Summary of Events Originating in the Hospital Transfusion Laboratory n=334

11

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Key SHOT messages

- Errors with sample receipt and registration, and testing all highlight key areas for improvement, particularly lack of effective communication together with poor serological knowledge and understanding in laboratory staff. During the 'booking in' process it is essential to take into account any historic patient laboratory information and to ensure that all previous results and any specific requirements have been taken into consideration
- The modern transfusion laboratory is critically dependent on IT and automation. Worryingly, there has been a number of cases in 2014 where the error in relation to the use of IT may have been an error in the actual software or function of the IT system
- The BCSH guidelines on IT in blood transfusion (BCSH Jones et al. 2015) and the UKTLC standards (Chaffe et al. 2014) have both been published recently, and laboratory staff are strongly encouraged to perform a gap analysis and ensure their laboratories comply with them

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 any of the above steps

Analysis of all cases reported to SHOT in 2014 shows that 2346/3017 (77.8%) were caused by error. Of these 334/1179 (28.3%) full cases originated in the laboratory, Table 11.1, and there were a further 313/1167 (26.8%) laboratory-related near miss cases, Table 11.2.

Table 11.1: Laboratory errors n=334

Laboratory categories	Total	Percentage	Chapter					
			IBCT	SRNM	HSE	RBRP	ANTI-D	ADU
Sample receipt and registration	94	28.1%	9	45	4	22	12	2
Testing	88	26.3%	11	32	9	0	23	13
Component selection	39	11.7%	13	8	6	1	11	0
Component labelling, availability, handling and storage	109	32.6%	3	0	44	50	2	10
Miscellaneous	4	1.2%	0	1	0	0	3	0
Total	**334**	**100%**	**36**	**86**	**63**	**73**	**51**	**25**

Key: IBCT – incorrect blood component transfused; SRNM – specific requirements not met; HSE – handling and storage errors; RBRP – right blood right patient; ADU – avoidable, delayed and undertransfusion.

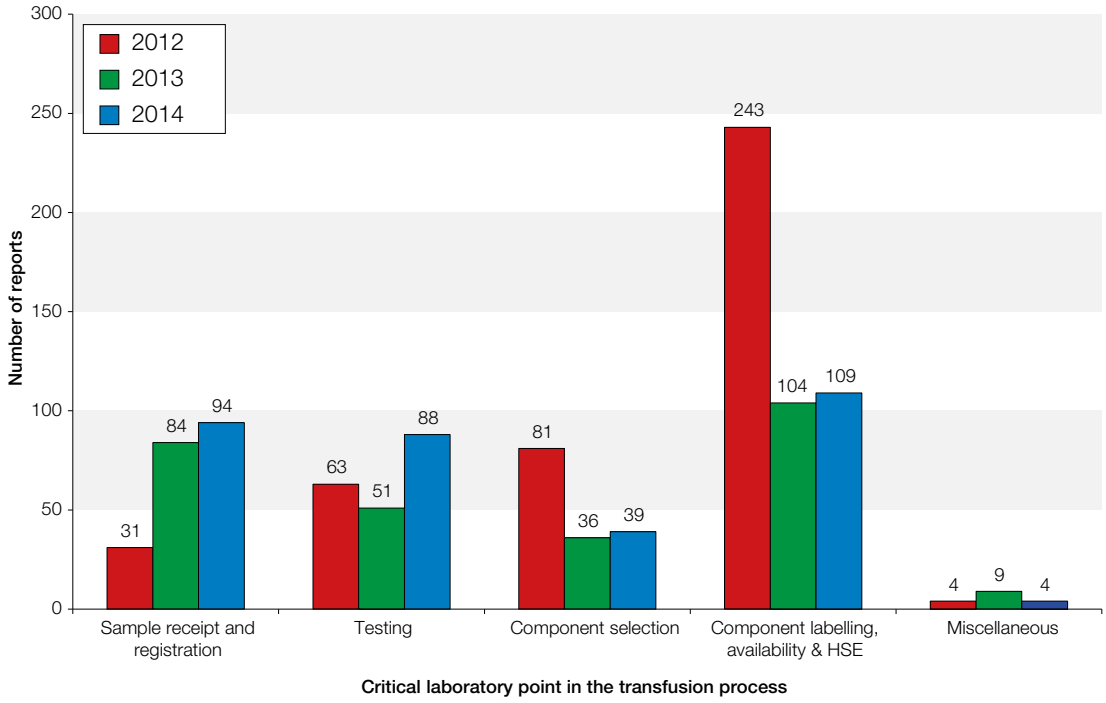
In 313 near miss cases the errors were detected prior to transfusion. This illustrates that when procedures are followed and staff involved in the transfusion process perform their role effectively, errors can often be detected before transfusion.

Table 11.2: Near miss laboratory errors n=313

Near miss laboratory categories	Total	Percentage	Derivative chapter					
			IBCT	SRNM	HSE	RBRP	ANTI-D	ADU
Sample receipt and registration	58	18.6%	14	29	0	14	1	0
Testing	36	11.5%	21	12	0	0	3	0
Component selection	68	21.7%	17	17	11	0	23	0
Component labelling, availability, handling and storage	150	47.9%	7	1	51	85	6	0
Other: bacterial contamination of a unit of platelets	1	0.3%	0	0	1	0	0	0
Total	**313**	**100%**	**59**	**59**	**63**	**99**	**33**	**0**

Figure 11.1 shows the 3 year trend and indicates the critical points in laboratory processes where errors occur.

Figure 11.1: Three year trend 2012-2014



The total number of laboratory cases reported in 2014 has increased n=334 compared with 2013 n=284. The number of cases related to sample receipt and registration and particularly testing errors have increased, Figure 11.1. The 4 cases classified as 'miscellaneous' are described later.

Sample receipt and registration errors n=94

Most errors at sample receipt and registration are similar to previous years. Failure to take into account available historic information accounts for 60/94 (63.8%), demographic data entry errors for 25/94 (26.6%) and information missed by laboratory staff that was provided on the request form for 9/94 (9.6%).

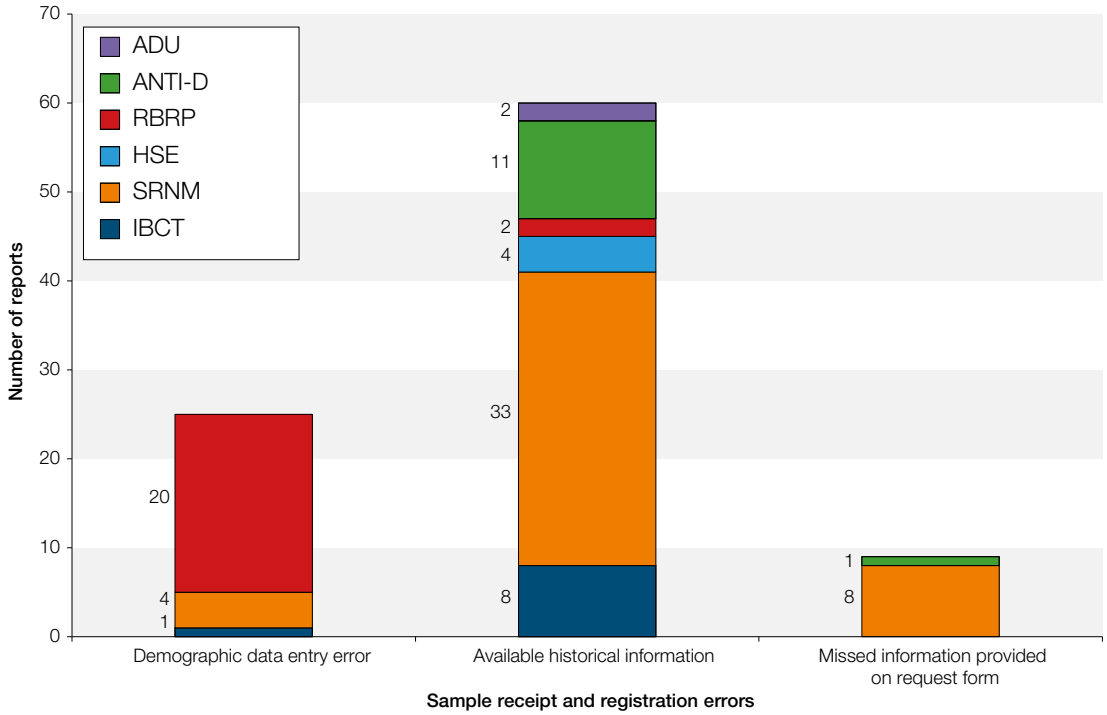


Figure 11.2: Sample receipt and registration errors n=94

The outcomes in each subcategory are given below, in Tables 11.3-11.5. The number of errors in 2014 for demographic data entry error have reduced, (35/84 cases in 2013, compared with 25/94 in 2014) and information missed by laboratory staff that was provided on the request form shows little change (10/84 cases in 2013, compared with 9/94 in 2014).

Demographic data entry error	Number of cases
Patient's name	9
Hospital/National Health Service (NHS) number	6
Date of birth	5
Ambiguous information regarding patient's previous history including antibody information and flags not being set up correctly	5
Total	**25**

Table 11.3: Demographic data entry error n=25

Available historic information missed on the LIMS	Number of cases	
Requirements or patient details on patient's historic record missed/not heeded	35	
Antibody history or specific requirements on patient records not heeded		*23*
Patient records not merged correctly		*7*
Flag not set up correctly		*3*
Flags not being activated		*1*
Shared care		*1*
Incorrect ABO/D group issued to patients including known haemopoietic stem cell transplant (HSCT) patients	8	
Anti-D immunoglobulin (Ig) inappropriately administered to women who had known immune anti-D	7	
Samples that had exceeded BCSH* sample timing guidelines (BCSH Milkins et al. 2013)	4	
Anti-D Ig inappropriately administered to a woman who had delivered a D-negative infant because the cord D status was not looked up and the infant was assumed to be D-positive	3	
Delay in transfusion due to information not being heeded on the patient's historical record i.e. correct blood group on the patient's record but the wrong blood group was ordered	2	
Anti-D Ig inappropriately administered to a known D-positive woman	1	
Total	**60**	

**BCSH = British Committee for Standards in Haematology*

Table 11.4: Available historic information missed on the laboratory information management system (LIMS) n=60

Table 11.5: Information missed by laboratory staff that was provided on the request form n=9

Details of information missed on request form	Number of cases
Request for irradiated components	6
Request for solvent-detergent fresh frozen plasma (SD-FFP)	1
Request for cytomegalovirus (CMV) negative (red blood cells)	1
Request for group and Kleihauer on maternal sample	1
Total	**9**

For an illustrative case and learning point about transfer of historic data from legacy systems to a new laboratory information system please see Case 9 in Chapter Incorrect Blood Component Transfused.

Table 11.6: Near miss sample registration and receipt errors n=58

Sample registration and receipt errors	Number of cases	Percentage of cases
Specific requirements not met	29	50.0%
Incorrect identifiers entered onto LIMS	14	24.1%
Sample booked under incorrect record	14	24.1%
Incorrect patient merge in LIMS/patient administration system (PAS)	1	1.8%
Total	**58**	**100%**

Testing errors n=88

Reports of testing errors have increased in 2014 compared with 2013 (n=51). The type of testing errors have been analysed below to highlight the different testing and procedural errors that are still recurring year after year.

Most errors that occurred in testing (Figure 11.3) were due to procedural errors:

- Incomplete testing in 54/88 (61.4%)
- Transcription errors in 14/88 (15.9%)
- Misinterpretation of results in 10/88 (11.4%)
- Technical errors in 10/88 (11.4%)

ABO/D grouping errors n=9

There were 9 grouping errors (5 ABO, 4 D), all involved manual intervention: interpretation errors n=5 and transcription errors n=4.

Case 1: Vague and non-prescriptive standard operating procedures (SOP) resulted in incorrect group interpretation

During a late shift for transfusion, a new sample was received from a 52 year old woman. The BMS performed a full forward/reverse group and also an abbreviated group in BioVue cassettes. Both groups gave a weak D-positive result. The BMS then performed a manual group that again gave a weak D-positive group and this was reported into the LIMS. The BMS then selected two D-positive red cell units which were compatible and transfused. A request for an additional unit was received and again a D-positive unit was compatible and transfused. The BMS tried to find the SOP but had not found any reference to weak D grouping in the automated grouping SOP. The ward later contacted the laboratory to state the patient believed she was D-negative. The BMS checked the SOPs again and found reference in the manual grouping SOP stating that a direct antiglobulin test (DAT) should have been performed, as a positive DAT can cause weak positive reactions with the anti-D reagents. The patient was found to have a weakly positive DAT and was confirmed to be D negative. The patient is being monitored to see if she develops anti-D. The incident investigation noted that the SOPs were vague but also there was no positive reaction with the anti-D control, which influenced the result interpretation.

Pre-transfusion testing is an essential part of the transfusion process: accurate ABO/D grouping is the most important serological test. Despite recommendations for fully automated grouping some laboratories continue to perform manual ABO/D grouping for example in emergencies or out-of-hours, and in very small laboratories where large automation is not feasible. SHOT supports the standards published by the UK Transfusion Laboratory Collaborative (UKTLC) in 2014 (Chaffe et al. 2014) for routine use of full automation for all samples throughout 24 hours, to eliminate manual errors.

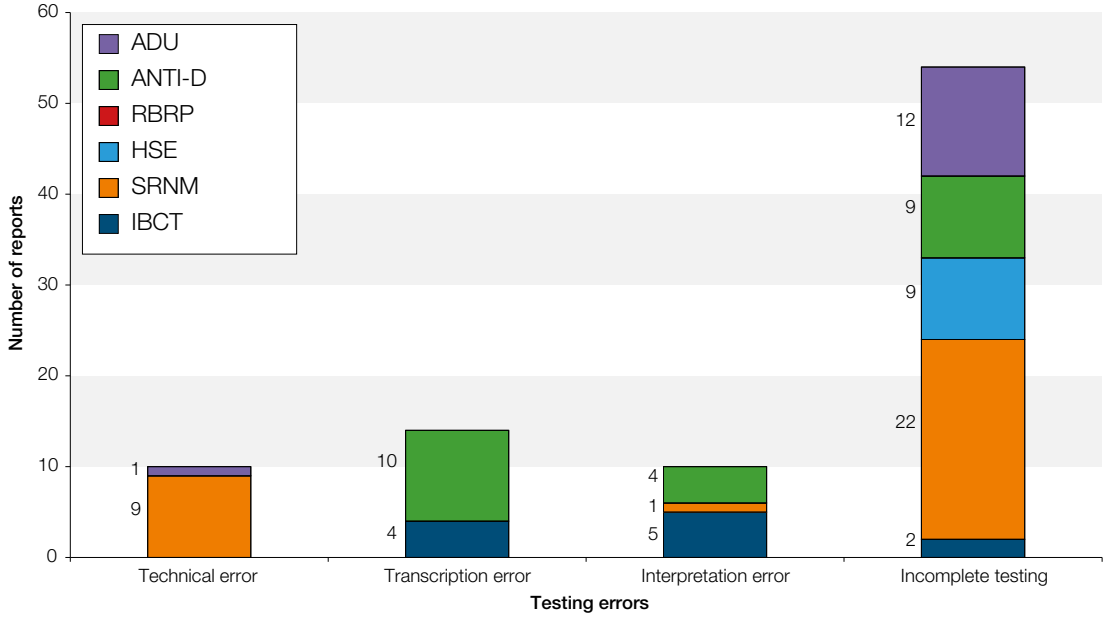


Figure 11.3: Testing errors n=88 with their outcome

These all resulted from laboratory staff not following SOP (incomplete testing).

Table 11.7: Procedural errors n=54

Procedural errors	Number of cases
Red cell units issued based on an invalid sample according to the BCSH guidelines (BCSH Milkins et al. 2013)	9
Clinically significant antibodies not excluded during antibody identification/positive antibody panel not fully identified (testing errors)	7
Components issued based on erroneous results (e.g. fibrinogen and Hb)	7
Antibody identification not performed following a positive antibody screen	7
Erroneous low platelet counts reported for patients whose platelets were known to 'clump' in ethylenediaminetetraacetic acid (EDTA)	5
Omission or late administration of anti-D Ig because Kleihauer test: a) Was not performed within 72 hours post delivery b) Was performed within 72 hours but anti-D Ig was not administered within 72 hours	4
Components issued based on a single sample and no confirmatory blood group check taken	3
D group performed on maternal sample rather than cord sample	2
Anti-D Ig issued to a D-negative mother who delivered a D-negative baby	2
Red cells transfused to neonate which were not crossmatched against the maternal sample which contained multiple alloantibodies	1
Red cells issued and transfused before crossmatch results had been confirmed	1
Blood group performed using invalidated methodology	1
Excessive dose of anti-D Ig administered because the BMS did not wait for the flow cytometry results which would have been available within 72 hours	1
Red cells issued from an incomplete crossmatch	1
Platelets issued on an incomplete group and antibody screen	1
Failure to perform DAT on a 1 day old baby prior to issue of red cells	1
BMS did not perform complete testing as stated in SOP for D status of patient following a mixed field reaction	1
Total	**54**

Table 11.8: Transcription errors n=14

Transcription errors	Number of cases
Cord samples tested post delivery incorrectly reported as D-negative resulting in omission of anti-D Ig to D-negative women	4
ABO/D group transcribed incorrectly onto LIMS	4
Cord samples tested post delivery incorrectly reported as D-positive resulting in inappropriate administration of anti-D Ig	3
Mother (D-negative) transcribed as D-positive was not given anti-D Ig in a timely manner	1
Inaccurate comments input into LIMS regarding testing that had been performed, resulting in red cell units being issued to the baby that were not crossmatched against mother	1
Misleading code entered onto LIMS resulting in failure to issue anti-D Ig within 72 hours	1
Total	**14**

Table 11.9: Technical errors n=10

Technical errors	Number of cases
Inappropriate use of electronic issue	9
Sample analysed, results not appearing in the authorisation queue in Winpath. Three emergency units taken from the transfusion laboratory. IT problem took approximately 30 minutes to resolve	1
Total	**10**

Table 11.10: Interpretation errors n=10

Interpretation errors	Number of cases
ABO/D grouping errors	5
Antibody identification results	1
Misinterpretation of fetomaternal haemorrhage (FMH) result leading to excessive dose of anti-D Ig being given	1
BMS misinterpreted the anti-D algorithm for repeat bleeding in pregnancy therefore anti-D Ig was not administered	1
Patient D typed incorrectly by Blood Service. D-positive initially, changed to treat as D-negative, anti-D Ig administration was delayed	1
Anti-D Ig inappropriately administered to a woman who had delivered a D-negative infant but the cord group incorrectly reported as D-positive following manual testing	1
Total	**10**

Case 2: Insufficient testing for antibody identification

A sample was received for crossmatching out-of-hours. The antibody screen was found to be positive and the antibody identification was concluded as 'irregular anti-human globulin (AHG)-reactive antibodies'. All clinically-significant antibodies on the identification panel were excluded by the homozygous expression of the antigen on test cells and unselected units compatible by indirect antiglobulin test (IAT) crossmatch were issued. Further investigation the following morning with an enzyme-treated cell panel identified anti-c. The enzyme panel is not routinely performed. Both units issued were retrospectively identified as R2r (cDE/cde).

Learning point

- Enzyme-treated cell panels are useful to detect Rh antibodies and can improve the chances of correctly identifying an antibody mixture. Enzyme-treated identification panels should be considered for routine use (Milkins et al. 2013)

Testing errors	Number of cases	Percentage of cases
Procedural errors	12	33.3%
Interpretation errors	8	22.2%
Transcription errors	6	16.7%
Equipment failure/testing problem	6	16.7%
Manual grouping errors	4	11.1%
Total	**36**	**100%**

Table 11.11: Near miss testing errors

IT and analyser-related near miss reports

Surprisingly in 2014 there were several reports of equipment failures leading to testing problems, n=6. All incidents were in separate Trusts/Health Boards and where stated different analysers were implicated. The issues can be summarised as:

- Two analysers mis-grouped samples, exact causes not known
- A sample with a known antibody was reported as antibody screen negative by two analysers in the same laboratory, but the antibody screen was positive on both analyser databases. The manufacturer has investigated the error and resolved it to the satisfaction of the Medicines and Healthcare products Regulatory Agency (MHRA) Medical Devices section
- A poorly printed barcode was misread by an analyser as a different number, so an incorrect grouping result was reported on another patient's record
- An incorrect group was transferred from the analyser to the laboratory information management system (LIMS) exact cause not known
- An initial suspected wrong blood in tube (WBIT) was determined to be a laboratory analysis error, probably IT related, but exact cause not known

Laboratories are increasingly reliant on IT. The UK Transfusion Laboratory Collaborative (UKTLC) minimum standards (Chaffe et al. 2014) recommend that all laboratories have complete walk-away automation which is in use 24 hours, 7 days a week. In the absence of complete automation, documented measures must be taken to mitigate procedural laboratory errors.

Learning point

- Laboratories should ensure all automated processes are fully validated and constantly monitored for accuracy. IT systems should be audited on a regular basis against the BCSH guidelines for the specification, implementation and management of IT systems in hospital transfusion laboratories (BCSH Jones et al. 2014)

Further IT errors are discussed in the relevant chapters.

Component selection errors n=39

A variety of component selection errors were reported including:

- Selecting the wrong component n=13 e.g. FFP when cryoprecipitate was requested
- Late/omitted or insufficient dose of anti-D Ig to women n=11
- Units that are not of the correct specification n=8 (i.e. not irradiated or of the correct phenotype)
- Selection of expired units n=6
- Selecting the wrong pack i.e. RBRP n=1

These component selection errors could have been prevented if laboratory staff maintained their understanding, knowledge and skills within the transfusion laboratory.

Learning point

- Regular participation or assessment within a continuing professional development (CPD) scheme is essential for all transfusion laboratory staff

Component labelling, availability and handling and storage errors n=109

Many cases in this category are due to labelling errors (n=50), where labels were transposed when more than 1 unit was issued to the same patient. In 44 cases expired units were not discarded but reissued to patients or cold chain errors occurred that resulted in units which had been out of controlled temperature being transfused to patients. The remaining 15 were:

- 12 cases related to availability of components
- 3 further labelling errors where the labels for 2 units that were intended for different patients were transposed

Miscellaneous n=4

There were 4 cases that did not result from errors in the transfusion process and are described below. All of these were due to lack of communication and lack of knowledge by laboratory staff.

Case 3: Omission of anti-D Ig treatment during D-mismatched human leucocyte antigen (HLA)-matched platelet transfusion

HLA-matched platelets were transfused to a patient on two occasions. The female patient (42 years) was D-negative and the platelets on both occasions were D-positive. No consideration was given to administration of anti-D Ig by laboratory or clinical staff at the time of transfusion.

Case 4: Inappropriate administration of anti-D Ig

A female patient with major haemorrhage required 4 units of FFP as part of the component replacement. The patient grouped as A D-negative and the BMS only had group A D-positive FFP available. The BMS wrongly thought that, as with platelets, anti-D Ig was required when transfusing mismatched D-grouped FFP to a woman of childbearing potential and informed the clinical staff. The patient was wrongly issued anti-D Ig by the laboratory which was then administered.

Case 5: Poor communication leads to delayed anti-D Ig administration

A BMS working on a Friday failed to fully follow the SOP in a timely manner. A female patient grouped as D-negative and as a result of poor handover the next BMS failed to issue anti-D Ig prophylaxis that night. This omission was not detected until after the weekend and so anti-D Ig was issued outside the 72-hour period following a sensitising event.

Case 6: Incomplete information transmitted from the Blood Service - communication failure

This case is described in Chapter 9 Serial Errors and Multiple Missed Opportunities to Detect an Earlier Error, Case 18.

Learning points and suggested actions

- Standardisation of laboratory reports so they cannot be misinterpreted
- Standardisation of patient records with electronic transfer of D-grouping results where possible

UK Transfusion Laboratory Collaborative (UKTLC)

The UKTLC recommendations as published in 2009 and updated in 2010 targeted a 50% reduction in laboratory related errors by September 2012 (Chaffe et al. 2010). The deadline for this target reduction coincided with an upsurge of pathology reorganisations designed to deliver the level of savings as outlined in the Carter review of 2008 (Lord Carter of Coles, 2008). The target incident reduction of 50% was not met and the move towards merging pathology services within Trusts/Health Boards and the formation of pathology networks has presented new challenges to achieving ongoing error reduction.

Pathology modernisation has seen the implementation of blood sciences departments across pathology networks where cross-trained BMS staff have provided the flexibility needed to provide 24/7 cover. However, integration of blood transfusion services into the blood sciences model within pathology networks is harder as, unlike the diagnostic nature of haematology and biochemistry services, blood transfusion is a therapeutic service requiring different skills. It is essential that blood transfusion services are included in the modernisation of pathology services in a manner that ensures the safety of the service at ALL times.

The UKTLC Standards 2014 have been published to help facilitate safe and effective integration while aiding the reduction of laboratory related errors.

Laboratory surveys undertaken in 2011 and 2013 both showed a reluctance by laboratories to implement the UKTLC recommendations as there was no formal requirement to do so. The data collected in 2014 clearly show that laboratory-related errors continue to occur at an unacceptably high rate and would appear to be increasing. These findings underpin the urgent need for laboratories to assess their service against the newly published UKTLC standards.

The UKTLC Standards 2014 are supported by the Clinical Pathology Accreditation, UK Accreditation Service and the Medicines and Healthcare products Regulatory Agency. The published new standards are available on both the SHOT and Institute of Biomedical Science (IBMS) websites by open access (Chaffe et al. 2014). The standards are divided into three sections, staffing, information technology, knowledge and skills. Each section is designed to encourage laboratories to adopt effective and appropriate practices in order to address incident reduction in a responsible and professional manner that recognises the current framework of legislative requirements as well as the absolute need to ensure that specialist knowledge is maintained within the local/network blood transfusion chain of practice at all times. To many the knowledge and skills requirement for the future will be the biggest challenge. Guidance on the implementation of standards relating to knowledge and skills will be available on the IBMS website.

COMMENTARY

The number of cases relating to sample receipt and registration, and testing errors highlight key areas, particularly lack of effective communication together with poor serological knowledge and understanding in laboratory staff. National guidelines define the minimum dataset required for samples and requests (BCSH Harris et al. 2009).

All ABO and D testing errors occurred as a result of manual interventions, such as transcription and interpretation. In addition to serological testing, historical laboratory records may influence the selection of the most appropriate components for the patient, so must be consulted and actioned.

Pathology services within the NHS are undergoing fundamental changes. The pressure of such changes are being cited as mitigating circumstances in a number of cases. These incidents raise concern in relation to laboratory staff shortages and pressures associated with heavy workload and distractions.

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