SHOT and Anti-D
- an overview of reports from the Serious Hazards of Transfusion scheme

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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...
Haemovigilance in the UK

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<th>MHRA</th>
<th>SHOT</th>
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<td><strong>Medicines &amp; Healthcare Products Regulatory Agency</strong></td>
<td><strong>Serious Hazards of Transfusion</strong></td>
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| • Competent Authority’ for the BSQR 2005  
  – QMS in blood establishments and hospital blood banks. | • Confidential enquiry |
| • Competent Authority for the Medicines Act 1968 | • Serious adverse reactions/events AND near misses all of which occur in BOTH a laboratory and CLINICAL environment. |
| • Competent Authority for the Medical Devices Regulations 2008 | **PROFESSIONALLY MANDATED** reporting |
| • **STATUTORY** reporting | |
SHOT Aims

Improving patient safety by

– Raising standards of hospital transfusion practice

– Informing policy with UK Blood Services

– Aiding production of clinical guidelines

– Educating users on transfusion hazards and their prevention
SHOT Reports 2011

• 3435 reports made to the scheme
  – 2768 analysed
    • 204 in an inappropriate category, moved
    – 667 withdrawn (20%)

• + 270 reports made in 2010, but only completed in 2011

• 3038 cases including ‘near miss’ and ‘right blood right patient’
- **ATR** Acute Transfusion Reaction
- **HTR** Haemolytic Transfusion Reaction
- **TACO** Transfusion Associated Circulatory Overload
- **TRALI** Transfusion Related Acute lung Injury
- **TAD** Transfusion Associated Dyspnoea
- **I&U** Inappropriate & Unnecessary (and delayed) tx
- **IBCT** Incorrect blood Component Transfused
- **SRNM** Special Requirements Not Met
- **TAGvHD** Transfusion Associated Graft v Host Disease
- **TTI** Transfusion Transmitted Infection (Hepatitis, HIV, CMV, WNV, bacterial)
- **PTP** Post Transfusion Purpura
- **PUCT** Previously Uncategorised Complication of Trans.
- **WBIT** Wrong Blood in Tube
SHOT reports 2011

* Excluding NM and RBRP
Cumulative Reports 1996-2011

- CS: Cell salvage and autologous transfusion
- TTI: Transfusion-transmitted infection
- PTP: Post-transfusion purpura
- PUCT: Previously uncategorised complication of transfusion
- ATR: Acute transfusion reaction
- TAD: Transfusion-associated dyspnoea
- HTR: Haemolytic transfusion reaction
- TA-GvHD: Transfusion-associated graft vs host disease
- TRALI: Transfusion-related acute lung injury
- TACO: Transfusion-associated circulatory overload
- Anti-D: Anti-D errors
- HSE: Handling & storage errors
- I&U: Inappropriate & unnecessary
- IBCT: Incorrect blood component transfused

Number of reports

Pathological reactions which may not be preventable
Probably or possibly preventable by improved practice and monitoring
Adverse events caused by error

[Bar chart showing the number of reports for each category]
The PUCT incident was a case of NEC in a baby that is not categorically linked to the transfusion, but is an association that could not be ignored.

I&U – Inappropriate & unnecessary transfusion

ATR – Acute transfusion reaction

TRALI – Transfusion related acute lung injury

TACO – Transfusion associated circulatory overload

PUCT – Previously uncharacterised complication of transfusion
ABO incompatible transfusions

• 12 in 2011 - Listed as a DOH ‘never event’
  • 8 clinical
    • - 2 WBIT
    • - 6 Administration
  • 4 laboratory
    • - 1 wrong sample tested
    • - 2 grouping errors
    • - 1 component selection error
Special requirements in obstetrics

• RCOG Green Top Guidelines 2007
  – Use K(-) units for women of childbearing age

• NICE guidance for Routine Antenatal Anti-D Prophylaxis

• SaBTO guidance 2012
  – Use CMV- units for regular transfusions in pregnancy (ie Haemoglobinopathies)

• RCOG Green Top Guidelines 2011
  – Use of anti-D
Why Anti-D Ig?

Although it is a medicinal blood product rather than a blood component, adverse events associated with anti-D immunoglobulin are included in the annual SHOT report as they provide a useful insight into process errors which may be applied to transfusion as a whole.
Anti-D Ig - the background....

- To prevent Haemolytic Disease of the Newborn (HDN) due to immune anti-D

- Offered to all RhD negative pregnant women who are not known to be sensitised to the RhD antigen

- 500iu of anti-D Ig is capable of suppressing immunisation by 4ml of RhD positive red cells
Anti-D Ig Prophylaxis

- Post-delivery anti-D Ig prophylaxis began in the UK in 1969
- The programme has been a huge success
- Deaths fell from 46 / 100,000 births pre-1969 to 1.6 / 100,000 births by 1990
  
  but......

- RhD alloimmunisation continues to occur
• Maternal anti-D level 10.5iu/ml

• Unmonitored pregnancy

• Bilirubin reached exchange trigger by end of day 1
Anti-D Ig Reporting Categories

- Omission or late administration of anti-D immunoglobulin

- Inappropriate administration of anti-D immunoglobulin to:
  - a RhD positive patient
  - a patient who already has immune anti-D
  - a mother of a RhD negative infant
  - a different patient from the patient it was issued for

- Incorrect dose of anti-D Ig given

- Handling and storage errors
  - administration of expired, or otherwise out of temperature control, anti-D immunoglobulin
Anti-D Ig cases 1996 - 2011

Year of Report

- 1997/98: 3
- 1998/99: 5
- 1999/00: 12
- 2000/01: 17
- 2001/02 (Yr mins): 43
- 2002/03: 24
- 2003/04: 67
- 2004/05: 87
- 2005/06: 77
- 2006/07: 63
- 2007/08: 137
- 2008/09: 186
- 2009/10: 241
- 2010/11: 249

Numbers of Reports
Anti-D Ig events in 2011  \( n = 249 \)

- **60** cases where anti-D Ig was inappropriately administered - *unnecessary exposure to a human blood product*

- **157** cases where anti-D Ig was delayed or omitted, putting patient at risk of sensitisation to the D antigen - *potential Major Morbidity*

- **24** cases where the wrong dose of anti-D Ig was administered

- **8** handling and storage errors
Anti-D Ig....who makes the errors?

- Midwives 176 (70.5 %)
- Laboratory 59 (24 %)
- Medical staff 14 (5.5 %)
Lack of knowledge results in delay of administration of anti-D Ig

A woman presented with a PV bleed at 19 weeks of gestation, but was discharged by a doctor who informed her that anti-D Ig should only be given if a Kleihauer test is positive. The woman was recalled and given anti-D Ig four days later.
Lack of understanding results in omission of RAADP

Community midwives at a GP surgery returned a dose of anti-D Ig intended for a woman with the comment “already given in hospital”. The woman had received prophylaxis for a PSE earlier in her pregnancy.
Anti-D Ig administered to a RhD positive woman after grouping results were mis-transcribed into her notes.

Blood grouping results from booking were incorrectly transcribed into a woman’s notes and anti-D Ig was issued in response to a sensitising event from stock held in the clinical area.
Poor advice from the laboratory results in incorrect route of administration of anti-D Ig

A BMS advised administering a 1500iu dose of anti-D Ig intravenously when the product (DGAM) issued was licensed only for intramuscular injection
Anti-D
When and How Much?

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

At less than 12 weeks
- Anti-D is not usually indicated unless there has been therapeutic termination, toxoplasmic or ectopic pregnancy, surgical intervention associated with miscarriage, or continued painful vaginal bleeding (requiring at least 2 bloods within 72 hours in these cases).

Between 12 and 20 weeks
- Administer at least 250iu anti-D Ig within 72 hours of a potentially sensitising event.

Between 20 weeks and delivery
- Administer at least 300iu anti-D Ig within 72 hours of a potentially sensitising event.
- Send a sample for a Kleihauer test in case additional anti-D Ig is needed.
- Anti-D Ig should be given for potentially sensitising events, even if RAADP has been given already.

Routine Antenatal Anti-D Prophylaxis (RAADP) should be administered between 28 and 30 weeks
- Send a sample for blood group and antibody screen and then administer RAADP according to local policy, even if anti-D Ig has been recently given for a sensitising event.
  - SINGLE DOSE: Administer 1500iu anti-D Ig at 28-30 weeks.
  - TWO-DOSE: Administer at least 1000iu anti-D Ig at 28 and 34 weeks.

After delivery
- Send another anti-D sample for testing.
- When the baby is D positive, administer at least 500iu anti-D Ig within 72 hours of delivery.
- Administer further anti-D Ig on the advice of the laboratory if the Kleihauer shows a large fetomaternal haemorrhage.

For further information please refer to your local policy.

British Committee for Standards in Haematology (BCSH) Guidelines for the use of prophylactic anti-D immunoglobulin 2006
Royal College of Obstetricians and Gynaecologists (RCOG) Green top Guidance no 22
The Use of Anti-D Immunoglobulin at Risk to D Positive Pregnant 2011.

July 2012 Version 2

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- 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
Anti-D Administration Checklist

Always confirm:
• The woman’s identity
• That the woman is RhD Negative using the latest laboratory report
• That the woman does not have immune anti-D using the latest laboratory report
• That informed consent for administration of anti-D Ig has been recorded in notes

Potentially Sensitizing Events (PSEs) during pregnancy

Gestation LESS than 12 weeks
- Vaginal bleeding associated with severe pain
- ERCP / instrumentation of the uterus
- Medical or surgical termination of pregnancy

Gestation 12 to 20 weeks
- For any Potentially Sensitizing Event (PSE)
  Confirm anti-D Ig (0.5 mL) within 72 hours of event
  Confirm product dose / expiry and patient ID pre-administration

Gestation 20 weeks to term
- For any Potentially Sensitizing Event (PSE)
  Request a Kleihauer Test and immediately administer at least 300IU of anti-D Ig within 72 hours of event
  Confirm product dose / expiry and patient ID pre-administration
  Administer more anti-D Ig following discussion with laboratory

For continuous vaginal bleeding at least 900 IU anti-D Ig should be administered at a minimum of every 4 hours, irrespective of the presence of detectable anti-D, and a Kleihauer Test required in case more anti-D Ig is required.

Routine Antenatal Anti-D Prophylaxis (RAUDP)

For Routine Antenatal Anti-D Prophylaxis
- Take a blood sample to confirm group & check antibody screen
- Administer 300 IU anti-D Ig as 30+2 weeks
- Administer at least 500 IU anti-D Ig at 28-32 weeks
- Confirm product dose / expiry and patient ID pre-administration

At Delivery (or Intra Uterine Death > 20 weeks)
- Is the baby’s group confirmed as RhD positive?
  OR
  Are cord samples available?
  OR
  Does the Kleihauer Test indicate that further anti-D Ig is required?

- Request a Kleihauer Test
- Confirm anti-D Ig (0.5 mL) within 72 hours of delivery
  Confirm product dose / expiry and patient ID pre-administration

AT DELIVERY (for Intra Uterine Death > 20 weeks)
- Is the baby’s group confirmed as RhD positive?
  OR
  Are cord samples available?
  OR
  Does the Kleihauer Test indicate that further anti-D Ig is required?

- Request a Kleihauer Test
- Administer at least 500 IU anti-D Ig within 72 hours of delivery
  Confirm product dose / expiry and patient ID pre-administration

Note: For RhD Negative women, anti-D Ig prophylaxis is recommended as part of standard antenatal care.
Anti-D Summary

• Many of the cases involve:
  – failure to follow basic clinical and laboratory protocols
  – clerical / testing errors
  – ignoring / overriding hazard flags on IT systems
  – lack of understanding

• Effective anti-D prophylaxis is a partnership between the laboratory and the clinical area – the clinical area must be responsive to requests for follow-up from the laboratory, and the lab must not assume that action will be taken purely because they have issued a report
Cell Salvage in Obstetrics

An example of evolving practice, with increasing use of intra-operative cell salvage in the obstetric setting;

– Remember appropriate dosage of anti-D in RhD negative women – *at least* 1500iu following cell salvage reinfusion, more if the Kleihauer indicates it
Anti-D Recommendations

• Obstetricians / midwives / lab staff must be familiar with national guidance for RAADP
  – HTC / lab must engage with obstetricians and midwives to produce local guidelines

• All organisations issuing anti-D must ensure that their systems are robust with respect to issue, receipt and recording of administration, and should regularly audit their systems

• All staff should complete the anti-D modules on ‘Learn Blood Transfusion’ e-learning
Key Messages & Recommendations 2011 – ‘Back to Basics’

- Correct patient ID should be a core clinical skill
- Transfusion checklist – template available [www.shotuk.org/resources/current-resources/](http://www.shotuk.org/resources/current-resources/)
- Staff knowledge and competency – knowledge should underpin practice
- Prescribing/authorisation knowledge
- Comprehensive clinical and transfusion laboratory handover templates
Resources from your regional NHSBT Transfusion Liaison Nurse /Practitioner

- Will I need a blood transfusion?
- Iron in your diet
- Information for patients needing irradiated blood
- Receiving a plasma transfusion
- Blood group and red cell antibodies in pregnancy
- Anti-D – when and how much?
- Children’s leaflets
- Educational posters

http://hospital.blood.co.uk
Thanks to

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- Paula Bolton-Maggs, SHOT Medical Director

- You for listening

www.shotuk.org