8 Adverse Events Related to Anti-D immunoglobulin (Ig) n=413

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Definition:

An adverse event related to anti-D immunoglobulin (Ig) is defined as related to the prescription, requesting, administration or omission of anti-D Ig which has the potential to cause harm to the mother or fetus immediately or in the future.

Key SHOT messages

- Cell-free fetal deoxyribonucleic acid (cffDNA) results were incorrect in 5 cases. Please report all such cases to SHOT
- There appears to be a misunderstanding of the need for routine antenatal anti-D Ig prophylaxis (RAADP) when a recent dose of anti-D Ig had been administered for a potentially sensitising event (PSE)
- Due to the potential for transcription errors on handheld records, clinical decisions must be based on blood results reviewed on an electronic interface
- Robust protocols and systems for refrigerator monitoring and traceability must be in place and adherence monitored as part of normal ward/department/Trust/Health Board assurance metrics

Abbreviations used in this chapter

cffDNA	Cell-free fetal deoxyribonucleic acid	**NICE**	National Institute for Health and Care Excellence
HSE	Handling and storage errors	**PSE**	Potentially sensitising event
Ig	Immunoglobulin	**RAADP**	Routine antenatal anti-D Ig prophylaxis

Recommendations

- Delivery suites should review early discharge procedures to avoid omission or late administration of anti-D immunoglobulin (Ig)
- In cases of early discharge, consideration should be given to administration of anti-D Ig on day two of delivery in the community

Action: Maternity units, maternity governance departments and hospital transfusion laboratories or pharmacy departments

Introduction

SHOT reports related to the provision of anti-D Ig totalled 413. Late administration or omission of anti-D Ig account for 271/413 (65.6%), the theme for these errors appears to be lack of knowledge amongst staff and about those of childbearing potential with D-negative blood groups, or insufficiently robust procedures. These cases should be viewed with concern due to the potential to develop immune anti-D.

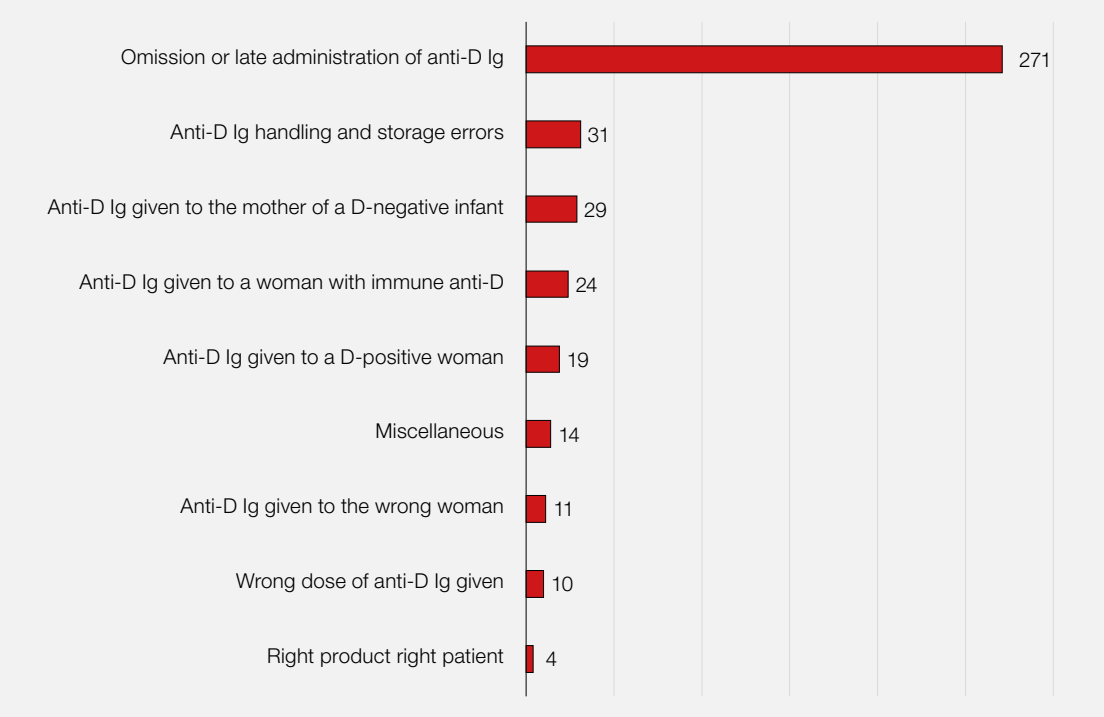


Figure 8.1: Distribution of anti-D Ig related error reports 2019 n=413

Death n=0

There were no deaths reported during 2019 related to errors in anti-D Ig administration.

Major morbidity n=0

There were no reported cases of immune anti-D following errors in clinical management of pregnancy in 2019. It should be noted that immune anti-D may not be evident until a subsequent pregnancy and the anonymity of SHOT reports is such that we cannot link cases of immune anti-D to a reporting year unless specified. **Nevertheless, all cases of alloimmune anti-D identified in pregnancy should be reported to SHOT.**

Omission or late administration of anti-D Ig n=271 (65.6%)

The three areas of care where late administration or omission of anti-D Ig are most implicated are management within 72 hours of a PSE 129/271 (47.6%), RAADP 63/271(23.2%) and at delivery 79/271 (29.1%). Whilst small numbers, there are reports where a pregnant person treated in the emergency department did not receive anti-D Ig 9/129 (7.0%) for a PSE.

There have been 8 reported cases of an incorrect medical decision to omit RAADP following a recent administration of anti-D Ig due to a PSE.

The submitted reports indicate that areas have tried to address the causes of these errors by using checklists or stickers on the front of the case notes, often the checklist is ticked but no action taken. Thomassen et al. (2011) describe the use of checklists as a tool to aid cognition, realising how prone humans are to short term memory loss. If used, a checklist should only be ticked as completed when the task has been completed. Simply ticking it, intending to complete the task negates the intended benefit.

In busy day case areas or delivery suites prompt discharge is appropriate but more robust procedures are required to ensure treatment within the 72-hour window. Delivery suites should consider administration on day two of delivery in the community. A discharge checklist with communication between teams is vital to ensure timely administration. Maternity or gynaecology/early pregnancy day case units should include administration of anti-D Ig for a D-negative birth parent as part of their care pathways. SHOT has produced an anti-D Ig administration aide memoir (https://www.shotuk.org/resources/current-resources/) to assist clinical teams when writing their guidelines and pathways.

There were 20 reports of non-attendance for administration of anti-D Ig, some people refused to wait for the injection or refused to return, these have been removed from the overall numbers as no error was made by the healthcare professionals, but this could be the tip of the iceberg. It does suggest that more robust pathways and more effective education of the risks of D-negative blood group in pregnancy may be required.

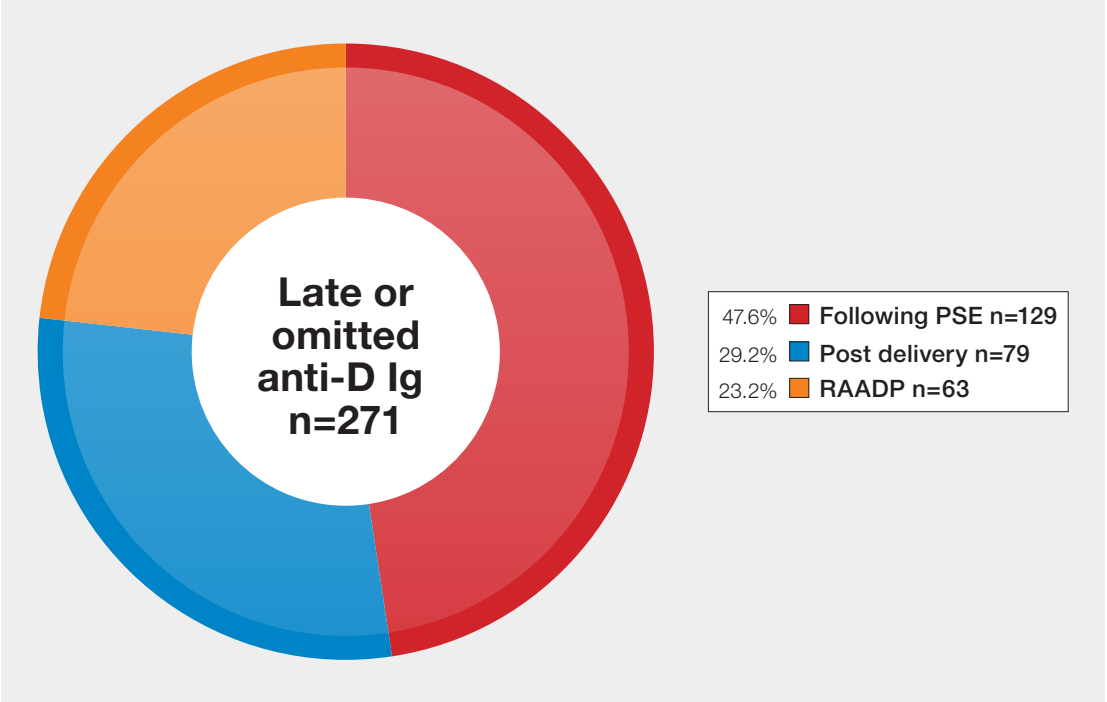
Case 8.1: Patient refused blood products on religious grounds

A woman informed her midwife at booking that she was a Jehovah's Witness and did not wish to receive blood products. This was documented. She was administered anti-D Ig despite this. There is no record of a discussion or documented consent in relation to the anti-D Ig.

This case illustrates the need for robust pathways and raises the question of whether all staff realise anti-D Ig is a blood product.

There were 10 cases where all antenatal appointments were attended, there was a recorded D-negative blood group and yet no RAADP was administered throughout the pregnancy.

Figure 8.2: The three main areas for late administration or omission of anti-D Ig 2019 n=271



Cell-free fetal deoxyribonucleic acid (cffDNA) n=5

There have been 5 reported cases of incorrect cffDNA results. Three were predicted D-negative and 2 D-positive. In each case the healthcare teams acted for the predicted results. All 3 cases re-checked the blood group results at birth, believing there to be a wrong blood in tube (WBIT) error. When results were consistent for the revised group the International Blood Group Reference Laboratory (IBGRL) was informed. Unfortunately, the samples were no longer available at the IBGRL to reference. SHOT will continue to monitor this and encourage reporting.

Overview of cases

Most errors occurred in the hospital setting and within normal working hours (08:00-20:00). Clinical staff were implicated in 340/413 (82.3%) cases. This would suggest that a review of care pathways and guidelines may be appropriate.

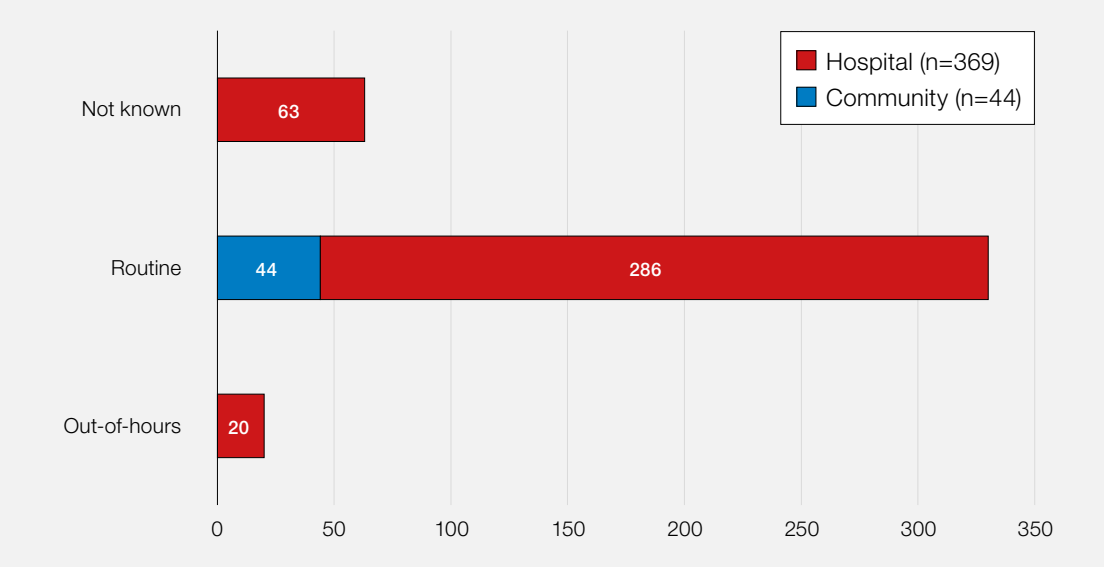


Figure 8.3: Location and time of errors associated with anti-D Ig administration

Recurring themes identified were:

- 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 both 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

Manual transcription errors n=5

There were 5 reported cases where a manual entry of a blood group and D status into handheld records resulted in an omission of anti-D Ig. In each case the results were available on an electronic results system and easily accessible. Handheld records clearly have their place, but care must be taken when inputting results. When a clinical decision is based on blood results they should be reviewed on an electronic interface.

Handling and storage errors (HSE) n=31

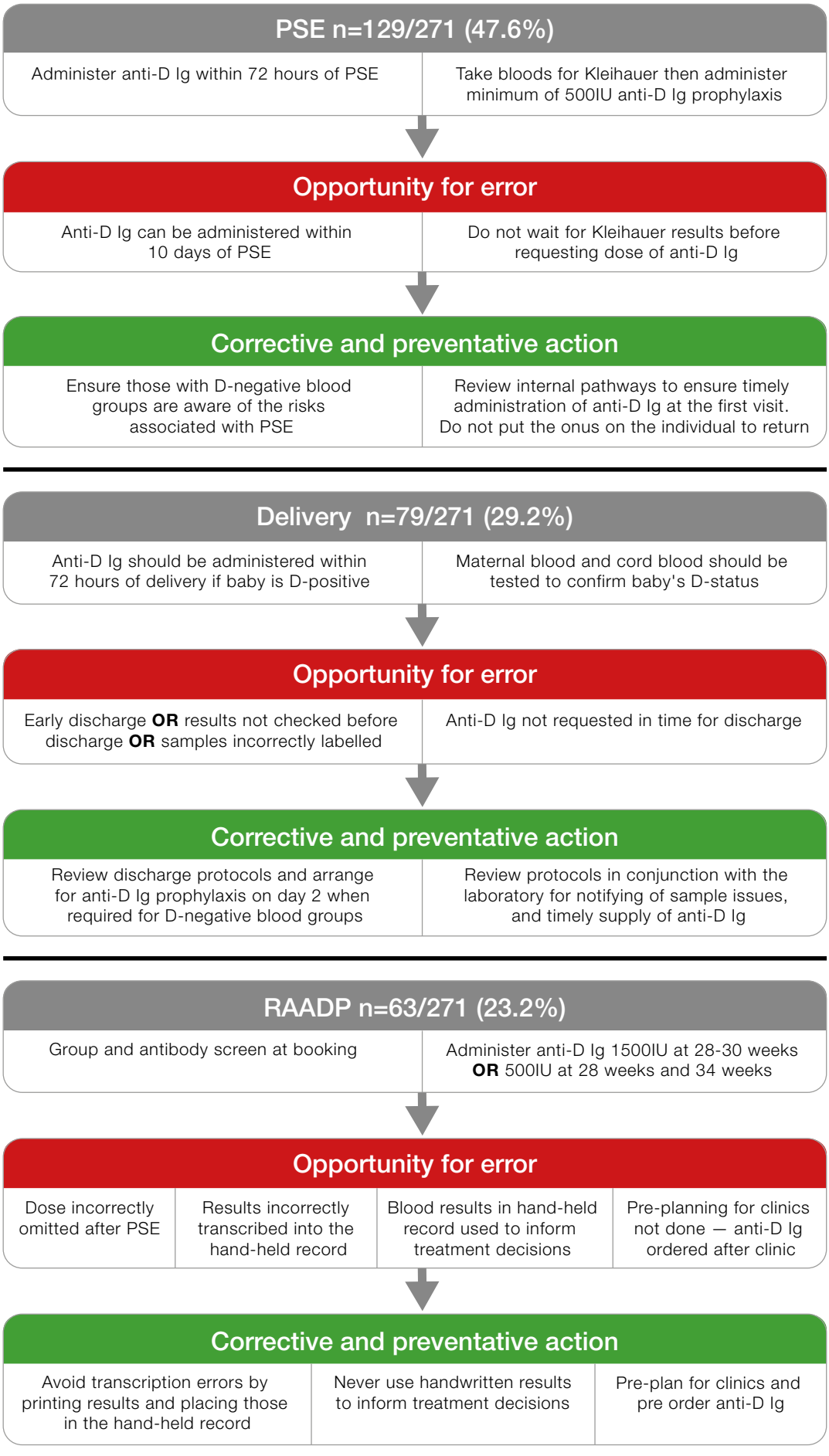
The number of HSE included in the report is misleading as there were 2 cases involving large numbers of individuals, 1 of 25 doses and the other 372. The multiple instances have not been included in the overall figures because the required traceability is not available.

The first was a laboratory error where anti-D Ig was inappropriately stored at refrigerator temperatures ranging from 8-9^{0}C (instead of the manufacturer's recommended 2-8^{0}C). Over 4 days anti-D Ig was issued and administered to multiple recipients.

The second was a refrigerator on a maternity unit with anti-D Ig dispensed and monitored by pharmacy. The refrigerator had been monitored daily by staff on the unit and the temperature recorded, but no action was taken when the refrigerator was recorded as being outside of controlled temperature continuously during a 3-month period. During this period 372 doses of anti-D Ig were issued, however there was no traceability to determine which refrigerator the anti-D Ig had been stored in. Approximately 50 recipients had delivered D-negative babies and the hospital intended to recall the remaining recipients who were cared for during this period for testing due to concerns about the efficacy of the anti-D Ig.

Robust protocols and systems for refrigerator monitoring and traceability must be in place and adherence monitored as part of normal ward/department/Trust/Health Board assurance metrics.

Figure 8.4: Overview of late administration or omission of Anti-D Ig



Learning points

- Handheld records can contain manual transcription errors of blood results and should not be used to make clinical decisions
- Routine antenatal anti-D Ig prophylaxis (RAADP) should be administered according to Trust/Health Board policy and in accordance with National Institute for Health and Care Excellence (NICE) guidance and not omitted if the woman has had a recent potentially sensitising event (PSE)

Near miss cases n=33

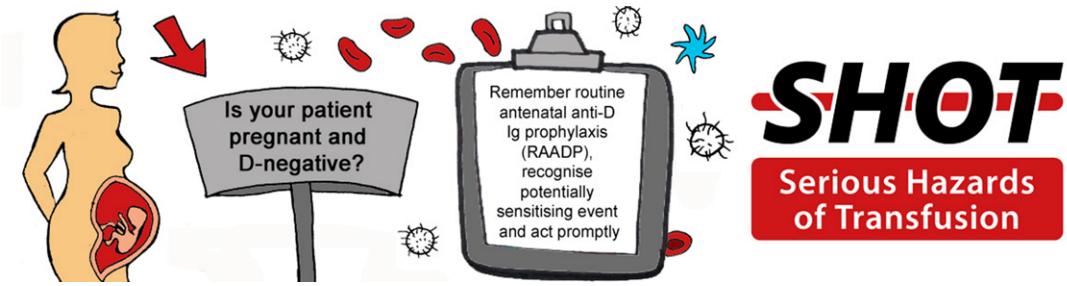
Near miss incidents involving the laboratory numbered 23 with the majority involving errors in sample receipt and registration. The remaining 10 clinical errors largely involved failure to follow standard operating procedures or were transcription errors.

IT-related anti-D Ig cases n=13

Further details of the IT-related reports can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2019/).

Conclusion

The overall number of reports is similar to 2018. SHOT has developed an aide memoire to remind staff when anti-D Ig should be administered, but it is incumbent on all maternity units and gynaecology early pregnancy units to review their care pathways and develop robust systems to address avoidable omissions or late administration of anti-D Ig.



References

Thomassen Ø, Espeland A, Søftelan E, et al. (2011) Implementation of checklists in health care; learning from high-reliability organisations. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3205016/ [accessed 08 June 2020].