SHOT Serious Hazards of Transfusion

NHS East of England Regional Transfusion Committee

Mums, Babies and Blood
Anti-D errors

Vera Rosa SHOT Incident Specialist

Laura Duffy Transfusion Practitioner and midwife

Learning points

- SHOT data related to anti-D Ig errors
- Anti-D Ig errors reported to SHOT in 2023
- SHOT case-studies and respective investigation of the most common errors reported to SHOT
- Share alternative actions

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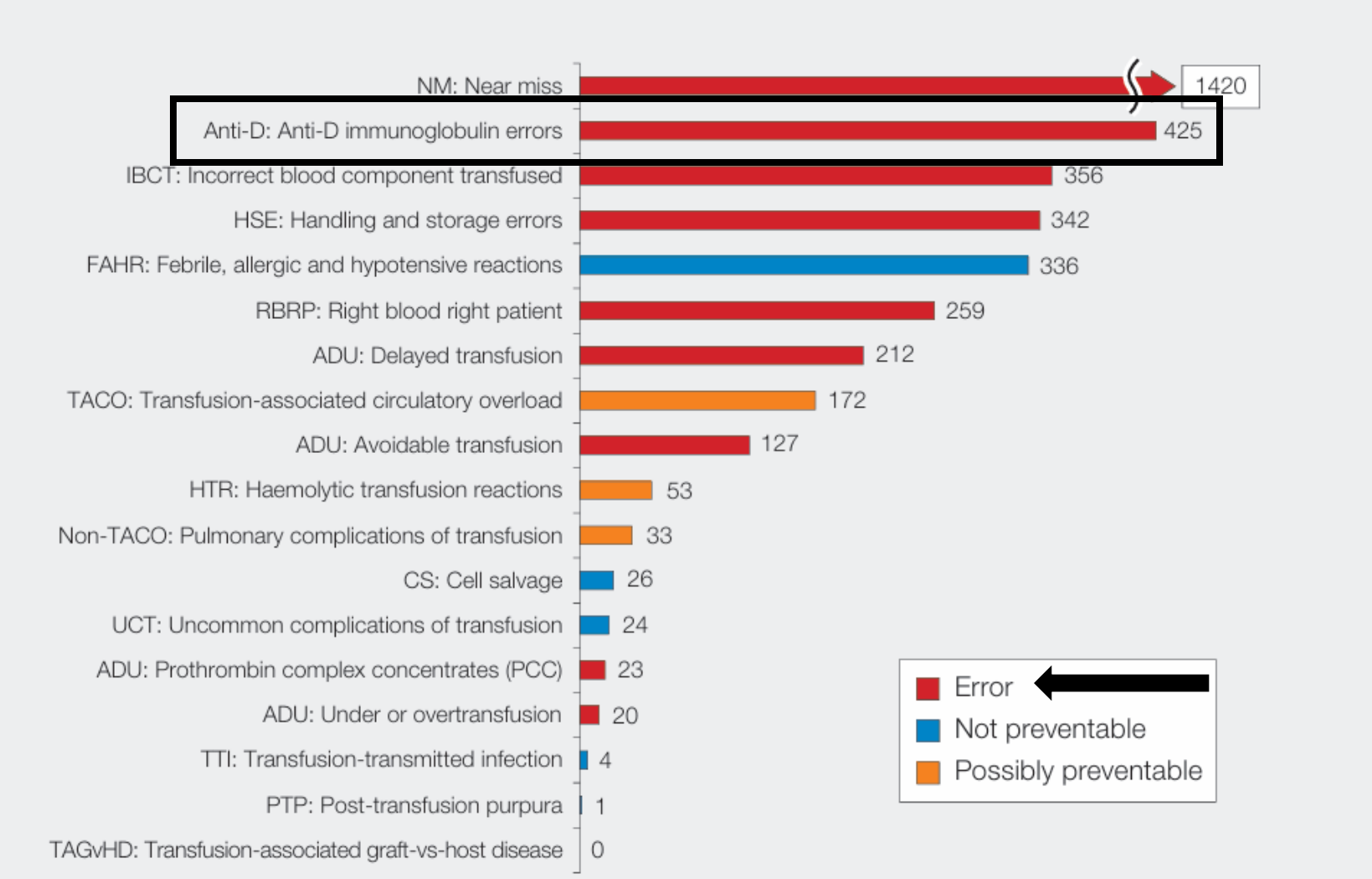
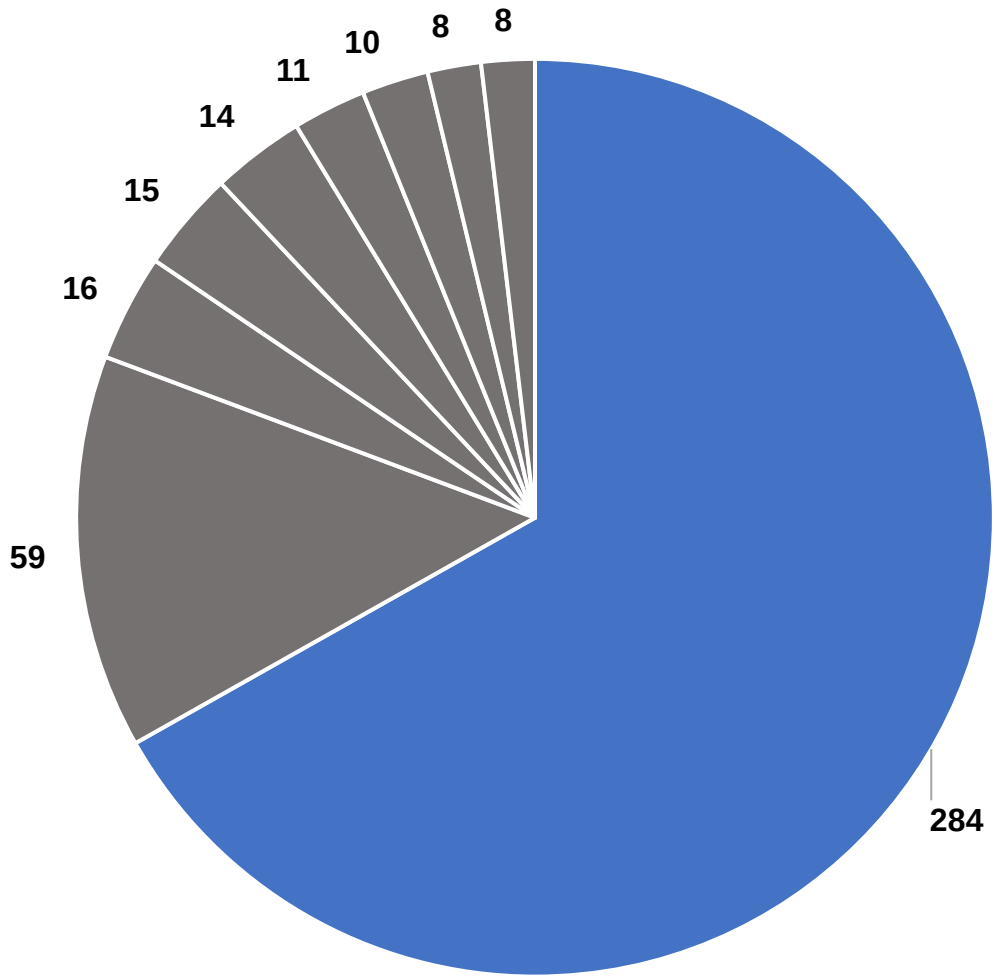
Summary 2023 SHOT data



2023 SHOT data – Anti-D Ig errors



- Omission or late administration of anti-D Ig
- Anti-D Ig given to the mother of a D-negative infant
- Wrong dose of anti-D Ig given
- Anti-D Ig given to a woman with immune anti-D
- Anti-D Ig handling and storage errors
- Anti-D Ig given to a D-positive woman
- Anti-D Ig given to the wrong woman
- Right product right patient
- Miscellaneous

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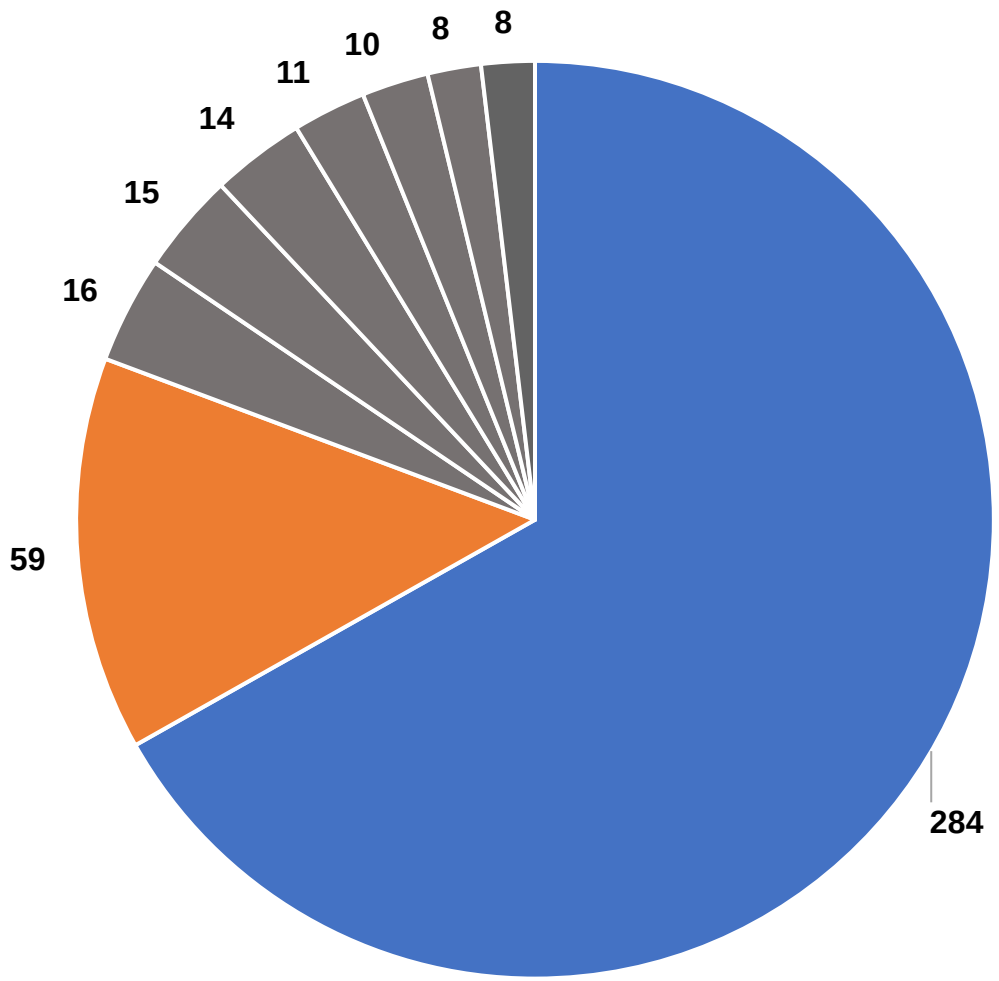

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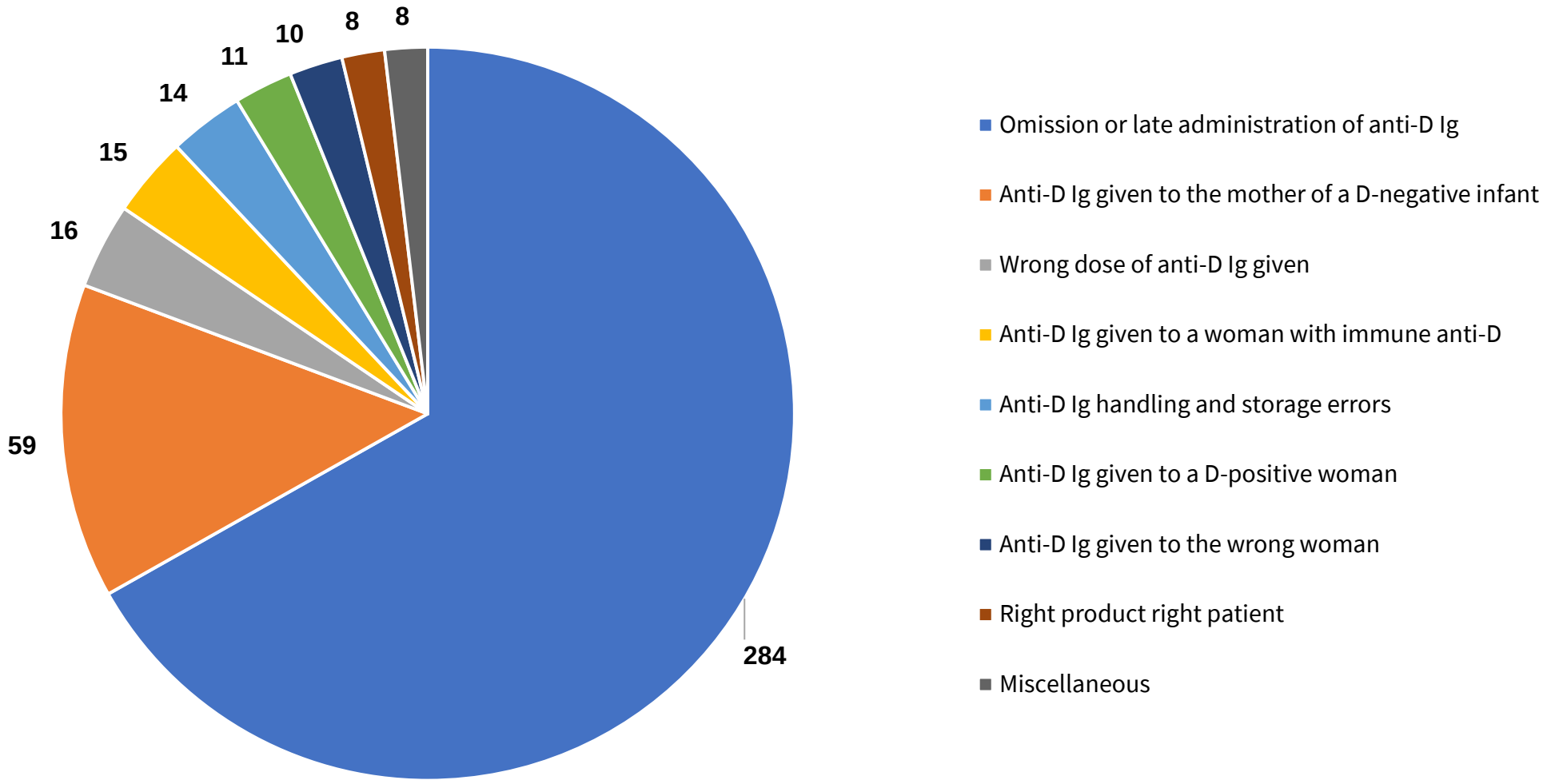
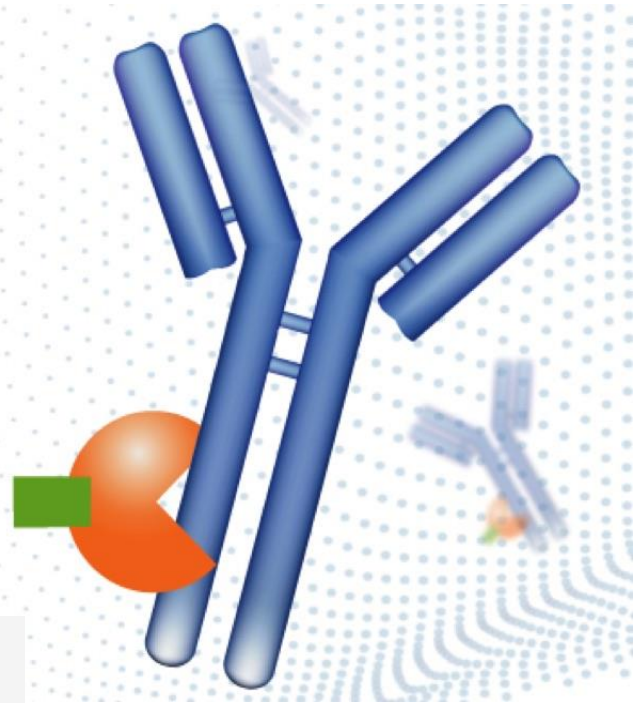


Why is important to avoid these errors?

Anti-D immunisation 2023 data
Outcome of pregnancy

No previous pregnancy n=7, all live births

- 2 - no treatment required
- 4 - required phototherapy
- 1 - required phototherapy exchange transf.



Previous pregnancy n=35

- 2 miscarriage
- 1 data missing
- 32 live births

17	No treatment
15	Treatment
6	Phototherapy
1	Phototherapy and IV fluids
2	Phototherapy and Immunoglobulin
1	Phototherapy, IV fluids, IV antibiotics and immunoglobulin
2	Phototherapy and top-up transfusions
1	Phototherapy, Immunoglobulin and exchange transfusion
1	Phototherapy, exchange transfusion and folic acid
1	Multiple transfusions

Case-studies

Case-study 1 – Discharged before administration

D-negative patient delivered D-positive baby. Kleihauer (KLH) was performed, and anti-D Ig was issued by the laboratory. Two days later the patient attended for NIPE but the requirement for anti-D Ig was not noted until the patient had left the ward. Patient was called back but could only attend after 72-hours post-delivery.

Communication issues between staff on delivery suite and postnatal ward were appointed as contributory factor.

Actions from incident review

- ✓Anti-D Ig log was added to the maternity fridge to track anti-D Ig received from laboratory. Included in the ward safety checks during night shifts
- ✓Laboratory introduced a failsafe to check maternity fridge and contact ward if anti-D Ig not collected
- ✓Communication sent out to all staff as a reminder to review patient's D-status when attending for NIPE
- ✓Highlighted when booking NIPE, anti-D Ig might be required as well as chasing Kleihauer results
- ✓Board to record the patients that require Kleihauer results chasing

Action effectiveness

Consider electronic tracking system with an alert to the lab if injection not collected

The majority do not need extra anti-D – as soon as baby group is known issue standard dose of anti-D. Keep the majority safe and save resources for chasing the minority

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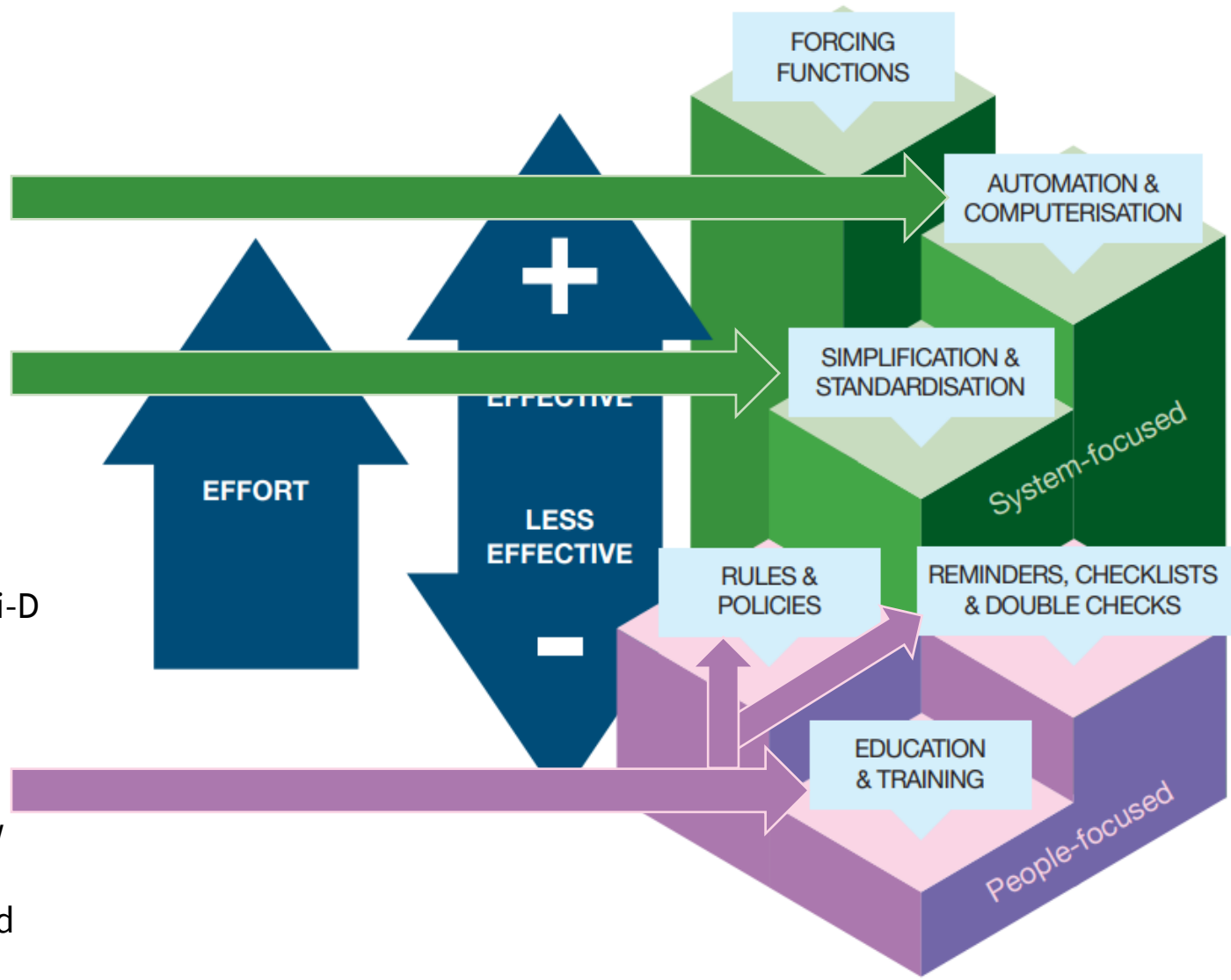

Adapted from the figure in 'From Discovery to Design: The Evolution of Human Factors in Healthcare' by Joseph A. Cafazzo and Olivier St-Cyr in the Healthcare Quarterly 15 (Special Issue) April 2012: 24-29.doi:10.12927/hcq.2012.22845

Case-study 2 – Knowledge gap relating to anti-D Ig requirement when cell salvage is used

D-negative patient received cell salvage during emergency caesarean section. The use of cell salvage was documented in theatre, but midwives failed to recognise the need for higher anti-D Ig dose and requested 500IU. Maternal and cord samples sent to the laboratory, but no information provided about the use of cell salvage. Kleihauer result was <2mL and the baby's group found to be D-positive. Patient received 500IU postnatally before being discharged.

The following day patient attended maternity triage and was re-admitted due to pre-eclampsia symptoms post-delivery. The next day, 4 days after delivery, midwife noticed the error before discharge and a further 1000IU was administered.

Actions from incident review

- ✓ Communication sent out to consultants and junior grades to share the incident and to remind the requirement for larger anti-D Ig doses when cell salvage is used
- ✓Blood conservation co-ordinator to share incident with the emergency theatre team and the importance of midwife's presence at 'sign out' from theatre where anti-D Ig requirements need to be discussed
- ✓Practice Development Midwife to publish a brief communication in the internal social media page for midwives to increase communication and awareness
- ✓Request for reviewing the transfusion request form as no box/section to inform blood transfusion laboratory that cell salvage was used
- ✓Midwife mandatory study day and PROMPT to include anti-D as part of the content
- ✓New electronic patient record system in maternity going live soon – lead midwife for the IT project to explore possibility of built in an alert for discharge form completion – prompting the midwife to check if cell salvage had been used

Action effectiveness

New electronic patient record system in maternity going live soon – lead midwife for the IT project to explore possibility of built in an alert for discharge form completion – prompting the midwife to check if cell salvage had been used

Change SOP to give 1500 iu from a set point in the pregnancy so 1500iu would be the standard dose

Communication sent out to consultants and junior grades to share the incident and to remind the requirement for larger anti-D dose when cell salvage is used

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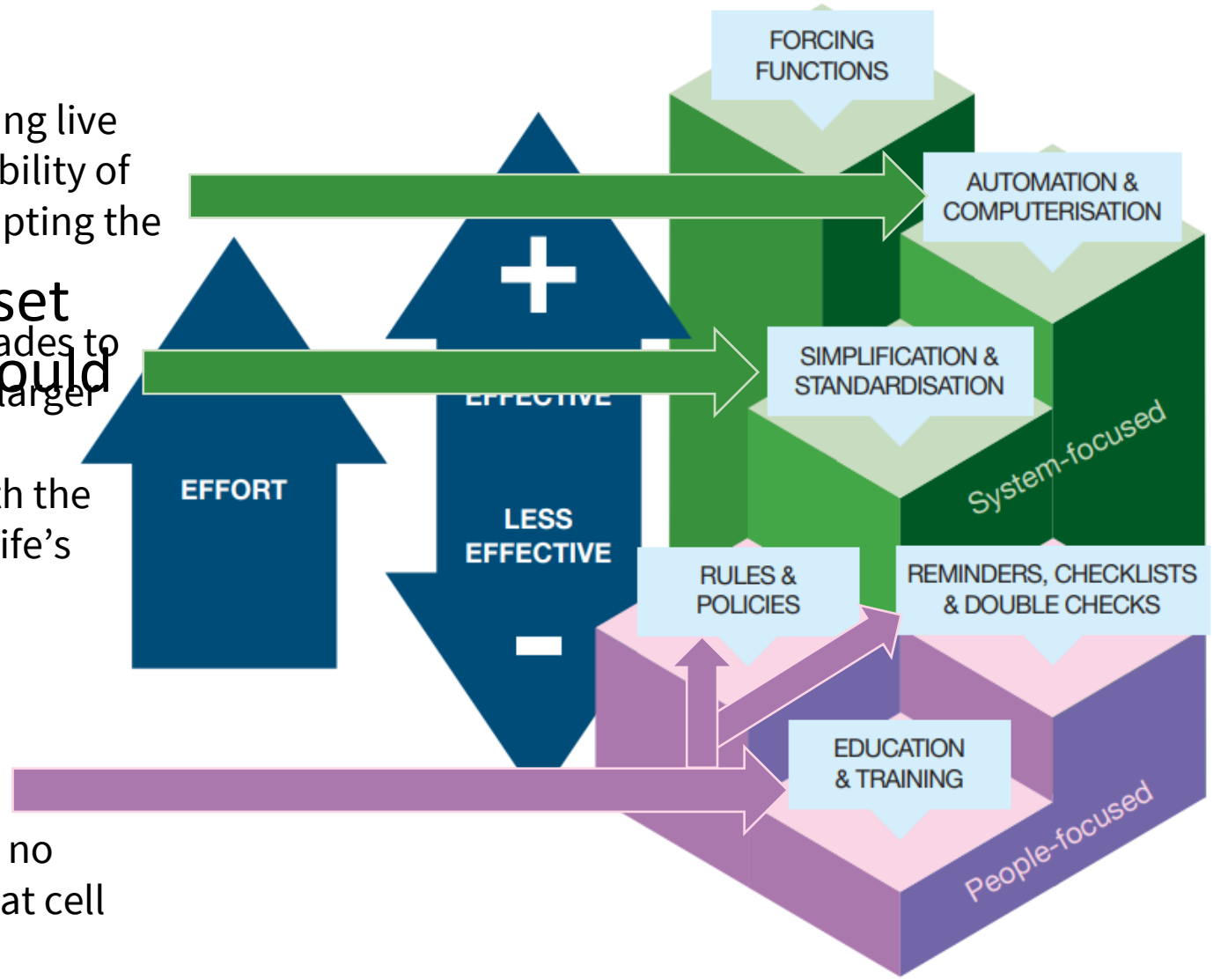

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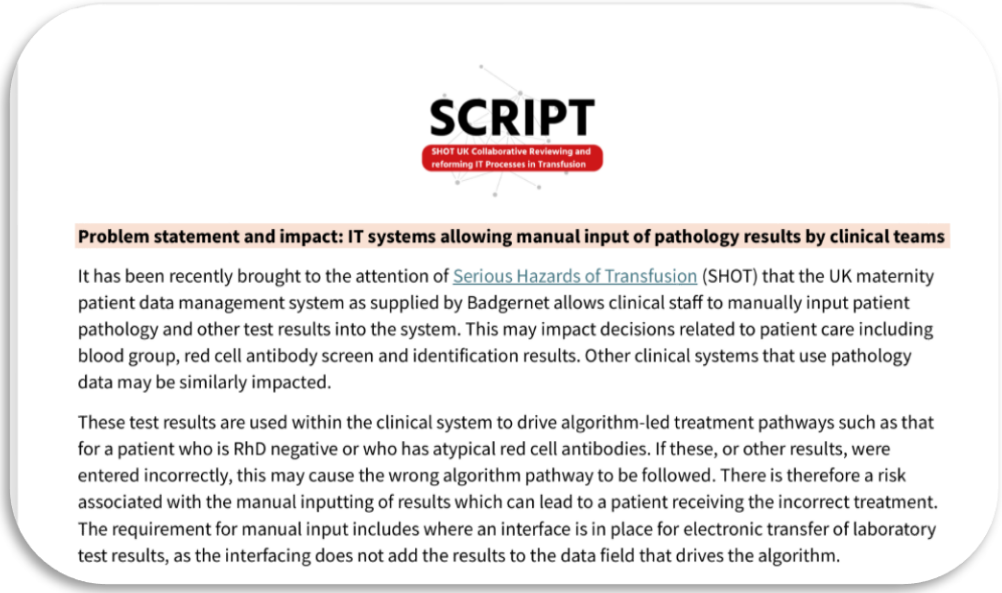
Case-study 3 – Incorrect manual input on maternity IT system results in late RAADP administration

Patient attended routine appointment at 35 weeks gestation with community midwife. During the appointment patient mentioned that her group is D-negative. When midwife checked the maternity IT system, noticed the patient's blood group had been entered as D-positive, which was discrepant to the results from the laboratory. Due to the transcription error, patient had not received RAADP at 28 weeks. RAADP given at 35 weeks gestation.

The main contributory factor identified was the lack of inter-operability between the main patient electronic record and the maternity electronic patient record.

Actions from incident review

- ✓Obstetric representative to provide feedback to the department and share this event
- ✓Patient's blood group to be checked on the main electronic patient record not on the maternity IT system
- ✓Liaise with the maternity record software team to determine safer IT solutions



SCRIPT

SHOT UK Collaborative Reviewing and reforming IT Processes in Transfusion

Problem statement and impact: IT systems allowing manual input of pathology results by clinical teams

It has been recently brought to the attention of Serious Hazards of Transfusion (SHOT) that the UK maternity patient data management system as supplied by Badgernet allows clinical staff to manually input patient pathology and other test results into the system. This may impact decisions related to patient care including blood group, red cell antibody screen and identification results. Other clinical systems that use pathology data may be similarly impacted.

These test results are used within the clinical system to drive algorithm-led treatment pathways such as that for a patient who is RhD negative or who has atypical red cell antibodies. If these, or other results, were entered incorrectly, this may cause the wrong algorithm pathway to be followed. There is therefore a risk associated with the manual inputting of results which can lead to a patient receiving the incorrect treatment. The requirement for manual input includes where an interface is in place for electronic transfer of laboratory test results, as the interfacing does not add the results to the data field that drives the algorithm.

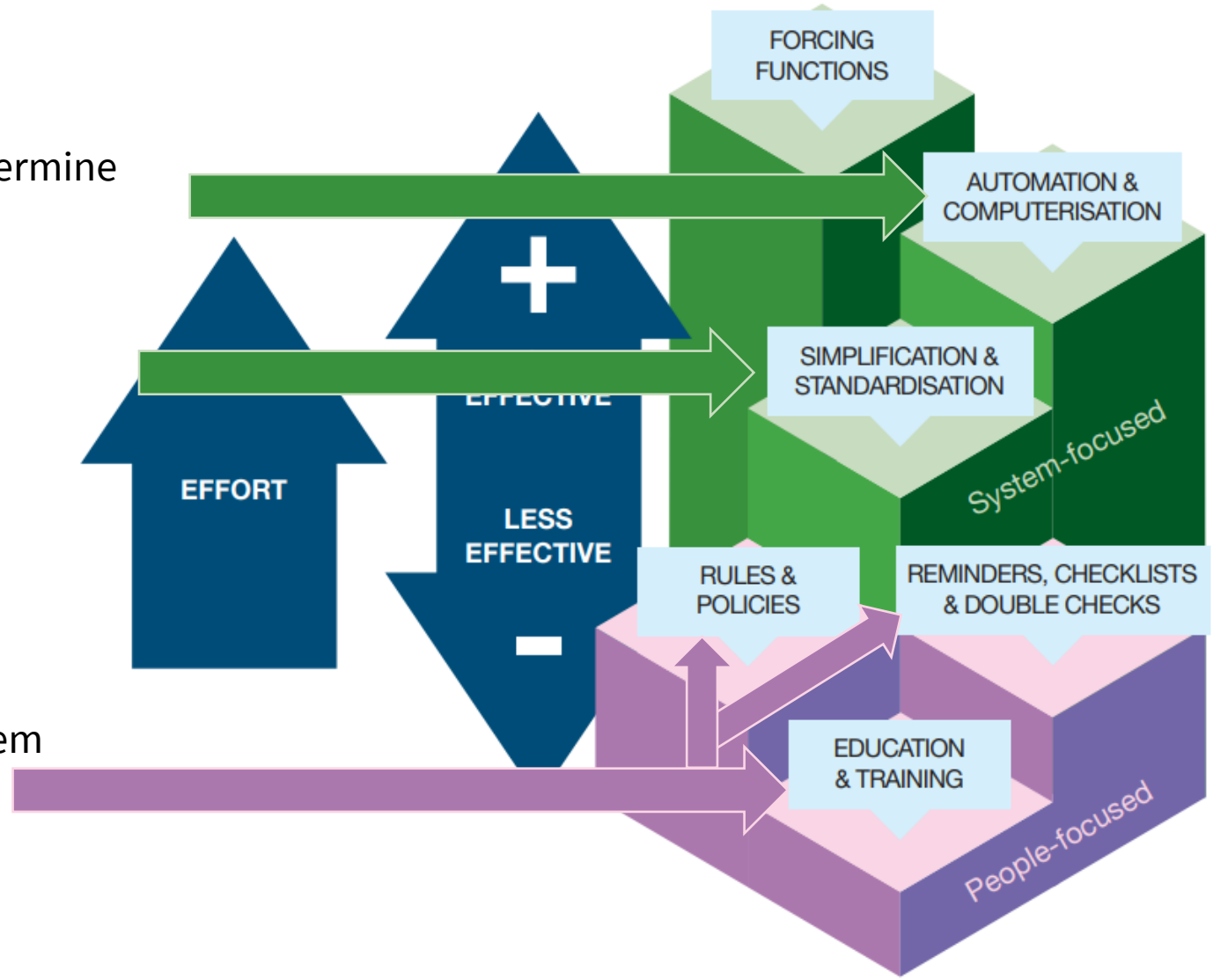
Action effectiveness

Liaise with the maternity record software team to determine safer IT solutions

Patient's blood group to be checked on the main electronic patient record not on the maternity IT system

Obstetric representative to provide feedback to the department and share this event

If results must be transcribed, have a double check step before they are deemed correct



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SHOT Resources

SHOT Bite No. 29
Differences of reporting errors related to anti-D Ig and immune anti-D
SHOT Serious Hazards of Transfusion
March 2024

Background

Immune anti-D

This category was introduced in 2012 as a separate study from the standard SHOT reporting categories. Accordingly, SHOT has been reviewing cases where immune anti-D has been detected for the first time, in the current pregn
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SHOT Bite No. 28
Cell-free fetal DNA (cffDNA) screening errors
SHOT Serious Hazards of Transfusion
November 2023

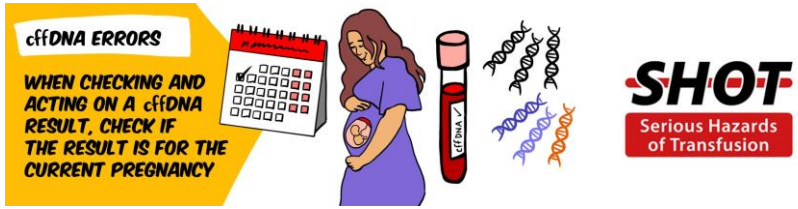
During pregnancy, fetal DNA is shed into the maternal blood system. This is referred to as cell-free fetal deoxyribonucleic acid (cffDNA). The cffDNA is cleared from the maternal circulation soon after delivery. Fetal DNA can be extracted from a maternal blood sample allowing for non-invasive prenatal testing (NIPT) for a variety of screening and diagnostic assays, including predicting the fetal D-type. In 2016, the National Institute for Health and Care Excellence (NICE) recommended high-throughput NIPT for fetal *RHD* genotype. In non-immunised women, the cffDNA screening testing predicts the fetal D-type for the current pregnancy so that D-negative pregnant mothers can avoid receiving antenatal anti-D Immunoglobulin (Ig) if carrying a D-negative baby. Since 2018, SHOT has been collecting data on anti-D Ig errors relating to cffDNA screening to provide recommendations for improvements in practice.

Useful facts relating to the cffDNA screening test

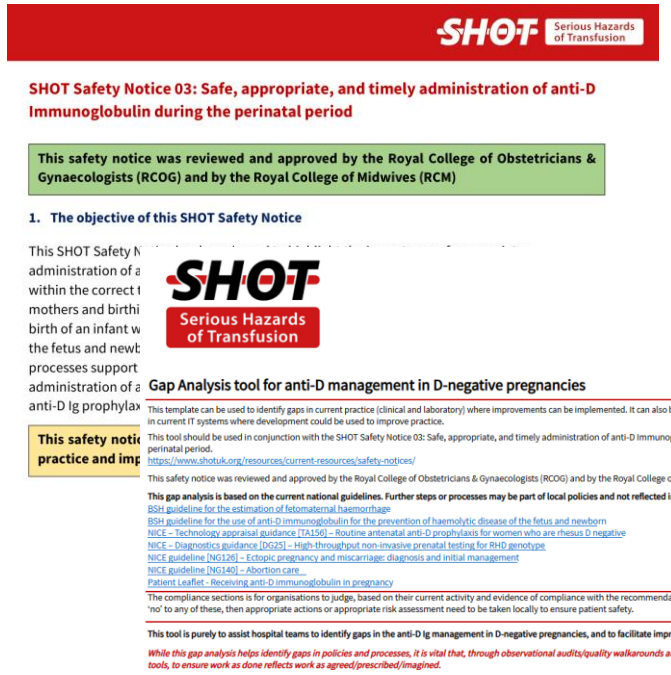
- Fetal *RHD* screening service is available from 11+2 weeks gestation in D-negative pregnancies
- This test is not indicated for pregnant women with immune anti-D In these cases, samples should be tested for non-invasive fetal genotyping (diagnostic testing)
- The assay has limitations, with sensitivity of 99.3% (95% confidence interval [CI] 0.982-0.997) and specificity of 98.4% (95% CI 0.964-0.993) (Mackie et al. 2017), leading to a small risk of false-positive or false-negative cffDNA screening results
- False-positive and false-negative cffDNA screening results should be reported to SHOT and to the test provider to assess accuracy of the test
- False positives can be due to vanishing twin, extraneous assay or sample contamination, wrong blood in tube (WBIT), error (human or mechanical) in testing and presence of genes but antigen not expressed on red cell. False negatives can result from insufficient fetal DNA, WBIT or error (human or mechanical) in testing
- Errors related to interpretation, reporting by hospitals or availability of cffDNA screening results should also be submitted to SHOT

Summary of cases reported to SHOT 2019-2022: SHOT analysed 127 cases relating to cffDNA screening during this period

Failure to check cffDNA screening results prior to order, release or administration of anti-D Ig leading to inappropriate administration of anti-D Ig to mother with D-negative fetus	47
Cord blood D-type discrepant with predicted D-type – false positive leading to inappropriate administration of anti-D Ig to mother with D-negative fetus	34
Cord blood D-type discrepant with predicted D-type – false negative leading to omission of anti-D Ig	24
Misinterpretation or misunderstanding cffDNA screening results causing unnecessary administration or omitted administration of anti-D Ig	14
Results not available to the clinical team due to a laboratory delay in entering cffDNA screening results into the laboratory information management system (LIMS) leading to inappropriate administration of anti-D Ig to mother with D-negative fetus	2
The cffDNA result checked prior to administration of anti-D Ig was from a previous pregnancy causing unnecessary administration or omitted/late administration of anti-D Ig	2
Miscellaneous – incorrect advice from laboratory, WBIT (cord sample), transcription error and patient insistence on received anti-D Ig despite cffDNA screening predicting D-negative fetus	4



Alternative video format:



SHOT Serious Hazards of Transfusion

SHOT Safety Notice 03: Safe, appropriate, and timely administration of anti-D Immunoglobulin during the perinatal period

This safety notice was reviewed and approved by the Royal College of Obstetricians & Gynaecologists (RCOG) and by the Royal College of Midwives (RCM)

1. The objective of this SHOT Safety Notice

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SHOT Serious Hazards of Transfusion

Gap Analysis tool for anti-D management in D-negative pregnancies

This template can be used to identify gaps in current practice (clinical and laboratory) where improvements can be implemented. It can also be used to identify gaps in current IT systems where development could be used to improve practice.

This tool should be used in conjunction with the SHOT Safety Notice 03: Safe, appropriate, and timely administration of anti-D Immunoglobulin during the perinatal period.
https://www.shotuk.org/resources/current-resources/safety-notices/

This safety notice was reviewed and approved by the Royal College of Obstetricians & Gynaecologists (RCOG) and by the Royal College of Midwives (RCM)

This gap analysis is based on the current national guidelines. Further steps or processes may be part of local policies and not reflected in this gap analysis.

BSH guideline for the estimation of fetomaternal haemorrhage
BSH guideline for the use of anti-D immunoglobulin for the prevention of haemolytic disease of the fetus and newborn
NICE – Technology appraisal guidance [TA156] – Routine antenatal anti-D prophylaxis for women who are rhesus D negative
NICE – Diagnostics guidance [DG25] – High-throughput non-invasive prenatal testing for RHD genotype
NICE guideline [NG126] – Ectopic pregnancy and miscarriage: diagnosis and initial management
NICE guideline [NG140] – Abortion care
Patient Leaflet - Receiving anti-D immunoglobulin in pregnancy

The compliance sections is for organisations to judge, based on their current activity and evidence of compliance with the recommendation. If the answer is 'no' to any of these, then appropriate actions or appropriate risk assessment need to be taken locally to ensure patient safety.

This tool is purely to assist hospital teams to identify gaps in the anti-D Ig management in D-negative pregnancies, and to facilitate improvement actions.

While this gap analysis helps identify gaps in policies and processes, it is vital that, through observational audits/quality walkarounds and other relevant tools, to ensure work as done reflects work as agreed/prescribed/imagined.

Thank you for listening