Prophylactic Anti-D Immunoglobulin

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Departments/Group this Document applies to:	Maternity Services. Doctors of all grades, Midwives, Nurses and Maternity Health Care Assistants

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Guideline to be followed by (target staff): This document applies to all obstetric and midwifery staff within the maternity department. There is a training implication to this document as information on implementing this guideline is needed.

To be read in conjunction with the following documents:

Milton Keynes University Hospital NHS Foundation Trust (2023) Antenatal Care Pathway, MIDW/GL/137, Version 10.1 [Online] Available at: https://mkuhcloud.sharepoint.com/sites/TrustDocumentation/Trust%20Documentation%20%20policies%20guideslines%20patient/Maternity/Maternity%20Polices%20and%20Guidelines/Antenatal%20Care%20Pathway%20Guideline%20.pdf [Accessed 31 August 2023]

Milton Keynes University Hospital NHS Foundation Trust (2022) Care during labour and birth, MIDW/GL/183, Version 2 [Online] Available at: https://mkuhcloud.sharepoint.com/sites/TrustDocumentation/Trust%20Documentation%20%20policies%20guideslines%20patient/Maternity/Maternity%20Polices%20and%20Guidelines/Labour%20and%20birth.pdf [Accessed 31 August 2023]

CQC Fundamental standards:

Regulation 9 – person centred care
Regulation 10 – dignity and respect
Regulation 11 – Need for consent
Regulation 12 – Safe care and treatment
Regulation 13 – Safeguarding service users from abuse and improper treatment
Regulation 15 – Premises and equipment
Regulation 16 – Receiving and acting on complaints
Regulation 17 – Good governance
Regulation 18 – Staffing
Regulation 19 – Fit and proper

Disclaimer

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual. The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioner.

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Guideline Statement

Prior to 1970 Haemolytic Disease of the Newborn (HDN) due to Anti-D was a significant cause of morbidity and mortality. By 1990, a reduction in mortality from 1.2 per 1000 births to 0.02 per 1000 births had been achieved in response to the introduction of immuno prophylaxis with Anti-D Ig.

During that time the sensitisation rate dropped to about 1.2%. A further reduction to between 0.17 to 0.28% was achieved by introducing prophylaxis during the third trimester of pregnancy. These findings contributed to the National Institute for Clinical Excellence (NICE) and the British Committee for Standards in Haematology recommend that all Rh(D) Negative pregnant women should be offered Anti-D immunoglobulin routinely during the third trimester of pregnancy (BCSH, 2014; NICE, 2008).

Executive Summary

This document provides guidance to all practitioners involved in providing care to women who are Rh(D) Negative. Midwives, Nurses, GPs, Obstetricians, Haematologists, clinical specialists and other health care professionals who have responsibility for providing women with information to make informed choices, both in the antenatal and postnatal periods. It also considers for some women due to religious, social and medical reasons the use of Anti-D Ig may not be a suitable option

Definitions

ADAU – Ante-natal Day Assessment Unit
APH – Antepartum haemorrhage
BCSH – British Committee for Standards in Haematology
CIG – Clinical Improvement Group
DAT – Direct Antiglobulin Test
ED – Emergency Department

EDD – Estimated Date of Delivery
EDTA – Ethylenediaminetetraacetic
EPAU – Early Pregnancy Assessment Unit
FMH – Fetal Maternal Haemorrhage
GP – General Practitioner
HbF – Fetal Haemoglobin
HDN – Haemolytic Disease of the Newborn
IM – Intramuscular
IU – International Unit
IUD – Intrauterine Death
NICE – National Institute for Clinical Excellence
PSE – potentially sensitising event
RAADP – Routine Antenatal Anti-D Prophylaxis
Rh(D) – Rhesus
SBAR – Situation, Background, Assessment, Recommendation

1.0 Roles and Responsibilities:

The guidance has been developed to standardise the practice of all practitioners involved in providing antenatal and post-natal care for women who are Rh(D) Negative and those who have responsibility for providing these women with up to date information to make informed choices, i.e. Midwives, Nurses, GPs, Obstetricians, Haematologists and clinical specialists.

2.0 Implementation and dissemination of document

This Guideline is available on the intranet and has followed the Trust's Guideline review process.

3.0 Processes and procedures

Remember that Ani-D Ig is a blood product and should be managed and administered as such

Key Points

- Women who are confirmed to have immune(allo) anti-D (see section 4.0) do not need (or should not receive) anti-D Ig
- The RAADP scheme should be regarded as supplementary to any Anti-D Ig administered for sensitising episodes listed in section 6.0.
- Person administering anti-D Ig should confirm the woman's identity, discuss risk/benefits, gain informed consent and record in patient's notes. Confirm product dose and expiry date
- Following potentially sensitising events , anti-D Ig should be administered as soon as possible and always within 72 hours of the event. If, exceptionally, this deadline has not been met some protection may be offered if anti-D Ig is given up to 10 days after the sensitising event

- Each new sensitising event should be managed with a dose of anti-D Ig independent of previous or subsequent planned doses (including RAADP)

- In the event of continual uterine bleeding which is clinically judged to represent the same sensitising event, with no features suggestive of a new presentation or a significant change in pattern or severity of bleeding, a dose of anti-D Ig should be given at 6 weekly intervals. Feto-maternal haemorrhage (FMH) screening should be performed every 2 weeks from 20 weeks onwards

- Appropriate tests for FMH should be carried out for all D-negative, pregnant women who have had a PSE after 20 weeks of gestation and additional dose(s) of anti-D Ig should be administered if indicated

- The 28-week antibody screening sample must be taken prior to the routine prophylactic injection being given

- For women with a clotting disorder e.g. severe thrombocytopenia (platelets <50,000) or disorders of haemostasis intravenous (IV) Anti-D Ig should be given instead of intramuscular (IM) at the same timing and dose required

3.1 Storage

- Anti-D Ig should be stored according to manufacturer's instructions: maintaining cold chain conditions between 2 and 8°C in an appropriate clinical refrigerator and it must not be frozen. It has a shelf life of 2-3 years depending on the type used at your hospital.

- The Anti-D Ig vial or prefilled syringe should be kept in the outer carton until ready to use in order to protect it from light. It should be brought to room temperature (25°C) before use.

- Following removal from the refrigerator it may be stored at a temperature below 25^{o}C for up to a maximum of 72 hours.

3.2 Preparation of Anti-D Immunoglobulin

The following preparation is available in the Milton Keynes University Hospital Blood Bank as at the time of writing this guideline.
Rhophylac (CSL Behring) available as 1500 IU preloaded syringe for IM or IV use.

Under no circumstances must the 1500IU vials be split and the whole dose of 1500IU must be administered even though this dose may be higher than is clinically indicated. (BCSH guideline for the use of Anti-D immunoglobulin for the prevention of haemolytic disease of the fetus and newborn 2014).

3.3 Informed Consent

- For informed consent nurses/midwives should ensure that the woman has received the Anti-D patient information leaflet (PATH/GL/5). This Patient Leaflet is sent directly to the patient after

analysis of the booking bloods. If presenting with a sensitising event prior to having received this or if a late booker, known to be Rh Negative, or found to be so when a group and save is taken this leaflet must be offered by the nurse or midwife The leaflet explains the risk and benefits of Anti-D including when it may require If the woman declines blood products ensure the policy for patients declining blood and blood components (PATH/GL/O4) has been followed.

- Prior to administration of Anti-D Ig the woman's informed consent, including information of product being a blood derivative should be obtained and documented in eCare and in hospital or GP case notes by the healthcare professional responsible for the administration. There is transfusion autotext in eCare for this purpose - /BTconsent.

3.4 Record keeping

The details of the administration of Anti-D Ig must be recorded both in eCare and GP electronic record. On eCare there is a section for Anti-D administration antenatally and postnatally. It is also important that these details are centrally recorded in the hospital blood bank computerised system. This information can only be recorded on receipt of a fully completed traceability tag.

The EU guide on good manufacturing practice recommends that records are kept to enable traceability of all blood products (of which Anti-D Ig is included) from donors to recipients and vice versa. (European Commission 2000).

Documentation accompanying the injection must include a report containing the following:

- Identity of the patient to include surname, forename, date of birth, a unique ID number and the date of administration.
- Identity and address of the GP Surgery/Antenatal Clinic or postnatal ward and the name of the clinician and position.
- Details of the injection should include Batch Number and strength, dose, site and route of administration.

Documentation on eCare

The administration of any Anti-D must be recorded in eCare under "assessments", "fluid balance", "Anti-D" in the relevant antenatal or postnatal section . Details of the injection must include batch number, dose, site and route of administration.

4.0 Antibody Screening

The booking blood antibody screen on maternal samples may detect Anti-D. The Anti-D present may be passive i.e from a preparation of Anti-D or immune (allo) i.e produced by the mother in response to stimulation from Rh(D) Positive cells in her circulation. Passive Anti-D rarely exceeds 0.4 IU/ml unless a larger than standard dose has been given, and the level falls with time.

If there is significant doubt about the immune or passive nature of Anti-D, the sample will be referred by the laboratory for quantitation of Anti-D

If there has been an Anti-D Ig injection within the past 12 weeks and the level is below 0.4 IU/ml, a further sample should be tested at 28 weeks and prophylaxis should continue. If there is no record of Anti-D Ig injection the antibody should be monitored as for immune Anti-D i.e. at 4 weekly intervals to 28 weeks and at fortnightly intervals thereafter.

Prophylactic Anti-D should continue in either case unless it is established that the Anti-D is immune. (Recommendation 9, British Committee for Standards in Haematology BCSH, 2014).

5.0 Management of Routine Antenatal Anti-D Prophylaxis (RAADP)

The NICE guidance TA156 (2008) recommends that RAADP is offered to all Rh(D) Negative non-sensitised pregnant women. There is no evidence of a difference in efficacy between a single dose regime, and the two-dose regime. Milton Keynes University Hospital Foundation Trust has decided to offer a single dose scheme to reduce risk and wastage and improve compliance with RAADP.

Use of routine antenatal Anti-D prophylaxis should not be affected by previous Anti-D prophylaxis for a sensitising event early in the same pregnancy. Likewise, Anti-D Ig given for a sensitising event should be given, with consent, regardless of any routine Anti-D Ig prophylactic dose given previously.

5.1 Administration of Routine Antenatal Anti-D Prophylaxis (RAADP) – (process see Appendix 2)

- All women who are Rh(D) Negative and who are not known to have Anti-D antibodies should be offered routine Anti-D Ig prophylaxis by their community midwife

- 28 – 30 weeks gestation, 1500 IU given intramuscularly. This should be facilitated during the routine 28 week appointment for all Rh Negative pregnant women

- It is recommended that the deltoid muscle be used for the site of administration for routine Anti-D prophylaxis. The 1500 IU dose of Anti-D is 2mls.There is varying evidence on how many mls can be given in the deltoid muscle from1- 4mls (The provider does not recommend splitting the 2mls dose across two injection sites).

- The blood transfusion traceability tag issued with the Anti-D Ig should be signed and dated by the administering midwife and returned to Blood Bank for their records. Details of the administration should be recorded in the GP notes, and the maternity notes in eCare records.

- Bloods should be taken at 28 weeks prior to administration of Anti-D prophylaxis, for Group and antibody status. For a clear audit trail, the time of administration of the Anti-D on the traceability record must be different to the time on the group and save request.

- In the event that routine prophylaxis is not given at 28 weeks, this should be offered at the earliest contact prior to labour and birth.

Routine testing for Group and antibodies is not recommended to be repeated at 34 weeks and should only occur at booking & 28 weeks unless laboratory antibody screening results indicate otherwise.

5.2 Process (RAADP)

See appendix 2 – Management of antenatal Anti-D prophylaxis (RAADP) in pregnancy pathway.

5.2.1 **Booking**

The community midwife will confirm the patient's identity and estimated date of delivery (EDD) where possible when taking the booking bloods on the client. GP records should be reviewed prior to or at the time of booking.

The Midwife should inform the women that if they have an Rh(D) Negative blood group they will receive a letter (appendix 3) from the Blood Transfusion laboratory, sent on behalf of the Midwifery Team, informing them of this with advice that if they should have a sensitising event then they should contact ADAU (Ante-natal Day Assessment Unit) or Maternity Triage on 01908996481

5.2.2 **16 Weeks**

- Antenatal booking bloods will be reviewed and documented at 16 weeks by the Community Midwife. A request for Anti-D Ig, for any Rh(D) Negative woman should be made in eCare at this time and the request documented in eCare. The woman should have received a blood group card and an Anti-D information leaflet along with the letter mentioned above in the Booking section from the laboratory after the analysis of the booking bloods. In addition, the midwife shall give advice and information to the woman regarding action to be taken in the event of a potentially sensitising event (PSE) and the discussion documented.

- Following the receipt of this request the lab will issue Anti-D Ig for the named woman at the surgery recorded on the request within 14 working days of the date identified for issue.

- If the midwife is aware of any imminent change of address or GP practice, it is the community midwife's responsibility to update the laboratory to changes in GP practice registration. This may be either through the former GP practice or the newly registered GP practice.

5.2.3 28 weeks

- **Before** administration of the Anti-D Ig a further sample for blood group and antibody screen should be collected.

- RADDP should be administered regardless of prior administration of Anti-D Ig for potentially sensitising event however close this event was to the 28-week routine prophylaxis appointment.

- Following the administration of the Anti-D Ig the detachable portion of the traceability tag must be returned to the laboratory in the envelope provided. This is essential for all prophylaxis.

- Where women have declined RADDP then this should be clearly documented on the group and save request when bloods are taken at 28 weeks. Any unused Anti-D should be returned to the laboratory for disposal, letting them know the reason for wastage.

Out of Area Women

Routinely all out of area women are the responsibility of the GP/midwife/laboratory providing routine antenatal care and undertaking routine blood tests.

- Out of area women who consent for routine antenatal Anti-D prophylaxis to be administered by the Trust are to attend a hospital midwife led Antenatal Clinic. The laboratory will require a sample to verify the Patient's Rh(D) status.

- For women who have received Anti-D Ig not supplied by this Trust outside of the RAADP scheme or as a treatment for any underlying complication, it is essential that this information is clearly documented on the request during any further testing as this may greatly influence further management of the pregnancy.

This is essential because it is not possible to differentiate between administered prophylactic Anti-D Ig and immune Anti-D in laboratory tests. This lack of information could potentially delay future transfusions as we have to assume the Anti-D detected is immune and the patient does not then qualify for the much faster electronic issue of red cells. This block remains on their records permanently.

6.0 Sensitising events and their management

6.1 Potentially sensitising events for pregnant women who are Rh(D) Negative.

Pregnant women who are Rh D negative must be considered for prophylactic Anti-D Ig for any of the following potentially sensitising events.

- Amniocentesis
- Cordocentesis
- Chorionic villus biopsy
- Other in-utero therapeutic intervention/surgery (e.g. intrauterine transfusion, surgical insertion of shunts)
- Antepartum haemorrhage (APH)
- Ectopic pregnancy
- Evacuation of molar pregnancy
- External cephalic version
- Fall / abdominal trauma
- Intrauterine death & stillbirth
- Delivery – normal, instrumental or by caesarean section
- Cell salvage
- Termination of pregnancy
- Medical and surgical management of miscarriage (see section 6.1)

It is recommended following sensitising events Anti-D Ig should be offered and administered as soon as possible and certainly within 72 hours of the event. However, if this deadline cannot be met due to exceptional circumstances, some protection may be offered up to 10 days after the sensitising event.

6.2 Process – Anti-D for sensitising events (see Appendix 1)

6.2.1 Before 12 weeks gestation

Where the gestation is confirmed by scan, in uncomplicated miscarriage where the uterus is not instrumented, or mild painless vaginal bleeding, prophylactic Anti-D immunoglobulin is not necessary because the risk of feto-maternal haemorrhage (FMH) is negligible. However following termination of pregnancy, whether by surgical or medical methods, ectopic pregnancy, molar pregnancy and cases of uterine bleeding where this is repeated, heavy or associated with abdominal pain. A 1500 IU Anti-D immunoglobulin should be offered and administered to confirmed Rh(D) Negative women who are not known to be already sensitised to Anti-D. In medical management of missed miscarriage, Anti-D should be given at the start of the medical treatment.

6.2.2 Between 12 and 20 weeks gestation

For any potentially sensitising event listed in 5.0**,** a blood sample should be obtained and tested to ensure the woman is Rh(D) Negative and that she has not been sensitised and is producing immune Anti-D antibody. Anti-D immunoglobulin (1500 IU) should be administered within 72 hours of the event between 12 and 20 weeks.

Where gestation is uncertain administer a dose of Anti-D.

6.2.3 After 20 weeks gestation

- Following any potentially sensitising event listed in 6.0. A 1500 IU Anti-D Ig dose should be offered and administered within 72 hours of the event regardless of whether the patient has already received RAADP at 28 weeks or Anti-D Ig for a previous sensitising event.

There is an additional requirement to assess the volume of FMH. If the acid elution (Kleihauer) technique is used and a FMH of >2ml is indicated, the test should be repeated using flow cytometry*.

- Note if new symptoms develop suggestive of a sensitising event in addition to continual uterine bleeding 6.3 i.e. abdominal pain associated with a significant change in pattern or severity of bleeding then it should be managed as a separate event.

- Each new sensitising event should be managed with an appropriate additional dose of Anti-D Ig regardless of timing or dose of Anti-D Ig administered for a previous event.

6.3 Prevention of Anti-D formation in the event of recurrent uterine bleeding

6.3.1 Recurrent uterine bleeding before 12 weeks gestation

Evidence that women are sensitised after uterine bleeding in the first 12 weeks of pregnancy where the fetus is viable and the pregnancy continues is scant. Therefore, Anti-D immunoglobulin is not

necessary in women with threatened miscarriage with a viable fetus where bleeding completely stops before 12 weeks gestation.
However, offer and administer 1500 IU Anti-D Immunoglobulin where bleeding is heavy or repeated or where there is associated abdominal pain. The period of gestation should be confirmed by ultrasound.

6.3.2 Recurrent uterine bleeding between 12 and 20 weeks gestation

Rh(D) Negative women with recurrent PV bleeding between 12 and 20 weeks gestation should be offered 1500 IU Anti-D immunoglobulin at 6 weekly intervals.

6.3.3 Recurrent uterine bleeding after 20 weeks gestation

Anti-D immunoglobulin 1500 IU should be given at a minimum of 6 weekly intervals. Estimation of FMH by acid elution technique should be carried out at 2 weekly intervals. If the 2 weekly FMH is positive, additional dose of Anti-D immunoglobulin (1500 IU minimum, more if FMH exceeds 4mls) should be offered regardless of the presence or absence of passive Anti-D in maternal plasma, and FMH should be retested after 72 hours. An appointment should be made in ADAU to facilitate this.

7.0 Post Natal

A cord blood sample should be taken and tested to obtain the ABO and Rh(D) type of the baby. If this is not collected for any reason, a heel prick sample from the baby should be obtained as soon as possible. **The sample must be clearly labelled with the baby's details including where possible the MRN** or the NHS number. On the request card the mother's NHS number or MRN should be entered otherwise the lab cannot link the baby to the mother to know if post-natal Anti-D is required. Twins should be treated as two separate individuals and the lab will link them together on the system.

Maternal samples for confirmatory ABO and Rh(D) type and FMH testing (feto-maternal haemorrhage) should be collected after sufficient time has elapsed for any feto-maternal haemorrhage to be dispersed in the maternal circulation. A period of 30-45 minutes is considered adequate, but samples should be collected within 2 hours of birth and before the patient is discharged.

A Kleihauer Care Set should be requested on eCare and the following bloods sent on mum (2 EDTAs required) and a Baby Group and DAT on the cord blood. (1 EDTA).

Both samples should be sent to the lab on separate blood forms however the forms can be stapled together to ensure they remain paired. Where it is not possible to send both samples at the same time request forms should clearly indicate the relationship of one patient to another and whether one sample has already been sent.

Where received singly and it is apparent that the sample received is post-delivery cord/baby or maternal, laboratory staff shall contact midwifery staff to confirm the identity of the corresponding mother or baby and when confirmed the record shall be linked

Following birth of a Rh(D) Positive infant a 1500 IU Anti-D Ig dose is offered and administered to the woman. Women who are transferred to postnatal wards will have their Rh status discussed as part of the SBAR handover from Labour Ward to the postnatal ward.

Where an early discharge has been requested, the delivering midwife must call the Blood Bank BMS (out of hours bleep the BMS on 1412) to inform them that blood has been sent for baby's blood group and Direct Antiglobulin Test (DAT) and Kleihauer. The baby blood group result will normally be available within approximately 1 hour from receipt of the sample in Blood Bank and Anti-D will be issued immediately. The mother and baby must not be discharged home until the mother is given her Anti-D Ig injection if it is required.

Note: Occasionally blood bank may take longer than 1 hour to group the baby cord sample and issue Anti-D Ig when dealing with high workloads e.g. major haemorrhage

On the rare occasions the mother refuses to wait for the baby cord blood group to be confirmed and the Anti-D Ig made available the discharging midwife must ensure that it is clearly documented on the community midwife discharge form that we are awaiting the Baby Blood group and Kleihauer and that Anti-D Ig may be required.

Once the baby cord group is confirmed and Anti-D Ig is required the blood bank will phone the results to Ward 9. It remains the responsibility of the midwife taking the telephone call from the lab to ensure that this is arranged/ followed up. The lab is responsible for taking the name of the midwife they have given the result to.

If an additional dose of Anti-D is necessary because the laboratory have identified a large FMH, they will inform the clinical area of the need for this, calculate and issue the required dose and request a follow up Kleihauer sample to be taken after a specific time period.

It is recommended if the pregnancy is non-viable and no sample can be obtained from the baby, prophylactic Anti-D Ig should be offered and administered to the woman, if she is Rh(D) Negative. Administration of Anti-D Ig should occur within 72 hours of diagnosis of IUD and at delivery. Rationale for FMH testing should follow that of live birth.

8.0 Assessment of Fetal Maternal Haemorrhage (FMH)

It is essential to assess the volume of FMH in order to calculate the appropriate Anti- D dosage for administration. This is done by the laboratory and requires an EDTA sample and a Kleihauer request.

- It is required when a woman who is Rh(D) Negative experiences a potential sensitising event after 20 weeks gestation and following the birth of an Rh(D) Positive baby.
- Following the administration of IM Anti-D Ig for a sensitising event where the FMH was greater than 4mls, an appointment should be made in ADAU within 72 hours for a follow up maternal sample to be taken and tested to assess the removal of fetal cells. Further Anti-D Ig may be required if residual fetal cells remain present and the laboratory will inform the clinical area of this.

- A joint clinical decision between the laboratory and clinicians would be required to determine the dosage and frequency of any further injection's dependent on the volume of residual fetal cells detected 72 hours following the original administration of Anti-D Ig. (48 hours if Anti-D is administered intravenously)
- In cases of a very large FMH i.e. in excess of 80mls, intravenous Anti-D should be considered. Only Anti-D Ig preparations licenced for IV administration should be used (contact Blood Transfusion Laboratory for further information).

9.0 Other indications for the use of Anti-D Ig

9.1 D positive platelet transfusions

Whenever possible, D negative platelets should be transfused to D negative girls or women of child bearing potential, who need a platelet transfusion. Occasionally, if the appropriate product is not available or its availability would cause unacceptable delay, it may be necessary to transfuse D positive platelets. In these circumstances, prophylaxis against possible sensitisation to the D antigen by red cells contaminating the platelet product should be given.
A dose of 1500 IU anti-D immunoglobulin should be sufficient to cover up to five adult therapeutic doses of D positive platelets given within a 6-week period.
It is not necessary to administer anti-D Ig to D negative females without childbearing potential, or males who receive D positive platelets. unless they are regularly transfused where anti-D will be offered to help prevent any allo-immunisation.

9.2 Inadvertent transfusion of D positive blood to D negative women of childbearing potential

IV anti-D immunoglobulin is the preparation of choice, achieving adequate plasma levels of Anti-D IG immediately. Advice on the dose required will be provided by a Haematology Consultant.

10.0 Managing patients with allergic reactions

- Allergic reactions to anti-D Ig are very rare but severe hypersensitivity including anaphylaxis can occur.

- If a pregnant D negative woman has had a previous allergic reaction to anti-D Ig, plasma or a plasma containing blood components, it is important to have a plan for managing this early on in pregnancy. An individualised plan should be developed with the involvement of a Consultant Haematologist and Obstetrician which will take into account the nature of the previous reaction(s).

- Anti-D Ig preparations may contain trace amounts of Immunoglobulin A (IgA). Individuals with known antibodies to IgA have a greater risk of developing potentially severe allergic and anaphylactic reactions. Consider investigating for the presence of antibodies to IgA in a pregnant women who has a previous history of severe allergic or anaphylactic reaction

- Any reaction to Anti-D should be reported to the MHRA using the Yellow Card system.

11.0 Statement of evidence/references

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(Linked from British Society for Haematology: https://b-s-h.org.uk/guidelines/guidelines/use-of-anti-d-immunoglobin-for-the-prevention-of-haemolytic-disease-of-the-fetus-and-newborn/) [Accessed 31 August 2023]

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12.0 Governance

12.1 Document review history

Version	Date	Name	Reason
1	March 2003	Sue Cole	Response to NICE guidance on Anti-D prophylaxis published in 2002
2	March 2009 / June 2009	Esther valentine Mark Ashmore Grant Barker Elizabeth Miller	Reviewed and updated
Draft 3	June 2011	Esther Valentine	Change in practice, from 2 dose scheme to Single dose
3	November 2011	n/a	Document published following approval
4	February 2015	Grant Barker	Review following revised BCSH guideline 2014
5	August 2017	Lydia Stratton Fry Caroline Lowe	Change in operational process

		Anna Madeley	
6	June 2019	Ghaly Hanna, Janice Styles, Terrie Perry	Updated with latest guidance
6.1	March 2020	Natalie Lucas	Amendment to section 4.1 to include blood bank letter to women. Addition of appendix 3 – Blood bank letter to Rh(D) Negative women
7	July 2023	Terrie Perry, Katie Selby, Karen Evans	Standardisation of dose to 1500IU. Additions of section on reactions. Additional information on storage.
7.1	November	Terrie Perry, Caroline Lowe	Section 9.1 added *'It is not necessary to administer anti-D Ig to D negative females without childbearing potential, or males who receive D positive platelets. unless they are regularly transfused where anti-D will be offered to help prevent any allo-immunisation.'*

12.2 Consultation History

Stakeholders Name	Area of Expertise	Date Sent	Date Received	Comments	Changes Made
Jayne Plant	Library	November 2018		Comments received	Yes
Women's Health, Surgery, ED, Caroline Lowe, Joshna Gopal-Patel; Khan Mohammed		15/02/2019		See individual comments	
Jasmine MBeharry	Biomedical Scientist	15/02/2019	17/02/2019	Comments received	Yes
Vanessa Braithwaite	Nurse EPAU	24/06/2019	10/07/2019	Comments received	Yes
Melissa Coles	Midwife	24/06/2019	29/07/2019	Comments received	Yes
Terrie Perry	Specialist Transfusion Practitioner	24/06/2019	07/08/2019	Comments received	Yes
Julie Cooper	Head of Midwifery	24/06/2019	25/06/2019	Comments received	Yes
Mary Plummer	Matron	24/06/2019	18/07/2019	Comments received	Yes

Niamh Kelly	Clinical Governance	November 2018		Comments received	Yes
Women's Health Guideline Group	Women's Health	September 2023		Complete review and update	Yes
Women's Health Guideline Group	Women's Health	November 2023		Version 7.1 approved as chairman's actions	Yes

12.3 Audit and monitoring

Audit Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee	How changes will be implemented	Responsibility for Actions
a) Compliance with Routine Antenatal Prophylaxis Programme b) Compliance with Postnatal Administration for women who give birth to Rh(D) Positive Babies. c) Compliance with the use of prophylactic Anti-D immunoglobulin for potentially sensitizing episodes	Audit	Midwives, Doctors, Laboratory staff	Annually	• Clinical governance Group • Hospital Transfusion Committee	Action plan to be completed	Midwives, Doctors, Laboratory staff

12.4 Equality Impact Assessment

As part of its development, this Guideline and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified. Equality Impact assessments will show any future actions required to overcome any identified barriers or discriminatory practice

Equality Impact Assessment			
Division	Women and Children's	Department	Maternity
Person completing the EqIA	Ghaly Hanna	Contact No.	87080
Others involved:		Date of assessment:	14/06/2019
Existing policy/service	Yes	New policy/service	No

Will patients, carers, the public or staff be affected by the policy/service?	Yes
If staff, how many/which groups will be affected?	*Staff working within maternity, blood transfusion*

Protected characteristic	Any impact?	Comments
Age	NO	Positive impact as the policy aims to recognise diversity, promote inclusion and fair treatment for patients and staff
Disability	NO	
Gender reassignment	NO	
Marriage and civil partnership	NO	
Pregnancy and maternity	NO	
Race	NO	
Religion or belief	NO	
Sex	NO	
Sexual orientation	NO	

What consultation method(s) have you carried out?
Anti-D focus group meetings with staff from maternity, blood transfusion and the labs. Document sent out for consultation to women's health, surgery, ED, blood transfusion and the labs.
How are the changes/amendments to the policies/services communicated?
Via minutes of meetings, email and training will be arranged due to change in practice.
What future actions need to be taken to overcome any barriers or discrimination?

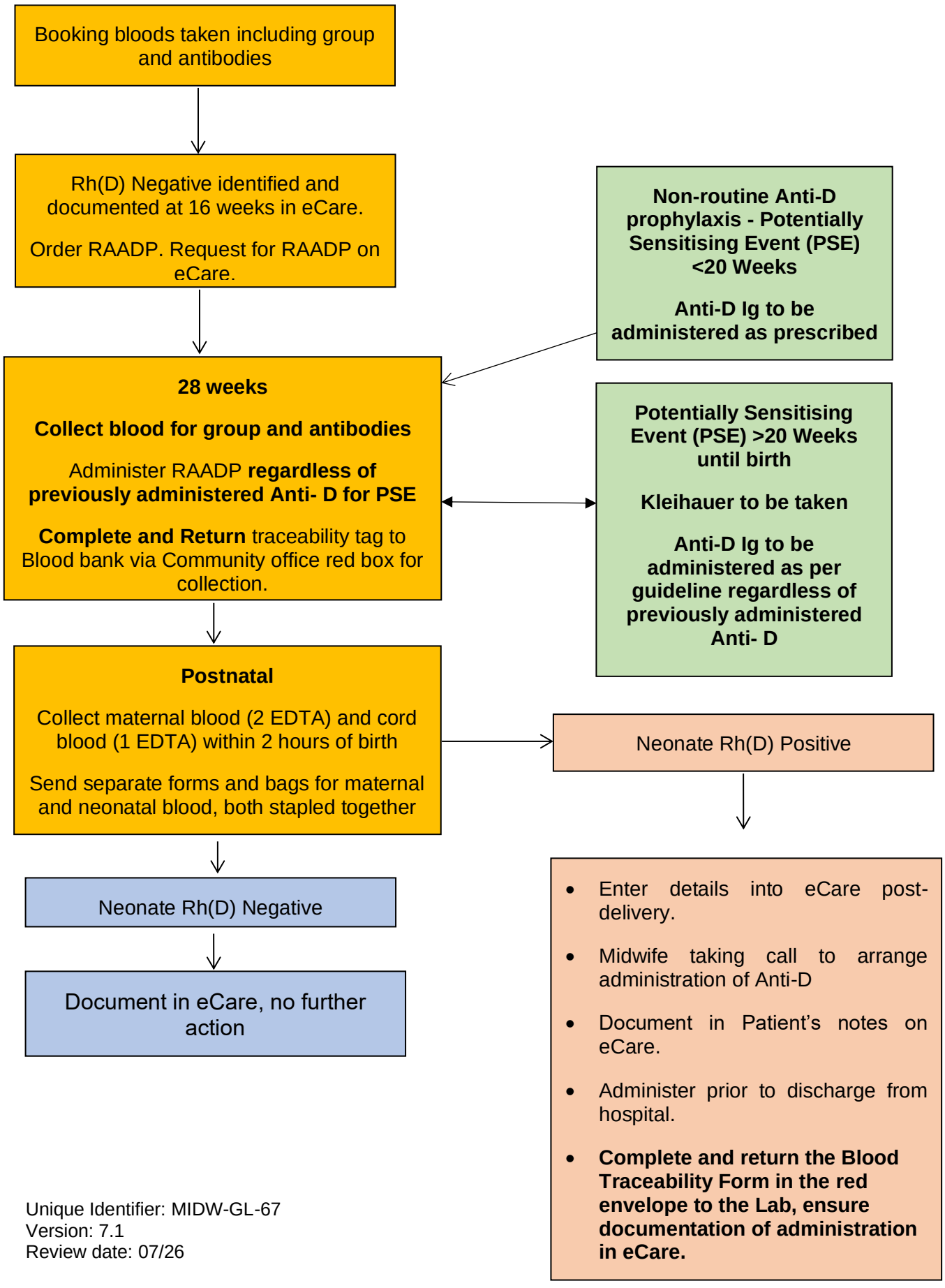
What?	Who will lead this?	Date of completion	Resources needed
Review date of EqIA			

Appendix 1: Recommendations for Antenatal and Postnatal Tests and the Prevention of Sensitisation

Gestation	Summary of tests and treatment
Less than 12 weeks	In all cases check ABO and Rh(D) type to confirm Rh(D) status. Confirm absence of immune Anti-D. Issue and administer 1500 IU (I.M) Anti-D Ig for therapeutic abortion. No action is required for uncomplicated complete miscarriage or painless vaginal bleeding. For vaginal bleed with persistent abdominal pain or where surgical intervention is required or in molar or ectopic pregnancy, 1500 IU Anti-D should be administered.
12 weeks – 20 weeks	For all potentially sensitising episodes ABO and D type to confirm D negativity. Confirm absence of immune Anti-D. Issue and administer 1500 IU Anti-D Ig, I.M.
After 20 weeks	For all potentially sensitising episodes ABO and Rh(D) type to confirm D negativity. Confirm absence of immune Anti-D. Assess FMH Issue and administer 1500 IU Anti-D Ig, I.M. or more depending on the size of FMH.
16 weeks	**REQUEST FOR** 28 week prophylactic **ANTI-D MUST BE COMPLETED** on eCare
28 weeks	**RAADP (Routine Antenatal Anti-D Prophylaxis)** Take sample for group and antibodies and administer 1500 IU prophylactic Anti-D Ig
29+ weeks - Term	**If RAADP has been missed administer routine prophylaxis dosage at the earliest contact.** Issue and administer 1500 IU Anti-D Ig

Birth	TESTS ON BABY – Take cord sample at birth. Establish ABO and Rh(D) status MATERNAL TESTS – Check ABO and Rh(D) status Assess FMH if baby is Rh(D) Positive Issue and administer 1500 IU Anti-D Ig to the mother if baby is Rh(D) Positive or Rh(D) status of baby or IUD cannot be assessed More Anti-D Ig may be required depending upon the size of any FMH.

Appendix 2 – Management of Antenatal Anti-D Prophylaxis (RAADP) in Pregnancy Pathway



Appendix 3: Blood bank letter to Rh(D) Negative women

Date:

Dear

The blood tests taken at your booking appointment have shown that you have a **Rhesus (RhD) Negative** blood group. This is a normal result and about 15% of the UK population are Rh(D) Negative.

If your baby has Rh(D) Positive blood, different from yours, there is a chance if the two bloods mix you may develop antibodies. At present, we will not know the group of your baby until your baby is born.

"This is called "sensitisation ". As a general rule the first child that triggers this sensitisation does not suffer any adverse consequences as it will already have been born by the time antibodies have developed. However, if the woman becomes pregnant again with an Rh(D) positive baby, antibodies may cross into the baby's bloodstream and attack baby's red blood cells which can lead to the baby suffering anaemia, heart failure, brain damage or even to the death of the baby"

In order to prevent you developing antibodies if your bloods are different your midwife will offer you **Anti D** when you are 28 weeks pregnant. It is an injection in your arm which prevents your Rh(D) negative blood from reacting to your baby's blood if it is Rh(D) Positive. This injection protects the baby and is very effective at preventing problems caused by mum and baby having different blood groups.

It is also important for you to know that if you have any vaginal bleeding during your pregnancy or have an impact to your stomach such as a car crash or heavy fall there is a chance you could react to your baby's different blood group. If this happens it is important that we know, and we would like you to call Ante-natal Day Assessment Unit (**ADAU) on 01908 996481** and let them know what happened and that you have Rh(D) Negative blood. They will arrange for you to have an Anti D injection regardless of however many weeks pregnant you are and even if you have already had the 28 week injection. It is a safe treatment and can be given a number of times in pregnancy if needed.

After the birth of the baby the midwife will check your baby's blood group by taking some blood from the cord. If your baby is Rh(D) Positive you will be offered another Anti D injection to prevent this reaction happening in future pregnancies.

There is a leaflet enclosed which explains in more detail about Rh(D) Negative blood and Anti D injections. If you have any further questions, please call your midwife or ask her at your next appointment.

Yours sincerely,
The Midwifery Team