National Comparative Audit of Blood Transfusion

2013 Audit of Anti-D Immunoglobulin Prophylaxis

Acknowledgements

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Summary of Key audit findings

The combination of anti-D immunoglobulin prophylaxis and the active management of women who develop immune anti-D means that neonatal deaths due to severe haemolytic disease of the fetus and newborn [HDFN] are very rare[1]. The majority of staff working today will never have to witness the devastating effect this condition used to have on women and their families.

Anti-D immunoglobulin [anti-D Ig] prophylaxis is a complex clinical pathway whose purpose is preventing the development of HDFN due to immune anti-D. It requires close coordination and cooperation between the transfusion laboratory and the maternity unit as well as the RhD negative pregnant woman herself. This National Comparative Audit covers the whole pathway of care from booking to delivery.

Compliance with the four key audit standards and other significant findings relating to the anti-D Ig prophylaxis given to 5972 RhD negative pregnant women at 153 sites in the UK is summarised below.

Audit Standard 1: All eligible RhD negative pregnant women receive routine antenatal anti-D immunoglobulin prophylaxis [RAADP] in the third trimester at the correct time and at the correct dose

As recommended by NICE[2] all audited sites have introduced RAADP and the majority of sites (94%) are using the single-dose regime.

The care of 5276 RhD negative women eligible for RAADP was audited against this standard.

National Compliance with Audit Standard 1: 99% received at least one RAADP injection and 87.5% received the correct dose at the correct time. Full compliance (correct dose, correct time) was better with the single-dose regime (90%) compared to the two-dose regime (59%)

Excluding women who had immune anti-D and those who declined RAADP, there were 52 women *at risk* of developing immune anti-D because there was no auditable documentation that RAADP had been given. **This is 1% of all RhD negative women eligible for RAADP.**

Audit Standard 2: All eligible RhD negative pregnant women delivering RhD positive babies receive anti-D Ig prophylaxis post-delivery at the correct time and the correct dose

National guidelines[3],[4] state that RhD negative women without confirmed immune anti-D who deliver a live RhD positive or RhD unknown baby should receive at least 500 IU anti-D Ig post-delivery [PD] and should have a maternal Kleihauer (FMH) test to determine if additional anti-D Ig is required.

This is the most important part of the anti-D Ig prophylaxis pathway as fetomaternal haemorrhage is more likely to occur around the time of delivery than at any other time in pregnancy.

The care of 3392 RhD negative women eligible for PD anti- D Ig was audited against this standard.

National Compliance with Audit Standard 2: 98.4% received PD prophylaxis and 91.6% received the anti-D Ig injection at the correct dose and at the correct time

Excluding women who had immune anti-D and those who declined PD anti-D, there were 19 women *at risk* of developing immune anti-D because there was no auditable documentation that anti-D had been given. **This is 0.5% of all RhD negative women eligible for post-delivery prophylaxis.**

97% of women in this group had a Kleihauer test for fetomaternal haemorrhage estimation. Where the FMH result was available, 88% of deliveries had less than 2mL of fetal red cells [RBCs] in the maternal circulation and 97% of deliveries less than 4mL fetal RBCs. 15 women needed additional anti-D Ig to cover the estimated FMH because the standard post-delivery dose was insufficient to cover the confirmed FMH. **0.5% of eligible RhD negative women needed additional anti-D Ig**.

Audit Standard 3: All RhD negative pregnant women receive anti-D immunoglobulin prophylaxis after a potentially sensitising event in pregnancy

There is a risk of fetomaternal haemorrhage during pregnancy in relation to a number of clinical situations known as potentially sensitising events [PSE] and national guidelines[3, 4] state that a minimum of 500 IU anti-D Ig should be given within 72 hours (250 IU if the PSE is before 20 weeks gestation). A maternal Kleihauer is required after 20 weeks to determine if additional anti-D Ig is required.

Details of PSEs in this audit were obtained from both maternity notes and laboratory records. Where discrepancies arose between the clinical details, the timing of the event and the anti-D prophylaxis, the clinical record was deemed the most accurate. There may have been additional PSEs missing from the audit because they were not documented.

1052 potentially sensitising events in 942 RhD negative women were audited in this section.

National Compliance with Audit Standard 3: 95.8% received anti-D Ig for documented PSEs with 96.3% receiving the correct anti-D Ig dose and 79% receiving anti-D Ig at the correct time

87% of PSEs in RhD negative women after 20 weeks had a Kleihauer test for fetomaternal haemorrhage estimation. Where the FMH result was available, 90.4% of PSEs showed less than 2mL of fetal RBCs in the maternal circulation and 98.4% had less than 4mL fetal RBCs. 11 PSEs would have required further investigation and follow-up testing which is more difficult in pregnancy because the RhD group of the fetus is unknown. **Follow-up testing and possible additional anti-D Ig may have been required in 1.6% of PSEs.**

Audit Standard 4: All RhD negative women are given information about anti-D Ig prophylaxis, have documented consent to receive the anti-D and in the event that anti-D Ig prophylaxis is declined, the reason is recorded

This standard relates to the NICE guidance on RAADP[2]. National anti-D Ig prophylaxis guidelines[3, 4] also highlight the importance of explaining the risk and benefits of anti-D Ig prophylaxis to RhD negative women. The use of standardised patient information should be used when counseling women and obtaining and documenting informed consent.

National Compliance with Audit Standard 4: 36% had documentation of written patient information and 57% had documentation of consent to receive RAADP

Where it was documented that an RhD negative woman declined anti-D, there was a reason documented in 74% of cases. The commonest reason for declining anti-D Ig is because the father of the baby is known to be RhD negative. **In this audit women who declined anti-D were not included in the count of women whose care is considered to have failed the audit standards.**

Other Key Audit Findings

Demographic information

This audit provided useful demographic information on the group of pregnant women audited and, where it was available, the median weight (IQR) of the women at booking was 67 (59-78) and 20% had a BMI at booking of ≥30. In addition the gestational age at delivery was ≥40 weeks in 23%.

In the UK the national guidelines recommend a standard minimum dose of anti-D Ig prophylaxis according to gestation for all RhD negative women and they did not consider that there was evidence to support any modification to this recommendation for RAADP in larger women or for women whose pregnancy goes beyond 'term'[5]. However, In January 2014 CSL Behring (the manufacturers and distributors of Rhophylac™), issued a clarification to their SPC[6] recommending that obese women (defined as a BMI of 30 or more) should be given anti-D Ig by the intravenous route. The BCSH Transfusion Taskforce subsequently issued a clarification notice standing by their original statement[7].

Dosage and formulation of anti-D

The dosage and formulation of anti-D Ig in use in all sites for PSEs complies with minimum recommended doses but 27% of sites use more than the minimum recommended 250 IU for PSEs before 20 weeks gestation and 32% use more than the minimum recommended 500 IU for PSEs after 20 weeks gestation. For PD prophylaxis 33% of sites are using more than the minimum recommended 500 IU anti-D Ig.

In the UK the national guidance recommends a maternal Kleihauer test (FMH) after 20 weeks gestation and post delivery[8]. This audit (see standards 2 and 3) shows 500 IU would be sufficient to have covered the 97% of deliveries and the 98.4% of PSEs that were documented as having a FMH of 4mL or less. The policies in place in some of the sites audited promote using more anti-D Ig than actually required.

In this audit all audited sites had introduced RAADP with 23% of maternity units stating this was introduced before the first NICE guidance in 2002; a further 62% introduced RAADP between 2003 and 2008 and the remainder after the second NICE guidance in 2008. For RAADP 94% of sites now use a single-dose at 20-30 weeks gestation with only 6% using a two-dose regime. 71% of sites had changed from the two-dose to the single-dose regime with 17% of those who had changed citing compliance with the prophylactic regime as one of the drivers for change.

Both NICE RAADP guidance and national anti-D prophylaxis guidance recognise the emerging technology of high-throughput cell-free fetal DNA testing of maternal blood to predict the fetal RhD type[9]. If and when this becomes widely available, RhD negative women with RhD negative babies would potentially no longer require RAADP (or anti-D Ig for PSEs in pregnancy). This has advantages in reducing the pressure on a limited resource (anti-D Ig) as well as preventing exposure of RhD negative women to a blood-derived product[10].

Error reporting

80% of sites reported at the time of the audit that they had submitted an anti-D incident to SHOT in the last year. SHOT define an adverse event relating to anti-D immunoglobulin as one "relating 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". In the 2013 SHOT annual report[11] there were 277 errors reported by UK hospitals that related to omission or late administration of anti-D. The SHOT authors note that 10% of these cases were detected and subsequently reported as a result of this audit which underlines the fact that errors may simply remain unnoticed or are noted but not reported to SHOT.

Organisation and Documentation

The majority of transfusion laboratories (90%) stated that they were responsible for the issue of anti-D Ig to named patients and 86% record that anti-D Ig has been administered to a named patient on the laboratory information management system [LIMS].

It is primarily the responsibility of the maternity unit to prescribe and administer anti-D Ig to the correct patients in the correct dose at the correct time but the transfusion laboratory (or in some cases the pharmacy) plays a major role in ordering, stocking and issuing anti-D Ig as well as recording that it has been given. There does need to be a robust system in place for assuring that care is delivered in a timely and accurate manner, and that system should be auditable.

Training and education

In the organisational questionnaire we asked about the availability of local update training on anti-D Ig prophylaxis for different staff groups and 80% of sites reported it was available for midwifery staff and 88% reported that updates were available for transfusion laboratory staff. However, fewer sites (55%) provided anti-D updates for obstetricians and only 42% responded that they trained haematology medical staff on this topic. We did not ask what proportion of staff was trained in each category, nor did we ask how the training was delivered.

One of the features demonstrated by the audit was faulty decision-making around the need for RAADP or PD prophylaxis when anti-D Ig had been separately given for a PSE. This and other issues need to be addressed by training updates. Training against a locally agreed policy to support the implementation of change as well as the effective delivery across the whole care pathway is essential.

Recommendations and guidance on implementation

The recommendations based on the findings of the National Comparative Audit of anti-D prophylaxis are:

Recommendation 1 – Maternity units and associated transfusion laboratories have a duty of care to deliver anti-D Ig prophylaxis to RhD negative women at the correct dose and the correct time. The organisation of maternity services should ensure that women are aware that they are eligible for anti-D Ig and that service delivery is matched to this requirement.

Recommendation 2 – Where women move from the jurisdiction of one maternity service to another, the results of screening blood tests and record of anti-D Ig administration should be transferred to the new maternity record and, where any omissions are identified, they should be investigated, documented and rectified in as timely a way as possible.

Recommendations 1 and 2 concern the organisation of care and are the responsibility of Lead Clinicians, Lead Midwives and Maternity Service Managers.

Recommendation 3 – Hospitals using the two-dose RAADP regime should review their compliance with both anti-D Ig injections and, if it is inadequate, they should take action to improve compliance including giving consideration to the single dose regime which, in this audit, shows better compliance.

Recommendation 4 – Post delivery anti-D prophylaxis is vital to prevent sensitisation and women who are eligible should not be able to leave hospital without the injection, or a robust plan in place for them to receive the anti-D Ig and any additional dose of anti-D Ig as indicated by the result of the Kleihauer test.

Recommendation 5 – Staff should be made aware that national guidelines specifically recommend that RAADP and prophylaxis for PSEs should be regarded as separate events and anti-D Ig given for both at a dose indicated by the local policy.

Recommendations 3, 4 and 5 concern local policies for anti-D prophylaxis and sites participating in this audit should review their performance against the audit standards to identify any areas for improvement.

Recommendation 6 – Patient information about anti-D prophylaxis is currently available from anti-D Ig manufacturers or can be locally produced. The information provided to RhD negative women must provide accessible and accurate information to support consent and decision-making. It should be available for midwives and obstetricians to use at the time of counselling RhD negative women and the consultation and any outcomes should be recorded in the maternity record.

Recommendation 6 concerns a fundamental principle of patient care – involving women in decision-making about anti-D prophylaxis. Anti-D Ig manufacturers could work with local maternity units to improve the quality and accessibility of patient information. This could include electronic methods of communication to supplement the traditional leaflets.

Recommendation 7 - Any errors in requesting and administration of anti-D Ig that could lead to sensitisation and development of immune anti-D, or inappropriate administration of a medicinal blood product, should be investigated locally and reported to SHOT.

This recommendation applies to everyone involved in the delivery of anti-D prophylaxis. The combination of incident reporting and auditing anti-D prophylaxis regimes serves to continuously improve practice. The Serious Hazards of Transfusion haemovigilance scheme produces an annual report summarizing errors in anti-D Ig administration[12]. It is suggested that midwives, obstetricians and laboratory staff should regularly read this section of the SHOT report.

Recommendation 8 – all staff groups involved with anti-D prophylaxis should receive appropriate education and updates.

Anti-D prophylaxis is a complicated pathway of care involving many staff groups and grades of staff. Education about the purpose and importance of anti-D prophylaxis and the detail of local policies is vital to the delivery of effective care. A compendium of currently national educational resources is given in **Appendix 2**.

Conclusions

The audit findings reflect that most anti-D immunoglobulin prophylaxis is delivered correctly and RhD negative women should be reassured that this is an important and effective programme that prevents a serious and life-threatening condition which used to affect large numbers of babies but no longer does.

The recommendations apply to all maternity units and associated support departments whether audited practice was good or not, but individual units may want to prioritise their actions in response to these recommendations depending on local needs.

Although similar in content and regularly updated, guidance on anti-D prophylaxis for the UK is provided by two professional organisations, the Royal College of Obstetricians and Gynaecologists (RCOG) and British Committee for Standards in Haematology (BCSH). It is highly commendable and very welcome that on 17th October 2014 the RCOG guidance (last updated in 2011) was archived[4]. The current guidance from BCSH (published 2014) now provides a single point of reference for all healthcare professionals concerned in the delivery of anti-D prophylaxis for the prevention of haemolytic disease of the fetus and newborn in RhD negative women.

Now that there is a single UK evidence-based guideline for anti-D immunoglobulin prophylaxis the results of this audit, and local policies, should be reviewed against the guideline and when local quality improvements have been introduced to address any deficiencies in the service, a modified version of this audit (or a QuickAudit[13]) should be undertaken.

Introduction and background

Anti-D immunoglobulin prophylaxis [anti-D Ig] is given to RhD negative pregnant women to prevent the development of haemolytic disease of the fetus and newborn due to immune anti-D.

In the UK RhD negative women are identified at booking (10-12 weeks gestation) and if the antibody screen is negative they are offered anti-D immunoglobulin prophylaxis a) for potentially sensitising events [PSEs] during pregnancy, b) routinely in the third trimester to prevent sensitisation by 'silent' fetomaternal haemorrhage (Routine Antenatal Anti-D Prophylaxis [RAADP]), and c) after delivery if they have an RhD positive baby (post-delivery [PD] prophylaxis).

The British Committee for Standards in Haematology [BCSH] [3] and the Royal College of Obstetricians and Gynaecologists [RCOG] [4] and have published guidance on anti-D immunoglobulin prophylaxis and these guidelines are regularly reviewed and updated. The National Institute for Health and Care Excellence [NICE] first published guidance on RAADP in 2002 and this was updated in 2008[2]. The standards for this audit have been taken from these three guidelines.

A survey on behalf of the Royal College of Pathologists [RCPath] in 2007 showed that whilst the majority of centres were using RAADP, there was considerable variation in the Anti-D Ig regimes in use and a number of different systems were in place for documenting that the anti-D Ig injections had been given to named women. This survey was repeated in 2010 following the release of updated NICE RAADP guidance and showed an increasing trend towards use of the single-dose RAADP regime[14].

The Serious Hazards of Transfusion [SHOT] UK haemovigilance scheme has raised concerns about the correct use of anti-D Ig with reported errors arising in the laboratory and clinical areas leading to omission of anti-D prophylaxis as well as incorrect dosing and timing of anti-D Ig. In 2013 SHOT introduced, as a pilot, a reporting category for cases of anti-D alloimmunisation and these data are in the SHOT report published in July 2013[11].

The Department of Health and Chief Medical Officer's National Blood Transfusion Committee [NBTC] issued a series of Health Service Circulars – the 'Better Blood Transfusion' [BBT] initiative[15] – and these emphasise the importance of improving anti-D Ig prophylaxis.

There have been no previous national audits on this topic but a regional audit has been carried out in Northern Ireland[16]. Audits of RAADP were also published from a single centre in England[17] and from Scotland[18].

Aims of the audit

The aim is to audit compliance with UK guidance on anti-D immunoglobulin prophylaxis in pregnancy.

This audit was not designed to consider administration of anti-D Ig prophylaxis for termination of pregnancy or early miscarriages prior to the first antenatal booking appointment.

Participation

All UK hospital laboratories that provide a service to one or more maternity units were invited to register for the audit and advised to establish local audit leads for the laboratory and maternity service. The audit was a joint venture between the Transfusion Team (comprising Transfusion Practitioners, Laboratory Scientists and Haematologists) and the Obstetric Team (Midwives and Obstetricians).

Audit standards[3, 4]

Audit Standard 1:

All eligible RhD negative pregnant women receive routine antenatal anti-D immunoglobulin prophylaxis (RAADP) in the third trimester at the correct time and at the correct dose

- Either 1500 IU anti-D Ig at 28-30 weeks of gestation ('single-dose regime')
- Or *at least* 500 IU anti-D Ig at 28 and 34 weeks of gestation ('two-dose regime')

Audit Standard 2:

All eligible RhD negative pregnant women delivering RhD positive babies receive anti-D Ig prophylaxis post-delivery [PD] at the correct time and the correct dose

A dose of *at least* 500 IU anti-D Ig within 72 hours of delivery

A maternal Kleihauer (or equivalent) test is performed after delivery to estimate any fetomaternal haemorrhage [FMH] and determine if additional anti-D Ig is required

Audit Standard 3:

All RhD negative pregnant women receive anti-D immunoglobulin prophylaxis after a potentially sensitising event [PSE] in pregnancy

- A dose of *at least* 250 IU anti-D Ig before 20 weeks and *at least* 500 IU anti-D Ig after 20 weeks gestation is given within 72 hours of the PSE
- A maternal Kleihauer (or equivalent) test is performed after 20 weeks gestation to estimate any FMH and determine if additional anti-D Ig is required

Audit Standard 4:

All RhD negative women

- Are given information about anti-D Ig prophylaxis
- Have documented consent to receive the anti-D Ig
- Have, in the event that anti-D Ig prophylaxis is declined, the reason recorded

Methodology

Clinical audit using case notes and laboratory information management system [LIMS]:

The case-capture for this audit was designed to start at the beginning of the pregnancy (the booking appointment in September 2012) with the intention of collecting audit data retrospectively following delivery so as to audit across the whole pathway and thereby include pregnancies that were not completed or did not go to term.

- All women booking in September 2012 were identified by the Maternity Unit and then the RhD group of the mother was determined from the LIMS by a member of the Transfusion Team to define the cohort of RhD negative women to be audited (the 'audit cases')
- Each audit case was assigned an audit linkage number and the initial audit data (**Section 1: Questions 1-6**) was obtained from the LIMS
- The clinical data (**Section 2: Questions 7-10**) was obtained from the maternity case notes by the designated midwife
- Where the delivery of anti-D Ig did not meet the audit standards as identified by the auditors, supplementary questions were answered in **Section 3: (Questions 11-16)** to determine the reason for the discrepancy.
- The data was submitted using the on-line audit tool

The clinical audit questions can be found in **Appendix 3**.

Organisational audit: a paper-based questionnaire was completed to collect data on service configuration, anti-D Ig policies, documentation of anti-D Ig including traceability, and SHOT reports in the anti-D Ig category. The organisational audit questions can be found in **Appendix 4**.

Results

Participation

161 sites participated in this audit, of which 139 submitted data to both organisational and clinical audits, 8 only to the organisational audit and 14 only to the clinical audit.

Your site submitted **23 cases** to the clinical audit.
Your site **did** participate in the organisational audit

Table 1: Participation by country

Level of Participation	England	Scotland	Wales	Total
Both clinical and organisational	123	6	10	139
Organisational only	8	-	-	8
Clinical only	13	-	1	14
Declined to participate in this audit	4	-	-	-
Clinical audit cases	5574	161	237	5972

Comment
Only sites with maternity units were expected to participate in this audit. Some sites with maternity units did not participate because they could not commit the resources to undertake the data collection. Others cited that the reason for non-participation was the configuration of their maternity records and booking appointments, which did not enable accurate case-capture for the designated calendar month. Northern Ireland did not participate in this audit having recently undertaken a regional audit on the same topic.

Clinical Audit

Your site contributed data on 23 RhD negative women.

Description of the audited patients

A total of 5972 cases were submitted to the clinical audit, median 33, IQR 19-49 per site. Most (80% 4759/5972) were booked during September 2012, 2% (164) before September 2012, and 18% (954) after September 2012, and the booking date was unknown for 95 women.

91% (5333/5884) of the women audited delivered in the maternity unit, 9% (551/5884) did not, and in 88 it was not known whether they delivered in the maternity unit or not. Reasons given by the midwife auditor for not delivering in the maternity unit were: delivered at another maternity unit (205), delivered at home (2), miscarriage (172), termination of pregnancy (47), intrauterine death (8), stillbirth (3), neonatal death (1), unknown/no records (113).

Comment
It was intended that the women booking in September 2012 would be audited after delivery with the data collection period being June 2013. The reason for this was to capture all the instances in pregnancy when anti-D Ig should be administered, across the whole pathway of maternity care.

Not all sites followed this method but it was decided that all audited cases submitted were included for analysis. Hospitals should be mindful of the fact that if their audited cases were not sequential, local data on compliance with the audit standards might not be complete.
During this audit, there were a number of cases that could not be audited across the whole maternity pathway because care transferred to another unit. Throughout the audit there is evidence of missing data because there was not a complete audit trail on these women and, whilst this does not necessarily mean that anti-D Ig was not given, it does demonstrate a potential loss of continuity of care.
As to why some pregnancies were not delivered in the maternity unit (Q10), 2.9% of pregnancies ended in miscarriage and 0.8% in termination of pregnancy although, using additional information from across the audit record, 3.1% of audited pregnancies ended in miscarriage and 0.9% in termination of pregnancy. Data from Q10 shows that there were 12 cases reported to have intrauterine death, stillbirth or neonatal death, which is 0.2% of the audit cohort.

Additional demographic data

Figure 1: Distribution of maternal weight at booking

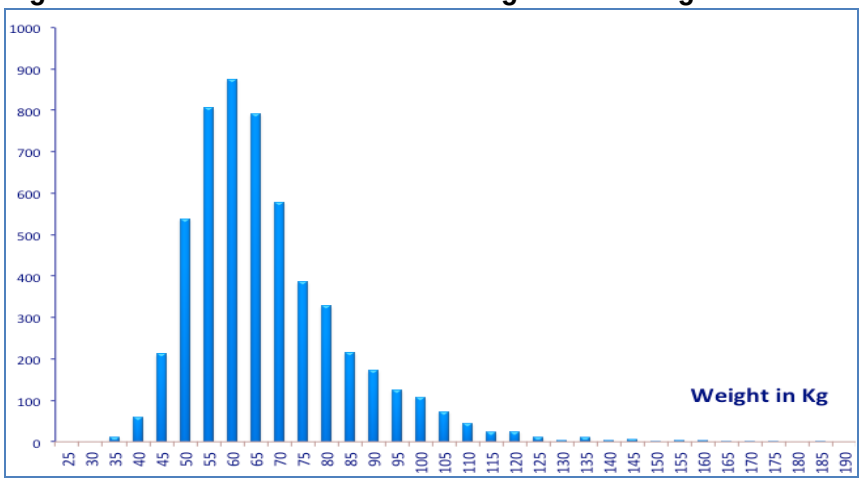
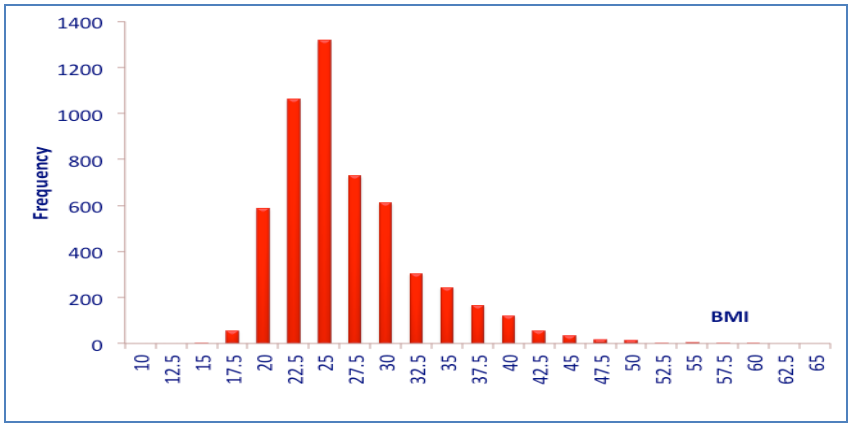
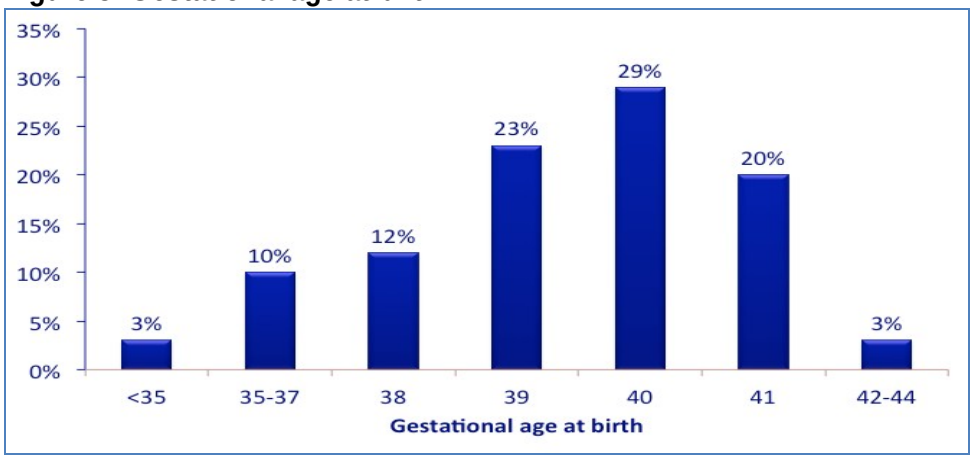


Figure 2: Distribution of maternal BMI at booking



At booking, the median (IQR) weight of the women was 67 (59-78) Kg for n=5472, and the median (IQR) BMI was 25 (22-29) for n=5331.
Just under half (49%, 2590) had a BMI ≥25, 20%(1073) had a BMI ≥30, 9%(467) BMI ≥35 and 3% (160) had a BMI ≥40 (figures 1 and 2).

Figure 3: Gestational age at birth



Gestational age at delivery was stated for 5263: 3% (159) were born before 35 weeks, 10% (520) were born at 35-37 weeks, 12% (652) at 38 weeks, 23% (1205) at 39 weeks, 29% (1518) at 40 weeks, 20% (1068) at 41 weeks and 3% (141) at 42-44 weeks (figure 3).

Comment

The demographic data puts the audit data and associated anti-D Ig policies into context, in particular the current debate about whether larger women should be given RAADP by the iv route as recommended by one of the anti-D Ig manufacturers[6]. 20% of women in this audit had a BMI of ≥30. Additionally, there may be a risk of sensitisation in RhD negative women who go beyond 40 weeks gestation and in this audit 23% of women delivered between 41 and 44 weeks gestation.

AUDIT STANDARD 1

All eligible RhD negative pregnant women receive routine antenatal anti-D immunoglobulin prophylaxis (RAADP) in the third trimester at the correct time and at the correct dose

Some women did not get RAADP, or RAADP is not recorded as being given, for acceptable or understandable reasons. These cases were not included in the subsequent cohort of women 'eligible' for anti-D Ig.

Table 2: Cases where RAADP was not given for 'acceptable' or 'understandable' reasons (N=696, 11.7% of audited cases)

		National	Your site	
	Total	5972	23	
Group 1: Not eligible for RAADP		**Gp 1 total = 296 (5.0%)**	**1**	**= 4%**
Confirmed immune anti-D		39	**1**	
Miscarriage before 28 weeks gestation		183	**0**	
Termination of pregnancy		51	**0**	
Delivered before 28 weeks gestation		23	**0**	
Group 2: Decision not to give RAADP		**Gp 2 total = 114 (1.9%)**	**0**	**= 0%**
Father RhD negative		79	**0**	
Declined anti-D Ig		35	**0**	
Group 3: Not under the care of the unit at the time of RAADP		**Gp 3 total = 125 (2.1%)**	**0**	**= 0%**
Late bookers (after 30 weeks gestation)		27	**0**	
Transferred elsewhere before RAADP		66	**0**	
Did not attend		32	**0**	
Group 4: Unable to classify (lack of information)		**Gp 4 total = 161 (2.7%)**	**0**	**= 0%**

The following table shows whether **Audit Standard 1** was met for the residual 5276 cases where it was established by the auditors that women were 'eligible' for anti-D Ig and therefore RAADP should have been given. Of these, 92.6% were in hospitals using a single-dose RAADP regime and the remaining 389 cases were in 9 hospitals where the two-dose RAADP regime was in use.

For your site there were 22 women eligible for RAADP

Your site used the single dose RAADP regime

Table 3: RAADP given on time according to the regime in use (N=5276)

	National		Your site	
	N	%	N	%
RAADP single dose regime* N=4887		Of 4887		Of 22
Single dose at right time (28-30 weeks)	**4388**	**89.8**	**14**	**64**
Single dose before 28w 0d	235	4.8	**5**	**23**
Single dose after 30w 6d	217	4.4	**3**	**14**
Single dose not given	47	1.0	**0**	**0**
RAADP two-dose regime** N=389		Of 389		
Two-dose: both doses given at right time	**228**	**58.6**	**0**	**0**
Two-dose: only first dose given at right time	57	14.6	**0**	**0**
Two-dose: only second dose given at right time	43	11.1	**0**	**0**
Two-dose: neither dose given at right time	61§	15.7	**0**	**0**

For the purposes of this audit, women were defined as getting *single dose* RAADP at the correct time if it was given between the gestation dates of 28 weeks 0 days and 30 weeks 6 days* and *two-dose* RAADP between the gestational dates of 28 weeks 0 days to 28 weeks 6 days** (dose 1) and 34 weeks 0 days to 34 weeks 6 days** (dose 2).
§ this includes 5 cases eligible for the two-dose regime who were not given any anti-D at all

As a result of omission of RAADP, your site would have put 0 women at risk of sensitisation. These cases should have been investigated locally and reported to SHOT

Compliance with RAADP

A total of 5276 women were eligible for RAADP and 99.0% (5224/5276) received an anti-D Ig injection with 99.0% (4840/4887) of cases received a single-dose RAADP and 98.7% (384/389) received at least one dose of a two-dose regime.

Full compliance (correct dose, correct time) was better with the single dose compared to the two-dose regime. A total of 4616/5276 (87.5%) women received the correct RAADP dose at the correct time with 89.8% (4388/4887) receiving the single dose on time but only 58.6% (228/389) receiving both of the two-dose regime on time.

Non-compliance with the single-dose RAADP regime

In 47/4887 cases it was stated by auditors that the single-dose had either been missed (n=13) or that they did not know why it had not been given (n=34).

In 14 of the 235 cases in which a single-dose had been given early, a PSE was known to have occurred at 20-28 weeks gestation. For comparison, it was noted that in 97 of the 4388 cases where a single-dose had been administered at the right time a PSE was known to have occurred at 28-30 weeks gestation.

Non-compliance with the two-dose RAADP regime
Only 9 hospitals used the two-dose RAADP regime and audited 389 cases (see Table 2).

Reasons offered for not receiving the first dose (10/389, 2.6%) were:
Not known (3), PSE at a similar time (3), missed (2), wrong address (1) and RhD positive/negative blood grouping error (1).

Reasons offered for not receiving the second dose (21/389, 5.4%) were:
Early labour (11), not known (6), PSE at a similar time (2), missed (1), moved away (1).
5/389, 1.3% did not receive either dose of anti-D Ig. These cases were from five sites. Two cases were pre-term deliveries at 33 weeks. One case had already received several doses for PSEs so RAADP was omitted deliberately but against national guidance. In the other cases it was not known why RAADP had been omitted.

Comment
In the cases where RAADP could be successfully audited, only 52 women did not receive any anti-D Ig injection at all which is 1% of the women eligible giving 99% compliance with standard 1.

There are a number of valid reasons why RAADP is not given. First, there were 39 women who had immune anti-D (0.65% of all audited care). Second, it is acceptable to decline RAADP and nationally 114 women did this, which was 1.9% of all audited care.

Of more concern is that information was not available on whether RAADP was given to 161 women and in a further 125 women RAADP was not given because their care was being given elsewhere or they did not attend antenatal appointments. 4.8% of audited women may or may not have received RAADP because of lack of continuity of care.

It is incorrect to assume that RAADP is not required if it has recently been given for a PSE. Although it was not specifically stated as such, it was possible to analyse the audit data to show that in some cases where RAADP had been omitted or given at the wrong time, there was a recent PSE. The guidelines specifically recommend that RAADP and prophylaxis for PSEs should be regarded as separate events and anti-D Ig given for both at a dose indicated by the local anti-D Ig policy.

The timing of RAADP is important. Giving anti-D Ig too early might mean lower blood levels of anti-D in the critical time close to delivery. Giving anti-D Ig too late could potentially lead to sensitisation if there is a silent fetomaternal haemorrhage. Compliance with standard 1 is better for the single-dose RAADP regime in that 89.8% of women were given anti-D Ig injection on time compared to only 58.6% of women given the two-dose RAADP regime.

In the organisational questionnaire (see next section), 71% of hospitals had changed from the two-dose to the single dose regime and 17% of those changes cited compliance with the prophylactic regime as one of the drivers for change.

AUDIT STANDARD 2:
All eligible RhD negative pregnant women delivering RhD positive babies receive anti-D Ig prophylaxis post-delivery [PD] at the correct time and the correct dose

Additional relevant standards

- A dose of *at least* 500 IU anti-D Ig within 72 hours of delivery
- A maternal Kleihauer (or equivalent) test is performed after delivery to estimate any fetomaternal haemorrhage [FMH] and determine if additional anti-D Ig is required

There were 3392 RhD negative women without confirmed immune anti-D who delivered a live RhD positive (3308) or RhD unknown (84) baby.

For your site there were 13 women who were eligible for post-delivery anti-D Ig prophylaxis.

Nationally, compliance with standard 2 was 91.6% (3106/3392) - these women received post-delivery (PD) anti-D Ig at the right dose and on time.

Table 4: Compliance with post-delivery anti-D Ig (N=3392)

	National		Your site	
	%	N	%	N
Dose of at least 500 IU, given within 3 days of delivery	91.6	3106	**100**	**13**
Dose of at least 500 IU, given later than 3 days of delivery	0.9	29	**0**	**0**
Dose of at least 500 IU, timing not stated	1.7	57	**0**	**0**
Dose not stated, given within 3 days of delivery	4.3	146	**0**	**0**
Anti-D Ig not given*(see Table 5)	1.0	33	**0**	**0**
Delivered elsewhere, post natal anti-D administration unknown	0.4	13	**0**	**0**
Unknown, no post-natal records	0.2	8	**0**	**0**
Total	100	3392	**100**	**13**

Table 5: Reason for omission of post-delivery anti-D Ig to eligible women (N=33*)

	Number of cases	% of Anti-D Ig omissions
Declined anti-D Ig	9	27%
Omission investigated but reason unknown	7	22%
No comment on omission of anti-D Ig	4	12%
Did not attend for anti-D Ig injection	2	6%
Hysterectomy or sterilisation post delivery**	3	9%
Recent anti-D Ig for PSE so anti-D Ig not 'deemed necessary'	3	9%
Immune anti-D at delivery**	2	6%
Laboratory error	2	6%
No postnatal bloods taken	1	3%
TOTAL	33	

** These women did not need anti-D Ig

Table 5 is a further analysis of the 33 cases where PD anti-D Ig had not been recorded as having been given based on the audited records. In 19/33 cases PD anti-D Ig should have been given and wasn't (or there was no record of it being given).

In the remaining 14 women there were no errors of omission. Nine of these women declined anti-D Ig (27%) and a further five women (15%) did not need it either because they had been sensitised or had immune anti-D (n=2) or because they were unable to have any more babies (n=3).

Omission of care in respect of PD anti-D Ig prophylaxis for 19 women (0.6% of all women eligible to receive anti-D Ig in this context) arose because of errors in the laboratory or clinical areas but the reason for omission was unknown for 7/33 women and for a further 4/33 women there was no comment by the auditor on the reason for admission. For three women anti-D Ig should have been given but was incorrectly omitted on the basis that an injection had recently been given for a PSE.

Maternal Kleihauer tests and anti-D Ig dose post-delivery

Kleihauer (FMH) test taken and analysed in eligible women for your site: 100% (13/13).

There was evidence of a Kleihauer (FMH) test being taken and analysed for 97% (3274/3392) of eligible women. For these 3274 Kleihauer tests a summary of FMH test result and the associated anti-D Ig dose is given below in Table 6.

Table 6: Post-delivery FMH (Kleihauer) testing (N=3274)

Q6: Dose of anti-D Ig (IU)		FMH covered by this anti-D Ig dose	Kleihauer test result					Total
			No fetal cells seen	FMH 2 mL or less	FMH more than 2mL but less than 4mL	FMH 4mL or more	FMH volume not stated	
'Standard' anti-D Ig doses	500	4mL	952	935	96	45	45	2073
	1500	12mL	334	422	159	33	105	1053
	1250	10mL	-	1	-	-	-	1
'Additional' anti-D Ig doses	750	6mL	-	-	-	1	-	1
	1000	8mL	-	-	-	1	-	1
	1750	14mL	-	-	-	1	-	1
	2000	16mL	-	-	-	3	-	3
	No anti-D Ig dose stated		49	55	24	9	4	141
	Total		1335	1413	279	93	154	3274

Data on the FMH volume was not available for 154/3274 women (4.7%). Although it might be assumed that these women fell into the 'no fetal cells seen' category, these have been excluded from the subsequent analysis.

Where data on FMH volumes was given (3120 women), 42.8% (1335/3120) of FMH tests showed 'no fetal cells seen' and 45.3% (1413/3120) showed that the FMH was 2mL or less. So in 88.1% (2748/3120) no confirmatory or follow-up FMH testing was required after the initial Kleihauer.

For FMH of more than 2mL, confirmatory testing using flow cytometry is required[19]. In 279/3120 (8.9%) women, the confirmed FMH was less than 4mL so no additional anti-D Ig was required.

In only 3% of all women (93/3120) the confirmed FMH was 4mL or more. The confirmed FMH was covered by the 'standard' anti-D Ig dose already given for 78 women and additional anti-D Ig was required for 15 women, although the amount of 'additional' anti-D Ig administered was not stated for nine of these. Follow-up testing would be required for 3% of women (93/3120) to ensure the FMH had cleared but only 0.5% (15/3120) needed 'additional' anti-D Ig administered.

Miscarriage and termination of pregnancy

Of the 234 women who were known to have had either a miscarriage (183) or termination of pregnancy (51) the information submitted by auditors varied in detail regarding the gestation for the miscarriage/TOP and in whether anti-D Ig had been given following the event, so the information presented in Table 7 below derives from across the audit record and may be incomplete.

Table 7: Anti-D Ig after miscarriage or termination of pregnancy*

Gestation	Anti-D (IU)	Miscarriage	Termination of pregnancy
Less than/equal to 20 weeks	250	33	13
Less than/equal to 20 weeks	500	10	6
Less than/equal to 20 weeks	1500	11	5
Greater than/equal to 21 weeks	500	4	2
Greater than/equal to 21 weeks	1500	3	1
Anti-D given but dose not known		1	1
Gestation not known	250	14	3
Gestation not known	500	1	3
Gestation not known	1500	0	2
Anti-D at same gestation but reason for anti-D not known		7	1
Other PSE which could include miscarriage / TOP (from Q9) but cannot verify because birth gestation not known		8	1
Not known if anti-D Ig given		91 (50%)	13 (25%)
Total		183	51

*These data are included here rather than in the PSE section because they were included by auditors as post-delivery prophylaxis.

As far as these audit records go and giving the benefit of doubt the auditors indicated that anti-D Ig had been given after at least half (50%, 91/183) of the miscarriages and three-quarters (75%, 38/51) of termination of pregnancy.

Comment

This is the most important part of the anti-D Ig prophylaxis pathway as sensitisation is more likely to occur around the time of delivery because of fetomaternal haemorrhage.

There is very good compliance with Standard 2 - post-delivery anti-D Ig prophylaxis - in that 98.4% of RhD negative women who were eligible had documentation that anti-D Ig was given post-delivery although in only 91.6% was the standard met in full because the dose was given on time and at the correct dose.

Of the 33 women where anti-D Ig administration could not be confirmed as being given it was not necessary or declined in a total of 14 of them, leaving 19 women at risk of sensitization - that is 0.5% of the RhD negative women delivering RhD positive babies in this audit. Once again there were instances where PD anti-D Ig was omitted possibly because it had recently been given for a PSE but this demonstrates incorrect clinical decision-making.

Kleihauer testing is an essential part of the pathway that delivers effective PD prophylaxis and 97% of women had FMH testing. Where data on the volume of FMH was available, 88.1% of RhD negative women delivering RhD positive babies had an FMH of less than 2mL. After confirmatory testing on the remainder, a total of 97% of deliveries had an FMH of less than 4mL. Of the 3% who had confirmed FMH of more than 4mL, only 0.5% needed additional anti-D Ig, as the 'standard' dose already given was sufficient to cover the FMH in the remainder.

AUDIT STANDARD 3:
All RhD negative pregnant women receive anti-D immunoglobulin prophylaxis after a potentially sensitising event [PSE] in pregnancy

Additional relevant standards:

- A dose of *at least* 250 IU anti-D Ig before 20 weeks and *at least* 500 IU anti-D Ig after 20 weeks gestation is given within 72 hours of the PSE
- A maternal Kleihauer (or equivalent) test is performed after delivery to estimate any FMH and determine if additional anti-D Ig is required

Eligibility for this category is RhD negative women who had a PSE and were not sensitised (in other words, who did not have immune anti-D).

Below is a national summary of the data for all PSEs reported and whether the audit standard was met. The national data on individual PSEs can be found in **Appendix One** – supplementary data. It was not possible to give a your site report for compliance with this category.

Table 8: Summary of anti-D Ig prophylaxis given to potentially sensitising events at all gestations (N=1052)

	Potentially Sensitising Events		Anti-D Ig dose for PSE			Timing of anti-D Ig for PSE		
	N	%	Correct	Incorrect	Missing data	Correct	Incorrect	Missing data
Amniocentesis	49	4.7	43	0	6	32	1	16
Chorionic villus sampling	31	2.9	28	2	1	25	2	4
In-utero procedure	11	1.0	9	0	2	5	0	6
Antepartum haemorrhage	438	41.6	405	21	12	347	2	89
External cephalic version	47	4.5	47	0	0	43	1	3
Fall/trauma	198	18.8	181	9	8	165	1	32
Miscarriage & Stillbirth	278	26.4	256	7	15	214	0	64
Total PSE	1052		969 (92%)	39 (3.7%)	44	831 (79%)	7 (0.7%)	214

There were 1052 potentially sensitising events recorded in 924 women of which the largest group was antepartum haemorrhage comprising 41.6% of all PSEs (438/1052) with miscarriage (including stillbirth and IUD) accounting for 26.4% (278/1052) and falls or other abdominal trauma accounting for 18.1% (198/1052).

Overall 95.8% (1008/1052) of PSEs were recorded as having been treated with anti-D Ig although 3.7% did not get the correct dose and 79% probably received the anti-D dose within 3 days of the event.

Maternal Kleihauer tests and anti-D Ig dose for PSEs after 20 weeks

Responding to Q6 the laboratory auditors gave information about additional anti-D Ig doses and in relation to Kleihauer testing they indicated that gestation was either more than 20 weeks and the test was done (538) or was less than 20 weeks and the test was not done (427).

For other PSEs reported under Q6, the gestation at PSE was calculated from available dates as either ≥20 weeks (297) or <20 weeks (95) whilst gestations for 22 PSEs were not known. Overall there was evidence within the audit records of a Kleihauer test being done for 87% (729/835) of those PSEs occurring at 20 weeks or later. For these 729 tests (in 633 women) a summary of test results and anti-D Ig doses is given in Table 9.

Table 9: Anti-D doses and Kleihauer (FMH) tests for potentially sensitising events after 20 weeks (n=729)

Q6: dose of anti-D Ig (IU)	FMH covered by this anti-D Ig dose	Kleihauer test result					Total
		No fetal cells seen	FMH less than or equal to 2mL	FMH more than 2mL but less than 4mL	FMH 4mL or more	FMH volume not stated	
250	2mL	9	4	3	1	3	20
500	4mL	262	191	21	3	24	501
1500	12mL	76	61	29	7	15	188
Not stated		5	13	2	0	0	20
Total		352	269	55	11	42	729

Although Kleihauer tests are only required after 20 weeks gestation, 20 cases appear to have been given 250 IU anti-D Ig which is the minimum dose required before 20 weeks gestation. Either the Kleihauer tests were done unnecessarily or insufficient anti-D Ig was given. Alternatively the anti-D Ig dose identified by the auditors could have been the 'additional' dose given after the 'standard' dose had been administered.

Data on the FMH volume was not available for 42 women (5.8%). Although it might be assumed that these women fell into the 'no fetal cells seen' category, they have been excluded from the subsequent analysis.

Where data on FMH volumes was given 352/687 (51.2%) of FMH tests showed no fetal cells and in 269/687 (39.2%) the FMH was 2mL or less so in 90.4% (621/687) no confirmatory or follow-up FMH testing was required after the initial Kleihauer.

66/687 women required confirmatory testing and 55/687 (8%) had a confirmed FMH of less than 4mL giving a total of 676/687 (98.4%) who did not require follow-up testing.

Follow-up testing is required to check for clearance of fetal cells after administration of additional anti-D Ig. However anti-D Ig will only clear fetal cells from RhD positive babies and, during pregnancy, the baby's RhD group is unknown. In this audit follow-up testing would be required for 11/687 women (1.6%) where the confirmed FMH was 4mL or more.

Commentary on the data analysed in this section

- Information in the audit about PSEs came from two sources: One source was Q9 in the midwife section of the audit tool asking specifically about amniocentesis, chorionic villous sampling, cordocentesis, other in-utero therapeutic intervention/surgery, ante partum haemorrhage, external cephalic version, fall/abdominal trauma and other (including miscarriage & still birth). The other source was Q6 as completed by the hospital transfusion laboratory that described up to 6 additional doses of anti-D Ig.
- The midwife auditor gave dates of PSE, gestation at PSE and anti-D Ig dose but not the date when the anti-D Ig was given. This was available from the laboratory auditor, and checking to see if the anti-D was administered within 3 days of the PSE required matching up the records across the two sources.
- Sometimes information was missing from one or other source and sometimes the reason for giving the anti-D Ig dose as stated by the laboratory (as free-text) either did not match that indicated at the same gestation by the midwife or was said to be 'unknown'.
- To maximise the yield of information and to provide firm denominators for analysis it was decided to start with the specified PSEs from the midwife audit and for these see what information could be matched from the laboratory audit as to the timing of anti-D in relation to the PSE. The guideline indicates a timescale of within 72 hours, but as times were not available to the audit this was analysed by proxy as within 3 days of the PSE.

Comment

It is more helpful to give national data here because of the small numbers of PSEs in any one maternity unit.

Where documentation exists, Standard 3 – Anti-D Ig Prophylaxis for PSEs - is met in 95.8% of potentially sensitising events. Where the PSE was recorded as being after 20 weeks gestation, 87% of women had a Kleihauer test for estimation of FMH. Where data was available on the volume of FMH, only 11/687 (1.6%) had a confirmed FMH of more than 4mL and would have required follow-up testing and may have required additional anti-D Ig.

The consistent lack of information - reflecting either a lack of documentation at site level or less than complete auditing by the auditors or a mix of both - is the most notable observation.

Audit Standard 4:
All RhD negative women are given information about anti-D Ig prophylaxis and consent to receive the anti-D Ig is documented

Additional relevant standard
- In the event that anti-D Ig prophylaxis is declined, the reason is recorded

This standard relates to the availability of documentation that the action took place and may underestimate the number of women who were informed about anti-D prophylaxis and gave their consent to receive it.

Compliance with this standard can be found in the tables below.

Table 10: Did the mother receive a patient information leaflet explaining the Rh factor and anti-D prophylaxis?

	National (5972)		Your site	
	%	N	%	N
Yes	36	2144	78	18
No	61	3664	22	5
Not stated by auditor	3	164	0	0

Table 11: Is there documented evidence that the mother consented to have RAADP?

Table	National (5972)		Your site	
	%	N	%	N
Yes	57	3424	87	20
No	40	2364	13	3
Not stated by auditor	3	184	0	0

Table 12: Reasons given where RAADP was declined (N=131)

	National	
	%	N
Partner RhD negative	58	76
Personal objections or concerns	4.6	6
Fully informed but declined	3.8	5
No further pregnancies planned	1.5	2
Allergy	1.5	2
Needle phobia	1.5	2
Religious reasons, Jehovah's Witness	1.5	2
Other (did not want any intervention, refused to discuss)	1.5	2
No reason given	26	34
Total		**131**

Comment

This standard relates to NICE guidance on RAADP[2] including the importance of documenting the nature of the discussion when women decline anti-D Ig. Both the RCOG[4] and BCSH[3] guidelines stress the importance of informing women who are RhD negative about the importance, risk and benefits of anti-D Ig prophylaxis.

In this audit only 36% of women were given written patient information and 57% gave consent to receive RAADP. It should be the policy of a maternity unit to follow this guidance but there should be a method of recording that this has taken place.

The commonest reason for declining anti-D Ig is where the mother states the father of the baby is RhD negative but just over a quarter of this group did not have a reason for refusing anti-D Ig recorded.

Organisational Audit

147 sites participated in the Organisational Audit. The results of this part of the audit provide an understanding of the organisation of antenatal care and how this reflects on the delivery of an effective anti-D Ig prophylaxis programme.

The data is presented in the order that the questions were asked and the detail of these questions can be found in **Appendix 4**.

The data supplied about the number of deliveries were a mix of precise figures and estimates; most sites were able to give estimates per maternity unit but some only for the whole site.

Description of service and workload

Deliveries per unit were summed per site for the 142 sites supplying data. The median annual deliveries per site were 4233 (IQR 2922-5765) giving a grand annual total of 607,338 deliveries for the hospitals that participated in this audit.

Table 13: The maternity units stated in the audit for your site:

Unit name	Number of deliveries
Birth Centre	5878
,	
,	
,	
,	
,	
,	
,	
SITE TOTAL	5878

NICE technology appraisal guidance 156[3] states that: "The incidence of HDN depends on the proportion of the population that is RhD negative. This proportion varies between ethnic groups and is highest in the white population; in the UK, approximately 16% of the white population is RhD negative".

As a sense check on audit cases submitted, it was expected that about 15% of the total number of deliveries per month by audit sites would have been eligible for the audit.

- In the organisation audit 142 sites supplied estimated annual deliveries; 15% of their estimated annual total of 607,338 deliveries indicates 91,101 deliveries to RhD negative mothers over 12 months i.e. 7592 per month.
- In the clinical audit 153 sites audited 4759 bookings during September 2012.

It seems likely, therefore, that somewhere between half and two-thirds of eligible RhD negative women were captured by the clinical audit, and this should be taken into account when reviewing local data.

Product name and dosage of anti-D Ig

There are two manufacturers who provide anti-D Ig for prophylaxis in pregnancy in the UK and tables 14-17 summarise the products and doses in use for anti-D Ig prophylaxis programme and table 18 shows a national summary of the data.

Table 14: Product/dose used for PSEs before 20 weeks

Q5: Anti-D Ig Product	National (147) %	National (147) N	Your site
BPL D-Gam	86	126	D-Gam BPL
CSL Rhophylac	14	20	
Both (different maternity units)	1	1	
Q5: Anti-D Ig Dose	**National (147) %**	**National (147) N**	**Your site**
250 IU	71	104	250 or 500
250/500 IU (different maternity units)	2	3	
500 IU	14	21	
1500 IU	13	19	

Table 15: Product/dose used for PSEs after 20 weeks

Q6: Anti-D Ig Product	National (147) %	National (147) N	Your site
D-Gam BPL	69	101	Rhophylac
Rhophylac	31	46	
Q6: Anti-D Ig Dose	**National (147) %**	**National (147) N**	**Your site**
250 IU	1	1	1500
250 or 500 IU	1	2	
500 IU	66	97	
1500 IU	32	47	

Table 16: Product/dose used post-delivery

Q7: Anti-D Ig Product	National (147) %	National (147) N	Your site
D-Gam BPL	68	100	D-Gam BPL
Rhophylac	31	46	
Not known	1	1	
Q7: Anti-D Ig Dose	**National (147) %**	**National (147) N**	**Your site**
500 IU	66	97	500
1500 IU	33	49	
Not known	1	1	

Table 17: Product/Dose for RAADP*

Anti-D Ig Product	National (147) %	National (147) N	Your site
D-Gam BPL	41	61	D-Gam BPL
Rhophylac	56	82	
Both (different maternity units)	2	3	
Not known	1	1	
Anti-D Ig Dose	**National (147) %**	**National (147) N**	**Your site**
500	3	5	500
1500	95	140	
Other**	1	2	

* We intended to ascertain how many hospitals routinely administer anti-D Ig intravenously for RAADP but this question was poorly phrased and the data could not be reliably analysed.
**D-Gam BPL 250 & Rhophylac 1500, D-Gam BPL 250 & D-Gam BPL 500

Table 18: National overview of anti-D Ig prophylaxis dosage according to indication

Dose anti-D Ig	250 IU	500 IU	1500 IU	Other
PSE before 20 weeks	71%	14%	13%	2%
PSE after 20 weeks	(1%)	66%	32%	1%
RAADP	-	3%	95%	2%
Post delivery	-	66%	33%	1%

Comment

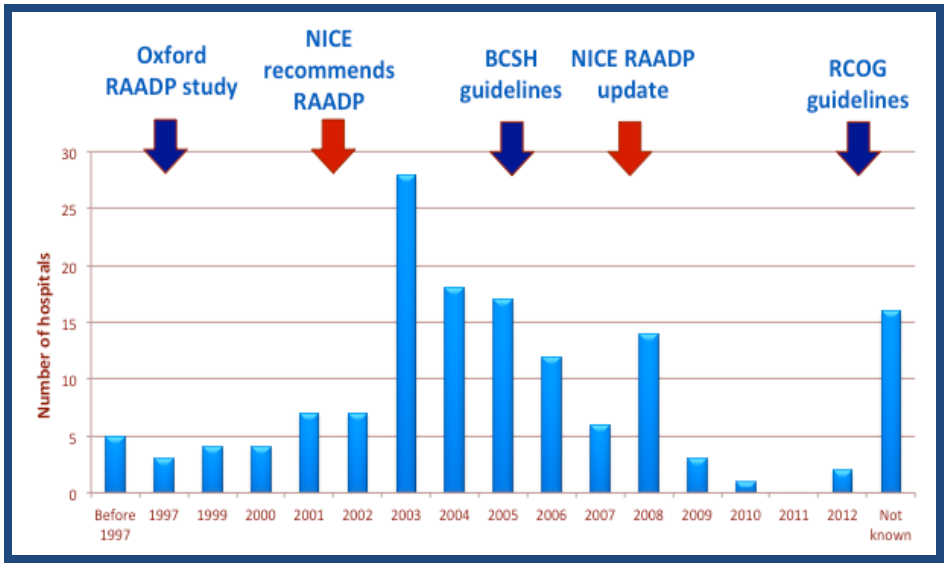
There is a tendency to use higher anti-D Ig doses than the minimum dose required for PSEs and post delivery prophylaxis; 27% of maternity units use more than 250 IU for PSEs before 20 weeks gestation; 32% use more than 500 IU for PSEs after 20 weeks gestation and 33% use more than 500 IU anti-D Ig post-delivery.

Implementation of Routine Antenatal Anti-D Prophylaxis (RAADP)

145 sites answered 'Yes' to this and 2 did not answer but did give details in Q10 of the product and dosage of anti-D used for RAADP. So the audit indicates that all 147 sites have implemented RAADP.

Figure 4 below shows the year in which hospitals stated that RAADP was introduced with an indication of the key milestones in anti-D prophylaxis.

Figure 4: Year in which RAADP was first introduced



Nationally 23% (30/131) of the uptake of RAADP was before or during 2002, with a further 35% (46/131) uptake during 2003-2004, 27% (35/131) during 2005-2007 and 15% (20/131) from 2008, unknown for 16. Hospitals were asked if they had changed the product and/or the dosage since the original introduction of RAADP and 71% (104/147) indicated that they had. The following table summarises the reason for this.

Table 19: Categories of reason for changing RAADP regime

Q12 Category	Detail	Count
Cost reasons	Cost saving, one product cheaper than another. Single dose cheaper than two doses	25
Manufacturer reasons	Problem with supplying anti-D, Baxter (Partobulin) withdrawn from UK market, D-Gam (BPL) unable to supply due to batch failure	20
Patient reasons	Improved patient experience. Fewer clinic visits, more convenient to have one injection than two	17
Compliance reasons	Improved compliance with a single dose, previous problems with missed second dose, change after audit of compliance, fewer errors with administering single dose	18
Guidelines	NICE guidance 2008, single dose regime as good as two-dose, BCSH anti-D guidelines	16
Staff or admin reasons	Easier for midwifery staff, easier for laboratory or pharmacy staff, fewer ANC visits, easier to give single dose, easier to organise single dose	16
Product reasons	Pre-filled syringe more acceptable, peel-off label for maternity notes, cold storage requirements, product that can be give iv in large bleeds	10
Standardisation	Trust mergers, variable dosing to single product, issue of named product, streamline antenatal procedure	9
No reason given	Unknown or not answered. Stated regime had changed but did not give a reason	34
Total reasons (from 104 hospitals)		165

Comment

All sites participating in this audit have introduced RAADP with 94% of sites now using a single RAADP dose at 20-30 weeks gestation and only 6% using a two-dose regime. 23% of sites introduced RAADP before the first NICE guidance in 2002; a further 62% introduced RAADP between 2003 and 2008 and the remainder after the second NICE guidance in 2008.

When originally published NICE recommended either the two-dose or single-dose RAADP regime but most hospitals initially implemented a two-dose regime. In 2008 NICE stated that both regimes were of equal efficacy and encouraged hospitals to select the regime based on local preference and cost. 71% of sites audited stated they had changed their regime since introduction of RAADP and it is assumed the change was from the two-dose to the single-dose regime. One third gave no reason for changing regime and 30% changed for a single reason. The others gave a whole range of reasons of which 'cost' and 'supply problems' were the commonest.

Organisation and documentation of anti-D Ig prophylaxis

90% (132/147) of transfusion laboratories state they are responsible for the issue of anti-D Ig to named patients. Where this is the case 79% (104/132) of these laboratories issue all of the anti-D Ig to named patients. Six laboratories labs stated that they issued less than 50% of the anti-D Ig to named patients.

26% (38/147) of transfusion laboratories state that they provide stocks of anti-D Ig on a NON-NAMED patient basis to other departments for them to issue to NAMED patients and table 19 summarises the location that anti-D Ig is issued to by the transfusion laboratory.

Table 20: Location, other than transfusion department, issuing anti-D Ig to NAMED patients (N=38)

	National (52 locations from 38 sites)	
	%	N
Antenatal clinic, maternity assessment wards, maternity day unit	25	13
Gynaecology clinics, acute gynaecology units, early pregnancy units	23	12
Community midwives	13	7
Emergency supply (overnight, in ultrasound, in case can't transfer)	9	5
Other (included 'obstetrics' 'maternity')	8	4
GP clinics, community clinics, community hospital	8	4
Day surgery	6	3
Labour ward, delivery ward, antenatal ward, postnatal ward	4	2
Fetal medicine unit	4	2

17/38 sites (45%) issued anti-D Ig in one non-laboratory location, 5/38 (13%) two locations and 10/38 (26%) three locations. Six did not give any details.

Only 8% (12/147) of transfusion laboratories stated they were aware of anti-D Ig being supplied for obstetric use that has not been issued either on a named patient basis or as stock from a transfusion department. Ten respondents indicated the source of anti-D Ig was the pharmacy department with one maternity unit obtaining supplies from another hospital and only one obtaining anti-D Ig direct from the supplier.

Finally, 86% (127/147) of transfusion laboratories stated that they were responsible for recording that anti-D Ig had been administered to a NAMED patient on the laboratory information management system (LIMS).

Comment

Although the ultimate responsibility for prescribing and administering anti-D Ig prophylaxis must rest with the clinicians responsible for delivering maternity care, the transfusion laboratory plays a major role in ordering, stocking, issuing and recording that anti-D Ig has been given to the right women at the right time. Hospitals who do not record the issue and administration of all anti-D Ig to named patients in the transfusion laboratory, either directly or indirectly, should be confident that they have an alternative system in place that is both auditable in the event of sensitisation and will ensure a batch of anti-D Ig can be traced to an individual recipient.

Audit, incident reporting and training

36% (53/147) of sites stated had undertaken a previous audit of anti-D prophylaxis.

80% (117/147) of sites stated that they had made an anti-D Ig related report to SHOT in the last 12 months

Table 21: Is there update training in place for the following groups of staff?

Q22	National (147) %**	N	**Your site**
Haematology laboratory staff	85	(119/140)	**Yes**
Transfusion laboratory staff	88	(126/143)	**Yes**
Midwifery staff	80	(110/138)	**Yes**
Obstetric medical staff	55	(72/131)	**Yes**
Haematology medical staff	42	(55/132)	**Yes**

** A small number of "not known" or blank responses were excluded from denominators.

Comment

In order to maintain excellent patient care staff training, clinical audit and incident reporting and investigation are important and this is stated by NHSLA and CQC as well as by NICE. For delivery of an effective anti-D Ig prophylaxis programme, all of these elements should be in place. Only 36% of sites had undertaken a previous anti-D Ig audit. Sites can compare performance in this audit where previous audit has taken place and use this audit framework to review future performance, particularly after implementation of changes to the anti-D Ig prophylaxis regime. It is encouraging that 80% of sites had reported anti-D errors to SHOT. Any errors detected as a result of this national audit should be reported where they meet the SHOT criteria. Although the reason for sensitisation was not explored as part of this audit, any women with immune anti-D that were included in the initial case-capture part of this audit can be reported as part of the SHOT anti-D alloimmunisation pilot. The stated availability of training for haematology (42%) and obstetric (55%) medical staff was poor compared to laboratory staff (85% for haematology laboratory and 88% for transfusion laboratory) and midwifery staff (80%) but it is possible that the auditors were not aware of the training provided to all staff groups at their site. For example, trainees in haematology and obstetrics may receive training outside the Hospital/Trust and experienced consultant obstetricians and haematologists are likely to be involved with local policy and protocol development against which other staff will be trained.

Discussion

It has been recognised for some time that a national audit of anti-D Ig prophylaxis was required and the project group is grateful for those who helped design and pilot this audit as well as all the many midwives and transfusion staff who undertook the audit data collection.

There were clearly difficulties encountered by the auditors in identifying the cohort of women to be audited because of the configuration of antenatal clinic records. This was the preferred method of case-capture to ensure that the whole pathway was covered from the booking appointment to the post-delivery period.

There were also problems encountered by the midwives and transfusion laboratory staff with respect to obtaining all the necessary data. As this was an audit of documented care, lack of documentation was taken to mean omission of the required anti-D injection but there may well have been some women who were categorised as not having appropriate anti-D prophylaxis but who did receive it, albeit undocumented.

RhD negative women not eligible for anti-D include those with immune anti-D and 39 women with a viable pregnancy at the time RAADP was due (28-30 weeks gestation) were already sensitised and a further 2 cases developed immune anti-D during pregnancy so did not need PD prophylaxis. This is 0.7% of all the patients audited. If blood tests are taken after anti-D Ig has been given, the anti-D is detectable in the antibody screen. The auditors were not always clear whether the anti-D detected in these laboratory tests was passive or immune and this is a common clinical problem particularly if there is not a record of anti-D Ig being given or if it has been given under the jurisdiction of another organisation where documentation is not accessible or not linked.

The audit data was much more complex to analyse than was originally envisaged and this was, in part, due to the discrepancies between the clinical record and the laboratory record. Assumptions were sometimes made that may have miscategorised the care of an individual audited case and sites participating in this audit should take this into account when reviewing their cases against the standards and against national performance.

Appendix 1 - Supplementary information

Amniocentesis

Anti-D dose (IU) and gestation	Days from Amniocentesis to Anti-D Ig				Total
	Anti-D given within 3 days	Anti-D given > 3 days	Anti-D within 3 days but different / unknown reason (Q6)	Unclear	
GE 250 and gestation 12w 0d to 20w 0d	11	-	10	8	29
GE 500 and gestation 20w 1d or later	7	1	3	3	14
Unclear	-	-	1	5	6
Total	18	1	14	16	49

Amniocentesis – correct minimum dose in relation to gestation in 43/49, unclear in 6/49
Amniocentesis – correct timing of administration in relation to the event: definitely in 18/49, probably/possibly in another 14/49, too late in 1/49 and unclear in 16/49.

Chorionic villous sampling - CVS

Anti-D dose (IU) and gestation	Days from CVS to anti-D Ig				Total
	Anti-D given within 3 days	Anti-D given > 3 days	Anti-D within 3days but different / unknown reason (Q6)	Unclear	
GE250 given before 12w 0d	1	-	-	-	1
GE250 and gestation 12w 0d to 20w 0d	20	2	2	3	27
250 and gestation 20w 1d or later	2	-	-	-	2
Unclear	-	-	-	1	1
Total	23	2	2	4	31

CVS – correct minimum dose in relation to gestation in 28/31, inappropriate 2/31, unclear in 1/31
CVS – correct timing of administration in relation to the event: definitely in 23/31, probably/possibly in another 2/31, too late in 2/31 and unclear in 4/31.

Other in-utero therapeutic intervention/surgery (E.g. intrauterine transfusion, shunting)

Anti-D dose (IU) and gestation	Days from event to anti-D Ig		Total
	Anti-D given within 3 days	Unclear	
GE250 given before 12w 0d	-	1	1
GE250 and gestation 12w 0d to 20w 0d	4	-	4
GE500 and gestation 20w 1d or later	1	3	4
Unclear	-	2	2
Total	5	6	11

Other in-utero – correct minimum dose in relation to gestation in 9/11, unclear in 2/11
Other in-utero – correct timing of administration in relation to the event: definitely in 5/11, unclear in 6/11

Ante partum haemorrhage (APH)

Anti-D dose (IU) and gestation	Days from APH to Anti-D				Total
	Anti-D given within 3 days	Anti-D given > 3 days	Anti-D within 3days but different / unknown reason (Q6)	Unclear	
GE250 given before 12w 0d	-	-	1	-	1
GE250 and gestation 12w 0d to 20w 0d	87	-	19	18	124
GE500 and gestation 20w 1d or later	215	2	21	42	280
250 and gestation 20w 1d or later	1	-	-	-	1
Not given, gestation 12w 0d to 20w 0d	-	-	-	8	8
Not given, gestation 20w 1d or later	-	-	-	12	12
Unclear	3	-	-	9	12
Total	306	2	41	89	438

APH– correct minimum dose in relation to gestation in 405/438, inappropriate 21/438, unclear in 12/438

APH – correct timing of administration in relation to the event: definitely in 306/438, probably/possibly in another 41/438, too late in 2/438 and unclear in 89/438.

External cephalic version - ECV

Anti-D dose (IU) and gestation	Days from ECV to Anti-D Ig				Total
	Anti-D given within 3 days	Anti-D given > 3 days	Anti-D within 3days but different / unknown reason (Q6)	Unclear	
GE500 and gestation 20w 1d or later	31	1	12	3	47
Total	31	1	12	3	47

ECV– correct minimum dose in relation to gestation in 47/47

ECV – correct timing of administration in relation to the event: definitely in 31/47, probably/possibly in another 12/47, too late in 1/47 and unclear in 3/47.

Fall / abdominal trauma

Anti-D dose (IU) and gestation	Days from Fall/Trauma to Anti-D Ig				Total
	Anti-D given within 3 days	Anti-D given > 3 days	Anti-D within 3days but different / unknown reason (Q6)	Unclear	
GE250 and gestation 12w 0d to 20w 0d	31	1	7	4	43
GE500 and gestation 20w 1d or later	108	-	17	13	138
250 and gestation 20w 1d or later	-	-	-	1	1
Not given, gestation before 12w 0d	-	-	-	1	1
Not given, gestation 12w 0d to 20w 0d	-	-	-	2	2
Not given, gestation 20w 1d or later	-	-	-	5	5
Unclear	1	-	1	6	8
Total	140	1	25	32	198

Fall/Trauma– correct minimum dose in relation to gestation in 181/198, inappropriate 9/198, unclear in 8/198

Fall/Trauma – correct timing of administration in relation to the event: definitely in 140/198, probably/possibly in another 25/198, too late in 1/198 and unclear in 32/198.

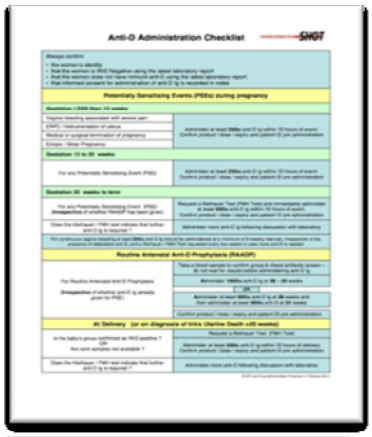
Other (including miscarriage & stillbirth)

Anti-D dose (IU) and gestation	Days from other PSE to Anti-D		
	Anti-D given within 3 days	Unclear	Total
GE250 given before 12w 0d	23	4	27
GE250 and gestation 12w 0d to 20w 0d	85	20	105
GE500 and gestation 20w 1d or later	100	24	124
Not given, gestation 20w 1d or later	-	7	7
Unclear	6	9	15
Total	214	64	278

Other PSE– correct minimum dose in relation to gestation in 256/278, inappropriate 7/278, unclear in 15/278
Other PSE – correct timing of administration in relation to the event: definitely in 214/278 and unclear in 64/278.

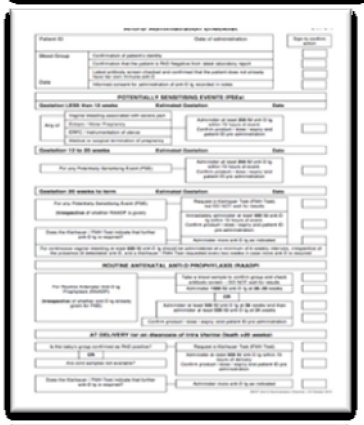
Appendix 2 Educational resources for Anti-D prophylaxis

Serious Hazards of Transfusion Resources WWW.SHOTUK.ORG



SHOT anti-D administration checklist poster

http://www.shotuk.org/wp-content/uploads/2010/03/SHOT-Anti-D-Administration-Checklist-Poster-v7-Oct-2012.pdf



SHOT anti-D administration checklist

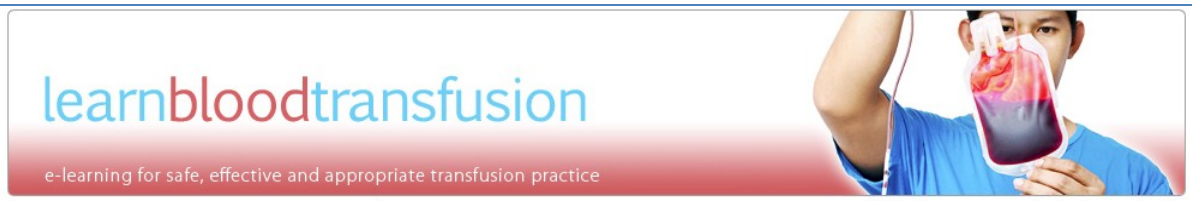
http://www.shotuk.org/wp-content/uploads/2010/03/SHOT-Anti-D-Administration-Checklist-v12-Oct-2012.pdf

SHOT article for Midwives journal 2013 by Tony Davies

http://www.shotuk.org/wp-content/uploads/Anti-D-Article-for-Midwives-Jan-13.pdf

2014 SHOT Symposium Presentation Dr Jane Keidan Anti-D sensitisation. Why is it still happening?
http://www.shotuk.org/wp-content/uploads/Jane-Keidan-Anti-D-for-website-SHOT-2014.pdf

Learn Blood Transfusion e-learning Modules



Learnbloodtransfusion is a suite of e-learning courses that have been developed to ensure that all healthcare workers can participate safely in the transfusion process. The courses are reviewed regularly by a UK-wide editorial board and are intended to complement rather than replace existing teaching initiatives.

The **Anti-D Clinical course** covers pathophysiology, management of routine and non-routine care during pregnancy, informed decision making and administration of anti-D immunoglobulin.

This course is aimed primarily at clinicians (obstetricians), midwives, nurses and general practitioners.
1. Understanding Maternal Sensitisation
2. Anti-D Prophylaxis
3. Management of Pregnancies at Increased Risk
4. Anti-D - Routine Use
5. Anti-D - Informed Decision Making
6. Anti-D - Safe Storage and Administration

The **Anti-D Laboratory course** covers routine laboratory testing in pregnancy and the role of the laboratory in anti-D prophylaxis and anti-D sensitised pregnancies.

This course is aimed primarily at biomedical scientists working in haematology and transfusion laboratories, clinicians (obstetricians), midwives, nurses and general practitioners.
1. Understanding Maternal Sensitisation
2. Anti-D Prophylaxis
3. Routine Laboratory Testing in Pregnancy
4. The Role of the Laboratory in Anti-D Prophylaxis
5. The Role of the Laboratory in Anti-D Sensitised Pregnancies

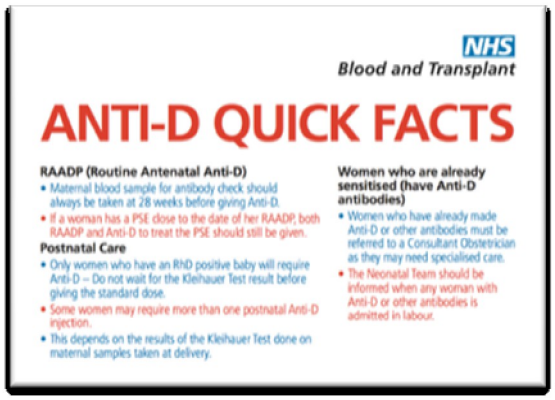
To access learnbloodtransfusion, go to www.e-lfh.org.uk/projects/blood-transfusion/access-the-e-learning/

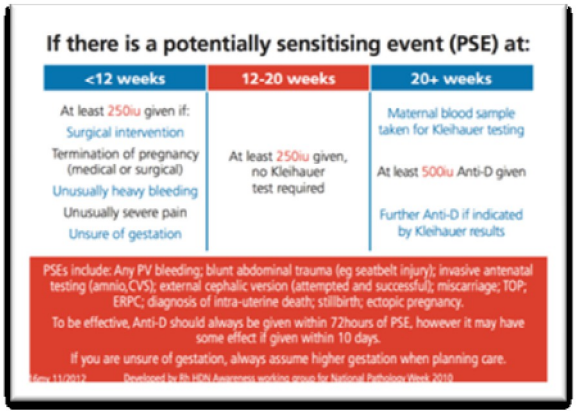
NHS Blood and Transplant Resources http://hospital.blood.co.uk

These resources can be ordered from NHSBT. Follow the instructions on the website at http://hospital.blood.co.uk/patient-services/patient-blood-management-resources/

POSTER: **Anti-D** When and How Much?

ANTI-D QUICK FACTS card for clinical staff





RhD Haemolytic Disease of the Newborn (HDN) - advances in prevention and treatment

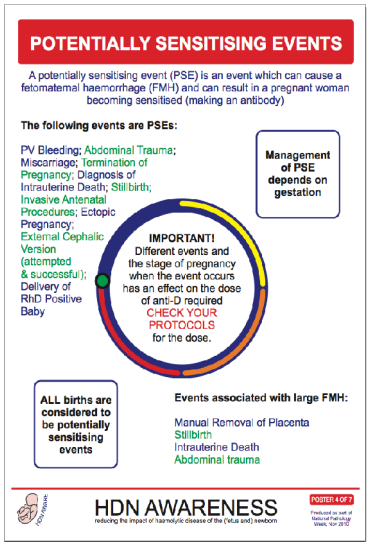
RhD HDN awareness displays were held at the Royal College of Pathologists, Royal College of Obstetricians and Gynaecologists, and at the Royal College of Midwives annual conference as part of National Pathology Week in November 2010 and many hospitals organised local RhD HDN awareness events as part of this initiative.

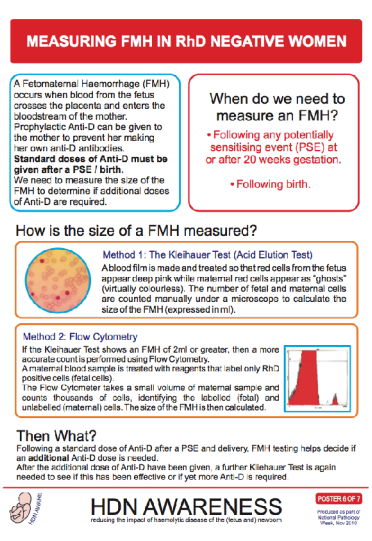
The resources for this campaign are available on the NBTC website by following this link: http://www.transfusionguidelines.org.uk/uk-transfusion-committees/national-blood-transfusion-committee/transfusion-awareness/rhd-haemolytic-disease-of-the-newborn

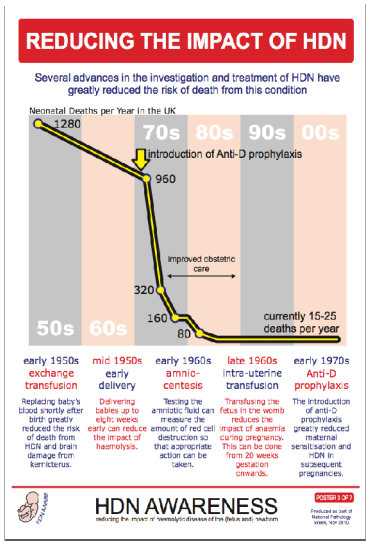
Resources

The following **posters** can still be used to support ongoing RhD HDN awareness initiatives.

Which antibodies are important in causing HDN?
Reducing the impact of HDN
Potentially sensitising events
Anti-D: when and how much?
Measuring FMH in RhD negative women
Sensitised pregnancies and RhD HDN: current management







Appendix 3 – Clinical Data Questionnaire

CLINICAL STANDARDS
Royal College of Physicians
Setting higher medical standards

National Comparative Audit of Blood Transfusion

NHS Blood and Transplant

Audit of the use of Anti-D

Audited Patient Number

SECTION 1

Hospital Transfusion Laboratory

Results obtained at the mother's booking appointment in September 2012

Note 1) If blood tests not done at booking go to Section 3 Q11

1) **What was the date of the booking appointment test results?** (dd/mm/yy)

1a) **What was the mother's blood group?**

RhD negative

RhD variant

RhD unknown

Note 2) If blood group is RhD variant and not eligible for anti-D prophylaxis go to section 3 Q13

1b) **What was the result of the mother's antibody screen?**

Negative

Positive

1c) **If antibody screen was positive, what was the antibody identification?**

Passive Anti-D

Immune Anti-D

Other antibody specificity

Note 3) If confirmed immune anti-D go to Section 3 Q12

Results obtained at the 28-week blood tests (use Mother's EDD to calculate, if necessary)

Note 4) If blood tests not done at 28 weeks go to section 3 Q11

2) What was the date of 28-week test results? (dd/mm/yy)

2a) What was the mother's blood group?

RhD negative

RhD variant

RhD unknown

Note 5) If blood group is RhD variant and not eligible for anti-D prophylaxis go to section 3 Q13

2b) What was the result of the mother's antibody screen?

Negative

Positive

2c) If antibody screen was positive, what was the antibody identification?

Passive Anti-D

Immune Anti-D

Other antibody specificity

Note 6) If confirmed immune anti-D go to section 3 Q12

Details of routine Antenatal Anti-D Prophylaxis (RAADP)

3) Indicate which RAADP regime is being used for this mother:

Single dose regime at 28-30 weeks *(If yes, complete Q3a &3b)*

Two-dose regime at 28 and 34 weeks *(If yes, Complete Q3a,b,c & d)*

Note 7) If Single Dose OR Dose 1 RAADP not given go to section 3, Q16

3a) What was the Single Dose OR Dose 1 RAADP given?

500 units

1250 units

1500 units

Other, please state:

3b) **On what date was the Single Dose OR Dose 1 RAADP given?** (dd/mm/yy)

3c) **What was the Dose 2 RAADP given?**

500 units

1250 units

Other, please state:

Note 8) If Dose 2 of a 2 dose regime not given go to section 3, Q16

3d) **On what date was Dose 2 RAADP given?** (dd/mm/yy)

Results obtained for the post delivery blood tests

4) **What was the date of Baby/Cord blood group test results?** (dd/mm/yy)

4a) **What was the baby/cord blood group?**

RhD negative

RhD positive

RhD unknown

4b) **Was a Kleihauer test indicated for the mother?**

Not indicated – baby RhD negative

Indicated – baby RhD positive

Indicated – baby RhD unknown

4c) **If indicated, what was the Kleihauer test result?**

(NB: if the confirmed value is >2 but ≤4, please record the actual value in the "Confirmed: FMH value =" option below)

No fetal cells seen

FMH <2 mL

FMH >4 mL

OR

Confirmed: FMH value =

4d) What was the date of this Kleihauer test result? (dd/mm/yy or leave blank if test not indicated)

Note 9) If RhD positive or RhD unknown and no Kleihauer, go to section 3 Q14

Note 10) If RhD positive/unknown and confirmed FMH >4mL, go to section 3 Q15

Details of postnatal anti-D Immunoglobulin

If the answer to Q4a is 'RhD negative', do not complete Q5 or 5a, since Anti-D would not be indicated. Go to Q6 to record details of any possible PSEs.

5) On what date was the standard postnatal anti-D given? (dd/mm/yy)

Note 11) If standard postnatal anti-D not given go to section 3, Q16

5a) What standard postnatal anti-D dose was given?

500 units

1250 units

1500 units

Other, please state:

Details of potentially sensitising events

If there is a record of anti-D Ig administration ADDITIONAL to the POSTNATAL and RAADP doses it should be recorded here. If more than one ADDITIONAL anti-D dose given, complete these questions for every dose. This form allows for 6 PSEs. If there are no PSEs, go to Q7a, Section 2 (page 10).

Additional dose 1

Date given

6) Additional dose of anti-D Ig

250 units

500 units

1250 units

1500 units

Other formulation (Please state):

Other dose (please state):

6a) Reason for additional dose (Please state reason or write "Not known")

6b) Was a Kleihauer test taken?

No, less than 20 weeks

Yes, greater than 20 weeks

Note 12) If >20 weeks and no Kleihauer, go to section3 Q14

6c) Kleihauer test result

(NB: if the confirmed value is >2 but ≤4, please record the actual value in the "Confirmed: FMH value =" option below)

No fetal cells seen

FMH <2 mL

FMH >4 mL

OR

Confirmed: FMH value =

6d) Date of Kleihauer test result (dd/mm/yy)

Note 13) If confirmed FMH >4mL, go to section 3 Q15

If there are no more PSEs, go to Q7a, Section 2 (page 10).

NB In the event of additional PSEs, then auditors were provided with the means to provide additional answers to the Q6 question set

SECTION 2

Midwife auditor

Notes:

- The name and identification details of this **RhD negative mother** can be found in the **audit data linkage record** using the assigned **audited patient number**
- Using the name and identification details, identify the **maternity notes**, **hospital notes** or **electronic patient record** to obtain the following information for each **RhD negative mother**

Expected date of delivery, mother's weight & BMI

7a) What was the mother's EDD? (dd/ mm/ yy)

7b) What was the mother's weight at booking? Kg

7c) What was the mother's BMI at booking?

NB: If weight and/or BMI not recorded, write "DK"

Routine Antenatal Anti-D Prophylaxis (RAADP)

8a) Is there a record that this mother received a patient information leaflet explaining the Rh factor and anti-D prophylaxis? Yes No

8b) Is there documented evidence that the mother consented to have RAADP? Yes No

8c) If the mother declined RAADP, what was the reason given?

No documented reason given

Known to have immune anti-D

Partner known to be RhD negative

No further pregnancies planned

Objections/concerns about anti-D

Other (please state):

By referring to the data recorded by the transfusion laboratory in Q3b:

8d) **Was the single dose RAADP given between 28 and 30 weeks gestation?** Yes No

8e) **If NO, at what gestation was it given?** Weeks ____ Days ____

OR

8f) **Was the first dose of two-dose regime RAADP given at 28 weeks gestation?** Yes No

8g) **If NO, at what gestation was it given?** Weeks ____ Days ____

8h) **Was the second dose two-dose regime RAADP given at 34 weeks gestation?** Yes No

8i) **If NO, at what gestation was it given?** Weeks ____ Days ____

Note 14) If RAADP not given, or given at incorrect time, go to section 3 Q16

Potentially sensitising events during pregnancy

RhD negative mothers should receive anti-D Ig if there are any sensitising events during pregnancy. Use the following table to record the details.

9	If **YES**, please give the following details where available			
	Potentially sensitising event	**Date of PSE**	**Gestation**	**Anti-D Ig dose**
a)	Amniocentesis			
b)	Chorionic villous sampling			
c)	Cordocentesis			
d)	Other in-utero therapeutic intervention/surgery (e.g. intrauterine transfusion, shunting)			
e)	Ante partum haemorrhage (APH)			
f)	External cephalic version			
g)	Fall / abdominal trauma			
h)	Other (including miscarriage & stillbirth)			

Note 15) If there was a PSE and anti-D Ig was not given, go to section 3 Q16

Delivery

10) Did this mother deliver her baby in your maternity unit? Yes No

10a) If NO, what was the reason?

Miscarriage

Termination of pregnancy

Intrauterine death

Stillbirth

Delivered at another maternity unit

Unknown, no records

10b) If YES, what was the date of delivery? (dd/mm/yy)

10c) What was the gestation at delivery?

Weeks		Days	

10d) Was the baby RhD positive? Yes No RhD Unknown

10e) If Yes or RhD Unknown, was anti-D Ig given within 72 hours of delivery? Yes No

Note 16) If baby was RhD positive or RhD Unknown and anti-D not given go to section 3, Q16

SECTION 3

Note: This section is to record the reasons for not giving anti-D prophylaxis, if applicable

Q11: Blood Group and Antibody Screen

You are completing this because either

Blood tests were not done at the booking appointment in September 2012 **and/or** Blood tests were not done at 28 weeks

Using the clinical and laboratory records available to you, please summarize any reasons why tests were not done. If there is no known reason, please write "unknown"

Note: You may find it helpful to check if the woman had another hospital number or if the tests were sent to another laboratory

Q11a Reasons why blood tests were not done at booking:

Q11b Reasons why blood tests were not done at 28 weeks:

Q12 Immune anti-D

You are completing this because either

Blood tests done at the booking appointment confirmed immune anti-D **and/or** Blood tests done at 28 weeks confirmed immune anti-D

Using the clinical and laboratory records available to you, please try to determine if the cause of immune anti-D is known. If there is no known cause, please write "unknown"

Note: You may find it helpful to look for evidence of a PSE in previous pregnancy, a PSE in current pregnancy, or transfusion. There may be evidence that anti-D was omitted in a previous pregnancy, or it is possible that the woman was sensitised in another country (as not all countries have a prophylactic regime). You may also be able to find evidence on whether it could be prophylactic or immune anti-D.

Q12a Reasons for confirmed immune anti-D at booking

Q12b Reasons for confirmed immune anti-D at 28 weeks

Q13	Anomalous D group

You are completing this because either

Blood tests done at the booking appointment confirmed the mother's blood group is RhD variant and not eligible for anti-D prophylaxis **and/or** blood tests done at 28 weeks confirmed the mother's blood group is RhD variant and not eligible for anti-D prophylaxis

Using the clinical and laboratory records available to you, please try to determine if there was specific advice that anti-D was not required and where that advice came from. If there is no information on this, please write "unknown"

Note: You may be able to find a copy of a reference lab report.

Q13a Reasons why the mother was not eligible for anti-D prophylaxis

Q14	No Kleihauer test

You are completing this because either

Baby's blood group was RhD positive or RhD unknown and there was no Kleihauer test for the mother **and/or** there was a potentially sensitising event at >20 weeks and there was no Kleihauer test for the mother.

Using the clinical and laboratory records available to you, please try to determine why a Kleihauer was not done. If there is no information on this, please write "unknown"

Note: You may discover that there was no sample or a sample was lost. There may be evidence of a technical failure.

Q14a Reasons why a Kleihauer was not done

Q15	Additional anti-D required after standard dose

You are completing this because either

Baby's blood group was RhD positive or RhD unknown and there was a confirmed FMH >4 ml

and/or there was a potentially sensitising event at >20 weeks and there was a confirmed FMH >4 ml.

Using the clinical and laboratory records available to you, please try to provide the following information. If there is no information on this, please write "unknown"

Q15a What details are recorded of any large bleeds?

Q15b Was the FMH >4mL confirmed by flow cytometry? Yes No

Q15c If yes, what was the result?

Q15d How much additional anti-D was given, by what route and within what timescale?

Q15e Was a follow-up sample taken? Yes No

Q15f Had the FMH cleared? Yes No Don't know

Q16	Anti-D not given

You are completing this because either

- Single dose or Dose 1 RAADP was not given. or was given at the incorrect time, **and/or**
- Dose 2 of a 2-dose regime was given at an incorrect time, **and/or**
- Standard postnatal anti-D not given, **and/or**
- If there was a potentially sensitising event and anti-D was not given, **and/or**
- Baby was RhD positive and anti-D was not given.

Using the clinical and laboratory records available to you, please try to provide the following information. If there is no information on this, please write "unknown"

Note: These are the most important supplementary questions

These cases are SHOT reportable and therefore if not recorded in lab, every effort should be made to look at mother's notes to see if anti-D was given, not traceable by the lab

Categories include

- *Mother declined*
- *Issued but not given*
- *Prescribed but not given*
- *Given too late*

> 3 days from delivery or PSE

Single dose RAADP <28 weeks or >30 weeks

NB: Double dose should allow 2 weeks either side of 28 and 34 week dose

Q16a Please record any reasons you can find why anti-D was not given

Appendix 4 – Organisational Questionnaire

CLINICAL STANDARDS
Royal College of Physicians
Setting higher medical standards

National Comparative Audit of Blood Transfusion

NHS Blood and Transplant

2013 National Comparative Audit of the Use of Anti-D

ORGANISATIONAL AUDIT

This questionnaire should be completed by the transfusion laboratory manager in consultation with the hospital transfusion team and the obstetric team

Name of your hospital/Trust/LHB:

Section 1 - Organisation details of service delivery

1. Does your transfusion laboratory serve maternity/obstetric units that are based outside of the hospital/Trust/LHB? Yes No

2. If yes, how many separate maternity units does your laboratory serve? ☐

3. Approximately how many deliveries are there per year per maternity unit that you serve? *(Please complete the table below using as many rows as is required, or use additional sheets if more than 5 units are served)*

	Name of Maternity Unit	*Location of Maternity Unit*	*Approx number of deliveries per annum*
1			
2			
3, etc			

NB: Use the bold numbers in the table above to refer to that maternity unit for the remainder of the table-type questions below

4. Do the same policies for anti-D prophylaxis apply in all obstetric/ maternity units supported by your transfusion department? Yes No

Section 2 - Anti-D Ig dosing and formulation : PSEs and Postnatal use

5. Please indicate the product and dosage of anti-D Ig used for potentially sensitising events during pregnancy, but BEFORE 20 weeks gestation.

Unit reference from Q3	*Product*	*Dosage(units)*
1		
2		
3, etc		

6. Please indicate the product and dosage of anti-D Ig used for potentially sensitising events during pregnancy, AFTER 20 weeks gestation.

Unit reference from Q3	*Product*	*Dosage(units)*
1		
2, etc		

7. Please indicate the product and dosage of anti-D Ig used for standard post natal Anti-D prophylaxis.

Unit reference from Q3	*Product*	*Dosage(units)*	*Routinely given i.m? (Yes or No)*
1			
2			
3, etc			

Notes: Use this space to provide us with other information, if you wish.

Section 3 - Anti-D dosing and formulations : RAADP

8. Has your hospital/Trust/LHB implemented Routine Antenatal Anti-D Prophylaxis (RAADP)? Yes No

9. If yes, in which year was RAADP first introduced?

10 . Please indicate the product and dosage of anti-D Ig used for RAADP

Unit reference from Q3	*Product*	*Dosage(units)*	*Routinely given i.m? (Yes or No)*
1, etc			

11. Since RAADP was first introduced in your hospital/Trust/LHB, have you changed the product and/or dosage? Yes No

12. If yes, please state when and give the reason(s):

13. Has your hospital / Trust undertaken any audit of compliance with RAADP? Yes No

Section 4 - Documentation and traceability

14. Is the transfusion department responsible for the issue of Anti-D Ig to NAMED PATIENTS? Yes No

15. If yes, please estimate what proportion is issued by your transfusion department to NAMED PATIENTS.

16. Does your transfusion department provide stocks of Anti-D Ig on a NON-NAMED patient basis for other Departments for them to issue to named patients? Yes No

17. If 'Yes' which other departments issue Anti-D to named patients (for obstetric use only)?

18. Are you aware of Anti-D being supplied for obstetric use that has not been issued on a named patient basis, or as stock from a transfusion department? Yes No

19. If 'Yes' please state which departments or organisation(s) receive Anti-D Ig directly from the supplier without this supply being recorded in a transfusion department.

20. Is the transfusion department responsible for recording on the laboratory information management system (LIMS) that Anti-D Ig has been administered to a NAMED patient?

(*NB this refers to the same level of traceability expected for red cells and other blood components).*

Yes No

Section 5 - Adverse events

21. Have you made any Anti-D related reports

to SHOT in the last 12 months? Yes No

Section 6 – Training

22. Is there any update training in place for the following groups of staff?

Staff group	*Yes or No*
Haematology laboratory staff?	
Transfusion laboratory staff?	
Midwifery staff?	
Obstetric medical staff?	
Haematology medical staff?	

Thank you for completing this organisational audit questionnaire

Please return it to:

David Dalton, National Comparative Audit of Blood Transfusion, FREEPOST, Birmingham B2 4BR

Or email a word version to him at david.dalton@nhsbt.nhs.uk

References

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[2] **NICE Technology Appraisal. Routine antenatal anti-D prophylaxis for women who are rhesus D negative** (August 2008) http://www.nice.org.uk/guidance/TA156

[3] **BCSH guideline for the use of anti-D immunoglobulin for the prevention of haemolytic disease of the fetus and newborn.** Qureshi H, Massey E, Kirwan D, Davies T, Robson S, White J, Jones J and Allard S. Transfusion Medicine. 2014;24(1):8-20

[4] **RCOG Green Top Guidelines No. 22 The Use of Anti-D Immunoglobulin for Rhesus D Prophylaxis** https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg22/ *(Archived 17/10/2014 following publication of the BCSH guidelines)*

[5] **Risk factors for RhD immunisation despite antenatal and postnatal anti-D prophylaxis.** Koelewijn JM, de Haas M, Vrijkotte TG, van der Schoot CE, Bonsel GJ. British Journal of Obstetrics and Gynaecology. 2009; 116 (10): 1307-14.

[6] **CSL Behring UK Ltd. Rhophylac SPC in Electronic Medicines Compendium** http://www.medicines.org.uk/emc/medicine/12087 Sections 4.2 Method of administration and 4.4 Special warnings and precautions for use (updated 8th January 2014)

[7] **BCSH Anti-D Guidelines 2014 - Amendment 4.8.14 1) Anti D prophylaxis in overweight women** http://www.bcshguidelines.com/documents/BCSH_Anti_D_guidelines_-__Amendment_4_8_14_(2).pdf

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[10] **Routine administration of Anti-D: the ethical case for offering pregnant women fetal RHD genotyping and a review of policy and practice** Julie Kent, Anne-Maree Farrell and Peter Soothill
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[11] **Errors in anti-D immunoglobulin administration: retrospective analysis of 15 years of reports to the UK confidential haemovigilance scheme.** Bolton-Maggs PH, Davies T, Poles D, Cohen H. British Journal of Obstetrics and Gynaecology. 2013;120(7):873-8.

[12] **The 2013 Annual SHOT Report (2014).** PHB Bolton-Maggs (Ed), D Poles, A Watt and D Thomas on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. http://www.shotuk.org/shot-reports/report-summary-supplement-2013/

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[14] **Current laboratory practice in managing anti-D prophylaxis in the UK and Eire**. Rowley M, White J, Allard S, Jones J. (Poster at BBTS ASM 2010)*Transfusion Medicine. 2010; 20: Suppl 1*

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