LESSONS FOR TRANSFUSION LABORATORY STAFF

Update 2013 incorporating guidance from SHOT Annual Reports 2011 and 2012
INTRODUCTION

The Serious Hazards of Transfusion Scheme (SHOT) is the UK-wide confidential enquiry that collects data on adverse incidents related to transfusion of blood and blood components. These are red cells (including autologous and salvaged red cells), platelets, fresh frozen plasma (FFP, including solvent detergent-treated FFP (SD-FFP), cryodepleted plasma (CDP) and methylene blue-treated FFP (MB-FFP)), granulocytes and cryoprecipitate. Errors associated with anti-D immunoglobulin (ig) are also reportable to SHOT because the administration of anti-D Ig is closely dependent on the work of the blood transfusion laboratories, particularly the correct interpretation of the RhD group and maternal antibody status.

SHOT findings are used to:

- Support development or revision of national clinical and laboratory guidelines for all aspects of transfusion
- Improve standards of hospital transfusion practice
- Educate users on transfusion hazards and their prevention
- Inform policy within the four UK Blood Services
- Identify new trends in adverse events and stimulate research

An annual report has been published since 1998. Recommendations are made, which are relevant at all levels of medical practice from the Chief Medical Officers, professional bodies, Trust Chief Executive Officers, to every member of hospital staff involved in the transfusion process, because everyone has responsibility for safe practice.

SUMMARY OF ALL LABORATORY CASES REPORTED 2011–2012 (n=647)

This review focuses on laboratory-related incidents reported to SHOT in 2011 and 2012. Figure 1 shows the type of laboratory incidents, and at what point in the transfusion process the errors occurred.

Figure 1. Laboratory incidents 2011–2012
Table 1 shows how laboratory incidents are separated according to the category. A detailed ‘definitions’ document on reportable categories to SHOT can be found on the SHOT website www.shotuk.org under ‘Reporting to SHOT and the MHRA’.

Table 1. A detailed split of the laboratory incidents 2011–2012

<table>
<thead>
<tr>
<th></th>
<th>IBCT</th>
<th>SRNM</th>
<th>HSE</th>
<th>Anti-D Ig</th>
<th>ADU</th>
<th>RBRP</th>
<th>TOTAL</th>
</tr>
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<tbody>
<tr>
<td>Sample receipt and registration</td>
<td>9</td>
<td>29</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>25</td>
<td>66</td>
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<tr>
<td>Testing</td>
<td>29</td>
<td>27</td>
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<td>28</td>
<td>2</td>
<td>1</td>
<td>87</td>
</tr>
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<td>Component selection</td>
<td>22</td>
<td>63</td>
<td>0</td>
<td>25</td>
<td>1</td>
<td>0</td>
<td>111</td>
</tr>
<tr>
<td>Component labelling, availability &amp; handling and storage</td>
<td>0</td>
<td>3</td>
<td>240</td>
<td>23</td>
<td>2</td>
<td>115</td>
<td>383</td>
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<tr>
<td>Miscellaneous</td>
<td>5</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>655</strong></td>
<td><strong>3</strong></td>
<td><strong>240</strong></td>
<td><strong>206</strong></td>
<td><strong>2</strong></td>
<td><strong>124</strong></td>
<td><strong>1110</strong></td>
</tr>
</tbody>
</table>

*IBCT, Incorrect Blood Component Transfused; SRNM, Specific Requirements Not Met; HSE, Handling & Storage Errors; ADU, Avoidable, Delayed or Under transfusion; RBRP, Right Blood Right Patient.

WHAT IS THE MOST FREQUENT LABORATORY RELATED TRANSFUSION HAZARD REPORTED TO SHOT?

Errors were the main cause in more than half – 58% (1996/3460) of the cases reported to SHOT in 2011 and 2012. This figure excludes Right Blood Right Patient and Near Miss events which are also error-related but in these cases no harm resulted to the patients. The leading error remains transfusion of an incorrect blood component. This has been the most frequent transfusion hazard reported to SHOT since the scheme started in 1996.

Why do these ERRORS occur?

- Attention lapses (being distracted/interrupted during a task)
- Deliberate non-compliance (taking short cuts and failing to follow SOP)
- Genuine errors (intention of carrying out correct procedure but failed)
- Misperceptions (what the task involves)
- Misplaced priorities (mixed messages over clinical priorities)

Learn from adverse incidents: Incident reviews and root cause analyses should be completed and the findings reported back to the participants and the patients to ensure that lessons are learned which may reduce future errors.
WHAT ARE THE KEY RECOMMENDATIONS FROM SHOT?

**PATIENT IDENTIFICATION:** Correct and positive patient identification at every step remains absolutely essential and is the responsibility of every member of staff.

**COMMUNICATION AND HANOVER:** All staff involved in the blood transfusion process should work at building relationships to improve communication and handover.

Good communication is essential between laboratory and clinical staff to ensure specific requirements are met, and correct results communicated to clinical areas.

Clinical Pathology Accreditation standard G3 requires that the laboratory establishes a procedure when giving telephoned results to minimise the risk of error and to confirm correct transmission and understanding. The individuals involved in transmitting and receiving telephoned results should be identified (and recorded) and the recipient should repeat the details back to ensure that the message has been understood correctly.

Patients whose care is shared between departments and/or between different hospitals are particularly at risk. It is important for clinical and laboratory staff to communicate clearly with each other, avoiding technical language used in one area which may be misinterpreted in another.

**SERIOUS HARM TO PATIENTS: MAJOR MORBIDITY 2011–2012**

No deaths were reported, but there were 3 cases of major morbidity reported in this period:

- **Case 1:** A 70 year old patient whose blood group was O RhD negative was transfused 50mL of group A RhD negative red cells and developed rigors. The red cells were issued on the basis of a handwritten blood group on the request form, which was not checked with historical records, and a misread result on an immediate spin crossmatch.
- **Case 2:** An 11 year old rhD negative girl was wrongly rhD grouped as rhD positive and was transfused rhD positive units, resulting in the development of anti-D.
- **Case 3:** A patient (group A) who received a minor ABO mismatched haemopoietic stem cell transplant (HSCT) (group O) developed evidence of haemolysis with increased bilirubin and falling Hb after a red cell transfusion of the wrong group (group A) 10 days following transplant.

**ABO/RhD INCOMPATIBILITY 2011–2012 (Originating in the blood transfusion laboratory)**

In this 2 year period there were 6 ABO incompatible transfusions as a result of errors originating in the blood transfusion laboratory (3 transfusions of red cells and 3 of fresh frozen plasma), and 4 cases where RhD positive red cells were transfused to RhD negative females of childbearing potential. These events are described below.
ABO incompatible transfusions (n=6)

- Testing the wrong sample resulted in 3 units of group AB RhD positive red cells being transfused to a group A RhD positive patient.
- Two cases were caused by testing errors because the ABO group was misinterpreted. One resulted in 80 mL of group B RhD positive red cells being transfused to a group O RhD positive recipient (who suffered no harm). The second case resulted in patient harm, Case 1 below.
- One case was caused by selection of the wrong component resulting in transfusion of group O FFP to a group B patient.
- Two patients received ABO incompatible SD-FFP as the result of failure to follow standard operating procedures (SOPs). In one case SD-FFP of an incorrect ABO group was issued to a 1 month old female and in the second to a 15 year old male.

RhD mismatches (n=4)

- One case resulted from a transcription error when entering the RhD type into the laboratory information management system (LiMS).
- One case resulted from a component selection error when the patient required irradiated red cells. Irradiated units that were close to expiry but of the wrong group were selected and issued resulting in RhD positive red cells being transfused to an RhD negative patient.
- One case was caused by a testing error resulting in patient harm, Case 2 below.
- In another case RhD positive red cells were selected and transfused to a 10 month old RhD negative female, no anti-D Ig was administered. No immune anti-D had been formed at the time of reporting.

Laboratory errors associated with haemopoietic stem cell transplant (HSCT) patients

There were 22 cases in which HSCT patients received a component of an unsuitable ABO/RhD group (17 red cell and 5 platelet transfusions). The incorrect ABO group was given in 15 cases (10 red cell and 5 platelet transfusions). RhD positive red cells were given in 7 cases following incorrect component selection. Many of these HSCT errors resulted from poor communication between the clinical and laboratory areas. One case led to major morbidity, see Case 3 under ‘Serious harm to patients: Major Morbidity 2011–2012.’

Learning Point
Laboratories should have written procedures to ensure that patient needs are recorded in the laboratory information management system (LiMS) transfusion record and in particular the blood group as it changes through the transplant period. Laboratory staff must be vigilant and in particular take heed of LiMS warning flags.

Recommendation
SHOT recommends that guidelines should be developed that cover the procedures, particularly communication protocols, necessary for managing transplant patients, especially where ABO/RhD mismatched transplants have been given.
SAMPLE RECEIPT & REGISTRATION (n=66)

Most cases were due to errors made by transfusion laboratory staff who:

- missed requests for specific requirements (43% – 29/66)
- failed to notice patient identification errors (38% – 25/66) e.g. incorrect spelling of name or date of birth. These mistakes should have been detected at booking in of the sample; nevertheless the outcome was transfusion of the right blood to the right patient.

All laboratory staff 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 to note all previous results and any specific requirements. The minimum dataset required for samples and requests are defined in both the BCSH Administration of blood guidelines 2009 and the IBMS professional guidance ‘Patient Sample and Request Form Identification Criteria.’ These are the first and last name, date of birth, unique identification number with some organisations also requiring address.

Learning Point

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).

Hospital Transfusion Teams and Transfusion Laboratory Managers should risk assess the process in place for alerting the laboratory to the need for specific requirements and ascertain that the method is as robust as possible.

TESTING (n=131)

- All the reported ABO and RhD typing errors (22% -29/131) occurred as a result of manual interventions. Manual testing is known to carry a high risk of error and should only be used when unavoidable as indicated in the BCSH guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories.
- RhD testing errors resulted in late administration or omission of Anti-D Ig in 37% (48/131).
- Blood components with an incorrect phenotype/specific requirement were transfused in 21% (27/131) and all of these occurred as a result of failure to follow SOPs during testing.
Learning Point

Successive SHOT reports have demonstrated that manual procedures are particularly prone to error, including ABO/RhD grouping, antibody screening and estimation of fetomaternal haemorrhage (FMH).

Use of automation and IT can increase the security of testing but only if the alerts/flags are heeded and acted on appropriately.

The ABO and RhD group must wherever possible be verified against previous results. Updated BCSH guidelines state ‘unless secure electronic patient identification systems are in place a second sample should be requested for confirmation of the ABO group of a first time patient prior to transfusion, where this does not impede the delivery of urgent red cells or other components.’

COMPONENT SELECTION (n=134)

The specific requirements for individual patients were not met in 60% (62/134) cases of selection error. The breakdown of these 62 component selection failures showed that:

- 33% (21/62) were an incorrect phenotype
- 18% (11/62) were not irradiated cellular components
- 16% (10/62) were not CMV negative cellular components
- 18% (11/62) were instances where children were not issued with MB-FFP/Cryo
- 11% (7/62) were failures to issue K negative red cells to women of childbearing potential
- 4% (2/62) were instances where the patient required both CMV negative and irradiated components

Learning Point

Competency assessment of Biomedical Scientists must comprehensively cover the areas of phenotype selection, antibody history and appropriate use of electronic issue (EI).

IT systems should be used to their full potential to prompt staff about specific requirements either through algorithms based on the date of birth and/or gender, or by warning flags. If this is not possible locally, then these development requirements must be raised with the LIMS suppliers, see errors relating to IT systems.
COMPONENT LABELLING, AVAILABILITY & HANDLING AND STORAGE ERRORS (HSE) (n=308)

Poor handling and/or storage was responsible for 63% (240/308) of laboratory reports. These 240 cases consisted of:

- 81% (195/240) cold chain errors,
- 11% (27/240) instances where expired units transfused
- 7% (18/240) instances where the sample age exceeded the recommended time intervals between sampling and pre-transfusion compatibility testing.

Some errors did not prevent the right blood being given to the right patient – 12% (36/308) of laboratory cases, but lessons should be learnt from these errors because they could potentially lead to an incorrect blood component being transfused (IBCT). These 36 cases consisted of:

- 61% (22/36) transposed labels
- 39% (14/36) patient ID errors

**Learning Point**

Errors are still being made by using samples with an inappropriate time interval between collection and pre-transfusion testing. Computer warnings are useful tools but must be backed up with strong theoretical knowledge. New BCSH guidelines on compatibility procedures in blood transfusion laboratories simplify sample age requirements\(^4\).

Hospitals should have a robust policy in place for removing expired blood components and components past their suitability date from the satellite refrigerator.

MISCELLANEOUS (n=8)

- Failure to follow recall procedures: there were 4 failures to follow SOPs that require the quarantine of components when alerted by a fax from the Blood Service as part of the recall procedures
- There were 2 cases where EI was used inappropriately following manual edits of grouping results. In both cases the LIMS could not identify the edited results as part of the EI algorithm so the BMS should have added these patients to the EI exclusion list. IT systems should prompt staff about specific requirements either through algorithms based on data incorporated in the component label or by warning flags. If this is not possible locally then these development requirements must be raised with the LIMS suppliers. These improvements should be in line with the BCSH guidelines on laboratory IT systems\(^5\).
• In 1 case cryodepleted plasma (CDP) was mistakenly ordered and issued as cryoprecipitate when cryoprecipitate was indicated for the patient. This was inappropriate as CDP does not contain fibrinogen which is the main indication for cryoprecipitate infusion.

• In 1 case a 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, so the mother should have received a dose of anti-D Ig as the RhD status of the baby was unknown.

ERRORS RELATING TO INFORMATION TECHNOLOGY SYSTEMS (n=154)

IT systems were implicated in 154 cases from the two year period 2011–2012, compared with 117 in the two years 2009-2010. In these reports, IT systems may have caused or contributed to the errors, been used incorrectly or could have been used to prevent errors. The types of reported incidents are similar every year:

Examples include:

• Ignoring/missing warning flags
• Failure to update warning flags
• Misuse or error associated with an electronic blood tracking system
• Failure to merge or reconcile patient records

LIMS can improve safety by removing manual steps, but must be configured carefully.

Learning Point

Warning flags in the LIMS must be heeded and the culture of staff automatically overriding or ignoring them should be discouraged. If warning flags are overridden, then a positive response from the user should be required with a reason given for this decision.

Training and competency-based assessment must include appropriate actions on receipt of alerts/warnings on the LIMS or an analyser.

Medicines and Healthcare products Regulatory Agency (MHRA)

Many of the laboratory incidents will also be reported to the MHRA which is responsible for ensuring that blood establishments and hospital transfusion laboratories comply with the European Union (EU) Directives translated into UK law. Further details can be found in the MHRA Chapters in Annual SHOT reports (2011 and 2012).

The UK Transfusion Laboratory Collaborative (UKTLC)

In April 2011 and again in March 2013, surveys were distributed by NEQAS (Blood Transfusion and Laboratory Practice) to the lead BMS/technical lead in blood transfusion laboratories in order to provide comparative data and evaluate progress on implementation of the UKTLC recommendations. The UKTLC recommendations focus on three main areas: staffing, technology and knowledge and skills and were intended to encourage
effective and appropriate use of technology and staff in hospital transfusion laboratories within the framework of current legislative requirements. The UKTLC standards have been updated and are available on the SHOT website.

SHOT RECOMMENDATIONS from previous years are available on the SHOT website, www.shotuk.org Supplementary information under ‘SHOT Annual Reports and Summaries 2012’.

References

# SHOT LABORATORY REPORTING GUIDE

## Sample Receipt and Registration

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-transfusion sample received in blood bank with discrepant details on bottle and request form</td>
<td>These errors should be collated and investigated internally, but are <strong>not</strong> reportable to SHOT</td>
</tr>
</tbody>
</table>

## Laboratory Testing – Grouping

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grouping results do not match with historic patient record – blood probably from a different patient</td>
<td>Report to SHOT as a <strong>NEAR MISS (WBIT)</strong></td>
</tr>
</tbody>
</table>

## Laboratory Testing – Component Selection & Compatibility Testing

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timing of the sample does not comply with BCSH guidelines or local policy</td>
<td>Blood component was transfused: Report to SHOT as a <strong>HANDLING &amp; STORAGE ERROR (HSE)</strong>; Blood component was <strong>NOT</strong> transfused: Report to SHOT as a <strong>NEAR MISS HSE</strong></td>
</tr>
<tr>
<td>Specific transfusion requirements not met for the patient (including failure to provide irradiated/CMV-negative units, incorrect phenotype or inappropriate use of Electronic Issue)</td>
<td>Blood component was transfused: Report to SHOT as <strong>SPECIFIC REQUIREMENTS NOT MET (SRNM)</strong>; Blood component was <strong>NOT</strong> transfused: Report to SHOT as <strong>NEAR MISS SRNM</strong></td>
</tr>
<tr>
<td>Incorrect blood group or incorrect component type selected</td>
<td>Blood component was transfused: Report to SHOT as <strong>INCORRECT BLOOD COMPONENT TRANSFUSED (IBCT)</strong>; Blood component was <strong>NOT</strong> transfused: Report to SHOT as <strong>NEAR MISS IBCT</strong></td>
</tr>
</tbody>
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## Handling & Storage

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood component time-expires or becomes otherwise unsuitable for transfusion when available in the issue refrigerator</td>
<td>Component <strong>not collected</strong> for the patient: <strong>Not reportable</strong> to SHOT; Component collected for the patient but <strong>NOT</strong> transfused: Report to SHOT as <strong>NEAR MISS HSE</strong>; Component collected for the patient and transfused: Report to SHOT as <strong>HANDLING &amp; STORAGE ERROR (HSE)</strong></td>
</tr>
</tbody>
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## Component Labelling

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component is labelled incorrectly – patient details incorrect or labels transposed</td>
<td>Blood component was transfused: Report to SHOT as <strong>IBCT or RBRP</strong>; Blood component was <strong>NOT</strong> transfused: Report to SHOT as <strong>NEAR MISS</strong></td>
</tr>
</tbody>
</table>
Further information can be found on the SHOT website: www.shotuk.org

The SHOT Office can be contacted at:
The SHOT Office
Manchester Blood Centre
Plymouth Grove
Manchester M13 9LL
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