Anti-D

SHOT, NEQAS & NCA

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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

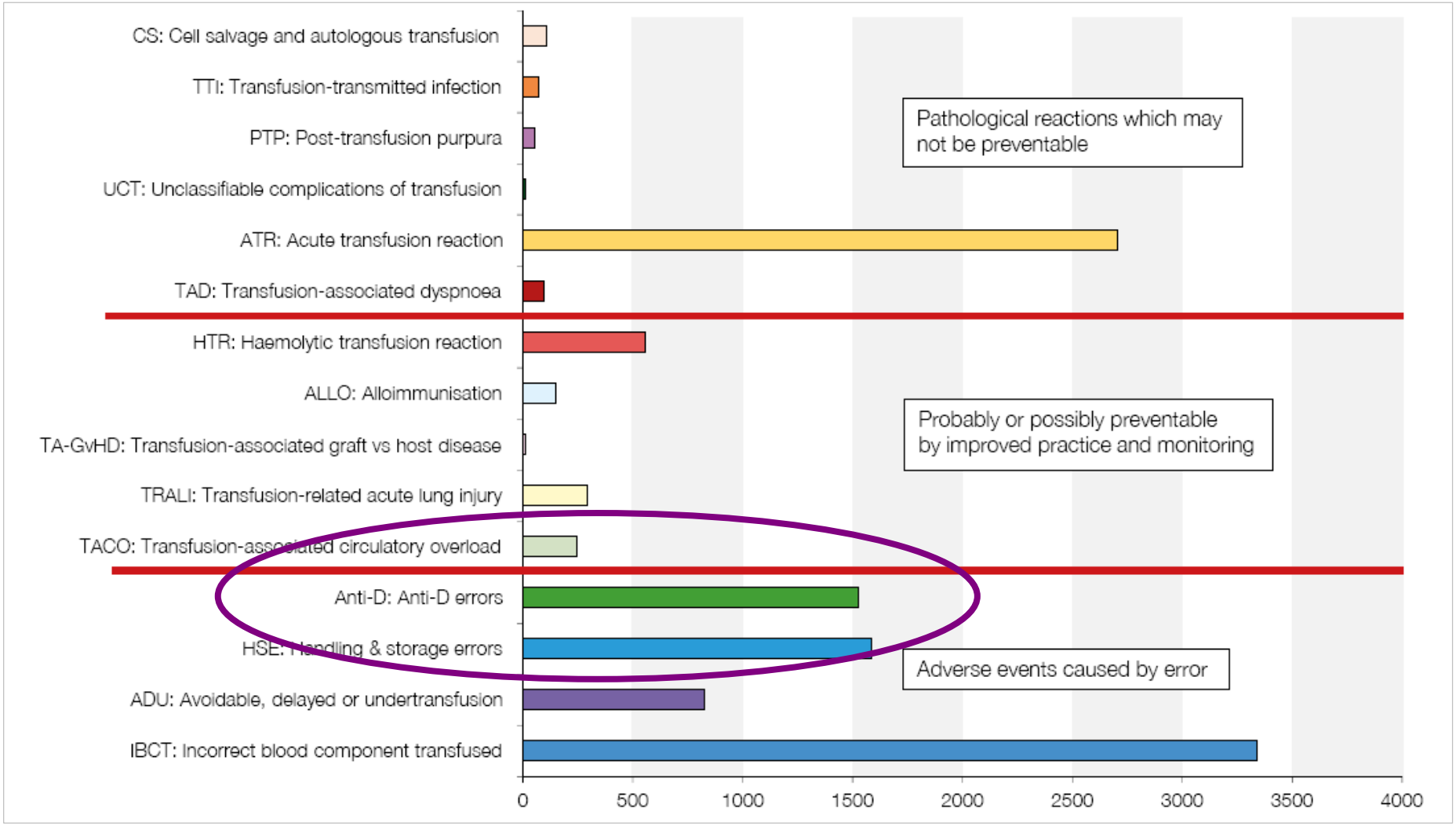
SHOT

Serious Hazards of Transfusion haemovigilance scheme

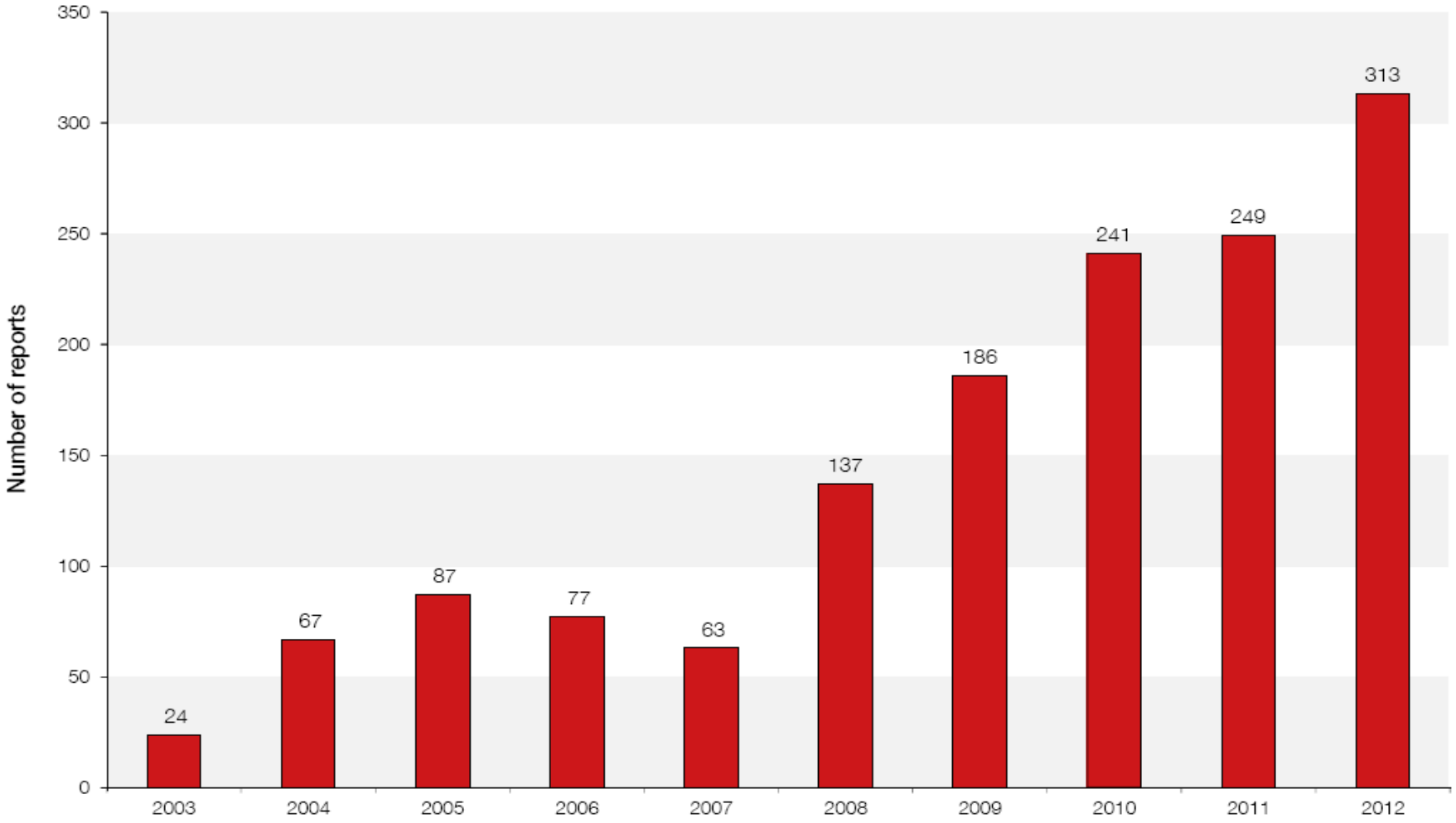
Why report Anti-D Ig errors to SHOT ?

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

SHOT cumulative data 1996-2012
(n=11,570)



Trend in Anti-D Ig reports



Anti-D Ig reports in 2012 (n = 313)

- **63** cases where anti-D Ig was inappropriately administered - *unnecessary exposure to a human medicinal blood product*
- **204** cases where anti-D Ig was delayed or omitted, putting patient at risk of sensitisation to the D antigen - *potential Major Morbidity*
- **20** cases where the wrong dose of anti-D Ig was administered
- **26** handling and storage errors

Anti-D Ig….who makes the errors ?

	2012	1996-2012
• Midwives *and Nurses*	225 (72 %)	1067 (70%)
• Laboratory	80 (25.5 %)	412 (27%)
• Medical staff	8 (2.5 %)	45 (3%)
• Total cases	313	1524

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*

Failure to issue anti-D Ig cover for RhD-incompatible platelets

- *A 4 year old female child with ALL whose group is A RhD negative was issued with RhD positive platelets*
- *The trainee biomedical scientist (BMS) did not issue anti-D Ig as cover, even though it was clearly stated in laboratory and clinical protocols, thus putting this child at risk of sensitisation to the D antigen and therefore compromising her future childbearing potential*

Catalogue of errors leads to incorrect administration of anti-D Ig

- *A woman told her consultant that she was RhD negative, and anti-D Ig was requested on that basis*
- *The biomedical scientist (BMS) issued anti-D Ig even though the laboratory information management system (LIMS) record clearly showed the woman to be RhD positive*
- *The midwife administered the anti-D Ig, knowing the woman was RhD positive, because the consultant had prescribed it*

Failure to check historical laboratory records and lack of understanding by the midwife

- *A biomedical scientist (BMS) was 'busy' and failed to check computer records before issuing anti-D Ig for a woman known to have immune anti-D*
- *The midwife assumed that because the laboratory had issued it, it should be given, citing a lack of understanding of the 'science' of anti-D*
- *She also carried out a 'straw poll' of her midwifery colleagues that indicated every one of them would have administered the anti-D Ig because it had been issued by the laboratory*

Incorrect route of administration results in an inadequate dose

- *A woman required anti-D Ig following a reported TPH of 100 mL fetal cells*
- *Seven 1500 IU vials of anti-D Ig were sourced from another hospital; the dose was calculated assuming they were to be given **intravenously** (100 IU/mL)*
- *Due to unfamiliarity with the particular formulation of anti-D Ig in the receiving hospital, all 7 vials were administered **intramuscularly** (IM).*
- *Not only was this extremely uncomfortable for the woman, but it also resulted in an underdosing by 2000 IU if calculated according to recommendations for IM route of administration (125 IU/mL)*

- If outside 72 hrs still give anti-D, as a dose up to 10 days may provide some protection
- Give RAADP **in addition** to prophylaxis for sensitising events, and *vice versa*

Anti-D Administration Flowchart for RhD Negative Pregnant Women

Wye Valley NHS Trust

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	Administer at least **250 IU** anti-D Ig within 72 hours of event. Confirm product / dose / expiry and patient ID pre administration
ERPC / Instrumentation of uterus	
Medical or surgical termination of pregnancy	
Ectopic / Molar Pregnancy	
Gestation 12 to 20 weeks	
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	
For any Potentially Sensitising Event (PSE) (**Irrespective** of whether RAADP has been given)	Request a Kleihauer Test (FMH Test) and 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 / FMH test indicate that further anti-D Ig is required ?	Administer more anti-D Ig following discussion with laboratory
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. A Kleihauer / FMH Test should be requested every two weeks in case more anti-D is needed. Cases where bleeding stops, then starts again should be treated as a new event.	
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 **1500 IU** anti-D Ig at **28 – 30** weeks
	Confirm product / dose / expiry and patient ID pre administration
At Delivery (or on diagnosis of Intra Uterine Death >20 weeks)	
Is the baby's group confirmed as RhD positive ? OR Are cord samples not available ?	Request a Kleihauer Test (FMH Test)
	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 / FMH test indicate that further anti-D Ig is required ?	Administer more anti-D following discussion with laboratory

SHOT anti-D Ig Administration Flowchart v7 October 2012

Key Messages

- DO NOT wait for the result of a Kleihauer test before giving a standard dose of anti-D Ig
- If in doubt – GIVE IT !

NEQAS

UK National External Quality Assessment Service

Anti-D Survey 2007

Distributed by UK NEQAS BTLP on paper & analysed by Dr A Benton

Anti-D Survey 2010

Distributed by UK NEQAS BTLP via Survey Monkey & analysed by NEQAS

Survey results

- 206/389 hospitals responded, including 164 with obstetric practice within their NHS Trust

  (121 England, 21 Scotland, 10 Wales, 4 NI, and 8 Eire),

  .....but not all respondents answered all questions.

Data from 164 responses

- 154/164 (93.9%) had implemented the 2008 NICE guidance on RAADP
  - (rising to 98.5% in England & Wales)
- Eire had not implemented RAADP

Routine antenatal anti-D prophylaxis
(n=135)

- 16% issued 500 IU at 28 and 34 weeks,
- **81% issue 1500 IU at 28 weeks,**
- 2% issued 1500 IU at 30 weeks,
- 1% issued 1250 IU at 28 and 34 weeks.
- 14% gave RAADP intravenously, using a single 1500 IU dose of anti-D

Between the 2007 and 2010 surveys;

- 41% had not changed their RAADP regime
- **47% had changed to a single dose from a 2-dose regime**
- 8% had changed to a higher dose.

Post natal (PN) & Potentially Sensitising Events (PSE) (n=137)

Clinical scenario	Number (%) using anti-D Ig dose				
	250IU	500IU	1250IU	1500IU	Other
PSE <20 weeks	99 (72%)	11 (8%)	7 (5%)	19 (14%)	1 (1%)
PSE > 20 weeks	1 (1%)	104 (76%)	10 (7%)	22 (16%)	0 (0%)
Post-natal	0 (0%)	100 (73%)	10 (7%)	27 (20%)	0 (0%)

Issue of anti-D (n=134)

- The blood transfusion laboratory (BTL) was responsible for issuing anti-D Ig to named patients in 89% cases
- 36/134 laboratories also issue to other departments on a ‘non-named’ patient basis
- 10 were aware of ‘non-named’ anti-D Ig issue with no input from a BTL (6 via pharmacy, 2 maternity, 1 day surgery unit and 1 GP surgery)
- BTL had responsibility for traceability of all anti-D issued in 43% cases, and for anti-D issued only from the BTL in 47%.

NCA

National Comparative Audit of Blood Transfusion

National Comparative Audit of anti-D

- Looking at a cohort of women who booked around September 2012, with expected delivery around May 2013
  - Were they RhD Negative ?
  - Did they receive RAADP (dose / timing) ?
  - Did they receive anti-D for PSE (dose / timing)?
  - Did they deliver a RhD positive baby ?
  - Did they receive post-natal anti-D (dose / timing)?
  - Did they receive further anti-D if indicated by FMH test (Kleihauer) ?

National Comparative Audit of anti-D

- Blood group and antibody screen on **all** pregnant women **at booking** to identify RhD negative women then **exclude** RhD positive women and RhD negative women with immune anti-D
- Looking at selected case notes to identify PSEs, RAADP and Post-Natal administration of anti-D, or if not received, then WHY not ?
- Organisational audit – Where ? numbers ? dosages stocked and used ? RAADP regime ? route of administration ? Traceability ?

National Comparative Audit of anti-D

- 4 Feb 2013 — Audit recruitment starts
- 29 March 2013 — Pilot ends
- 15 April 2013 — Audit documents to participating sites
- May 2013 — One month case capture phase – cases to be audited are identified and notes obtained
- June 2013 — Data collection starts with case note audit and organisational audit
- 1 October 2013 — On-line data entry closes

National Comparative Audit of anti-D - Preliminary findings from one NW Hospital

- 65 women were identified by the lab as qualifying for the audit

Local results

Booking bloods

- 62 / 65 women had their booking bloods tested (one sample was rejected – no follow up sample received, one woman terminated the pregnancy prior to booking blood)

- All women tested were RhD negative and only one woman had a positive antibody screen – 32 weeks, given RAADP elsewhere

Local results

Repeat bloods at 28 weeks

- 55 / 65 women had their repeat bloods taken
  - 7 had passive anti-D due to documented prophylaxis

- Reasons for omission in 8 /10 cases:
  - 3 TOPs
  - 2 moved out-of-area
  - 1 late booker
  - 1 woman delivered at 26+2 weeks
  - 1 sample rejection – no repeat received

Local results

Timing of RAADP injection

- 59 / 65 women were eligible for RAADP
- 53 / 59 eligible women had their injection between 28 and 30 weeks
- 2 / 59 had RAADP slightly late (31+2 & 31+6)
- 4 / 59 did not receive RAADP at all

Local results

Evidence of RAADP leaflet & consent

- 30 / 55 women who received RAADP had documented evidence of receiving the leaflet
- 32 / 55 women had documented consent for the injection

Local results

Potentially Sensitising Events

- 17/65 women had a single PSE and three of these had a further PSE (according to the laboratory records)

- On interrogation of the case notes a woman who had already had a PSE at 14+2 weeks had a further PV bleed at 22 weeks but was not given more anti-D Ig

Local reasons for omissions

- Not all women who book their antenatal care have their booking blood group bloods done
  - should now be rectified as G&S taken at first appt
- Not all RhD negative women appear on weekly list supplied for RAADP appointment
- Not all women who book their antenatal care have their repeat blood group bloods done

Local reasons for omissions

- Not all RhD negative women are receiving RAADP appointments/injections
- Not all RhD negative women are receiving their RAADP injections at 28-30 weeks
- Evidence of use of RAADP leaflets and consent is scant

Local recommendations

- Positive antibody screens post 28 weeks should not be assumed to be due to RAADP
- PSEs should be treated even if there is no evidence of current bleeding
- Regular review of the woman's pregnancy had not occurred in these incidents – review is clearly necessary to pick up the shortfalls in care

National Comparative Audit

- Audit is looking to report by Christmas 2013

Thanks to;

- SHOT Team
- UK NEQAS
- NCA Team
- Lynne Mannion for local audit results
- **YOU** for listening