2: Categories of SHOT laboratory near miss errors

Near miss laboratory categories	Total	%	Near miss would have resulted in:					
			IBCT	SRNM	HSE	RBRP	Anti-D Ig	ADU
Sample receipt and registration	44	14.7%	2	23	0	18	1	0
Testing	46	15.3%	19	20	0	0	7	0
Component selection	66	22.0%	13	42	7	0	4	0
Component labelling, availability, handling and storage	144	48.0%	11	0	55	73	5	0
Total	**300**	**100%**	**45**	**85**	**62**	**91**	**17**	**0**

In 2016 there was an increase in near miss SRNM reports. Failures to notice requests for specific requirements at sample receipt were n=23 in 2016; n=7 in 2015.

Figure 7.2: SHOT laboratory errors 5-year trend



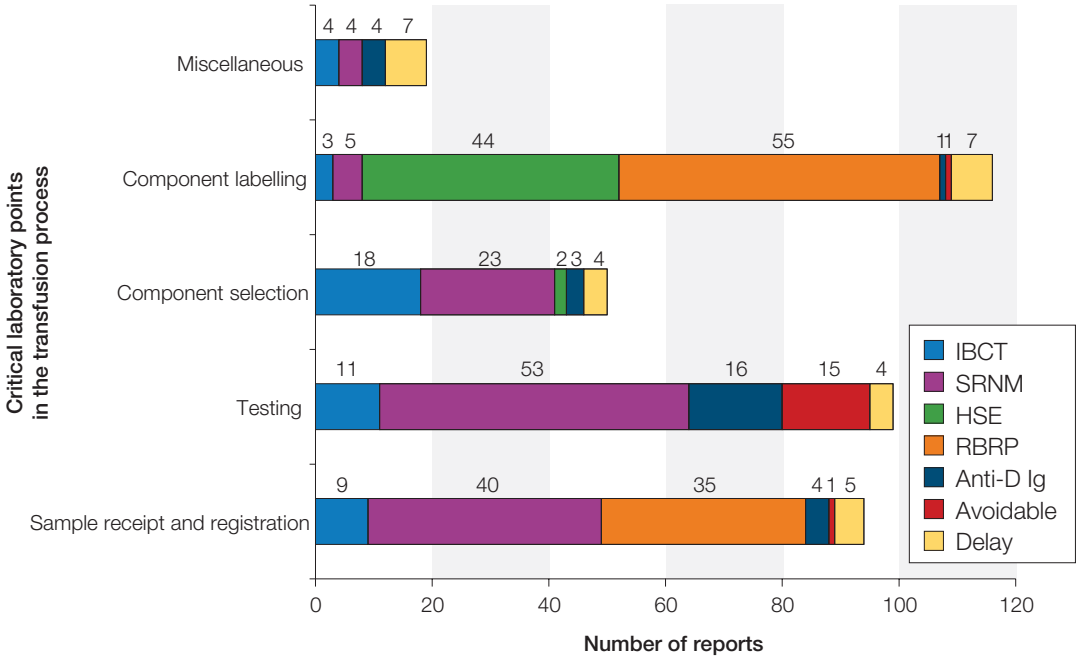


Figure 7.3a: 2016 SHOT data (n=378) including cases that were not reported/reportable to the MHRA showing outcome

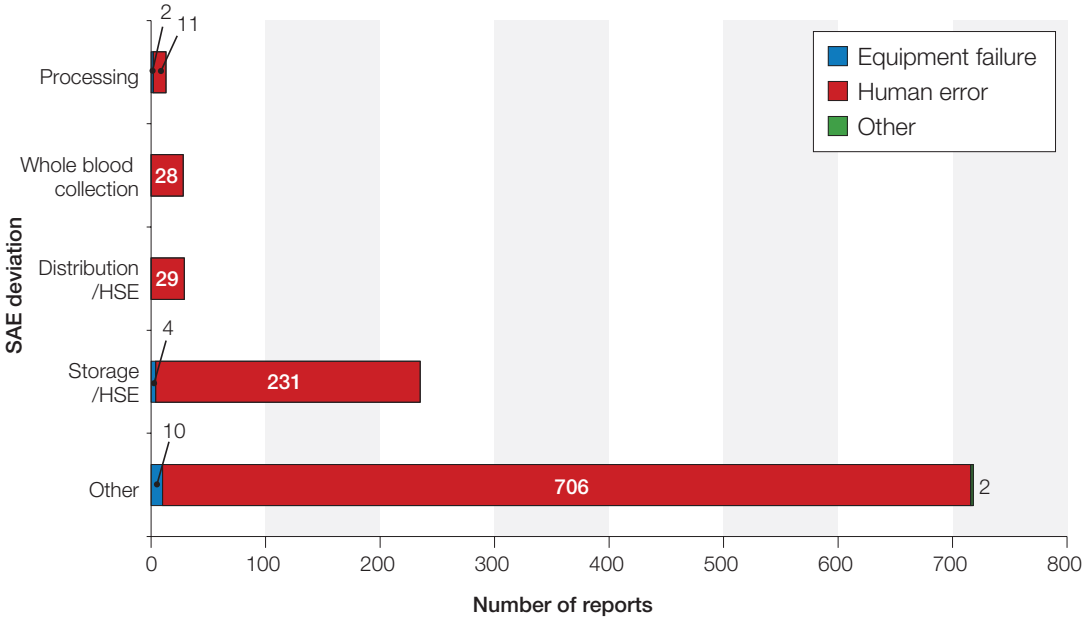


Figure 7.3b: 2016 MHRA SAE data (n=1027) including cases that were not reportable to SHOT

4 additional reports excluded from Figure 7.3b above due to small numbers: 3 testing of donations (human error) and 1 apheresis collection (product defect)

Discussion of incidents reported to both SHOT and the MHRA n=252

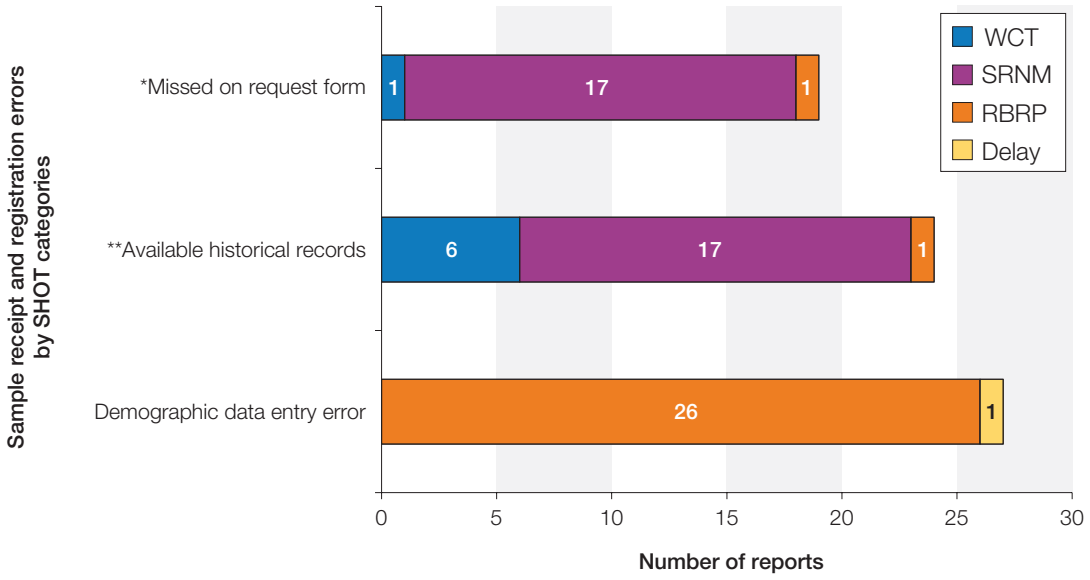
Cases reported to both organisations during 2016 are analysed in this section. The numbers differ from the numbers in the graphs shown in Figures 7.1-7.3 because not all incidents were analysed by both organisations. This could be because they were not reportable to the other organisation, or that they were not completed in time to be included in the analysis for that organisation (and may be included in the 2017 dataset). Incidents that were not analysed by both organisations have been included under the SHOT-only or MHRA-only headings.

Sample receipt and registration n=70

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 (depending on the patient's transfusion history). The SOP for sample acceptance by the laboratory must define locally agreed and minimum acceptable identification criteria and the course of action to be followed when these criteria are not met, and should comply with the British Society for Haematology (BSH) guidelines on administration of blood components (BSH Harris et al. 2017).

This is a complex step, much more than just 'booking in' of a sample, as staff need to ensure that the request and sample match up and then accurately transcribe that into the LIMS, including noting any specific requirements on the request form or in the LIMS patient history.

Figure 7.4a: Sample receipt and registration errors by SHOT categories n=70



**Cases where specific requirements were indicated on the request form but missed by laboratory staff*

***Cases where patient history was not heeded that would have indicated specific requirements e.g. antibody history, or information if a patient had received a HSCT*

Figure 7.4b shows the same 70 cases by MHRA classification.

Figure 7.4b: Sample receipt and registration errors by MHRA categories n=70

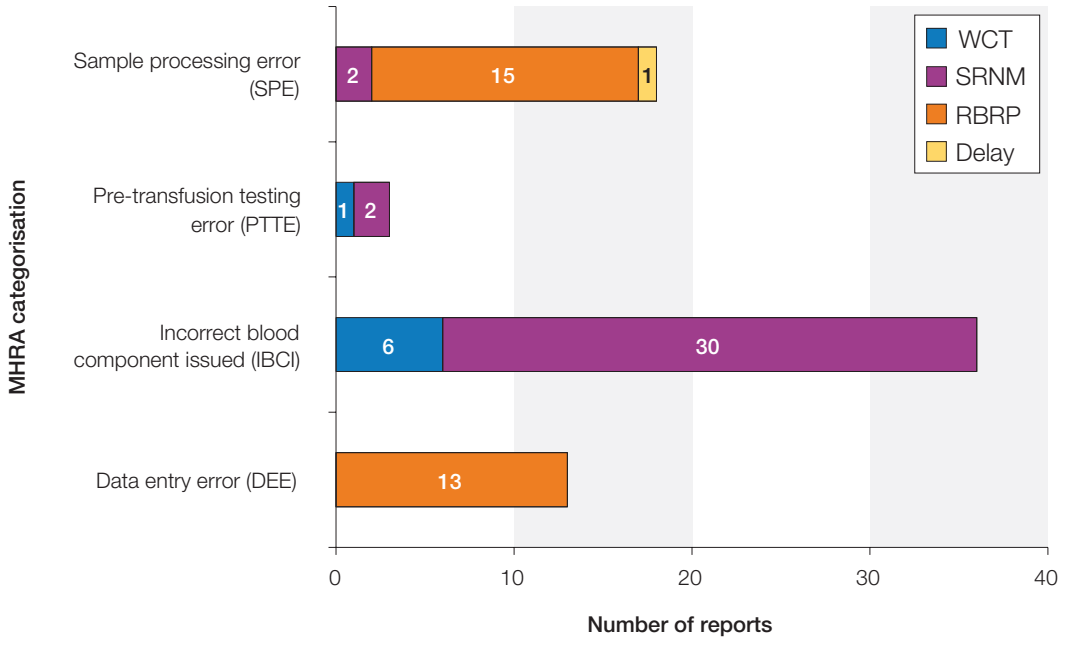


Figure 7.4b demonstrates the subtle differences between SHOT and MHRA classifications. The MHRA recorded 134 sample processing errors (SPE), but since these may be identified prior to any components being issued, these will not be included in the SHOT 'sample receipt and registration' category, but are categorised in SHOT as near misses, see Chapter 12, Near Miss Reporting (NM). SPE refer to errors where discrepancies between sample, forms and LIMS are not identified when the sample is booked in. Data entry errors (DEE) refer to those which are correctly labelled, but for first time patients are booked into the LIMS with errors, creating an inaccurate LIMS entry. Incorrect blood component issued (IBCI) are incidents where specific requirements may not have been entered onto the LIMS at the sample registration stage, but this information was otherwise available to laboratory staff, e.g. on the request form. Pre-transfusion testing errors (PTTE) are those where there was an error in the testing process or in the interpretation of test results.

Case 7.1: Failure to use correct documentation leads to IBCT and formation of an antibody in a female of childbearing potential

A 15-year-old female patient presented to the emergency department (ED) at 22:30 in sickle cell crisis. At 01:30 two units of red cells were requested, the HbSS diagnosis was recorded on the request form but missed. The group and screen was converted to crossmatch, the biomedical scientist (BMS) printed a screen shot of the patient record that did not include the requirement for HbS-negative units instead of using the original request form that identified the patient's requirements and the diagnosis of sickle cell disease. The patient, subsequently known to be phenotype R2R2 (cDE/cDE), developed anti-e as a result of the transfusion of emergency blood (i.e. negative for C, E, and K, and HbS-negative). The patient record was updated incorrectly to recommend transfusion of C-, E- and K-negative units following the initial transfusion. The correct units should be e-negative.

It is important to always use all information available (LIMS record and request form) to make the correct choice of components. Updates to patient records should be carefully noted especially if there are specific requirements. The patient record should have been reviewed more thoroughly to identify previous history including pre-transfusion extended red cell typing for this sickle patient if available.

MHRA regulatory view: The SOP was not followed and staff used a number of ways of performing the procedure contrary to the written SOP. The SOP was reviewed, improved and re-written. Staff should be trained to follow the SOP without deviating from it.

Case 7.2: Incorrect patient record association fortuitously resulted in the right blood to the right patient

A male patient who had been stabbed was transfused with two units of emergency O D-negative red cells on admission to the ED. Samples were sent to the laboratory labelled: 'Surname: unknown, Forename: unknown, Hospital number 479628, date of birth (DOB) 01/01/1902' and a further six units were requested. Instead of creating a new patient record the BMS pulled up a previous record of 'Surname: unknown, Forename: unknown' and appended the group O D-negative to this new patient as they thought this would be quicker and that they could retrospectively edit the result. Labels were printed out and read: 'unknown, unknown, 415735, 11/02/1895' and red cells issued (so with wrong number and wrong DOB). Due to the urgency the red cell units were not placed into the electronic tracking system and were collected by a porter and signed for manually. The porter failed to notice the discrepancy in the patient identification number and DOB. In the ED the red cells were noted as O D-negative and only 'unknown, unknown' was checked. There was no check of the patient identification number or DOB. The patient was transfused three of the four units and the discrepancy was detected when the fourth unit was returned to the laboratory and could not be returned to stock.

This case shows three major errors. The clinical area was contacted following the discovery of the error. They stated that staff only checked the name and group and as the patient was in a very unstable condition they would have transfused the O D-negative units anyway as it was 'a matter of life and death'.

Even in emergency or high pressure situations short cuts in processes must not be undertaken as failure to follow procedure can lead to errors. The identifiers for all patients, including emergency patients should include the gender. The use of 'unknown/unknown' is an unsatisfactory naming system for unidentified patient. LIMS training and competency-assessments need to include the correct procedure for entering unknown patients' details onto LIMS. Full bedside identification checks should be undertaken at all times to include DOB.

Testing n=56

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

Pre-transfusion testing for ABO/D grouping is the most important serological test. With the introduction of electronic issue (EI) the antibody screen is now also very important as it is the only test, in addition to the blood group, which can ensure compatibility. There is no other opportunity to detect incompatibility in the absence of a serological crossmatch. Ten cases in 2016 demonstrated inappropriate use of EI. EI is increasingly used: data collected in surveys by the UK national external quality assessment scheme (NEQAS) for blood transfusion laboratory practice show an increase in use of EI from 140/392 (35.7%) in 2008 to 153/253 (60.5%) in 2016. See the 2015 Annual SHOT Report (Bolton-Maggs et al. 2016) chapter on haemolytic transfusion reactions (HTR) for more information about the risks/benefits associated with electronic issue.

Figure 7.5a: Testing errors by SHOT categories n=56

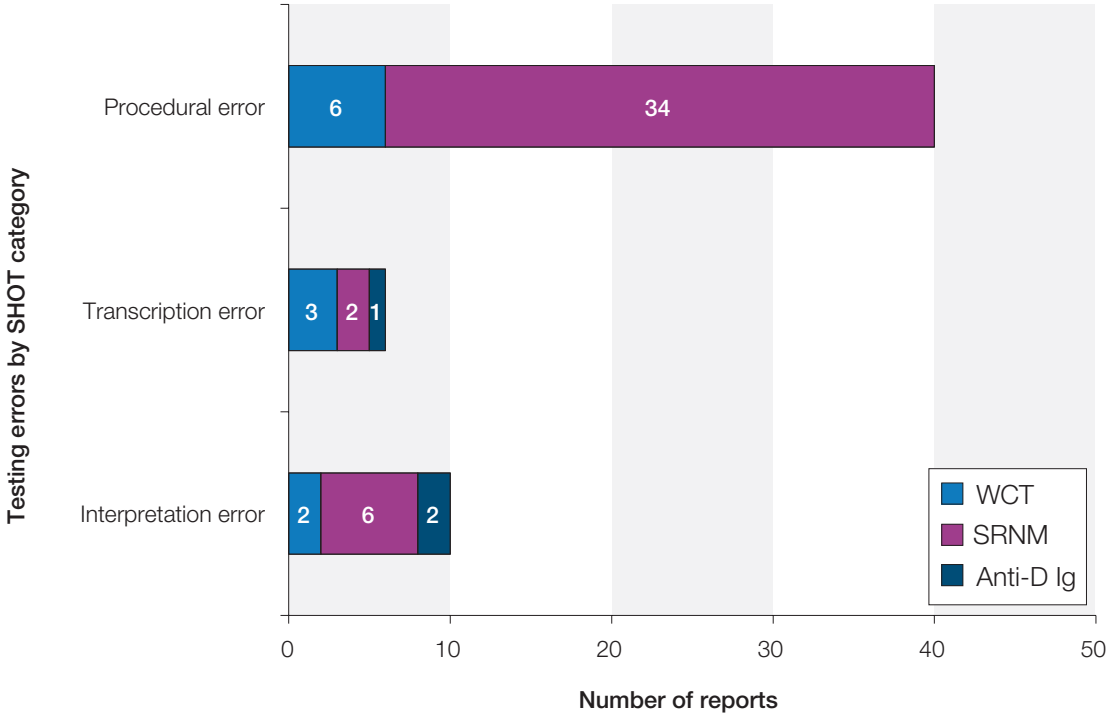


Figure 7.5b shows the same 56 cases by MHRA classification.

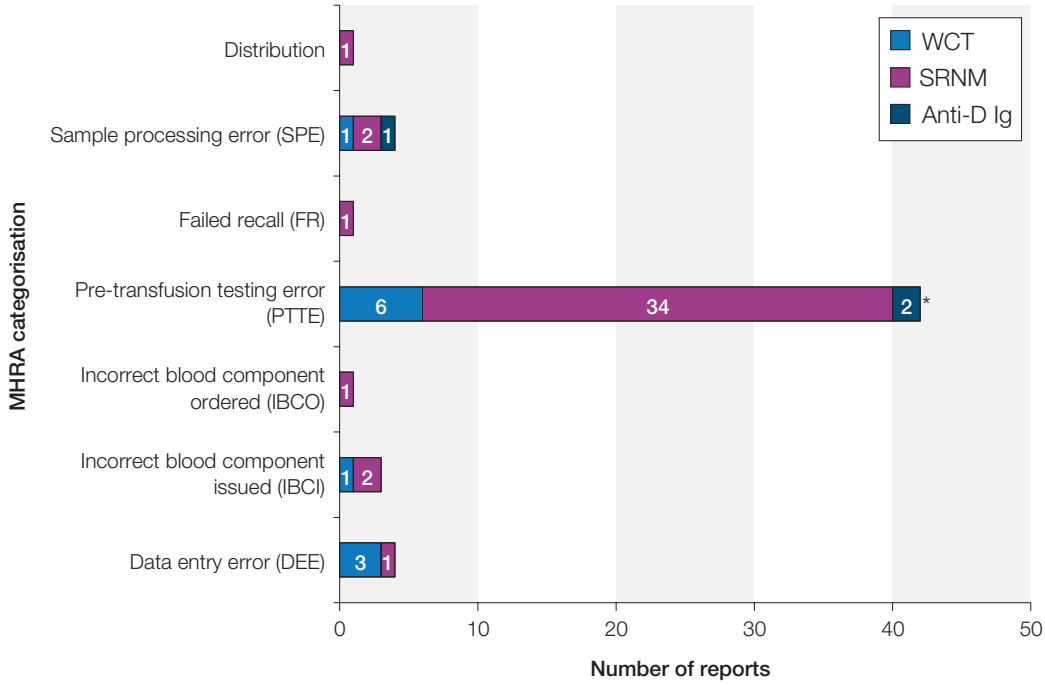


Figure 7.5b: Testing errors by MHRA categories n=56

**These were 2 errors where anti-D Ig was administered late/omitted*

The majority of testing errors that are reported to both haemovigilance organisations are recorded in the MHRA category pre-transfusion testing errors (PTTE). There were 110/1027 (10.7%) PTTE SAE reported to the MHRA of which 108/110 were caused by human factors. Analysis of these data demonstrates no common root cause. However these errors fall evenly into four of the MHRA root cause subcategories:

- **Inadequate processes** - where the process does not always ensure the correct outcome, even when followed correctly. Often a process might not include relevant steps that ensure a consistent and safe outcome, or has not even been designed and established and relies on staff performing tasks which have not been standardised
- **Incorrect procedure** - the correct process has not been properly described in the SOP. Key steps have been omitted, or do not describe what to do, e.g. if unexpected results are obtained
- **Procedural steps omitted/wrong procedure performed** - staff have either missed out key steps in a procedure or followed the wrong procedure from the start, such as a failure to perform the required antibody investigations following a positive antibody screen
- **Procedure performed incorrectly** - where the correct steps have been taken, but incorrect decision-making has resulted in the error being made, such as misinterpreting manual testing results

In these cases laboratory staff have been trained and should know what to do and be able to perform these tasks correctly and competently, but for some reason a slip or lapse of concentration results in mistakes.

Although each member of staff has a responsibility to work safely and accurately, slips or lapses may occur. There are steps that can be taken by both laboratory management and individuals to reduce the chances of these:

- Review process design and use of equipment to ensure they are robust
- Review the SOP ensuring the process is described in logical order and staff can perform the steps as written, including what to do if the task goes wrong
- Ensure that critical points are covered during training and that competency-assessment challenges them

- Minimise all distractions and ensure the layout of the laboratory is logical
- Allow staff to work safely at their own pace without rushing
- Have contingency plans in place for when staffing levels are below minimum or there are spikes in workload and ensure these contingency plans are activated when required
- Follow the SOP. Staffing pressures should never be an excuse to cut corners or deviate from a SOP
- Never improvise. Consult the SOP for the correct procedure rather than asking colleagues or working contrary to the defined process

The NEQAS for blood transfusion laboratory practice (BTLP) paragraph below describes additional testing errors identified from their annual pre-transfusion testing questionnaire. Laboratory-related errors in children are described in Chapter 22, Paediatric Summary.

Case 7.3: Inappropriate use of EI excludes essential crossmatch

Two units of group A red cells were electronically issued for a group A solid organ transplant patient. Prior to transfusion a full blood count (FBC) sample showed evidence of haemolysis on a blood film and was direct antiglobulin test (DAT)-positive. A recall of blood components issued to the patient was initiated. One unit already being transfused was stopped. Further group A red cell units were crossmatched by indirect antiglobulin test (IAT) and were found to be predominantly incompatible. The Blood Centre reference laboratory testing found no alloantibodies but the patient's eluate demonstrated anti-A as a result of passenger lymphocytes from the group O lung transplant. The SOP was not compliant with the BSH guidelines on pre-transfusion compatibility procedures in blood transfusion laboratories (BSH Milkins et al. 2013). This patient should have been excluded from EI. A serological IAT crossmatch would have demonstrated the incompatibility and then group O red cells selected as the alternative.

Learning point

- BSH guidelines (BSH Milkins et al. 2013) state that patients who have received solid organ transplants should be excluded from electronic issue for 3 months to enable the detection of IgG isoagglutinins produced by passenger lymphocytes

Component selection n=32

Component selection should ensure that the correct components (together with the correct specific requirements) are selected to comply with the patient's requirements and the clinical request. One serious selection error resulted in a 4-day-old baby with haemolytic disease of the fetus and newborn receiving incompatible red cells (group O D-positive cells to a baby with haemolysis due to anti-D). This is described in Chapter 10, Incorrect Blood Components Transfused (IBCT), Case 10.1.

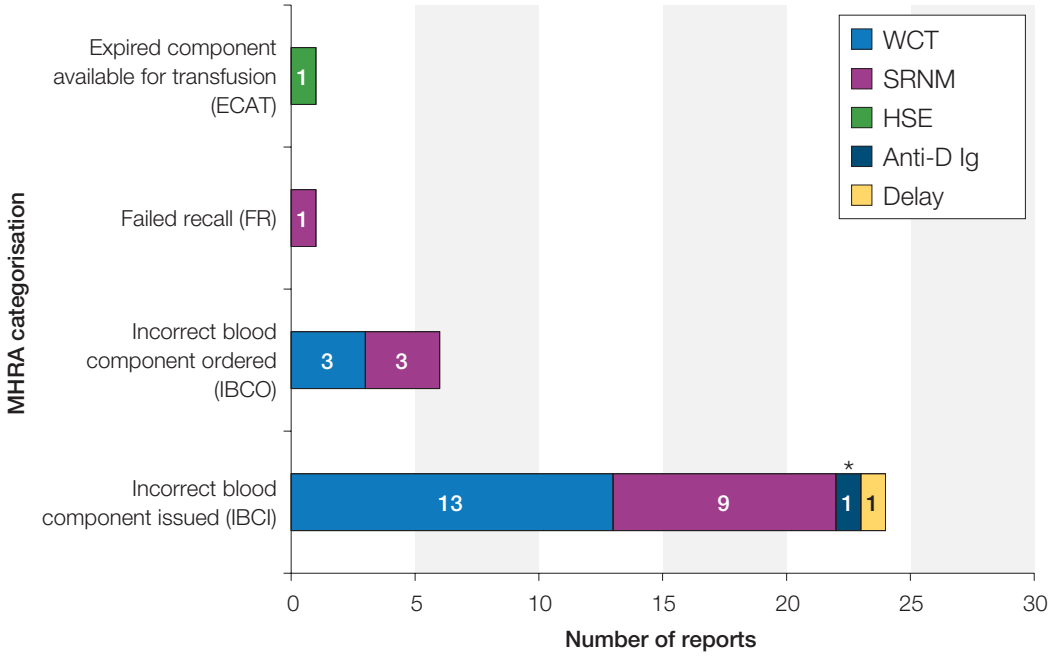


Figure 7.6: Selection errors by MHRA categories n=32

** Anti-D Ig was not given following a selection error (D-positive platelets selected)*

Incorrect selection of components can be assessed a number of different ways by the MHRA, and not just based on missing specific requirements on the request form (IBCI). Expired component available for transfusion (ECAT) refers to a case where an otherwise suitable unit was selected, but without reference to the planned transfusion date. The component was short-dated and issued before midnight when the planned transfusion was the next day. The incorrect component assessed by the MHRA as a failed recall (FR) refers to a case where the incorrect issue was identified in the laboratory, but was not recalled from the supply chain in a timely manner. Incorrect blood component ordered (IBCO) refers to those cases where the laboratory orders incorrect blood from the Blood Establishment and does not identify this prior to issuing the component to the patient.

Many of these reports relate to allogeneic haemopoetic stem cell transplant (HSCT) or solid organ transplant where the appropriate ABO and/or D group for transfusion has changed from the patient's original group (n=18), see Chapter 23, Summary of Incidents Related to Transplant Cases. The introduction of new guidelines for the use of hepatitis E virus (HEV)-screened components (SaBTO 2016) has had some impact on the number of incidents reported, see Chapter 10, Incorrect Blood Components Transfused (IBCT) Figures 10.4 and 10.5. Reasons for failure to provide HEV-screened components include not having a robust process for flagging these requirements, or the new guidance was not communicated to laboratory staff by means of a robust SOP and training.

Case 7.4: Inappropriate red cells issued by BMS unfamiliar with the LIMS

A 62-year-old female with newly diagnosed acute myeloid leukaemia (AML) required two units of red cells, the request noted these should be cytomegalovirus (CMV)-negative. This request was not urgent. The patient grouped as A D-negative. There was no historical record of the blood group on the LIMS. A group-check sample was not obtained. The BMS (working out-of-hours) selected and issued two units of group O D-positive red cells. The error was detected 6 days later when a mixed field blood group pattern was displayed. The BMS undertaking the selection had more than 15 years' experience overseas and was undergoing competency-assessment and had not been signed off to work autonomously. The BMS stated that they must have ignored the warning message on the LIMS as they were used to coloured (red) warnings using their former LIMS. The BMS was being indirectly supervised during component issue, by a BMS2 who was supervising two trainees at the same time, but failed to spot the D-positive selection error.

Irrespective of the error made in selection of D-positive red cells, there is no clear reason given why group O was selected and not group A (the patient's group). If this was because there was no group-check sample, the correct action would have been to request a second sample to confirm the patient's group, as this was not an urgent request. Group O may have been selected to meet the requirement for CMV-negative, but CMV-screened components are not required for this group of patients (SaBTO 2012).

LIMS technology can only support safe transfusion practice provided it is used according to a robust local SOP and by competent staff. BSH guidelines (BSH Milkins et al. 2013) state that in the absence of a robust electronic patient identification system a second sample is recommended to confirm the blood group. Laboratory staff did not consider the patient's historical information. This led to the issue of components to a patient who was known to have both antibodies and other specific requirements.

Learning point

- Compatibility labels should display the patient's blood group. This will help to alert the biomedical scientist (BMS) when labelling, and nursing staff when performing the final bedside check. Any discrepancies should be discussed with the laboratory immediately

MHRA regulatory view: New members of staff, even if they are experienced having worked elsewhere, must be trained and competency-assessed as they may be used to different procedures and equipment. They must be actively supervised prior to being signed off as competent and not expected to work unsupervised.

Case 7.5: Red cells reserved for multiple patients stored together leads to labelling error

A BMS selected two units of red cells for serological crossmatching and returned them to the refrigerator. When testing was complete, the two units were removed from the refrigerator and the printed compatibility labels attached. One of these units was not one of the crossmatched units, but fortuitously of the correct blood group. The label check was not completed correctly as the BMS was rushing to go home. While putting these units into the electronic blood tracking system, the second unit gave an error message that highlighted that this was an unknown unit for the patient. The BMS did not read the error message and thought the system had a fault. The BMS decided to release them manually. A porter collected one unit from the laboratory at 23:48 but did not perform the visual check properly or notice the label and the unit had different unit numbers. This may have been because the unit was collected face to face with a BMS. Nurse 1 receipting the blood did not notice the discrepancy and had not completed a competency-assessment for receipting blood components. Nurse 2 who ordered the red cells accompanied Nurse 1 to complete the bedside check. Neither of the nurses recollects any problems with numbers not matching nor were they competency-assessed for the bedside check. The red cell unit was administered to the patient without any adverse consequences.

Red cells allocated to a patient for crossmatching should be quarantined from stock units. If red cell units for more than one patient are being stored in the same location then they must be kept in a discrete area of the refrigerator and not together. Information technology (IT) systems are designed to support processes and any warning/error notification should be carefully noted and acted on appropriately. When two people are completing checks together, care must be taken as there can be complacency with neither person taking responsibility to complete the check properly. A better check may be to use a challenge and response method with two people as described in Chapter 10, Incorrect Blood Components Transfused (IBCT).

MHRA regulatory view: This report highlights the need for having a robust process in place when storing components during a serological crossmatch. No part of the quality check should be abbreviated due to time constraints. If staff do not have time to perform a task, they should leave it for another member of staff or take the extra time to complete it adequately rather than rushing through the process.

Component labelling, availability and HSE n=86

The correct component needs to be labelled with the correct four (or five) key patient identifiers; these are the first name, surname, DOB, unique patient ID identifier and first line of address if in Wales (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 method as defined in the guidelines (JPAC 2013).

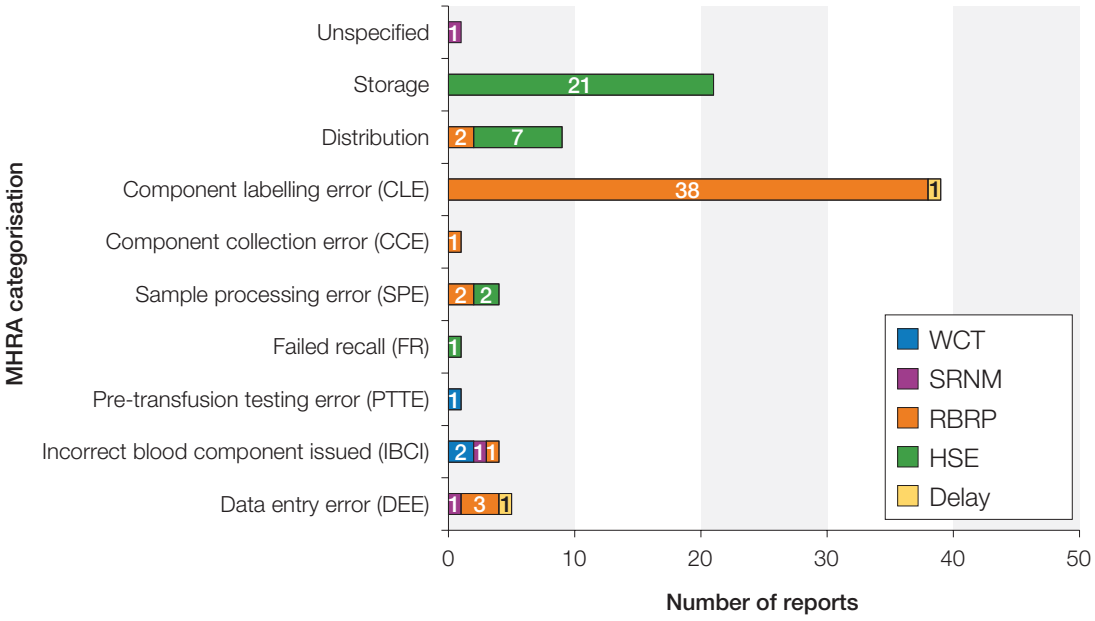


Figure 7.7: Component labelling, availability and HSE by MHRA categories n=86

There were 31 HSE laboratory cases reported to both SHOT and the MHRA (Table 7.3).

HSE subcategory	Number of incidents reported to both haemovigilance organisations
Failure to clear refrigerator/sample expiry	10
Stored inappropriately in laboratory area including cases where the transport and delivery was not adequate	8
Return to stock error/30 minute rule	7
Expired unit issued and transfused due to laboratory error	2
Equipment failure (alarm-related/not alarm-related)	2
Incomplete cold chain documentation	2
Total	**31**

Table 7.3: Handling and storage errors reported to both haemovigilance organisations

Last year the MHRA highlighted the need for improved processes regarding storage in general (The 2015 Annual SHOT Report - Web Edition, Chapter 18, 2016). While the total number of SAE reports has increased, the number of reports related to failure to respond to the alarm has decreased. This may suggest that laboratories have heeded this advice and as a result of improved process design, improved SOP, training and understanding, laboratory staff are acting on alarms from storage locations. As a result blood components are less likely to be wasted, or removed from the supply chain.

Incorrect storage of components is one of the most common errors. Typically storage of a component is at the wrong temperature or in an unmonitored storage device. Eighty five SAE were reported to the MHRA involving the incorrect storage of components. Only eight of these errors occurred in laboratories, which suggests that the remaining 77 occurred in the clinical area. Platelets are often reported to have been placed in refrigerators, and granulocytes have been reported to have been placed in agitators. Components have not been removed from transport containers and stored correctly, or have been left out by the bedside or elsewhere. The most common cause of components being stored incorrectly were:

- **Ineffective training** - of staff who had either not understood the process or had forgotten it due to infrequent update training for a rarely performed task
- **Inadequate processes** - where there was no defined process for what to do if blood was not administered immediately or where out-of-service storage equipment was not adequately prevented from being used

Staff in clinical and laboratory areas should be encouraged to ensure that procedures related to storage of components, temperature monitoring and removing unsuitable units from storage locations are robust and clear and that staff are trained in them and able to activate those procedures effectively, even when lone-working or during emergency situations.

Case 7.6: Labelling of red cells for two different patients simultaneously leads to error

Two units of red cells for Patient 1 and one unit for Patient 2 were manually crossmatched at the same time. Upon completion all three compatibility labels were printed together. The numbers on two of the donor units were similar. The label check was not completed correctly and one unit for Patient 1 was labelled for Patient 2 and one unit for Patient 2 labelled for Patient 1. All three units were placed into the electronic blood-tracking system but at this stage the system only identifies the unit number and not the patient as well (this part of the system was not purchased due to the additional cost as it was deemed unnecessary at the time). The first unit was transfused to Patient 1 without incident (correct label). A healthcare assistant (HCA) collected the second unit for Patient 1 and the tracking system showed the identity of Patient 2 on the screen and asked for confirmation that this was the correct patient. This was confirmed as being correct by the HCA by pressing the green confirmation button, even though it was not. The error came to light when the clinical area fated the second unit but the tracking system thought the unit was in the refrigerator.

Outcome: Verbal instruction was given to a locum BMS following the incident that only one patient should be crossmatched at a time in line with the SOP. The investigation also indicated that the lack of an additional centrifuge to process the serological crossmatches, in addition to a time-pressured environment, makes it much less efficient and practical to process one serological crossmatch at a time. The hospital's policy required two people to do the pre-transfusion checks but in this incident the component was checked by only one nurse.

Component selection, crossmatching and labelling should only be undertaken for one patient at a time and should be stated in the SOP. All staff, including locum staff, must undertake full training and competency-assessment although there is no evidence to suggest this locum BMS was not sufficiently trained. No short cuts should be taken and regular staffing reviews should be performed to ensure there are sufficient staff in both laboratory and clinical areas.

MHRA regulatory view: The report highlights the necessity to perform all checks thoroughly and to act on any discrepant information and system warnings without making assumptions.

Miscellaneous n=8

The 8 miscellaneous cases were reported as IBCT-WCT (4) and SRNM (4), and all of these occurred as a result of inadequate processes. In 3 cases the error originated at the Blood Service, where the wrong component was sent and it was not detected or communicated to the laboratory staff. One of these caused serious harm (development of anti-D in a D-negative woman following transfusion of D-positive platelets), see Chapter 10, Incorrect Blood Components Transfused (IBCT).

Human factors

Inadequate quality management systems (QMS) – staffing and workload. This category was introduced to gain insight in the extent of staffing and workload problems contributing to SAE. Evidence collected in previous years' serious adverse blood reactions and events (SABRE) reports, MHRA inspection reports, SHOT, UKTLC surveys and other sources suggest that resource issues are having a serious and detrimental effect on a laboratory's ability to function safely.

To qualify for this category, the SABRE team aimed to include SAE where staffing levels were below minimum levels as defined by the capacity plan or workload was high, either in the long term or short term. It is also important to consider the appropriate level of 'skill-mix' to ensure that the right level of suitably qualified and experienced members of staff are available. We have tried not to simply record every SAE where the report stated staff were busy. We assigned different subcategories where other human factors were more likely to have an impact, e.g. if a BMS has made errors by trying to perform more than one task at a time, this may be a result of poor work prioritisation as opposed to an unacceptably high workload. This first assessment of these types of error has demonstrated that several, (103/1027) 10.0%, of all SAE fall into this subcategory. Continued collection of these data with time will be informative. It is evident that these pressures are real and can affect the quality and safety of blood and the quality of service provided.

When resolving issues related to staffing and workload, laboratories have been successful in using QMS data as evidence to increase resource. However, not every laboratory will be successful. It may be the responsibility of laboratory managers and their staff to suggest novel and innovative solutions. Some solutions evident in SABRE reports include:

- Training laboratory support staff to perform some additional tasks to provide relief for BMS
- Changing shift patterns and reviewing break times to ensure greater numbers of staff are available at busier times
- Reviewing rules related to numbers of staff on leave at the same time
- Reviewing processes to ensure they are streamlined
- Reviewing workloads to spread the work out more effectively when staff are available

Laboratory incidents included as SHOT-only n=126

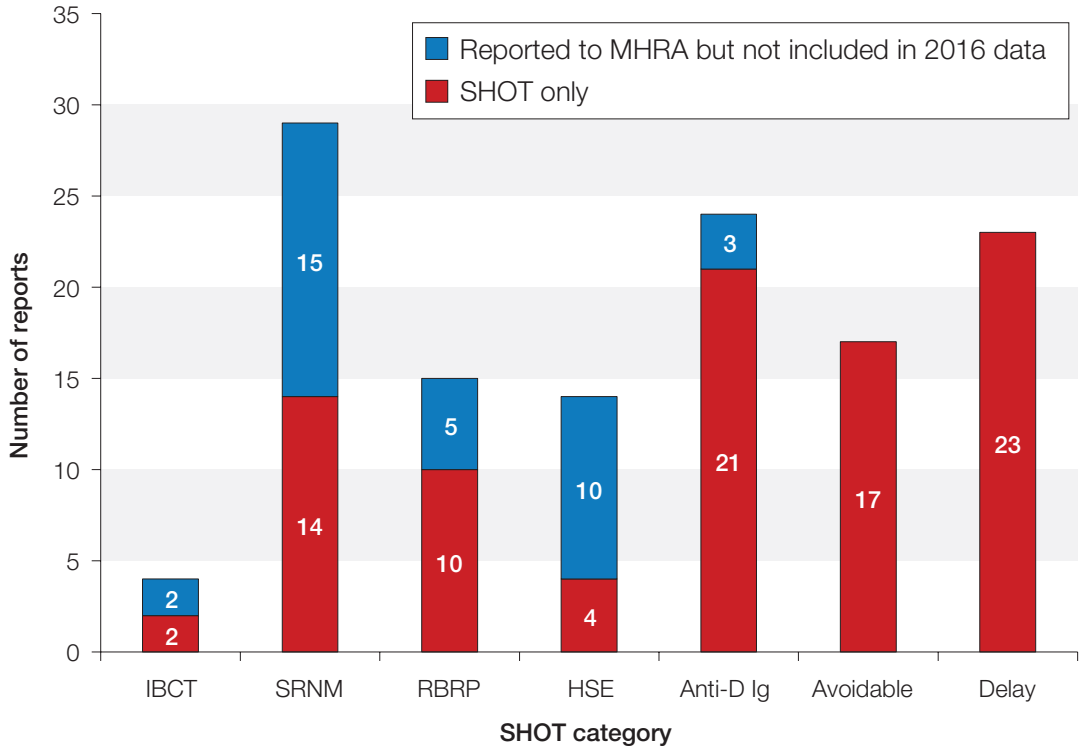


Figure 7.8: SHOT-only laboratory incidents n=126

A total of 91/126 cases were SHOT-only reportable excluding cases identified below because:

- 16/126 cases are at notification stage with the MHRA and will be included in the 2017 MHRA dataset
- 17/126 cases were duplicated by SHOT where the initial reports were submitted to both SHOT/MHRA but do not need to be duplicated for each patient for the MHRA whereas SHOT requires each incident to relate to one patient
- 2/126 were reported as serious adverse reactions (SAR) to the MHRA, both cases involved patients that had a reaction due to the transfusion of an incorrect blood component. SHOT categorises these cases as IBCT, but they are reportable to the MHRA as SAR, not SAE

There were 28 anti-D Ig errors that originated in the laboratory where laboratory staff had an opportunity to prevent the issue of anti-D Ig requested inappropriately from the clinical areas. Fundamental errors in knowledge resulted in issue of anti-D Ig to women with allo-anti-D, women with D-negative infants and to D-positive women. Laboratory staff should have this basic knowledge and the LIMS should support this with appropriate warning alerts. Staff should also be aware of the requirement for administration of prophylactic anti-D Ig within a 72-hour window following a potentially sensitising event or delivery. The request from the clinical area should allow sufficient time for the issue and administration of this product. These errors are discussed in greater detail in Chapter 14, Adverse Events Related to Anti-D Immunoglobulin (Ig).

In 6 cases laboratory staff failed to follow major haemorrhage protocols (MHP) correctly, Case 7.7.

Case 7.7: Contingency measures lead to delay and failure to follow MHP activation correctly

The ED activated the MHP at 03:00 for a gastrointestinal bleed in a 38-year-old patient. The refrigerator in the ED was not working and there was no emergency uncrossmatched red cell stock available. Despite the protocol being activated 15 minutes prior to the patient arriving no blood was available in the ED for 30 minutes or more after the patient arrived. Initially the transfusion laboratory staff refused to issue more than two uncrossmatched red cell units at a time for the first two occasions. The patient subsequently died in the intensive therapy unit (ITU), death unrelated to the delay.

The local investigation identified:

- Concerns that there was a deviation from the MHP as four units of red cells should have been issued
- Concerns surrounding the laboratory escalation, resilience and contingency when the refrigerator broke down
- Although there was a delay they did not believe it had an impact on the final outcome

Laboratory staff should undertake regular competency-assessment in critical procedures, i.e. emergency drills should be practiced to ensure there are no delays due to a gap in knowledge. If emergency uncrossmatched red cells are part of the protocol, any inability to meet this provision, such as refrigerator failure, must have a backup plan clearly communicated to clinical areas to inform them to the change, however temporary, in procedure.

Learning point

- The major haemorrhage protocol (MHP) must be agreed by the hospital transfusion committee and all staff trained to deliver components in line with the protocol. Any deviation should only be authorised by a senior clinician

Incidents reportable only to the MHRA n=233

There were 1027 MHRA SAE reports in 2016. However 233 were not reportable to SHOT. This section provides more detail to show why that is, and provides further analysis of those reports.

- 688/1027 reports were reported to SHOT but under various categories, i.e. a mixture of laboratory and clinical cases

- 47/1027 SAE were included in the 2015 Annual SHOT Report analysis but not the MHRA for that year because the confirmation report was not received by the MHRA until 2016
- 12/1027 SAE were submitted to SHOT but not completed by the SHOT deadline (31 December 2016), but received by the MHRA before 31 December 2016
- 47/1027 SAE were received by the MHRA but are still incomplete on the SHOT database (Dendrite)

Of the 233 reported to MHRA-only, 68 were from Blood Establishments and the remaining 165 were not SHOT-reportable.

The 233 MHRA-only SAE are displayed in Figure 7.9.

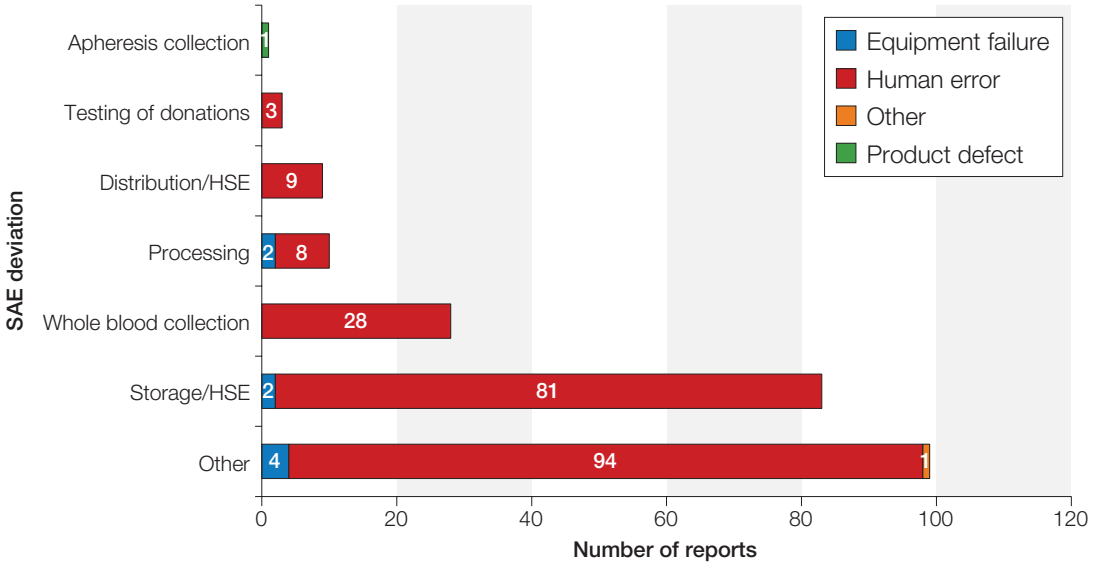


Figure 7.9: MHRA-only SAE by specification

The category **whole blood collection** refers only to the collection of donor blood by Blood Establishments and the majority of these refer to donors being accepted for donation who should have been deferred due to travel or lifestyle reasons. The largest category is 'other' and this is broken down by the MHRA 'other' subcategory in Figure 7.10.

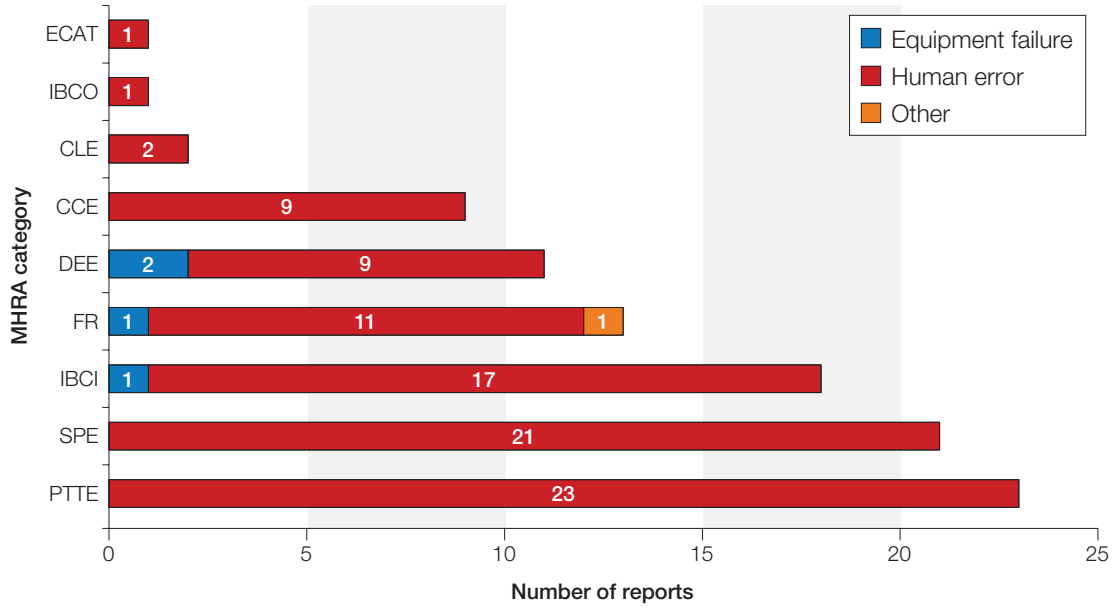
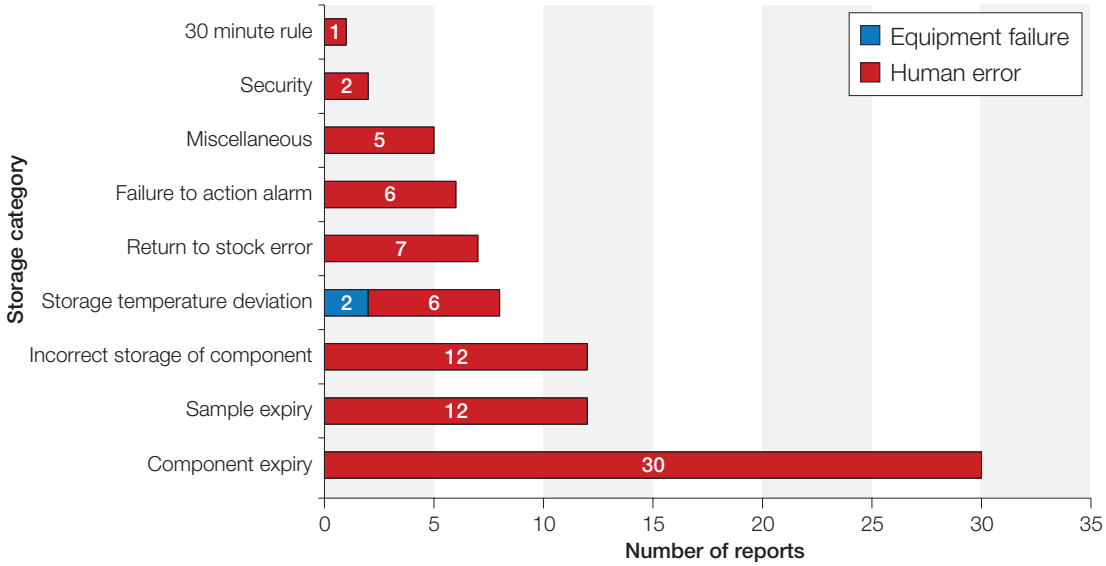


Figure 7.10. Subcategory 'other' by specification

The proportion of reports in each category is broadly similar to those where all MHRA SAE are analysed together. The only real difference is that these errors were detected prior to transfusion, often at the bedside, but demonstrate that the QMS did not detect the error at the point the error was made.

Figure 7.11 demonstrates further analysis of the storage SAE. These are a mixture of laboratory errors where components were not transfused, and errors by staff outside the laboratory which has affected the quality and safety of the component, such as incorrect storage of component where clinical staff have stored blood in unmonitored storage equipment, and security where access to storage equipment by untrained staff has occurred.

Figure 7.11: Storage error by specification



MHRA inspection activity on hospital blood banks 2015–2016

This is a summary of the full report which is included in Chapter 25, MHRA (available on the SHOT website www.shotuk.org).

A total of 303 blood compliance reports (BCR) were submitted for review for the reporting period 01 April 2015 to 31 March 2016. Following assessment, 17 hospital blood banks (HBB) including 1 control site were selected for inspection. One additional HBB was inspected following notification from the site that inaccurate information had been provided in the BCR.

Inspection outcomes

A total of 19 inspections were performed and the numbers of deficiencies are as follows:

Critical	Major	Other
1	43	67

One HBB resulted in a critical deficiency finding and was referred to the Inspection Action Group (IAG).

The critical deficiency was as a result of the following:

- Senior management had not ensured that there were sufficient resources to support the quality system
- Management of deviations (incidents) was inadequate in several respects (detailed in the full report)

Three HBBs had serious deficiency findings related to their operations and were escalated to the Compliance Management Team (CMT).

An overview of the compliance management escalation processes used by the GMP Inspectorate, including information on the CMT referral process is available from the MHRA Inspectorate Blog https://mhrainspectorate.blog.gov.uk/2017/02/06/overview-of-compliance-management-escalation-processes-used-by-the-gmp-inspectorate/

Deficiencies classified as ‘major’ and ‘other’ were identified in the deficiency group and are shown in Figures 25.7 and 25.8 in Chapter 25, MHRA (available on the SHOT website www.shotuk.org):

Summary of significant issues identified at inspected sites

These can be found in more detail in the full report in Chapter 25 (available on the SHOT website www.shotuk.org).

CAPA implementation

The implementation of CAPA was generally found to be deficient with no system in place to track and monitor the progress of CAPA closure and no requirement to monitor and assess the effectiveness of implemented CAPA.

Laboratory operations

Issues were identified from the sample receipt and acceptance process to suggest that the 'zero tolerance' approach could be bypassed.

Investigation of analyser quality control (QC) failure was in some cases inadequate. Little attention was given to establishing why the QC had failed before process re-runs were initiated. A single passing repeat could be used to invalidate a failed test. Investigation to identify potential causes of failure was not always evidenced.

Document control and data integrity

Poor documentation practices were the most cited deficiency.

Records that had not been completed contemporaneously or staff signed for incorrect results, e.g. out of temperature limits for the temperature-controlled storage facilities or signed for other staff without explanation, had the potential to result in serious data integrity issues. It is important to apply the basic ALCOA principle to all data: Attribute, Legible, Contemporaneous, Original, Accurate.

Personnel and training

A capacity plan should be put in place to demonstrate that the staffing level is sufficient to cover the workload including out-of-hours working and effective implementation of QMS. Where a shortfall is identified, senior management should ensure sufficient resource will be made available. Job descriptions and organisation diagrams should be consistent with respect to reporting lines and made available to all staff.

Evidence from inspection showed that staff were not being trained/updated following significant changes due to the lack of training policy and training matrix. Staff were not aware of, trained, and competent in the use of key quality system procedures, and this was especially an issue for staff working out-of-hours. Some training records did not reflect the correct competency assessment or the re-training was overdue. Training records were not always available for review including those for senior management.

Another area of concern related to nurses and porters who collect issued blood units from the issue refrigerator, as the re-training has not been performed in accordance with the training schedule. It was stated that the staff could not be released to complete the necessary training due to the demand on the wards. This is not acceptable practice and the senior management in the clinical area should also be made aware of the regulatory requirements.

Computerised systems

With the innovation and development of computerised systems and software, it is more common to see the use of electronic quality and documentation management systems, automatic analysers, patient databases, automatic issuing system, blood tracking systems and temperature monitoring systems. Special attention should be given to the control of such computerised systems and the integrity of QC data.

Some common IT errors included:

- Data quality issues – merging errors and quality control of data entry and transfer between systems
- Level of availability of technical support/knowledge – amongst laboratory users and the organisations IT
- User requirements – not always met
- System security – appropriate access level, individual login and password
- Storage – backup
- Alternation of data – audit trial
- Contingency and failure – business continuity planning

Summary of learning points from inspections

1. Define and review all system processes regularly to ensure that they are fit for purpose.
2. Improve root cause analysis procedures and applications ensuring that the whole process is looked at and areas of weakness identified (including internal and external QC) so that appropriate safeguards and corrective measures can be introduced.
3. Critically review all incidents so the severity of risk can be appropriately categorised and assessed and so that corrective and preventive actions can be introduced in an appropriate timeframe.
4. Senior management should ensure an effective quality system is in place, adequately resourced and that roles, responsibilities, and authorities are defined, communicated and implemented throughout the organisation.
5. Monitor system performance so that failures due to resource issues can be raised to the appropriate level.
6. Raise change controls in an effective and timely manner to ensure that process changes have an appropriate level of validation data.
7. Introduce measures that ensure effective laboratory housekeeping is undertaken and maintained. This applies particularly to the care and maintenance of storage facilities.
8. Design and implement an achievable and effective training plan for all routine and out-of-hours staff, and ensure that this includes the QMS procedures.
9. Attention and special care is required for the control of data in hard copy or in electronic format.
10. Good documentation practices must be followed.
11. Post-inspection actions must be completed as agreed or notify the inspector of slippage.

Information and guidance

For further information on **MHRA and the Regulation of Blood** please refer to the MHRA website:
https://www.gov.uk/topic/medicines-medical-devices-blood/blood-regulation-safety

The MHRA Blood forum was launched in June 2016 as a tool to help those involved in blood component collection, processing, testing and distribution to comply with the EU Blood Directives, UK Statutory Instruments and good practice requirements. It provides the ideal opportunity for extended communication between peers and allows users to put forward their comments and get 'real-life' examples of ways in which they can manage robust quality procedures that ensure compliance and which dovetail with their own business needs and resources.
http://forums.mhra.gov.uk/forumdisplay.php?60-Blood-Forum

United Kingdom Transfusion Laboratory Collaborative (UKTLC)

Author: Rashmi Rook

The published UKTLC Standards (Chaffe et al. 2014), can be mapped across to the BSQR 2005 and European good manufacturing practice (EU GMP) and lay out in more detail the actual qualifications, training and knowledge that staff working in transfusion laboratories are required to have. It is essential that senior pathology managers support the standards with the aim to fully implement these as soon as possible. Where there is restructuring of teams and changes to working practices, this is especially pivotal in providing and maintaining a safe service. As the hospital chief executive officer (CEO) is deemed the 'responsible person' to ensure compliance with the regulations then senior pathology managers have the responsibility to inform them where there is a gap between the standards and actual working practices. The need to meet the requirements of the UKTLC standards (Chaffe et al. 2014) is due to the uniqueness of this pathology discipline in providing both a diagnostic and therapeutic service that works closely with clinical staff, and helps provide better patient care. BMS have to make real time decisions that may directly affect patient safety in a stressful and time-pressured environment, and they must be allowed to work safely and confidently. This department is additionally challenged by the necessity to comply with good practice guidelines for blood components, products and testing as defined within the industry. Increasing the knowledge of our staff is the key to future-proofing the service and maintaining patient and transfusion safety.

Regulations:

BSQR Regulation Section 9. (1) (a): The person responsible for the management of a hospital blood bank shall… ensure that personnel directly involved in the testing, storage and distribution of human blood and blood components for the hospital blood bank are qualified to perform those and are provided with timely, relevant and regularly updated training.

EU GMP 2.1: The manufacturer should have an adequate number of personnel with the necessary qualifications and practical experience. Senior management should determine and provide adequate and appropriate resources (human, financial, materials, facilities and equipment) to implement and maintain the quality management system and continually improve its effectiveness (EU regulations, see reference list)

There are concerns that local transfusion meetings are not well attended by laboratory managers or their deputies, and reasons given are increasingly being cited as staffing difficulties. It is expected that this group plan educational leave well in advance to increase participation. The benefits of having a supportive professional network of colleagues and the sharing of ideas, and best practices can be of immense gain to the department, and can help to manage pressures that we all face from 'doing the job'. This should be reflected in adequate funding to attend meetings and courses.

- 'Drive out fear so that everyone may work effectively' (Deming 1982)
- 'Fear is toxic to safety and improvement' (Berwick 2013)

Despite the evidence from (Deming 1982) and (Berwick 2013) transfusion staff are nevertheless being penalised or censored for raising concerns within their hospitals. UKTLC stakeholders will be looking into this as it goes against the culture of encouraging candour, openness and honesty at all levels within an organisation. The culture of safety must become the overriding core principle within the department and throughout pathology. The impact of errors and mistakes not only affects the patient but also the staff (second victims). Regardless of the severity of an incident or error this may adversely affect performance of the team and overall department morale. Staff come to work wanting to do a good job, and it is faulty systems and processes that may let them down (see Chapter 6, Human Factors). In an open reporting and transparent culture, staff should be encouraged to easily record concerns, incidents, errors and mistakes to use as evidence to support resourcing without censor.

During 2017 the UKTLC is working on the following projects to support BMS to achieve delivery of the standards:

- Producing formal guidance on staff capacity planning
- Promote better communication, conversations and sharing of ideas and documents between laboratory staff, via the MHRA blood forum
- Continue monitoring changes through the 2017 UKTLC survey

The survey was distributed from NEQAS-BTLP on 15 March 2017 to 302 UK transfusion laboratories in order to give a snapshot of one day in line with previous UKTLC surveys.

The 2017 UKTLC survey showed the following results:

Response rate: 245/302 (81.1%). In 50.6% (124/245) the laboratories stated staffing levels have remained the same or decreased since the previous survey in March 2015, with many leaving the NHS for posts in other organisations at the same grade or taking early retirement. Vacancies have been present in some laboratories (particularly at Band 6 BMS) for 2 or more years.

The calibre and suitability of applicants to laboratory posts are unsatisfactory; 60.8% (149/245) of laboratories recorded that newly registered Health and Care Professions Council (HCPC) BMS do not have appropriate knowledge/skills to work in blood transfusion. There is increased dependence on locum and agency staff. There is an increase in multidisciplinary staff, and in those who do not work >75% in blood transfusion. Some laboratories 85/245 (34.7%) reported an increase in workload of >50%. Also, 62% (152/245) reported more difficulty in training/mentoring inexperienced staff with 42.0% (103/245) reporting no identified training and development budget.

UKTLC standards have been considered by many laboratories during ongoing changes especially in relation to staffing levels. However staffing shortages have still not been addressed. This together with increased workload contributes to lower morale and reduced job satisfaction, with many leaving for posts in other organisations or taking early retirement. This is resulting in a great deal of experience and a wealth of knowledge being lost from the organisations.

Learning point

- A gap analysis can be performed against the UKTLC standards and this can be used to demonstrate to senior management/executive teams where the laboratory is falling short of any standards that require resolution from senior levels

UK NEQAS

Author: Claire Whitham

In May 2016, UK NEQAS Blood Transfusion Laboratory Practice (BTLP) sent out the annual questionnaire about pre-transfusion testing to laboratories in the UK and overseas. Most of the data reported had not changed significantly from that collected in 2015. However, it is noted that:

- 65.7% (167/254) of laboratories (compared to 54.1% (151/279) in 2015) request two samples taken at separate times for a group check (one group could be historical), before group-specific blood is issued in a routine situation, and a further 23.2% (59/254) are in the process of implementing this policy (compared with 20.1% (56/279) in 2015)
- The numbers using automation and EI, and requiring a second sample, varies significantly by country

Results reported for BTLP external quality assessment (EQA) exercises have shown some issues with laboratories failing to either adhere to or understand recommendations made by the manufacturers of their chosen technology, e.g. during exercise 16R9, where Patient 2 red cells (AB D-positive) were coated with anti-D to give a 2-3+ positive DAT. This caused a positive reaction in the control well of BioVue grouping cassettes due to the presence of potentiators (polyethylene glycol) in the reagent and control columns, invalidating the ABO and D-typing results. The majority of laboratories using BioVue either reported that they were unable to interpret the blood group or undertook repeat testing with a

second technique enabling them to make an interpretation of AB D-positive. However, four laboratories made an interpretation of AB D-positive, a fifth reported group AB unable to interpret D and a sixth reported it as uninterpretable for ABO but D-positive, all using BioVue only. It is of course possible that these six laboratories undertook additional testing without recording it at data entry.

Data analysis of EQA exercises repeatedly shows transcription and transposition errors made either during testing or reporting of results (which is also evident in the SHOT testing errors reported in 2016). 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. Manual testing is vulnerable to transcription and interpretation errors and must include checks at critical points. 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.

EQA 'requests' are booked into the LIMS in 72.8% (185/254) laboratories (73.5% (205/279) in 2015), allowing the EQA samples to follow the same process as clinical samples, thus making the EQA results more relevant to clinical practice. Some laboratories cited sample format (i.e. not whole blood) as a reason for not booking EQA samples into the LIMS, and whilst it is appreciated that the sample format is not ideal, this does not seem to be a barrier to LIMS entry in the majority of laboratories. In some cases there are additional obstacles to overcome, e.g. where there is a shared database and/or problems with building up historical records for EQA 'patients'. It might be possible to overcome these issues with additional planning in allocating names and numbers to the EQA samples for entry to the LIMS. In 28 laboratories 'custom and practice' was cited as a reason not to book in EQA samples, with this being the only reason for 11 (4.3% (11/254)) of all respondents (compared with 6.5% (18/279) in 2015).

Commentary for errors that originated in the laboratory

Many errors originating within the laboratory are reportable to both haemovigilance organisations and reporting is a key requirement of any QMS. Thorough investigation and identification of the root causes are vital to implementing good quality corrective and preventive action (CAPA). Addressing errors and understanding the human factors involved will provide benefits in the long term by preventing errors from occurring and ensuring safe laboratory practices and the provision of components of the correct quality and safety. Evidence from the reporting of errors can be used to ensure laboratories are provided with the correct resources, but laboratory managers and staff may need to identify innovative and novel ways of utilising their existing resources effectively.

The standard of transfusion knowledge and education within laboratories is becoming a prevalent source of error. There is anecdotal evidence that there is a national shortage of qualified BMS staff applying for vacant positions and vacancies are being filled with trainee staff that require Institute of Biomedical Science (IBMS) portfolio, HCPC registration and the IBMS specialist portfolio. This is compounded by a lack of suitably skilled BMS staff able to train these new staff due to the workloads within their laboratories. This issue of concern is, at the time of publication of this report, being discussed nationally at the National Blood Transfusion Committee.

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