Towards unified haemovigilance

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EU Directives 2005

• UK Blood Safety and Quality Regulations (BSQR) 2005 (SI 50)
  – Became law Nov 2005
• Set up of MHRA as the ‘competent authority’
MHRA / SABRE reporting

- All serious adverse reactions – same as for SHOT
- All serious adverse events signalling a process failure in the Quality Management System (QMS), regardless of whether the component was transfused (SHOT reportable if transfused)
- Adverse events involving only clinical staff are not reportable to MHRA, but are reportable to SHOT, comprising the largest sub-group of SHOT reports
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 (and others)
- MANDATORY 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.
- Reporting is PROFESSIONALLY MANDATED
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
Role of MHRA

- ‘Competent Authorit’ appointed by DH to implement new legislation and as regulator for 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

**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.

Root cause analyses are extremely helpful.
Update

• Closer working relationship established between MHRA and SHOT:
  Reciprocal inclusion of JL/ PBM on expert panels for:
  – MHRA Blood Consultative Committee
  – MHRA Haemovigilance Expert Panel
  – SHOT Steering Group and Working Expert Group
  – National Blood Transfusion Committee

• Inclusion of MHRA chapter in 2012 SHOT report
Update

• Preliminary meetings have been held to understand the benefits/limitations of current software in use (SABRE/DENDRITE)

• Agreement to update current links between these systems and transfer more shared data
  – in progress, aiming for completion by August 2012

• Phase 1 review of the essential reporting requirements of each Organisation has been undertaken
Next Steps

- Circulation of questionnaire to haemovigilance reporters for their ideas and comments
- Feedback from questionnaire to guide the development of a User Specification document for a new unified haemovigilance reporting system
- Note that the objectives and methods of data analysis are different
- Any new system will incorporate the needs of both with different algorithms within