

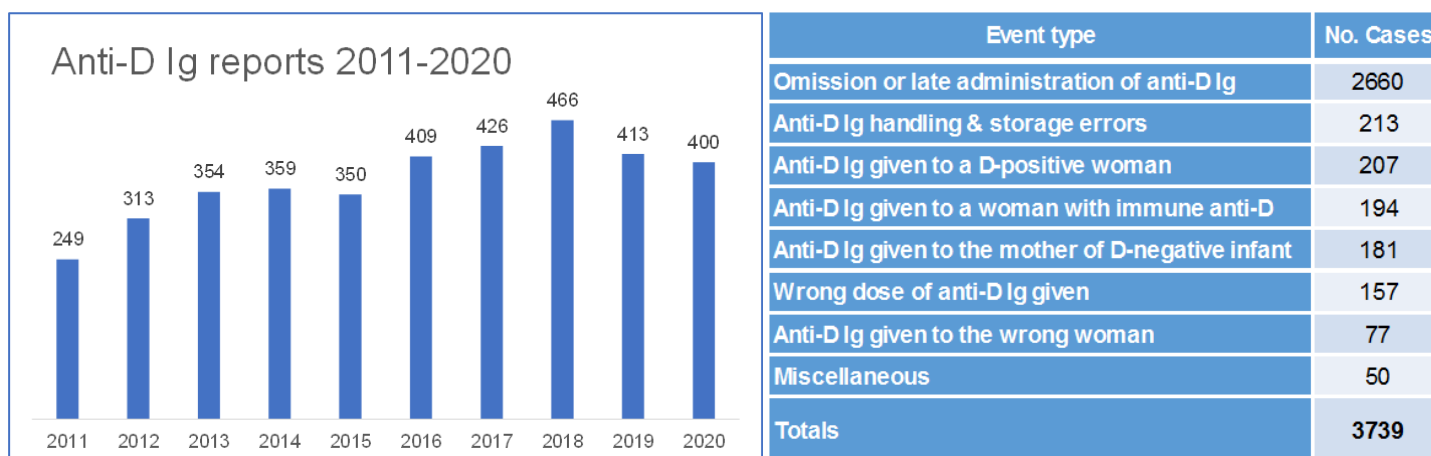
Are these events reportable to SHOT?

Anti-D immunoglobulin (Ig) is technically not a blood component, but a prescription-only medicinal blood product. Lessons learned from requesting, testing, issue and administration are reflective of, and can be applied to transfusion. Note that pathological reactions to anti-D Ig (such as a rash or other allergy) are not reportable to SHOT but should instead be reported via the MHRA 'Yellow Card' scheme <https://yellowcard.mhra.gov.uk/>. Errors in practice related to anti-D Ig have the potential to cause harm to the mother or child immediately or in the future. Evidence suggests that inadequate compliance with guidelines for anti-D Ig administration is a contributing factor to maternal sensitisation in the UK. Particularly there is consistent failure to recognise potentially sensitising events (PSE) in pregnancy, and failure to manage them appropriately when they do occur. Since 2012 SHOT has received reports of 377 women who have developed anti-D during pregnancy. The available data would suggest that anti-D immunisation in pregnancy remains under-reported.

What are the trends seen in anti-D Ig errors?

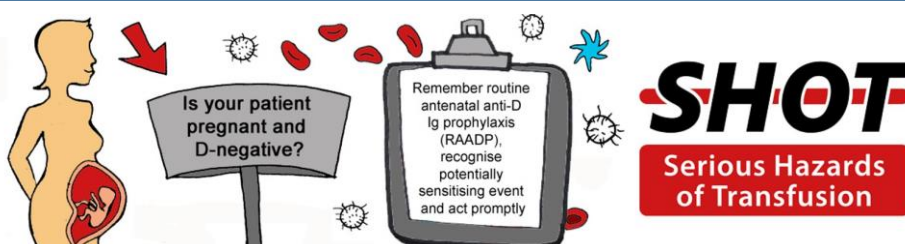
SHOT data shows that since 2011 there has been an overall increase in reported incidents involving anti-D Ig administration. Numbers of reports due to process errors related to anti-D Ig have risen from 249 cases in 2011 to 400 in 2020, making up an average of 9.5% of the total reports to SHOT each year. The increase in reports could reflect a growing awareness of the benefits of reporting and learning from errors rather than a deterioration in standards of practice.

In 2020 there were 16 reports of cell-free fetal deoxyribonucleic acid (cffDNA) test results that incorrectly predicted the baby's D status. Please report all such cases to SHOT.

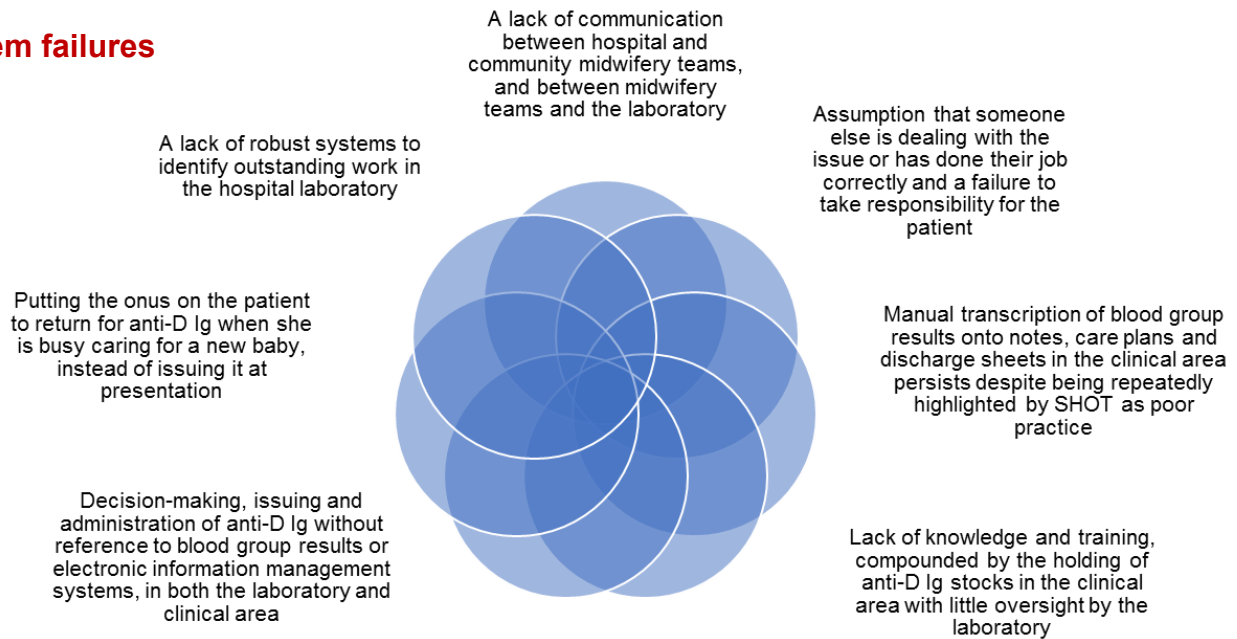


Common errors

- ☐ 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



System failures



Recommendations for safe practice

All organisations involved in the issue and administration of anti-D Ig must ensure that their systems are robust with respect to issue, receipt and recording, and should audit their systems to increase the safety and security of the process. There should be a robust, consistent Trust policy in place based on related guidelines from BSH, NICE and RCOG with regular audit of practices to identify areas for improvement.

The BSH fetomaternal haemorrhage (FMH) guidelines state that any FMH >2mL by Kleihauer should be confirmed by flow cytometry (FC), using the original sample. If the FC result will not be available within 72 hours, the Kleihauer test should be repeated (from the beginning) by a second operator and the results acted upon.

All healthcare professionals involved in the issue and administration of anti-D Ig must complete the anti-D modules in the Learn Blood Transfusion e-learning programme www.learnbloodtransfusion.org.uk

Current blood group and antibody screen results must be referred to when making decisions whether to issue or administer anti-D Ig. If there is doubt about the D-type, or whether detectable anti-D is immune or prophylactic, then anti-D Ig prophylaxis should continue until the problem is solved.

A larger dose of anti-D Ig should be given following delivery of a D-positive child when cell salvage is used – BSH recommend 1500IU as a standard dose.

Anti-D Ig must be administered to women when they are present, rather than asking them to return to the hospital again. Discharge protocols need to be reviewed and anti-D Ig arranged for patients when required.

Protocols need to be reviewed in conjunction with the laboratory for notifying of sample issues and timely supply of anti-D Ig. Preplanning for clinics and pre-ordering anti-D Ig for patients when needed is key to preventing omissions or delays.

Anti-D Ig is subject to the same standards of patient identification (ID) and traceability as blood components.

Transcription errors resulting in anti-D Ig administration errors can be avoided by printing results and placing those in the handheld record and always confirming results before treatment decisions.

Women who produce anti-D for the first time in the current pregnancy should be notified to SHOT for inclusion in the anti-D immunisation data and, all cases where cffDNA test results incorrectly predicted the baby's D status impacting management must also be reported to SHOT.

Peak levels of prophylactic anti-D following administration of 1500IU anti-D Ig will very rarely exceed 0.2 IU/mL if administered intramuscular (IM) or 0.4 IU/mL if administered intravenous (IV).



SHOT has developed an aide memoire to remind staff when anti-D Ig should be administered, but it is incumbent on all maternity units to review their care pathways and develop robust systems to address avoidable omissions or late administration of anti-D Ig. The aide memoir can be accessed on the SHOT website:

<https://www.shotuk.org/resources/current-resources/>