Haemovigilance reporting in the UK 2013: collaboration to reduce confusion
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Background
The Medicines and Healthcare products Regulatory Agency (MHRA) is the competent authority for the UK for the reporting of serious adverse events (SAE) and serious adverse reactions (SAR) in line with the definitions in the European Blood Directives adopted into UK Law under the Blood Safety and Quality Regulations (BSQR) 2005. Serious Hazards of Transfusion (SHOT), established in 1996, collects similar data, but also includes clinical incidents. Many of these are not required to be reported under BSQR. Currently, all reports are entered via the MHRA Serious Adverse Blood Reactions and Events (SABRE) system where the reporter can choose the subsequent allocation to MHRA or SHOT or both.

Methods
A review was undertaken of all reports made in 2013 (January to December). Cases were matched using the SABRE reference number, which is common to both organisation’s database systems, and analysed by category of report.

Results
Overall 3692 incidents were reported, 124 (0.4%) to MHRA only, 2415 (65.4%) to SHOT only and 1152 (31.2%) to both. Surprisingly, only 607 (16.4%) were common to both organisations after exclusions and withdrawals. There were 239 reaction reports and 368 adverse event reports common to both. However, altogether 450 reaction reports were made to SHOT of which 192 (42.67%) were not reported to the MHRA. These were found in most categories including 149 acute transfusion reactions (ATR), 13 haemolytic reactions (HTR) and 27 cases of transfusion-associated circulatory overload (TACO). A further 23 of the 450 SHOT reactions were reported to the MHRA but were either excluded (15) or incomplete (8). The adverse event categories were more difficult to compare as they are more variably defined by each organisation.

Conclusions
Reconciliation and comparison of reporting between SHOT and the MHRA suggests that there is some underreporting of SARs to the MHRA, and in turn to the EU. It also emphasises the need for a joint reporting system to reduce confusion. SHOT and the MHRA will continue working towards this common goal which may produce a more coherent picture of Serious Adverse Incident Reporting in the UK.

Recommendations
- Report all Serious Adverse Reactions to the MHRA and share with SHOT
- Include all relevant clinical information e.g. temperature rise, medication given etc
- Definitions of what to report are available on each organisation’s website
  - MHRA - www.mhra.gov.uk
  - SHOT - www.shotuk.org
- If in doubt – ask for advice
  - MHRA by email sabre@mhra.gsi.gov.uk or by telephone 020 3080 7336
  - SHOT by email shot@mhsbt.nhs.uk or by telephone 0161 423 4208

MHRA
MHRA is an Executive Agency of the Department of Health.

SHOT
SHOT is an independent registered charity. It is run by a body of 17 directors, all of whom are volunteer representatives of the blood and transfusion services in the UK.

MHRA reportable as SAR?

<table>
<thead>
<tr>
<th>SHOT Category</th>
<th>MHRA reportable as SAR?</th>
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<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>ATR</td>
<td>74</td>
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<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>Totals</td>
<td>98</td>
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*In some reports the brief description field did not include some important information which was provided later in SHOT fields which might have confirmed that these would fit the EU definition of an SAR.