7.

Errors Related to Laboratory Practice

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IBCT events originating in the hospital transfusion laboratory n=135

In 2011 a total of 135 IBCT cases were reported to SHOT in which the primary error occurred in the laboratory, which represents 55% of the total 247 IBCT cases. All IBCT cases have been summarised in the data summary table at the beginning of Chapter 6.

Overall laboratory errors account for 217 of the total 1815 cases (excluding near miss (NM) and right blood right patient (RBRP)) included in the 2011 Annual SHOT Report (12% of all reports). These consist of 135 IBCT events, which include 51 cases of special requirements not met, 20 anti-D Ig related events, 60 handling and storage errors and 2 I&U laboratory errors.

The increase in reporting to SHOT this year (from 1464 to 1815 reports excluding NM and RBRP) stands at 24% while the absolute increase in laboratory-based reports, from 205 to 217, is 5.85%

Table 7.1 Summary of laboratory-related errors n=217

Type of error	Number of cases in 2010	Number of cases in 2011
Wrong component transfused	**21**	**33**
Wrong sample selected	2	1
ABO grouping error	2	7
RhD grouping error	4	8
Incorrect component selected	11	15
Incorrect labelling	2	2
Wrong component selected for HSCT* patient	**15**	**9**
Wrong ABO group selected	9	5
Wrong RhD group selected	2	2
Procedural errors	4	2
Other pre-transfusion testing errors	**34**	**42**
Testing errors	8	8
Procedural errors	26	34
Special requirements not met (SRNM)	**37**	**51**
Due to failure to consult patient records thoroughly	18	28
Due to poor serological knowledge/ failure to recognise the special needs of a specific patient group	19	23
IBCT TOTAL	**107**	**135**
Anti-D Ig related laboratory errors	**45**	**20**
Handling and storage laboratory errors	**53**	**60**
I&U laboratory errors		**2**
GRAND TOTAL OF LABORATORY ERRORS	**205**	**217**

** Haemopoietic stem cell transplant*

Deaths
There were no transfusion-related deaths reported.

Major morbidity n=1
An 11 year old RhD negative girl was wrongly RhD grouped, was transfused with RhD positive units and developed anti-D as a result.

Potential for major morbidity n=6
There were 6 women of childbearing potential (from 5 reports) who produced anti-K as a result of failure to provide K negative units to this group of patients. Six babies were affected by haemolytic disease of the fetus and newborn (HDFN) due to new development of anti-D and are discussed in the Anti-D chapter (Chapter 12).

A group O RhD positive 70 year old patient suffered minor morbidity with rigors following transfusion of 50mL of group A RhD negative blood issued on the basis of a handwritten blood group on the request form and an immediate spin crossmatch.

ABO and RhD incompatibility

There has been an increase in the number of incompatible transfusions due to laboratory errors this year (6 cases – table 7.2) in comparison to 2010 (3 cases). There were 4 ABO-incompatible transfusions (3 red cells and 1 fresh frozen plasma (FFP)) and 2 cases in which RhD positive red cells were transfused to RhD negative females of childbearing potential. One of the ABO-incompatible transfusions was due to the wrong sample being tested resulting in 3 units of group AB RhD positive red cells being transfused to a group A RhD positive patient. The patient did not have a reaction. A further two cases were due to ABO grouping errors, one resulting in 50mL of group A RhD negative red cells being transfused to a group O RhD positive patient, the case of major morbidity, and the other resulting in 80mL of group B RhD positive red cells being transfused to a group O RhD positive patient who suffered no harm - see case studies 1-5 below. In one case group O FFP was transfused to a group B patient because of a component selection error. Again, the patient suffered no harm.

The cases in which RhD positive red cells were transfused to RhD negative females of childbearing potential followed a RhD typing error in one case, highlighted above, which resulted in the formation of immune anti-D, despite the administration of anti-D immunoglobulin once the error was realised. The second case followed a component selection error where RhD positive red cells were transfused to an RhD negative, 10 month old, female patient. In this case anti-D immunoglobulin was administered and no immune anti-D had been formed at the time of reporting.

Table 7.2 Summary of ABO and RhD incompatible transfusions n=6

Type/component	Patient group	Transfused	Reason	Outcome
ABO incompatibility/red cells	A RhD Positive	AB RhD Positive	Wrong sample used	No harm
ABO incompatibility/red cells	O RhD Positive	A RhD Negative	Testing error	Major morbidity
ABO incompatibility/red cells	O RhD Positive	B RhD Positive	Testing error	No harm
ABO incompatibility/FFP	B RhD Positive	O RhD Positive	Selection error	No harm
D incompatibility	D Negative	D Positive	Testing error	Anti-D formed
D incompatibility	D Negative	D Positive	Selection error	No harm to date

Wrong component transfused n=33

There has been an increase in this category this year with 24% (33/135) of laboratory errors resulting in wrong blood incidents compared to 19% (21/107) in 2010.

Table 7.3 illustrates the time and circumstances under which these wrong blood incidents took place.

Table 7.3 Summary representing when incidents occurred and their urgency

	In core hours	Out of core hours	Unknown
Emergency	4	1	1
Urgent	4	2	2
Routine	13	0	3
Unknown	2	1	0
Total	**23**	**4**	**6**

Unlike previous years, the error rate in core hours is greater than that out of core hours. The staff involved included 23 biomedical scientists (BMS) working in the transfusion laboratory during normal working hours, 5 BMS working out of hours who normally work in transfusion, 3 BMS working out of hours who do not normally work in transfusion and 8 cases where the information was not given.

Wrong sample selected n=1

Case 1

Wrong sample selected results in patient receiving an ABO-incompatible transfusion

Due to the wrong sample being selected for testing, a patient was typed as AB RhD positive and transfused 3 units of red cells. The patient's actual group was A RhD positive. The error was detected when a second group and save sample was processed at a later date. The patient suffered no harm.

The hospital involved in this incident did a root cause analysis that explained some mitigating factors:

The sample was treated as urgent so that the transfusion could be started on the same day. This resulted in a BMS processing the request over the poorly staffed lunch time period. The patient received a single unit that afternoon and returned for the other 2 units the next day. The error primarily related to failure to follow the sample checking process as directed by the standard operating procedure (SOP). This failure was probably a result of distractions, including interruptions from staff from other disciplines and phone calls.

A number of tested samples had been left out on the bench. If these had been stored immediately after testing the risk of selecting the wrong sample would have been removed.

Learning points

(taken from the root cause analysis (RCA) performed at the hospital)

- Sample identification is a critical point in the process and must always be ensured at every stage of laboratory testing.
- Define reasonable turnaround times for blood component provision and agree pathways to empower biomedical scientist (BMS) staff to negotiate unreasonable demands.
- Store samples immediately after testing is complete.
- Do not interrupt colleagues when in the middle of a process.
- Following an error of this nature request that the BMS does a piece of reflective writing on what went wrong.

No evaluation of the role automation could have played in mitigating this error was mentioned in either the root cause or corrective actions. The workload of the laboratory is not known.

A further example of samples being transposed in the laboratory was reported in the Anti-D chapter (Chapter 12) where maternal and cord samples were transposed. The ward noted the maternal grouping discrepancy and informed the laboratory but the error resulted in prophylactic anti-D Ig being administered late.

ABO grouping errors n=7

The numbers of ABO grouping errors have increased from 2 cases in 2010 to 7 cases in 2011. All errors involved manual steps that were performed incorrectly. Two ABO grouping errors resulted in ABO-incompatible red cell transfusions. In 5 cases the patient fortuitously received ABO compatible transfusions (4 red cells, 1 FFP).

Six cases involved BMS who normally work in blood transfusion, 3 working during core hours and 3 working outside core hours, and in one case this information was unknown. Four cases occurred during urgent situations. Four cases are discussed in detail below as they raise important learning points:

Case 2

Unacceptable pre-transfusion testing leads to ABO-incompatible transfusion

A patient had frank haematemesis and required 4 units of blood urgently. The ward was advised to send a new sample in order to provide group-specific blood. There were records in the laboratory for this patient who had been transfused one week previously. The doctor sent down the sample and request, giving the blood group as A RhD positive on the request form. The BMS felt rushed as there was a delay in this sample reaching the laboratory. A group A RhD negative unit was 'crossmatched' by 'immediate spin', the result seen as 'compatible' and the unit issued manually using an emergency compatibility tag. Following issue of the blood standard testing for group and an antibody screen was set up - the patient's blood group was found to be O RhD positive, not A RhD positive as written by the doctor on the request form. The blood bank rang the ward immediately and the transfusion was stopped. The patient had received approximately 30mL of red cells and was reported to have experienced rigors.

Learning points

This case highlights the need to adhere to some very important principles, when providing blood in emergency situations. These are made clear in the British Committee for Standards in Haematology (BCSH) Guidelines for compatibility procedures in Blood Transfusion laboratories[36 37]:

- The ABO and RhD group must, wherever possible, be verified against previous results for the patient.
- Emergency groups performed in these circumstances MUST include a test against anti-A, anti-B and anti-D with appropriate controls or a reverse group.
- If there is insufficient time to complete this level of testing group O red cells MUST be issued.

Case 3

Manual transcription error and failure to heed IT alert leads to ABO-incompatible transfusion

A previously unknown oncology patient grouped as O RhD positive but with no anti-B. This group was entered manually on to the laboratory information management system (LIMS) as group B with no anti-B but this result was not authorised. Blood, group B RhD positive, was reserved for the crossmatch prior to the grouping results being authorised. The crossmatch was serologically compatible (as there was no anti-B) and the blood was issued. The BMS issuing the blood overrode the IT alerts which indicated that the group had not yet been authorised. The patient received 80mL of ABO-incompatible red cells before the error was noticed and the transfusion was stopped. There was no transfusion reaction.

Learning points

- British Committee for Standards in Haematology (BCSH) guidelines for compatibility procedures[37] in Blood Transfusion laboratories state: If it is not possible to obtain a reliable reverse grouping result and there is no historical group against which to validate, the cell group must be repeated.
- Red cells, other than group O, should not be issued to a patient until the blood group for that patient has been authorised.
- Short cuts lead to errors. Process, as laid down in standard operating procedures (SOPs), must be followed. This is a primary principle of good manufacturing practice (GMP).

Case 4

Manual transcription leads to a blood group error and the failure to capture the error on that sample

A request for blood was received from the medical admissions unit (MAU). The crossmatch request was urgent. No diagnosis was reported but the national indicator code reported was 'R7 Chronic Anaemia'. There was no previous group on the LIMS. A group and screen and crossmatch were requested on the LIMS and the sample was centrifuged and placed on the analyser for testing. Due to clinical pressure, and trying to ensure that the patient received the blood quickly, once the group had been completed on the analyser these results were manually entered onto the LIMS. The results were entered incorrectly as O RhD positive when they were B RhD positive. Group O red cells were then selected for crossmatch and issued as compatible. The group and screen was completed on the analyser but because the group results were already on the LIMS they were not overwritten. The error was discovered one month later when a repeat sample was tested.

Failure to follow an SOP can lead to one error but, as in this case, also lead to failure of 'alert' systems that would be available if the process was correctly followed.

Case 5

Incorrect blood group result obtained by manual tube group

A patient presented with multiple injuries and was initially grouped by tube technique as O RhD positive. Based on this blood group 4 units of group O RhD negative red cells, 10 group O RhD positive red cells, 4 group AB FFP, 8 group A FFP, 3 group A platelets and 2 group A cryoprecipitate pools were transfused urgently. The patient was later found to be group AB RhD positive.

Investigation into this incident found no written record of the results of the tube group or second check by the Senior BMS as per SOP. The corrective action has been that staff have been reminded not to rush or cut corners and to follow SOPs.

Learning points (Good Practice Points)

- Transfusion laboratories should have standard operating procedures (SOPs) for abbreviated pre-transfusion testing for provision of blood in emergencies.
- Transfusion laboratories should have SOPs for provision of blood following complete testing with published urgent and routine turnaround times.
- Blood should be made available using one of these SOPs and short cuts to any SOP must not be taken.
- If blood cannot be provided in the time taken to follow one of these SOPs then group O blood should be issued.

In the 3 other cases it is unclear how the ABO error occurred although in all 3 cases the incorrect group was manually entered into the LIMS. Two of these cases were during routine provision of blood, one in a pre-op case and one in a dialysis patient, the other involved provision of blood to a neonate.

D grouping errors n=8

There were 8 errors in RhD typing reported. One case involved an old error which could not be investigated, two cases are discussed below. The other 5 errors were either misreading or transcription errors during recording of manual groups into the LIMS.

- Four occurred in an urgent setting and 4 in routine work
- Four occurred in core hours and 4 out of hours
- Out of hours 2/4 BMS usually worked in transfusion and 2 did not
- In 6/8 cases RhD negative patients were transfused with RhD positive red cells
- In 2/8 cases RhD positive patients were transfused with RhD negative blood
- In one case an 11 year old female went on to produce anti-D, case 6 below
- The 7 other cases involved patients who were females >60 year of age (4 cases) or males (3 cases)
- Three of these recipients also produced antibodies: anti-D+C, anti-D+E and anti-D+C+E respectively

Case 6

Female of childbearing potential develops anti-D as a result of a RhD grouping error

2 x 2mL samples were received for group and crossmatch of one unit of red cells for this 11 year old girl (one 5mL sample should have been sent). One sample was placed on the automated analyser but was too small to allow complete testing. (The partial grouping results obtained from the analyser gave the RhD type as RhD negative but these results were not taken into consideration by the BMS.) The sample was then tested manually. Positive RhD typing results of +1 and +2 were obtained which, according to the laboratory SOP, should have instigated further testing but this was not done. No explanation was given in the report as to how/why these 'false' positive results were obtained. One unit of RhD positive red cells was transfused. The error was noticed when a second unit was requested. The patient was immediately treated with high dose IV anti-D immunoglobulin but has since produced immune anti-D.

Learning points

- Acceptance and testing of 'small' samples increases risk as staff revert to manual methods which are more prone to error.
- When weak RhD typing results are obtained appropriate further testing must be undertaken to confirm the RhD status. Until this is completed RhD negative components should be issued.
- Before issuing components all results obtained must be reviewed and any anomalies explained.

Case 7

D grouping error due to misinterpretation of 'mixed field' reaction.

A patient was admitted with a gastrointestinal (GI) bleed and required transfusion. The patient was grouped as O RhD positive and transfused O RhD positive red cells. On routine testing the following day the analyser detected a dual population of cells when testing with anti-D but the patient's group was concluded and reported by staff as O RhD positive without any investigation into the reason for the 'mixed field' result in the RhD type. Later in the year the patient was admitted for transfusion, following a further GI bleed. Group and screen tests confirmed that the patient was O RhD negative and now had anti-C+D+E. It transpired that the presence of RhD positive cells resulted from a recent transfusion the patient had received in Portugal.

Learning points

- Clinical history must always be sought to explain 'mixed field' reactions. This error mirrors a number of interpretation errors made during UK National External Quality Assessment Scheme Blood Transfusion Laboratory Practice (UKNEQAS BTLP) exercises.
- RhD negative components should be given until the history can be ascertained.

A further 4 RhD typing errors were reported in the Anti-D chapter (Chapter 12). In 2 cases maternal blood was erroneously typed and in two cases the baby was erroneously typed. All 4 errors involved manual interventions. In one of the cases an equivocal result was deemed to be positive when it should have been treated as negative. These errors resulted in unnecessary anti-D Ig being given on 2 occasions, failure to give anti-D Ig once and anti-D Ig being given late once.

For all errors associated with anti-D immunoglobulin see Chapter 12.

Incorrect component selected n=15

In 15 cases the incorrect component was selected, 8 of these involved red cells. One case resulted in an RhD-incompatible transfusion when an RhD negative female neonate was transfused RhD positive red cells. Five cases where RhD positive red cells were given to RhD negative male patients, 2 of whom were paediatric haematology patients, 12 and 15 years of age and one who was a male transfusion-dependent renal patient. The final case was due to insufficient training for the NHSBT's Online Blood Ordering System (OBOS) whereby 4 units of large irradiated neonatal red cells were ordered and transfused to 2 adults.

In 2 cases cryoprecipitate was issued when FFP was requested and in 2 further cases cryo-depleted FFP was issued when FFP was required. In one case group O FFP was issued to a group B patient.

Two cases involved platelets. In one case RhD positive platelets were ordered for one patient but issued to an RhD negative patient in error and transfused. In the second case O RhD positive platelets were issued to an A RhD positive patient in error. In both cases alerts on the LIMS were not fully appreciated by the BMS or acted on in the appropriate way.

Incorrect labelling n=2

2 cases were reported as a result of incorrect labelling, both of which involved labels being transposed so that blood components were labelled for a patient for whom they were not intended (1 red cell and 1 platelet). The bedside checks did not pick up the discrepancy between the component number on the unit and the component number on the compatibility label. No adverse reactions were reported. Further cases involving mislabelling components are reported under Near Miss (Chapter 25) and under Right Blood Right Patient (RBRP) (Chapter 10).

COMMENTARY on wrong component transfused incidents

The number of laboratory errors contributing to wrong blood events has increased this year. Overall there was an increase in the number of ABO and RhD grouping errors, from a total of 7 cases (33% - 7/21) reported in 2010 to 16 cases (48% - 16/33) in 2011. There was a concomitant increase in ABO and D-incompatible transfusions, 6 cases, compared to 3 cases in 2010.

Table 7.5
Trends in laboratory based ABO grouping errors, with causes

		Causes of ABO grouping errors			Outcomes of ABO grouping errors	
Year	Total ABO grouping errors	Wrong sample tested	Interpretation / transcription errors	Other	ABO incompatible red cell transfusions	Sequelae
2011	8	1	6	1 poor process	4	1 rigors
2010	3	1	1	1	1	No morbidity
2009	7	2	5	0	2	1 AHTR*
2008	8	3	5	0	4	1 AHTR
2007	7	3	4	0	1	No morbidity
2006	6	2	3	1	0	No morbidity
2005	22	9	12	1	3	1 AHTR
2004	18	5	12	1	6	1 death 1 major morbidity
2003	17	8	9	0	6	2 major morbidity

** Acute haemolytic transfusion reaction (AHTR)*

Table 7.6 Trends in laboratory based RhD grouping errors with causes (including those reported in the anti-D Chapter 12)

		Causes of RhD grouping errors			Outcomes of RhD grouping errors	
Year	Total RhD grouping errors	Wrong sample tested	Interpretation / transcription errors	Other	Transfusion of RhD positive to RhD negative individual	Sequelae
2011	13	1	10 (1 weak D)	1 testing error 1 old error not investigated	6	1 11 year old female produced anti-D 3 other patients produced anti-D but were not of childbearing potential
2010	11	0	11 (3 weak D)	0	2	1 patient produced anti-D but was not of childbearing potential
2009	5	1	4	0	2	No morbidity
2008	11	0	11	0	10	3 patients produced anti-D but none were of childbearing potential
2007	4	1	3	0	3 (1 x 33 year old female)	No morbidity

All the **ABO and RhD typing errors** reported occurred whilst carrying out manual interventions. No errors occurred during ABO and RhD typing where full automation was used. As manual testing is more error prone, and therefore more high risk, manual testing should only be used when the clinical situation demands because of the requirement for speed. If the workload in the laboratory does not warrant automation then all reasonable measures must be taken to mitigate laboratory errors as stated in the recommendations of the UK Transfusion Laboratory Collaborative (UKTLC)[23]. Where possible this should include checks of the critical steps by a second person when manual methods are employed.

When performing manual tests the SOP must be followed. This is an important principle of good manufacturing practice (GMP). If there is not time for this then group O blood should be issued. If there is any doubt regarding the RhD type then RhD negative blood should be issued, particularly to females of childbearing potential and those who are transfusion dependent, until absolutely certain of the RhD group.

A number of cases provide useful learning points this year and these have been highlighted following the case studies. The SHOT team hope that these case studies will provide a useful tool for use as examples in teaching and knowledge based competency-assessment.

This year, in both cases that resulted in patient morbidity, BMS staff failed to follow procedure but also failed to consider all the information and/or results available to them. This should have alerted staff to discrepancies and prevented the errors.

Learning points

- Before issuing blood components ensure that all available history and current results have been taken into consideration.
- Group O blood should be issued if there is insufficient time for abbreviated testing to be performed to the level recommended in the British Committee for Standards in Haematology (BCSH) guidelines[36 37].
- Assessing clinical urgency: transfusion laboratory staff are constantly put under pressure to provide components urgently which can lead to short cuts being taken increasing the risk of error. Biomedical scientists (BMS) require knowledge and experience to be able to question clinicians and make robust judgements on appropriate pre-transfusion testing, balancing the risks of delaying the issue of blood against safe pre-transfusion testing practice. To make this judgement they must be aware of the risks. There is a requirement for annual training in GMP. Integral to GMP is the requirement to follow standard operating procedures (SOPs) - 'Say what you do and do what you say'. GMP training could cover the risks of not following SOPs, particularly taking short cuts, and these SHOT case studies provide examples of what can go wrong and the consequences.

Errors in component selection continue to occur. The cases involving red cells and platelets are largely incorrect selection of RhD positive units for RhD negative patients. Some LIMS did not appear to have warnings and corrective actions suggested by reporters included improvements to LIMS alerts. Other LIMS systems had warnings that were overridden. Heavy workload and distractions were cited as contributory factors in some cases, lack of knowledge by BMS staff was an issue in a couple of cases whilst no explanations could be found for other errors.

The cases involving plasma are largely due to selection of the wrong component. BMS staff must read the label on frozen components to ensure the right component is being used. It would be helpful if the LIMS alerted when one component had been requested and a different one reserved for a patient.

When analysing this data errors in component labelling do not appear to be an issue, however, when the data from the Near Miss chapter (Chapter 25) are analysed it can be seen that there is a significant number of labelling errors within the transfusion laboratory which are 'caught' at the bedside checking stage. Laboratories must analyse local component labelling errors and take suitable corrective action if required.

Learning points

- Ensure that biomedical scientist (BMS) staff understand when it is appropriate to issue RhD positive components to RhD negative recipients and when it is not, including different selections for patients who are transfusion dependent.
- Ensure appropriate laboratory information management system (LIMS) alerts are in use where available.
- Request appropriate action from LIMS suppliers if useful alerts are not available on the LIMS.
- When issuing components read the component label.

Wrong ABO or RhD type blood components issued for haemopoietic stem cell transplant (HSCT) recipients n=9

This year the errors from these cases are discussed in the section on pre-transfusion testing.

The number of reports received in this section has decreased this year. In 2009 there were 13 cases reported, 15 cases in 2010 and 9 cases this year. All cases, as in previous years, were routine transfusions. Two of the cases were in paediatric patients (9 and 15 years of age) and the rest were in adults. Four of the cases occurred during normal working hours, 1 outside normal working hours and in 3 cases this information was not provided.

Out of the 9 cases, 5 resulted in errors in selection of ABO group components (3 red cells, one FFP and one platelets) and two involved errors in selection of RhD components. In one case cytomegalovirus (CMV) negative components were not given when required and in the final case the correct red cells had been given but had been electronically issued when an indirect antiglobulin test (IAT) crossmatch should have been performed.

Other pre-transfusion errors n=111

In previous SHOT reports pre-transfusion testing errors that have resulted in IBCT errors (including those related to HSCT patients and SRNM) or anti-D Ig related errors have been analysed separately. This year the decision has been made to analyse them in one section as the primary errors are similar in many cases. The classifications of 'testing errors' and 'procedural errors' in table 7.1 at the beginning of this chapter only include errors related to IBCT cases to enable trending from previous years. The discussion that follows is based on primary errors of 111 laboratory errors from all other chapters.

Errors have been divided into:

- **Testing errors**, i.e. the correct tests were performed but incorrect results were obtained due to: wrong patient sample being tested, poor performance of the test, a transcription error or incorrect interpretation of the results.
- **Procedural errors**, e.g. testing unsuitable samples, failure to find historic records, missing vital information on request forms, failure to maintain correct warnings, failure to heed warnings, incorrect test selection, failure to follow procedure, failure to select a component of the correct specification.

Testing errors n=16 (8 IBCT and 8 anti-D)

Wrong sample n=3

Three cases where although the correct sample had been used for determining the ABO group the crossmatch was performed against the wrong sample resulting in units being issued that had not been crossmatched.

Transcription errors during crossmatch n=3

There were 3 examples of transcription errors when putting crossmatch results into the LIMS, either from an analyser or following manual crossmatching. These errors all resulted in incompatible units being issued.

Antibody screening error n=1

One case where manual testing took place because of a power failure and retrospective, automated testing showed that an anti-K had been missed. The patient had been transfused 3 units of red cells by the time the error was detected. Fortuitously these units were confirmed as K negative.

Interpretation error n=9

- A crossmatch was performed in which the control well was positive; this should have invalidated all test results. However not all tests were repeated.
- There were 8 errors in interpretation of antibody identification from the Anti-D chapter this year (Chapter 12). These were all cases of misinterpretation of the antibody as prophylactic anti-D when in fact in 7 cases there was no record of anti-D Ig having been administered and in one case follow up tests should have been performed but were not. In one case a reference laboratory had already reported an immune anti-D. Misinterpretation of anti-D meant that appropriate monitoring of the at-risk fetus was not performed. One fetus required an emergency intrauterine transfusion (IUT), two neonates required top up transfusions positive delivery, three babies were born with symptoms of HDFN, but did not require transfusion, and two babies were unaffected.

COMMENTARY

The main causes of error in this section are selection of the wrong sample and ‘careless’ transcription errors during manual data input. The test methodology and reagents appear to be robust as very few errors of this nature are reported. This year there have been 8 reports of incorrect antibody interpretation through the anti-D related error questionnaires which have had serious consequences.

Learning point

- It is essential that every hospital transfusion laboratory performing antenatal screening for blood group serology understands the importance of ensuring that all relevant history is obtained before interpreting whether the presence of anti-D antibodies may be a result of prophylaxis or immune. Further samples for follow up tests must be requested and tested appropriately.

Procedural errors n=95 (9 HSCT, 34 IBCT pre-transfusion testing errors, 51 SRNM errors and 1 anti-D)

This is the single biggest group of errors and they are many and varied, showing the multiple steps within the laboratory transfusion process that can go wrong.

Testing unsuitable samples n=16

In some laboratories the check of sample suitability is made by the staff and in others by a computer algorithm. In the majority of reports there has been a 'slip' by the BMS involved whilst in 3 reports there has been a lack of understanding on the part of the BMS as to the sample 'suitability' requirements. In one report the patient had been transfused at another hospital and the laboratory was not informed of this.

Learning point

- Computer prompts/warnings/flags are a valuable tool for trying to prevent human error through 'slips' but staff must also have the underpinning knowledge to understand and act appropriately to a warning.

Failure to find historic records n=10, (3 IBCT, 6 SRNM and 1 anti-D)

Relevant historic records were not found on 10 occasions. In 7 cases the search for a historic record on the LIMS was not properly carried out so that duplicate records were missed. In 3 cases there were IT issues that contributed to the failure to find historic records. Some examples are given below to highlight some pitfalls when searching for historic records and the ensuing risk from failing to find records:

- In one case a BMS searched on sample records, not patient records, entered an incorrect sample number and failed to find the history. This appeared to be the laboratory policy. As a result an unsuitable sample (too old) was used to issue blood.
- Six cases where duplicate records were present for a given patient, but were not found for various reasons, resulting in missed antibody history or missed special requirements:
- A BMS in another pathology discipline created a new record for a patient, which did not include the patient's antibody history of anti-Jk^a, resulting in the patient receiving 3 units of red cells which had not been typed for the Jk^a antigen.
- A patient was transferred from another hospital and a sample was received and processed, blood requested and issued. Only after the units had been transfused did the ward notify the laboratory that the patient had sickle cell disease (SCD). The transfused units were not Rh matched or HbS negative. It transpired that the patient did have historic records on the LIMS that gave the diagnosis and special requirements but these had not been found due to a name change and the manner in which the LIMS was set up in 2004. The records were not linked and the requirements were omitted from all later samples.
- In 4 further cases the failure to search the LIMS database properly resulted in:

– a patient with anti-Jk^a receiving units that had not been phenotyped for Jk^a;

– a patient with a history of a positive direct antiglobulin test (DAT), an auto-anti-M and non-specific IAT antibodies having blood electronically issued;

– failure to provide irradiated blood to a patient who required irradiation;

– failure to give anti-D Ig to a woman who was a known RhD variant. She had typed as RhD positive but previous history was available but not found.

- In 3 cases 'issues' with the LIMS, or access to it, meant that historic records were missed:

– In one case blood was required when IT systems were down and blood was issued without checking the historic, paper antibody record. This stated that the patient had an anti-E. Fortuitously E negative units were issued.

– In a second case the cause of the failure to find historic records was that the BMS had not kept his computer software access rights up to date. This resulted in the BMS being unable to look at the 'hospital patient master index'. Secondary to this was a fault on a particular PC within the laboratory which could have been worked around by going to another PC in the area (4 others available). The patient had an anti-Fy^a in 2002. The units issued were not phenotyped for Fy^a.

– In the third case a record was missed because of a 'glitch' in pulling patient records from an old LIMS database into a new one. This case is further described in the IT chapter (Chapter 8) and exemplifies the need for thorough validation of all scenarios.

Learning points

- Transfusion laboratories must have a robust search protocol in place to identify previous patient history, prior to booking in samples, taking into account the fact that duplicate hospital numbers DO exist and name changes WILL occur.
- Maintaining an accurate patient database is a critical safety measure in the safe treatment of patients.

Failure to notice information on the request form n=11 (1 HSCT, 1 IBCT and 9 SRNM)

- In one case the BMS failed to notice the antibody history noted on the request form.
- In 7 cases laboratory staff failed to notice a special requirement ticked on the request form. This appeared to be the primary method for alerting the laboratory to the need for the special requirement.
- In 3 further cases the need for a special requirement, ticked on the request form, was missed by the laboratory but this was not the primary method of informing the laboratory of special requirements, meaning that clinicians were also at fault in these cases.

These errors resulted in 6 cases of failure to give irradiated components, 2 cases of failure to give CMV negative components and 1 case of failure to give irradiated and CMV negative components, when required.

Learning points

- Hospital Transfusion Teams (HTTs) should perform a local risk assessment on the way in which the transfusion laboratory is informed by clinicians of either special requirements, or previous history provided by patients direct to clinicians. For example, having a robust process to inform the laboratory when treatment on purine analogues starts, rather than when blood is requested, has merit.
- If 'tick boxes' on request forms are used they should stand out.

Warning flags not entered accurately or kept up-to-date correctly n=13 (3 HSCT and 10 IBCT and SRNM)

As a result:

- In 2 cases HSCT patients received components of the incorrect ABO group (1 red cell and 1 FFP) and in 1 case red cells of the incorrect RhD type.
- In 4 of these 13 cases the patients received red cells of the wrong phenotype: in 2 cases information from red cell reference laboratories was inaccurately entered onto patient's notes. In one case the 'flag' for a patient with beta thalassaemia was not activated and in another case a flag blocking 'remote' issue of blood for a patient with SCD was not activated. This latter case resulted in the patient receiving blood not only of the incorrect Rh phenotype but also blood that was not HbS negative.
- Three cases where electronic issue (EI) was used inappropriately following manual edits of grouping results. The LIMS in use could not identify the edited results as part of the EI algorithm so the BMS should have added the patients to the EI exclusion list. This had not been done.
- One case where blood was issued by an 'immediate spin' technique despite the patient having an antibody. The antibody status had not been properly recorded in the LIMS so that an automatic flag did not alert the BMS. Fortunately the units selected lacked the required antigen.

- In one case a patient flag was added to the LIMS stating the temporary requirement for irradiated components but on subsequent requests the patient flag did not appear on the request entry screen, or the search screen and the patient received non-irradiated components. Six weeks later laboratory staff became aware of this issue and reported it to the LIMS supplier who could find no explanation.
- One case where the 'special requirement' flag was removed from the LIMS in error when the patient was on bendamustine. From the time the flag was removed to the time this error was discovered the patient had received 15 units of red cells and 5 units of platelets that were not irradiated.

Learning points

Addition of notes and activation of warning flags is another point of manual entry in the transfusion process therefore:

- As with any process the competence of the staff performing this task must be assessed.
- As with other manual interventions one person should perform the task and a second person check that it has been completed correctly.
- The use of 'checklists' may be helpful to ensure that all parts of the process have been completed.
- Use of Electronic Data Interchange (EDI) should be explored where possible e.g. Blood Service to Hospital Transfusion Laboratory.

Warning flags not heeded n=13 (3 HSCT, 10 IBCT and SRNM)

In 13 cases warning flags were missed. These errors lead to 2 HSCT patients receiving red cells of an incorrect ABO group, 1 HSCT patient receiving blood of the incorrect RhD group, 3 patients failing to receive irradiated red cells, 3 patients failing to receive CMV negative red cells, 1 patient failing to receive CMV negative, irradiated red cells, 2 females of childbearing potential receiving K positive red cells and 1 patient with SCD receiving E positive red cells when he was E negative.

They all seemed to be 'slips' on the part of the BMS and mitigating circumstances were cited in some cases e.g. distractions, multiple notes, remembering special requirements from the previous day and not realising more had been added, too many warnings leading to a tendency to push 'escape' perhaps because of the urgency of the case. Some reporters felt that the warning flags on the LIMS were not as good as they could be.

Cases in which blood components were issued following failures to follow the laboratory SOP n=24 (2 HSCT, 8 IBCT, 14 SRNM).

The causes were: incomplete pre-transfusion testing, wrong test selection, failure to select a blood component of the correct specification.

- One case where a patient had not received a HSCT, as recorded on the LIMS, but had received platelets of a group which would have been correct based on the group of the transplant donor.
- Two cases where blood was issued without an antibody panel, following a positive antibody screen, fortuitously antigen negative units were issued on both occasions.
- One case where, following a positive antibody screen, the antibody identification was not authorised because the control kept failing and the sample ran out. Although a repeat sample was requested it did not arrive before the patient's surgery. The panel results showed a clear anti-Jk^{a} in the patient sample despite the failure of the control. The patient went for a caesarean section, bled and was transfused 2 units of emergency O RhD negative blood which was later confirmed to be Jk^{a} positive.
- One case where the antibody status of the mother was not checked prior to issue of blood to a neonate. One unit had been transfused when a sample was requested from mother and found to contain no irregular red cell antibodies.

- Two cases where electronic issue was performed incorrectly: in one case blood was issued to a neonate whose mother had anti-D and the BMS did not seem to realise that an IAT crossmatch was required. The second case was inappropriate as the patient had undergone a HSCT.
- One case where a unit of blood was released and transfused before the compatibility testing had been completed due to the electronic release system being off line. This case is discussed further in the IT chapter (Chapter 8).

In 8 cases the incorrect phenotype of red cells was selected. There were a variety of root causes for these errors from 'slips' to lack of understanding of the need for phenotyped units. The 'slips' included:

- 4 cases of failure to provide K negative units to women of childbearing potential.
- One case where the patient was known to have anti-Fy^{a} but the BMS, who intended to select a Fy^{a} negative red cell, selected a Jk^{a} negative unit in error. As the antibody was no longer detectable the crossmatch was compatible.
- An interesting case where two crossmatches were performed by a reference laboratory for patients who had multiple antibodies. On both occasions, red cell units were issued as least incompatible. As the presence of low incidence antibodies could not be excluded, the routine practice was to type the units for the relevant low incidence antigens to the antibodies that could not be excluded during the investigation. This typing did not take place. On discovery of the error, the red cell suspensions from the crossmatches were retrospectively low incidence antigen typed and all units were found to be negative for Kp^{a}, Lu^{a} and Wr^{a}.
- In two cases the BMS's lack of knowledge was the reason why antigen typed units were not selected for patients who had clinically significant antibodies on file but which were not detectable in the current sample. Case 10 is described in some detail below as it highlights some important issues in terms of transfer of knowledge into practice and communication in the setting of multidisciplinary out of hours work.

In 5 cases there was failure to supply CMV negative units when required.

In 3 cases there was failure to supply methylene blue (MB) treated FFP when required.

Where these special requirements were not met (5+3 cases above) the reporters thought the errors were a result of 'slips' by the BMS in 6/8 cases. The BMS knew and understood the need for the requirement but forgot to provide it. There was no evidence that there were LIMS prompts in place to remind the BMS of the need for the special requirement in any of these cases. For the remaining 2/8, in one case there was no explanation for the error and in the other a paediatric patient did not receive MB treated FFP because the BMS was unaware of this product, only being aware of neonatal MB-FFP and adult FFP.

Learning points

- The laboratory information management system (LIMS) should be used as much as possible to help prevent 'slips' by biomedical scientists (BMS). There are many rules to remember during component selection so that a timely prompt based on, for example, the age and/or sex of a patient can be very helpful.

Case 8

A combination of uncertain understanding, unclear communication and a busy night contribute to an erroneous transfusion

A patient was admitted with a two day history of melaena, with symptomatic anaemia with haemoglobin of 5.4 g/dL. Four units of blood were requested. The multidisciplinary BMS on call (his discipline being biochemistry) was having a busy evening. He looked up the patient history and found a historic record of anti-c+E+S. The BMS understood the need for appropriately crossmatched, antigen-negative blood and believed that this would have to be provided from the blood service. He understood that this would take some time and phoned the ward to ask for two more samples for dispatch to the blood service.

The BMS telephoned the blood service to inform them that samples were being sent. The staff at the reference laboratory asked the BMS to screen the sample and let them know the result. The BMS's recollection of this conversation left him with the impression that the staff at the reference laboratory were 'leaving it with him'. He proceeded to screen the blood for antibodies.
The doctor then phoned the BMS to inform him that the patient's blood pressure was falling and to enquire 'what the backup scenario was'. The BMS informed him that he could crossmatch the blood and issue the most compatible if that was required. He understood that this proposal was accepted by the doctor. The BMS completed the antibody screen and crossmatched the blood. As there were no reactions he issued the four units of red cells.
The reference laboratory staff then called the BMS to check the results of the screening test as they had not heard back from him. They advised that the issued units should be recalled and that they would send 4 units of antigen negative blood. The BMS phoned the ward but did not recall the units. He started to crossmatch the antigen negative blood received from the blood service but ran in to problems with the analyser. He telephoned a colleague at another hospital and was advised not to attempt to fix the analyser but to revert to manual crossmatching. The BMS was not familiar with this process. Nonetheless he found the relevant SOP and tried to proceed with the crossmatch. He then found that the pipette was not working and that there was a reagent problem. He therefore reverted to trying to fix the analyser and reported being increasingly worried and tired and probably increasingly unable to think clearly.
When the day shift took over the units were immediately recalled but 2 units had been transfused. No reaction was reported.

A very comprehensive, local, root cause analysis was undertaken following this incident which raised important issues, a number of which related to multidisciplinary training for out of hours working. The requirement for senior management to take training and competency-assessment of BMS seriously across all their roles was highlighted. The reporters have offered to share this RCA and it can be found on the website under SHOT Annual Reports and Summaries/Report and Summary 2011.

Learning points

- Clear communication is vital, both inter laboratory communication (hospital laboratory staff to reference laboratory staff) and laboratory staff to clinician. Strong theoretical knowledge is required to be able to communicate effectively.
- Regular practice and competency-assessment of infrequently-used manual techniques is important. This means that multidisciplinary staff MUST have regular, high quality training rotations into blood transfusion. UK Transfusion Laboratory Collaborative (UKTLC) guidelines recommend the equivalent of 10 working days per annum supervised working in a hospital blood transfusion laboratory[23].
- At annual appraisal of multidisciplinary biomedical scientists (BMS) the training and competence for work performed 'out of hours' must be assessed as well as their 'primary' role. Effective avenues of line management need to be in place for the full range of duties undertaken by a BMS.
- A formal backup system must be in place that can be accessed should an 'out of hours' lone worker get into difficulty. The means of accessing this advice should be clear and simple.

Unacceptable process - using staff not trained for the level of activity n=2

There were 2 cases where transfusion laboratories relied on medical laboratory assistant (MLA) staff to alert the BMS staff to the need for special requirements.

Case 9
Misunderstanding of instruction by reception staff
A request was received for 6 units of blood for a patient transferred from another hospital. There was a special note in the LIMS stating that CMV negative, irradiated blood should be crossmatched. This was missed by laboratory reception staff, therefore not passed onto the BMS performing the test, and the patient did not receive the correct component.

Case 10

Another misunderstanding by reception staff

Irradiated blood was requested for a patient and written onto the request form but this was missed by the MLA booking in the request. At the time, request forms were not allowed on the crossmatch bench so the BMS was unaware of the need for irradiated blood and issued non-irradiated blood to the patient.

Learning point

- The qualified biomedical scientists (BMS) crossmatching red cells or issuing components must take responsibility for checking all the relevant history on a patient to ensure that they issue components of the correct specification.

Errors in recall of blood components n=2

There were 2 errors in laboratory recall procedures reported this year:

The introduction of extended life platelets by the NHSBT led to a number of platelet recalls. During one day when there was a large number of such recalls, the courier selected the wrong unit from the ward agitator for return. The implicated unit was subsequently transfused. The patient was not affected and NHSBT confirmed that this was a precautionary recall and no further action was required.

The laboratory received a request for non-irradiated components and issued 3 units. The patient informed clinical staff that irradiated components were necessary. 3 units of irradiated red cells were obtained and issued but the laboratory failed to recall the non-irradiated red cells in a timely fashion. There was a shift change on the ward and a nurse collected a non-irradiated red cell unit and administered it to the patient.

Miscellaneous cases n=4:

- The NHSBT sent out a unit that was not negative for the antigen that had been requested. The MLA entered the phenotype incorrectly onto the LIMS and the BMS did not check the phenotype before issuing the red cell unit.
- Failure by a hospital laboratory to irradiate a unit of platelets.
- The late issue of a revised policy lead to 2 patients receiving K positive blood when they should have been given K negative units. The patients involved were over 50 years of age.
- A paediatric platelet pack number 4 was physically issued but on the LIMS pack 1 was issued. Pack 1 was still in the platelet incubator.

Table 7.7
Special requirements not met because of failure to consult patient records thoroughly

Failure to	No. of cases 2010	No. of cases 2011
Failure to provide irradiated components	9	16
Failure to provide CMV negative components	4	11
Failure to provide CMV negative and irradiated components	3	2
Failure to provide human leucocyte antigen (HLA) matched platelets	1	0
Failure to provide human platelet antigen (HPA) matched platelets	1	0
TOTAL	**18**	**29***

** includes one HSCT patient who did not receive CMV negative components*

COMMENTARY on pre-transfusion testing

The search for a historic patient record is an integral part of the group and antibody screen procedure and must be performed according to a robust SOP.

Hospitals must ensure that there is a robust local protocol in place for informing the laboratory of the need for special requirements. Errors in this process continue to occur despite consecutive SHOT reports highlighting this process as an area of weakness in the transfusion pathway. Disappointingly

the number of cases of failure to supply components with the required specification has increased this year (29 cases compared to 18 last year).

The issues with regard to computer warning flags, their maintenance and use, are discussed in the IT chapter (Chapter 8).

Most of the errors in this section appear to be 'slips'. Heavy workload and distractions were cited as mitigating circumstances in a number of cases.

Errors which appear to demonstrate a lack of knowledge by the BMS staff are:

- Cases where identification panels have not been run, despite a positive antibody screen, because the antibody is already known. This demonstrates failure to appreciate that a second antibody might have developed.
- Cases where antigen-negative units have not been selected, despite a history of clinically significant antibodies, on the basis of the current antibody screen being negative. Antigen-negative units are still required in these cases to prevent a delayed haemolytic reaction resulting from a possible anamnestic response.

In order to try and prevent 'slips', warnings/flags/alerts in the LIMS can be helpful and should be in use where possible, whilst trying to avoid unnecessary messages that may lead to 'warning' overload. The requirement to have to positively confirm, in the LIMS, that a component carries the special requirement would be a useful tool in any LIMS upgrade. Some warnings are built into the system as 'logic' rules and must be validated thoroughly when added to the LIMS, other warnings are patient-specific. The addition of these warnings/flags/notes is a manual procedure and is itself prone to error and should be controlled, for example, entered by one BMS and checked by a second.

Learning points

- Distractions must be kept to a minimum.
- Competency-assessment of biomedical scientists (BMS) staff must include pre-transfusion testing and provision of red cells for patients with antibodies, historic and/or current. UK National External Quality Assessment Service for Blood Transfusion Laboratory Practice (UK NEQAS BTLP) are trialling a competency-assessment scheme in the near future which may prove helpful in this area.
- Competency-assessment must include understanding and knowledge as well as simply the ability to perform a standard operating procedure (SOP). An SOP cannot cover every scenario and the ability to apply knowledge and recognise personal limitations are essential requirements of a qualified BMS.
- A common theme running through this report is the failure of BMS staff to take into account all relevant data i.e. patient history, all results including discrepant results, maternal history when providing blood for neonates and this failure has contributed to all cases of morbidity.

Cross reference cases for I&U

There were two interesting cases this year reported in the I&U chapter (Chapter 9), which highlight emerging issues for laboratories and safe, rapid blood provision.

I&U Case 9 (Chapter 9) - There was a delay in the provision of red cells to a bleeding patient due to a 'mixed field' result not allowing 'electronic release' of blood components. The blood was crossmatched at the hub laboratory and couriered to the site. The delay resulted because the laboratory staff member did not realise why the blood could not be electronically released. Emergency O RhD negative blood was available on site but the clinicians decided not to use it.

I&U Case 6 (Chapter 9) - The massive haemorrhage protocol was activated. In this situation all components should have been issued in a cool box packed by a member of laboratory staff. Instead,

the blood units that were issued 'uncrossmatched' were placed into the issue refrigerator via the blood tracking system. When these units were subsequently crossmatched the tracking system 'quarantined' them in the main theatre blood refrigerator so that clinical staff did not have access to them. This led to a delay in blood being available for this patient.

Cases from HSE

These constitute errors in the post-analytical phase of the transfusion process.

The majority of the 60 errors were either:

- Failure to clear blood refrigerators in a timely manner. This led to blood being transfused that had either expired or was past its 'suitability' date or
- Failure to react appropriately to refrigerator 'failures' that meant the 'cold chain' of the blood components could not be assured.

Errors involving Blood Services

- 1 unit issued of the incorrect phenotype.
- 1 case where units were not phenotyped for antigens to low incidence antibodies in 2 patients with multiple antibodies.

Recommendations - see also IT chapter (Chapter 8)

As the specification of transfusion laboratory information management systems (LIMS) is further developed it is vital that:

- As a minimum there is a requirement for positive confirmation, by the biomedical scientist (BMS), at the point of component reservation, that special requirements have been met.
- Preferably, a requirement for a direct check within the LIMS, that the component meets the special requirement on record.
- Warnings must be clear and appear on all relevant screens in the transfusion process.
- Warning flags need a positive response from the user as to why they are being overridden.

Action: Transfusion Laboratory Managers, Pathology IT managers, LIMS Providers

Recommendations from previous years which are still active:

Competency-assessment of staff involved in the transfusion process must be relevant to the person's core role and knowledge requirements. Competency-assessment must be linked to process through clear, unambiguous SOPs but there must be an element of assessment of knowledge and understanding as well as the ability to simply follow the SOP. Competency-assessment of 'soft skills' such as communication should also be incorporated and could be achieved in line with the Knowledge and Skills Framework (KSF) requirements for the relevant BMS band. This is a role for Transfusion Laboratory Managers.

The revised guidelines on pre-transfusion testing are due for publication later this year. There are a number of helpful revisions from the 1996 guidelines, for example, a section on testing in urgent situations and a flow diagram on interpretation of and provision of red cells when weak RhD results are obtained. This is an action for Transfusion Laboratory Managers.

For additional active recommendations from previous years and an update on their progress, please refer to the SHOT website