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

MHRA

Medicines & Healthcare Products Regulatory Agency

- Competent Authority' for the BSQR 2005
  - QMS in blood establishments and hospital blood banks.
- Competent Authority for the Medicines Act 1968
- Competent Authority for the Medical Devices Regulations 2008
- **STATUTORY** reporting

SHOT

Serious Hazards of Transfusion

- Confidential enquiry
- Serious adverse reactions/events AND near misses all of which occur in BOTH a laboratory and CLINICAL environment.
- **PROFESSIONALLY MANDATED r**eporting

SHOT Aims

Improving patient safety by

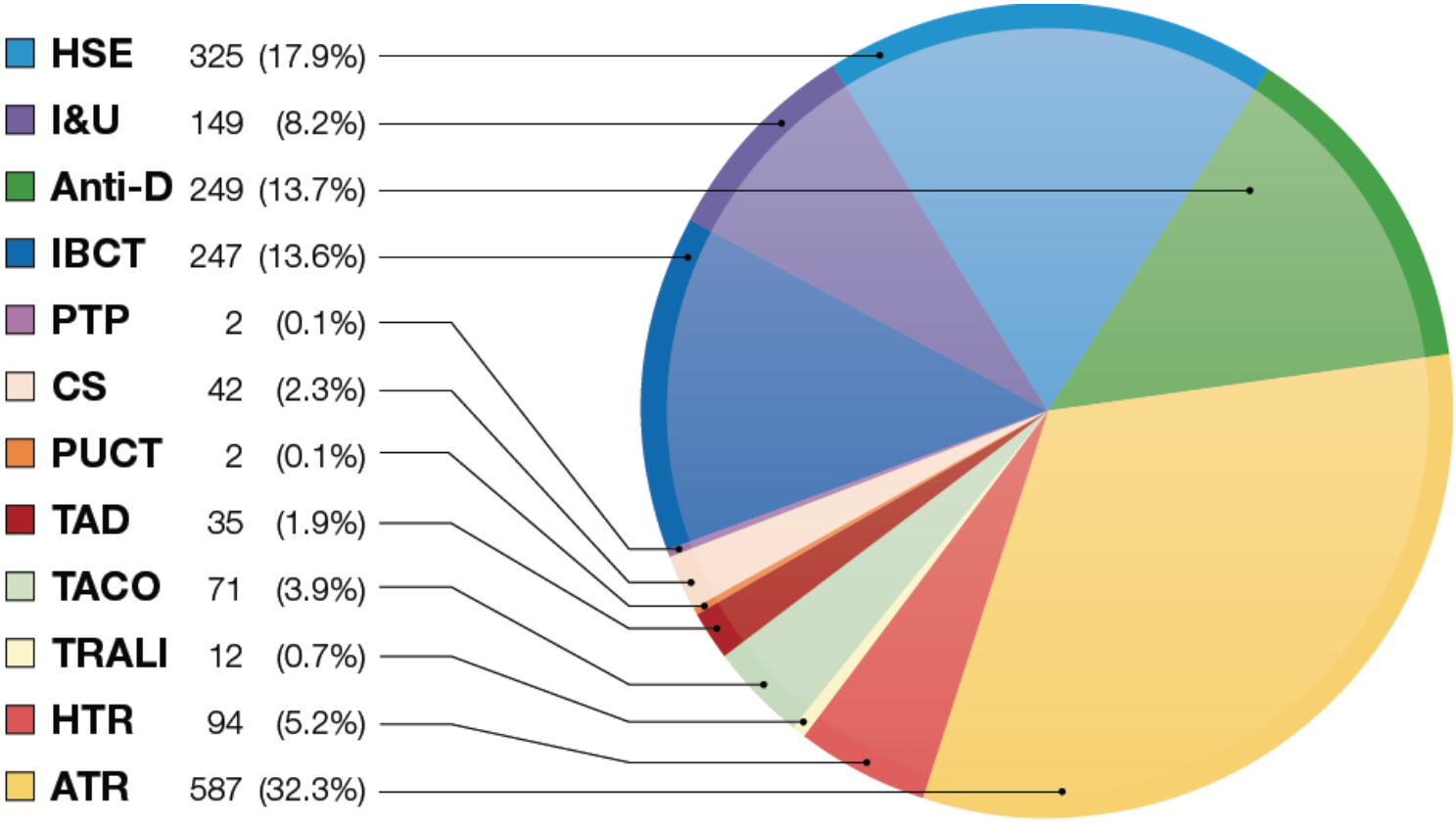
- Raising standards of hospital transfusion practice
- Informing policy with UK Blood Services
- Aiding production of clinical guidelines
- Educating users on transfusion hazards and their prevention

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  - 667 withdrawn (20%)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’

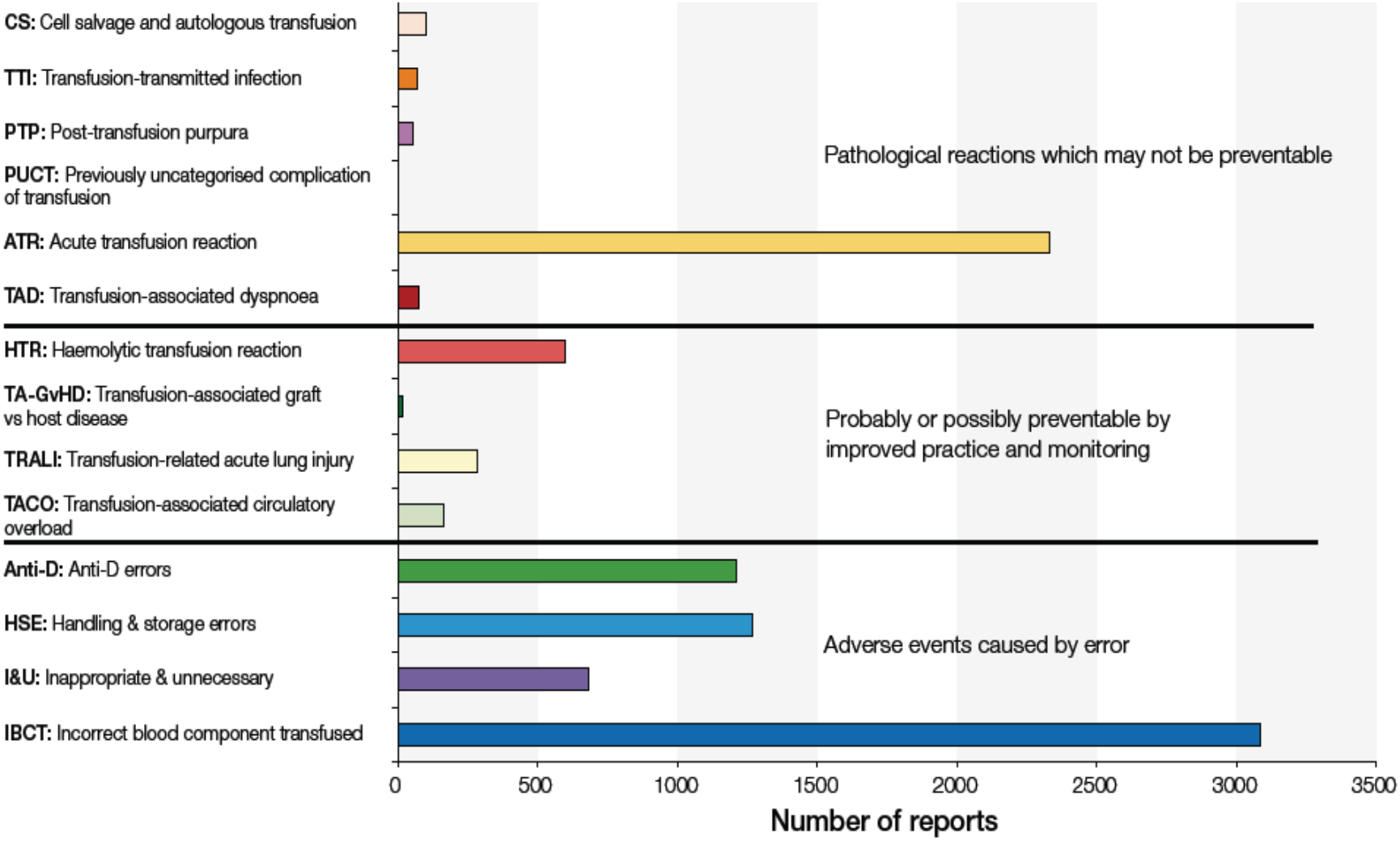
- **ATR** Acute Transfusion Reaction
- **HTR** Haemolytic Transfusion Reaction
- **TACO** Transfusion Associated Circulatory Overload
- **TRALI** Transfusion Related Acute lung Injury
- **TAD** Transfusion Associated Dyspnoea
- **I&U** Inappropriate & Unnecessary (and delayed) tx
- **IBCT** Incorrect 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

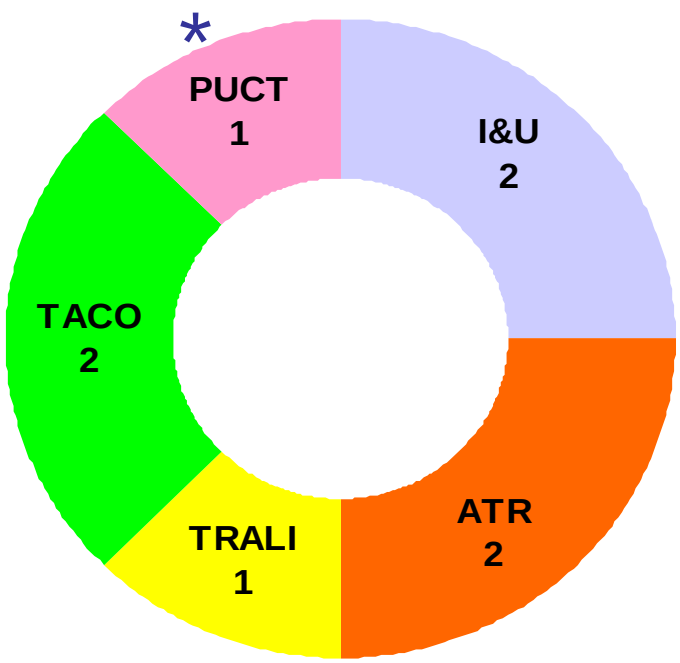


* Excluding NM and RBRP

Cumulative Reports 1996-2011



Deaths where transfusion was causal or contributory 2011 (n=8)



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

**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*

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.....

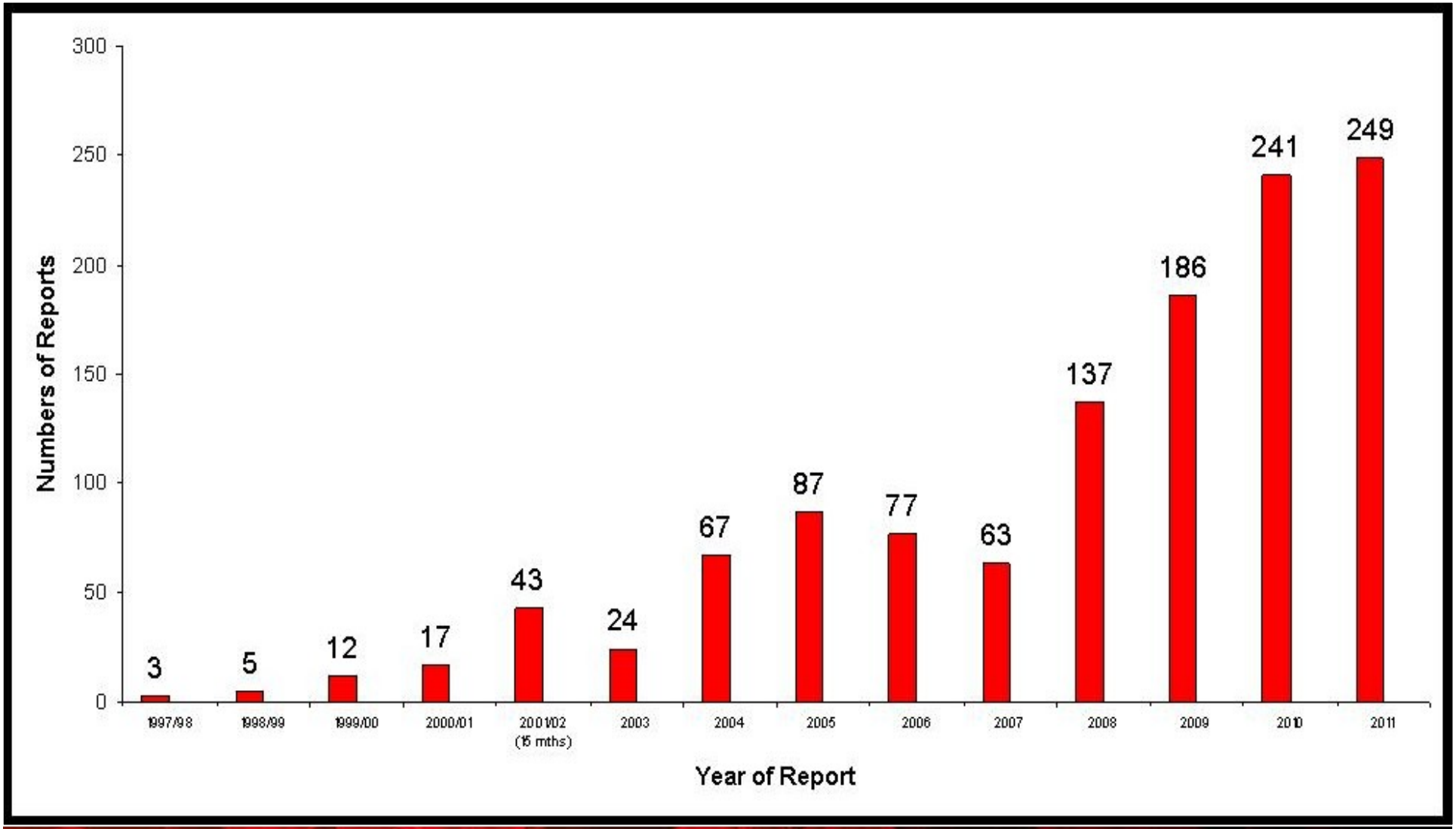
- RhD alloimmunisation continues to occur

- 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



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

- 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

SHOT

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 is recorded in notes

Potentially Sensitising Events (PSEs) during pregnancy

Gestation LESS than 12 weeks	
Vaginal bleeding associated with severe pain ERPC / Instrumentation of uterus Medical or surgical termination of pregnancy Ectopic / Molar Pregnancy	Administer at least **250iu** anti-D Ig within 72 hours of event. Confirm product / dose / expiry and patient ID pre administration
Gestation 12 to 20 weeks	
For any Potentially Sensitising Event (PSE)	Administer at least **250iu** anti-D Ig within 72 hours of event. Confirm product / dose / expiry and patient ID pre administration
Gestation 20 weeks to term	
For any Potentially Sensitising Event (PSE) (**Irrespective** of whether RAADP has been given)	Request a Kleihauer Test and immediately administer at least **500iu** anti-D Ig within 72 hours of event. Confirm product / dose / expiry and patient ID pre administration
Does the Kleihauer Test indicate that further anti-D Ig is required ?	Administer more anti-D Ig following discussion with laboratory
For continuous vaginal bleeding at least **500iu** anti-D Ig should be administered at a minimum of 6-weekly intervals, irrespective of the presence of detectable anti-D, and a Kleihauer Test requested in case more anti-D is required	

Routine Antenatal Anti-D Prophylaxis (RAADP)

For Routine Antenatal Anti-D Prophylaxis (**Irrespective** of whether anti-D Ig already given for PSE)	Take a blood sample to confirm group & check antibody screen – do not wait for results before administering anti-D Ig Administer **1500iu** anti-D Ig at **28 – 30** weeks OR Administer at least **500iu** anti-D Ig at **28** weeks and then administer at least **500iu** anti-D at **34** 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 not available ?	Request a Kleihauer Test Administer at least **500iu** anti-D Ig within 72 hours of delivery Confirm product / dose / expiry and patient ID pre administration
Does the Kleihauer Test indicate that further anti-D Ig is required ?	Administer more anti-D following discussion with laboratory

Anti-D Administration Checklist

SHOT

Patient ID	Date of administration	Sign to confirm action
Blood Group	Confirmation of patient's identity	
	Confirmation that the patient is RhD Negative from latest laboratory report	
	Latest antibody screen checked and confirmed that the patient does not already have her own immune anti-D	
Date	Informed consent for administration of anti-D Ig recorded in notes	

POTENTIALLY SENSITISING EVENTS (PSEs)

Gestation LESS than 12 weeks — **Estimated Gestation** — **Date**

Any of:
- Vaginal bleeding associated with severe pain
- Ectopic / Molar Pregnancy
- ERPC / Instrumentation of uterus
- Medical or surgical termination of pregnancy

→ Administer at least **250 IU** anti-D Ig within 72 hours of event.
Confirm product / dose / expiry and patient ID pre administration

Gestation 12 to 20 weeks — **Estimated Gestation** — **Date**

For any Potentially Sensitising Event (PSE) → Administer at least **250 IU** anti-D Ig within 72 hours of event.
Confirm product / dose / expiry and patient ID pre administration

Gestation 20 weeks to term — **Estimated Gestation** — **Date**

For any Potentially Sensitising Event (PSE)
(**Irrespective** of whether RAADP is given) → Request a Kleihauer Test but DO NOT wait for results

→ Immediately administer at least **500 IU** anti-D Ig within 72 hours of event.
Confirm product / dose / expiry and patient ID pre administration

Does the Kleihauer Test indicate that further anti-D Ig is required? → Administer more anti-D Ig as indicated

For continuous vaginal bleeding at least **500 IU** anti-D Ig should be administered at a minimum of 6-weekly intervals, irrespective of the presence of detectable anti-D, and a Kleihauer Test requested in case more anti-D is required

ROUTINE ANTENATAL ANTI-D PROPHYLAXIS (RAADP)

For Routine Antenatal Anti-D Ig Prophylaxis (RAADP)
(**Irrespective** of whether anti-D Ig already given for PSE)

- Take a blood sample to confirm group and check antibody screen – DO NOT wait for results
- Administer **1500 IU** anti-D Ig at **28–30** weeks
- OR
- Administer at least **500 IU** anti-D Ig at **28** weeks and then administer at least **500 IU** anti-D Ig at **34** 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? → Request a Kleihauer Test

OR

Are cord samples not available? → Administer at least **500 IU** anti-D Ig within 72 hours of delivery
Confirm product / dose / expiry and patient ID pre administration

Does the Kleihauer Test indicate that further anti-D Ig is required? → Administer more anti-D Ig as indicated

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

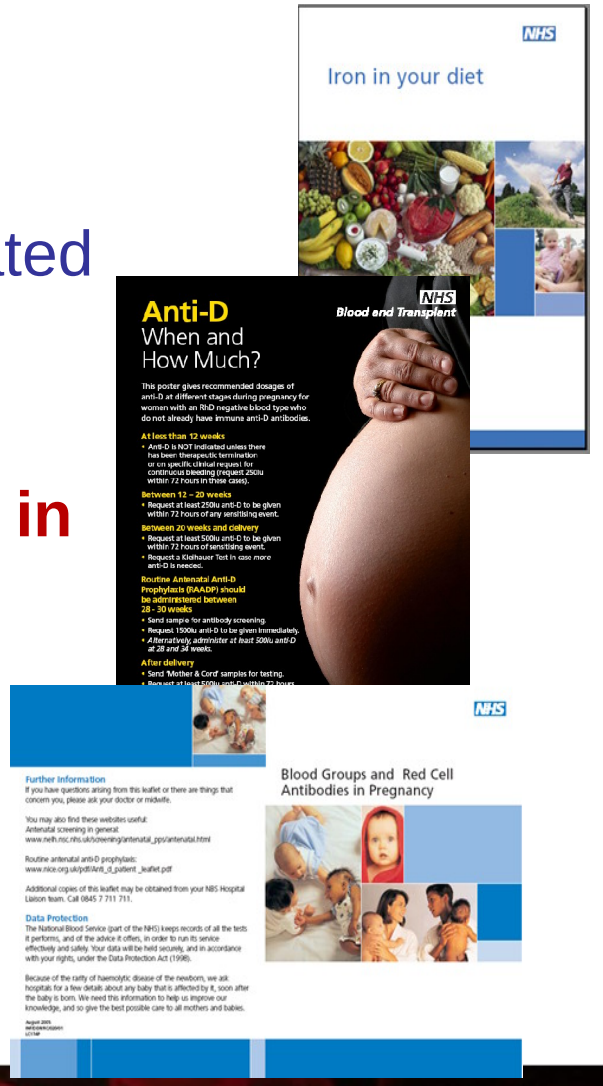
Key Messages & Recommendations 2011 – 'Back to Basics'

- Correct patient ID should be a core clinical skill
- Transfusion checklist – template available
  www.shotuk.org/resources/current-resources/
- 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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- **You for listening**

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