Summary of Events Originating in the Hospital Transfusion Laboratory 9

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This chapter includes all errors that originated in the laboratory associated with:

- Sample receipt and registration – information missed or not heeded during the 'booking in' stage
- Testing – pre-transfusion testing and procedural errors
- Component selection – selecting an unsuitable blood component
- Component labelling, availability and handling and storage of blood components – labelling errors, availability surrounding blood components and their correct storage conditions
- Miscellaneous – cases that are difficult to assign to a particular stage within the transfusion process described above

Analysis of all cases reported to SHOT (excluding 'near miss' events) in 2013 shows that 1139/1755 (64.9%) were adverse events caused by error and of these 284/1139 (24.9%) originated in the laboratory, Table 9.1. There were a further 251/996 (25.2%) laboratory-related 'near miss' cases, Table 9.2.

Analysis of laboratory errors derived from data in other chapters in this 2013 Annual SHOT Report shows:

- 84/284 (29.6%) reports where the right patient was given the right blood and transfused correctly despite one or more serious laboratory errors (RBRP)
- 56/284 (19.7%) reports of errors which resulted in the transfusion of components that did not meet the patient's specific requirements (SRNM)
- 55/284 (19.4%) reports of errors in the administration of anti-D immunoglobulin (Ig) to women of childbearing potential (Anti-D)
- 51/284 (18.0%) reports of transfusion episodes in which, during the transfusion process, inappropriate handling and/or storage errors (HSE) may have rendered the component less safe
- 24/284 (8.4%) reports of errors resulting in the transfusion of an incorrect blood component (IBCT)
- 14/284 (4.9%) reports of avoidable, delayed, or undertransfusion (ADU)

Table 9.1: Laboratory errors n=284

Laboratory categories	Total	Percentage	Chapter					
			IBCT	SRNM	HSE	RBRP	ANTI-D	ADU
Sample receipt and registration	84	29.6%	4	16	8	35	21	0
Testing	51	18.0%	8	19	0	0	18	6
Component selection	36	12.6%	9	19	0	1	7	0
Component labelling, availability, handling and storage	104	36.6%	3	0	43	48	9	1
Miscellaneous	9	3.2%	0	2	0	0	0	7
Total	**284**	**100%**	**24**	**56**	**51**	**84**	**55**	**14**

There were 251 'near miss' cases where an error was detected prior to transfusion. This illustrates that when procedures are followed and when staff involved in the transfusion process perform their role effectively errors can often be detected. A more detailed summary of all the 'near miss' laboratory

cases shown in Table 9.2 is available in the 2013 Annual SHOT Report Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2013.

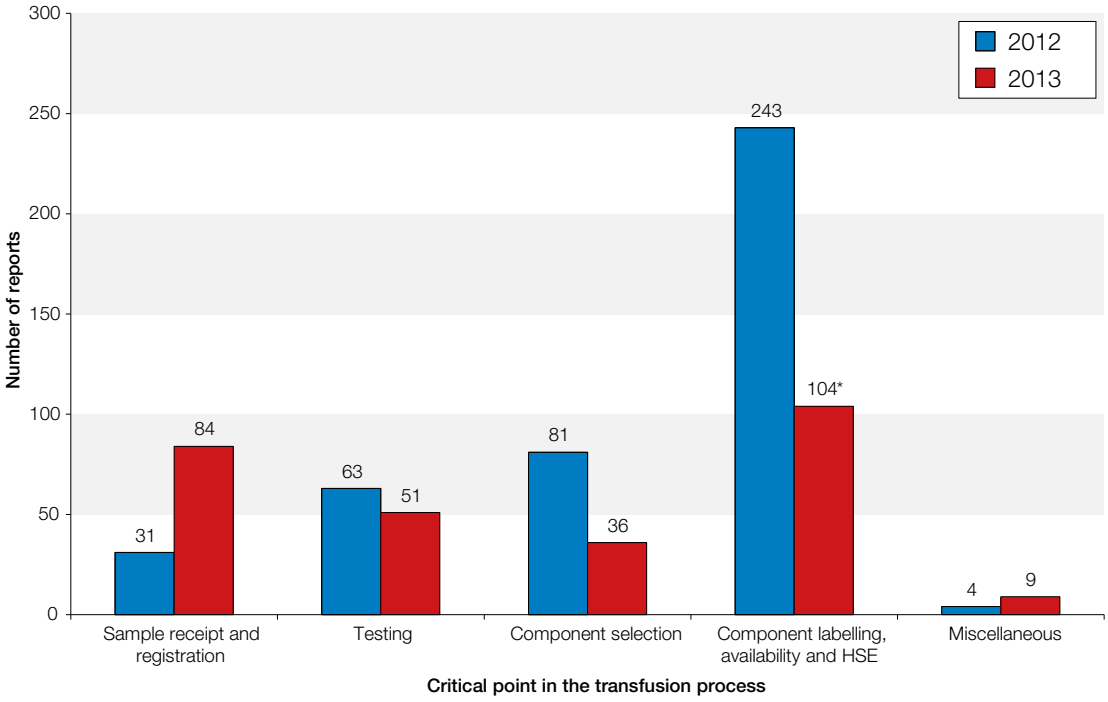
Table 9.2: Near miss laboratory errors n=251

Near miss laboratory categories	Total	Percentage	Chapter					
			IBCT	SRNM	HSE	RBRP	ANTI-D	ADU
Sample receipt and registration	26	10.4%	6	7	0	10	3	0
Testing	32	12.7%	16	9	0	0	4	3
Component selection	61	24.3%	6	39	3	0	13	0
Component labelling, availability, handling and storage	131	52.2%	17	0	38	72	4	0
Other = LIMS* bug, failed to detect group mismatch	1	0.4%	1	0	0	0	0	0
Total	**251**	**100%**	**46**	**55**	**41**	**82**	**24**	**3**

**LIMS = laboratory information management system*

This is the 2nd year that SHOT has provided a laboratory summary chapter. Figure 9.1 shows the 2 year trend and demonstrates the critical points in the laboratory process where errors occur.

Figure 9.1: Critical points in the transfusion process, two year trend 2012-2013



**There has been a decrease in errors related to component availability. This may be attributable to a single report in 2012 that involved 86 patients*

This year's chapter focusses on sample receipt and registration, testing and 9 miscellaneous cases. Most errors in component selection resulted in patients being transfused incorrect blood components and are described in Chapter 8 Incorrect Blood Component Transfused (IBCT). Most of the component labelling, availability and handling and storage errors (HSE) resulted in transfusion of the right blood component to the right patient despite a HSE that may have rendered the component less safe (HSE) or one or more serious identification/prescription errors which in other circumstances may have led to an IBCT (RBRP) [29]. These are discussed Chapter 12 Right Blood Right Patient (RBRP) and Chapter 13 Handling and Storage Errors (HSE).

A more detailed summary of all the laboratory cases shown in Table 9.1 is available in the 2013 Annual SHOT Report Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2013.

Sample receipt and registration errors n=84

Figure 9.1 shows an increase in 2013 in the number of errors at sample receipt and registration. Most of these are similar to those in 2012. Further analysis shows that failure to consider available historical information accounts for 39/84 (46.4%), demographic data entry errors 35/84 (41.7%) and missed information present on the request form 10/84 (11.9%), Figure 9.2.

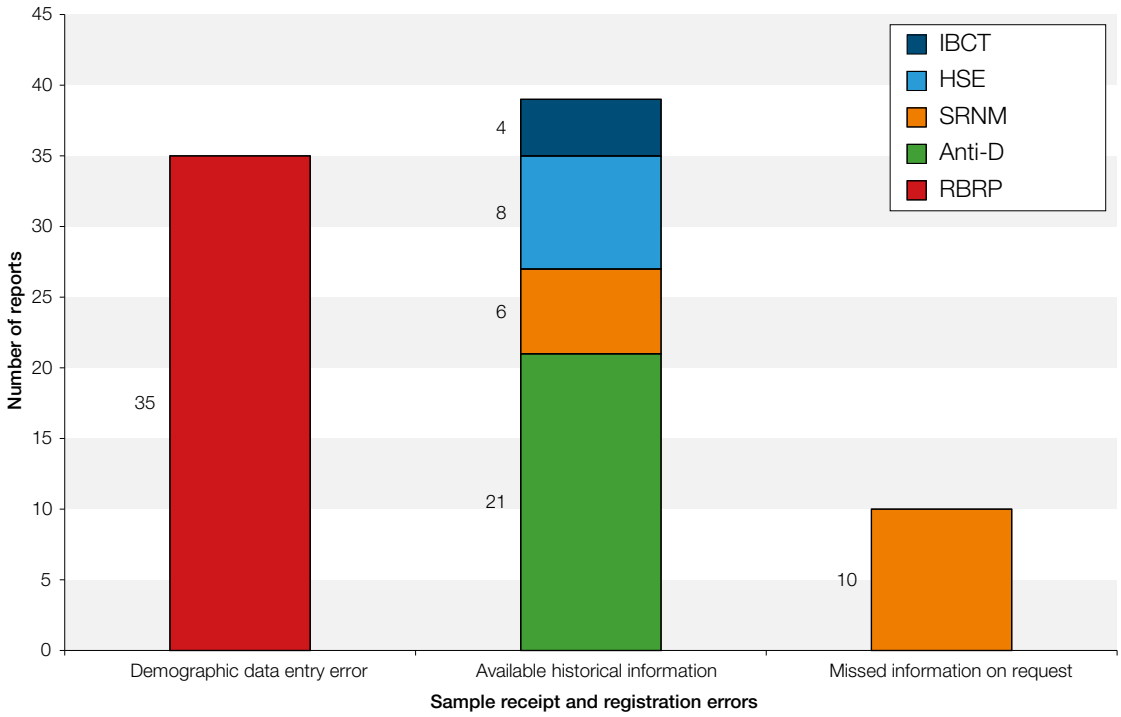


Figure 9.2: Sample receipt and registration errors with their outcome n=84

Most cases resulted in the right blood being given to the right patient despite a demographic data entry error. Further information on these reports by sub-category shown in Figure 9.2 is given below. A full analysis (where these errors are detailed under their SHOT categories so that they can be linked to outcome) of all the sample receipt and registration cases reported to SHOT in 2013 is available on the 2013 Annual SHOT Report Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2013.

Demographic data entry error	Number of reports
Patient's name	15
Date of birth (DOB)	10
Hospital number	8
Sample number	1
Address	1
Total	**35**

Table 9.3: Demographic data entry error n=35

Learning point

- Maintaining correct patient identification throughout the process is essential and must always be ensured at each critical point of the laboratory process starting with entry of correct patient demographics onto the laboratory information management system (LIMS)

Table 9.4: Available historical information missed on the LIMS n=39

Available historical information missed on the LIMS	Number of reports
Anti-D Ig inappropriately administered to women who had known immune anti-D	14
Samples that had exceeded BCSH* sample timing guidelines [19]	8
Specific requirements on patient's historical record missed/not heeded	6
Anti-D Ig inappropriately administered to women who had delivered an RhD negative infant as the cord RhD status was not checked and was assumed to be RhD positive	4
Incorrect ABO/RhD to known haemopoietic stem cell transplant (HSCT) patients	4
Anti-D Ig inappropriately administered to a known RhD positive woman	3
Total	**39**

**BCSH = British Committee for Standards in Haematology*

Case 1: A failure to consult historical records results in a patient with multiple antibodies receiving a red cell transfusion of incorrect phenotype

A patient had a positive antibody screen in 2002 which was flagged under the patient A&E (accident and emergency) number. The patient had received red cell transfusions on two occasions (2007 and 2013) that were not of the correct phenotype due to a failure to consult historical records. On these occasions the samples were booked in using the NHS/Hospital number, the antibody screens were negative and the patient was transfused red cells that had been electronically issued on both occasions. When a further request was received by the laboratory the patient's historical record under the A&E number was found and it was noted the patient had previously detectable anti-K, anti-Jk^a and anti-Kp^a in 2002.

Learning points

- Qualified biomedical scientists (BMS) crossmatching red cells and any member of staff issuing components must take responsibility for checking **all** the relevant laboratory history on a patient to ensure that they issue components of the correct specification
- Duplicate patient records must be avoided to prevent essential transfusion and/or antibody history being overlooked. There should be a policy to identify and link separate records that exist for each patient at the time of the transfusion request [19]

Table 9.5: Information provided on request form but missed n=10

Information provided on request form but missed by laboratory staff	Number of reports
Request for irradiated components	7
Request for RhD/K matched and HbS negative for sickle cell patient	2
Request for irradiated and cytomegalovirus (CMV) negative	1
Total	**10**

Learning points

- Maintaining an accurate patient database is a critical safety measure in the treatment of patients. Transfusion laboratories must have a robust search protocol in place to identify historical patient records in order to find details of known antibodies, haemoglobinopathies and previous relevant treatments, such as haemopoietic stem cell transplant or use of purine analogues
- The age and gender of a patient are required to determine some specific requirements

Testing errors n=51

Testing errors include misinterpretation of results 11/51 (21.6%), technical errors 11/51 (21.6%) and transcription errors 6/51 (11.7%). The remaining cases were due to procedural errors resulting in incomplete testing in 23/51 (45.1%), see Figure 9.3.

ABO/RhD grouping errors

There were 10 grouping errors (3 ABO, 7 RhD), all associated with manual interventions: transcription errors (6), interpretation errors (2) and technical errors (2).

Pre-transfusion testing is an essential part of the transfusion process: accurate ABO/RhD grouping is the most important serological test. Despite recommendations for fully automated grouping some laboratories continue to perform manual ABO/RhD grouping for example in emergencies or out-of-hours. SHOT supports recommendations published by the UK Transfusion Laboratory Collaborative (UKTLC) for routine use of full automation whenever possible for all samples throughout 24 hours, to eliminate manual errors [30].

Learning points

- Successive Annual SHOT Reports have demonstrated that manual intervention is prone to human error. SHOT error reports demonstrate a continuing need for appropriate serological knowledge and understanding by all blood transfusion laboratory staff to underpin the safety provided by automation and information technology (IT)
- The UK Transfusion Laboratory Collaborative (UKTLC) [30, 31] recommends that all laboratories should have full walk away automation which is in use 24 hours, 7 days a week, with bidirectional interfaces to the laboratory information system

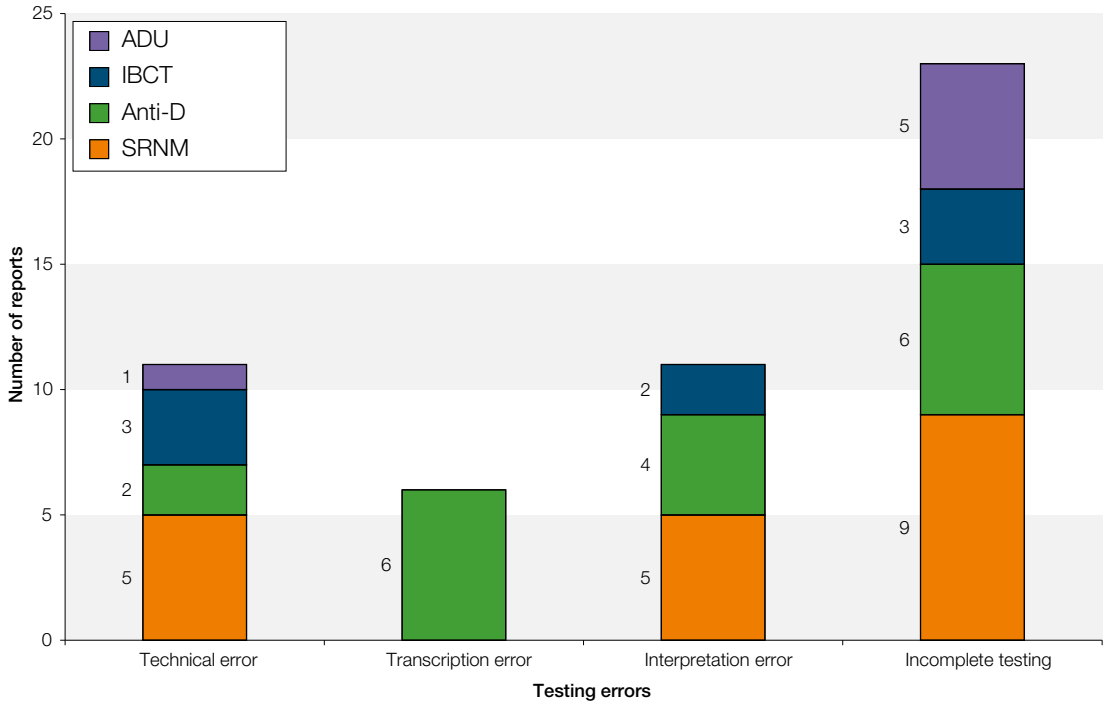


Figure 9.3: Testing errors with their outcomes n=51

Further analysis, where these testing errors are categorised under their main chapter headings, so that they can be linked to outcome is available in the 2013 Annual SHOT Report Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2013.

Table 9.6: Procedural error n=23 These all resulted from laboratory staff failing to follow standard operating procedures (incomplete testing)

Procedural errors	Number of reports
Omission or late administration of anti-D Ig because Kleihauer test was: a) not performed within 72 hours post delivery b) performed within 72 hours but anti-D Ig was not administered within 72 hours (Case 2)	6
Erroneous low platelet counts that were reported for patients whose platelets were known to 'clump' in ethylene diamine tetraacetic acid (EDTA)	4
Antibody identification not performed following a positive antibody screen	4
Red cells issued and transfused before crossmatch results had been confirmed	3
Group and antibody screen not performed prior to issue of crossmatched red cells	2
Antibody screen not performed	1
Red cells transfused to neonate not crossmatched against the maternal sample which contained multiple alloantibodies	1
Non–human leucocyte antigen (HLA)-matched platelets transfused due to failure to enter available HLA results into the computer system	1
Erroneous full blood count due to clotted sample	1
Total	**23**

Learning point

- Inappropriate transfusions could be avoided if laboratories did not transmit results they know or suspect to be inaccurate, but instead requested a second sample

Case 2: Delay in reporting positive Kleihauer caused by a laboratory processing error

A standard dose of 500IU anti-D Ig was given to a woman after delivery, but there was an estimated 9mL bleed by Kleihauer testing. The sample was referred to the Blood Service reference laboratory to confirm the result by flow cytometry. Further anti-D Ig was required to cover the fetomaternal haemorrhage (FMH) and was not administered within 72 hours, because the flow cytometry result was reported 60h after delivery leaving only 12 hours (overnight) to achieve administration of anti-D Ig which was to be given in the community.

Learning point

- A robust service should be in place to allow fetomaternal haemorrhage (FMH) testing to be completed with sufficient time to allow for referral for flow cytometry if required so that administration of a full dose of anti-D Ig can be completed within 72 hours of delivery, particularly where administration will take place within the community

Case 3: Incomplete testing results in a neonate receiving a red cell transfusion that did not meet their specific requirements

Compatibility testing was performed against a neonatal sample and not the maternal sample as required [32]. The mother had multiple antibodies including anti-D, anti-Fy^a, anti-Jk^b, anti-M and anti-S and subsequent testing showed that the unit issued to the neonate was incompatible with the mother.

While this may have been a short cut it is important to establish that all members of staff have appropriate knowledge and that they follow a correct standard operating procedure (SOP).

Learning points

- Omission of steps (taking short cuts) leads to errors, so processes must be followed according to a robust standard operating procedure (SOP). This is a primary principle of good manufacturing practice (GMP)
- Competency-assessment must include understanding and knowledge as well as simply the ability to follow 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 biomedical scientist (BMS)

Table 9.7: Interpretation errors n=11

Interpretation errors	Number of reports
Antibody identification results	5
ABO grouping errors	1
RhD grouping errors	1
Inappropriate administration of anti-D Ig to a woman with immune anti-D	1
Omission of anti-D Ig to a woman with 'partial D'	1
Inappropriate administration of anti-D Ig to an RhD positive woman	1
Anti-D Ig inappropriately administered to a woman who had delivered an RhD negative infant but the manual cord group was misinterpreted as RhD positive	1
Total	**11**

Table 9.8: Technical errors n=11

Technical errors	Number of reports
Inappropriate use of electronic issue	6
Anti-D Ig administered inappropriately as a result of incorrect estimation of fetomaternal haemorrhage (FMH) by Kleihauer testing	1
Anti-D Ig administered inappropriately as a result of a Kleihauer test that was mistakenly performed on the maternal sample of a woman who had delivered a RhD negative infant	1
No grouping reagents were added to manual ABO tube group	1
ABO grouping error due to possible contamination with incorrect antisera	1
Erroneous abnormal clotting results were reported on a sample suspected to have clotted prior to testing where a repeat test showed normal results	1
Total	**11**

Case 4: Manual ABO grouping error in an emergency

Group-specific red cells had been requested for a patient with a ruptured aortic aneurysm. A manual emergency blood group result was recorded as AB RhD positive but the confirmatory automated blood group result was A RhD positive. This was possibly caused by a contamination from the anti-A,B in the tube labelled anti-B. One unit of group AB RhD positive red cells had been transfused before the error was detected.

Learning points

- When emergency groups are performed they MUST include a test against anti-A, anti-B and anti-D with appropriate controls or reverse group, if there is insufficient time for this level of testing then group O red cells must be issued [19]
- The ABO and RhD group must, wherever possible, be verified against historical patient results
- 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 should be repeated [19]

Table 9.9: Transcription error n=6

Transcription errors	Number of reports
Cord samples tested post delivery incorrectly reported as RhD positive resulting in inappropriate administration of anti-D Ig	4
Cord samples tested post delivery incorrectly reported as RhD negative resulting in omission of Anti-D Ig to RhD negative women	2
Total	**6**

Learning point

- The laboratory should have a policy with respect to the manual editing and authorisation of test results [23]

Component selection n=36

Most of these errors resulted in patients receiving an incorrect blood component (9/36) or one not of the correct specification (19/36). More information can be found in the Annual SHOT Report 2013 Supplement for Chapter 9 located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2013.

Component labelling, availability and HSE n=104

Most errors in this group resulted in the correct blood being given to the correct patient despite a handling and storage error (43/104) or an error associated with patient identification resulting in 'right blood right patient' (48/104). More information can be found in the Annual SHOT Report 2013 Supplement for Chapter 9 located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2013.

Miscellaneous n=9

There were 9 miscellaneous cases that highlight a lack in communication and knowledge by laboratory staff.

Avoidable, delayed and undertransfusion n=7

There were delays caused by equipment failures or insufficient communication between the laboratory staff and clinical teams about the clinical urgency in 5/7 cases. In one case surgery was delayed until a new sample had been received in the laboratory following an initial enquiry when theatre staff were incorrectly informed that the previously sent preoperative sample was invalid.

Inappropriate use of O RhD negative red cells occurred in 2/7 cases because of inadequate communication between the clinical team and laboratory staff. There was a delay in provision of compatible units for patients with positive antibody screens.

Learning point

- In an emergency, laboratory staff can help clinical teams by providing clear timelines for expected component availability, particularly when further testing is required i.e. when a patient has irregular antibodies. Clinical teams can help laboratory staff by providing them with a clear assessment of the urgency of the situation and an assessment of when components are required without delay

Specific requirements not met n=2

Laboratory errors contributed to a failure to meet a patient's specific requirements due to erroneous removal of specific requirements flags (see Case 17 in Chapter 8 Incorrect Blood Component Transfused (IBCT)) and incomplete follow up of a transferred patient's previous hospital for records of known antibodies.

IT-related laboratory cases n=95

There were 95 laboratory cases that also had an IT element and these are described in their main chapters: Chapter 8 Incorrect Blood Component Transfused (IBCT), Chapter 11 Avoidable, Delayed or Undertransfusion (ADU), Chapter 12 Right Blood Right Patient (RBRP), Chapter 13 Handling and Storage Errors (HSE) and Chapter 14 Anti-D Immunoglobulin – Prescription, Administration and Sensitisation.

COMMENTARY

This chapter has focussed on sample receipt and registration, testing errors and miscellaneous cases. These reports highlight key areas that have still not been addressed, such as effective communication and poor serological knowledge and understanding by laboratory staff. During the 'booking in' process it is essential to take into account any historical patient information and ensure all previous results and any specific requirements have been taken into consideration. National guidelines define the minimum dataset required for samples and requests [25, 33].

As in previous years, 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 dictate. Reporters expressed concern over laboratory staff shortages and pressures associated with heavy workload and distractions were cited as contributory factors in a number of cases. Pre-transfusion testing has potential for error at a number of critical points and must be performed according to robust SOPs.

In addition to serological testing, historical records may influence the selection of the most appropriate components for the patient, so must be consulted and any necessary actions taken. In clinical emergencies clear timelines on the availability of requested components need to be communicated effectively to the clinical team. If crossmatched red cells are required for patients with known antibodies, delays in provision need to be discussed and agreed before crossmatching can be completed, as group specific units of appropriate phenotype should be selected when possible and the associated risks should be agreed with clinicians.

The modern transfusion laboratory is critically dependent on IT and automation. Common causes of wrong blood errors in this report are the failure to use warning flags on the LIMS properly, either because they have not been heeded or have not been set up or updated in a timely manner. Maintaining correct patient identification throughout the process is imperative and must always be ensured at each critical point of the laboratory process starting with entering correct patient demographics onto the laboratory information management system. Electronic issue (EI) must be under the control of the LIMS with no manual interventions. Logic rules and flags should be set up to support this.

Supplementary information, including further details of all laboratory cases reported to SHOT in 2013 can be found in the 2013 Annual SHOT Report Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2013.

Please note the updated SHOT Laboratory Lessons published 2013 are also available under the Current Resources section of the SHOT website www.shotuk.org.

UK Transfusion Laboratory Collaborative (UKTLC)

The members of the UKTLC have revised their recommendations and have produced updated standards [31] based on the findings from 2 national surveys performed in 2011 and 2013. These standards focus on 3 key areas: adequate staffing, adequate levels of knowledge and skills and technology. The laboratory accreditation organisation, Clinical Pathology Accreditation (UK) Ltd (CPA) has agreed to consider these standards when auditing compliance against their own standards. The Medicines and Healthcare products Regulatory Agency (MHRA) also confirmed that where circumstances have warranted it, inspectors have asked why a Trust/Health Board/Hospital does not work in line with the recommendations from a professional body. SHOT encourages all laboratories to comply with the UKTLC standards to improve patient safety.

Recommendation

- All blood transfusion laboratories should be familiar with and comply with the UK Transfusion Laboratory Collaborative (UKTLC) standards. Accrediting and regulatory organisations have supported this initiative, therefore compliance with these standards is strongly recommended

Action: Trust/Health Board Chief Executive Officers, Transfusion Laboratory Managers, Hospital Transfusion Teams

Recommendations still active from previous years are available in the 2013 Annual SHOT Report Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2013.