Anti-D Lessons from SHOT

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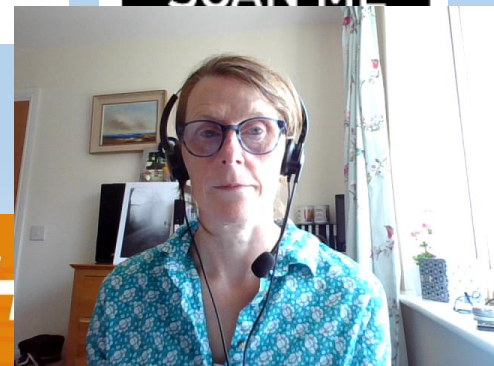
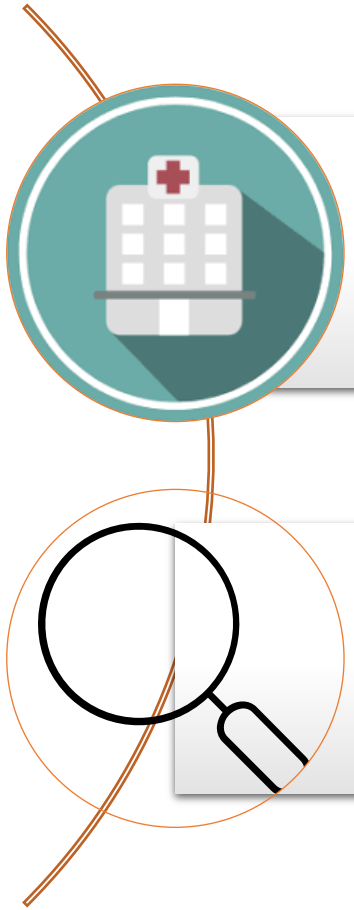


Background - haemovigilance

Refers to the systematic surveillance of adverse reactions and adverse events related to transfusion with the aim of improving transfusion safety

Background – SHOT aims

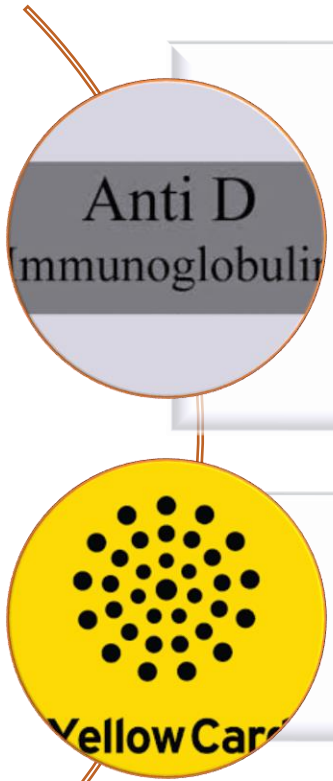


SHOT collects and analyses information on transfusion reactions and adverse events from all healthcare organisations in the UK that are involved in blood transfusion

Analyse Serious Adverse Reactions (SAR) and Serious Adverse Events (SAE), identify risks and provides recommendations for improvement based on learning from errors

Anti-D reporting

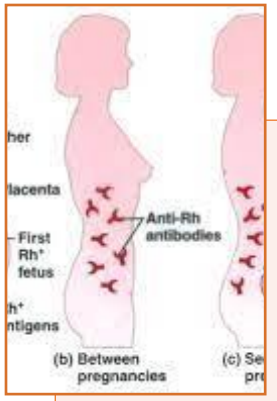
Anti-D Ig errors



Events relating to the requesting and administration of anti-D immunoglobulin (Ig) to individuals of childbearing potential

Cases of pathology reactions (e.g. allergy) reported to MHRA via Yellow Card

Immune anti-D



Cases of D-negative women who become sensitised and are found to have developed immune anti-D which is detected during pregnancy, either at booking or later in pregnancy

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Definitions of current SHOT reporting categories & what to report

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Revised February 2021

Why is anti-D important?

A woman who is D-negative is likely to make anti-D if exposed to the D antigen by pregnancy or blood transfusion

Immune anti-D can cause severe harm and death to a D-positive fetus (haemolytic disease of the fetus and new born – HDFN)

Prophylactic use of anti-D Ig can prevent D-negative women from making immune anti-D

- During pregnancy
- Following transfusion of D-positive blood components

Preventing HDFN due to anti-D

Identify D-negative women during pregnancy blood group screening

Check for immune anti-D at regular testing

Understanding of potentially sensitising events (PSE) and need for anti-D Ig

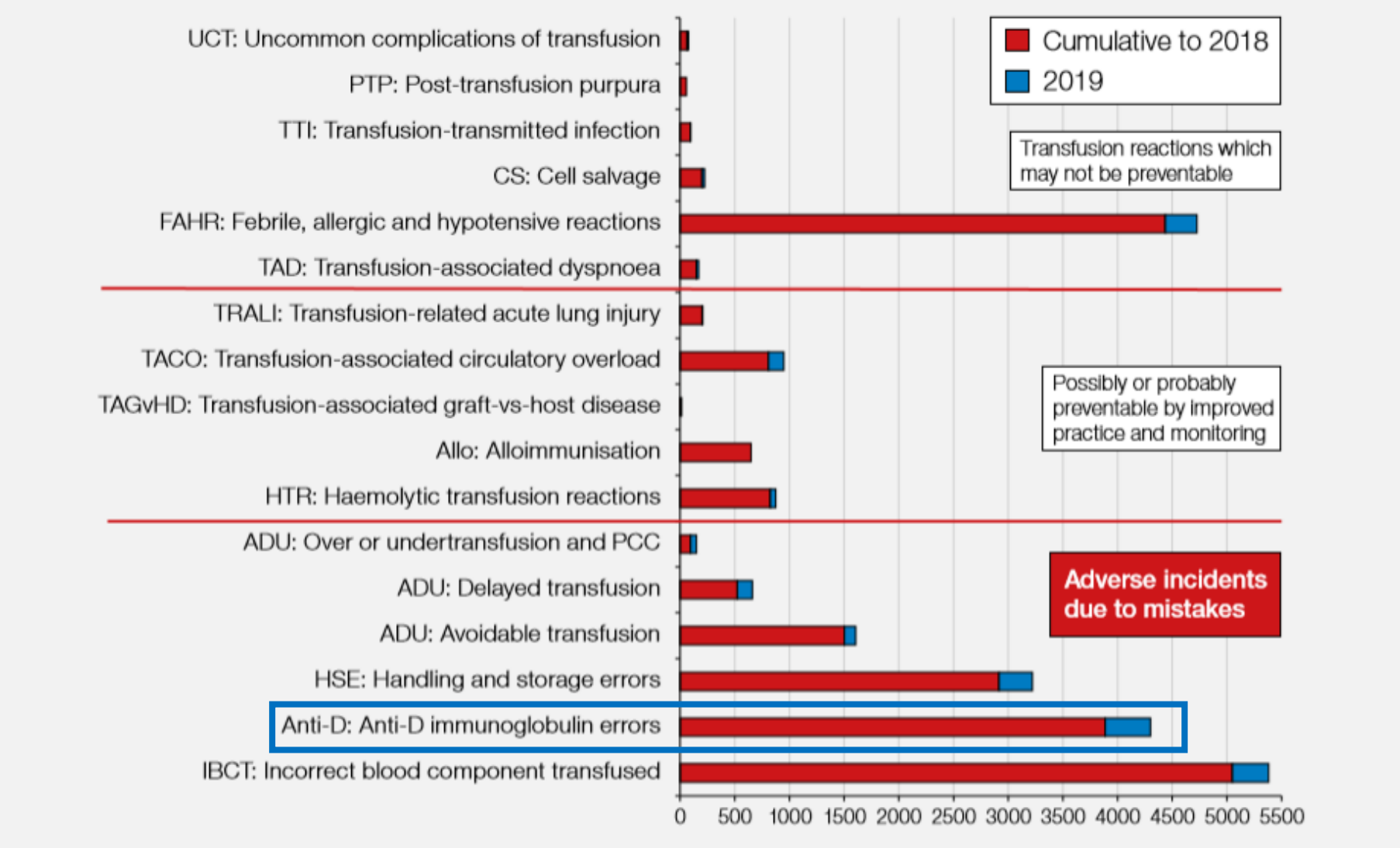
Giving the right dose of anti-D Ig at the right time

Understanding the difference between:

- Anti-D Ig given post PSE
- Anti-D Ig given as routine antenatal prophylaxis (RAADP)

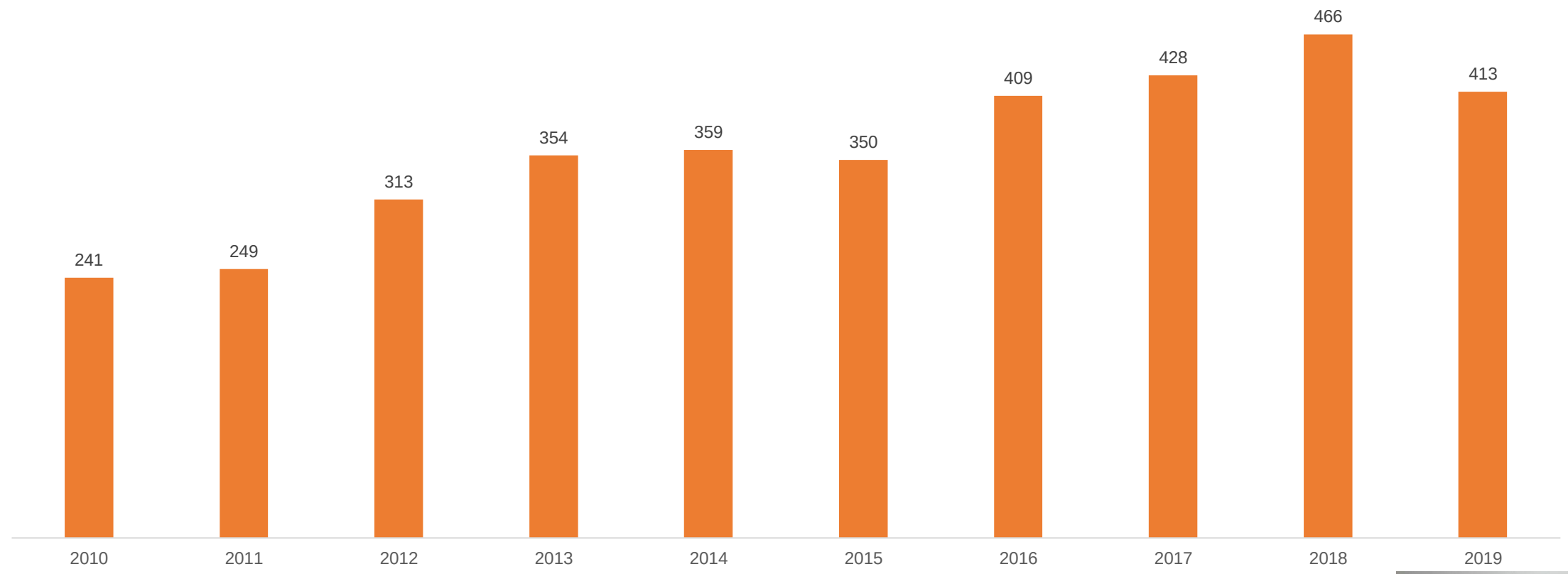
Testing for fetomaternal haemorrhage after 20 weeks gestation

SHOT Reporting - cumulative data



*Data on alloimmunisation has not been collected since 2015

Trend in anti-D Ig reports



Anti-D Ig errors 2010-2019

Event type	No. Cases
Omission or late administration of anti-D Ig	2553
Anti-D Ig given to a D-positive woman	217
Anti-D Ig handling & storage errors	215
Anti-D Ig given to a woman with immune anti-D	191
Wrong dose of anti-D Ig given	160
Anti-D Ig given to the mother of D-negative infant	132
Anti-D Ig given to the wrong woman	81
Miscellaneous	33
Totals	**3582**

Non-invasive prenatal testing for RhD

Cell free fetal DNA extracted from a maternal blood sample

Can be performed from 11 weeks gestation

Fetal D type predicted

Targeted use of anti-D Ig prophylaxis

False negative rate <0.1%

False positive rate <2%

- Incorrect test results
- Misinterpretation of the test results
- Failure to heed the test results

Case study 1: inappropriate administration of anti-D Ig

1. Patient refused blood products on religious grounds
2. A woman informed her midwife at booking that she was a Jehovah's Witness and did not wish to receive blood products
3. This was documented
4. She was administered anti-D immunoglobulin (Ig) despite this
5. There is no record of a discussion or documented consent in relation to the anti-D Ig

Case study 2: incomplete record keeping

- Ineffective recording of cffDNA result
- Anti-D Ig was given to a D-negative woman carrying a D-negative fetus

- The woman then presented late in pregnancy with reduced fetal movements and it was noted that she had not been given routine antenatal anti-D Ig prophylaxis (RAADP) so after checking with the laboratory it was given late

- The cffDNA result was not on the laboratory information management system (LIMS), however it was on Sp-ICE which was accessed the following day and the fetus was predicted to be D-negative

- In fact, this had also been accessed by the community midwife which is why RAADP had not been given, but this was not recorded
- There was no procedure in place for putting the cffDNA result onto the LIMS and therefore no way of ensuring that anti-D Ig prophylaxis is only given to those who need it

Common causes of errors

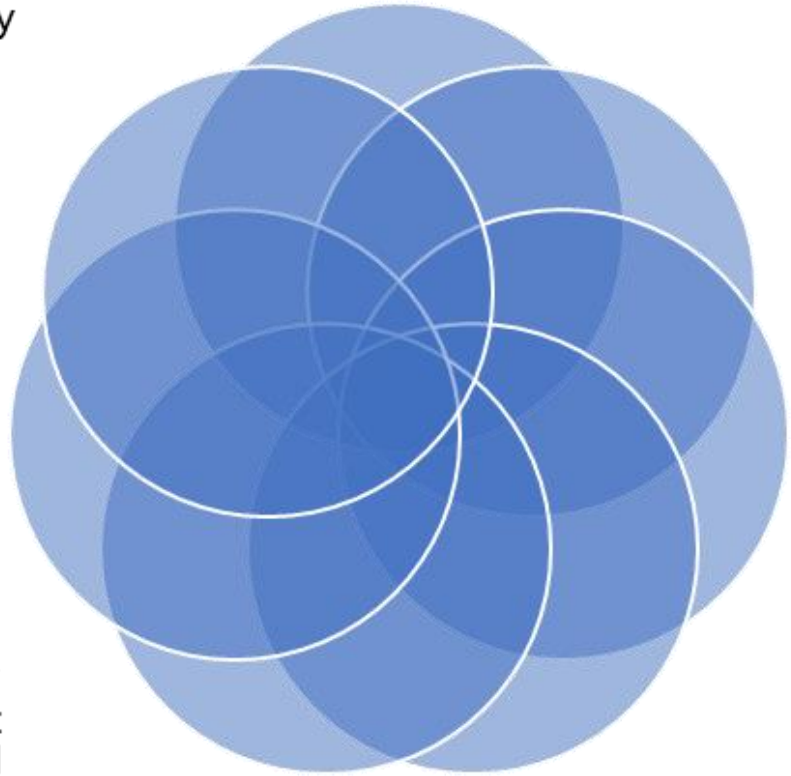
- Lack of communication between hospital and community midwifery teams, particularly in relation to early discharge
- Anti-D Ig not being administered within 72 hours for PSE and delivery
- Anti-D Ig being ordered from the laboratory but not administered. Largely associated with early discharge after a PSE or at delivery
- Checklists to prevent errors being ticked but not acted upon
- Lack of understanding among staff about when anti-D Ig is required

Systems failures

A lack of communication between hospital and community midwifery teams, and between midwifery teams and the laboratory

A lack of robust systems to identify outstanding work in the hospital laboratory

Assumption that someone else is dealing with the issue or has done their job correctly and a failure to take responsibility for the patient



Putting the onus on the patient to return for anti-D Ig when she is busy caring for a new baby, instead of issuing it at presentation

Manual transcription of blood group results onto notes, care plans and discharge sheets in the clinical area persists despite being repeatedly highlighted by SHOT as poor practice

Decision-making, issuing and administration of anti-D Ig without reference to blood group results or electronic information management systems, in both the laboratory and clinical area

Lack of knowledge and training, compounded by the holding of anti-D Ig stocks in the cli area with little oversight b laboratory

SHOT aide memoire

Anti-D Immunoglobulin (Ig) Administration to avoid sensitisation in pregnancy - an aide memoire

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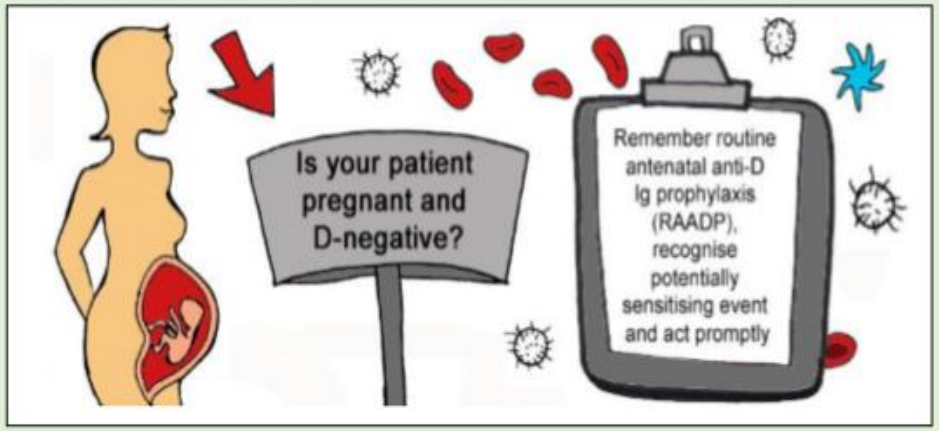
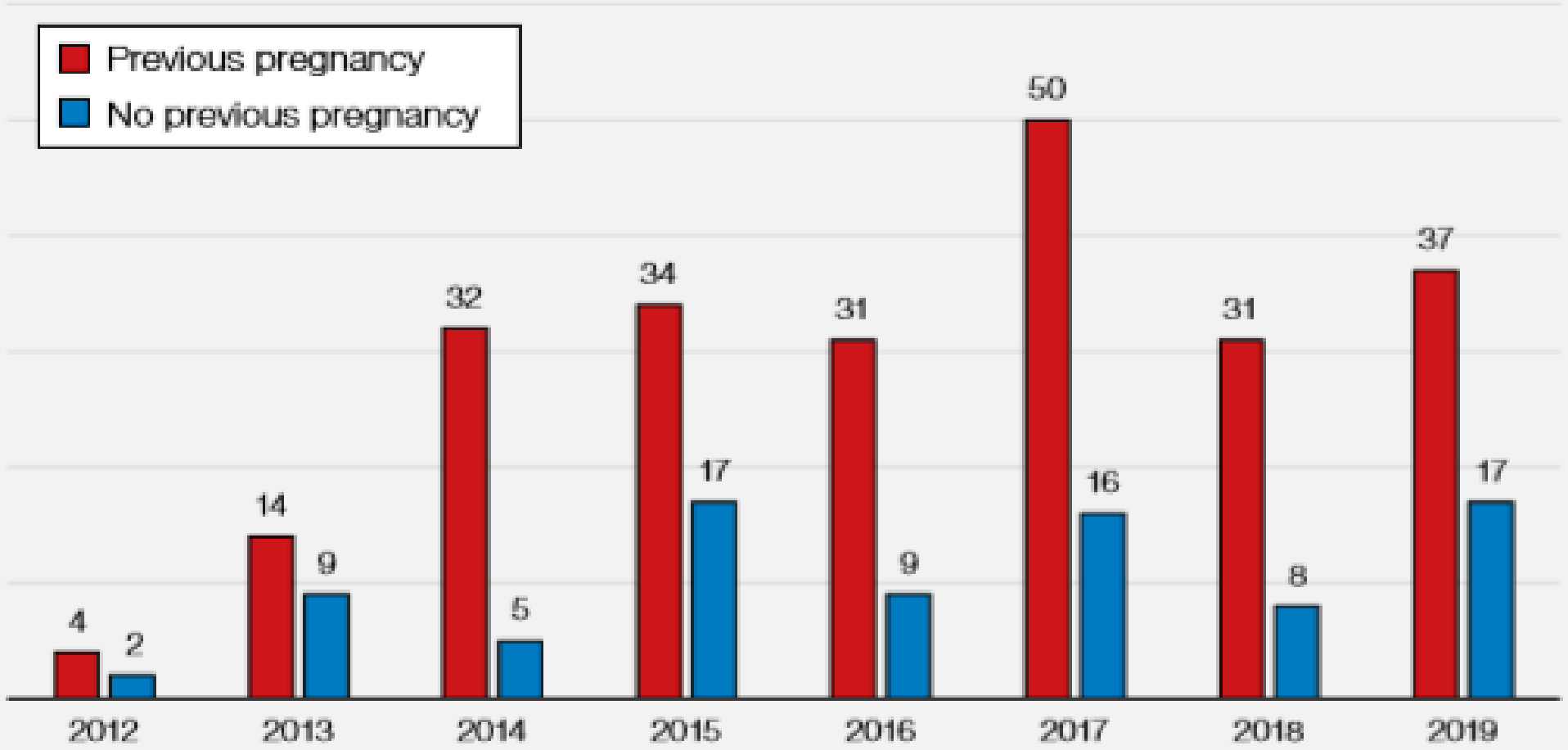
Key points to note:

- Women who are confirmed to have immune (allo) anti-D do not need (or should not receive) anti D Ig
- Where the results of the cffDNA (cell free fetal DNA) test are available and show that the fetus/baby is D-negative, anti-D Ig does not need to be given
- Confirm that the cffDNA result relates to the current pregnancy
- Person administering anti-D Ig should confirm the woman's' identity, discuss risk/benefits, gain informed consent and record in patient's notes. Confirm product dose and expiry date
- Following potentially sensitising events (*PSE- see appendix 1)*, anti-D Ig should be administered as soon as possible and always within 72 hours of the event. If, exceptionally, this deadline has not been met some protection may be offered if anti-D Ig is given up to 10 days after the sensitising event. After 10 days refer to local policy
- Each new sensitising event should be managed with an appropriate additional dose of anti-D Ig regardless of timing or dose of anti-D Ig administered for a previous event
- In the event of continual uterine bleeding which is clinically judged to represent the same sensitising event, with no features suggestive of a new presentation or a significant change in pattern or severity of bleeding, a minimum dose of 500 IU anti-D Ig should be given at 6 weekly intervals with 2 weekly estimations of fetomaternal haemorrhage (FMH)
- Appropriate tests for FMH should be carried out for all D-negative pregnancies when a PSE has occurred after 20 weeks of gestation and additional dose(s) of anti-D Ig should be administered as necessary
- Routine Antenatal Anti-D Ig Prophylaxis (RAADP) is a separate entity and should be always be given at the appropriate time in the second trimester, even if one or more doses of anti-D Ig for PSE have been administered
- Diagnosis AND delivery of intrauterine death (IUD) are 2 separate sensitising events



https://www.shotuk.org/wp-content/uploads/myimages/Anti-D-Aide-Memoire-July-2020.pdf

Immune anti-D



Immune anti-D: lessons from SHOT reporting

Cases of immunisation are still occurring even where current best practice is being followed

Cases of alloimmune anti-D found for the first time in pregnancy should be reported to SHOT, aiming to provide a complete data set after delivery

Obesity and delivery beyond 40 weeks remain as risk factors for sensitisation in cases which are otherwise ideally managed

Although managed in accordance with current guidelines, postpartum fetomaternal haemorrhage (FMH) >4mL, is an emerging possible risk factor

Following large FMH, every effort should be made to confirm all fetal cells are cleared, whilst balancing maternal contact and the upheaval of attending hospital repeatedly

There is a continued need to audit the anti-D pathway and provide ongoing education to clinical staff and pregnant women, and tools to support best practice

Case study 3: Large fetomaternal haemorrhage (FMH) where clearance of fetal cells was not checked

- A woman in her 30s, gravida 2 para 1 had anti-D detected at 7 weeks gestation with a quantification of 7.2IU/mL, which peaked at a quantification of 23.3IU/mL
- A cell-free fetal deoxyribonucleic acid (cffDNA) test at 16 weeks gestation predicted a D-positive fetus. A fetal intrauterine transfusion was given, and she delivered at 34+6
- Neonatal treatment for haemolytic disease of the fetus and newborn (HDFN) included phototherapy, immunoglobulin and exchange transfusion
- In the preceding pregnancy vaginal bleeding occurred at 16 weeks gestation and she received 1500IU anti-D Ig
- Routine antenatal anti-D Ig prophylaxis (RAADP) was given at 28 weeks gestation. She delivered at 35+6 by emergency caesarean section. A FMH of 79mL was confirmed by flow cytometry
- She received 12,000IU intravenous anti-D Ig, and the follow up FMH test at 48 hour showed 1mL fetal cells. She received a further 1500IU anti-D Ig, but it was not subsequently checked if the fetal cells had cleared completely

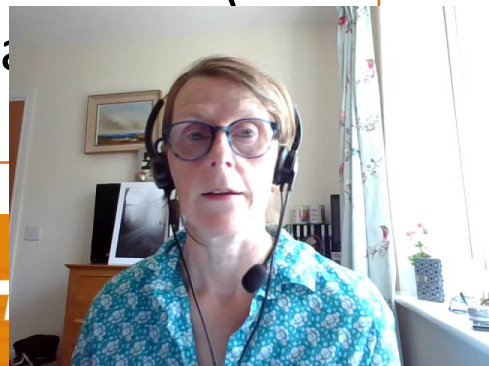
Case study 4: Failure to inform the laboratory of a potentially sensitising event (PSE)

Woman in her 30s, gravida 2 para 1, received routine antenatal anti-D Ig prophylaxis (RAADP) in the preceding pregnancy at 29 weeks

She experienced spotting at 35+2 weeks, but the midwife did not inform the laboratory so no prophylaxis was issued or given

She was delivered by elective caesarian section at 38+1 weeks and received appropriate anti-D Ig

In the next pregnancy alloimmune anti-D was detected at 28 weeks (not present at booking) and the infant was born at 38+2 weeks a
phototherapy



Key learning points

- Effective anti-D Ig prophylaxis is a partnership between the laboratory and the clinical area
- Women should not be discharged before anti-D is given
- Everyone needs knowledge and skills to play their role (midwives, clinicians, nurses, biomedical scientists)
- Requests for anti-D Ig should be driven by clinicians
- Clinical teams must be responsive to requests for follow-up from the laboratory
- NIPT should be implemented to target prophylaxis
- Thorough investigation of local incidents and near miss events

Improving awareness and educating patients is vital to improve safety as well

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Image from https://www.thecentrehki.co maternity-and-neonatal-safety-program-

Resources

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- Many more resources, including the 2019 Annual SHOT Report are available on the SHOT website

- In particular our educational resources
  - SHOT Bites
  - SHOTcasts
  - Webinars
  - Videos
  - Email signatures

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Resources

SHOT App

Download on the App Store

GET IT ON Google Play

SHOT Serious Hazards of Transfusion

Annual SHOT Symposium 2021

	Day one of the Annual SHOT symposium 2021: Wednesday 14 July 2021	
07:30-09:00	**Virtual platform open for delegates to attend exhibitor booths, view posters and network**	
08:00-09:00	**D1 Pre-symposium 'Meet the Experts' session – limited places available, entry in order of arrival**	
09:00-09:10	***Welcome by Prof Mark Bellamy (also chairing the sessions on day 1)***	
09:10- 09:40	Reflections, gratitude and optimism	Anthony Bennett, patient experience speaker
09:40-10:30	Making changes happen to improve safety	Helen Bevan, Chief Transformation Officer NHS Horizons
10:30-10:45	***Break time with exhibition, poster viewing and networking***	
10:45-11:45	Highlights from the 2020 Annual SHOT Report	Dr Shruthi Narayan, Medical Director SHOT
11:45-12:15	**Keynote speaker:** A just restorative culture – what does it mean and its impact on patient safety	Prof. Sidney Dekker, Professor at Griffith University in Brisbane, Australia, and Honorary Professor of Psychology at the University of Queensland, Australia
12:15-12:30	***Break time with exhibition, poster viewing and networking***	
12:30-13:30	**Panel discussion – moderated by Prof Mark Bellamy** Haemovigilance during the pandemic- challenges and lessons learnt – Panel discussion on key questions	Dr Barbee Whitaker, Lead General Health Scientist, Center for Biologics Evaluation and Research at FDA, USA Dr Mary Townsend, clinical pathologist and transfusion medicine specialist, USA Prof. Mindy Goldman Adjunct Professor, Department of Pathology and Laboratory Medicine, Faculty of Medicine, University of Ottawa Prof. Erica Wood (Transfusion Medicine Specialist, and Head of the Transfusion Research Unit at DEPM), Australia Prof. Jo Wiersum (Donor physician for the Dutch blood supply organisation, Sanquin) Dr Shruthi Narayan (Clinical Director SHOT) Chris Robbie (MHRA)
13:30-13:50		

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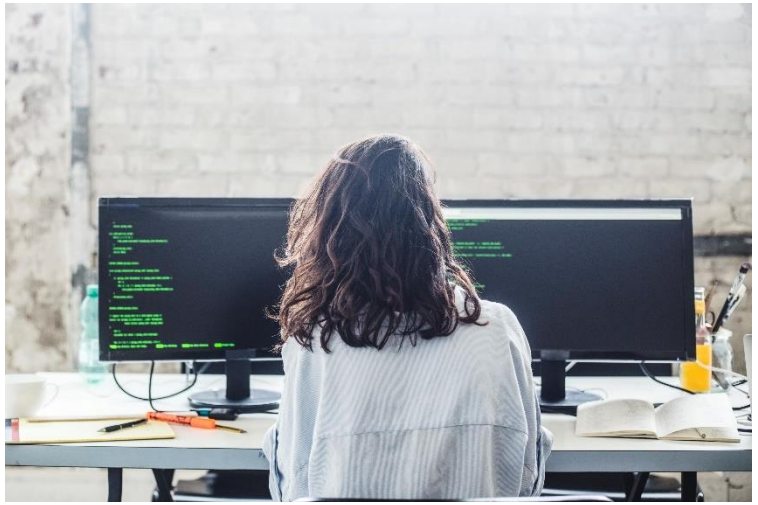

Annual SHOT Symposium 2021

Get in touch…

	Email shot@nhsbt.nhs.uk
	Tweet @SHOTHV1
	Call (+44)161 423 4208

Acknowledgements

- The vigilant reporters and hospital staff who share their incidents
- The SHOT team
- The Steering Group and Working Expert Group members
- MHRA haemovigilance team
- The UK Forum for funding

For further information visit: www.shotuk.org

Join us at the 2021 Annual SHOT Symposium

Wednesday 14th July and Thursday 15th July 2021 (Half day 08:30-14:00 on both days)

Full programme and registration available here: https://www.shotuk.org/annual-shot-symposium/annual-shot-symposium-2021/

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