UK Haemovigilance: Serious adverse events and their root causes – can you analyse them?

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Introduction

- Incident categorisation
- UK human error study
- Effective root cause analysis
- Targeted Corrective Measures
Categorisation

- Purpose of SAE reporting – to identify preventable causes

- UK categorisation is based on root cause rather than incident outcome

- 97% of UK SAEs were attributed to human error in 2011

- UK has chosen to sub-categorise human error and “Other” events in order to provide more useful haemovigilance data
## Sub-categorisation of Other/human error 2012 (n = 524)

<table>
<thead>
<tr>
<th>Sub-category</th>
<th>Code</th>
<th>No. of reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect blood component selected and issued</td>
<td>IBCI</td>
<td>125</td>
</tr>
<tr>
<td>Component labelling error</td>
<td>CLE</td>
<td>75</td>
</tr>
<tr>
<td>Sample processing error</td>
<td>SPE</td>
<td>71</td>
</tr>
<tr>
<td>Data entry error</td>
<td>DEE</td>
<td>73</td>
</tr>
<tr>
<td>Pre-transfusion testing error</td>
<td>PTTE</td>
<td>65</td>
</tr>
<tr>
<td>Component available past dereservation date</td>
<td>CATPD</td>
<td>40</td>
</tr>
<tr>
<td>Component collection error</td>
<td>CCE</td>
<td>26</td>
</tr>
<tr>
<td>Failed recall</td>
<td>FR</td>
<td>19</td>
</tr>
<tr>
<td>Expired component available for transfusion</td>
<td>ECAT</td>
<td>7</td>
</tr>
<tr>
<td>Incorrect blood component ordered</td>
<td>IBCO</td>
<td>4</td>
</tr>
<tr>
<td>Incorrect blood component accepted (from supplier)</td>
<td>IBCA</td>
<td>4</td>
</tr>
<tr>
<td>Delayed component supply (blood establishment only)</td>
<td>DCS</td>
<td>3</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>MISC</td>
<td>12</td>
</tr>
</tbody>
</table>
Root cause analysis

• What can be learnt from >90% “human error” SAEs?
  - Encourage thorough investigation/ RCA
  - Identify “why” the SAE occurred and not just “how”
    • Most human error SAEs are because someone didn’t follow a procedure but there may be numerous contributory factors
  - Understanding why something occurred leads to more effective, targeted CAPA
<table>
<thead>
<tr>
<th>Error Type</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate process</td>
<td>Process does not achieve correct outcome</td>
</tr>
<tr>
<td>Incorrect procedure</td>
<td>Procedure does not reflect the process</td>
</tr>
<tr>
<td>Lapsed/ no training</td>
<td>Training/competency assessment out of date, not completed</td>
</tr>
<tr>
<td>Inadequate training</td>
<td>Training/competency assessment does not cover error made</td>
</tr>
<tr>
<td>Ineffective training</td>
<td>Training is adequate, but misunderstood</td>
</tr>
<tr>
<td>Procedural steps omitted</td>
<td>Procedural steps missed out (Intentional or forgotten)</td>
</tr>
<tr>
<td>Concentration</td>
<td>Steps in the process have been completed, but not accurately, maybe due to rushing</td>
</tr>
</tbody>
</table>
Corrective Measures

- Avoid implementing unnecessary corrective measures
  - Changing procedures often leads to extra training/workload/confusion
  - Using extra checks to spot errors often leads to additional distraction and increases workload
  - Retraining staff who have already been trained and know what they did is burdensome. It may be managed better by encouraging them to reflect on the incident and how they could act differently to prevent recurrence
    E.g. considering how they could manage distractions more constructively.
Corrective Measures

- Good RCA is unlikely to require a single corrective measure as contributory factors may also need addressing

- Corrective measures are likely to require
  - Better education of staff in adhering to GMP principles
    - Following written procedures accurately
    - Improving concentration
    - Managing distractions
    - Keeping training up to date
  - Better planning
    - Workforce/ capacity planning
    - Process validation and regular procedural reviews
Corrective Measures

CAPA should be “appropriate”

- One-off/ infrequent error by individual
  - Discussion, reflection
- Infrequent error by a small number
  - Discussion, reflection, share with team
- Frequent error by individual
  - Discussion, reflection, formal retraining
- Frequent error by team
  - Process/procedure, training material
Now some interactive bits!!

- Have you ever reported to:
  1. SHOT only
  2. SABRE only
  3. Both
  4. None of the above
Case scenarios (1)

- Whilst validating an urgent crossmatch the BMS noticed that the sample had been entered on to the LIMS by the MLA using the Health and Care No. (3275986104) rather than the Hospital No (RV720044)

- She amended this but then inadvertently missed a digit out of the Hospital No. (RV 72044)

- Component labelling error noticed on ward and all incorrectly labelled units returned to lab.

- LIMS amended and correctly labelled units issued.
Case scenarios (1)

- Would you report this to SABRE
  1. Yes
  2. No
  3. Don’t know
Case scenarios (1)

• What would you classify the deviation as?

1. Processing
2. Testing of donations
3. Distribution
4. Other
Case scenarios (1)

- How would you classify the specification

1. Equipment failure
2. Human error (ineffective training)
3. Human error (inadequate process)
4. Human error (concentration)
Discussion
Case scenarios (1)

- Suggested Corrective Measures
  - Advise BMS of the RC (other, DEE)
  - Avoid rushing, increase level of concentration
  - Reflective statement
  - Investigate reasons for rushing
  - Similar for MLA (local report)
Case scenarios (2)

- Blood stock fridge failed, blood froze, alarm did not sound. Blood discarded before anything could be issued to a patient. Engineer called to attend as soon as possible. Fault located to a faulty temperature controller.
Case scenarios (2)

- What would you classify the deviation as?

1. Processing
2. Storage
3. Distribution
4. Other
Case scenarios (2)

- How would you classify the specification

1. Equipment failure
2. Human error
3. Materials
4. Product defect
Discussion
Case scenarios (2)

• Suggested Corrective Measures
  – Repair fridge
  – Define process ensure regular maintenance including probe/ alarm testing
Case scenarios (3)

- During routine dereservation of stock at a satellite hospital an expired unit of platelets was discovered. They had been issued for use the day before. A BMS checked with the ward that they would be used before midnight and was assured this would be the case. However, they failed to send a faxed handover sheet to the satellite hospital which would have warned them to initiate a recall at midnight.

- There was an SOP for management of short-dated components.

- The BMS believed the ward would collect and transfuse the component before it expired and therefore did not update the handover sheet.
Case scenarios (3)

How would you classify the deviation?

1. Other (ECAT Expired component issued and available for transfusion)
2. Storage
3. Distribution
4. Other (CATPD Components available for transfusion past de-reservation)
Case scenarios (3)

How would you specify this?

1. Equipment failure
2. Human error (procedural steps omitted)
3. Human error (concentration)
4. Human error (inadequate process)
Case scenarios (3)

From the information supplied what do you think the root cause is?

1. Human error (procedural steps omitted)
2. Human error (concentration)
3. Human error (inadequate process)
4. All of the above
Discussion
Case scenarios (3)

- Suggested Corrective Measures
  - Advise them of the RC (Other CATPD)
  - Advise them of the correct procedure
  - Reflective statement
Case scenarios (4)

- A fridge failure occurs and the temperature rises above 6°C. The alarm is activated but is muted because the member of staff is busy. The alarm does not re-alarm and the member of staff assumes that the temperature has returned to normal. The temperature excursion is noted 2 hours later by another BMS. The SOP clearly states the alarm must be investigated and dealt with when the first alarm goes off, as the system is not designed to regularly re-alarm.
Case scenarios (4)

- Would you report this to SABRE
  1. Yes
  2. No
  3. Don’t know
Case scenarios (4)

How would you classify the deviation?

1. Other (ICS Incorrect component storage)
2. Storage
3. Distribution
4. Other (CATPD Components available for transfusion past de-reservation)
Case scenarios (4)

From the information supplied what do you think the root cause is?

1. Equipment failure
2. Human error (procedural steps omitted)
3. Human error (concentration)
4. Human error (inadequate process)
Discussion
Case scenarios (4)

- Suggested Corrective Measures
  - Re-train/ re-competency assess
  - Inform other members of staff
  - No need to redefine process or re-write procedure
  - Get the unit to re-alarm
Case scenarios (5)

- Unit of FFP was issued to patient in theatre. On checking all the units on receipt, it was noticed that expiry date on the pack did not match the expiry date on the documentation.
- Error occurred when the incorrect date was entered at booking in.
- Unable to determine if wanded incorrectly, from another pack or hand-typed.
- Often FFP packs are difficult to wand in due to frosting.
- SOP does not describe how to deal with this situation.
Case scenarios (5)

- What would you classify the deviation as?

  1. Processing
  2. Materials
  3. Distribution
  4. Other (DEE Data entry error)
Case scenarios (5)

• How would you classify the specification

1. Equipment failure
2. Human error (Concentration)
3. Human error (Inadequate process)
4. Product defect
Discussion
Case scenarios (5)

• Suggested Corrective Measures
  – Define process with dealing with booking in these packs
  – Write SOP
  – Train staff
  – Re-educate staff in GMP principals
Case scenarios (6)

- A fridge failure occurs and the temperature rises above 6°C. The alarm is activated and a member of staff follows the correct procedure and transfers the stock to another fridge.
Case scenarios (6)

- Would you report this to SABRE

1. Yes
2. No
3. Don’t know
Case scenarios (7)

- Two packs of Cryoppt were thawed and issued by BMS. They were placed into incorrect storage conditions (issue fridge) instead of the platelet incubator and made available for collection.
- Cryoppt is rarely used at this trust and when it is required collection would usually be expected to be very shortly after issue.
Case scenarios (7)

• How would you classify the specification

1. Processing
2. Storage
3. Distribution
4. Other (CCE Component collection error)
Case scenarios (7)

From the information supplied what do you think the root cause is?

1. Human error (ineffective training)
2. Human error (concentration)
3. Human error (procedural steps omitted)
4. Product defect
Discussion
Case scenarios (7)

- Suggested Corrective Measures
  - Retrain member of staff
  - Inform other staff
  - Provide retraining/re-competency more frequently
  - Provide warning notice on fridge
Case scenarios (8)

- A unit of unknown CMV status was booked into stock as CMV neg. Unit was sent as stock to a remote issue blood fridge and was subsequently dispensed to a patient that required CMV neg blood.
- Staff member intended to book unit in as HT neg but there is no barcode label provided by NHSBT on the packs and this data must be booked in manually.
- The radio button to register HT neg on the LIMS system is above the CMV neg button and this was selected in error.
- The department has recently undergone an acute staff crisis and this incident occurred during the Olympic period where normal work patters / stock delivery cycles were disrupted.
Case scenarios (8)

• What would you classify the deviation as?

1. Processing
2. Other (IBCI Incorrect blood component issued)
3. Distribution
4. Other (Data entry error)
Case scenarios (8)

• How would you classify the specification

1. Equipment failure
2. Human error (ineffective training)
3. Human error (concentration)
4. Human error (inadequate process)
Discussion
Case scenarios (8)

• Suggested Corrective Measures
  – Advise staff of the error and RC
  – Reflective statement
  – Advise other staff
  – Re-educate GMP heightened concentration during unavoidably busy periods