SERIOUS HAZARDS OF TRANSFUSION SHOT

Reporting SAE and SAR – the UK experience

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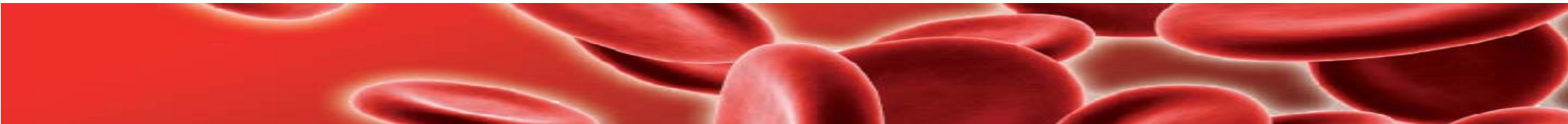
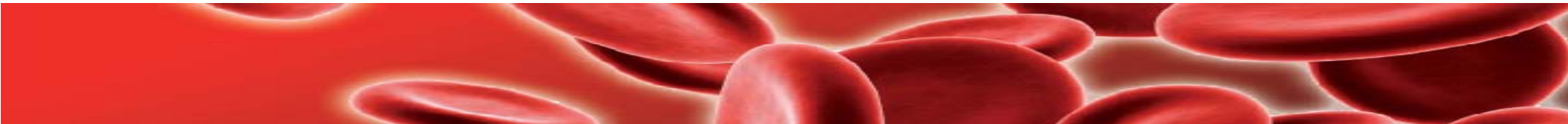
EHN meeting
29th February 2008
Frankfurt



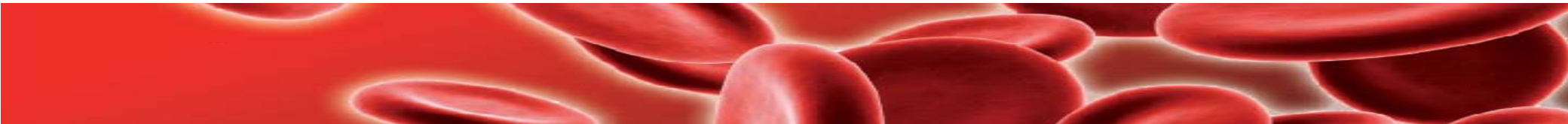
Existing HV scheme - SHOT

- Professionally led scheme providing analysis of anonymised data by experts in each area of reporting
  - Regular output in annual report, papers, meetings
  - Recommendations for actions made to CMOs, DH, hospitals, professional bodies and blood services
- Measurable impact on patient safety
  - Reduction in TRALI
  - Reduction in ABO incompatible transfusions
  - Reduction in bacterial contamination



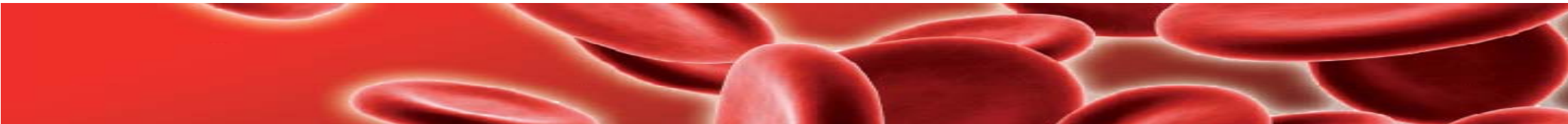
New role of MHRA

- ‘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



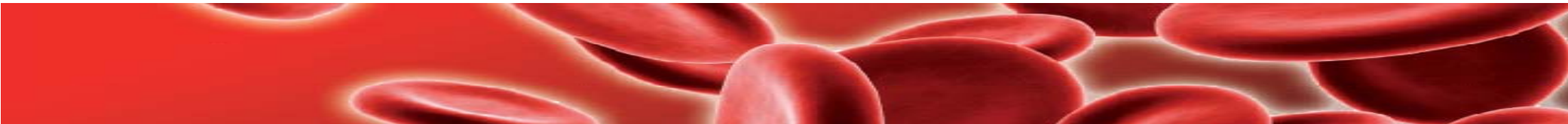
What was already in place

- Voluntary, blame free reporting culture
- Reports all related to incidents where components transfused to patients –others categorised as ‘Near Miss’
- 70% of reports are of AEs in clinical areas
- Increasing reporting year by year



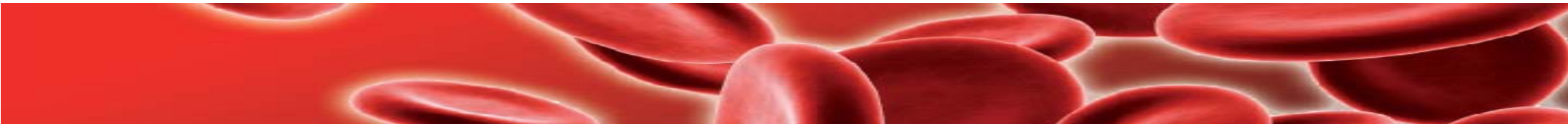
What was new for BSQR

- Mandatory reporting
- Data available to Blood Inspectors for consideration in conjunction with annual Compliance report
- SARs – collected by both SHOT and MHRA
  - More minor SARs seem to be required by MHRA
- Hospital transfusion laboratory and blood establishment reports required, not reports from clinical areas
- SAEs include those where blood not transfused
  - are ‘near miss’ for SHOT
- BE reports required to go to MHRA



How SAE and SAR reporting is done in UK

- SABRE
- Single portal for reporting to MHRA and SHOT
- Accessible via MHRA, SHOT, JPAC and blood services websites
- User friendly home page, welcome, explanatory pages
- Improvement for SHOT, now has online database
- Benefit to MHRA of tapping into existing reporting culture



Medicines and Healthcare products Regulatory Agency

An executive agency of the Department of Health

We protect and promote public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness in use, and are used safely.

Spotlight on...

MHRA e-mail alerting service

We are pleased to introduce the MHRA e-mail alerting service.

UK PRESIDENCY OF THE EU 2005

> UK's Presidency of the EU

What's new

08 Sep 2005

Press release: Prescription only medicines seized near Birmingham

Investigators from the MHRA and local police today seized 26 tubs (300ml) of steroid cream.

07 Sep 2005

MDA/2005/051 - All biochemical test kits for the identification of Neisseria gonorrhoeae (N. gonorrhoeae)

Increased risk of false negative or ambiguous results.

02 Sep 2005

Updated patient information leaflets and labelling for painkillers

The Medicines and Healthcare products Regulatory Agency (MHRA) has asked manufacturers of over-the-counter (OTC) medicines to voluntarily update their Patient Information Leaflets (PILs) and labelling of painkillers that contain codeine and dihydrocodeine.

02 Sep 2005

Seroxat statement

In 2004, the Committee on Safety of Medicines Expert Working Group on the Safety of SSRIs completed its review of the large body of safety evidence from a wide range of sources – spontaneous suspected adverse drug reactions (from health professionals and patients), clinical trials (including the available clinical trial data for paroxetine), published literature and epidemiological databases.

Report a suspected safety problem

Quick Links Go

Hot topics

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In Safety information

- Safety warnings, alerts and recalls
- General safety information and advice
- How we monitor the safety of products
- **Reporting safety problems**
  - › Medicines
  - › Devices
  - › Blood

Home › Safety information › **Reporting safety problems**

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.

In Reporting safety problems

- Medicines
- Devices
- Blood
  - Serious Adverse Blood Reactions & Events (SABRE)

Home › Safety information › Reporting safety problems › Blood › Serious Adverse Blood Reactions & Events (SABRE)

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.

As well as being able to draft and submit reports, registered reporters will have access to an online 'Workspace' containing a searchable library of all their reports. Reporters will be able to save draft reports, review submitted reports, and submit a confirmation report once their local investigation has been completed.

SABRE is not intended to replace existing local reporting arrangements. If an event or reaction would previously have been reported to local management, to a blood establishment, or elsewhere, those arrangements should continue. If information on an event or reaction would previously have been passed to SHOT (see below) that too should continue.

The new system has been designed to be very simple to use, and will incorporate comprehensive online helptext 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:

Related information:

Other sites:

» SHOT - Serious Hazards of Transfusion

SABRE: Serious Adverse Blood Reactions & Events

Reporter Registration

Title *

Forename *

Surname *

Email *

Job Title *

Password *

Retype Password *

Organisation name *

Organisation type *

Organisation address *

Contact telephone no. *

Contact fax no.

Tick box to indicate that you have read and accepted the Terms and Conditions

View Terms & Conditions

SABRE: Serious Adverse Blood Reactions & Events

Log In

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

SUBMIT

Forgotten Password? Please contact the Adverse Incident Centre on 020 7084 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.

SABRE: Serious Adverse Blood Reactions & Events

MANAGE FOLDERS

Your folders:

- Workspace
  - Drafts
  - Reactions
  - Events
  - SHOT
  - All Documents

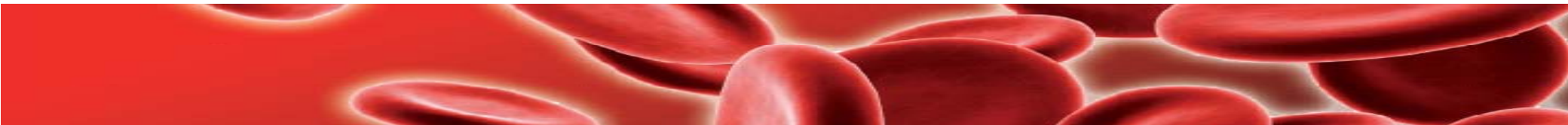
WorkSpace for:

Report Type	Blood Component	Date of Incident	Local Reference No.	Date of first report to MHRA	MHRA Reference No.	Date of last report to MHRA	SHOT questionnaire No.	SHOT questionnaire Date submitted
N Event	Whole blood	15/04/2005	ABC123	15/04/2005	2005/004/005/HV1/001	23/06/2005	2	20/04/2005
C Reaction	Platelets	10/05/2005	BI 005	11/05/2005	2005/005/011/HV1/005	02/07/2005	4	19/05/2005
C Reaction	Whole blood	08/11/2005	TA 942	11/11/2005	2005/011/011/HV1/002	11/11/2005	n/a	
N Event	Whole blood	14/02/2005	BI 006	29/02/05	2005/002/029/HV1/001	25/03/2005	6	

SAR and SAE data so far

SABRE - early statistics (Up to 30th Jan 2008)

- registered reporters 302
  - *'team' registrations* *164*
  - *blood establishments* *(includes MoD)* *5*



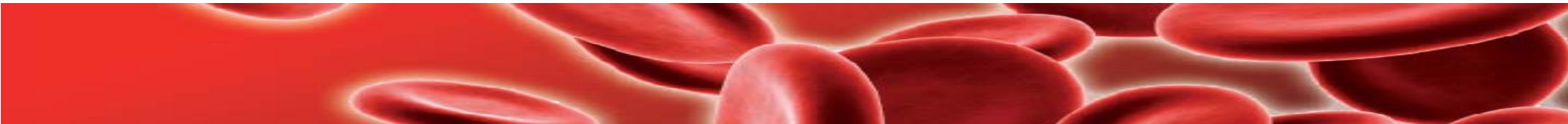
SABRE reports submitted

- **MHRA & SHOT** **2137**

  (includes 186 sent to MHRA only, but subsequently copied to SHOT or non-SHOT reportable)

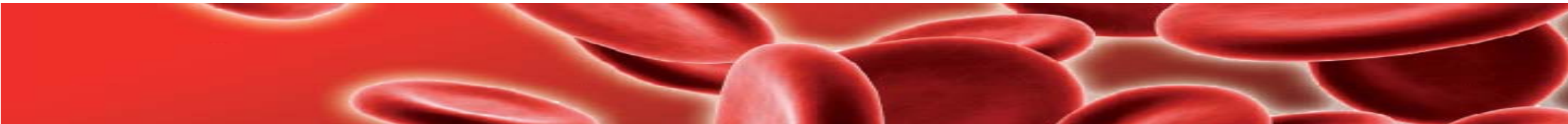
  - England 1743
  - Scotland 135
  - Wales 181
  - Northern Ireland 78

- **SHOT only** **1201**

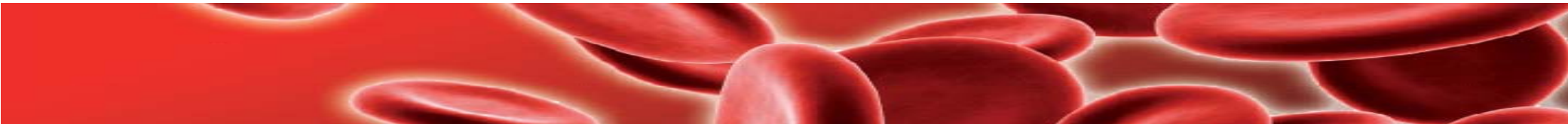


SABRE reports submitted

- Serious Adverse Reactions 623
- Serious Adverse Events 1514
- TOTAL 2137

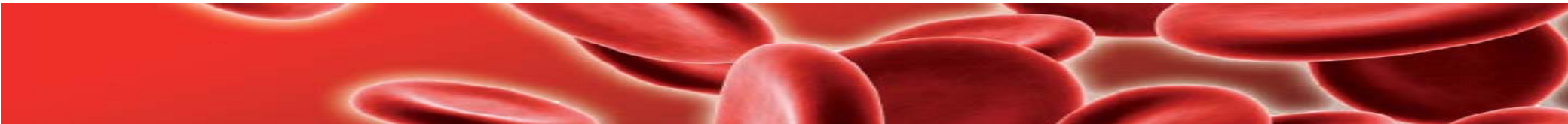


Notifications	80
Confirmations	1847
Exclusions	210
TOTAL	2137



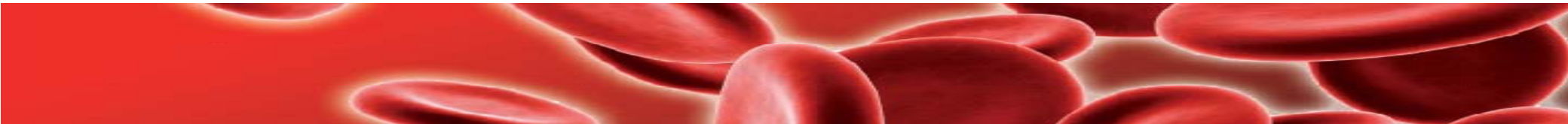
Working together

- Collaboration and co-operation between SHOT and MHRA
  - Strengthening of UK haemovigilance
  - Improved data collection for SHOT via SABRE
  - Potential for new developments in data analysis
  - Professional laboratory and clinical experience and expertise available to MHRA
  - Clear different remits for SHOT and MHRA but symbiotic, mutually enhancing relationship



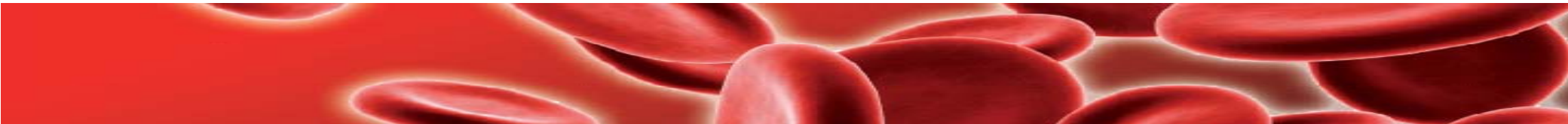
BCC AE sub-group

"A sub committee will be set up under the auspices of the Blood Consultative Committee. This will review any detailed operational issues relating to SABRE. It will also discuss any technical points related to the reporting of serious adverse reactions and events. This will be a primary focus for discussions between the MHRA and SHOT."



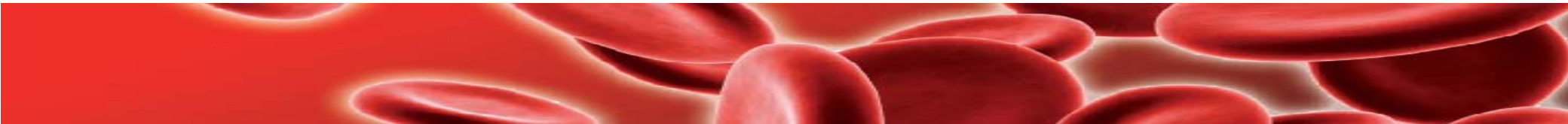
AE subgroup of BCC

- Representatives from MHRA, SHOT, four UK blood services, IBMS, TP, BBT,HPA, NPSA
- Forum for discussion of above issues and reconciliation of numbers and denominator data
- Agreement regarding identification of high risk reports relevant actions by SHOT and MHRA
- Reports back to Blood Consultative Committee of MHRA



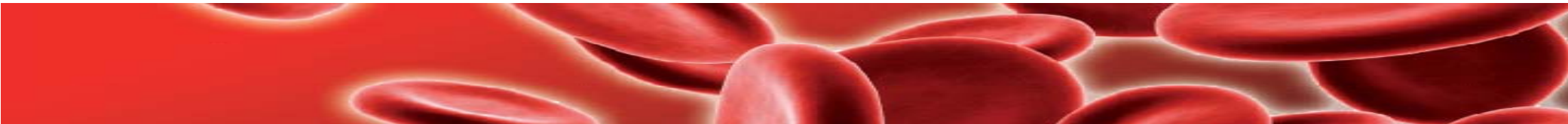
Representation

WBS
NBS
SNBTS
NIBTS
Quality Management (blood establishments)
BBT network
HPA
NPSA
Transfusion practitioner (SPOT)
Blood bank manager (IBMS)
SHOT
MHRA



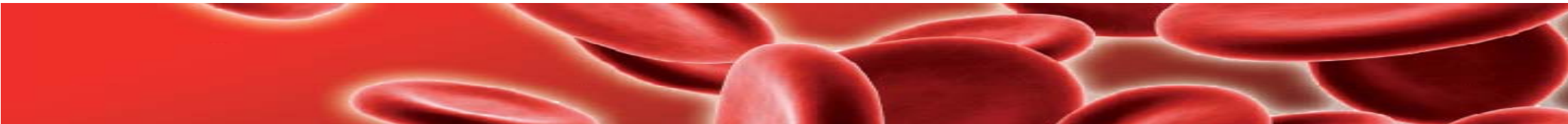
The Experience?

- Difficult transition for reporters
  - Extra work – new system to master
  - Problems and confusion regarding what to report
    - Meaning of ‘serious’
    - Timing of reports ‘as soon as known’
    - BSQR not covering clinical reporting
  - Suspicion about MHRA – fear or repercussions
  - Doubt about usefulness of exercise



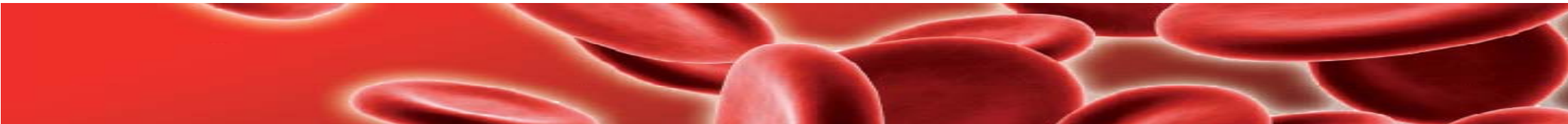
HV findings in inspections

- No inspections carried out so far on the basis of reports
- Inspectors look at SABRE reports from a site prior to visiting to inspect
- Some major deficiencies reported
  - Example of found in linkage of internal lab AE reporting procedures to Trust risk management and reporting systems. SOPs, training records required



Effect on SHOT

- Overall slight decrease in 2006 in SHOT reportable incidents – no specific category
  - Overall increase in HV reporting via SABRE
- Increased reports of minor reactions
- Increased reporting on ‘near miss’ from hospital transfusion labs in SAE category



Future strategy

- SHOT to continue, and expand to embrace new categories of AE
- SHOT to target specific areas of interest and begin in depth reporting – e.g. inappropriate use
- Work closely with MHRA – reconciliation of data, identification of problem areas
- Continue to develop close mutually enhancing relationship which fulfils both the regulatory and legislative role of MHRA and the professional and academic role of SHOT