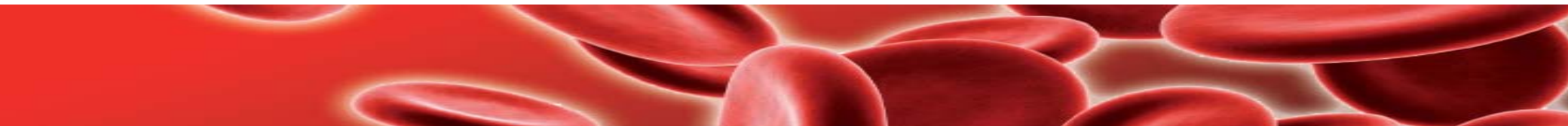


MHRA update

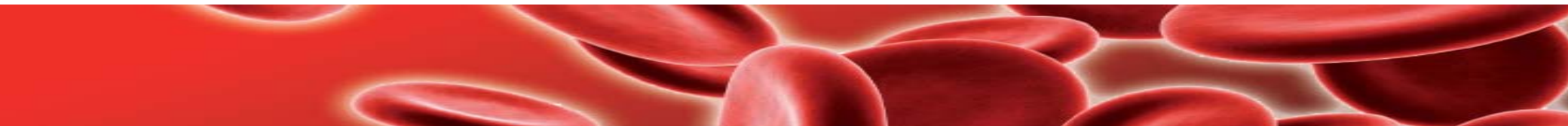
Dr Clare Taylor
National Medical Co-ordinator for SHOT
Haematology advisor to MHRA

SHOT/NEQAS meeting
20th November 2007
Birmingham



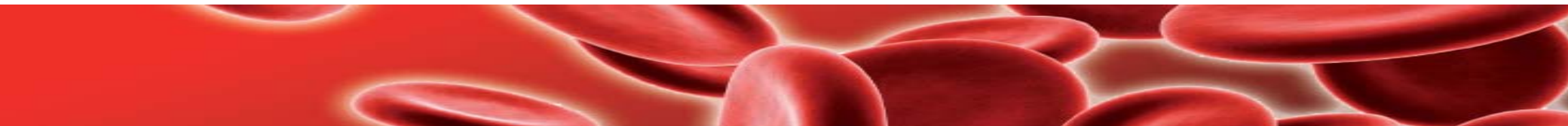
Haemovigilance in the UK

- SHOT since 1996
 - set standards in EU and beyond
- BSQR implemented from November 2005
 - adverse event reporting to EU mandatory
- SABRE web based reporting to both MHRA and SHOT
 - data entered via same system but used differently



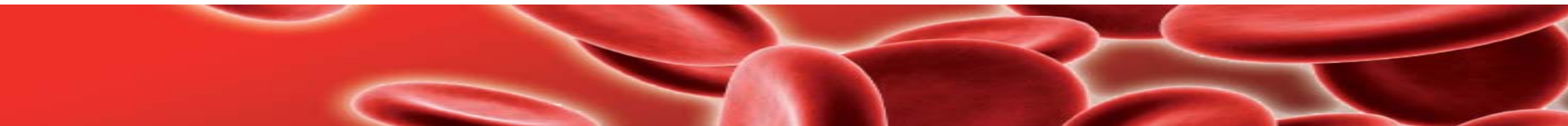
Role of MHRA

- ❑ '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



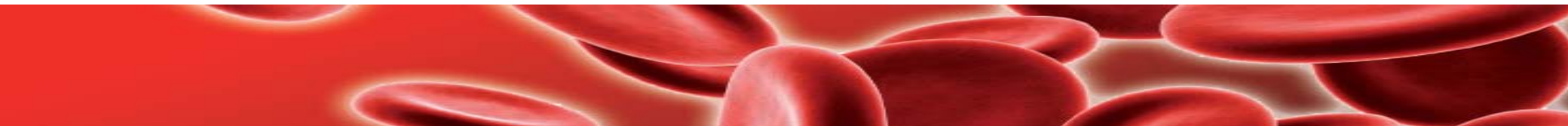
Role of SHOT

- ❑ 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



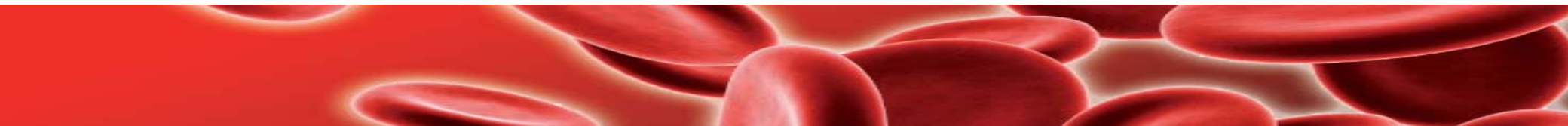
Working together

- 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



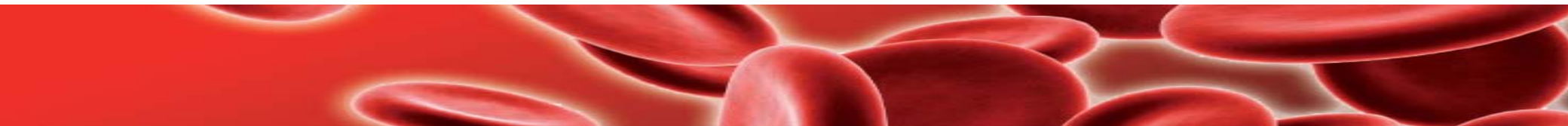
Differences in data

- ❑ SARs – collected by both SHOT and MHRA
 - ❑ Increased numbers of reports of less serious reactions now reaching SHOT e.g. simple febrile
 - ❑ Requires reconciliation of numbers in each category
- ❑ SAEs – if component is transfused then may be ‘IBCT’, if not then SHOT Near Miss
 - ❑ Sub-categorisation required for hospital SAEs
 - ❑ Break down and separate analysis of IBCT in future
- ❑ Blood establishment AEs – not reportable to SHOT but are to MHRA
- ❑ Clinical based AEs not reportable to MHRA but are to SHOT



Problems...

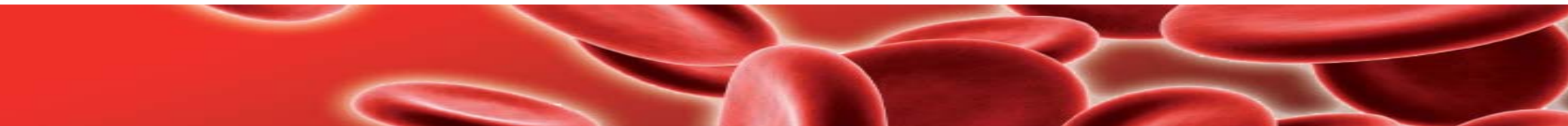
- ❑ Reporters decides if something is reportable and chooses which category to send report into – cannot be changed without liaison with reporter
- ❑ No current formal mechanism for decision to include or exclude reports at MHRA...at present not legally allowed to exclude items as “not reportable under the Directive” unless very clear cut
- ❑ Possibility that UK figures may not be comparable to SHOT figures
- ❑ Still lack of clarity as to what is the intention of the EU regarding what should be included





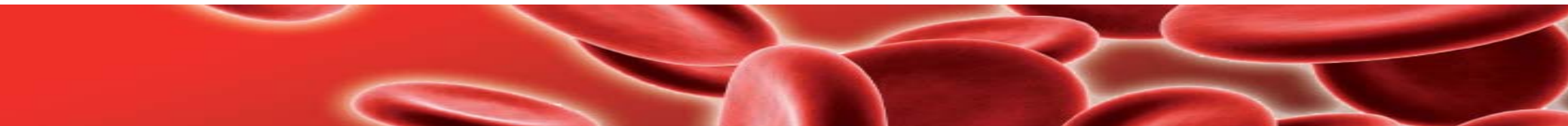
BCC AE sub-group

“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

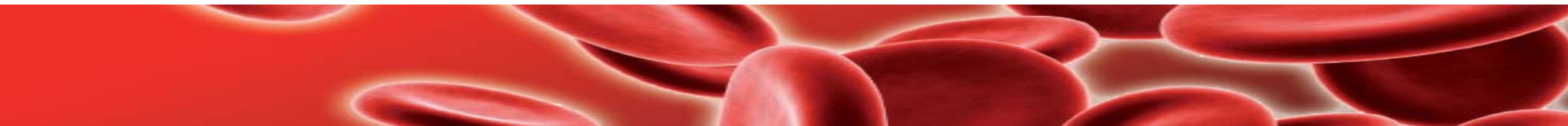
NPSA

Transfusion practitioner (SPOT)

Blood bank manager (IBMS)

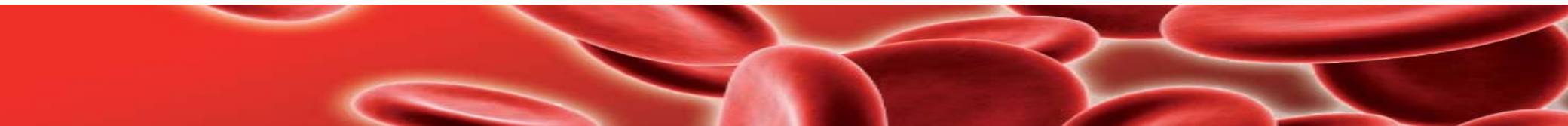
SHOT

MHRA

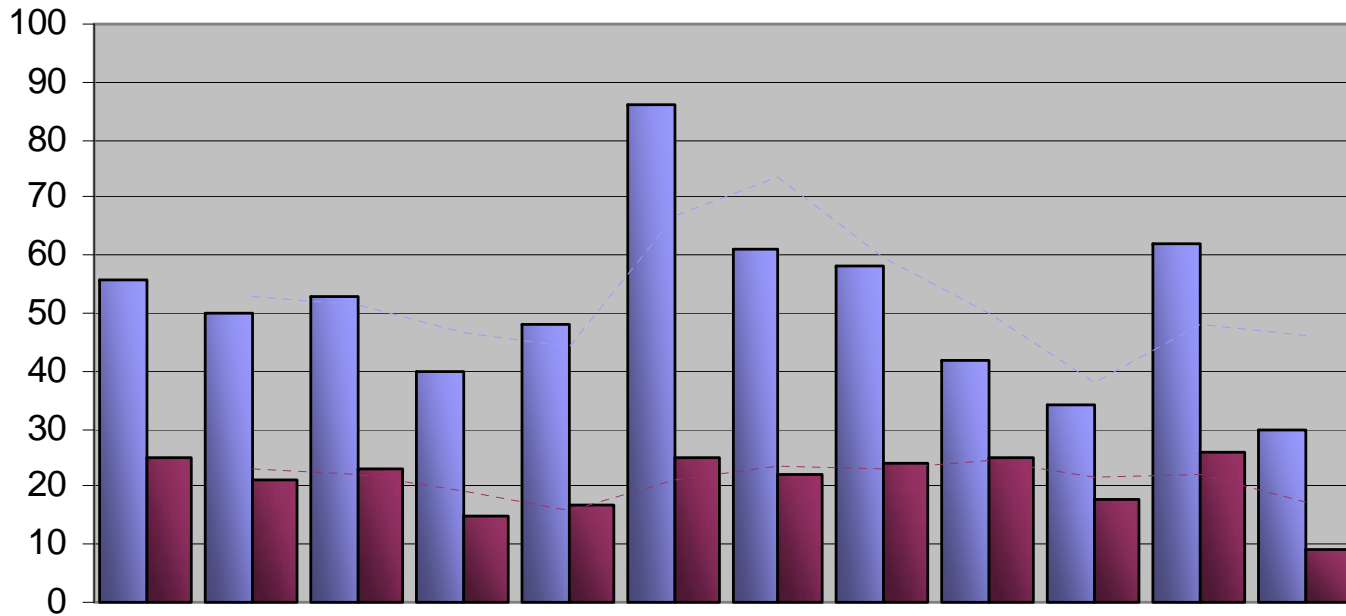


SABRE data

- ❑ 311 registered reporters to SABRE – some as Trusts some as individual hospitals
- ❑ 870 completed reports sent between January and December 2006
 - ❑ 620 SAEs
 - ❑ 250 SARs
- ❑ 567 SHOT only reports sent in same period
- ❑ Total 1437 adverse incidents reported through online SABRE system (531 in SHOT categories)



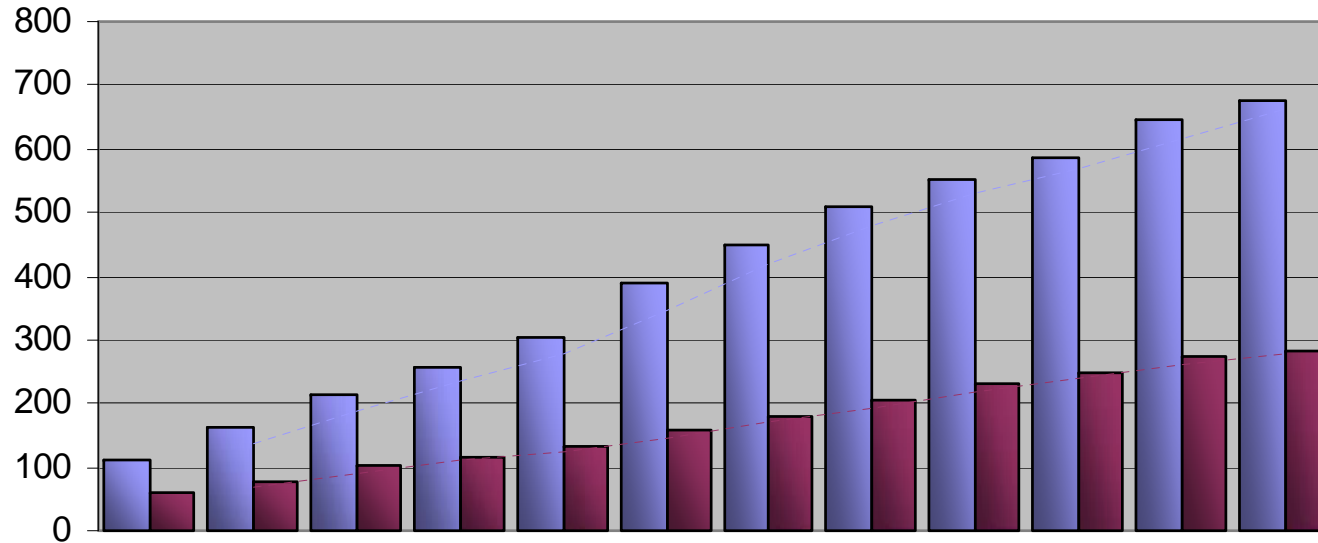
SAR & SAE notifications: Monthly



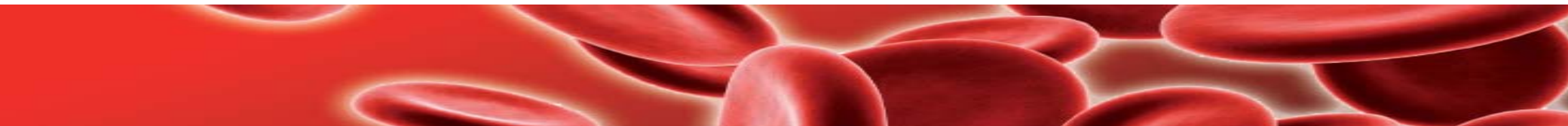
	Jan-06	Feb-06	Mar-06	Apr-06	May-06	Jun-06	Jul-06	Aug-06	Sep-06	Oct-06	Nov-06	Dec-06
■ Events	56	50	53	40	48	86	61	58	42	34	62	30
■ Reactions	25	21	23	15	17	25	22	24	25	18	26	9



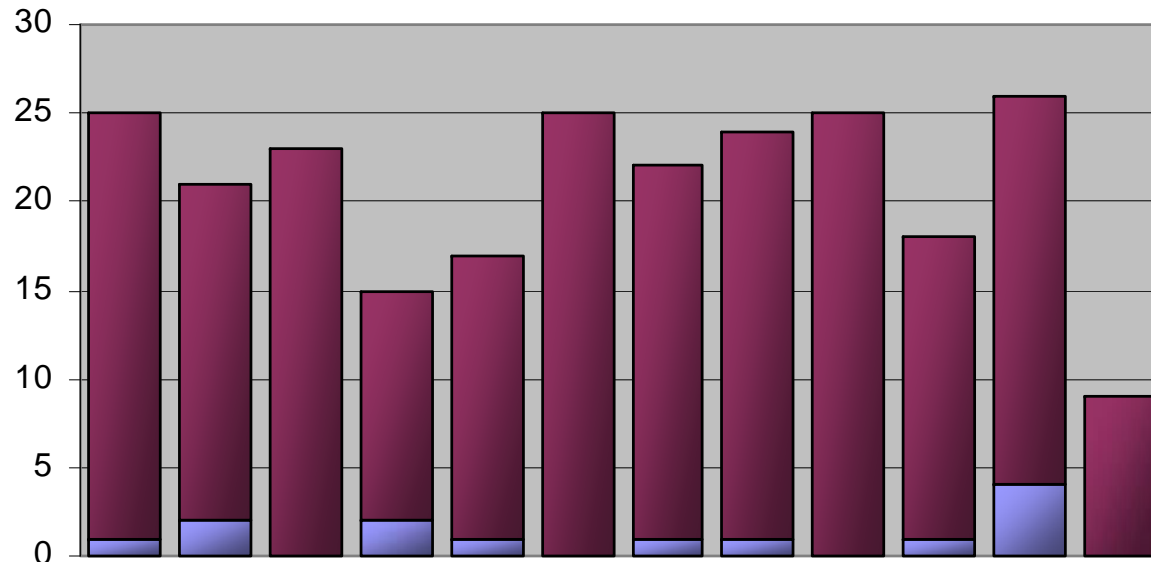
SAR & SAE notifications: Monthly - Cumulative



	Jan-06	Feb-06	Mar-06	Apr-06	May-06	Jun-06	Jul-06	Aug-06	Sep-06	Oct-06	Nov-06	Dec-06
■ Events	113	163	216	256	304	390	451	509	551	585	647	677
■ Reactions	58	79	102	117	134	159	181	205	230	248	274	283



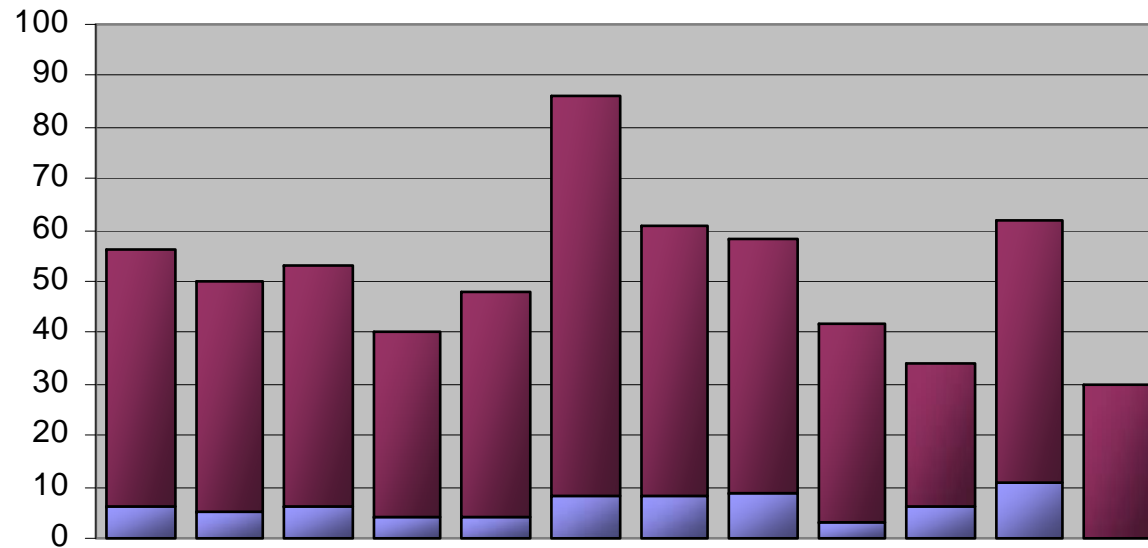
Total numbers of SARs included and excluded from the annual notification



	Jan-06	Feb-06	Mar-06	Apr-06	May-06	Jun-06	Jul-06	Aug-06	Sep-06	Oct-06	Nov-06	Dec-06
■ Included	24	19	23	13	16	25	21	23	25	17	22	9
■ Excluded	1	2	0	2	1	0	1	1	0	1	4	0



Total numbers of SAEs included and excluded from the annual notification

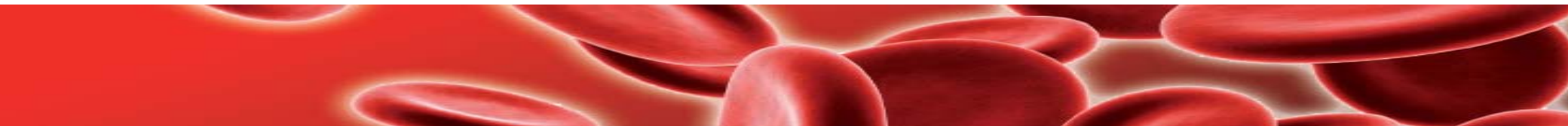


	Jan-06	Feb-06	Mar-06	Apr-06	May-06	Jun-06	Jul-06	Aug-06	Sep-06	Oct-06	Nov-06	Dec-06
■ Included	50	45	47	36	44	78	53	49	39	28	51	30
■ Excluded	6	5	6	4	4	8	8	9	3	6	11	0



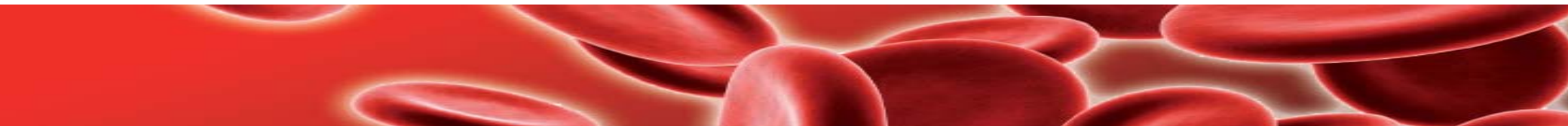
Inspections data

- ❑ 60 inspections carried out in 2006 – March 2007 (similar number identified for 2007-8)
- ❑ Average ~2.2 major deficiencies per site
- ❑ Average ~4.3 ‘other’ deficiencies per site
- ❑ 3 critical deficiencies in 2006-7
 - ❑ Traceability
 - ❑ QMS (multiple problems)
 - ❑ Validation post lab move



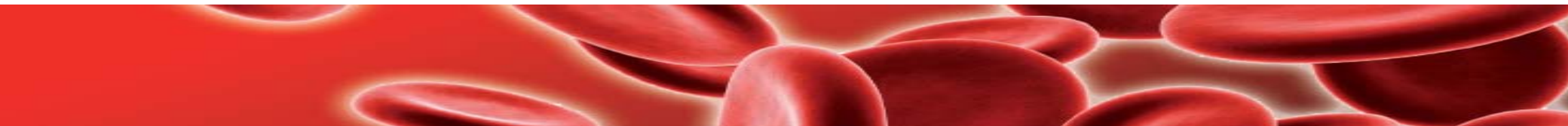
HV findings in inspections

- ❑ 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

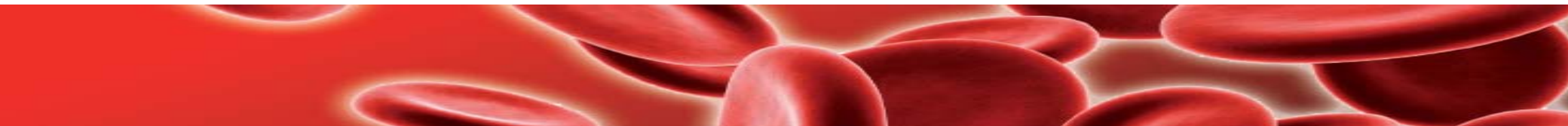


HV in the EU

- ❑ Competent authorities meeting, Brussels, October 18th 2007
- ❑ Draft proposals tabled from EHN and ISBT for standardisations of reporting categories
- ❑ Written comments from Member States by end of November
- ❑ HV working subgroup arranged involving UK, Netherlands, Ireland, France, Malta, Belgium Spain, Greece and Germany
- ❑ Reporting of donor adverse events raised but not discussed
- ❑ Electronic system to received standardised data needs to be in place for June 2008

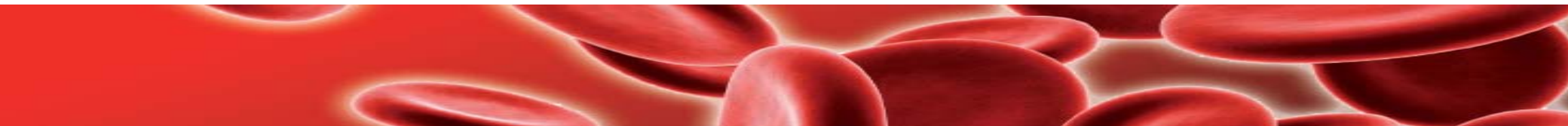


- ❑ Survey of EU delegates at EHN meeting in February showed wide disparity in what was felt to be reportable for example
 - ❑ Reportability of more minor SARs
 - ❑ Donor adverse events reporting
 - ❑ SAEs eg issue of non CMV neg component by BE
 - ❑ Nurse administering wrong unit to a patient
- ❑ EUD figures will be difficult or impossible to analyse or benchmark if standardisation not thorough



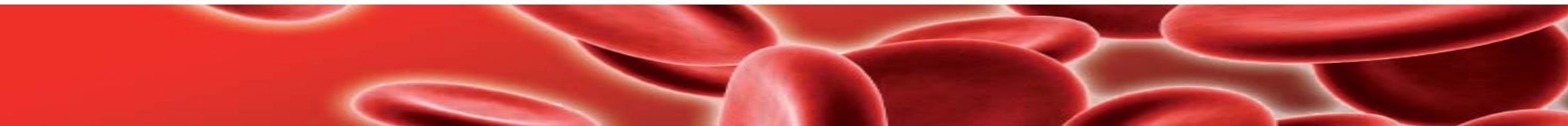
International standardisation?

- ❑ ISBT proposed standard definitions for surveillance of non-infectious adverse transfusion reactions - December 2006
- ❑ Better categories which reflect what actually happens to patients
- ❑ Currently some cases are very hard to fit into existing categories



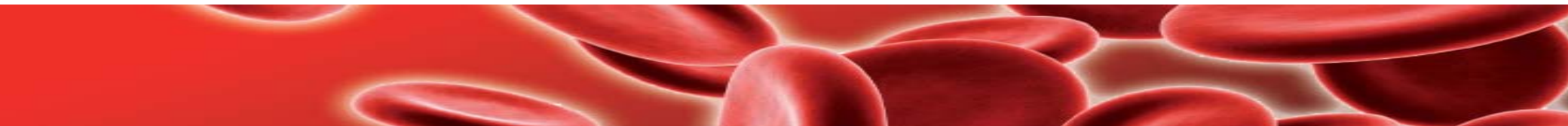
ISBT categories - 1

- Haemolytic Transfusion Reactions
 - AHTR - within 24 hours
 - DHTR - between 24 hours and 28 days
 - DSTR - delayed serologic transfusion reaction -
synonymous with alloimmunisation



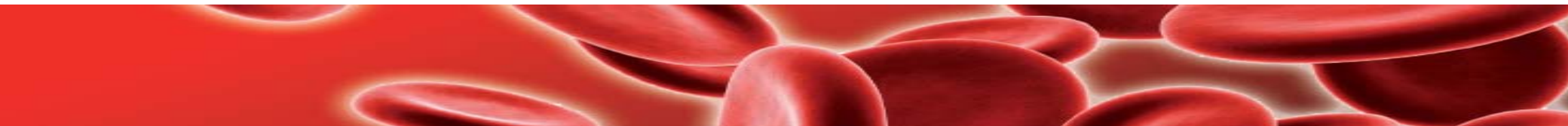
ISBT categories - 2

- Non Haemolytic transfusion reactions
 - FNHTR - $>39^{\circ}\text{C}$ or change of $> 2^{\circ}\text{C}$
 - Allergic reaction - different grades
 - TA-GvHD
 - PTP
 - TRALI - clearly defined
 - Transfusion associated dyspnoea
 - TACO
 - Hypotensive transfusion reaction



ISBT categories - 3

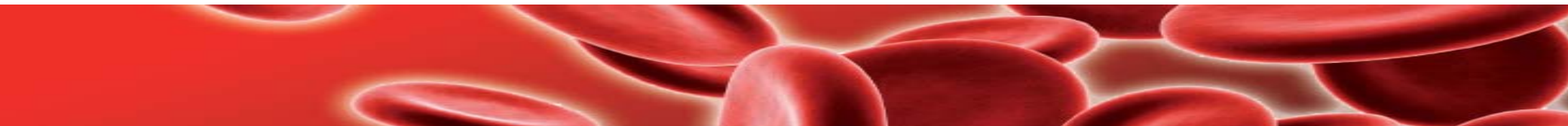
- Other transfusion reactions
 - Haemosiderosis
 - Hyperkalaemia
 - Unclassifiable Complication of Transfusion



ISBT continued

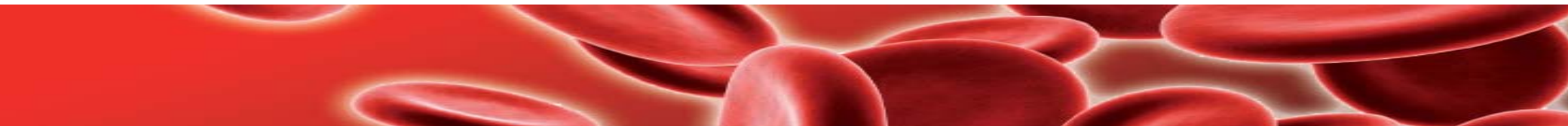
- Severity index
 - 1- non severe
 - 4 - death

- Imputability index
 - 4 - definite
 - 0 - excluded



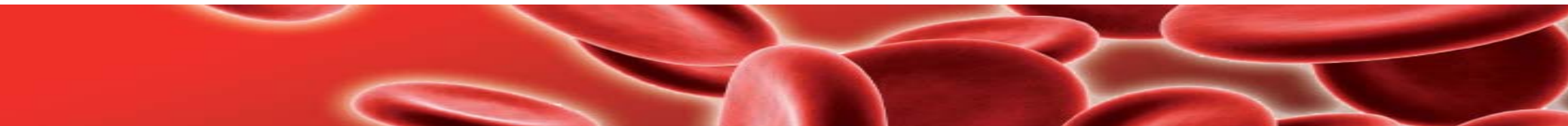
EHN role

- ❑ Professionally led group which can liaise in Europe between member states and EU commission
- ❑ Agree standardisation of categories to allow international comparison of data
- ❑ Develop subcategories of EU definitions to improve comparability of current reports
- ❑ Has drawn up list of reportable BE based SAEs but not yet tackled hospital based ones
 - ❑ These are largest group in UK, classified as 'other'



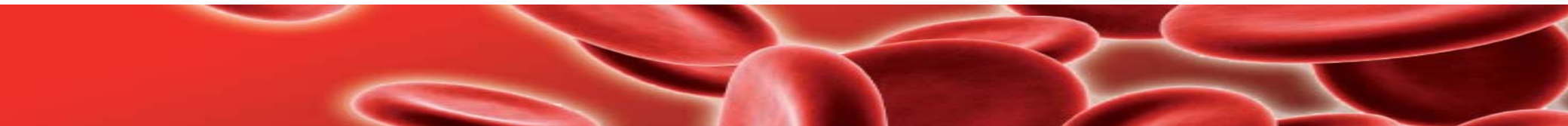
Possible sub-categories?

- ❑ Storage – at BE
- ❑ Storage – in HTL stock refrigerator
- ❑ Storage – in HTL issue fridge
- ❑ Storage – in hospital satellite fridges
- ❑ Storage - in transport boxes
- ❑ Distribution – from BE to hospital transfusion laboratory (HTL)
- ❑ Distribution – between hospitals
- ❑ Distribution – between CTS sites within Trust/satellites
- ❑ Distribution to clinical areas
- ❑ Distribution between clinical areas
- ❑ HTL – sample error
- ❑ HTL – grouping error
- ❑ HTL – component selection error (inc special requirements)
- ❑ HTL – labelling error



What do users want?

- ❑ What is already good?
- ❑ What could be improved?
- ❑ What have we seen from other countries that would be useful in UK?
- ❑ What sort of data is most helpful?
- ❑ What denominator data would help?
- ❑ How should data be presented?
- ❑ What sort of annual report would be most useful?



Aims and goals

- ❑ Streamlining of data between SHOT and MHRA
- ❑ Streamlining of data gathered with in EU haemovigilance
- ❑ Systems for comparison, standardisation, development
- ❑ Advent of cohesive haemovigilance system that fulfils the legislative requirements of the BSQR as well as the educational and academic requirements of the profession
- ❑ Working to increase patient safety

