Towards unified haemovigilance in the UK – Update
Partnership in practice

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Serious Hazards of Transfusion (SHOT) and MHRA
Cumulative cases reported to SHOT and MHRA
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.
BSQR and the Laboratory

- Traceability
- Quality System
  - Cold chain, collecting blood from the issue refrigerator
  - Change Management, processes, SLA
- Mandatory adverse event/reaction reporting
- Personnel
  - adequate numbers, trained and competent
- Premises
- Self-inspection, audit etc. etc.
# Haemovigilance in the UK

<table>
<thead>
<tr>
<th><strong>MHRA</strong></th>
<th><strong>SHOT</strong></th>
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<tr>
<td><strong>Medicines &amp; Healthcare products</strong>&lt;br&gt;<strong>Regulatory Agency</strong></td>
<td><strong>Serious Hazards of Transfusion</strong></td>
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<td>• Competent Authority for the BSQR 2005&lt;br&gt;  - QMS in blood establishments and hospital blood banks.</td>
<td>• Confidential enquiry</td>
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<tr>
<td>• Competent Authority for the Medicines Act 1968</td>
<td>• Serious adverse reactions/events AND near misses all of which occur in BOTH a laboratory and CLINICAL environment.</td>
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<td>• Competent Authority for the Medical Devices Regulations 2008 (and others)</td>
<td>• Reporting is PROFESSIONALLY MANDATED</td>
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<td>• MANDATORY reporting</td>
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Reporting is essential

- 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
‘If people are good only because they fear punishment, and hope for reward, then we are a sorry lot indeed’

Albert Einstein
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.
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

What is ‘Serious’?

• A **serious adverse reaction** is one which results in death, or is 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.’
Role of MHRA

• ‘Competent Authority’ appointed by DH to implement new legislation and as regulator
  • product quality and safety
  • compliance with requirements for QMS

• Legal requirement to send numbers of SAEs and SARs to EU annually
  • first year of mandatory reporting 2008 (June)

• May impose sanctions and demand corrective actions on individual sites
  • not analysing trends or making recommendations
Joint haemovigilance reporting

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.
The forward plan

Develop a joint haemovigilance system in three phases using the MHRA Lotus Notes platform

- **Phase 1**: designed to capture all SARs for MHRA and SHOT to fix the under-reporting issue
- **Phase 2**: Design an on-line HV system that incorporates both MHRA and SHOT datasets
- **Phase 3**: Develop a means of submitting SAR and SAE reports in line with Phase 2 from local risk management systems (DATiX etc.)
Joint UK Haemovigilance

• These steps will deliver a full joint HV system meeting all the key findings from stakeholder surveys.

• SHOT and MHRA together will be able to contribute most effectively to improving blood safety, practice and patient care.
‘Intellectuals solve problems, geniuses prevent them’

Albert Einstein
Acknowledgements

• Tony Sant, Mike Dawe and Chris Robbie, MHRA
• The SHOT team
• The vigilant reporters and hospital staff who share their incidents with us