ANNUAL SHOT REPORT
2016

LABORATORY ERRORS

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Outline

1. Key Laboratory messages
2. Errors in the laboratory
   Differences between MHRA and SHOT Laboratory data
3. Recurring laboratory errors – common themes
4. UK Transfusion Laboratory Collaborative (UKTLC)
5. MHRA inspection and feedback
6. Conclusions
Key SHOT Messages 2016

- Laboratories should always have adequate staffing at the appropriate grade to support those that require training.

- Appropriate use and management of Laboratory Information Management Systems (LIMS) are essential for patient safety.

- Gap analysis should be performed against national transfusion guidelines and SOPs amended to correct deficiencies.
SHOT Laboratory data – 5 year trend

1 REQUEST
2* SAMPLE
3 SAMPLE RECEIPT
4 TESTING
5 COMPONENT SELECTION
6 LABELLING
7 COLLECTION
8 PRESCRIPTION
9* ADMINISTRATION
SHOT Laboratory data – 5 year trend

Critical laboratory steps in the transfusion process

Number of reports

- Sample receipt and registration
- Testing
- Component selection
- Component labelling
- Miscellaneous

Years:
- 2012
- 2013
- 2014
- 2015
- 2016
Errors originating in the laboratory

252 reported to BOTH organisations in 2016
Differences in reporting between the two haemovigilance organisations

- Includes all SAE reports where a confirmation report was submitted in 2016
- Is based on reports made strictly under the BSQR
- Does not include errors in a clinical practice and administration of blood
- Does not include reactions to blood products which are classified as medicines rather than blood components such as Octaplas®
- Excludes some incidents reported to the MHRA as SAR where the reaction may have resulted from an SAE that originated in the laboratory

- Does not include cases of failed recall
- Each report is linked to a specific patient
- Does not include reports that have come from the Blood Services
Recurring laboratory errors

- Failure to heed and maintain accurate patient history
- Not following procedures
- IT errors: Failure to heed warning flags
- Multiple errors
- Errors associated with IT communication and teamwork
- Distracted: Interrupted, Poor knowledge and skills
Sample receipt and registration n=70

Sample receipt and registration errors by SHOT categories:
- **Available historical records**
  - WCT: 6
  - SRNM: 17
  - RBRP: 1
  - Delay: 1

- Demographic data entry error
  - 26

- Missed on request form
  - 1
  - 17
  - 1
Wrong component transfused where there were opportunities for detection

- A unit of red cells was commenced in error instead of the prescribed plasma

- The laboratory prepared the wrong component type following a telephone request

- Two registered nurses checked the red cells but did not refer to the prescription so failed to notice it was the wrong component type

- Verbal evidence from the ward manager confirms all patient details were checked correctly but the prescription form was not checked
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Testing n=56

Testing errors by SHOT category

- **Procedural error**
  - WCT: 6
  - SRNM: 34

- **Transcription error**
  - WCT: 3
  - SRNM: 2
  - Anti-D Ig: 1

- **Interpretation error**
  - WCT: 2
  - SRNM: 6
  - Anti-D Ig: 2
Testing n=56

Don't improvise

Can't follow the procedure?

Follow the procedure

Review and change the procedure
Errors in antibody identification

Claire Whitham

• Similar errors noted across 3 exercises
  – A process of exclusion not followed where antibodies were masked
  – Antibodies excluded with inappropriate cells
  – Making positive identification with only one example of an antigen positive cell
Learning Points

Claire Whitham

- Every antibody investigation should include a systematic process for exclusion and positive identification of antibody specificities
- All reactions should be accounted for before a conclusion is reached
- Errors in antibody identification cannot be detected at the bedside
Wrong component transfused n=170

- Incorrect blood component transfused n=170
- Wrong component transfused n=45

- Sampling errors: 2 reports
- Wrong ABO/D to HSCT patient: 5 reports
- D-mismatch: 5 reports, 8 reports, 1 report
- ABO non-identical: 2 reports, 1 report, 1 report, 1 report
- ABO-identical: 1 report, 2 reports, 1 report
- Wrong component: 1 report, 3 reports
- ABO-incompatible FFP: 1 report, 2 reports
- Serological crossmatch incompatible: 1 report

Legend:
- Sample receipt and registration
- Testing
- Component selection
- Component labelling
- Miscellaneous
Selection error leads to transfusion of incompatible FFP

- 83 year old male, blood group A, required 3 units of FFP
- 3 units of group O FFP were issued and 1 unit was transfused
- Post transfusion Hb fell from 80g/l to 72g/l, bilirubin was 19µmol/L and DAT was negative
- BMS was following the SOP for platelets rather than FFP during a busy period of the day
- There was no warning flag within the LIMS to prevent ABO-incompatible plasma components

Component selection
Component labelling
Administration
SHOT Learning Points

BMS staff should take care to use the correct procedure for each component type.

Staff should be conscious that during stressful periods errors are more likely and not rush procedures or short-cut procedural steps.

LIMS should have warning flags to highlight blood-group compatibility issues.

MHRA Regulatory Reflection

Poor change management when the new LIMS was introduced a number of years before.

Change management and validation protocols must challenge the new system or equipment to ensure it is fit for purpose.
IT incidents

- Knowledge and training
- Personal responsibility
- Fit for purpose
- Sharing information
Human Factors (comments)

n=83/96

- Poor communication: 8 cases
- Lack of resources: 12 cases
- Lack of knowledge or training: 18 cases
- High workload: 18 cases
- Staffing problems: 27 cases

“The BMS was sick and should not have been at work, but there was no one else available to cover the night shift so they came in. Staffing levels are critically low and there is no give in the system to allow for sickness. All band 6 staff are locums, because the pay is better...”
UKTLT 2017 Survey

Laboratory Errors

- Increasing workload
- Loss of “body of knowledge” as experienced staff leave
- Vacant posts unfilled for long periods
- Poor quality of applicants
- Reduction in funding for training & development
- Educational events not well attended – further loss of knowledge
- No staff available for training and keeping competencies up to date
- Increase use of BT unqualified, multidisciplinary & locum staff
General comments

- Quality of service is suffering due to increased numbers of very inexperienced staff and the inability to recruit anyone with BT experience.
- Rotation of staff due to shift systems means less continuity.
- As the technical transfusion lead I struggle to keep up with workload within my core 37.5 hours, and regularly work additional hours.
- Lack of resource and support leads me to feel stressed and under considerable pressure regularly, and the only aspect that keeps me in this profession is my personal interest in the subject.
MHRA Inspections feedback

- 303 blood compliance reports were submitted 1 Apr 2015–31 Mar 2016
- 19 inspections were performed – 1 critical, 43 major, 67 other
- Critical deficiency was as result of the following:
  - Senior management had not ensured that there were sufficient resources to support the quality system
  - Management of incidents was inadequate in several respects

Inspectors’ learning points

- Improve root cause analysis procedures
- Design and implement an achievable and effective training plan
- Post inspection actions must be completed
Conclusion

The standard of transfusion knowledge and education within laboratories is becoming a prevalent source of error.

Anecdotal evidence that there is a national shortage of qualified BMS staff applying for vacant positions and vacancies being filled with less qualified staff.

It is everyone's responsibility to ensure they complete their part of the process fully with care.
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