Guideline for Anti-D Prophylaxis and Administration Including Fetal RhD Screening

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Equality Impact Assessment	N/A if clinical guideline or procedure	Date:
Version	2	
Status	Approved	
Publication date	28/03/2023	
Review date	23/03/2026	
Approval recommended by	Maternity guideline group Hospital Transfusion Team	Date: Nov 2021 April 2023
	Women's Business and Governance Meeting	Date: 17/03/2023
Approved by	CBU 3 Overarching Governance Meeting	Date:22/03/2023
Distribution	Barnsley Hospital NHS Foundation Trust – intranet Please note that the intranet version of this document is the only version that is maintained. Any printed copies must therefore be viewed as "uncontrolled" and as such, may not necessarily contain the latest updates and amendments	

Contents

1.0 Introduction

During pregnancy small amounts of fetal blood can enter the maternal circulation, an event called feto-maternal haemorrhage (FMH). The presence of fetal RhD Positive cells in the maternal circulation of a mother who is RhD Negative causes the woman's body to mount an immune response and develop (Anti-D) antibodies against the RhD Antigen. This process is called sensitisation and can result in Haemolytic Disease of the Fetus and Newborn (HDFN) in the current and/or future pregnancies. Sensitisation can happen at any time during pregnancy but most commonly occurs in the third trimester and during childbirth.

NICE (2016) recommend non-invasive prenatal testing (NIPT) to determine the fetal RhD blood group type as a cost-effective option to guide antenatal prophylaxis with anti-D immunoglobulin.

Non-invasive prenatal testing (NIPT) for fetal RhD genotype involves analysing cell-free fetal DNA (cffDNA) in maternal blood. It is intended for use in pregnant women who are RhD negative and are not sensitised to the D antigen e.g. do not have anti-D or Anti-G antibodies (which also react against D antigen positive cells). Cell free fetal DNA can be tested between 11+2 weeks and 23+6 weeks.

Routine Antenatal Anti-D prophylaxis (RAADP) is recommended at 28 weeks gestation to prevent sensitisation in non-sensitised RhD Negative pregnant women who carry an RhD Positive fetus; or where the fetal blood group has not been determined.
In addition, any Potential Sensitising Events (PSE) requires a dose of prophylactic Anti-D (PAD) to prevent sensitisation.

2.0 Objective

The aims of this guideline are to:

- Ensure that women who are RhD negative are offered testing for fetal RhD genotype using cell free fetal DNA, and understand the risks/benefits associated with the test.
- Ensure that women who choose testing for fetal RhD genotype are given appropriate options regarding the administration of prophylactic Anti-D in pregnancy and the immediate postnatal period.
- Provide healthcare professionals with guidance on the use of prophylactic Anti-D to prevent sensitisation to the RhD antigen.
- Ensure staff are aware of the ordering and administration process for prophylactic Anti-D.

3.0 Scope

This guideline applies to all staff caring for pregnant woman who are identified as being RhD Negative.

4.0 Main Body of the Document

4.1 Identification of RhD Negative women at booking

If the woman's blood group is unknown at booking, a sample for group and antibody screening must be taken, and the result checked within seven days.

4.2 Process for offering Non-invasive prenatal testing for fetal RhD genotype using cell free fetal DNA testing

cffDNA testing should only be offered to patients who are identified as RhD negative at booking and do not have Anti-D antibodies.

Testing for cffDNA can be offered between 11+2 weeks and 23+6 weeks; the test is voluntary and some patients may decline testing.

The following patient information leaflet should be given to women: NHS blood and transplant – D negative mother's blood test to check her unborn baby's blood group – Document ref. INF1263) https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4401/inf1263.pdf

Women should be aware that there is both a false positive and a false negative rate with the test, such that:

- 2-4 fetuses per 1000 who are determined to be RhD Positive on cffDNA testing will actually be RhD Negative
- 13-57 fetuses per 1000 who are determined to be RhD Negative on cffDNA testing will actually be RhD Positive

The discussion and whether informed consent has been obtained or declined must be recorded in the Electronic Patient Record (EPR).

4.3 Taking the Test

Women who consent to the test will have a blood sample sent to Blood Bank with a completed NHSBT cffDNA request form.
Samples will only be accepted for testing if the following are met:

- A minimum of 6ml of maternal blood in an EDTA bottle
- The sample must not be opened following collection of the blood or used for any other testing prior to being sent
- The sample tube must be stored at room temperature and reach the laboratory within 7 days of being taken
- Sample must be hand written, dated and signed by the person taking the blood
- Addressograph/Pre-printed labels are not to be used on the sample bottles as per Hospital Transfusion Guidelines but they can be used for the request cards.
- Hand written alterations on the sample bottle or request card may make the sample invalid – minor alterations must be initialled by the person taking the sample for it to be acceptable for testing

NB – haemolysed samples may contain a high background level of maternal DNA and should not be tested

4.4 Results on ICE

Blood Bank will post the result on ICE as a separate report from the booking blood report.
This will indicate the pregnancy EDD and the baby's RhD blood group; the result is only valid for the current pregnancy.

The results will appear on the ICE system as 'Fetal RhD DNA Type'.
Antenatal Clinic staff are responsible for documentation of the results in the woman's hospital records and on EPR.
The midwife informs the woman of the result and documents the woman's care pathway on EPR.

4.5 Managing the pregnancy once results are available

The woman will be assigned to a pathway according to the results.

RhD Negative baby
Prophylactic Anti-D is not required

RhD Positive baby or where the fetal group is indeterminate
Prophylactic Anti-D is required:

Routinely at 28-30 weeks,
For sensitising events during pregnancy
At delivery if the baby is confirmed to be RhD Positive.

At BHNFT a standard 1500 IU dose is given

4.5.1 Patients awaiting cffDNA result

Patients who are awaiting their cffDNA result should be treated as carrying a RhD Positive baby.

4.5.2 Patients who decline testing, or who have not been tested by 24+0 weeks

Women who are more than 24+0 weeks are unsuitable for cffDNA testing
These women, and those who decline testing should be treated as carrying a RhD Positive baby.

4.6 Potential Sensitising Events (PSE)

Potential Sensitising Events (PSE) are defined as an event that could lead to the development of Anti-D antibodies due to maternal-fetal blood exchange (Fetal Maternal Haemorrhage) in a RhD Negative mother with a RhD Positive baby.

Sensitising events can include;

- Chorionic villous sampling/Placental biopsy
- Amniocentesis
- Insertion of a cervical suture
- External cephalic version
- Therapeutic termination of pregnancy
- Spontaneous miscarriage after 12 weeks gestation
- Expectant management of miscarriage after 12 weeks gestation
- Ectopic pregnancy
- Vaginal bleeding after 12 weeks gestation, includes threatened miscarriage and antepartum haemorrhage. If recurrent then administer 6 weekly
- Fall, abdominal trauma
- Intrauterine fetal death

A routine blood sample for group and antibody screen must be taken every time prior to administration of prophylactic Anti-D. It must be labelled correctly as per Hospital Transfusion Guidelines Blood Transfusion Specimen labelling policy.

4.7 Prophylactic Anti-D and gestation

Women experiencing a PSE up to 20 weeks gestation will be seen in the Gynaecology department. After 20 weeks, women will be seen in the Maternity department.

Prophylactic Anti-D is not indicated in uncomplicated miscarriage **up to 12 weeks** with mild painless bleeding, and where no medical or surgical intervention is required. The risk of sensitisation in these circumstances is negligible.
It may be prudent to administer prophylactic Anti-D where bleeding is heavy or repeated or where there is associated abdominal pain, particularly if these events occur as the gestation approaches 12 weeks. Women must be reviewed by an appropriate obstetrician to make this decision.

Women with recurrent PV bleeding **between 12 and 20 weeks' gestation**, should be given prophylactic Anti-D as soon as possible but within 72 hours of the event.
If intermittent bleeding continues, prophylactic Anti-D should be given at 6-week intervals.

In women who are bleeding **after 20 weeks' gestation**, two blood samples must be obtained:

A blue EDTA for Group and Screen
And a red EDTA for Kleihauer estimation.

Kleihauer is a semi-quantification test to calculate the size of any Feto-maternal Haemorrhage (FMH), and so should be taken as soon as possible after the episode of bleeding.
If the FMH estimation indicates the presence of fetal cells, additional prophylactic Anti-D should be administered in an appropriate dose as suggested by Blood Bank.
If intermittent bleeding occurs, a Kleihauer should be taken at two weekly intervals.
If intermittent bleeding continues, prophylactic Anti-D should be given at 6-week intervals.

4.8 Routine Antenatal Anti-D Prophylaxis (RAADP) at 28 weeks

Prophylactic Anti-D will be offered to RhD Negative women at 28-30 weeks gestation:

Who are known to be carrying a RhD Positive fetus following cffDNA testing
Or where the fetal group is not known because cffDNA has not been tested
Or the result is inconclusive.

N.B. the administration of prophylactic Anti–D at 28-30 weeks should be regarded as supplementary to any Anti-D administered for potentially sensitising events.
It should not be affected by previous Anti-D administered for a potentially sensitising event earlier in pregnancy.

If prophylactic Anti-D has been administered to a RhD Negative woman prior to the 28 week sample and 'Presumed prophylactic Anti-D' is detected in the sample, then a repeat should be obtained if instructed by blood bank.

If Anti-D is detected and there is no record of prophylactic Anti-D being administered, follow the guideline for Grouping and Antibody screening.

4.8.1 Ordering prophylactic Anti-D

- To order prophylactic Anti-D for either RAADP or a PSE, an Antenatal Blood Transfusion request form (see Appendix 1) must be completed and sent to Blood Bank for authorisation.
- If this hasn't been completed, prophylactic Anti-D cannot be issued.
- All forms must:
    - Contain the three compulsory identifiers for patient identification.
    - Be dated, signed and have EDD or gestation on.
    - Include the antenatal clinic appointment date where routine antenatal Anti-D prophylaxis is to be given.

For women who are booked in the Barnsley area

- At the 24-week routine antenatal appointment, the community midwife will:
    - Complete a Blood Bank request form to order the prophylactic Anti-D
    - Make an appointment for the patient to attend the Anti-D clinic at 28-30 weeks.
- At the 28-week antenatal appointment in the community:
    - FBC, Blood Group and Rhesus bloods should be obtained by the community midwife.
- The woman will attend the Anti-D Clinic after this at 28-30 weeks for administration of Routine Antenatal Anti-D Prophylaxis (RAADP)
- If the routine bloods have not been taken at the 28-week antenatal appointment by the community midwife, the FBC and Group and Screen bloods must be obtained at the anti-D appointment prior to giving the prophylactic Anti-D.
- Results are not needed prior to giving the prophylactic Anti-D.

For women who book from out of area

- RhD Negative women will be contacted by antenatal clinic (ANC), and cffDNA testing will be offered between 11+2 and 23+6.
- The midwife must ensure that an appointment has been made for the woman to attend the Anti-D clinic at 28 weeks gestation for RAADP if required.
- A Blood Transfusion request form (Appendix 1) will be completed by ANC midwives.
- Repeat FBC and Blood Group and Screen bloods will be taken in ANC prior to administration of Routine Antenatal Anti-D Prophylaxis (RAADP)

For RhD Negative women who transfer from other hospitals and the baby is RhD Positive or the RhD status is unknown

- All transfers will require full booking bloods at the first available opportunity.
- Book appointments and request prophylactic Anti-D as per the processes described above.
- If the woman transfers after 28 weeks' gestation, confirm with her if she has had prophylactic Anti-D at a previous trust. If the woman is unable to confirm this, contact the previous trust.

4.8.2 Ensuring availability of Routine Anti-D Prophylaxis at antenatal clinic appointment

- On Monday morning, ANC midwives will check appointments for the Friday Anti-D clinic and ensure all patients have prophylactic Anti-D ordered and available in the blood bank fridge for collection.
- Prophylactic Anti-D is ordered using the antenatal blood transfusion request form.
- Prophylactic Anti-D will be collected from blood bank for women attending on that day.

- Once the prophylactic Anti-D is collected, it must be transferred immediately to the designated prophylactic Anti-D fridge in ANC in the clean utility room (Room Number 0092).
    - The fridge temperature is checked daily using the temperature probe provided.
    - NB this fridge is mapped annually by Blood Bank to comply with MHRA guidance. If there are any issues with it, antenatal staff **MUST** inform the Blood Transfusion Manager or Blood Bank and return any prophylactic Anti-D stored in the fridge to Blood Bank ASAP.

4.8.3 Prophylactic Anti-D administration

- The Anti-D immunoglobulin preparation available at Barnsley Hospital NHS Foundation Trust is Rhophylac (CSL Behring) 1500 IU intramuscular.
- Prior to administration, patient consent should be obtained and recorded by the healthcare professional responsible for the administration.
- The prophylactic Anti-D Authorisation Form (for RAADP) – See Appendix 2
  Or Drug Chart (For PSE) should be completed and filed in the woman's hospital notes.
- The date and time of administration; batch number, dose, site and route of administration; signature and printed name of administrator are documented on EPR and the drug chart.
- The deltoid muscle is an appropriate and safe site for administration of the injection.
  The injection must be given into muscle, as absorption may be delayed if the injection only reaches the subcutaneous tissues.
- The traceability tag must be must be fully completed and returned to blood bank as positive confirmation that the product has been administered.
- Delayed administration of prophylactic Anti-D by more than 72 hours after a sensitising event is considered an incident and must be reported via DATIX.
    - The Transfusion Team are required to report the incident nationally to MHRA (Medicines and Healthcare products Regulatory Agency) and SHOT (Serious Hazards of Transfusion).
    - The woman should be made aware of the delay and that she may require follow-up bloods in 6 months depending on the RhD status of the baby.

- If there is a positive Kleihauer result, a follow up maternal sample should be obtained 72 hours after the intramuscular administration of prophylactic Anti-D.
  A further administration of prophylactic Anti-D may be required if any fetal cells remain, and a further follow up sample should be requested and tested.
  Repeated dosage should only be given following senior obstetric review and in collaboration with the Haematology department if clinically indicated.

4.8.4 Declining or deferring Prophylactic Anti-D

If a woman refuses prophylactic Anti-D, this must be clearly recorded on EPR, including evidence of discussion of the benefits and risks of having/ not having prophylactic Anti-D, and the woman's reasons for declining.
Inform blood bank that the woman has declined prophylactic Anti-D and return any unused Anti-D to blood bank as soon as possible.

4.9 Process for offering Prophylactic Anti-D in the postnatal period

All women who are RhD Negative will require post-delivery bloods from mum and baby irrespective of the fetal blood group.

- Cord samples for blood group and Direct Antiglobulin Test (DAT) should be taken immediately. If cord samples cannot be obtained, blood venous samples from the baby are required
- Maternal samples for blood group and Kleihauer should be taken at least 45 minutes following the birth for all RhD Negative mothers.
  This is to ensure an appropriate time has passed for any FMH to circulate for a more accurate Kleihauer test.

Post-delivery blood samples taken from the mother, and the cord sample should be sent to blood bank with the relevant request forms
The Zero Tolerance Blood Transfusion Labelling Policy also applies to these samples

Prophylactic Anti-D will be issued by blood bank once the maternal and cord samples have been tested, and the infant is confirmed to be RhD Positive.
If the baby is RhD Negative, the mother should not be offered prophylactic Anti-D.
If no sample can be obtained from either the baby's cord or a capillary sample from the baby, then prophylactic anti-D should be administered.

Additional samples may be required by blood bank if a baby has a discrepant RhD status to that reported on the cffDNA screen result.
Management will be discussed with blood bank on an individual basis.
This must be raised with the Blood Transfusion Manager or Senior Biomedical Scientist (BMS) for reporting via the Trust electronic reporting system (Datix), Laboratory System (Q-Pulse) and the SABRE website (MHRA/SHOT).

5.0 Roles and responsibilities

5.1 Midwives/Obstetricians

Have a responsibility to ensure that women identified as being RhD Negative are managed in accordance with this guideline.

5.2 Hospital Transfusion Team (HTT)

The Blood Transfusion Manager and Transfusion Practitioners are responsible for reporting and investigating any incidents which occurs in relation to prophylactic Anti-D

6.0 Associated documents and references

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Pilgrim H, Lloyd-Jones M, Rees A. Routine Antenatal Anti-D Prophylaxis for RhD – Negative women: a systematic review and economic evaluation. Health Tech Assess 2009; 13: iii, ix-x1.1-103.

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RCOG, Greentop Guideline No 22. The Use of Anti-D Immunoglobulin for Rhesus D Prophylaxis. March 2011.

White J, Quereshi H, Massey E, Byrne M, Daniels G, Allard S, & British Committee for Standards in Haematology (2016) Blood Grouping and Antibody Testing in Pregnancy. Transfusion Medicine (26) pp:246-263

7.0 Training and resources

Training will be delivered as outlined in the Maternity Training Needs Analysis. This is updated on an annual basis.

8.0 Monitoring and audit

Any adverse incidents relating to Non-Invasive Prenatal testing for Fetal RHD Genotype (to determine if prophylactic Anti-D is required) and the administration of prophylactic Anti-D will be monitored via the incident reporting system. Any problems will be actioned via the case review and root cause analysis action plans. The action plans are monitored by the risk midwife to ensure that improvements in care are made. The trends and any root cause analysis are discussed at the monthly risk meetings to ensure that appropriate action has been taken to maintain safety.
The guideline for Non-Invasive Prenatal testing for Fetal RHD Genotype (to determine if prophylactic Anti-D is required) and the administration of prophylactic Anti-D will be audited in line with the annual audit programme, as agreed by the CBU. The audit action plan will be reviewed at the monthly risk management meetings on a quarterly basis and monitored by the risk midwife to ensure that improvements in care are made.

9.0 Equality and Diversity

The Trust is committed to an environment that promotes equality and embraces diversity in its performance as an employer and service provider. It will adhere to legal and performance requirements and will mainstream equality, diversity and inclusion principles through its policies, procedures and processes. This guideline should be implemented with due regard to this commitment.

To ensure that the implementation of this guideline does not have an adverse impact in response to the requirements of the Equality Act 2010 this policy has been screened for relevance during the policy development process and a full equality impact assessment is conducted where

necessary prior to consultation. The Trust will take remedial action when necessary to address any unexpected or unwarranted disparities and monitor practice to ensure that this policy is fairly implemented.

This guideline can be made available in alternative formats on request including large print, Braille, moon, audio, and different languages. To arrange this please refer to the Trust translation and interpretation policy in the first instance.

The Trust will endeavor to make reasonable adjustments to accommodate any employee/patient with particular equality, diversity and inclusion requirements in implementing this guideline. This may include accessibility of meeting/appointment venues, providing translation, arranging an interpreter to attend appointments/meetings, extending policy timeframes to enable translation to be undertaken, or assistance with formulating any written statements.

9.1 Recording and Monitoring of Equality & Diversity

This section is mandatory for all Trust Approved Documents and must include the statement below:

The Trust understands the business case for equality, diversity and inclusion and will make sure that this is translated into practice. Accordingly, all guidelines will be monitored to ensure their effectiveness.

Monitoring information will be collated, analysed and published on an annual basis as part of Equality Delivery System. The monitoring will cover the nine protected characteristics and will meet statutory employment duties under the Equality Act 2010. Where adverse impact is identified through the monitoring process the Trust will investigate and take corrective action to mitigate and prevent any negative impact

Appendix 1: Antenatal Request Form for Prophylactic Anti-D request (Form ID 133832)

BLOOD TRANSFUSION DEPARTMENT, BARNSLEY HOSPITAL NHS FOUNDATION TRUST			
Addressograph labels may be used on the request form ONLY			
Forename		Consultant/GP	
Surname		Location	
DOB		NHS N°.	
Hospital N°.		Gender	Male/Female
The below MUST be completed by the person collecting the blood sample			
Sample taken by			
Date of sample		Time taken	
ANTENATAL SEROLOGY & KLEIHAUER REQUEST FORM			
Group & Screen	Y / N	Weeks of Gestation	
Kleihauer	Y / N	Previous Pregnancies	Y / N
Reason/PSE Event		Has Anti-D been given	Y / N
Date/Time of PSE		Date	Dose
PSE Anti-D Prophylaxis Request		Partner Details	
Anti-D required	Yes ☐	Surname	
Date required		Forename	
28 week RAADP Request		Hospital N°.	
Date 1500iu required		NHS N°.	
Location		DOB	
Midwife contact details			
Requesting/Named Midwife			
Contact details			
Authorised Practitioner Signature			
Print name		Signature	
LABORATORY USE ONLY			
Please attach internal barcode label here (with this orientation)			

Appendix 2: The Prophylactic Anti-D Authorisation Form (BHNFT1650)

Barnsley Hospital NHS
NHS Foundation Trust

Name: .....
D.O.B.: .....
Unit No.: .....
NHS Number: .....

AUTHORISATION AND CONSENT FOR ANTI D PROPHYLAXIS IN PREGNANCY

Date / Taken:	Request card completed by:	ANC		CMW	
GP:		Blood Group:			
Agreed Due Date:		Authorised by:			
Routine Examination performed prior to Anti D appointment.		Routine 28 week bloods taken by CMW prior to Anti D appointment.			
Routine 28 week bloods taken today with GTT.		HB		MCV	
Blood Group / Antibodies					

Prophylaxsis Anti D should be offered to pregnant women after 28 completed weeks of pregnancy who are Rhesus – ve. A full explanation / leaflet should be given to the patient prior to administering Anti D. Anti D Should be given as an intramuscular injection.

Affix Issued Anti D sticker here.

Anti D Given - including fully informed consent.		Information leaflet given.	
Print Name / Designation:		Signature:	

BHNFT1650

Appendix 3: Glossary of terms

ANC – Antenatal Clinic
cffDNA – cell-free fetal DNA
CBU – Clinical business unit
DNA – Deoxyribonucleic acid
EDD – Expected delivery date
EDTA - Ethylenediaminetetraacetic acid
FMH – Fetal Maternal Haemorrhage
HDFN – Haemolytic Disease of the Fetus and Newborn
ICE – Integrated Clinical Environment
MHRA – Medicines and Healthcare products Regulatory Agency
NHSBT – National Health Service blood and transport
NHS – National Health Service
NICE – National Institute of Clinical Excellence
NIPT – Non invasive prenatal testing
PV – pre vagina
RAADP – Routine Antenatal Anti –D Prophylaxis
RCOG – Royal College of Obstetricians and Gynaecologists
RhD – Rhesus
SHOT – Serious Hazards of Transfusion

Appendix 4 version control

Maintain a record of the document history, reviews and key changes made (including versions and dates)

Version	Date	Comments	Author

Review Process Prior to Ratification:

Name of Group/Department/Committee	Date
Reviewed by Maternity Guideline Group	N/A
Reviewed at Women's Business and Governance meeting	17/03/2023
Approved by CBU 3 Overarching Governance Meeting	22/03/2023
Approved at Trust Clinical Guidelines Group	N/A
Approved at Medicines Management Committee (if document relates to medicines)	N/A

Trust Approved Documents (policies, clinical guidelines and procedures)

Approval Form

Please complete the following information and attach to your document when submitting a policy, clinical guideline or procedure for approval.

Document type (policy, clinical guideline or procedure)	Guideline
Document title	Guideline for Anti-D Prophylaxis and Administration Including Fetal RhD Screening
Document author (Job title and team)	Lead Midwife for antenatal services/Transfusion Practitioner
New or reviewed document	Reviewed. Replaces; Anti D Prophylaxis
List staff groups/departments consulted with during document development	Midwives Transfusion
Approval recommended by (meeting and dates):	WB&G 17/03/2023 CBU3 22/03/2023
Date of next review (maximum 3 years)	23/03/2026
Key words for search criteria on intranet (max 10 words)	Rh Neg Kleihauer NIPT
Key messages for staff (consider changes from previous versions and any impact on patient safety)	
I confirm that this is the <u>FINAL</u> version of this document	Name: Jade Carritt Designation: Governance Midwife

FOR COMPLETION BY THE CLINICAL GOVERNANCE TEAM

Approved by (group/committee): CBU3 Governance **Date approved: 22/03/2023** **Date Clinical Governance Administrator informed of approval: 23/03/2023** **Date uploaded to Trust Approved Documents page: 28/03/2023**