Remit

• To explain how to successfully report to both MHRA and SHOT through the SABRE on-line reporting system

• Background
• Incident reporting and investigating system
• What to report
• The keys to successful reporting
Leeds Teaching Hospitals

St James’s University Hospital

The General Infirmary at Leeds
Bradford Teaching Hospitals

Leeds Teaching Hospitals Trust provides the Pathology services for Bradford Teaching Hospitals Foundation Trust

Bradford Royal Infirmary

This includes the Blood Transfusion Laboratory
Warning: Incident reporting involves lots of acronyms

• Examples of ones I may use
  • SHOT – Serious Hazards of Transfusion (UK)
  • MHRA - Medicines and Healthcare Products Regulatory Agency
  • BSQR – Blood Safety and Quality Regulations
  • SABRE – Serious Adverse Blood Reactions and Events (on line reporting system)
  • SAE – Serious Adverse Event
  • SAR – Serious Adverse Reaction
The Danger of acronyms

- People don’t always mean the same thing when using an acronym

  - MHRA
    - Michigan Hot Rod Association
    - Medicines and Healthcare Products Regulatory Agency

  - SHOT
    - Single-Hull Oil Tanker
    - Serious Hazards of Transfusion (UK)

  - SABRE
    - Somali Abyssinian Breed Rescue Education
    - Serious Adverse Blood Reactions and Events

  - GDAP
    - Growing Danger of Acronym Proliferation
Background

• November 1996 – SHOT launched

• Collect data on transfusion related deaths and major complications
• Based at Manchester Blood Transfusion Centre
• Anonymous
• Voluntary
• Produces annual reports on incidents and reactions which include recommendations on best practice and areas for further study
Background


  - ...ensure that blood and its components are of comparable quality and safety throughout the blood transfusion chain...

  - ...introduce a set of organised surveillance procedures to collect and evaluate information on the adverse or unexpected events or reactions resulting from the collection of blood or blood components in order to prevent similar or equivalent events or reactions from occurring...
Background


• Article 5: Notification of serious adverse reactions
• Article 6: Notification of serious adverse events
• Reporting to the “Competent Authority” – the MHRA
Background

• February 2005 – Blood Safety and Quality Regulations (SI 50/2005) *as amended*


• Legal requirement to report Serious Adverse Blood Reactions and Events to the Competent Authority

• Criminal law
The SABRE system

• On-line reporting system accessed through the MHRA’s website
  • For reporting
    • Serious Adverse Reactions (SAR)
    • Serious Adverse Events (SAE)
    • Reporting to SHOT

• Reporting to SHOT still remains voluntary but is required by HSC 2004/009 ‘Better Blood Transfusion’
Reporting

• 2007 SHOT report
  • Figures from both SHOT and MHRA show that a substantial number of hospitals, including some high users, are not sending reports. This is in breach of European and UK legislation

• Report from Blood Consultative Committee, January 2009
  • 45 laboratories had not reported any events or reactions to SABRE in a three year period
  • 5 of those were issuing in excess of 5000 units per year
Successful reporting
Understand the whole process

1. Identify event or reaction
2. Immediate corrective action to protect patients
3. Local reporting system
4. Start investigation process
5. Gather data
6. Produce report
7. Identify root cause
8. Put in place corrective / preventive action
9. System for tracking / trending incidents
10. Review of effectiveness of CAPA

- Is further reporting needed (SHOT and MHRA)?
  - Yes
    - Notify through SABRE system
    - Complete MHRA confirmation and SHOT questionnaire (if assigned)
    - Notify MHRA Devices
  - No

- SHOT only
  - Notify MHRA Devices

- SHOT and MHRA
  - Notify MHRA Devices
Identify event or reaction

Local reporting system

Immediate corrective action to protect patients

Gather data

Produce report

Identify root cause

Put in place corrective / preventive action

System for tracking / trending incidents

Review of effectiveness of CAPA

Complete MHRA confirmation and SHOT questionnaire (if assigned)

Notify through SABRE system

Notify MHRA

Devices

Immediate corrective action to protect patients

Local reporting system
Knowing about the incident

• If you don’t know about it you won’t be able to report it

• Need a simple local reporting system
  • Simple reporting form

  • Encourage self reporting of ‘events’ in the laboratory
    • Avoid the blame game

  • Encourage reporting of suspected reactions by clinical areas to the laboratory or hospital transfusion team
    • Make it easy for them to report to the lab
    • Make it easy for the lab staff to deal with
TIRF – Transfusion incident and reaction form

<table>
<thead>
<tr>
<th>Blood Transfusion</th>
<th>BRI</th>
<th>CAH</th>
<th>LGI</th>
<th>SFT</th>
<th>SHH</th>
<th>St L</th>
<th>WGH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident: please select</td>
<td>Clinical incident</td>
<td>Non-clinical incident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (24hr clock):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Location: Include room N° if known</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient/Staff member/Other person/ Sample involved</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Complete in full or attach request form copy)</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>DOB</td>
<td>/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N° or NHS N°</td>
<td>Staff N°</td>
<td>Ward</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For reactions only</th>
<th>Tick</th>
<th>Tick</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red cell reaction sent to ward</td>
<td>Form 2 - Platelet / plasma reaction sent to ward</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For all incidents - do not request or complete an IR1 form (HTT will decide)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>of all implicated units requested</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ward staff: name and contact details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Time reported to BB</td>
<td></td>
</tr>
<tr>
<td>If senior staff (BB) reported to</td>
<td></td>
</tr>
</tbody>
</table>

| Event happened: brief details (state facts if assumptions say so) Include names and contact details of Witness(es) (if any) |  |

| Continue overleaf if necessary |  |
| Please give brief details of any immediate remedial action taken: (Please state if no action taken) |  |

| Continue overleaf if necessary |  |
| Form completed by |  |
| Signature | Date |
| Incident reviewed by |  |
| Signature | Date |
| Comments including actions taken or initiated |  |

If this is a transfusion reaction forward this completed form to the HTT at LGI (fax to 23318) and send a copy to the Quality Manager. If a laboratory incident please forward to the Quality Manager (LGI fax number 25540)
Transfusion reaction ward forms

Form 1 – Transfusion reaction to red cells
A possible transfusion reaction has been reported for this patient: please complete actions detailed on this form. Please note urticarial and minor febrile (temp rise of less than 1.5°C) reactions with no other symptoms do not need investigating

<table>
<thead>
<tr>
<th>Patient name</th>
<th>DOB</th>
<th>Hospital Number</th>
<th>Ward/Hospital</th>
</tr>
</thead>
</table>

- Please return all used and unused units of any blood product administered in previous 24 hours
- Please send samples as listed in table below
- Please arrange for the patient to have a chest X ray if they suffered from breathing difficulties during the reaction

<table>
<thead>
<tr>
<th>Samples needed</th>
<th>Tests to be performed / requested</th>
<th>Laboratory in which tests performed</th>
<th>Tick once sent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clotted (1x 6ml Red top, lack inner)</td>
<td>Group, antibody screen, re-crossmatch</td>
<td>Blood Bank</td>
<td></td>
</tr>
<tr>
<td>EDTA (1x 6ml Pink top)</td>
<td>DAT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EDTA (4ml purple top)</td>
<td>Full blood count (FBC)</td>
<td>Haematology</td>
<td></td>
</tr>
<tr>
<td>Blood cultures</td>
<td>Blood cultures</td>
<td>Microbiology</td>
<td></td>
</tr>
<tr>
<td>Urine passed post transfusion (sterile universal container)</td>
<td>Urobilin</td>
<td>Biochemistry</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Urine bilirubin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clotted (1x red top, lack inner)</td>
<td>Serum immunoglobulins</td>
<td>Immunology</td>
<td></td>
</tr>
<tr>
<td>Clotted (1x red top, lack inner)</td>
<td>Mast cell tryptase - to be taken</td>
<td>Immunology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Immediately</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>@4 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>@24 hours</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If you have any queries please contact Blood Bank on: LGI: 23398 SJUH: 65559
Or the Hospital transfusion team on 23984 or 67657

Form 2 – Transfusion Reaction to Platelets / Plasma / Cryoprecipitate
A possible transfusion reaction has been reported for this patient: please complete actions detailed on this form. Please note urticarial and minor febrile (temp rise of less than 1.5°C) reactions with no other symptoms do not need investigating

<table>
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- Please return all used and unused units of any blood product administered in previous 24 hours
- Please send samples as listed in table below
- Please arrange for the patient to have a chest X ray if they suffered from breathing difficulties during the reaction

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<th>Laboratory in which tests performed</th>
<th>Tick once sent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clotted (2 x 6ml Red top, lack inner)</td>
<td>National Blood service H and I testing – HTT will advise if needed</td>
<td>Blood Bank</td>
<td></td>
</tr>
<tr>
<td>EDTA (2 x 6ml Pink top)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood cultures</td>
<td>Blood cultures</td>
<td>Microbiology</td>
<td></td>
</tr>
<tr>
<td>Clotted (1x red top, lack inner)</td>
<td>Serum immunoglobulins</td>
<td>Immunology</td>
<td></td>
</tr>
<tr>
<td>EDTA (4ml purple top)</td>
<td>Full blood count (FBC)</td>
<td>Haematology</td>
<td></td>
</tr>
<tr>
<td>Clotted (1x red top, lack inner)</td>
<td>Mast cell tryptase - to be taken</td>
<td>Immunology</td>
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<td></td>
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If you have any queries please contact Blood Bank on: LGI: 23398 SJUH: 65559
Or the Hospital transfusion team on 23984 or 67657

Note for lab staff: do not send NBS samples until discussed with HTT
Immediate corrective action

- This is what you do immediately following an event or reaction to protect this patient and other patients

- Have a system in place to ensure this happens
  - Empowering staff
  - Training staff
  - Having a system to escalate more serious incidents

- Examples
  - Suspected ABO HTR – informing appropriate medical staff (Haematologist / Renal Medicine Specialist) – *protecting this patient*
  
  - Red cell transfusion reaction – recall of other units issued for this patient; *protecting this patient*
  
  - Suspected bacterial reaction – inform the National Blood Service; *protecting other patients*
  
  - Blood fridge failure – quarantine units from fridge; *protecting other patients*
The next stage – Further reporting and investigation

Identify event or reaction

Local reporting system

Start investigation process

Is further reporting needed (SHOT and MHRA)

No

Yes

Gather data

Produce report

Identify root cause

SHOT only

SHOT and MHRA

Notify through SABRE system

Notify MHRA

Devices

Put in place corrective/preventive action

System for tracking/trending incidents

Review of effectiveness of CAPA

Complete MHRA confirmation and SHOT questionnaire (if assigned)

Immediate corrective action to protect patients

Complete MHRA confirmation and SHOT questionnaire (if assigned)
Further reporting / investigation

• These will probably start at around the same time

• MHRA expect reporting within 7 days
  • You may have time to start investigating before further reporting

• If you are unsure about whether an incident is reportable, ask the SABRE team or SHOT
Deciding what you need to report further

- What constitutes a **Serious** Adverse Reaction
  - Definition ‘*an unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity*’

- Also need reporting to SHOT
Deciding what you need to report further

- **What constitutes a **Serious** Adverse Event**
  - ‘any untoward occurrence associated with the **collection, testing, processing, storage and distribution**, of blood or blood components that **might** lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.’

- Errors in the laboratory, or in storage and distribution that are not picked up by the normal laboratory quality system checks

- It includes near-miss events

- Reporting to SHOT; these will be either
  - Incorrect blood component transfused (IBCT)
  - Right blood, right patient
  - Or Near miss, testing, storage or distribution
Serious Adverse Events (Yes or No?)

- Non irradiated component issued to Hodgkin’s Disease patient; error made in lab. Error detected after transfusion started
  - YES SAE
  - Also report to SHOT as IBCT

- Non irradiated component issued to Hodgkin’s Disease patient; error made in lab. Error detected on ward before transfusion started
  - YES SAE. Error was not detected as part of the laboratory’s quality system
  - Also report to SHOT as Near miss

- Non irradiated component issued to Hodgkin’s Disease patient; lab unaware of diagnosis, found on ward after transfusion.
  - NO not SAE. Error was outside the laboratory’s control
  - Report to SHOT only as IBCT
Serious Adverse Events (Yes or No?)

• Expired unit of blood not removed from issue fridge by lab staff. Taken to ward but not transfused
  • YES SAE. Laboratory has responsibility for removing expired units and failed to do this
  • Also report to SHOT as a near miss

• Ward removes a unit from fridge and returns it 45 minutes later. Laboratory is alerted by tracking system and recalls unit
  • NO Not SAE. Error was picked up as part of the laboratory’s quality system
  • Not reportable to SHOT

• Ward removes unit from fridge but does not commence transfusion for 45 minutes. 15 minutes after start of transfusion member of ward staff realises that donation was out of fridge more than 30 minutes before commencing transfusion and contacts lab for advice.
  • NO not SAE. 30 minute rule only applies to returning blood to storage. Transfusion should be completed within 4 hours
  • Not reportable to SHOT
Serious Adverse Events (Yes or No?)

- Nurse collects blood for patient A from blood fridge and transfuses it to patient B. No bedside check performed
  - Not an SAE – error occurred in clinical area
  - No transfusion reaction
    - Report to SHOT only as IBCT
  - Transfusion reaction
    - Report to MHRA as SAR
    - Report to SHOT as IBCT / Haemolytic transfusion reaction

- Further scenarios are available on the SHOT website
  http://www.shotuk.org/SABRESCENARIOS&SOLUTIONS.pdf
Further reporting

Local reporting system

Is further reporting needed

No

Yes

SHOT and MHRA

SHOT only

MHRA devices

Notify through SABRE system

Gather data

Produce report

Identify root cause

SHOT only

SHOT and MHRA

Complete MHRA confirmation and SHOT questionnaire (if assigned)

Notify MHRA

Put in place corrective/preventive action

System for tracking/trending incidents

Review of effectiveness of CAPA

Complete MHRA confirmation and SHOT questionnaire (if assigned)

Notify MHRA

Immediate corrective action to protect patients
Investigation

Start investigation process

Gather data

Produce report

Identify root cause

Put in place corrective/preventive action

Identify event or reaction

Local reporting system

Start investigation process

Identify root cause

Put in place corrective/preventive action

Identify event or reaction

Immediate corrective action to protect patients

Start investigation process

Identify event or reaction

Local reporting system

Is further reporting needed (SHOT and MHRA)

No

Yes

Gather data

Produce report

Identify root cause

Put in place corrective/preventive action

Identify event or reaction

Immediate corrective action to protect patients

Notify through SABRE system

Notify MHRA

Devices

Put in place corrective/preventive action

System for tracking/trending incidents

Review of effectiveness of CAPA

Complete MHRA confirmation and SHOT questionnaire (if assigned)

Immediate corrective action to protect patients

Notify MHRA

Devices

Notify through SABRE system

Identifying event or reaction

Immediate corrective action to protect patients

Local reporting system
Investigation - Serious adverse reaction

- Gather information to determine

- What type of reaction was it?
  - Don’t always believe the type of reaction that was initially reported
  - Reaction types are not always easy to determine.
  - SHOT and MHRA have different categories – familiarise yourself with them
Investigation - Serious adverse reaction

**SHOT**
- Acute Transfusion Reaction
- Haemolytic Transfusion Reaction (delayed or acute)
- Transfusion Related Acute Lung Injury
- Transfusion Transmitted Infection
- Post Transfusion Purpura
- Transfusion Associated Graft v Host Disease
- Transfusion Associated Circulatory Overload

**MHRA**
- Anaphylaxis / hypersensitivity
- Immunological haemolysis due to ABO incompatibility
- Immunological haemolysis due to other allo-antibody
- Non-immunological haemolysis
- Transfusion related acute lung injury
- Transfusion-transmitted bacterial infection
- Transfusion-transmitted viral infection (HBV)
- Transfusion-transmitted viral infection (HCV)
- Transfusion-transmitted viral infection (HIV-1/2)
- Transfusion-transmitted viral infection, Other (Specify)
- Transfusion-transmitted parasitical infection (Malaria)
- Transfusion-transmitted parasitical infection, Other (Specify)
- Post-transfusion purpura
- Graft versus host disease
- Other serious reaction(s) (Specify)
Investigation - Serious adverse reaction

• Gather information to determine
  • Imputability
    • How likely was the transfusion the cause of the patient’s symptoms?

• When gathering the information gather what you need to complete the appropriate shot questionnaire
Investigation - Serious Adverse Event

• Gather information

• Determine root cause. Use the SHOT/NPSA toolkits
  • http://www.shotuk.org/RCA%20toolkit.pdf

• Put in place corrective and preventive action

• If it is an IBCT gather the information you will need to complete a questionnaire
Bringing it all together

1. Identify event or reaction
   - Local reporting system

2. Start investigation process
   - ProMed
   - MHRA devices
   - Notify through SABRE system
   - Notify MHRA Devices
   - Complete MHRA confirmation and SHOT questionnaire (if assigned)

3. Is further reporting needed (SHOT and MHRA)?
   - No
   - Yes

4. Gather data
   - ProMed
   - MHRA devices
   - Notify through SABRE system

5. Produce report
   - SHOT and MHRA
   - SHOT only

6. Identify root cause
   - Complete MHRA confirmation and SHOT questionnaire (if assigned)

7. Put in place corrective / preventive action
   - System for tracking / trending incidents
   - Review of effectiveness of CAPA

Immediate corrective action to protect patients
Confirmation on SABRE system

• Use your reports to complete the confirmation section of the SAE/SAR reporting

• Complete SHOT questionnaire – if one is allocated

• MHRA expect completion of investigation and confirmation *normally* within 30 days.
  • Extending beyond 30 days should be on a case by case basis. E.g. TRALI investigations which may take months if many donors are involved
Keys to making it all work successfully

• To understand the *whole process* for management of incidents and non-conformances

• Have a robust local system for identifying and reporting incidents

• Empower key personnel to investigate and report on SABRE.

• Make sure the reporting is done by someone who understands the incident
  • SAR – needs clinical /HTT input
  • SAE – needs to be done by someone who understands laboratory quality processes
Keys to making it all work successfully

• Don’t worry about reporting events to MHRA
  
  • It will not result in immediate inspection *(usually)*
  
  • Detecting and reporting incidents is a sign of a functioning quality management system.
Food for thought

- Put in place corrective / preventive action
  - System for tracking / trending incidents
  - Review of effectiveness of CAPA
Acknowledgements

• SHOT

• Leeds Teaching Hospitals Blood Transfusion Lab staff and Hospital Transfusion Team
And Finally…

Enjoy failure and learn from it. You can never learn from success

James Dyson

I claim to be a simple individual liable to err like any other fellow mortal. I own, however, that I have humility enough to confess my errors and to retrace my steps.

Mohandas K. Ghandi