SHOT Update

for Basic Serology Day

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Chesterfield 22nd June 2012

Acronym-buster !

- **BSQR** Blood Safety and Quality Regulations 2005
- MHRA Medicines & Healthcare products Regulatory Agency
- **SHOT** Serious Hazards of Transfusion
- **SABRE** Serious Adverse Blood Reactions & Events web portal
- **HPA-CI** Health Protection Agency Centre for Infections
- **NPSA** National Patient Safety Agency
- CQC Care Quality Commission
- CPA Clinical Pathology Accreditation
- **BCSH** British Committee for Standards in Haematology

SHOT Background

- Serious Hazards of Transfusion (SHOT) is the UK Haemovigilance scheme, monitoring errors across the whole spectrum of the transfusion process.
- Mandatory reporting to the EU Commission is via the Medicines and Healthcare products Regulatory Agency (MHRA)
- Voluntary reporting to SHOT but.....

SHOT Reporting now a requirement

- Clinical Pathology Accreditation (CPA UK) Standard H2
- National Patient Safety Agency (NPSA) Safer Practice Notice SPN 14
- Health Service Circular (HSC) 2007/001
 Better Blood Transfusion, Standard 4b.3
- Welsh Assembly Government, Healthcare Standards for Wales, Standard 16
- General Medical Council

AIMS of SHOT

- **IMPROVE** standards of hospital transfusion practice by **EDUCATING** users on transfusion hazards and their prevention
- INFLUENCE clinical guidelines for the use of blood components
- **INFORM** policy within transfusion services

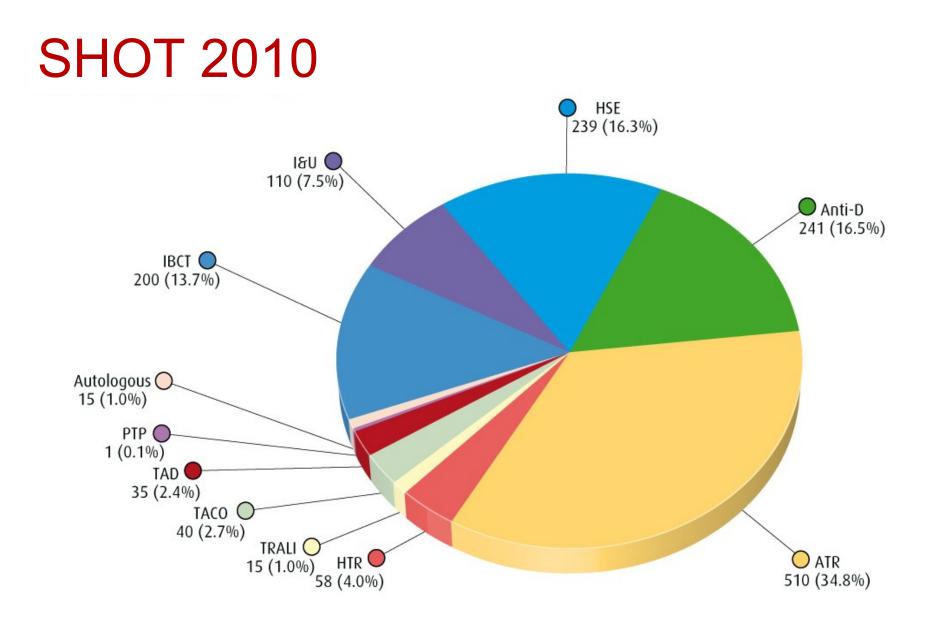
The GOOD news.....

- Participation increased
 - 22% in 1996 94.7% in 2010
- Reduction in mortality and major morbidity
 - hallmark of an effective haemovigilance system
- Reduction in ABO incompatible transfusions; 29% reduction in IBCT: 57% in clinical areas and 28% less in the laboratory
- Observed rates of TRALI consistently lower since 2003/04
 - Collecting male FFP where possible and using male plasma to re-suspend platelet pools

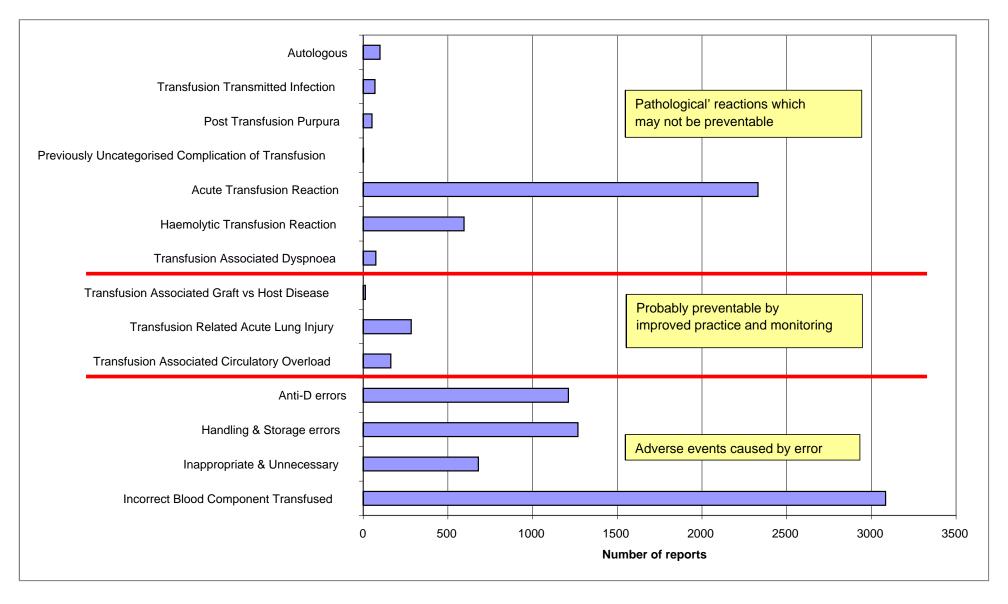
The BAD news.....

13 transfusion-related deaths

- 3 were *imputability* 3
 - Sudden unexpected death ATR
 - TACO
 - Hyperhaemolysis in child with SCD
- Of the remainder
 - 6 due to TACO
 - 1 under-transfusion
 - 2 Acute reactions to platelets
 - 1 TRALI after platelet transfusion



SHOT Categories 1996 - 2011



Critical points in the transfusion process

- Decision to transfuse
- Prescription/request
- Sampling for pre-transfusion testing
- Laboratory testing
- Collection of blood from storage site
- Bedside administration

IBCT events originating in the hospital transfusion laboratory

- 107 cases in which the primary error occurred in the laboratory i.e.
 - 54% of the total 200 IBCT cases
 - 28% decrease in laboratory related errors in 2010 compared with 2009

Summary of laboratory related error from IBCT chapter 2010

Type of error	No. of cases in 2009	No. of cases in 2010
Wrong blood	21	21
Wrong sample selected	2	2
ABO grouping error	5	2
D grouping error	4	4
Incorrect component selected	9	11
Incorrect labelling	1	2
Wrong group selected for SCT patient	13	15
Wrong ABO group selected	7	9
Wrong D group selected	2	2
Procedural errors	4	4
Other pre-transfusion testing errors	48	34
Testing errors	9	8
Procedural errors	39	26
SRNM (Special Requirements Not Met)	67	37
Due to failure to consult patient records thoroughly	40	18
Due to poor serological knowledge/failure to recognise the special needs of a specific patient group	27	19
Total	149	107

SHO

Learning points

- UKTLC recommends the use of 24/7 automation for ABO/D typing
- Variations in D typing of patients with a weak D antigen may be unavoidable as technologies differ in their sensitivity but it is important that the D type is determined by the most robust routine method available

Other pre transfusion errors

- Poor database maintenance
 - Failure to find patient records (legacy systems)
 - Failure to update patient history
- Testing unsuitable samples
- Incomplete testing
 - Tests resulted before being read
 - No antibody identification following a positive antibody screen
- Antibody identification errors
- Inappropriate electronic issue

Blood component issued to the clinical area with two labels

The laboratory was phoned by a member of the ward nursing staff concerned about the safety of a blood unit issued to their unit. The unit was labelled with the details of another patient. The nurse immediately contacted the laboratory. It transpired that the laboratory did not have a formal policy for removing the labels from non-transfused blood components returned to CTS or for the final patient ID check prior to issue of the component.

Special Requirements Not Met - SRNM

- Due to poor serological knowledge/carelessness in selection
 - Incorrect phenotype selection
- Failure to recognise the needs of specific patient groups
 - K positive units against national recommendation/local protocol
 - Non MB-treated FFP and cryoprecipitate to children <16 yrs old
 - CMV unscreened units to children <1 yr old
 - CMV unscreened units to pregnant women
- Failure to consult patient records thoroughly:

Failure to check historical record leads to issue of non-HLA-matched platelets

A patient with severe aplastic anaemia was refractory to random donor platelets because of HLA-alloimmunisation. A non-urgent request for further platelets was made in normal working hours but the transfusion scientist did not check the historical record on LIMS and unselected platelets were issued.

Paediatric cases

- Babies treated as neonates when they were > 4 months
- Blood issued electronically when maternal antibodies had been detected
- Failure to supply MB treated FFP/cryoprecipitate
- Patient <1 year old not receiving CMV neg components

Learning points

- Laboratories should critically assess:
 - the way in which mother and baby records are linked on the LIMS
 - the way in which alerts/warnings/algorithms are used on the LIMS
 - the process in place for alerting the laboratory to patient specific special requirements
- Training and competency based assessment must include:
 - actions to take on receipt of alerts/warnings on both the LIMS and on analysers
 - and highlight the less common transfusion scenarios

Anti-D Events in 2010 n = 241

- **59** cases where anti-D was inappropriately administered *unnecessary exposure to a human blood product*
- 166 cases where anti-D was delayed or omitted, putting patient at risk of sensitisation to the D antigen - potential Major Morbidity
- 12 cases where the wrong dose of anti-D was administered
- 4 handling and storage errors

Anti-D When and How Much?

This poster gives recommended dosages of anti-D at different stages during pregnancy for women with an RhD negative blood type who do not already have immune anti-D antibodies.

At less than 12 weeks

 Anti-D is NOT indicated unless there has been therapeutic termination or on specific clinical request for continuous bleeding (request 250iu within 72 hours in these cases).

Between 12 – 20 weeks

 Request at least 250iu anti-D to be given within 72 hours of any sensitising event.

Between 20 weeks and delivery

- Request at least 500iu anti-D to be given within 72 hours of sensitising event.
- Request a Kleihauer Test in case more anti-D is needed.

Routine Antenatal Anti-D Prophylaxis (RAADP) should be administered between 28 - 30 weeks

- Send sample for antibody screening.
- Request 1500iu anti-D to be given immediately.
- Alternatively, administer at least 500iu anti-D at 28 and 34 weeks.

After delivery

- Send 'Mother & Cord' samples for testing.
- Request at least 500iu anti-D within 72 hours of birth where baby is RhD-positive.
- Kleihauer test performed if baby is RhD positive.
- Request further anti-D in the event of a raised Kleihauer.

For further information please refer to your local policy

British Committee for Standards in Haematology (BCSH) Guidelines for the use of prophylactic ant-D immunoglobulin 2006 April 2011 1011761

NHS Blood and Transplant



- If outside 72 hrs still give anti-D, as a dose within 9-10 days may provide some protection
- Give RAADP in addition to prophylaxis for sensitising events, and vice versa
- Do NOT wait for the Kleihauer result before giving anti-D

Manual entry of results onto the laboratory computer system leads to inappropriate administration of anti-D Immunoglobulin

A cord sample was received and grouped (correctly) by a BMS as AB RhD negative, but during manual entry of the blood group into the laboratory computer the result was mis-transcribed as AB RhD positive. There was no double check of the group entry, and 1500 iu anti-D Ig was subsequently issued on the basis of the computer record.

Change in laboratory reporting procedure results in significant delays in administration of RAADP

- A laboratory changed the mechanism of reporting blood groups from paper to electronic. Community midwives had relied on the paper reports to generate appointment lists for RAADP. The change in the reporting mechanism resulted in 15 reports of delayed RAADP and 1 omission
- Laboratories must employ formal change control procedures which must involve ALL stakeholders.

Near miss reporting

Category of incidents	No. of cases	
Sample errors	409	
Request errors	44	
Laboratory procedural or testing errors	119	
Laboratory component selection errors	100	
Component collection/administration errors	50	
Expired components available	29	
Cold chain events	97	
Others	15	
Total	863	

Near Miss reporting

Category of error	No of errors	Error detected by laboratory	Error detected at collection / bedside
Incorrect patient identifiers entered onto LIMS	27	8	16
Component mislabelled (Transposed labels from RBRP chapter = 25)	34	0	24
Special requirements or specification not met	65	4	61

RBRP / Near miss reporting

Learning point:

• Training and competency based assessment must include basic manual checking procedures

Handling & storage errors

Learning point:

 Hospitals should have a robust policy in place for removing expired blood components and components past their suitability date from satellite fridges

Inappropriate, unnecessary, delayed & under-transfusion

Learning point:

- 12% of the reported unnecessary transfusions could have been avoided if laboratories had not transmitted results they knew or suspected to be inaccurate, but instead requested a second sample
- A further 12% of the reported unnecessary transfusions could have been avoided if laboratories had required confirmation of correct transmission of telephoned results. CPA Standard G3 requires that the laboratory establishes a procedure for telephoned results that ensures confirmation of correct transmission

Inappropriate, unnecessary, delayed & under-transfusion

Learning point:

 In accordance with Better Blood Transfusion 2007/001, protocols should be in existence which empower laboratory staff to question the appropriateness of requests for transfusion.

Recommendations

- Robust communication procedures are required both within the laboratory and at the laboratory/clinical interface
 Action: Transfusion Laboratories, HTTs, HTCs
- Easily interpreted flowcharts should be considered to clarify existing policies and procedures
 Action: Transfusion Laboratories, HTTs, HTCs

Recommendations

 If there is any doubt as to the true RhD status of a patient, or whether anti-D detected in an antibody screen is immune or prophylactic in origin, and these questions cannot be resolved quickly, then prophylactic anti-D should be administered rather than placing the patient at risk of withholding it.

Action: HTCs

SHOT Website

www.shotuk.org

SHOT / RCA Toolkits

Reports and Summaries

Lessons for Laboratory Staff Lessons for Clinical Staff

Thanks to;

- The SHOT Team
 - Vicky, Julie, Hema, Debbi & Alison
- Hannah Cohen, Chair SHOT Steering Group
- Paula Bolton-Maggs, SHOT Medical Director
- You for listening

www.shotuk.org