Summary of Events originating in the Hospital Transfusion Laboratory 10

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Analysis of all cases reported to SHOT in 2012 (excluding 'near miss' events) shows that 1168/1787 (65.4%) were adverse events caused by error and of these 430/1168 (36.8%) originated in the laboratory. In this chapter we highlight the critical points in the laboratory process where errors occur.

Analysis of laboratory errors derived from data in other chapters in this annual report shows:

- 182/430 (42.3%) reports of transfusion episodes in which, during the transfusion process, inappropriate handling and storage errors (HSE) may have rendered the component less safe
- 80/430 (18.6%) reports related to errors in the administration of anti-D immunoglobulin to women of childbearing potential
- 70/430 (16.3%) reports of errors which resulted in the transfusion of components that did not meet the patient's specific requirements (specific requirement not met – SRNM)
- 62/430 (14.4%) reports where a patient was transfused correctly despite one or more serious laboratory error(s) (right blood right patient – RBRP)
- 31/430 (7.2%) reports of errors which resulted in the transfusion of an incorrect blood component (incorrect blood component transfused – IBCT)
- 5/430 (1.2%) reports of avoidable, delayed, or undertransfusion (ADU)

The reports are broken down into the categories shown in Table 10.1

Table 10.1: Laboratory errors by category n=430

Critical point in the laboratory process	Total	Chapter					
		IBCT	SRNM	HSE	RBRP	ANTI-D	ADU
Sample receipt & registration	**39**		11		25	3	
Testing	**63**	8	24		1	28	2
Component selection	**81**	22	33			25	1
Component labelling, availability & HSE	**243**		2	180*	36	23*	2
Misc	**4**	1		2		1	
Total	**430**	**31**	**70**	**182***	**62**	**80***	**5**

** There were 10 HSE reports with multiple cases which provided details for 121 patients. This makes the total HSE cases 182 from 71 reports. There were 2 Anti-D reports with multiple cases, one report with 2 and another with 10 making a total number of 80 patients affected from 70 reports.*

Sample receipt and registration errors n=39

- There were 25/39 (64.1%) reports of patients who received the correct component but had one or more patient identification errors, including incorrect spelling of the name (12) or incorrect date of birth (7). These were sample labelling errors that should have been detected at 'booking in'
- In 11/39 (28.2%) reports patients were transfused components that did not meet their specific requirements. This information had been indicated on the request form (8) or in the patient's historic record (3)
- In 3/39 (7.7%) reports women of childbearing potential received anti-D immunoglobulin (Ig) despite the availability of historic information indicating the patient was RhD positive (2) or had immune anti-D (1)

Case 1: Transcription error of patient identification details

Two units of red cells were issued using an incorrect spelling of the patient's surname, even though the request form and blood sample were correctly labelled, and the first unit was transfused. The ward staff realised the error when performing the bedside administration checks on the second unit. This unit was returned to the hospital transfusion laboratory and the unit was re-issued with the correct patient details.

COMMENTARY

Laboratory staff working in transfusion must be diligent at all times to avoid making errors. During the 'booking in' process it is vital to take into account any historic patient information and ensure all previous results and any specific requirements have been taken into consideration. There is national guidance available on the minimum dataset required for samples and requests[27,50].

Learning points

- Correct patient identification is imperative and must always be ensured at each critical point of the laboratory process starting with entering patient demographics onto the laboratory information management system (LIMS)
- Maintaining an accurate patient database is a critical safety measure in the treatment of patients and transfusion laboratories must have a robust search protocol in place to identify historic patient records

Testing errors n=63

- In 28/63 (44.4%) testing errors were related to the administration of anti-D Ig to women of childbearing potential, and included errors in testing maternal and neonatal samples.

Table 10.2: Testing errors related to the administration of anti-D Ig

Testing errors related to the administration of anti-D Ig			28/63
Maternal sample errors			**20**
RhD errors	5 patients were weak RhD positive and reported as RhD negative by manual tube technique; (2 of these patients were known weak RhD positive, 2 had equivocal reactions by automated techniques, 1 was RhD positive by automated techniques) 1 patient had a confirmed D variant but was reported to the clinical area as RhD positive and not requiring anti-D Ig prophylaxis	*6*	
Errors in the estimation of fetomaternal haemorrhage (FMH)		*5*	
Misinterpretation of anti-D antibodies assuming them to be from prophylaxis rather than immune		*5*	
Post delivery samples not processed within 72 hours		*3*	
RhD transcription error		*1*	
Transposition of cord and maternal samples			**1**
Neonatal sample errors			**7**
Cases where the cord sample was incorrectly reported as RhD positive when a positive direct antiglobulin test (DAT) invalidated the results		*3*	
RhD transcription errors		*2*	
Incomplete cord D-typing		*2*	

- 24/63 (38.1%) resulted in a failure to meet the patient's specific requirements

Testing errors resulting in a failure to meet the patient's specific requirements	24/63
Antibody identification/exclusions not performed following a positive antibody screen result	**11**
Manual ABO errors	**6**
Inappropriate use of electronic issue	**5**
Errors in interpreting antibody identification results	**2**

Table 10.3: Testing errors resulting in a failure to meet the patient's specific requirements

- 8/63 (12.7%) testing errors resulted in the transfusion of an incorrect blood component

Testing errors resulting in the transfusion of an incorrect blood component		8/63
Manual ABO errors		**6**
Transcription errors	*3*	
Interpretation errors	*2*	
Selection of the wrong sample for testing	*1*	
Manual RhD errors		**2**
Interpretation error – mixed field reaction misinterpreted as RhD positive	*1*	
Manual transcription error	*1*	

Table 10.4: Testing errors resulting in the transfusion of an incorrect blood component

- 2/63 (3.2%) testing errors resulted in inappropriate and unnecessary transfusions

Testing errors resulting in inappropriate and unnecessary transfusions	2/63
False low haemoglobin – clotted sample – 2 units of red cells transfused	**1**
False low platelet count – platelet clumps were seen on blood film examination – but the low result was reported nevertheless – as a consequence 2 paediatric platelet packs were transfused	**1**

Table 10.5: Testing errors resulting in inappropriate and unnecessary transfusions

- 1/63 (1.6%) testing errors resulted in the right blood being transfused to the right patient (Case 2)

Case 2: Failure to exclude the presence of additional alloantibodies

Two units of red cells were requested for a patient with known anti-c and anti-E. Two units of R1R1 red cells were selected, crossmatched and issued but an antibody identification panel was not performed on this sample to exclude the presence of additional alloantibodies.

COMMENTARY

All ABO and RhD typing errors occurred as a result of manual interventions. Manual testing is known to carry a high risk of error and should only be used when urgent clinical situations demand. If a positive antibody screen result is obtained, the specificity should be determined and the clinical significance assessed. Any patient with known alloantibodies should have each new sample fully tested to exclude the presence of further alloantibodies[35].

Learning points

- Successive SHOT reports have demonstrated that the majority of ABO/RhD grouping errors result from manual procedures and this extends to other manual techniques including antibody identification and estimation of fetomaternal haemorrhage (FMH)
- The ABO and RhD group must wherever possible be verified against previous results

Component selection errors n=81

- In 33/81 (40.7%) cases patients were transfused with components that did not meet their specific transfusion requirements. These were all patients where details of their specific requirements were available on the historic record

Table 10.6: Cases where patients were transfused with components that did not meet their specific transfusion requirements

Cases where patients were transfused with components that did not meet their specific transfusion requirements		33/81
Warning flag failures were identified		**15**
Not implemented or updated	*8*	
Erroneously overridden or ignored	*7*	
Cases where there was no information relating to information technology (IT) systems to identify whether flag failures were involved		**18**

- 25/81 (30.9%) cases resulted in the inappropriate administration of anti-D Ig

Table 10.7: Cases resulting in the inappropriate administration of anti-D Ig

Cases resulting in the inappropriate administration of anti-D Ig	25/81
Women known to have immune anti-D	**7**
Administration of the wrong dose of anti-D Ig	**5**
Mothers of RhD negative infants	**4**
RhD positive women	**4**
RhD negative women did not receive anti-D Ig prophylaxis when RhD positive platelets transfused	**4**
RhD negative male inappropriately received anti-D Ig prophylaxis when RhD positive platelets transfused	**1**

- In 22/81 (27.2%) cases an incorrect blood component was selected and transfused

Table 10.8: Cases where an incorrect blood component was selected and transfused

Cases where an incorrect blood component was selected and transfused		22/81
Haemopoietic stem cell transplant (HSCT) patients		**10**
RhD negative recipients received RhD positive red cells		**7**
Cases where an inappropriate unit was issued		**5**
Fresh frozen plasma (FFP)	1 patient received FFP when cryoprecipitate was requested 1 patient received ABO non identical FFP following a renal transplant 1 patient received ABO non identical SD-FFP for a plasma exchange	*3*
A neonate received a transfusion of a red cell unit that was not suitable for exchange transfusion		*1*
In 1 case group specific red cells and FFP were issued for a neonate when the age was misread as 1 year when the patient was 1 month old. The laboratory policy was to issue group O red cells and group AB FFP to neonates when there was no record of the maternal group or antibody status[35].		*1*

- 1/81 (1.2%) cases resulted in an inappropriate transfusion where FFP was issued and transfused when platelets were requested

Case 3: RhD mismatched transfusion due to component selection error

Two units of group B RhD positive red cells were issued and subsequently transfused to a group B RhD negative female patient of childbearing potential. The laboratory information management system (LIMS) gave a warning that was overridden by the biomedical scientist (BMS). At the time the BMS was newly qualified and under the supervision of another BMS.

COMMENTARY

The RhD mismatches reported are those that resulted from errors. In some cases the selection of RhD non-identical components is a pragmatic decision based on a combination of individual patient assessment, clinical urgency and availability, and these cases are not SHOT reportable.

Learning points

- The information technology (IT) system should be configured to flag a component discrepancy and this should be fully validated. If this is not possible locally then these development requirements must be raised with the laboratory information management system (LIMS) suppliers
- Training and competency-based assessment must include appropriate actions on receipt of alerts/warnings on the laboratory information management system (LIMS) or an analyser.
- Laboratories need to look critically at the way in which mother and baby records are linked and how robust this linkage is
- The qualified biomedical scientist (BMS) crossmatching red cells or issuing components must take responsibility for checking all historic patient information to ensure that components issued are of the correct specification

Component labelling, availability, handling and storage errors n=243

- In 180/243 (74.1%) cases there were errors associated with handling and storage which could have rendered the component unsafe to transfuse

Cases where there were errors associated with handling and storage, which could have rendered the component unsafe to transfuse	180/243
Cold chain not monitored (121 patients from 10 incidents)	154
Samples exceeded the recommended time intervals (following transfusion within the last 3 months) between sampling and pre-transfusion compatibility testing[45].	18
Patients were transfused expired units	8

Table 10.9: Cases where there were errors associated with handling and storage, which could have rendered the component unsafe to transfuse

- In 36/243 (14.8%) cases a patient was transfused with the correct component despite component labelling errors – RBRP. Causes were:

Cases where a patient was transfused with the correct component despite component labelling errors – RBRP	36/243
Transposed labels	25
Labels contained incorrect patient details	9
No labels attached to component	2

Table 10.10: Cases where a patient was transfused with the correct component despite component labelling errors – RBRP

- In 23/243 (9.5%) cases there were errors relating to the labelling, availability, handling and storage of anti-D Ig

Cases where there were errors relating to the labelling, availability, handling and storage of anti-D Ig	23/243
Anti-D Ig not issued to the clinical area within 72 hours of delivery or a potentially sensitising episode	10
Cases from 2 reports (10 in one incident) anti-D Ig issued with an incorrect batch number	11
Expired anti-D Ig administered (both cases from one incident)	2

Table 10.11: Cases where there were errors relating to the labelling, availability, handling and storage of anti-D Ig

The remaining 4 were isolated cases

Isolated cases		4/243
Labelling errors		**2**
Transposed label meant a patient received a unit intended for a different patient	*1*	
Patient was transfused blood that had not been serologically crossmatched as the wrong units were labelled	*1*	
Cases of delayed transfusions caused by the lack of availability		**2**
Platelets required urgently but were delayed, as the BMS did not place a 'blue light' order with the Blood Service	*1*	
Crossmatched units were transported to the wrong hospital site and unavailable when the patient was in theatre	*1*	

Table 10.12: Isolated cases

Learning points

- When issuing components always check the component label and the compatibility tag
- Laboratory staff must ensure that all components are made available for issue within date

Miscellaneous n=4

The 4 miscellaneous cases included

- 1 cryodepleted plasma (CDP) was mistakenly ordered and issued when cryoprecipitate was indicated for the patient
- 2 failures to follow standard operating procedures (SOPs) requiring the quarantine of components on receipt of fax as part of Blood Service recall procedures
- 1 mother failed to receive post delivery anti-D Ig. Consent to take a repeat sample from the baby was denied by the mother after the initial sample was rejected for testing

Recommendations

- Regular practice and competency-assessment of manual techniques is important, where possible this should include checks of the critical steps by a second person when manual methods are employed

Action: Transfusion Laboratory Managers

- Competency assessment in laboratories must be linked to process. Biomedical scientist (BMS) staff must be competent performing the test but must also have a thorough understanding of the context in which the test is being performed, i.e. the test in relation to a specific patient and the clinical information. Basing competency assessment on National Occupational Standards (NOS) will enable this, as NOS have both 'Performance' criteria and 'Knowledge and Understanding' criteria

Action: Transfusion Laboratory Managers

- Hospital Transfusion Teams (HTTs) should perform a local risk assessment on the way in which the transfusion laboratory is informed by clinicians of either specific 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

Action: Transfusion Laboratory Managers, Pathology Information Technology (IT) Managers, Laboratory information management systems (LIMS) providers, Hospital Transfusion Teams (HTTs)

- Warning flags must be clear and appear on all relevant screens in the transfusion process and if overridden, should include a positive response from the user with rational behind the decision

Action: Transfusion Laboratory Managers, Pathology IT Managers, LIMS providers, HTTs

Recommendations from previous years are available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.