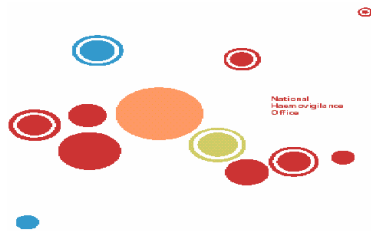


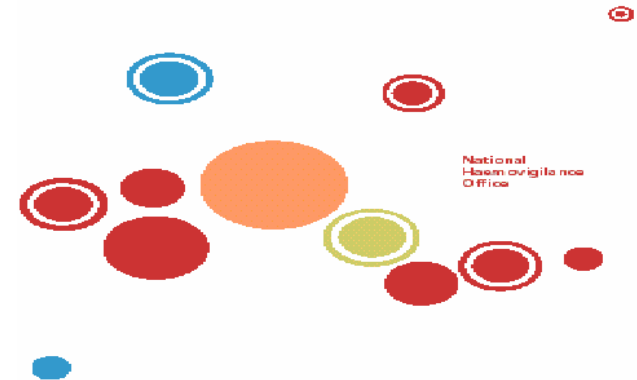
Serious Adverse Events involving Anti D (2010)

Jacqueline Sweeney
Haemovigilance Officer
National Haemovigilance Office
(NHO)



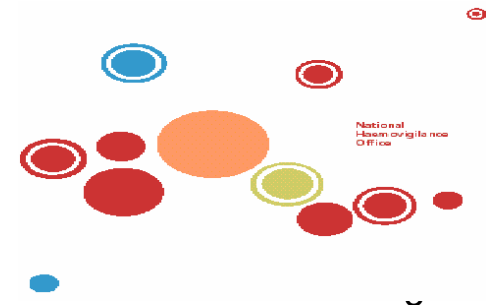
What is your professional background?

1. Doctor
2. Nurse
3. Medical Scientist
4. Other



What is your current role?

1. Haemovigilance Officer
2. Consultant Haematologist
3. Medical Scientist
4. Non consultant hospital doctor
5. Other



What is reportable to NHO?

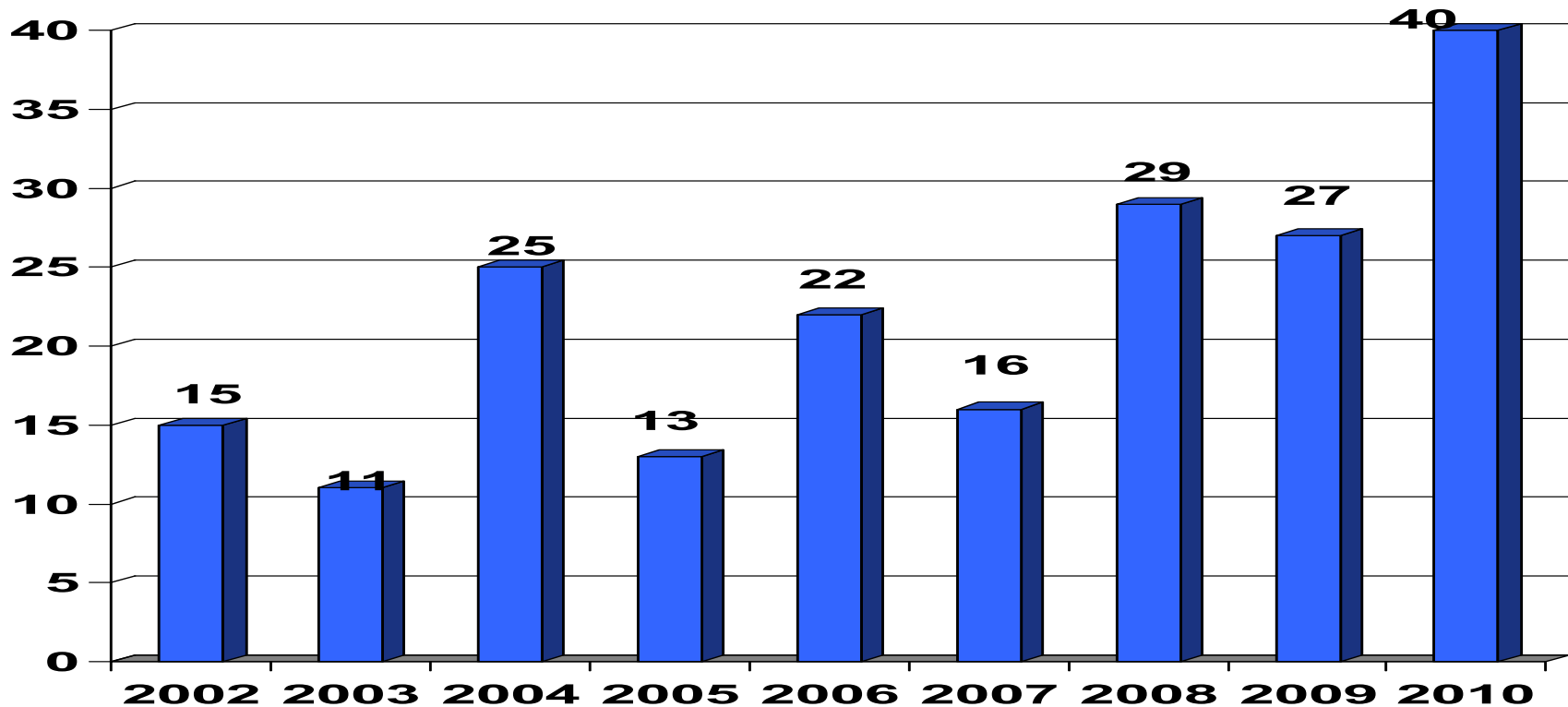


NHO collects reports of incidents resulting in:

1. Omission of anti-D immunoglobulin (Ig).
2. Delay in administration of anti-D Ig
3. Unnecessary of administration of anti-D Ig

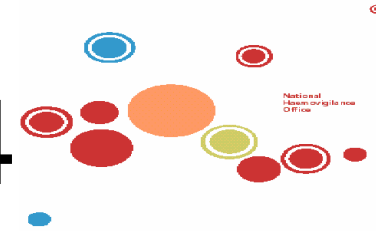
- These are not reportable under EU Blood Directive, but NHO collects as non-mandatory serious adverse events.
- Should be reported internally according to hospital risk management procedures.
- Adverse reactions related anti-D Ig administration reportable directly to the IMB under Pharmacovigilance Scheme.

Findings 2002-2010 (n=198)



- 41 SAE associated with anti-D Ig administration. One case 'Did not progress'.
- Increase of 14 (34%) compared to 2009, continues upward trend in reporting since NHO began collecting such reports in 2002.

Findings:2010 (n=40)

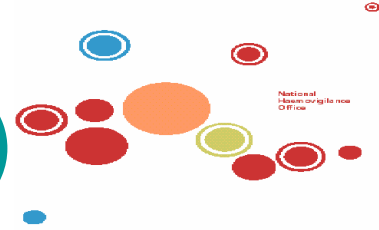


	Total (n)	Antenatal	Postnatal
Omission of anti D Ig	12 (30%)	11	1
Delay in administration of anti D Ig	25 (62%)	22	3
Unnecessary administration of anti D Ig	3 (8%)	1	2
Total	40 (100%)	34 (85%)	6 (15%)

All cases considered to be 'high risk':

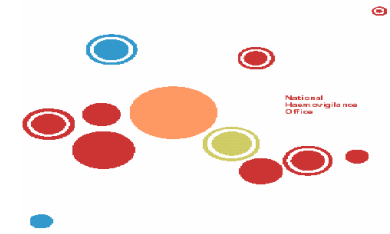
i.e. have real potential for sensitisation or, to cause harm to mother or fetus,

Anti D cases 2010 (n=40)



- One patient less than 18 years of age. Remaining cases associated with adult patients.
- 20 hospitals provide maternity services in Ireland. Reports received from 8 compared to 10 in 2009.
- Majority of reports from dedicated maternity hospitals rather than general hospitals providing obstetric care.

Omissions related to failure to give Anti D Ig (n=12).



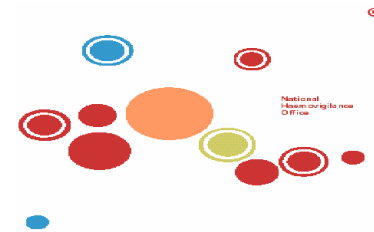
- Eleven cases occurred in antenatal patients.
- One case occurred in RhD negative woman following delivery of RhD positive infant in maternity hospital.

Case History:

- Post delivery patient was given an initial dose of anti-D Ig for a fetomaternal haemorrhage.
- Further testing showed she required an additional dose of anti-D Ig, but she was discharged early for family reasons.
- Despite repeated attempts to contact her she did not return for second treatment.

Omissions of Anti-D Ig: antenatal patients (n=11)

- 2 patients who received medical management of miscarriage were discharged without receiving anti-D Ig.
Both cases occurred in maternity hospitals.
- 2 Rh D negative antenatal patients presented following trauma. Both patients attended the Emergency Department (ED) of general hospitals providing maternity services



Omissions of Anti-D Ig: antenatal patients (n=11).



Case History

- Patient presented to ED at 28 weeks gestation following trauma.
- Blood sample taken & patient admitted to hospital.
- Reviewed next day by senior doctor, who stated she could go home, providing her RhD status verified.
- NCHD informed another senior doctor patient was RhD negative & advised anti- D Ig not required & she was discharged.
- Investigations failed to reveal who gave instruction.
- Error discovered during antenatal visit 6 days later.
- Further error: It was decided no benefit in giving anti-D Ig⁰

Omissions of Anti-D Ig: antenatal patients (n=11)



7 cases involved patients presenting with bleeding per vagina (PV) during pregnancy.

- 5 cases patients' blood group not checked (Historical group available 2 cases)
- Another patient presented to the emergency room of a maternity hospital with history of PV bleeding for 3 days.
- She was sent home, & advised to return the next day.
- Final case: patient presented to admission unit of general at 14 weeks gestation with PV bleeding. Transferred to ward with instruction to receive anti-D Ig: order not communicated to ward staff, nor was patient's chart reviewed.

Delay in administering Anti D Ig (n=25): Postnatal patients (n=3)

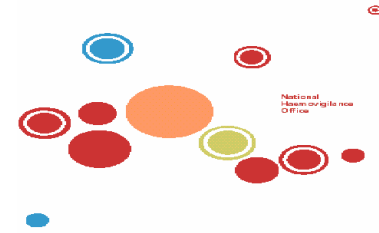


Postnatal Patients who delivered RhD positive infants. Two cases occurred in dedicated maternity hospital and one in a general hospital providing maternity care.

Case History:

- Infant was in special care baby unit.
- Midwife against hospital policy accepted a verbal report that the infant was RhD negative.
- Therefore, thought mother did not require anti-D Ig.
- Error discovered when anti-D Ig found in issue fridge.

Delay in administering Anti D Ig (n=25): Postnatal patients (n=3)



Case History:

- Midwife confused 2 RhD negative patients with same surname.
- The infants' blood results were filed correctly.
- But midwife linked a report that infant was RhD negative to a mother who delivered an RhD positive infant.

Delay in administering Anti-D Ig: Antenatal patients (n=22).



2 cases the requirement for anti-D Ig was identified by patients themselves (clinical staff failed to identify need).
Both incidents occurred at maternity hospitals.

Case History:

- One patient presented to ED with PV bleeding at 37 weeks gestation.
- Historical blood group not checked & no blood sample taken.
- Patient knew her blood group & highlighted this when she attended antenatal clinic next day.
- Sample taken & anti-D Ig administered.

Delay in administering Anti-D Ig: Antenatal patients (n=22).



Case History:

- RhD negative patient had medical treatment for miscarriage at 9 weeks gestation.
- Discharged before blood sample was collected.
- On reading information leaflet patient contacted hospital & was advised to return for treatment.
- Anti-D given 6 days following sensitising event.

Delay in administering Anti D Ig: Antenatal patients (n=22).



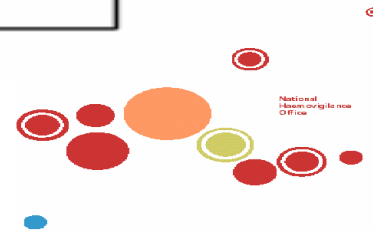
- Another RhD negative patient presented to an maternity hospital with Hx of PV bleeding for 72 hours. GP advised it was unnecessary to attend hospital. Urgent antibody screen negative & anti-D Ig administered.
- 17 cases patients presented with PV bleeding (2 associated with trauma).
- Number of cases delay caused by hospital systems requiring patients' blood samples to be processed prior to issue of anti-D Ig.
- If this is possible within 72 hours patients requested to return to hospital following day for results of blood tests & receive anti-D Ig if required.
- In several instances patients failed to return & had to be contacted by hospital.

Unnecessary Anti D Ig (n=3)

Two involved postnatal patients and one an antenatal patient.



"Her husband? No, I'm her lawyer."

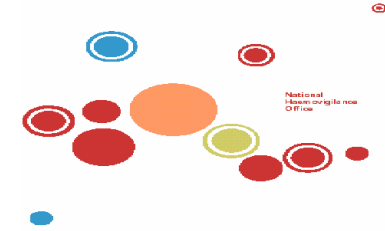


Unnecessary Anti D Ig (n=3)

Case Histories:

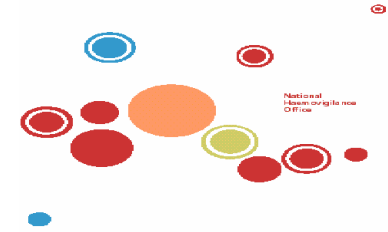
- RhD positive patient given anti-D Ig in error.
 - Primary carer agency nurse (not a midwife) & thought patient was RhD negative, & required anti-D Ig.
 - Neither midwife checking anti-D Ig, nor prescribing doctor verified patient's blood group.
 - This incident occurred at a general hospital providing maternity care.
- RhD negative female delivered RhD positive infant in a maternity hospital. The patient was given two additional doses of anti-D Ig without review by Consultant Haematologist.

Key Points



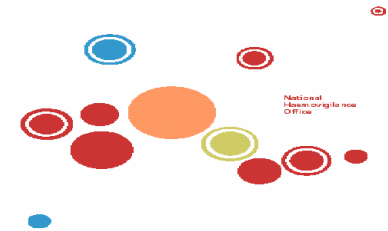
- The need for patients to return to hospital to receive the results of blood tests and anti-D Ig if required does not appear to have been addressed.
- Of particular concern is failure to process samples outside routine working hours.
- Hospitals must consider feasibility of asking patients in advanced pregnancy, possibly with family commitments & transport difficulties to return for follow up.

Key Points



- 2 cases in where patients identified need for anti-D Ig highlight the importance of informing patients of their blood group & potentially sensitising events that may require the administration of anti D Ig.
- In 13 cases (32%) error discovered when patient presented for routine antenatal visit.
- If patients had not attended the clinic incident may never have been followed up, highlighting need for regular audit.

Recommendations



- A number of 2008/2009 recommendations remain:
 - National system to record sensitised patients.
 - Hospitals must have 24 hour systems to manage RhD negative patients presenting with potentially sensitising events.
 - Patients must be informed if RhD negative & they may require Anti D Ig.
 - the possible need for anti-D Ig must be included in maternity discharge checklist procedure.
- Most significant cause of anti D antibodies is immunisation in antenatal period. Routine antenatal prophylaxis programme not provided in Ireland, but patients presenting with a potentially sensitising event should receive anti-D Ig as soon as possible, preferably within 72 hours.

Recommendations



- Patients with recurrent PV bleeding must be treated as detailed in published guidelines.
- Health care professionals involved in the management of patients who may require anti D Ig must complete the anti-D module of e-learning programme. Access: <http://nhs.learnprouk.com>
Clinical Module: consists of 6 modules.
Laboratory Module: consists of 5 units.
- Assessment after each unit.

Understanding Maternal Sensitisation

SCORM Player - Microsoft Internet Explorer provided by Irish Blood Transfusion Service

http://nhs.learnprouk.com/ScormPlayer/skins/LMSMain.aspx?learnerID=16886&courseID=10667_20101115094923&learnerName=...

File Edit View Favorites Tools Help

SCORM Player

navigation accessible version how to use guide glossary references

ANTI-D CLINICAL MODULE

Unit 1 - Understanding Maternal Sensitisation

NHS SCOTLAND

Introduction **Learning** Assessment

1.2 Pathogenesis of Haemolytic Disease of the Fetus and Newborn

Click on the buttons below to explore fetomaternal haemorrhage (FMH) and subsequent anti-D formation.

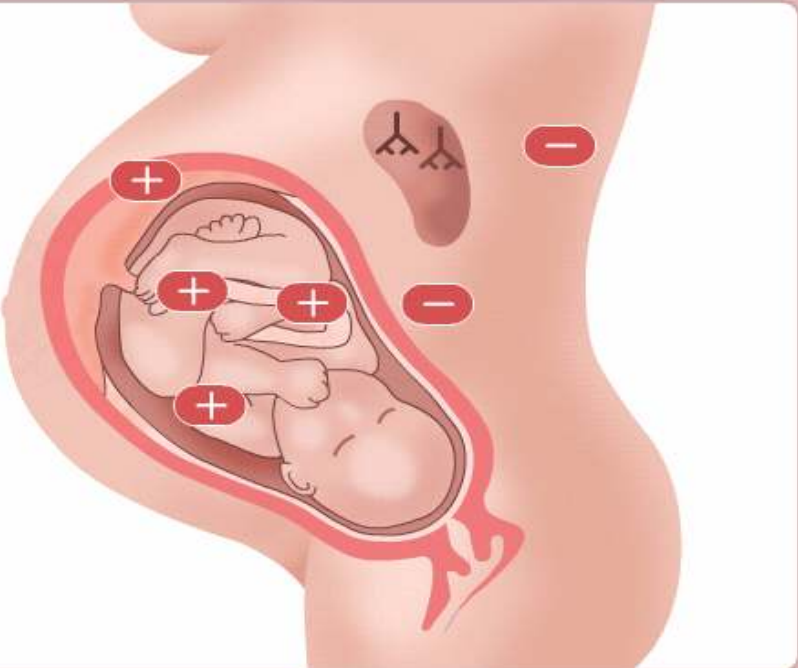
fetomaternal haemorrhage **anti-D formation**

The spleen is activated by the fetal RhD positive RBCs to produce anti-D antibodies (IgG1 and IgG3).

The presence of 'foreign' RhD positive fetal RBC's in maternal circulation stimulates the production of anti-D antibodies.

Rollover the diagram for further information.

Click on the next button to continue.



part 4 of 8

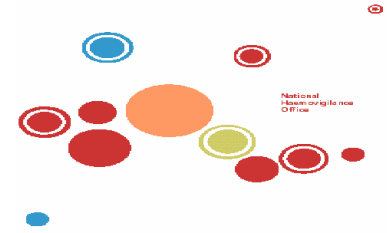
back next

Done

Internet 100%

Start | Inbox - Microsoft... | FW: Att Simon - ... | Microsoft Excel - ... | learnPro NHS - Mi... | SCORM Player ... | ANNUAL REPORT | Anti_D_presenta... | 12:50

Interactive Case Study 1



One report submitted to the NHO stated the ward received a laboratory report that the infant of an RhD negative woman was

‘RhD positive and the antibody screen was negative’

Q: Did this patient require Anti D Ig?

- 1) Yes
- 2) No
- 3) Unclear

Interactive Case Study 1: Delay in administration of anti-D Ig



Answer: Yes.

- The midwife incorrectly read the report (focused on ‘antibody negative’ aspect of the report instead of ‘RhD positive’).
- Error was missed by a doctor who also reviewed the report.
- Discovered by during review of results
- Anti-D Ig administered > 72 hours post delivery.
- Error cause: inattention to detail & failure to communicate information.

Interactive case study:2



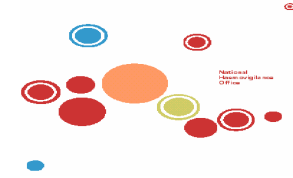
- Antenatal RhD negative patient presented to ED with PV bleeding at 6 weeks gestation.
- Blood samples taken for blood grouping, & patient asked to return next day.
- Patient reviewed again, 2nd blood sample taken, & anti-D Ig issued & administered.

Q: This case was determined to be:

1. Delay in administration of anti-D Ig
2. Unnecessary administration of anti-D Ig

Interactive case study:2

Unnecessary Anti D Ig



- Review of case determined unnecessary administration of anti-D Ig.
- In a miscarriage of <12 weeks gestation, confirmed by scan, and no complications with no surgical or medical intervention, or mild PV bleeding anti-D Ig is not required (minimal risk of feto-maternal haemorrhage)

(Royal College of Gynaecologists cited by BCSH, 2006)

Interactive Question:



Anti-D Ig is usually only effective if given within 72 hours following a potentially sensitising event, therefore no anti-D Ig was given.

Q: Is there any benefit in administering Anti D Ig after 72 hours?

- 1) Yes
- 2) No
- 3) Don't know

Interactive Question



Answer: Yes.

- Anti-D Ig should be administered as soon as possible following potentially sensitising event, preferably within 72 hours.
- In cases of delay of administration of anti-D Ig some protection may be offered if given within 10 days of a potentially sensitising event some protection may be offered

(Lee *et al*, 1999; RCOG, 2002 as cited by BCSH, 2006)

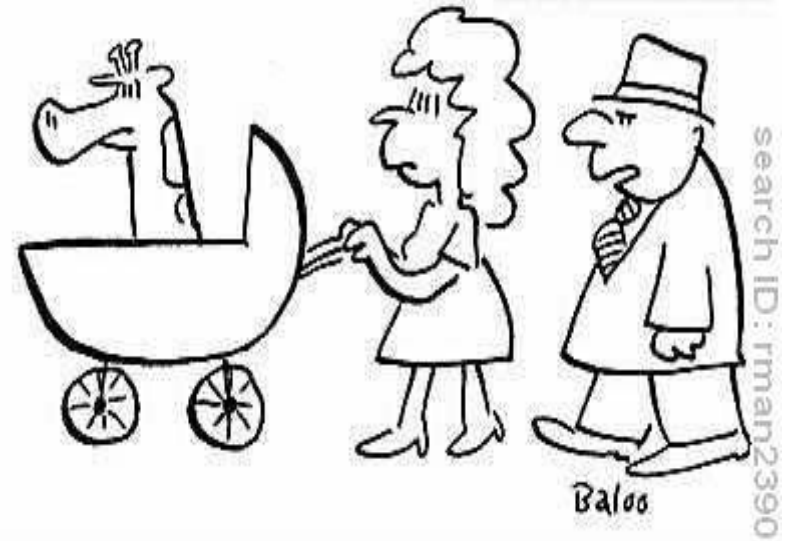
Thank You



References

- British Committee for Standards in Haematology (2006) Guidelines for the prophylactic use of anti-D immunoglobulin.
- Royal College of Gynaecologists (2002) Clinical green top guidelines-Use of anti-D immunoglobulin for Rh prophylaxis.

© Original Artist
Reproduction rights obtainable from
www.CartoonStock.com



"I still say there was some kind of mixup at the hospital!"