Risks, Reactions and Reporting: the Role of Haemovigilance

Paula Bolton-Maggs
Medical Director
SHOT
Definition of Haemovigilance

EU Directive

- surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients and the epidemiological follow up of donors

International Haemovigilance Network

- surveillance procedures from the collection of blood and its components to the follow up of the recipients, to collect and assess information on unexpected and undesirable effects resulting from the therapeutic use of labile blood components and to prevent their occurrence or recurrence
**Aims of Haemovigilance**

- Identify trends in adverse reactions and events
- Inform policy within transfusion services, DH, EU
- Target areas for improvement of practice
  - Aid production of clinical guidelines for use of blood components
  - Promote development of suitable education and training
  - Identify and promote standards of practice
- Stimulate research and detailed audit
- Raise awareness of transfusion hazards and their prevention
- Be an ‘early warning’ of new complications
- Improve safety of transfusion for patients
Role of SHOT

• Professionally led scheme providing analysis of anonymised data by experts in each area of reporting
  • Regular output in annual report, papers, meetings
  • Recommendations for actions made to CMOs, DH, hospitals, professional bodies and blood services

• Measurable impact on patient safety
  • Reduction in TRALI
  • Reduction in ABO incompatible transfusions
  • Reduction in bacterial contamination

• Reporting is NOT voluntary, but professionally mandated
Unique features of SHOT

- Longest cumulative haemovigilance reporting scheme. Core team 7.7 WTE
- Adaptable reporting categories
  - Anti-D errors
  - Delayed transfusions
- Expert working group of clinicians and laboratory scientists
- Linked to ISBT/IHN to discuss and influence evolution of international definitions
- Extensive educational activity
Haemovigilance feedback loop

Participation (incident reports)

Education and resources on web

Data & Analysis → the SHOT Report

Recommendations and learning points
Blood Safety & Quality Regulations

Statutory Instrument 2005 No. 50

The European Union Directive on Blood Safety and Quality was transposed into UK law on 8th November 2005.

The MHRA (Medicines & Healthcare products Regulatory Agency) is the Competent Authority to administer the regulations on behalf of the Secretary of State.
Quality Assurance

• EVERY part of the blood supply chain is covered by Good Manufacturing Practice

......including Hospital Transfusion Laboratories
BSQR and the Laboratory

- Traceability
- Quality System
  - Cold chain
  - Collecting blood from the issue fridge
  - Change Management
- **Mandatory adverse event/reaction reporting**
- Personnel
  - adequate numbers, trained and competent
- Premises
Haemovigilance in the UK

**MHRA**
Medicines and Healthcare Products Regulatory Agency

- Looking for **Serious Adverse Reactions** in patients
- Looking for **QUALITY** incidents (SAEs) that may cause (or have caused) harm

**SHOT**
Serious Hazards of Transfusion

- Looking for **Serious Adverse Reactions** in patients
- Looking for **NEAR MISS** errors in the process leading to a transfusion for a specific patient
What is ‘Serious’?

- “Death, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity”

- “The person responsible ... shall notify... any serious adverse events related to the collection, testing, processing, storage and distribution of blood or blood components by ...... which may have an influence on their quality and safety.”
# Haemovigilance in the UK

## MHRA
- **Medicines & Healthcare Products Regulatory Agency**
  - Competent Authority for the BSQR 2005
    - QMS in blood establishments and hospital blood banks.
  - Competent Authority for the Medicines Act 1968
  - Competent Authority for the Medical Devices Regulations 2008
  - **STATUTORY** reporting

## SHOT
- **Serious Hazards of Transfusion**
  - Confidential enquiry
  - Serious adverse reactions/events AND near misses all of which occur in BOTH a laboratory and CLINICAL environment.
  - **PROFESSIONALLY MANDATED** reporting
The General Medical Council published new guidance for doctors in March 2013 which states that ‘patients must be able to trust doctors with their lives and health. You must make the care of your patient your first concern’ and reminds doctors that we ‘must contribute to confidential enquiries and to adverse event recognition’

Adverse incident reporting is therefore mandatory not voluntary
ENCOURAGEMENT NOT FEAR

The purpose of both MHRA and SHOT is to improve quality and safety for patients.

Our objective is to learn from events, and to look at the systems problems leading to corrective and preventive actions.
Reporting levels for MHRA and SHOT
Withdrawn SHOT Reports

• Using reporting to SHOT as a ‘stick’ to beat people with
  – Unhappy with current lab IT system
  – Unhappy with portering / bleep system
  – Unhappy with compliance with paperwork

• Using SHOT to challenge reasoned decisions by experienced clinicians

• Reporting to SHOT where there is no patient involved

• Reporting BSQR quality incidents to SHOT
Withdrawn from MHRA

- Can be by reporter or MHRA
- Blood product incidents e.g. anti-D Ig
- Remember to downgrade imputability on SABRE if investigation shows the blood component was not implicated (e.g. the patient got Hep-C from other sources)
Overlap of critical points in the process between SHOT and MHRA

- Decision to transfuse
- Prescription/request
- Sampling for pre-transfusion testing
- Laboratory testing
- Collection of blood from issue refrigerator
- Bedside administration
- Monitoring the patient
SHOT Cumulative data: 17 years n=13,141

Transfusion reactions which may not be preventable

Possibly or probably preventable by improved practice and monitoring

Adverse events due to human factors – 78%
It’s not OK to do your own thing

• ‘To achieve a continual reduction in harm, we must persist in reducing unwanted variation, better share learning from mistakes and from improvement activity, and continue to promote professional responsibility’
  – Standardisation
  – Education and training
  – Harmonisation of activity to support patient safety

Human factors in 2013

Errors with potential for harm 955
- Wrong component transfused 57
- Specific requirements not met 190
- Avoidable 120, delayed 34, undertransfusion 7
- Anti-D Ig 354
- Handling and storage 193

Errors with no harm 1180
- Near miss 996
- Right blood right patient 184

1 ABO death
5 deaths from delays
Not all delays relate to major haemorrhage

SHOT accepts any case where the clinician considers there has been delay

26 cases to end October 2014
Outcome of ABO incompatible red cell transfusions
66% have no adverse effect

15 deaths to 2005
4 deaths 2006-2013

BSQR
NPSA SPN 14
Competency assessments
ABO-incompatible transfusions:
Relationship between volume transfused and reaction
Recommendation

ALL ABO incompatible transfusions should be included by NHS England as Never Events, not just those associated with serious harm or death.

Draft Never Events list October 2014 confirms this change.
Change in culture 2000 onwards?

- Introduction of the ‘no blame’ culture
- Importance of learning from our errors
- Need for full and honest reporting
- So how are hospitals dealing with serious adverse reactions and errors?
Local newspaper
Front page headline:

HOSPITAL STAFF SACKED OVER BLOOD BLUNDER

Two workers dismissed for putting patient’s life at risk
Human factors

• The science of optimising human performance through better understanding of human behaviour and interactions
• Clinical Human Factors Group – see (www.chfg.org)
• The Human Factors Concordat (available on that website)
Not just in transfusion practice:

Thousands of patients killed by drug and equipment errors

Safe as Planes

The NHS has a lot to learn from airlines about avoiding unnecessary risk

‘Official figures show that at least 8000 patients a year are killed or severely harmed needlessly by drug errors’ - a report by Jane Reid

‘We should errors design out of the system by making them much harder or impossible to commit’ - Leading article
1 REQUEST
2* SAMPLE
3 SAMPLE RECEIPT
4 TESTING
5 COMPONENT SELECTION
6 LABELLING
7 COLLECTION
8 PRESCRIPTION
9* ADMINISTRATION

* Critical points where positive patient identification is essential

Multidisciplinary steps in the transfusion process
Incorrect blood component transfused
Where are the mistakes made?

Near miss – 714 detected
Clinical errors
Laboratory errors

Number of errors

Request: 109
Sample taking: 2
Sample receipt: 30
Testing: 30
Component selection/Labeling: 58
Collection: 3
Prescription: 132
Administration: 157
Incorrect blood component transfused
Multiple errors are common

Data from 220 reports
547 errors

Number of reports

Number of errors

1  2  3  4  5
53 33 117 8  9
Case 1: How many errors?

- A pharmacy list is updated monthly for patients who have been started on drugs that require a patient to have irradiated components.
- The list was e-mailed to the transfusion laboratory nine days into the next month.
- A renal transplant patient was on the list but the laboratory had not been informed in time.
- The patient had already been transfused non-irradiated red cells on 3 occasions.
- The request form for the 2nd transfusion had been marked for irradiated components but had not been noticed by the BMS and there was no flag on the LIMS computer to alert them.
- Patient was transfused non-irradiated components.
Case 1: How many errors?

- A pharmacy list is updated monthly for patients who have been started on drugs that require a patient to have irradiated components.
- The list was e-mailed to the transfusion laboratory nine days into the next month.
- A renal transplant patient was on the list but the laboratory had not been informed in time. The patient had already been transfused non-irradiated red cells on 3 occasions.
- The request form for the 2nd transfusion had been marked for irradiated components but had not been noticed by the BMS, and there was no flag on the LIMS computer.
- Patient was transfused non-irradiated components.

**Error:** No flag on laboratory system as missed off previous request form

**Error 2:** BMS did not note the specific requirement on the 2nd request form at sample receipt

**Error 3:** BMS did not select irradiated units on this occasion

**Error 4:** Specific requirements not indicated on the prescription

**Error 5:** Need for irradiated units not noted at the final check at the patient’s side prior to administration
Competency based training is a framework for incompetence

‘When novice artists joined the studios of the great Renaissance painters, I suspect they didn’t just want to be assessed on how they used a paintbrush ...

It’s about seeing the whole picture in its complete form and coordinating the work of others whose focus is on a small area’

Jonathan Glass BMJ: 7 June 2014

Competency assessments had been passed by 66.7% of persons responsible for errors (9.3% not, 24% not answered)
Case 2: several errors and not saved by the IT system

- An ABO incompatible red cell unit was transfused resulting in a haemolytic transfusion reaction
- The computer warning flag indicated that the units were incompatible but was overridden several times by the biomedical scientist
- This was not picked up at the bedside
- When the patient reacted the doctor who was consulted said to continue the transfusion, without reviewing the patient
Near miss vs actual incorrect transfusions (2010-13)

- 3823 Total near misses and transfusion errors
- 75.3% errors detected
- 2877 Near miss detected
- 946 Actual detected

Ratio 3:1
Total IBCT reports 2010-2013
Near miss vs transfused

Year of report

Number of reports

- Near miss
- Transfused

2010: Near miss - 572, Transfused - 200
2011: Near miss - 757, Transfused - 247
2012: Near miss - 761, Transfused - 252
2013: Near miss - 787, Transfused - 247
Near Miss – sample errors

- Near miss reports are about 30% of the total reports
- Sample errors are about 50% to 66% of the near misses
- Wrong blood in tube (WBfT) are >90% of the sample errors

<table>
<thead>
<tr>
<th></th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total SHOT reports</td>
<td>2464</td>
<td>3038</td>
<td>2466</td>
<td>2751</td>
</tr>
<tr>
<td>analysed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Near misses</td>
<td>921</td>
<td>1080</td>
<td>980</td>
<td>996</td>
</tr>
<tr>
<td>Sample errors</td>
<td>409</td>
<td>508</td>
<td>534</td>
<td>658</td>
</tr>
<tr>
<td>Wrong blood in tube</td>
<td>386</td>
<td>469</td>
<td>505</td>
<td>643</td>
</tr>
</tbody>
</table>

Most ‘wrong blood in tube’ samples are collected by doctors, nurses or midwives and result from failure to identify the patient positively and/or not labelling at the patient’s side.
Remember.....

• ‘Right Blood Right Patient’ is for when the component was always intended for the patient, not for when a wrong blood component happens to be compatible in retrospect

• Failure to sign the crossmatch register does not constitute a SHOT report if the patient gets the right blood

• SHOT and MHRA have good guidance and flowcharts as to what to report – if in doubt ASK!
Root Cause and CAPA

• Defining the Root Cause
  – Important to get to the bottom of errors, WHY did this happen?

• Corrective Actions (CA)
  – What do you need to do now

• Preventive Actions (PA)
  – What to do to prevent it happening again
Recommendation
check these at the bedside:

1. Positive patient identification
2. Check identification of component against patient wristband
3. Check the prescription: has this component been prescribed?
4. Check the prescription: is this the correct component?
5. Check for specific requirements – does the patient need irradiated components or other specially selected units?
But this is not enough

• SHOT has been reporting errors as the main category causing harm to patients for 17 years
• This is also true for medicines
• Errors are the most common cause of MHRA serious adverse events – 97.8%
• The correct process is difficult to follow
• Can we redesign the process?
Recommendation

Process redesign

Process mapping and engagement of the human factors specialists

Working through:

National Blood Transfusion and Regional Transfusion Committees

NHS England Patient Safety Domain

National Comparative Audit Programme
What about the other Serious Adverse Reactions?

Transfusion-associated circulatory overload
Case 3: Fatal TACO as a result of transfusion following spurious result

- 96 year old woman admitted with a GI bleed
- FBC sample sent to the laboratory underfilled and gave Hb result of 50 g/L
- Result telephoned to ward and authorised in the computer with a text comment “sample underfilled, result subject to error”
- No repeat sample was sent but a 6 unit crossmatch was ordered
- Three units were transfused and the post-transfusion Hb was 200 g/L
- Patient developed TACO and an emergency venesection was requested but she died the following day
Case 4: Over-transfusion due to lack of monitoring of response to transfusion

• Elderly patient admitted to the Medical Admissions Unit with haematemesis and initial Hb 106 g/L
• No details provided of her observations or the findings on endoscopy but she had further episodes of vomiting blood
• Five units of red cells were transfused before a repeat Hb was performed which was 204 g/L
• The patient was recognised to have circulatory overload and died shortly afterwards
Case 5: life-threatening management of iron deficiency

- 82 yr old woman with chronic iron deficiency, Hb 45 g/L
- Transfused 4 units, each over 2.5h
- Developed TACO with tachycardia, hypertension, short of breath etc.
- Intubation, ventilation 2d
- Full recovery
Cumulative TACO-related deaths n=36
Cases of major morbidity n=122

Includes 4 deaths and 5 cases of major morbidity from avoidable transfusions
Recommendation

Don’t give two without review
Transfusion reactions may occur hours or days later

- Transfusion-associated circulatory overload
- Haemolytic transfusion reactions
- Some allergic reactions
Case 6: Respiratory arrest after patient sent home following outpatient red cell transfusion

- A 67 year old female was transfused 3 units of red cells for chronic anaemia related to myelodysplastic syndrome between 10:00 and 17:00 in the haematology day unit.
- She was discharged home after the transfusion, but felt ill on the way and returned immediately to the ED, where she suffered a respiratory arrest and was admitted to ITU.
- The chest X-ray appearances were reported to be in keeping with LVF. She made a full recovery.
Case 7: HDU admission in patient at increased risk of TACO after transfusion as a day case

- A 78 year old female with myeloma, wt 56 kg, was transfused 3 units of red cells as a day case despite being at increased risk of TACO (renal impairment, hypoalbuminaemia, age ≥70 years, low bodyweight)

- She developed fluid overload and pulmonary oedema with hypertension and hypoxia before the end of the third unit. She initially responded to diuretic and was sent home by a junior doctor, but was unable to lie flat all night because of shortness of breath

- She was readmitted, to the HDU, within 24 hours with pulmonary oedema and myocardial infarction
Case 8: Unrecognised delayed HTR at home

• An elderly woman with myelodysplastic syndrome received 2 units of red cells on the haematology day unit with no ill effect
• Eight days later she experienced loin pain and passed black urine, which continued for 5 days
• The primary care team prescribed antibiotics, but did not take a urine sample or report this to the haematologist
• It was not until 3 weeks later, when the patient returned to the day unit for an appointment that a DHTR (due to anti-c) was diagnosed
Recommendation

Patients transfused as day cases or outpatients must be given printed advice and a 24-hour contact telephone number and warned to report any adverse symptoms or complications (BCSH guidelines 2009)
SHOT outcomes

- Identify trends in adverse reactions and events
- Stimulate research and detailed audit
- Raise awareness of transfusion hazards and their prevention
- Be an ‘early warning’ of new complications
- Improve safety of transfusion for patients
Decision to use male donors for FFP

TRALI

Leucocyte depletion

PTP
Omission of irradiation in 1085 patients at risk

Many cases missed in patients who have received fludarabine
Leucodepletion is probably protective
What’s new?

- Joint haemovigilance
- Benchmarking
- Data analyses by specialty
We were surprised by the lack of overlap with only 16.4% of reports to both systems.
Review of the 192 SHOT-only reaction reports was performed by reviewing the description only.

Each report was classified according to whether or not the report met the European Union (EU) definitions of severity for a Serious Adverse Reaction (SAR).

The outcome of this analysis was:

- **98/192 (51%)** SAR
- **30/192 (16%)** Possible SAR
- **64/192 (33%)** Not SAR*

In some reports the brief description field did not include important information which was provided later in SHOT fields which might have confirmed that these would fit the EU definition of SAR

<table>
<thead>
<tr>
<th>SHOT Category</th>
<th>MHRA reportable as SAR?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>ATR</td>
<td>74</td>
</tr>
<tr>
<td>HTR</td>
<td>4</td>
</tr>
<tr>
<td>TACO</td>
<td>20</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td>98</td>
</tr>
</tbody>
</table>
Are reporters confused?

- When you submit a report it will be given an MHRA number.
- If you tick SHOT only, despite the MHRA number the report is NOT available for review by the MHRA.
- All serious adverse reactions must be reported to the EU – was the reaction incapacitating or disabling?
Number of reports made each year

Number of reports per reporting organisation

<table>
<thead>
<tr>
<th></th>
<th>1-5</th>
<th>6-10</th>
<th>11-15</th>
<th>16-20</th>
<th>21-25</th>
<th>26-30</th>
<th>31-35</th>
<th>36-40</th>
<th>41-45</th>
<th>46-50</th>
<th>51-55</th>
<th>56-60</th>
<th>61-70</th>
<th>71+</th>
</tr>
</thead>
<tbody>
<tr>
<td>010</td>
<td>60</td>
<td>47</td>
<td>31</td>
<td>19</td>
<td>12</td>
<td>12</td>
<td>7</td>
<td>7</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>011</td>
<td>56</td>
<td>38</td>
<td>28</td>
<td>26</td>
<td>22</td>
<td>9</td>
<td>9</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>012</td>
<td>48</td>
<td>42</td>
<td>34</td>
<td>20</td>
<td>16</td>
<td>13</td>
<td>6</td>
<td>7</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>013</td>
<td>46</td>
<td>33</td>
<td>38</td>
<td>26</td>
<td>15</td>
<td>11</td>
<td>5</td>
<td>6</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>
Serious adverse reactions

Adverse event reports

Near miss reports

Withdrawn

Reports by RTC or country per 1000 components issued
London RTC compared with NW RTC

Serious adverse reactions

Adverse event reports
Differences between specialties

Emergency Medicine

- Delays and Avoidable transfusions

Haematology

- Failure to provide irradiated units
Participation is the key to successful haemovigilance

- Don’t be afraid to report – a certain level is expected
  but...
- Don’t over-report when you don’t need to and can deal with issues ‘in-house’
- Don’t shift responsibility for dealing with an incident by reporting it externally
Putting the patient at the centre of everything we do

Feedback to individual laboratories

MHRA
1282 reports

Detailed analysis
Trending
Clinical feedback

From blood safety to transfusion safety

Patient Blood Management

SHOT
3568 reports
SHOT RESOURCES

see www.shotuk.org

Laboratory Lessons
Clinical Lessons

All the annual reports
Cases from previous reports
Figures from reports
Acknowledgements

• The SHOT team
• Our working expert group
• MHRA haemovigilance team
• The vigilant reporters and hospital staff who share their incidents with us