

# Haemovigilance reporting systems



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# HV in UK

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- ❑ SHOT launched in 1996
- ❑ 9 annual reports to date
- ❑ One of first in Europe and set standards for other countries
- ❑ Increasing number of reports each year until 2006
- ❑ Participation 69%
- ❑ Voluntary anonymised system
- ❑ Influenced component development, clinical practice, guidelines and education

# SHOT reporting categories

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- IBCT
- ATR
- DTR
- TRALI
- TTI
- PTP
- GvH
- NM
- Anti-D related

# SHOT reporting

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- ❑ Does not collect minor FNHTR or minor allergy without hypotension
- ❑ Not yet collecting TACO
- ❑ Donor AEs collected by separate systems within four blood services
- ❑ 3240 reports, 30 million components
- ❑ Rate of about 1:10,000 components

# BSQR

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- ❑ Requirement for mandatory SAR and SAE reporting from 8th November 2005
- ❑ Includes all “serious” reactions
- ❑ May include donor reactions
- ❑ Regulations are of HBBs, so SAEs only reportable if relate to HBB (?)
- ❑ Collection of annual reports by CA in each member state
- ❑ Sending of annual figures to EU - first date of mandatory reporting June 2008

# MHRA

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- ❑ Designated CA
- ❑ Not legal for SHOT to collect data and forward to MHRA (voluntary status may have been a problem)
- ❑ MHRA to have all reports first
- ❑ SHOT to have data from MHRA via same database
- ❑ Two parallel co-operating systems

# New system options

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- ❑ Continue with existing and enhance or augment as necessary to fulfil requirements of BSQR
- ❑ Abandon existing system and create new one within CA to fulfil requirements
- ❑ Develop new system to encompass both the existing and the new system in parallel, gradually evolving towards unified single HV system

# SABRE

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- ❑ Mandatory on-line reporting system
- ❑ Reporting categories reflect EUD
- ❑ Ability to forward reports directly to SHOT, and then to fill in assigned SHOT questionnaire online
- ❑ MHRA can create annual reports for all users to verify
- ❑ 960 reports in first year
- ❑ Some problems....

# Problems...

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- ❑ Reporters decides if something is reportable and chooses which category to send report into
- ❑ No formal mechanism for evaluation of reports at MHRA...at present not legally allowed to change reporting categories or exclude items as “not reportable under the Directive”
- ❑ Possibility that UK figures may not be comparable to SHOT figures
- ❑ Still lack of clarity as to what should be included
- ❑ Survey of EU delegates at EHN showed wide disparity in what was felt to be reportable
- ❑ EUD figures will be difficult to analyse

# SAEs : Reporting categories

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- Whole blood collection
- Apheresis collection
- Testing of donations
- Processing
- Storage
- Distribution
- Materials
- Other

Further divide these into

- Product defect
- Equipment failure
- Human error
- Other

# SAEs : Reporting issues

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- Wrongly categorised on SABRE form
- Approximately 15% of SAE reports
- Responsibility for correction before submission of figures to EU
- Incorrect assignment of “processing” category probably commonest
- Still problems relating to “distribution”

# SAR

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- All reactions in patients are reportable to MHRA via SABRE regardless of whether any related “cause” took place in BE, BB or clinical arena
- Only difficulty is to discern what is meant by “serious”....
- Still under discussion, to be further clarified if possible
- Reactions in donors are reportable only in so far as they might affect the quality and safety of the blood

# SAR categories

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

# SAR reporting

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Very approximate figures:

- Approximately 5% reports excluded as very minor reaction
- About 40% reports of mild reactions, but included as patients care was altered as a result
- Around 25% more serious reactions which are unclassifiable or allergic/hypersensitivity type
- Approximately 30% accounts for other reactions including HTRs, TRALI, suspected TTI (viral or bacterial), anaphylaxis etc.



# Annual notification to EU

L 256/38

EN

Official Journal of the European Union

1.10.2005

PART D

Annual notification form for serious adverse reactions

Reporting establishment

Reporting period

This Table refers to Whole blood Red blood cells Platelets Plasma Other (use separate table for each component)	Number of units issued (total number of units issued with a given number of blood components)
	Number of recipients transfused (total number of recipients transfused with a given number of blood components) (if available)
	Number of units transfused (the total number of blood components (units) transfused over the reporting period) (if available)

Total number reported	Number of serious adverse reactions with imputability level 0 to 3 after confirmation (see Annex II A)				
	Number of deaths	not assessable	Level 0	Level 1	Level 2

Immunological Haemolysis	Due to ABO incompatibility	Total	not assessable	Level 0	Level 1	Level 2	Level 3
			Deaths				
	Due to other allo-antibody	Total					
		Deaths					
Non-immunological haemolysis		Total					
		Deaths					
Transfusion-transmitted bacterial infection		Total					
		Deaths					
Anaphylaxis/hypersensitivity		Total					
		Deaths					
Transfusion related acute lung injury		Total					
		Deaths					
Transfusion-transmitted viral infection	HBV	Total					
		Deaths					
	HCV	Total					
		Deaths					
	HEV-1,2	Total					
		Deaths					
	Other (specify)	Total					
		Deaths					
Transfusion-transmitted parasitological infection	Malaria	Total					
		Deaths					
	Other (specify)	Total					
		Deaths					

PART C

Annual Notification Form for Serious Adverse Events

Reporting establishment

Reporting period

1 January-31 December (year)

Total number of blood and blood components processed

Serious adverse event, affecting quality and safety of blood component due to a deviation in	Total number	Specification			
		Product defect	Equipment failure	Human error	Other (specify)
Whole blood collection					
Apheresis collection					
Testing of donations					
Processing					
Storage					
Distribution					
Materials					
Others (specify)					

# Other existing HV systems

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- ❑ Those in Europe (27 member states) now all under same legislation, but transposed into National law
- ❑ More variation outside Europe
- ❑ Most systems not mandatory outside EU
- ❑ Differences in reporting categories
- ❑ Differences in degree of seriousness required for incident to be reportable
- ❑ Differing systems for donor adverse incidents
- ❑ Wide variation in rate of incidents reported per number of units released for transfusion

# Ireland

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- ❑ Established 1999
- ❑ Each hospital has a Haemovigilance Officer
- ❑ IBCT includes unnecessary transfusion based on erroneous Hb
- ❑ Excludes minor FNHTR or allergy
- ❑ Includes "Suspected TTI" - of 25 reports in 6 years only 1 proven
- ❑ Includes TACO
- ❑ TRALI cases - of 6, 4 confirmed and 1 probable. 11 suspected cases were reclassified as TACO, AHOSTR or not Tx related
- ❑ Rate of reports 1:1000 components

# Slovenia

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- ❑ Collected by Blood Transfusion Centre of Slovenia
- ❑ Started 2002
- ❑ Added NM in 2005
- ❑ Many FNHTR. No TRALI, GvH or PTP.
- ❑ One suspected bacterial infection
- ❑ Considered to be underreporting over years 2002-2005
- ❑ Rate is 1.1:1000

# Netherlands

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- ❑ TRIP started 2003
- ❑ High participation, online reporting, numbers increasing
- ❑ Collected mandatory reports on behalf of MoH - to extend into tissues and cells +/- organs.
- ❑ Collects TACO, NM and FNHTR, with optional reporting of mild febrile reaction ( $<2^{\circ}\text{C}$  with no other symptoms)
- ❑ Category for development of antibodies previously absent
- ❑ Rate about (bit under) 3:10,000 in 2005

# Norway

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- ❑ TROLL - started up 2003, two reports so far for 2005 and 2006
- ❑ Voluntary with high participation (only 7 HBBs not reported, using 2.6% components)
- ❑ Electronic reporting
- ❑ Includes FNHTR, TACO, HLA antibodies and “lack of effect”
- ❑ No denominator data, so rate not available

# France

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- ❑ Pre-existing HV system is now also CA - French Health Products Safety Agency (AFSSAPS)
- ❑ Now mandatory because of EUD
- ❑ Includes a seriousness scale (4-death, 0-no consequences)
- ❑ Includes an imputability scale (4-certain, 0-excluded)
- ❑ Rate of reports 3:1000 components

# Canada

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- ❑ Quebec Haemovigilance System started in 2000
- ❑ Voluntary participation - hospitals have dedicated transfusion safety officers
- ❑ Includes ALL errors recognised before the start of Tx and ALL adverse reactions and events even if no reaction, even minor
- ❑ Includes fractionated products
- ❑ Overall report rate 1:150 components

# Czech republic

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- ❑ In 1997 a Drug Law included blood components so reporting narrowed to “adverse effects related to the quality of the product” and other reports were voluntarily collected by Blood Transfusion Society with low effectivity.
- ❑ New system with EUD to include more in mandatory reporting
- ❑ Reporting rate in 2003 1:1000 components

# Denmark

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- ❑ DART and the Danish Transfusion Database
- ❑ Voluntary and confidential until EUD
- ❑ 6 years of reporting from 1999
- ❑ 4:100,000 components

# Greece

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- Hellenic National Co-ordinating Haemovigilance Centre started 1995
- Voluntary with under 50% participation
- Fewer categories than SHOT
- Collects donor data as well
- Rate 1:1000 components

# South Africa

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- ❑ Haemovigilance Programme for South Africa started in 2000
- ❑ Similar categories to SHOT
- ❑ Report rate 1:1000 components

# Spain

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- ❑ Agreement between Spanish Ministry of Health and Spanish Blood Transfusion Association started 2004
- ❑ Voluntary until EUD
- ❑ Includes donor related events
- ❑ Includes hypotensive reactions and FNHTR
- ❑ Includes Haemosiderosis, TACO and NM
- ❑ Not including misuse of blood components
- ❑ No denominator data

# USA

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- ❑ FDA requires reporting of transfusion related fatalities
- ❑ No centralised agency in USA monitors, receives reports, analyses or trends data for any non-fatal events
- ❑ BUT the MERS-TM system (Medical Event Reporting System - Transfusion Medicine) has been developed in USA and may be a very useful tool

# International standardisation?

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- ❑ 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

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- 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

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- 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

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

# ISBT continued

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- Severity index
  - 1- non severe
  - 4 - death
  
- Imputability index
  - 4 - definite
  - 0 - excluded

# EHN role

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- ❑ 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

# What do users want?

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- ❑ 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?