Blood Safety and Quality Regulations

Thursday 29 September 2005
Hastings Stormont Hotel, Belfast
SABRE

Serious Adverse Blood Reactions & Events

Roy Saunders
September/October 2005
Why MHRA?
What is SABRE?
What next?
Why MHRA?

- respected Competent Authority
  - partner in European and global initiatives
  - medicines and medical devices
  … and now haemovigilance
Why MHRA?

- experience of adverse incident reporting & investigation
  - 9,000 medical device incident reports pa
  - 18,000 medicines adverse reaction reports pa
Why MHRA?

- existing online reporting systems
  - for medical device users since 2001
  - for medical device manufacturers since 2003
  - approx. 40% medical device adverse incident reports now submitted online
What is SABRE?

- Serious Adverse Blood Reactions & Events
- allows reporting in accordance with EU & UK legislation
- online system for submission of notifications and confirmations of SARs & SAEs to MHRA
- secure system, based on existing technology
- online reporting to SHOT
What is SABRE?

• simple to use
• guidance documents and online Helpertext
• online registration for reporters
• electronic report form
What is SABRE?

- draft, edit and save reports
- attach docs, images, etc.
- ‘Workspace’ - library of all draft & submitted reports
- electronic version of SHOT questionnaires
SABRE
an interactive mock-up of the new SABRE haemovigilance reporting system

Roy Saunders
September/October 2005
Reporting safety problems

This section provides access to information on how to report suspected safety problems with medicines, medical devices, blood and blood components.

**Medicines**

Report a suspected adverse reaction or defect

The MHRA collects information on suspected adverse drug reactions and suspected defects in medicinal products.

**Devices**

Report an adverse incident

Any adverse incident involving a medical device or its instructions for use should be reported to the MHRA, especially if it lead to, or could have lead to, death, life-threatening illness or injury.

**Blood**

Report an adverse event or reaction

From 8 November 2005 the EU Blood Safety Directive will require that serious adverse events and serious adverse reactions related to blood and blood components are reported to the MHRA, the UK Competent Authority for blood safety.
Serious Adverse Blood Reactions & Events (SABRE)

From 8 November 2005 the EU Blood Safety Directive will require that serious adverse events and serious adverse reactions related to blood and blood components are reported to the MHRA, the UK Competent Authority for blood safety.

By November, this web page will contain an active link to a new, secure and confidential online reporting system that will enable Blood Establishments, Blood Banks and Hospital Transfusion Teams electronically to submit reports of serious adverse event or serious adverse reaction directly to the MHRA. This new reporting system is to be known as SABRE – Serious Adverse Blood Reactions & Events.

Healthcare and blood service staff will be able to register, log on to SABRE and then draft and submit Initial Notifications and Confirmations of adverse events and adverse reactions.

The new system has been designed to be very simple to use, and will incorporate comprehensive online help text at all stages. If at any time reporters require advice or assistance, staff in the MHRA Adverse Incident Centre will be available to provide assistance. Enquiries may be made either by e-mail or by telephone:

sabra@mhra.gsi.gov.uk  
020 7084 3338

The MHRA, recognising the considerable experience and expertise held by SHOT (Serious Hazards Of Transfusion) and the value of the data that they collect and analyse, has included SHOT’s questionnaires within the new reporting system. The questionnaires are an integral part of the online report form and, for the first time, enable SHOT to receive, store and analyse their questionnaire data electronically.

Enquiries for SHOT may be made either by e-mail or by telephone:

shot@nbs.nhs.uk  
0161 235 4208
<table>
<thead>
<tr>
<th>Report Source</th>
<th>Serious Adverse Reaction</th>
<th>Serious Adverse Event</th>
<th>Report to</th>
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<tbody>
<tr>
<td>Reporting Organisation</td>
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</tr>
<tr>
<td>Reporting Organisation Address</td>
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</tr>
<tr>
<td>Reporter's Name (if different to Registered User)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporter's Email</td>
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<tr>
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<tr>
<td>Fax No.</td>
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<tr>
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</tr>
<tr>
<td>Local Reference No.</td>
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<tr>
<td>MHRA Reference</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital Consultant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incident Location *</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Do you wish SHOT to have access to this *</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Report to SHOT only</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Email address for Reported locally? *</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Reported to Blood Establishment? *</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>If so, which Blood Establishment?</td>
<td></td>
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</tr>
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</table>
Not yet Registered? If you have not yet registered as a SABRE User, click the link above and submit the requested details for verification. Please note that the provision of certain information is compulsory for registration. On-line Help is available if required. For security reasons, new registrations will not be activated until registration details have been checked and verified by the MHRA.

Email address

Registration No.

Password

Forgotten Password? Please contact the Adverse Incident Centre on 020 7034 3080 or by email to sabre@mhra.gsi.gov.uk and be prepared to provide your registration number and to answer other questions in order to confirm your identity. Once we have verified your identity, we will set a new password and email it to you as soon as possible.
<table>
<thead>
<tr>
<th>Report Type</th>
<th>Blood Component</th>
<th>Date of Incident</th>
<th>Local Reference No.</th>
<th>Date of first report to MHRA</th>
<th>MHRA Reference No.</th>
<th>Date of last report to MHRA</th>
<th>Date submitted</th>
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<tbody>
<tr>
<td>Reaction</td>
<td>Platelets</td>
<td>10/05/2005</td>
<td>BI 005</td>
<td>11/05/2005</td>
<td>2005/005/011/HV1/005</td>
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<td>14/02/2005</td>
<td>BI 006</td>
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</table>
Acknowledgment of SABRE report submission

Your form has been submitted to the Medicines and Healthcare products Regulatory Agency and has been given the following reference number:

2005/011/008/HV1/001

Should you wish to contact us regarding this report please telephone us on 020 7084 3080 or e-mail us at aic@mhra.gsi.gov.uk quoting the above-mentioned reference number.
Questionnaire No X - Haemolytic Transfusion Reaction
(Acute and Delayed)

Haemolytic Transfusion Reaction (Acute and Delayed)

SECTION 1 – WHAT HAPPENED

1.1 Please give a brief account of the sequence of events. DO NOT include names of patients or staff.
What next?

• SABRE training
• reporter registration
• live on 8th November 2005
Contacts

MHRA
sabre@mhra.gsi.gov.uk

SHOT
shot@nbs.nhs.uk
SABRE  -  What to report

Clare Taylor and Dorothy Stainsby
September/October 2005
SAR - any unintended response in a donor or in a patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity
First question

Did the patient have an untoward reaction?

If ‘yes’ - report as SAR

If the reaction was caused by an error or system failure, it will also be reportable to SHOT as ‘Incorrect Blood Component Transfused’ - you will be directed to the correct questionnaire after completing the notification form.

If ‘no’ consider whether it was a SAE
Categories:

- Immunological haemolysis due to ABO incompatibility
- Haemolysis due to other allo-antibody (includes AHTR and DHTR)
- Anaphylactic/anaphylactoid reactions
- Severe allergic reaction
- Transfusion Related Acute Lung Injury
- PTP
- TA-GvHD
- TTI (viral, bacterial, parasitic, other)

Similar to existing SHOT categories
Reportable to SHOT also
Will need to assess ‘imputability’ i.e. likelihood of reaction being caused by transfusion (may be revised later)
Component types:

- Whole Blood
- Red cells
- Platelets
- Plasma

These are reporting categories for legislation. Sub types of each of these can be reported - will be explained in help text. Further detail section will allow for stating exactly what component was involved.
SAE - any untoward occurrence associated with the collection, testing, processing, storage or distribution of blood and blood components that might lead to death or life threatening, disabling or incapacitating conditions for patients (or which results in or prolongs hospitalisation or morbidity)
What must be reported?

‘any serious adverse events (accidents and errors) related to the collection, testing, processing, storage and distribution of blood or blood components which might have an influence on their quality and safety’

Interpreted in UK as ‘quality and safety for the individual recipient’
General principle of reporting

Regulations cover all activities in blood establishments and hospital blood banks or areas managed by BB staff e.g. satellite labs and fridges, and all events, errors, mistakes are reportable to MHRA as well as to SHOT.

Errors, mistakes and near misses in clinical areas and involving non BB staff are reportable to SHOT as at present but not necessarily to MHRA.

If in doubt, report to both!
Definitions - 1

Collection
- of whole blood from a donor
- NOT of blood from a BB fridge by a nurse, midwife, ODA, porter or doctor
- NOT of blood samples from patients by phlebotomists, nurses, doctors or midwives
Definitions - 2

Testing

- testing of the donation by the BE
- testing in the BB on the unit OR on patients samples, including grouping, antibody screening, compatibility testing, antenatal testing, reference laboratory tests and any supplementary tests
Definitions - 3

Processing

• manipulation of the donation by a blood establishment
• discussed in detail elsewhere in the directive
Definitions - 4

Storage

• Safe husbandry of blood at all stages of the cold chain in BE and BB
• includes satellite labs and fridges under the control of BB
• does NOT include handling in clinical areas
Definitions - 5

Distribution

• from BE to BB and as far as issue fridges and BB controlled satellite fridges
• includes inter-hospital transfer of blood from BB to BB
Reporting to SHOT

- essential to continue, so as to preserve the complete picture that we have now

- SHOT will continue to analyse reports, feed back and make recommendations

- Culture of anonymised, blame free reporting will remain unchanged

- 70% of ‘wrong blood’ events occur in clinical areas - we must keep collecting these to improve patient safety

- made easier by on-line reporting
If patient has had any reaction, then it should be reported as a SAR, wherever the problem originated - BE, BB or clinical area.

If there has been NO reaction in the patient, it should be reported as a SAE, if it is possible that the problem arose in a BE or in BB. This includes near misses in BE or BB, unless detected by the quality system.

If an SAE occurs which clearly originated with clinical staff, including sampling of patients, bedside checking, prescription errors etc, then this can be reported to SHOT only. This includes near misses.
Contacts

MHRA  sabre@mhra.gsi.gov.uk

SHOT  shot@nbs.nhs.uk