SERIOUS HAZARDS OF TRANSFUSION SHOT

# Anti D Errors
# Lessons from SHOT


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Joint London and South East Coast Regional Transfusion Committees
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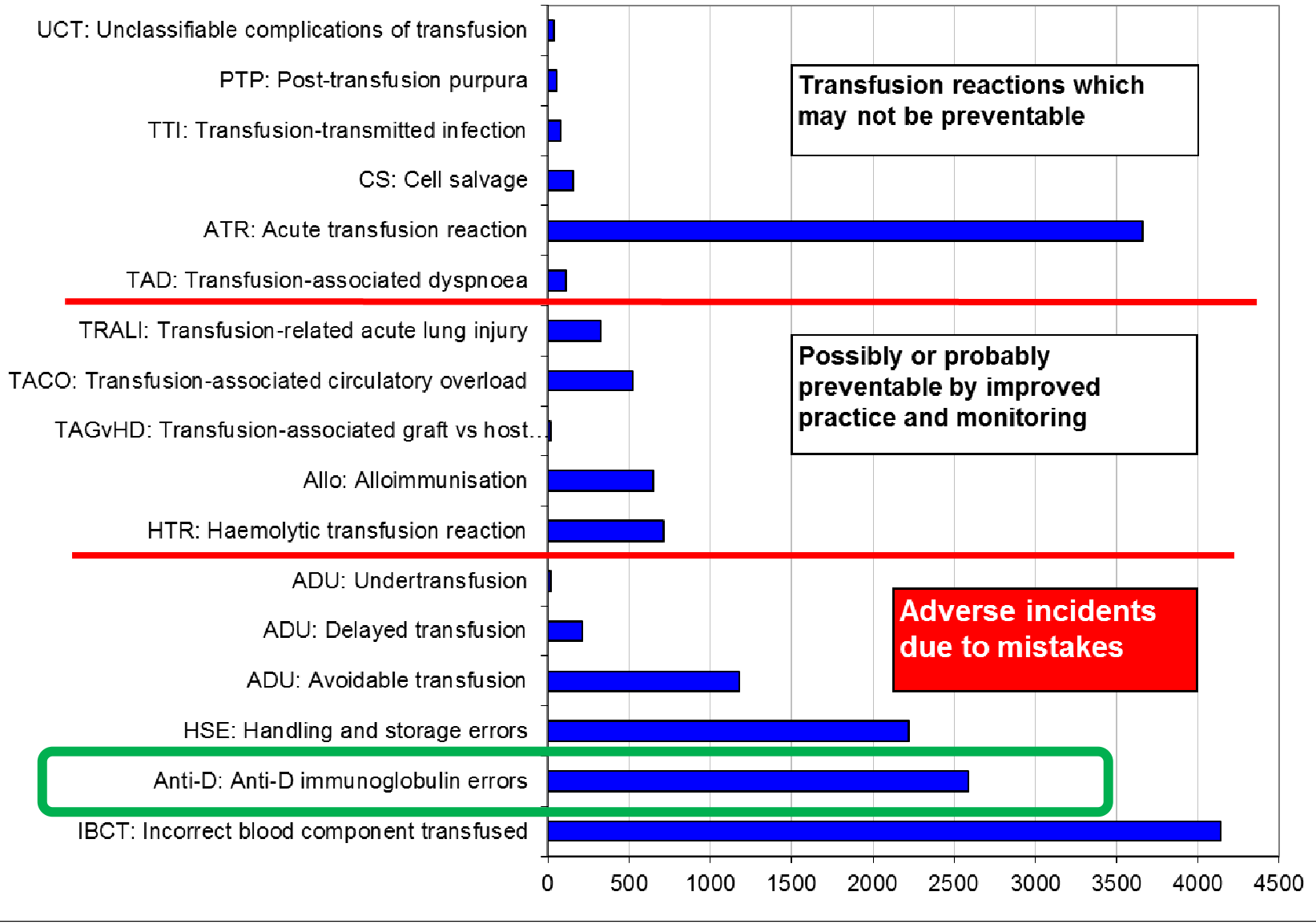
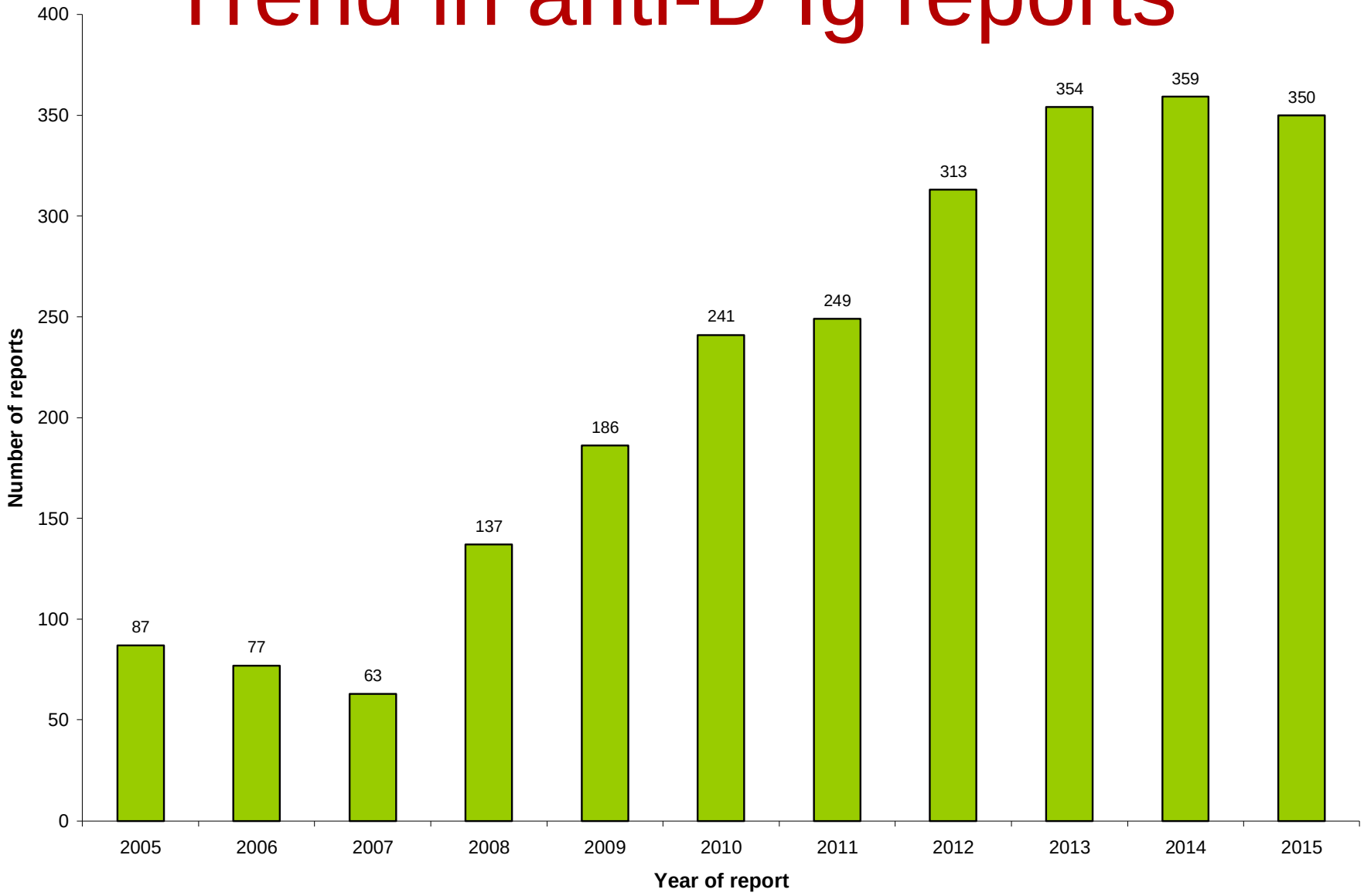
# Traceability and adverse reactions to anti-D Ig

- Anti-D Ig is made from human plasma and must be traceable
- In the past hepatitis C was transmitted to many women in Ireland and Italy
- Clinical adverse reactions (e.g. allergy) to anti-D are reportable via the MHRA Yellow Card scheme
- Procedural errors associated with anti-D Ig are SHOT-reportable

# SHOT Reports – cumulative results to end of 2015 n=16,677



# Trend in anti-D Ig reports



# Why are there so many errors?

- Multiple steps
- Different professional groups
  - Midwives and nurses
  - Laboratory staff
  - Medical staff
- Assumptions and failure to check
- So it needs a checklist

# Key risks in medicine

- **Identification**
- **Documentation** – manual transcription of results in the laboratory or by midwives into maternity notes is a DANGER point
- **Communication** – several biomedical scientists and different midwives increase risk of missed or mixed messages

# Case Study - Anti-D Ig issued without reference to grouping results

- During the on-call period, the duty BMS issued 1500 IU anti-D Ig to the mother of a baby confirmed to be D-negative
- The BMS was ‘very busy’ and did not check the LIMS to confirm blood groups before issuing the anti-D Ig

# Case Study - Bedside checking means ‘at the bedside’

- Anti-D Ig was issued by the laboratory for a post-natal woman
- The anti-D Ig was checked by two qualified midwives away from the woman and then taken to the wrong woman for administration

# Case Study - Laboratory report misinterpreted

- Anti-D Ig was issued for routine prophylaxis at 28 weeks from clinical stock, after midwives misinterpreted ‘Antibody Screen Negative’ as ‘D negative’
- The laboratory has changed the wording on their grouping reports to ‘No antibodies detected’ in an attempt to stop this happening again

# Messing up anti-D can be disastrous

# Case Study
# Failure to recognise a complication of pregnancy 1

- A baby was born with unexpected jaundice and haemolytic disease of the fetus and newborn (HDFN) due to anti-D antibodies which had not been anticipated
- The baby required urgent red cell exchange transfusion during which a cardiac arrest occurred, and the baby subsequently died
- This was the second pregnancy in a D-negative woman

How did this happen?

# Failure to recognise a complication of pregnancy 2

- There were multiple errors in the first pregnancy
- Anti-D antibody was detected prior to the administration of routine anti-D immunoglobulin (Ig) but was misinterpreted on two separate occasions and not followed up 4
- The first baby was born with HDFN requiring exchange transfusion, but there was then ‘no mechanism for ensuring that information was fed into future pregnancies’ 1
- At booking for the second pregnancy the history of jaundice and transfusion at birth for the first baby was noted but this was not identified as indicating a risk for the current pregnancy 1

# Failure to recognise a complication of pregnancy 3

- The laboratory staff then misinterpreted the presence of anti-D in the booking bloods at 10 weeks as being due to prophylactic anti-D Ig administration but the midwife did not pick up this error 2
- The woman was reviewed by an obstetric registrar at 20 weeks who noted that the first baby had required phototherapy for jaundice but missed the history of exchange transfusion 1
- Anti-D was again detected in blood samples at 28 weeks and was again wrongly assumed to be due to anti-D Ig administration (which had not been given) 18 weeks before 1

# Failure to recognise a complication of pregnancy 4

- Five hours after birth (39 weeks' gestation) the baby was jaundiced (group O D-positive) and required exchange transfusion
- The baby suffered complications and subsequently died (January 2015)
- The hospital review of this case was signed off by the hospital in June 2015
- The post-mortem report had not been available so the review was unable to determine the cause of death

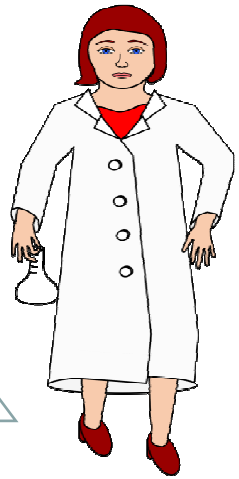
# Laboratory error and poor communication

Maternal anti-D and anti-C detected at 17 weeks
Advised close follow up with titres
Monitored in tertiary centre

Baby induced at 36 weeks in local centre:
hyperbilirubinaemia
Admitted to NICU
Group O D pos
NICU not aware of this baby prior to delivery**; not discussed in obstetric high risk meeting**

**Policies not followed**
Day 3: Verbal requests for urgent blood for exchange
2 BMS did not look at maternal results so provided wrong group

Given the **WRONG BLOOD**
O D-pos (incompatible), should be O D-neg



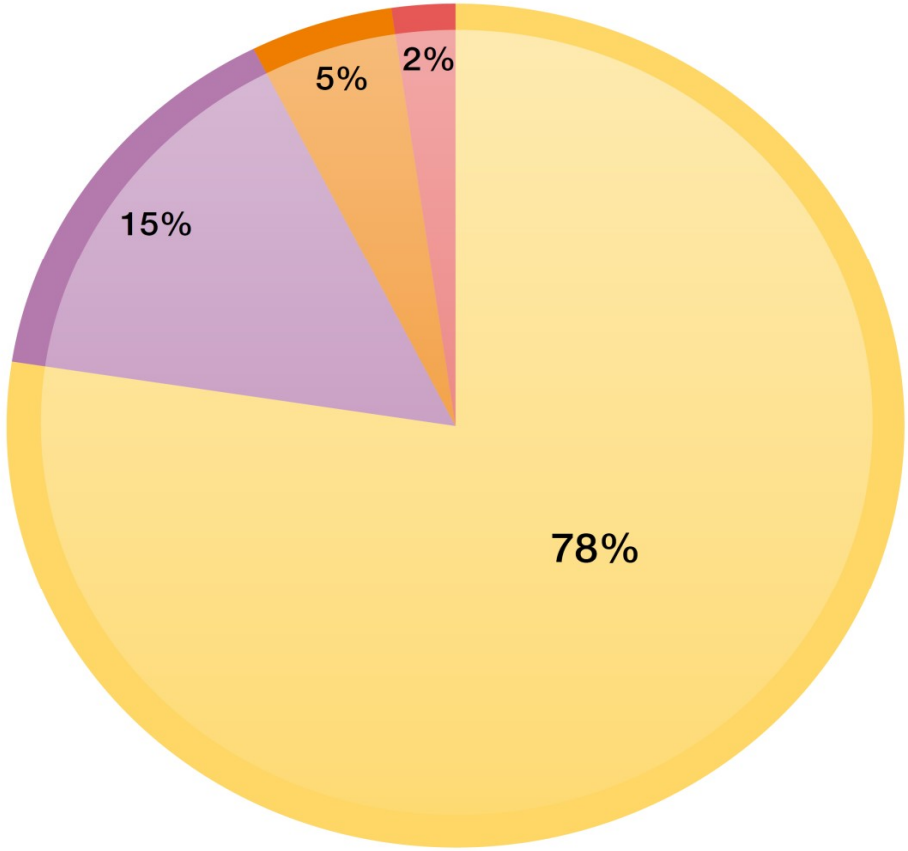
The baby required repeat exchange transfusion with O D-neg on day 6

# Steps where errors are likely

- Blood sample for group check
  - Is it the correct woman?
- Check the laboratory report
  - If anti-D is detected, what is the cause
  - **COMMUNICATION** (is the anti-D immune or a result of previous treatment?)
- Check the product and dose (whose responsibility?)
- Record the informed consent

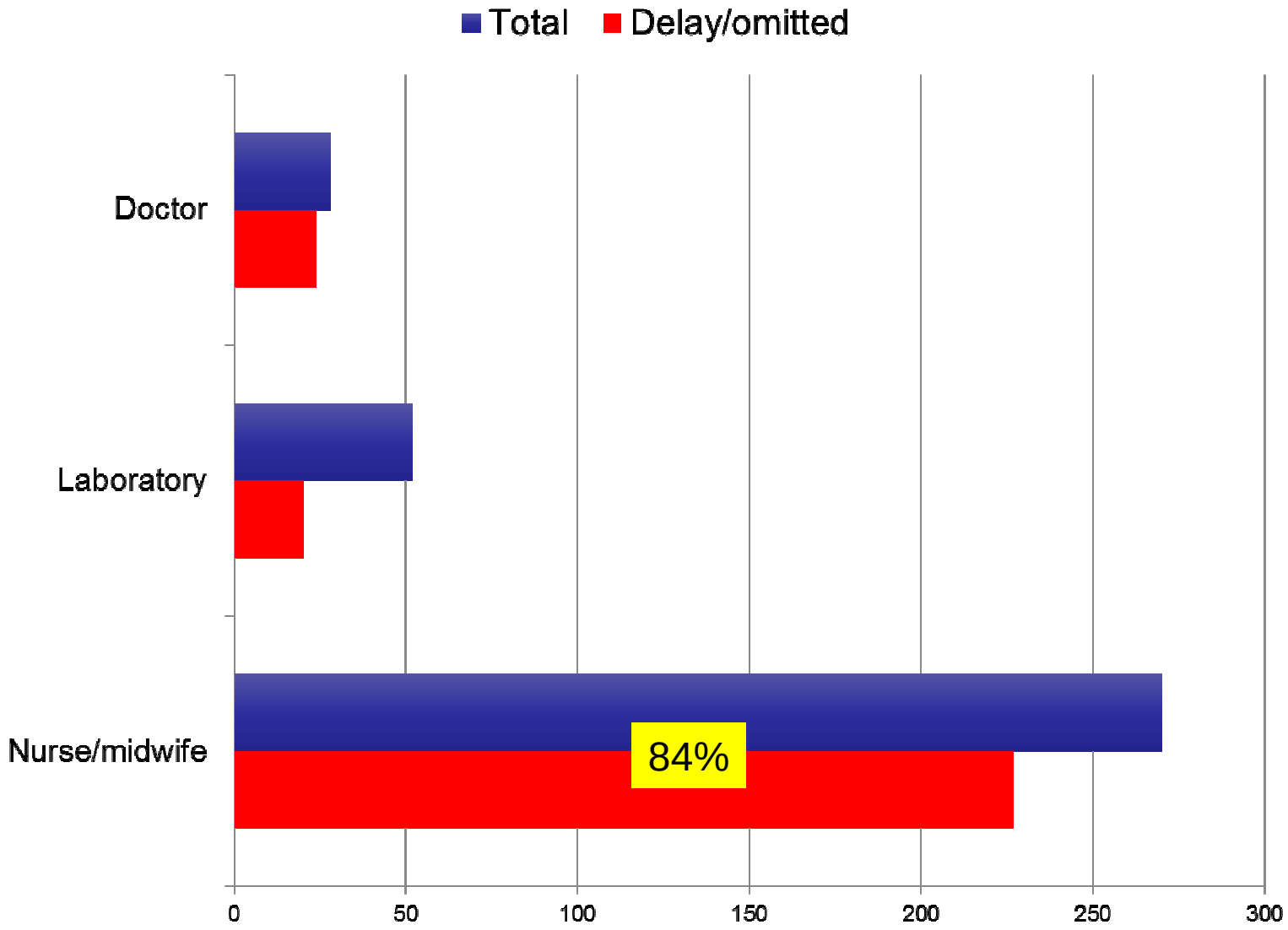
# Anti-D Ig reports in 2015 (n=350)

- **Handling and storage errors related to anti-D Ig** n=8 (2%)
- **Wrong dose of anti-D Ig given according to local policy** n=18 (5%)
- **Inappropriate administration of anti-D Ig** n=53 (15%)
- **Omission or late administration of anti-D Ig** n=271 (78%)




3 women developed anti-D as a result

# Who makes the errors?



# Anti-D Ig….who makes the errors ?

| | 2015 | 1996-2012 |
|---|---|---|
| • Midwives *and Nurses* | 227 (84%) | 1067 (70%) |
| • Laboratory | 20 (7%) | 412 (27%) |
| • Medical staff | 24 (9%) | 45 (3%) |
| • Total cases | 350 | 1524 |

# Case Study - Lack of knowledge results in delay of administration of anti-D Ig

- A woman presented with a vaginal 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

# Misinterpretation of the Kleihauer test

- A negative Kleihauer test does not exclude a sensitising fetomaternal haemorrhage
- The test is done to ensure that enough anti-D Ig is given to cover the size of any bleed and NOT to decide whether a dose is needed
- The current recommended dose of anti-D Ig should cover a bleed of up to 4mL

# Prophylaxis and PSEs

Staff should be made aware that national guidelines specifically recommend that RAADP and prophylaxis for PSEs should be regarded as **separate events** and anti-D Ig given for both at a dose indicated by the local policy

# Case Study - Failure to issue anti-D Ig cover for D-mismatched platelets

- A 4 year old female child with acute lymphoblastic leukaemia whose group is A D-negative was issued with D-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
- The child was put at risk of sensitisation to the D antigen and  the risk of compromising her future childbearing potential

# Case Study - Catalogue of errors leads to incorrect administration of anti-D Ig

- A woman told her consultant that she was D-negative, and anti-D Ig was requested on that basis **ALWAYS CHECK THE LABORATORY RESULT**
- The BMS issued anti-D Ig even though the laboratory information management system record clearly showed the woman to be D-positive **SERIOUS FAILURE OF PROCEDURE**
- The midwife administered the anti-D Ig, knowing the woman was D-positive, because the consultant had prescribed it **DO NOT DISENGAGE BRAIN**

# Case Study

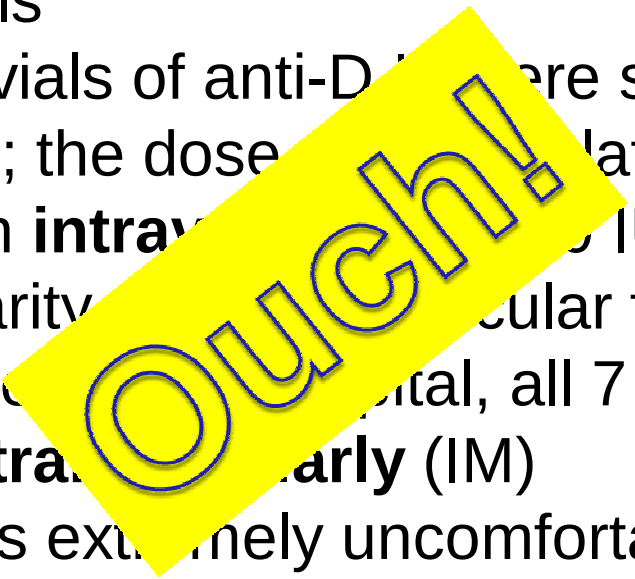
## Failure to check historical laboratory records and lack of understanding by the midwife

- A BMS was ‘busy’ and failed to ch… …mputer records before issuing anti-D Ig … …man known to have immune anti-D [1]
- The midwife assumed th… …se the laboratory had issued it, it shou… …n, citing a lack of understanding of t… …ce’ of anti-D [2]
- She also carri… …straw poll’ of her midwifery colleagues … …cated every one of them would have admini… …d the anti-D Ig because it had been issued by the laboratory [3]

ASSUMPTIONS

# Case Study - 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 [illegible]ere sourced from another hospital; the dose [illegible]lated assuming they were to be given **intra[illegible]** IU/mL)
- Due to unfamiliarity [illegible]cular formulation of anti-D Ig in the re[illegible]ital, all 7 vials were administered **intra[illegible]arly** (IM)
- Not only was this ext[illegible]mely 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)



# Case Study - Student midwife relies on patient to confirm anti-D Ig administration

- A student midwife asked a postnatal [illegible]man whether she had received her anti-D Ig and th[illegible] confirmed that she had
- The anti-D Ig labelled for th[illegible]was found some days later in the maternit[illegible]ator, and it transpired that the woman had r[illegible]n injection of Syntometrine (oxytocin with erg[illegible]
- She was recall[illegible]ven her anti-D Ig injection a week late

ASSUMPTION

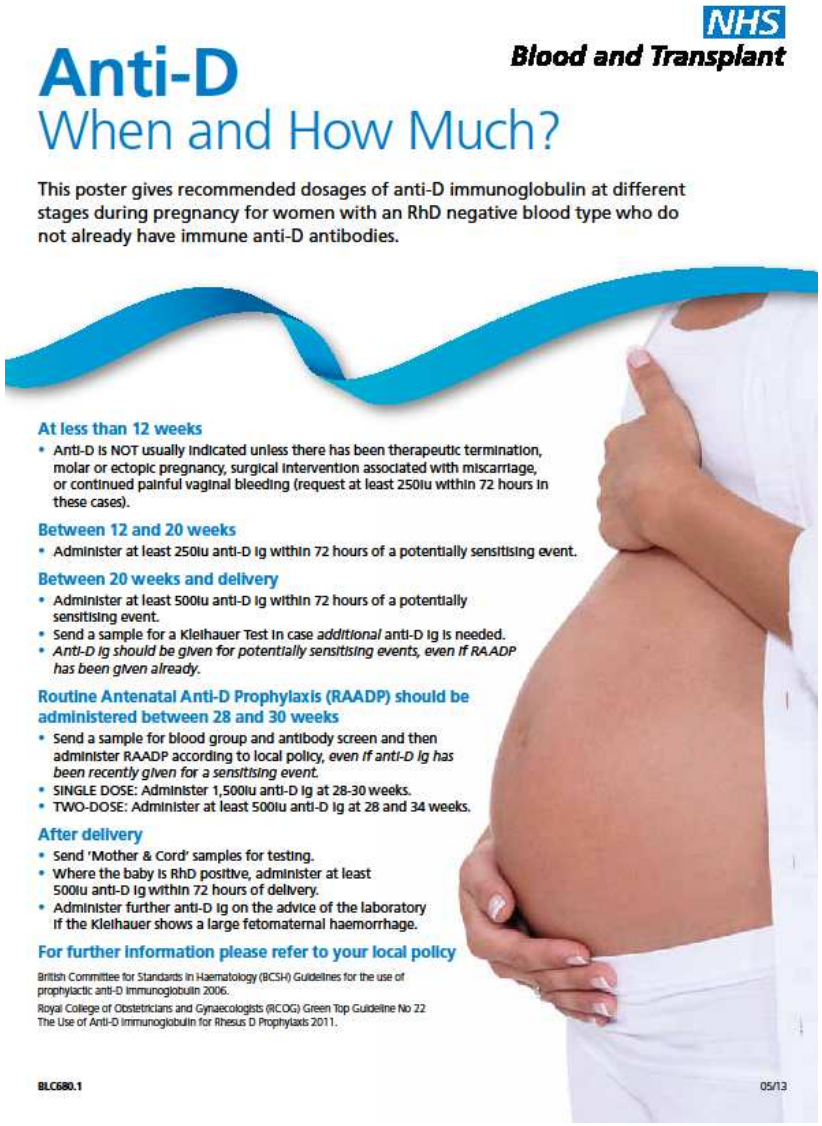
# Case Study - Failure to give anti-D Ig in first pregnancy results in sensitisation – multiple errors

- A woman delivered a RhD positive baby in 2011. She booked at 17 weeks but did not receive anti-D Ig in pregnancy because she did not return at 28 weeks
- She missed some appointments, but many opportunities were missed (at least 8)
- She was delivered by emergency CS but also did not receive her postnatal dose despite it having been ordered and issued

- Anti-D discovered in 2nd pregnancy in 2013

# Case Study - Group change following merger of patient records

- Two patient records with identical names were merged in the laboratory computer, although one patient was O RhD negative and the other B RhD positive
- The merged record showed the patient as blood group O RhD negative, on which basis anti-D Ig was issued
- The current sample from the pregnant woman was erroneously rejected as ‘wrong blood in tube’ by the laboratory as it grouped as B RhD positive and was discrepant with the blood group on record



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# Anti-D
## When and How Much?

This poster gives recommended dosages of anti-D immunoglobulin 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 usually indicated unless there has been therapeutic termination, molar or ectopic pregnancy, surgical intervention associated with miscarriage, or continued painful vaginal bleeding (request at least 250iu 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 500iu 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 1,500iu anti-D Ig at 28-30 weeks.
- TWO-DOSE: Administer at least 500iu anti-D Ig at 28 and 34 weeks.

**After delivery**

- Send 'Mother & Cord' samples for testing.
- Where the baby is RhD 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.

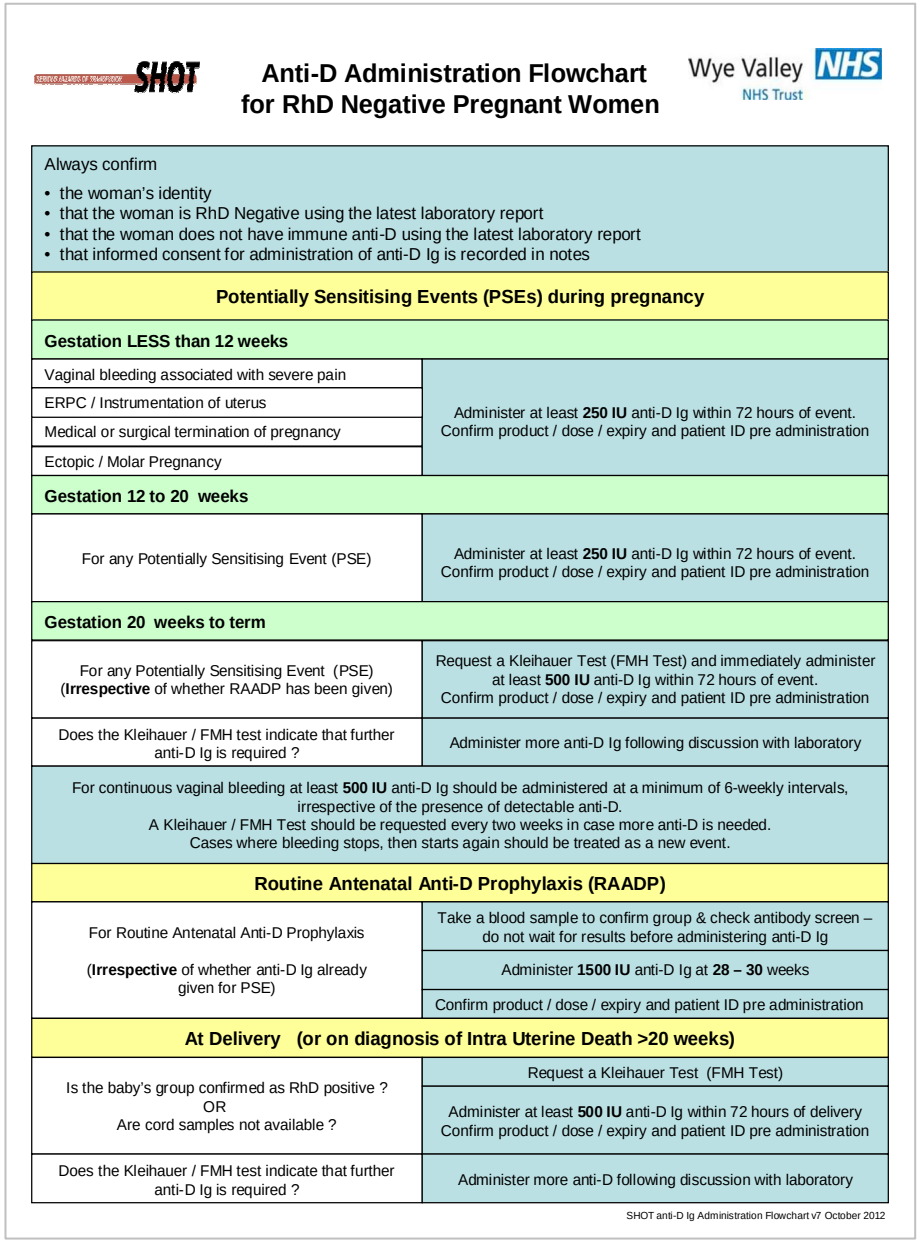
**For further information please refer to your local policy**

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 Guideline No 22 The Use of Anti-D Immunoglobulin for Rhesus D Prophylaxis 2011.

BLC680.1 05/13

- 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*



SHOT

## Anti-D Administration Flowchart for RhD Negative Pregnant Women

Wye Valley NHS Trust

| | |
|---|---|
| Always confirm<br>• the woman's identity<br>• that the woman is RhD Negative using the latest laboratory report<br>• that the woman does not have immune anti-D using the latest laboratory report<br>• 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.<br>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.<br>Confirm product / dose / expiry and patient ID pre administration |
| **Gestation 20 weeks to term** | |
| For any Potentially Sensitising Event (PSE)<br>(**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.<br>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.<br>A Kleihauer / FMH Test should be requested every two weeks in case more anti-D is needed.<br>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<br>(**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 ?<br>OR<br>Are cord samples not available ? | Request a Kleihauer Test (FMH Test) |
| | Administer at least **500 IU** anti-D Ig within 72 hours of delivery<br>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

# Use a checklist

# 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 !

# Prevention of HDN

- Identify RhD-negative women, check for immune anti-D
- Give right blood components to RhD negative women
- Counsel about sensitising events in pregnancy
- Give right dose of anti-D immunoglobulin at the right time
  - Sensitising events, routine antenatal prophylaxis and post delivery
- Do a test for FMH after 20 weeks gestation

# From 2012: anti-D sensitisation discovered in pregnancy

- Although SHOT receives many reports of late or missed anti-D Ig prophylaxis, the long-term outcome is rarely reported, despite reminders
- New questionnaire for reporting new anti-D picked up at booking or during pregnancy

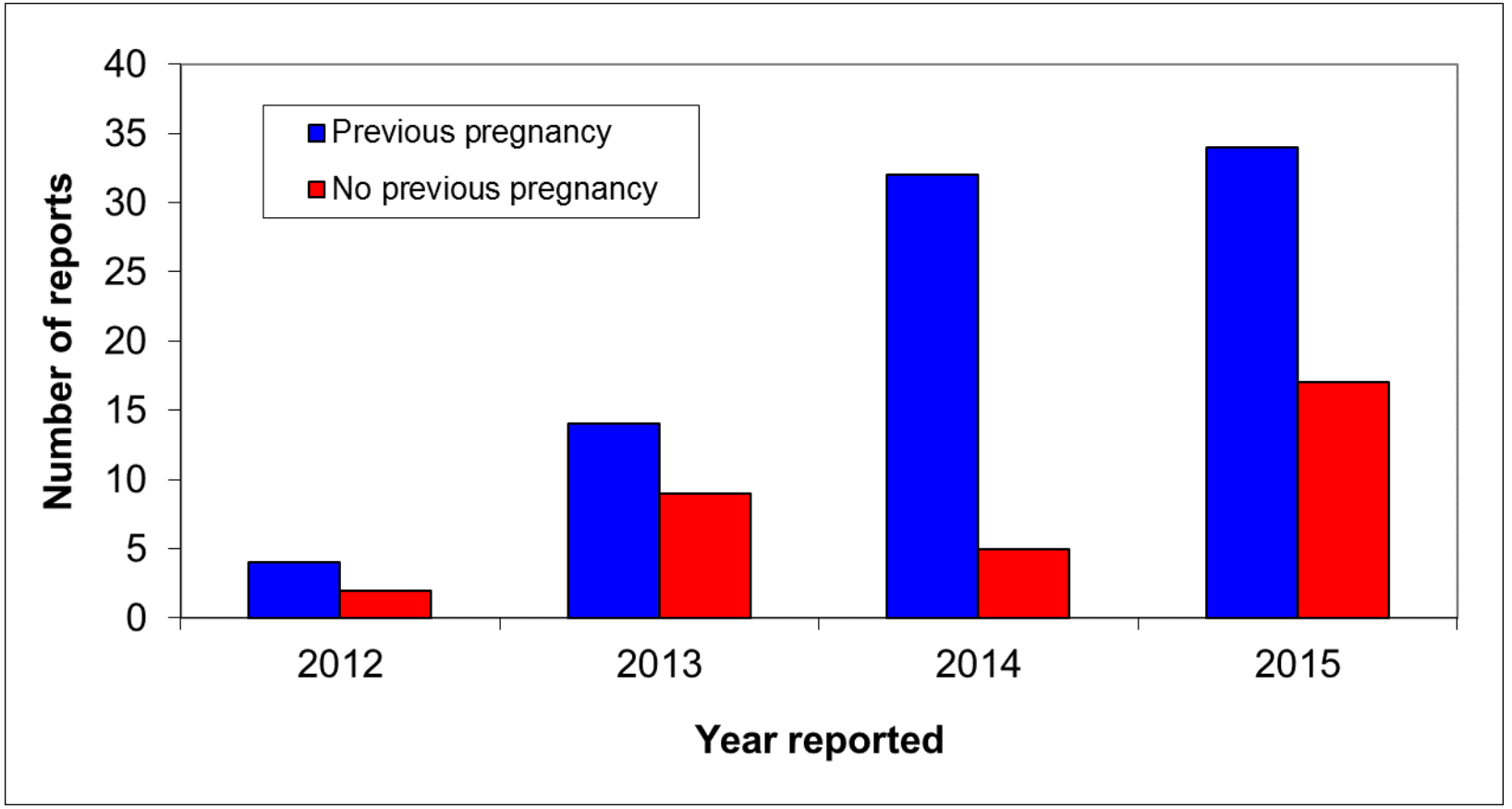
# Case Study - Woman sensitised despite prophylaxis

- 29 year old woman, first pregnancy
- Received 1500iu anti-D Ig at 28 weeks
- Blood sample at 38 weeks showed anti-D level 5.9 IU/mL
- Result not available until after delivery
- Baby O Pos, +DCT, bilirubin 318
- Treated with phototherapy

# Anti-D discovered in pregnancy

- Total 33 no previous pregnancy
- Total 84 who had a previous pregnancy
- Cumulative data demonstrates that 13/41 (31.7%) women found to be immunised at booking had apparently ideal management in the previous pregnancy
- Still worth giving anti-D Ig >72h or >10 days after a sensitising event

# Summary so far



# National Comparative Audit 2013

- Cases identified at BOOKING (**September 2012**) and followed to DELIVERY (**April/May 2013**): data collected retrospectively from June to October 2013

161 UK sites (232 maternity units) participated in the audit

- 5972* clinical cases audited in one month of 'bookings'

*NICE, RCOG, BCSH guidelines

# Compliance with RAADP

ALL HOSPITALS GIVE RAADP

5276 (of 5972) RhD negative pregnant women eligible for RAADP

- Single-dose 1500 IU at 28-30 weeks (n=4887)
  - 99% received the anti-D Ig injection
  - 89.9% received the dose at the right time
- Two-dose 500 IU at 28 and 34 weeks (n=389)
  - 98.7% received at least one anti-D injection
  - 58.6% received both doses at the right time**

93% of women audited were treated in units using single-dose RAADP

**But this was a much narrower time-window

# RAADP not given

**Single-dose:**

- 47/4887 (**1%**) not given RAADP injection

**Two-dose:**

- 10/389 (2.6%) not given first injection
- 21*/389 (5.4%) not given the second injection
- 5**/389 (1.3%) not given either RAADP injection

* 11 and ** 2 cases were because of pre-term labour

Since RAADP implementation 71% of sites have changed to the single-dose regime

# Compliance with anti-D Ig prophylaxis post delivery

**3392** RhD negative pregnant women delivered a RhD positive baby and were eligible for post-delivery anti-D

- 98.5% received post delivery anti-D Ig
    - 91.6% received the right dose at the right time
- 0.56% (19 cases) should have been given anti-D Ig and were not
- 97% had a Kleihauer (FMH) test

# Recommendation

Post delivery anti-D prophylaxis is vital to prevent sensitisation and women who are eligible should not be able to leave hospital without the injection, or a robust plan in place for them to receive the anti-D Ig and any additional dose of anti-D Ig as indicated by the result of the Kleihauer test.

# Key Issues with anti-D Ig

- Ignorance
- Failure to adhere to local protocol
- Failure to use IT systems properly / fully
- Late bookers
- Transfers of care
- Assumptions
- Failures of communication
- Failure to obtain valid consent for anti-D Ig

# We know what we should do….

Everyone needs knowledge to play their role

Midwives
Obstetricians
Doctors
Nurses
Biomedical Scientists

And ……. Women themselves

**Professional education**

**Update sessions**

**E-learning packages**

**HDN awareness campaign**

**Patient information**

# Anti-D Summary

- Effective anti-D Ig prophylaxis is a *partnership* between the laboratory and the clinical area
- Requests for anti-D Ig should be driven by the clinicians, especially in early pregnancy
- The clinical area must be responsive to requests for follow-up from the laboratory, and the laboratory must not assume that action will be taken purely because they have issued a report

# Acknowledgements: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**@SHOTHV1**

**#SHOTHV**

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