5.1 IBCT Events Originating in the Hospital Transfusion Laboratory

There are a total of 121 cases in which the primary error arose in the laboratory. Of these, 96 events are a subset of the 332 IBCT events reported in 2007. They have all been referred to at the beginning of that chapter and in the relevant sections, but they are discussed in more detail here.

Laboratory errors from the anti-D chapter are also included in this table, to allow a complete picture of laboratory errors, as is one case from the HTR chapter where sample age was probably a contributory factor in the delayed haemolytic transfusion reaction (DHTR). However, these cases are not discussed in this section, but in their own chapters.

Table 15
Summary of laboratory-related errors n = 121

Type of error	Number of cases from this chapter	Number of cases from anti-D chapter	Number of cases from HTR chapter
Wrong Blood	**15**		
Wrong sample selected	3		
ABO grouping error	4		
D grouping error	3	10	
Incorrect component selected	3		
Incorrect labelling	1		
WBIT which should have been detected	1		
Wrong group selected for SCT patient	**5**		
Wrong ABO group	4		
Wrong D group	1		
Other pre-transfusion testing errors	**20**		
Testing errors	5		1, Case D6, sample age was a factor
Procedural errors	15	11	
Special requirements not met	**36**		
Irradiated component	21		
CMV negative component	3		
CMV negative and irradiated	1		
Phenotyped component	6		
MB treated FFP	3		
IgA deficient cells	1		
Correct component (cryo issued instead of FFP)	1		
Incorrect dose of anti-D issued		2	
Handling and storage errors	**20**		
Alarm related	7		
Non-clearance of fridge	4		
Issued blood known to be out of CTS	4		
Expired components used	3	1	
Other	2		
TOTAL	**96**	**24**	**1**

Wrong Blood Incidents n = 15

This year 'wrong blood' incidents resulted from laboratory errors in 15 cases. One case involved a baby <1 year old, the remaining cases were in patients over 16 years of age. None of the errors caused adverse reactions. Twelve of the cases occurred 'out of hours', 5 classed by the reporter as being during a 'shift' system and 7 during 'on call' systems. Three of the errors were made by staff who normally work in blood transfusion while 7 errors were made by staff who did not work regularly in transfusion; 1 error was made by a locum staff member and in 1 case the staff details were not stated.

The 15 errors were:

- 3 cases where the wrong sample was selected for test. These errors resulted in group A FFP being transfused to a group B recipient; group A D positive red cells to a group A D negative female recipient (see Case 1); and group O red cells to a group A recipient.
- 4 errors in ABO grouping. One case resulted in group B D negative red cells being transfused to a group A D negative recipient, fortunately with no adverse reaction. In the second case a group A patient was typed as AB but was transfused group A red cells because AB red cells were not routinely held at the hospital. In the third case group A red cells were provided for a group AB patient (see Case 2). No details were provided in the fourth case.
- 3 errors in D typing. These resulted in transfusion of D positive red cells, in 1 case, and D positive platelets in another, both to D negative males. In the third case D negative red cells were given to a D positive recipient.
- 3 cases of incorrect component selection. In 1 case D positive red cells were selected for a D negative elderly female, in another group O red cells were selected for a group A recipient and in the third case group O FFP was selected for a group A recipient. This third case was human error and occurred during computer downtime so that the usual warning flags were not available.
- 1 case of incorrect labelling where the wrong platelet unit was selected and labelled for a patient. Fortunately the platelets were of the right specification for the patient to whom it was transfused.
- 1 case where the primary error was in sampling i.e. WBIT, but the laboratory failed to find the error and prevent a mis-transfusion, see Case 3.

All of the ABO grouping errors were made while providing blood urgently. Three of the 4 cases involved manual methods: 1 error was regarded as incorrect interpretation of the group and 2 as transcription errors. In the fourth case an automated group was performed but required manual interpretation – a mixed field reaction was incorrectly interpreted by the BMS.

All of the D typing errors were made using manual methods. In one case the patient was typed as D negative but was actually a weak D. The incubation time for the test was shortened and the test was not repeated with further anti-D reagents as per the SOP. The second was a recording error and the third error was a missed a mixed field (MF) reaction using microplate technology.

Case 1

SOPs are in place for good reasons

A laboratory mix up of two samples resulted in a 33-year-old group A D negative female patient receiving some group A D positive blood. When the error was discovered in the laboratory the ward was contacted and the transfusion was stopped after approximately 20 mL of blood. Anti-D was given. Investigations revealed that pressure owing to staff shortages was the main contributory factor for the breach in laboratory policy, which states that samples are to be opened, checked and labelled one at a time.

Case 2

The power of suggestion

A patient was admitted to hospital B, having been transfused at hospital A, and a verbal message was given to blood bank that the patient was group A D positive. The BMS on call obtained mixed field reactions and manipulated the blood group results to reflect a group A D positive blood group. The patient was transfused group A D positive blood and plasma as a result. The patient was grouped wrongly by blood bank a further 11 times as a result of misleading information on the computer. Finally a senior BMS grouped the patient and recognized that this patient was actually group AB D positive.

Case 3

Question a changed blood group

A patient had been grouped as O D negative by the laboratory on two previous occasions. On the third occasion the sample grouped as O D positive. The BMS repeated the group on that sample, which was correct, and changed the group of the patient on the computer. The BMS had not realised that the sample was from a different patient.

COMMENTARY

The number of laboratory errors contributing to 'wrong blood' events has decreased this year from 25 to 15 and the reduction in ABO typing errors reported last year has continued, see Table 16. The number of D typing errors also remains low. This continued reduction in the types of error with potentially the most serious outcome is encouraging, although it is interesting that this reduction has occurred at the same time as the commencement of MHRA inspections. This trend may represent a genuine improvement in practice as a consequence of more stringent regulation, or could potentially be the result of under-reporting since the BSQR came into effect.

Table 16

Laboratory errors resulting in wrong blood events 2003--2007

Year	Total no of cases	Wrong sample tested	Interpretation / transcription errors	Other	ABO-incompatible transfusions	Sequelae
2003	17	8	9		7	2 major morbidity
2004	18	5	12	1	6	1 death 1 major morbidity
2005	22	9	12	1	9	1 AHTR
2006	6	2	3	1		No morbidity
2007	7	3	4			No morbidity

This year there have been two errors involving mixed field reactions. This mirrors errors seen in National External Quality Assurance Scheme (NEQAS) BTLP exercises over the years. In NEQAS the overall detection rate of a 50:50 MF reaction has improved in successive exercises, from 13% in exercise 99R2 and 20% in 02R2 to the current rate of 41% in 06R9. NEQAS evidence shows that laboratories using CAT and automation are significantly more likely to detect an MF reaction ($p = <0.001$ for each factor independently). However, once a mixed field reaction is detected it must then be correctly interpreted, after obtaining a thorough clinical and transfusion history. NEQAS exercise 06R9 provides a concise method for investigation of an ABO MF reaction. Clearly training and competence assessment of ABO/D typing must include this phenomenon.

Previous SHOT reports have detailed that manual techniques carry greater risk of error. This year all the ABO and D typing errors have involved manual techniques or manual interventions in automated methods.

This year all the ABO errors were made while providing blood for urgent cases and the majority, 12 out of 15 cases, of 'wrong blood' incidents have occurred out of routine hours.

Learning Points

- Manual processes are more prone to error. During process validation ensure that manual procedures and interventions are kept to a minimum and that appropriate checks are in place at weak, manual points of a process.
- Competency assessment in ABO/D typing should include detection and interpretation of mixed field reactions.

The following learning point from a previous report remains pertinent:

- Training and competency assessment in the laboratory must cover basic manual checking procedures to ensure that these are second nature at a time when automation and computerisation will have lessened experience and practice in these basic skills.

Wrong ABO or D type blood issued for SCT recipients n = 5

There were 5 cases this year where blood of the wrong ABO or D type was given to recipients of mismatched bone marrow/cord/stem cell transplants. Three of the 5 cases involved children under 1 year of age, 1 a child under 16, and 1 an adult. Four of the errors occurred during routine hours and 1 out of hours on a shift system.
In 4 cases group A red cells were transfused when O was the group of choice, and in 1 case D positive components were transfused when D negative should have been provided.

There were a number of causes: 1 case involved communication breakdown between the laboratory and the clinicians and it was difficult to ascertain the root of the problem; 4 cases were clearly laboratory errors including the following:

- bone marrow transplant (BMT) protocol not followed
- computer alert bypassed
- computer flags misunderstood and overridden
- incomplete data entered on computer

Other pre-transfusion testing errors n = 20

Three of the 20 cases involved children under 1 year of age, and the remaining cases were in adults over 16 years of age. Twelve of the cases occurred out of hours, 6 classed by the reporter as being during a 'shift' system and 6 during 'on-call' systems. Six of the errors were made by staff who normally work in blood transfusion while 6 errors were made by staff who did not work regularly in transfusion.

The 20 errors can be arbitrarily split into:

- Testing errors, i.e. the correct tests were performed but incorrect results obtained, either by poor performance of the test, transcription error or incorrect interpretation
- procedural errors, i.e. incorrect test selection

Testing errors n = 5

There were 5 examples of testing errors, 2 of which led to transfusion reactions.
One example of missed incompatibility in a crossmatch led to a haemolytic transfusion reaction (Case 4): imputability 3.

Case 4

Haemolysis owing to missed antibody reaction

A patient had a known anti-K and anti-Co^{b}. The laboratory issued K negative, crossmatch compatible blood as per NHSBT advice (Co(b-) units are not routinely supplied). At the end of transfusion of the first unit (after 1 hour 25 min) patient had rigor, tachycardia and haemoglobinuria (although there was some haemoglobinuria prior to transfusion). The unit was returned to the transfusion laboratory, with fresh samples. The unit was incompatible with both pre- and post-transfusion samples, presumably due to anti-Co^{b} as units confirmed O D positive, K negative, direct antiglobulin test (DAT) negative. The laboratory can only assume that plasma had not been added to the original crossmatch tests as the antibody reaction was strong. The patient was sent home to return the following day for reassessment.

A transcription error took place in a 3 unit manual, indirect antiglobulin test (IAT) crossmatch, after identifying an anti-Kpa, where 1 unit was incompatible and 2 units were compatible. This resulted in transfusion of the incompatible unit. A transfusion reaction was reported by medical staff, which led to discovery of the error (Case 5): imputability 3.

Case 5

Erroneous selection of incompatible unit by BMS

A sample was tested and the antibody screen was positive: the antibody was correctly identified as anti-Kpa. The BMS issued red cell components, which were transfused. The doctor then telephoned 2 days later to inform blood bank that the patient had had a transfusion reaction. Repeat samples were requested. On re-crossmatching the units using pre and post samples, 1 of the red cells issued was found to be incompatible – the BMS had selected the incorrect unit.

There were 2 missed weak reactions in manual antibody screens (an anti-K and anti-E), one of these errors was not repeatable, the other was due to plasma being added before the cells when performing a manual Diamed IAT column technique.

There was 1 interpretation error when an anti-Jka was missed in the presence of anti-K + anti-C

Procedural errors n = 15

There were 15 examples of procedural errors:

- Three cases where tests were performed on samples that were not properly labelled according to local protocol: 2 undated samples and 1 having an addressograph label
- Three cases where the sample used for compatibility testing was too old (there is an additional case here, D6 from HTR, see Table 25)
- Three cases involving babies: failure to test maternal sample before issuing blood to a baby, failure to link mum and baby when maternal antibodies were present, failure to obtain a fresh sample for pre-transfusion testing when the baby was over 4 months old
- Two cases where a positive antibody screen result was missed and the crossmatch performed without antibody identification/selection of antigen negative units or IAT crossmatch. The patients had anti-K and anti-K+C, respectively
- One case where the blood was issued before the group and screen was complete (Case 6)
- Two cases where staff failed to exclude other clinically significant antibodies in the presence of a known antibody. In 1 case a weak anti-Jka was missed and the units issued, although serologically compatible by IAT, were not Jka typed; fortunately there was no adverse reaction. In the second case serologically compatible red cells were also issued and when further tests were carried out there were no further antibodies detected
- One example of electronic issue of red cells when there was no current sample in the laboratory

Case 6

Blood issued before group and screen complete

The BMS did not complete pre-transfusion testing of a patient with known atypical antibodies and issued blood. The antibody panel was not done although blood had been transfused since the last identification. The BMS left a note for day staff to ask if a panel should have been performed. It was reported that the BMS was put under pressure by medical staff as the patient required blood urgently. The right blood was transfused as no further antibodies were found on investigation.

COMMENTARY

Errors in pre-transfusion testing continue to occur although the number of errors are down from last year (28 in 2006). Non-observance of protocols still occurs but it is unclear from many reports whether this is due to lack of knowledge, poor training or 'slips' that have occurred. Clearly, both from these pre-transfusion testing errors and those errors occurring in the 'wrong blood' section, there is a particular problem with error rates 'out-of-hours'. Again, whether this is due to problems with training staff who work 'out-of-hours' or because staff working 'out-of-hours' are more tired or under more stress is unclear. The NTLC has started work to try to gain better understanding of why errors are occurring and why a greater percentage are occurring 'out-of-hours' nationally. Local review of errors is also vital to understand local factors contributing to error and to identify useful corrective measures. Laboratory information systems must provide as much guidance as possible, in the form of prompts and warnings, for example on sample age and outstanding work. Systems must provide easy solutions to problems such as linking mothers and babies.

Learning Points

- Laboratories must ensure that robust systems are in place for highlighting 'outstanding' work on a patient, for example positive antibody screen awaiting identification, group and screen not complete.
- Competency-based training for laboratory staff must include staff who work out of hours, both those staff who do not work routinely in transfusion and those who do, and must apply to locum members of staff.
- A laboratory quality system, as required by the Blood Safety and Quality Regulations, must include internal incident reporting mechanisms and appropriate, documented, corrective actions.

Failure to provide components of appropriate specification or that did not meet special requirements n = 36

Laboratory errors accounted for 36 cases in this category: by far the most common error was failure to provide irradiated components (21 cases) when required. The other cases were failure to provide: CMV negative (3), CMV negative and irradiated (1), phenotyped components (6), MB treated FFP (3), washed or immunoglobulin IgA deficient red cells (1), and in 1 case cryoprecipitate was provided when FFP had been requested.

Six of the 36 cases involved children under 1 year of age, a further 5 cases involved children under 16 years of age and the remaining 25 cases were in adults. Interestingly, in this category of error, more errors were made during routine hours: 23 cases occurred during routine hours and 8 cases out of hours, 5 classed by the reporter as being during a 'shift' system and 3 during 'on-call' systems. In 5 cases the time of the error was not given.

COMMENTARY

Issuing blood that does not meet the special requirements of the patient continues to be a major source of error and this type of error is not decreasing. A number of these errors occur due to patients having multiple numbers during hospital visits so that their complete history is not available.

Laboratory computer systems must provide bold warning flags. However, warning flags must be set correctly in the first instance and this is a source of error. The procedures for adding flags to a patient's laboratory record must be robust. Warning flags must always be set against the patient not a sample.

Learning Points
[These learning points are also applicable to the errors occurring in blood issue for SCT patients]

- Transfusion laboratories must have thorough search strategies when looking for patient histories in order to find and reconcile multiple entries for a patient – see the section on laboratory errors related to IT.
- A laboratory quality system must include process validation. The process of recording special transfusion requirements within the transfusion laboratory should be validated and must be kept as simple as possible.
- Competency assessment of staff working in the transfusion department must include competencies in the provision of blood for specific groups of patients and in understanding the importance and use of 'special requirement' flags.

Handling and storage errors n = 20

Some of the errors in this category were due to problems with satellite blood fridges and in many of these cases it was difficult to ascertain responsibility for the error. The 20 errors attributed to the laboratory in this category were as follows:

- Blood fridge not cleared 4
- Alarm failure of blood fridge or platelet incubator 4
- Failure to react to a blood fridge alarm 1
- Blood fridge/platelet incubator failure – no alarm 2
- Component known to be 'out of temperature control' but transfused 4
- Cold chain incomplete 1
- Incorrect thawing of cryoprecipitate 1
- Blood components used past their expiry 3

Case 7

The laboratory must be involved in validation of equipment following a move

A blood fridge was relocated into a small room where the size of the room contributed to a rise in temperature of the surroundings. The fridge could not cope with the ambient rise and the temperature increased to over 6°C. The incident was noticed only when the chart recorder was returned to the blood transfusion laboratory. In addition, when the fridge was relocated the temperature alarm was incorrectly fitted and not tested at the time of fitting. A patient was transfused with blood that had been stored at too high a temperature. No adverse symptoms were reported by the patient or nurse following the transfusion. Staff were retrained on temperature monitoring, the alarm was refitted and tested and the room has been ventilated, which has reduced the ambient temperature to acceptable levels.

COMMENTARY

Errors continue to occur in the storage and handling of blood. As laboratories continue to improve their quality management systems (QMS) in line with the Blood Safety and Quality Regulations (2005) the number of these errors should fall. The management of satellite fridges should be tightly controlled by a written SOP/SLA/technical agreement. This must very clearly specify responsibilities and must be comprehensive. It must contain a thorough protocol for managing a blood bank fridge move to include change control. Staff must be trained and competent in these tasks before being permitted to carry them out. Documentation, risk assessment of the move and validation and temperature mapping of the fridge post move must be included.

A QMS should include regular alarm testing to cover appropriate responses to the alarm as well as testing that the alarm is functioning correctly. The system should also cover safe partitioning of blood. Having well labelled, defined areas of storage for quarantined blood, for example, should help to prevent reissue of inappropriately stored blood.

Learning Points

- Ensure implementation and monitoring of a comprehensive quality system covering blood component handling and storage to meet the requirements of the Blood Safety and Quality Regulations.

SHOT has, for many years, been advocating improved IT to help prevent transfusion errors. This year, there have been 2 cases reported where a BMS has overridden electronic blood tracking systems to allow the transfusion of expired components. This is a training and knowledge issue. All staff should have signed and competency assessed training in these systems, and they must also fully understand the rationale for the system and have sufficient knowledge to support their safe use of the system.

Case 8

FFP issued despite warning from electronic tracking system

FFP was issued on request, but was not used within 24 hours of thawing. It was taken out of the issue fridge 9 hours later despite warnings from the electronic blood tracking system which were overridden by a BMS. The unit was transfused to the patient. No adverse effects were noticed.

Case 9

BMS overrides warning from electronic tracking system

Cryoprecipitate was issued on request, but was not used within 4 hours of thawing. It was taken out of the issue fridge the next day despite warnings from the electronic blood tracking system which were overridden by a BMS. The unit was then given to the patient. No adverse effects were noticed.

RECOMMENDATIONS

New recommendations from this year

- Laboratories must develop a robust quality system in line with the Blood Safety and Quality Regulations. This should include:
  - task-based training and competency assessment for all staff in the transfusion laboratory
  - a robust quality incident reporting system which encompasses root cause analysis and CAPA
  - documented change control
  - defined communication systems for staff at handover periods and following implementation of change.

Action: Trust CEOs, HTCs, HTTs

Recommendations still active from previous years

Year first made	Recommendation	Target	Progress
2006	The National Transfusion Laboratory Collaborative aims to improve standards, staffing levels, knowledge, competency and skills in hospital laboratories, and should be supported	**National Transfusion Laboratory Collaborative, stakeholder professional bodies, Trust CEOs**	Recommendations are under consultation by stakeholders
2005	Better laboratory practice – improved staffing levels, appropriate skill mix, competency assessment, safe on-call structures	**Trust CEOs**	National Transfusion Laboratory Collaborative started – see above
2005	Avoid Blood Transfusion outside core hours	**Trust CEOs, consultant haematologists with responsibility for transfusion together with HTCs and HTTs**	National Comparative Audit was done; national figures now available and, where recommendations followed, participants able to benchmark locally against national performance
2004	The EU Directive requires that hospital transfusion laboratories implement a Quality System; this presents an opportunity to drive improvements in practice and must be fully supported, resourced and monitored	**Trust CEOs**	Considerable progress has been made in this area, and a toolkit and examples of advice and good practice is available at www.transfusionguidelines.org

2004	Further national initiatives are needed to drive forward blood safety issues in hospital transfusion laboratories	**NBTCs, with relevant professional bodies**	Identified as a key recommendation in 2005; launch of National Transfusion Laboratory Collaborative in 2007 aimed at improving laboratory practice
2003	Hospital transfusion laboratory staffing must be sufficient for safe transfusion practice	**Trust CEOs**	
2000–2001	Establish protocols for timely removal of blood from blood banks to prevent transfusion of expired units	**Trust CEOs**	Considerable progress has been made with these recommendations, as Trusts seek to comply with the requirements of the BSQR and NHS Litigation Authority risk management standards
2000–2001	Labs must be vigilant in reviewing procedures and systems against current guidelines. Ongoing staff training is essential		
1999–2000	Labs must vigilant in reviewing procedures and systems and training to prevent sample handling and technical errors		
1998–1999	Hospitals must develop unambiguous protocols for the management of satellite refrigerators and their stock		
1998–1999	Labs must be vigilant in reviewing procedures and systems and training to prevent sample handling and technical errors		