Adverse Events Related to Anti-D Immunoglobulin (Ig) n=466

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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

- A total of 466 reports related to errors involving anti-D immunoglobulin (Ig) were reviewed by SHOT in 2018. In 272/466 (58.4%) the reports related to the omission or late administration of anti-D Ig. This is an ongoing and concerning trend that results in large numbers of women being put at risk of sensitisation to the D antigen which could have associated morbidity and mortality in affected neonates
- Cell-free fetal deoxyribonucleic acid (cffDNA) testing is being carried out more widely, but there are indications that clinicians are not acting on the results
- There is evidence of misunderstanding of routine antenatal anti-D Ig prophylaxis (RAADP) and the need for **additional** anti-D Ig for any potentially sensitising events (PSE)
- There is evidence to indicate that anti-D Ig is not being administered in response to PSE. This is particularly happening in departments whose main expertise may not be management of pregnancy
- Women seem to be unaware of the importance of reporting PSE in a timely manner which is resulting in them receiving anti-D Ig later than the recommended 72 hours post PSE
- There continues to be poor communication between hospital and community midwifery teams regarding the need for anti-D Ig, particularly in the care of those women who have early hospital discharges

Recommendations

- All staff involved in the requesting, issuing and administering of anti-D immunoglobulin (Ig) must have received appropriate training and education in relation to anti-D Ig, such as completion of the anti-D Ig module in the Learn Blood Transfusion (LBT) e-learning package (www.learnbloodtransfusion.org.uk)

Action: Hospital Transfusion Laboratories, Hospital Transfusion Committees, Trust/Health Board Chief Executive Officers (CEO), Obstetric Departments, Community Midwifery Teams, Early Pregnancy Units, Emergency Departments

- Midwives must be vigilant with correct sample taking and labelling technique when taking samples for cell-free fetal deoxyribonucleic acid (cffDNA) testing, and then check and document the results clearly

Action: Community Midwifery Teams, Obstetric Departments

- Maternity services need to have systems in place to ensure that those women who are D-negative understand the importance of anti-D Ig prophylaxis in the event of a potentially sensitising event (PSE). It is also vital that women understand what constitutes a PSE in order for them to know when to attend for care

Action: Community Midwifery Teams, Obstetric Departments, General Practitioners

Commentary

This year's Annual SHOT Report, once again emphasises persistent misunderstandings about the provision of anti-D Ig. Due to this ongoing lack of knowledge and understanding, women continue to be put at risk of sensitisation.

The persistent high numbers of reports of late administration or omission of anti-D Ig reveal insufficient understanding of the importance of anti-D Ig being administered within 72 hours following a PSE. This issue applies to both clinical staff and the D-negative women concerned. There were a number of reports this year where women did not report the PSE until after 72 hours had passed. These reports are not included in the overall numbers in this chapter, as there was no error made by the healthcare professionals involved, however, these women are still at risk of sensitisation. Guidance on the use of anti-D Ig should be followed (BSH Austin et al. 2009, BSH Qureshi et al. 2014, BSH White et al. 2016, NICE 2012 and NICE 2016).

Deaths n=0

There were no deaths reported that related to errors associated with anti-D Ig in 2018.

Major morbidity n=0

No women were reported to have developed immune anti-D following errors in clinical management in 2018. However, the follow up on cases is short and alloimmune anti-D may not be evident until the next pregnancy. It is therefore important that any new cases of alloimmune anti-D identified in pregnancy are reported to SHOT, so that a real picture can be compiled of the implications of the errors reported.

Potential for major morbidity n=272

In 2018, 272 of the reports received related to the omission or late administration of anti-D Ig. These incidents all have the potential for the women involved to develop an immune anti-D and are therefore a considerable concern for the risk of fetal morbidity in future pregnancies.

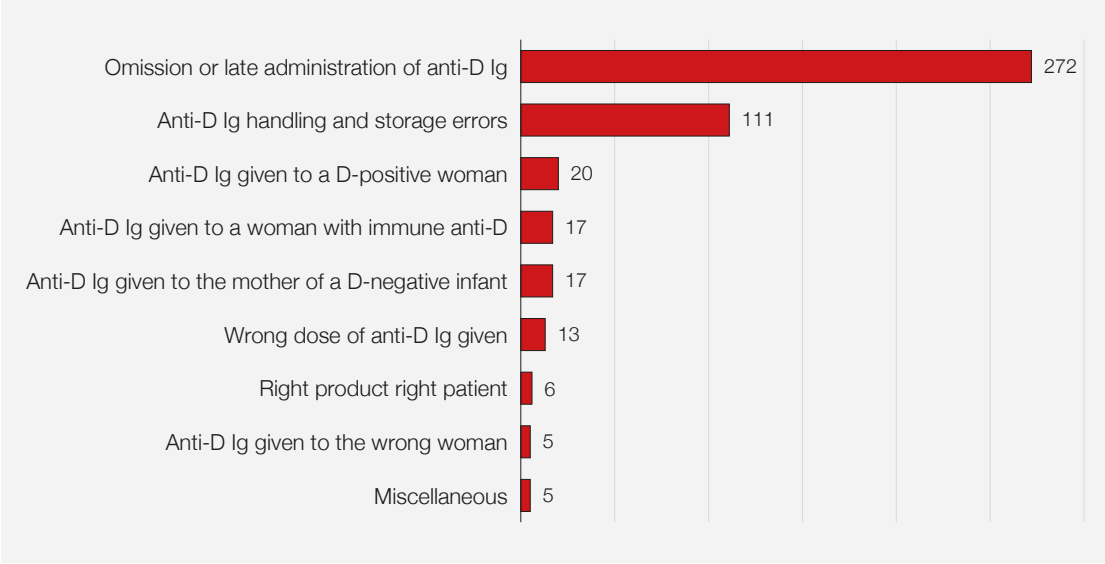


Figure 7.1: Distribution of anti-D Ig related error reports in 2018 n=466

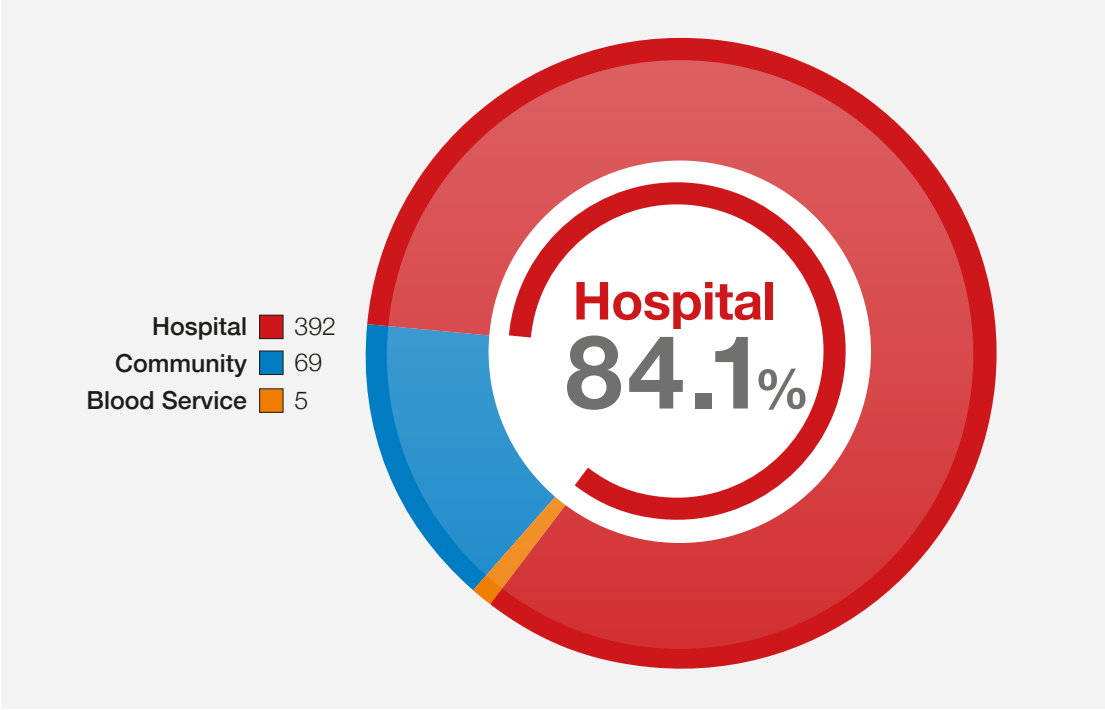
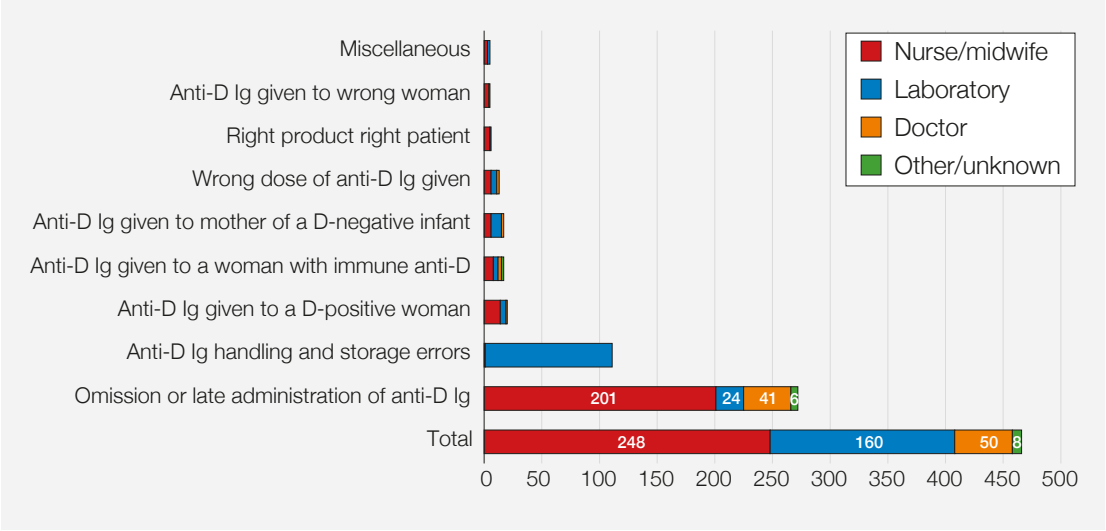


Figure 7.2: Location of errors associated with anti-D Ig

Overview of cases

Most errors, 440/466 (94.4%) occurred during normal working hours (08:00–20:00). Clinical staff were responsible for 298/466 (63.9%) of the errors reported across all of the categories. Of the clinical errors, 229/298 (76.8%) were made by midwives, 19/298 (6.4%) by nurses and 50/298 (16.8%) by doctors of all grades, including both consultants and general practitioners (GP).

Figure 7.3: Staff group responsible for the primary error associated with anti-D Ig by category



Omission or late administration of anti-D Ig n=272 (58.4%)

Errors associated with omission or late administration of anti-D Ig occurred most often in a hospital setting 213/272 (78.3%), although there were still numerous reports occurring in the community including GP practices.

Recurring themes identified were:

- Anti-D Ig not being administered within 72 hours of a PSE
- Lack of understanding amongst staff of when anti-D Ig is required
- Lack of communication between hospital and community midwifery teams – particularly in those patients discharged early after delivery
- Failure to understand and act upon the results of cffDNA testing resulting in both missed and unnecessary doses of anti-D Ig being given
- Anti-D Ig being ordered from the laboratory but not collected. Again, this particularly seems to be around the early discharge of patients

Case 7.1: Anti-D Ig not collected from the refrigerator

A known D-negative woman had an elective caesarian section following induction of labour, failure to progress and a large baby. Post delivery the baby's group was determined to be D-positive and anti-D Ig was issued day 1 postnatally. The mother did not receive anti-D Ig until day 5 postnatally.

Handling and storage errors related to anti-D Ig n=111 (23.8%)

There were 110 laboratory errors, and 1 clinical error; 110 of which occurred within a hospital environment. There was a large refrigerator failure which accounted for 106 reports.

Anti-D Ig given to D-positive women n=20 (4.3%)

These were split into 15 clinical and 5 laboratory errors. There were 13 in hospital and 7 in the community. In 2 cases the woman's blood group was confirmed as 'weak D-positive' and anti-D Ig was still issued from the laboratory. The most common error was failure to check the historical blood group results prior to the ordering or issuing of anti-D Ig.

Case 7.2: Failure to check blood results

A patient informed a newly qualified midwife that she was 'due a jab' at 28 weeks. This information was acted on rather than following policy and checking the blood group first. The patient was new to the hospital and had no obstetric notes with her. The woman was D-positive and received 1500IU anti-D Ig unnecessarily.

Anti-D Ig given to a woman with a known immune anti-D n=17 (3.6%)

There were 12 clinical errors and 5 laboratory errors, with the main error for both staff groups being the failure to check the historical blood group before requesting and administering anti-D Ig.

Case 7.3: Anti-D Ig given to a woman with known immune anti-D

A sample was received from a patient who had to come in every 4 weeks for anti-D quantification. The biomedical scientist (BMS) noted on the form that there was a tick in the box for anti-D Ig having been administered. The transfusion manager was informed who asked the transfusion practitioner to investigate. The transfusion practitioner checked the patient's notes and found evidence that anti-D Ig had been administered despite a laboratory report stating that it was not to be given.

Case 7.4: Anti-D Ig given to a woman with known immune anti-D

A patient with known immune anti-D was given 500IU prophylactic anti-D Ig when attending a day assessment unit in a maternity hospital following a PSE. The midwife did consult the doctor who suggested that the patient should be given it.

Anti-D Ig given to the mother of a D-negative infant n=17 (3.6%)

There were 8 clinical errors and 9 laboratory errors. There were two main themes in these reports:

- Anti-D Ig being issued prior to the infant blood group being checked
- Misinterpretation or misunderstanding of, or failure to check the results of cffDNA test results

In 7 reports women received anti-D Ig despite a cffDNA test confirming that they had a D-negative fetus.

Case 7.5: Misunderstanding of cffDNA test result

The International Blood Group Reference Laboratory (IBGRL) reported that the cffDNA test predicted the fetus to be D-negative. This document was scanned onto the maternity system and the electronic record completed correctly. This flagged that the fetus was D-negative. Later in pregnancy the woman presented with a per vaginal (PV) bleed. There was a request for Kleihauer and anti-D Ig. The Kleihauer was reported as not required with the comment that the fetus of this pregnancy was predicted to be D-negative. The obstetrics and gynaecology registrar prescribed anti-D Ig. Anti-D Ig was issued and administered to the woman.

Anti-D Ig being given to the wrong woman n=5 (1.1%)

These were 4 errors made by midwives and 1 by a doctor.

The dominant theme amongst these reports was a failure to perform positive patient identification (ID) prior to the administration of anti-D Ig.

Case 7.6: Positive patient ID not carried out prior to administration of anti-D Ig

A dose of anti-D Ig intended for a D-negative patient was incorrectly administered to the wrong patient (who was D-positive). The midwife performed a verbal ID on the name only (which the patient confirmed) but did not check the date of birth or patient ID wristband.

Wrong dose of anti-D Ig given n=13 (2.8%)

Doses of anti-D Ig should never be split to give a smaller dose (to maintain traceability and follow manufacturers recommendations). It is safe to give a larger dose.

There were 8 errors in the clinical area and 5 originated in the laboratory. In 2/13 cases women received less than the recommended dose and 3/13 women had not had a Kleihauer taken within the recommended timeframe to establish whether or not they required further anti-D Ig, leaving these 5 women potentially susceptible to sensitisation.

Case 7.7: 1500IU vial of anti-D Ig split

A lady who had miscarried booked in to see her GP for anti-D Ig administration. The GP gave anti-D Ig from midwives' clinic stock and only gave 0.3mL of the 1500IU in a 1mL vial.

Right product, right patient n=6 (1.3%)

In 5 of these cases the error originated with the midwife and 1 from the laboratory. Anti-D Ig was issued and administered to women who needed it, but there were subsequently errors identified related to the blood sample that had been received in the laboratory.

Case 7.8: Patient given anti-D Ig without waiting for results of blood group and save sample

A patient had a group and save taken prior to administration of anti-D Ig for a PV bleed at 15 weeks gestation. The sample was rejected and no further sample was taken prior to the injection. Therefore, it was not known if the patient had immune anti-D.

Miscellaneous n=5 (1.1%)

Of these errors, 3 were clinical and 2 from the laboratory.

Case 7.9: Kleihauer sample found to be haemolysed after anti-D Ig had been issued

A sample was received into the laboratory post delivery for neonatal grouping and Kleihauer request on a D-negative lady. The anti-D Ig was issued and the sample was centrifuged before the Kleihauer film was spread. The sample was found to be haemolysed the following day, too late to test a repeat sample as the anti-D Ig had been administered. A further repeat sample was then not requested in order for the quantification to be carried out for fetomaternal haemorrhage (FMH).

Case 7.10: Anti-D Ig issued before group and screen completed

A Kleihauer was performed for a PSE at 37 weeks gestation for a patient who was historically AB D-negative. The anti-D Ig was administered to the patient the next day. However, 4 days later, the blood transfusion laboratory realised that the group and screen had not been completed.

Near miss anti-D Ig cases n=31

Of the near miss cases, 12 originated in the clinical area and 19 from the laboratory. The majority of the near misses, 20/31 (65.5%), were due to staff failure to follow standard operating procedure (SOP) or policy.

IT-related Anti-D Ig cases n=12

Further details of the IT-related reports can be found in the supplementary information on the SHOT website www.shotuk.org.

References

BSH Austin E, Bates S, de Silva M, et al. (2009) Guidelines for the estimation of fetomaternal haemorrhage. http://www.b-s-h.org.uk/media/15705/transfusion-austin-the-estimation-of-fetomaternal-haemorrhage.pdf [accessed 31 May 2019].

BSH Qureshi H, Massey E, Kirwan D, et al. (2014) Guideline for the use of anti-D immunoglobulin for the prevention of haemolytic disease of the fetus and newborn. *Transfus Med* 2014;**24(1)**:8–20. https://onlinelibrary.wiley.com/doi/epdf/10.1111/tme.12091 [Accessed 03 June 2019].

BSH White, J Qureshi H, Massey E, et al. (2016) Guideline for blood grouping and red cell antibody testing in pregnancy. *Transfus Med* 2016;**26**:246-263. https://onlinelibrary.wiley.com/doi/epdf/10.1111/tme.12299 [accessed 31 May 2019].

Learn Blood Transfusion e-learning programme. http://www.learnbloodtransfusion.org.uk/ [accessed 03 June 2019].

NICE (2012) Ectopic pregnancy and miscarriage: diagnosis and initial management. https://www.nice.org.uk/guidance/cg154 [accessed 03 June 2019].

NICE (2016) High-throughput non-invasive prenatal testing for fetal RHD genotype. https://www.nice.org.uk/guidance/dg25 [accessed 03 June 2019].