Aneurin Bevan University Health Board

Policy on the Use of Anti D Immunoglobulin in the Management of Rh (D) Negative Pregnant Women

Please see important note on page 3 regarding blood transfusion testing.

N.B. Staff should be discouraged from printing this document. This is to avoid the risk of out of date printed versions of the document. The Intranet should be referred to for the current version of the document.

Status: Issue 5 | Issue date: 30th October2023
Approved by: Clinical Effectiveness Forum | Review by date: 30th October 2026
Owner: Maternity Services | Number: ABUHB/F&T/0610

Contents

1. Executive Summary

All Rhesus D (RhD) negative women/ service users who carry a RhD antigen positive fetus are at risk of being sensitised to produce immune anti-D antibodies following a feto-maternal haemorrhage (FMH). Rhesus Haemolytic Disease of the Fetus and Newborn (Rh-HDFN) occurs when the maternal immune anti-D antibodies cross the placenta resulting in haemolysis of the fetal/ newborn red blood cells (RBC). Severe Rh-HDFN may cause fetal death or can result in hydrops and jaundice, leading to kernicterus and permanent cerebral damage or infant death. Mild neonatal jaundice may be indicative of mild Rh-HDFN, which is often treated with phototherapy alone. [1]

Antenatal and post-partum immune-prophylaxis using anti-D immunoglobulin (anti-D Ig) began in the United Kingdom (UK) in 1969. Following routine post-partum administration of anti-D Ig and routine antenatal prophylaxis during the third trimester of pregnancy, mortality associated with severe Rh-HDFN decreased from 46/100,000 births to 1.6/100,000 births. [2]

In 2008, the National Institute for Clinical Excellence (NICE) produced guidance on the use of Routine Antenatal Anti-D Prophylaxis (RAADP) for RhD negative women/ service users. NICE recommended that RAADP should be a treatment option for all pregnant women/ people who are RhD negative, and who are not known to have sensitised to the RhD antigen. This guidance/ evidence was reviewed in March 2015, with no additional recommendations/ alterations required. [3]

1.1. Important note regarding effect of prophylactic anti-D on compatibility testing:

The administration of prophylactic anti-D will result in a positive antibody screen test for as long as the injected anti-D remains detectable in the sample. This may be upwards of 6-months. [2]

There is no method to distinguish between prophylactic and immune anti-D. When circulating anti-D is still detectable after the administration of anti-D Ig to RhD negative women/ service users, an anti-human globulin (AHG) crossmatch should be performed to ensure compatible blood is provided. [4]

In clinical terms, this means that it will take longer for compatible blood to be made available. A full serological crossmatch will take approximately 40-minutes following receipt of the sample in the laboratory for patients who still have detectable prophylactic anti-D in their circulation.

In an emergency situation, O RhD negative blood may be issued without a known patient blood group, until the group specific and antibody compatible units can be provided. [4]

1.2. Scope of policy

The scope of this policy applies to **all non-sensitised RhD negative** women/ service users who are pregnant.

If it is found that a woman/ service user has been sensitised to the RhD antigen, then this policy does not apply and guidance must be sought from a consultant obstetrician.

1.3. Essential Implementation Criteria

- Identification of RhD negative women/ service users at booking,
- Appropriate management of sensitising events during the antenatal period,
- Administration of RAADP at 28 weeks' gestation to all non-sensitised RhD negative women who are pregnant.
- Appropriate post-partum prophylaxis if the woman has a RhD positive baby.

This policy has undergone an equality impact assessment screening process using the toolkit designed by the National Health Service (NHS) Centre for Equality and Human Rights. Details of the screening process for this policy are available from the policy department.

2. Aims

The aim of this policy is to provide clear direction for midwives, nurses and doctors in the management of RhD negative women/ service users. This will ensure:

- That all RhD negative pregnant women/ people receive information and advice on RAADP and, therefore, will be able to make an informed choice about its administration.
- That the risk of an immune response to potential sensitising events (PSE) to the RhD antigen during the antenatal and post- partum period is reduced.
- That there is appropriate requisition, storage, administration and audit control of anti-D Ig. [5]

3. Responsibilities

All staff have a responsibility to practice safe transfusion in their specific roles and to be aware of possible errors made earlier in the chain. All errors and incidents must be reported to the appropriate internal and external agencies, including the internal DATIX system and external Medicines and Healthcare products Regulatory Agency (MHRA) in the event of serious adverse incidents.

Correct patient identification, accurate documentation and clear communication are fundamental principles of safe and appropriate transfusion, and thus the implementation of this policy. [6]

3.1. Ante-natal / Obstetric Staff

- Clinical management,
- Informed consent (**See Appendix B**),
- Appropriate requesting of prophylactic anti-D Ig,

- Safe product handling,
- Appropriate administration of prophylactic anti-D Ig,
- Traceability of the product,
- Return of unused products,
- Reporting of errors and incidents.

3.2. Blood Bank staff

- Product storage and stock control including recall, if necessary,
- Sample testing and issue of correct dose of prophylactic anti-D Ig,
- Recording of Traceability,
- Recording and notification of errors.

3.3. Transfusion Practitioners and Transfusion Link Nurses

- Training and Incident Investigation.

4. The Administration of Prophylactic Anti-D

These are the general principles required in the event of prophylactic anti-D administration.

4.1. Contraindications

- Informed consent not provided by the patient,
- Previous sensitisation resulting in presence of immune anti-D,

- Allergy/ hypersensitivity to human Igs or human albumin,
- Known low Immunoglobulin A (IgA).

Anti-D must not be administered intra-muscularly if there is a history or evidence of:

- Severe thrombocytopenia,
- Other disorders of haemostasis.

In these cases, anti-D should be administered intravenously, ensuring the manufacturer's instructions are followed explicitly.

4.2. Interaction with other medicines

According to NICE, anti-D (Rh0) Ig may reduce the efficacy of the following vaccines-

- Bacillus Calmette-Guérin vaccine,
- Herpes-zoster vaccine (live),
- Influenza vaccine (live),
- Measles, mumps and rubella (MMR) vaccine (live),
- Rotavirus vaccine,
- Typhoid vaccine (oral),
- Varicella-zoster vaccine.

In the case of the above vaccines, the manufacturers advise to avoid vaccination for 3-months after anti-D (Rh0) Ig administration. [7]

MMR vaccine may be given simultaneously with anti-D (Rh0) Ig injection, provided that separate syringes are used and the products are administered into different limbs. If not given simultaneously, the manufacturer advises to avoid MMR vaccination for 3-months after anti-D (Rh0) Ig administration. [7]

4.3. Possible Side effects [7]

4.3.1. Uncommon

- Chills,
- Fever,
- Headache,
- Malaise,
- Skin reactions.

4.3.2. Rare or very rare

- Arthralgia,
- Dyspnoea,
- Hypersensitivity,
- Hypotension,
- Nausea,
- Tachycardia,
- Vomiting.

4.3.3. Frequency not known

- Intravascular haemolysis.

4.4. Omission or late Administration

Anti-D Ig should be given prophylactically between 28- and 30-weeks' gestation and within 72 hours of a potentially sensitizing event (PSE) or following the delivery of a RhD positive baby. All instances of late or missed administration should be reported via the DATIX incident report system and arrangements made by the clinical team for a repeat antibody screen to be taken after 6-months to check for the presence of immune anti-D.

Anti-D Ig may provide some protection up to 10 days following a PSE and should, therefore, be a consideration in these circumstances.

4.5. Request for anti-D

Transfusion request forms and samples must be completed in accordance with the Aneurin Bevan University Health Board (ABUHB) Blood Transfusion Sample Acceptance Policy. [8]

There is an All-Wales 'zero tolerance' approach to sampling discrepancies in transfusion requests as per Welsh Government guidance, and clinical staff are responsible for performing positive patient identification and accurate sample labelling.

Incorrectly labelled requests constitute a breach of best practice and may delay treatment and/ or result in a serious adverse event. These incidents warrant a DATIX incident report submission, and may require national reporting to Serious Hazards of Transfusion (SHOT)/ MHRA.

4.6. Dosing

The Kleihauer Screen is a test used to determine if more than the standard dose of prophylactic anti-D Ig is required for RhD negative women/ service users following a PSE after 20 weeks' gestation or following the delivery of a RhD positive infant. Where a FMH of > or = 4ml is estimated, the sample will be referred for Flow Cytometry.

A FMH confirmed by flow cytometry as > or = 4ml is considered to be significant, and even if such a bleed is covered by the standard anti-D Ig dose administered, a follow-up FMH sample is still required to confirm that anti-D Ig has been administered and to check for clearance of fetal cells.

A follow-up FMH sample should be tested, after 72 hours if the additional anti-D Ig is given intramuscularly or after 48 hours if given intravenously, to check for clearance of fetal cells. Further dose(s) of anti-D Ig and continued follow-up will be necessary if fetal cells remain detectable. [1]

4.7. Deadline for optimum effect

Anti-D Ig should be given prophylactically between 28- and 30-weeks' gestation and **within 72 hours** of a PSE or following the delivery of a RhD positive baby.

Anti-D Ig may provide some protection **up to 10 days** following a PSE and should, therefore, be a consideration in the event of late/ missed dosing.

RAADP and non-routine anti-D Ig prophylaxis for PSEs should be viewed as completely separate entities. Anti-D prophylaxis should be considered for all PSEs either side of the 28 weeks' RAADP period. [1]

4.8. Administration

Anti-D Ig should always be administered in accordance with the manufacturer's instructions and the ABUHB Medicines Management Policy Code of Practice. [9]

Hyperlinks to product administration leaflets are provided in **Appendix A**.

4.8.1. Post administration observation

The woman/ service user must be observed for signs of an adverse reaction for **20- minutes** following the administration of anti-D Ig. All adverse reactions will require medical assessment.

4.9. Traceability

Procedures for traceability to confirm the final fate of the product must be followed in accordance with the ABUHB Blood Component Transfusion Policy. Full traceability of blood components is a legal requirement and requires clinical staff to be vigilant in the return of completed documentation. [6]

All unused components must be returned to the supplying Hospital Transfusion Lab (HTL) as soon as possible by an agreed route. [10]

4.10. Error and Incident Reporting

Errors in the storage, issue, collection and administration of anti-D Ig must be appropriately reported via the DATIX incident report system in a timely fashion, with correction and preventative actions implemented as deemed necessary following root cause analysis.

Serious incidents may require external reporting to SHOT and/or MHRA.

5. Routine Antenatal Anti D prophylaxis (RAADP) at 28 weeks' gestation

5.1. Product and dosage

The product routinely used within ABUHB for RAADP is Rhophylac 1,500units/ 2ml solution for injection pre-filled syringes.

5.2. Indication

All RhD negative pregnant women/ service users who have not been previously sensitized should be offered routine antenatal prophylaxis with RAADP.

5.3. Procedures

5.3.1. Booking appointment

Blood sampling should be undertaken at booking for ABO Blood Group, RhD status and antibody screen.

If a woman/service user is RhD negative, she will be provided with information regarding RAADP/ anti-D Ig and a clinic appointment for RAADP at 28 weeks' gestation. Written information should be given in the woman's/service user's first language where ever possible.

All RhD negative women/ service users will receive verbal and written information to enable them to make an informed choice about treatment.

RhD negative women who do not wish to have RAADP/ anti-D Ig administered must have their wishes respected. A record of the discussion with the woman should be made in the woman's All-Wales Maternity Hand Held Record/ Badgernet system.

5.3.2. 28 weeks' gestation

RAADP must be requested on an individual basis from the HTL with a written request at least 24 hours prior to the patient's 28-week RAADP appointment. The patient's prescription chart containing the RAADP prescription and Summary of Anti-D Administration form (**Appendix D**) should be taken to the HTL.

Please note that if the RAADP clinic is held on a **Tuesday**, then all requests are to be received by the **Monday** of the same week to ensure on timely delivery of the RAADP. Bank holidays must also be taken into account.

At 28 weeks' gestation, the midwife should verbally discuss the benefits and risks of RAADP administration with the woman/ service user. If they consent to receive RAADP, a consent form must be signed as per **Appendix B**.

If a woman/ service user declines RAADP administration, a note of this and the preceding discussion must be documented within the woman's/ service

user's All Wales Maternity Hand Held Record/ Badgernet and on Clinical Workstation (CWS).

Blood sampling in the form of a Full Blood Count (FBC) and a Group and Antibody Screen should be completed **at least 1 week prior to RAADP administration by the community midwife.** This is to check for the presence of immune anti-D due to a silent/ undisclosed PSE. It is important to indicate on the Summary of Anti-D Administration form (**Appendix C**) whether the woman/ service user has already received anti-D Ig earlier in the pregnancy and when.

RAADP should still be offered to all RhD negative pregnant women/ people who have received anti-D Ig earlier in pregnancy. Please contact the HTL for further information if required/ uncertain.

A 1,500unit/ 2ml dose will be supplied by the HTL on an individual, named patient basis. A traceability tag with the patient details and RAADP batch number will be attached.

5.3.3. Storage

Once delivered to the clinical area, the **RAADP should receive refrigerated storage**. Many immunoglobulins need to be stored at 2-8°C and not allowed to freeze. Igs should also be protected from direct light.

5.3.4. Administration route

RAADP should be administered by deep intra-muscular (IM) injection route. Patients with a Body Mass Index (BMI) <30 should receive an IM injection into the thigh. Patients with a BMI of >30 should receive an IM injection into the deltoid.

For patients with a BMI >30, intravenous (IV) administration of RAADP should be considered. [11]

5.3.5. Post-administration observations

The woman/ service user must remain in the clinic for **20-minutes** post RAADP administration to observe for signs of adverse effects.

5.3.6. Documentation

A record of administration must be documented within the All-Wales maternity hand-held record/ Badgernet, the prescription chart, CWS and CSC.

The traceability tag must be completed and returned to the supplying HTL by the agreed route as per the ABUHB Blood Component Transfusion Policy and the ABUHB Blood Transfusion Sample Acceptance Policy.

5.3.7. Did not attend

If the woman/ service user does not wish to attend the RAADP clinic, the RAADP must be returned to the HTL as soon as possible after the completion of the clinic. The RAADP must not be left un-refrigerated or exposed to light as per manufacturer's instructions.

Women/ service users who fail to attend their 28-week appointment will be reappointed with a 2nd invitation. Depending upon gestation:

- 1,500 international units (IU) should be offered up to 36 weeks' gestation,
- 500IU should be offered over 36 weeks' gestation.

This protects late bookers, transfers and women/ service users who may not have attended their previous appointments.

5.3.8. Transfer of care

For women/ service users who have transferred their care into ABUHB from other health authority and have been commenced on the two-dose RAADP regime:

Give 1,500IU RAADP at the time that the 2nd RAADP dose was due on the two-dose regime- this is usually done at 34 weeks' gestation.

RAADP does not exclude the need for additional prophylactic anti-D Ig to cover subsequent PSEs, regardless of the time interval since previous administration. [1]

6. Non-routine Antenatal Anti-D Prophylaxis (AADP)

These procedures apply where PSEs occur during differing stages of pregnancy.

6.1. AADP before 12^{+0} weeks gestation

The standard dose for AADP is 500IU currently supplied as D-Gam Anti-D immunoglobulin 500unit solution for injection vials.

A maternal blood group and antibody screen should be performed to determine or confirm the RhD group and check for the presence of immune anti-D. **Kleihauer sampling for FMH is not required at this gestation**.

6.1.1. Therapeutic termination of pregnancy

In cases of therapeutic termination of pregnancy, whether by surgical or medical methods, and regardless of gestational age, previously non-sensitised RhD negative women/ service users should receive AADP within 72 hours of the event. [1]

6.1.2. Miscarriage

In cases of spontaneous complete miscarriage confirmed by scan where the uterus is not instrumented, or where mild painless vaginal bleeding occurs before 12 weeks' gestation, AADP is not necessary because the risk of FMH and hence maternal exposure to the D antigen is negligible. [1]

Gynaecology staff must liaise with the antenatal clinic (ANC) to ensure that the 28-week RAADP outpatient appointment is cancelled, preventing unnecessary distress for the patient by ANC contact.

6.1.3. Threatened miscarriage

Evidence that women/ service users sensitized after uterine bleeding in the first 12 weeks of pregnancy, where the fetus is viable and the pregnancy continues, is scant. Therefore, AADP is not necessary in women/ service users with threatened miscarriage with a viable fetus where bleeding completely stops before 12 weeks' gestation. [1]

AADP should be administered where bleeding is heavy or repeated or where there is associated abdominal pain particularly if the events occur as gestation approaches 12 weeks' gestation. Gestational age should be confirmed by ultrasound. [1]

6.1.4. Ectopic pregnancy

AADP should be administered in all cases of ectopic pregnancy for previously non-sensitized, RhD negative women/ service users regardless of the mode of management. [1]

6.2. AADP between 12- 19+6 weeks' gestation

The standard dose is 500IU, with the product currently being used in ABUHB being D-Gam Anti-D immunoglobulin 500unit solution for injection vials.

Kleihauer sampling for FMH is not required prior to 20 weeks' gestation.

6.2.1. Indications

The following events constitute PSEs:

- Amniocentesis, chorionic villus biopsy and cordocentesis,
- Antepartum haemorrhage/ uterine bleeding in pregnancy,
- External cephalic version (ECV),
- Abdominal trauma (sharp/ blunt, open/closed),
- Ectopic pregnancy,
- Evacuation of molar pregnancy,
- Intrauterine death and stillbirth,

- In-utero therapeutic interventions (transfusion, surgery, insertion of shunts, laser),
- Miscarriage, threatened miscarriage,
- Therapeutic termination of pregnancy,
- Delivery- normal, instrumental or caesarean section,
- Intra-operative cell salvage.

In the event of continual uterine bleeding which is clinically judged to represent the same sensitizing event, with no features suggestive of a new presentation or a significant change in the pattern or severity of bleeding, such as the presence of abdominal pain or another clinical presentation, a minimum dose of 500IU anti-D Ig should be given at 6-weekly intervals. [1]

6.3. AADP after 20 weeks' gestation

The standard dose is 500IU, with the product currently being used in ABUHB being D-Gam Anti-D immunoglobulin 500unit solution for injection vials. A Kleihauer screen is required for gestations of 20 weeks or more.

The HTL will advise upon the appropriate dose of AADP in the published CWS report. This is based upon 125IU anti-D Ig being effective for a FMH of 1ml red cells.

6.3.1. Indications

Indications are the listed PSEs as per section 6.2.1.

6.4. Post-delivery AADP

The standard dose is 500IU, with the product currently being used in ABUHB being D-Gam Anti-D immunoglobulin 500unit solution for injection vials.

Cord and Maternal samples are required.

6.4.1. Procedures

Following delivery, a cord blood sample should be taken from the baby of a RhD negative woman to establish the ABO and RhD group. The sample should be obtained with a needle and syringe from an umbilical cord blood vessel wherever possible into a 6ml EDTA specimen bottle.

If cord blood is unobtainable, consideration should be given to alternative sampling methods for ABO and RhD blood grouping, such as heel prick sampling. **If alternative methods for sampling are not possible, it should be assumed that the baby is RhD positive for the purpose of AADP administration.**

Maternal samples for confirmatory ABO and RhD type and FMH testing should be collected after sufficient time has elapsed for any FMH to be dispersed in the maternal circulation. A period of 30- 45 minutes is considered adequate, and the samples should ideally be taken within 2-hours of delivery primarily to ensure that the sample is taken prior to the woman's/ service user's discharge from hospital. A 6ml EDTA sample must be collected and labelled in accordance with the ABUHB Blood Transfusion Sample Acceptance policy. [1]

Strict adherence to the ABUHB Blood Transfusion Sample Acceptance Policy is required for both maternal and cord blood samples. The samples must be handwritten immediately following collection, and the words **cord blood** should be written on the cord sample. Addressographs are not acceptable and must not be used. [7]

The NHS/ Hospital number of the baby must also be provided if available. If the baby has not been registered, the NHS/ Hospital Number field must be left blank on the form and sample. Do not use the maternal NHS/ Hospital Number for the cord sample.

The forename (if available), surname, date of birth (DOB) and NHS/ Hospital Number (if available) must be clearly written on the baby's sample. In the absence of a baby's forename, the sample must be clearly labelled with the words *'infant', 'female infant'* or *'male infant'*. The DOB on the sample must be that of the baby and not the mother. It is not acceptable to use a pre-registered DOB or 01.01.1900.

If the baby is confirmed as being RhD positive, a minimum of 500IU AADP is recommended to be administered to the mother. 500IU Anti-D Ig will cover a FMH of 4ml. However, depending upon the result of the Kleihauer screen, additional doses of AADP may be required.

Where intra-operative cell salvage (ICS) is used during caesarean section in RhD negative previously non-sensitized women/ service users, and where cord blood group is confirmed as RhD positive (or unknown), a minimum dose of 1,500IU anti-D Ig should be

administered following the re-infusion of the salvaged red cells, and a maternal sample should be taken for estimation of FMH 30-45 minutes after reinfusion in case more anti-D Ig is indicated. It is important for clinicians to inform the HTL if ICS has been used to ensure that the correct dose of anti-D Ig is issued. [1]

Following PSEs/ birth, 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 PSE.

If a sample cannot be obtained from the baby or the mother declines to have the sample collected from the baby, it should be assumed that the baby is RhD positive and the mother offered anti-D Ig at the dose indicated by the maternal Kleihauer screen.

The clinician in charge of the patient's care must provide counselling before an informed decision is taken by the patient to receive anti-D Ig without a baby RhD group being known, as they are being offered a product of human origin which they may not require.

The clinician must document this discussion and receipt of informed consent within the All-Wales handheld maternity record/ Badgernet and on CWS.

7. Training

Blood Transfusion theory sessions provided by the transfusion practitioners will be included within the mandatory training agenda for maternity on a 2-yearly basis as required. This was last included within the mandatory training agenda for 2022- 2023.

Blood Transfusion theory sessions provided by the transfusion practitioners will also be included within the preceptorship midwife theory block in accordance with the Once for Wales Preceptorship Program prior to the commencement of clinical practice.

Blood Transfusion Learning Certifications can also be accessed by staff via the Electronic Staff Record (ESR).

It is recommended that practitioners involved in the administration of anti-D Ig complete the *000 NHS Wales Blood Transfusion Training 07: Use of Anti-D Immunoglobulin in Pregnancy* training accessible via ESR.

Completion of the *000 An Introduction to Anaphylaxis* via ESR is a necessary component prior to the administration of Anti-D Ig, and should be completed on a yearly basis thereafter.

8. References

1. Qureshi, H., Massey, E., Kirwan, D., Davies, T., Robson, S., White, J., Jones, J. and Allard, S. (2014) 'BCSH guideline for the use of anti-D immunoglobulin for the prevention of haemolytic disease of the fetus and newborn' [online], available at: https://onlinelibrary.wiley.com/doi/full/10.1111/tme.12091#tme12091-bib-0035 (Accessed 03/09/2023)

2. Pilgrim, H., Lloyd-Jones, M. and Rees, A. (2009) 'Routine antenatal anti-D prophylaxis for RhD-negative women: a systematic review and economic evaluation' [online], available at: https://pubmed.ncbi.nlm.nih.gov/19210896/ (Accessed 03/09/2023)

3. National Institute for Health and Care Excellence (2008) 'Routine antenatal anti-D prophylaxis for women who are rhesus D negative' [online], available at: https://www.nice.org.uk/guidance/ta156 (Accessed 03/09/2023)

4. British Committee for Standards in Haematology Blood Transfusion Task Force (2018) 'The specification and use of information technology systems in blood transfusion practice' [online], available at: https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-3148.2007.00743.x (Accessed 03/09/2023)

5. The European Parliament and the Council of the European Union (2003) 'DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 setting standards of quality and safety for

the collection, testing, processing, storage and distribution of human blood components and amending Directive 2001/83/EC' [online], available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:033:0030:0040:EN:PDF (Accessed: 03/09/2023)

6. Aneurin Bevan University Health Board (2019) 'Blood Component Transfusion Policy (Red Blood Cells, Platelets and Fresh Frozen Plasma) 2019' [Online], available at: https://nhswales365.sharepoint.com/sites/ABB_Pulse_Policies/Clinical%20Policies/Forms/All%20Staff%20Documents.aspx?id=%2Fsites%2FABB%5FPulse%5FPolicies%2FClinical%20Policies%2FBlood%20Component%20Transfusion%20Policy%20Issue%205%20Rev%202%2Epdf&parent=%2Fsites%2FABB%5FPulse%5FPolicies%2FClinical%20Policies (Accessed: 03/09/2023)

7. British National Formulary (2023) 'Anti-D (Rh_0) immunoglobulin' [online], available at: https://bnf.nice.org.uk/drugs/anti-d-rh0-immunoglobulin/ (Accessed 03/09/2023)

8. Aneurin Bevan University Health Board (2022) 'Blood Transfusion Sample Acceptance Policy' [online], available at: https://nhswales365.sharepoint.com/sites/ABB_Pulse_Policies/Clinical%20Policies/Forms/All%20Staff%20Documents.aspx?id=%2Fsites%2FABB%5FPulse%5FPolicies%2FClinical%20Policies%2FBlood%20Transfusion%20Sample%20Acceptance%20Policy%2Epdf&parent=%2Fsites%2FABB%5FPulse%5FPolicies%2FClinical%20Policies (Accessed 03/09/2023)

9. Aneurin Bevan University Health Board (2020) 'Medicines Management Policy, Code of Practice' [online], available at: https://nhswales365.sharepoint.com/sites/ABB_Pulse_Policies/Clinical%20Policies/Medicines%20Management%20Policy%20Code%20of%20Practice.pdf (Accessed: 03/09/2023)

10. Aneurin Bevan University Health Board (2021) 'Clinical Standard Operating Procedure (CSOP) Transferring Blood Components with Patients' [online], available at: https://nhswales365.sharepoint.com/sites/ABB_Pulse_Policies/Clinical%20Policies/Forms/All%20Staff%20Documents.aspx?id=%2Fsites%2FABB%5FPulse%5FPolicies%2FClinical%20Policies%2FStandard%20Operating%20Procedure%20for%20Transferring%20Blood%20Components%20with%20Patients%5FIssue%205%2E3docx%2Epdf&parent=%2Fsites%2FABB%5FPulse%5FPolicies%2FClinical%20Policies (Accessed: 03/09/2023)

11. Electronic Medicines Compendium (2019) 'Rhophylac 300 micrograms/ 2 ml, solution for injection in pre-filled syring' [online], available at: https://www.medicines.org.uk/emc/product/6791/smpc#gref (Accessed: 03/09/2023)

9. Appendices

9.1. Appendix A: Administration of medicines leaflet links

9.1.1. D Gam anti-D

https://www.medicines.org.uk/emc/product/10346/smpc

9.1.2. Rhophylac anti-D

https://www.medicines.org.uk/emc/product/6791/smpc#gref

9.2. Appendix B: Anti D Consent Form

Your blood test shows that your blood group is Rhesus negative. This is not uncommon as about 15% of women have Rhesus negative blood group.

Approximately 5-10% of pregnant mothers who are Rhesus negative are found to have antibodies to Rhesus Positive blood cells after the first pregnancy. These antibodies could affect the next baby.

The condition is called Rhesus haemolytic disease. It can be mild or severe and if severe it can seriously affect your next baby.

Fortunately, this condition is now very rare as a result of giving women like you an injection called anti D human gamma globulin. This is made from human plasma. All plasma products are prepared under strict control and all donors are tested for known infections. However, the risk of infection by certain germs cannot be totally ruled out and some may not have been discovered.

The risk of infection from the product is very small and advantages of having the injection are huge. Anti D has been used safely and successfully since 1969 and its use had transformed the pregnancy of Rhesus negative mothers from a complicated one into a safe one. Medical Opinion Universally advises you to have the injection.

If you would like to know more about Haemolytic disease or anti D please ask your midwife or doctor before signing this consent form.

I wish to have an injection of anti D gamma globulin
: Please circle **Yes** **No**

Signature: ……
Address: ……
……
Date: ……
Please place this consent form into patient's case notes.

9.3. Appendix C: Routine Antenatal Anti-D Prophylaxis

For all non-sensitized RhD negative women/ service users

8/40- Community Midwife discusses and offers blood grouping and antibody screen. Document in handheld record/ Badgernet.

12/40- Hospital dating screening bloods documented in All-Wales Maternity Record/ Badgernet. **Results reviewed**.

16/40- Patient is informed of screening results by community midwife.

27/40- Community midwife to obtain Kleihauer around 27 weeks' gestation in preparation for anti-D clinic.

RhD Negative

RhD Positive

Prophylactic anti-D required.

1. Sent anti-D leaflet
2. Send Welsh Blood Service leaflet (WBS)
3. Send appointment for anti-D clinic for 28/40

Exit

24 hours prior to anti-D clinic, check the list to ensure the pregnancy is ongoing. Anti-D must be ordered on an individual prescription from Blood Bank and charted on their individual prescription chart noting any allergies.

28/40- Anti-D clinic- Results of blood group, Rh factor and antibody status checked. Discussion anti-D again and obtain written consent for the administration of RAADP.

- **If declined, document this decision in the hospital handheld and electronic records.**
- Ensure no history of thrombocytopaenia, bleeding disorders, known IgA deficiency or allergies to human Ig or albumin.
- Take Full Blood Count and antibody screen BEFORE anti-D administration if not taken by the community midwife already, or if not on WBS site.
- Check the patient's identifiers before administration- full name, 1st line of address, date of birth, hospital number
- Administer anti-D 1,500IU via deep IM injection (NB site depending on BMI)- unless this site is contraindicated (p.g. 7- 8).
- Complete and place anti-D traceability sticker in the handheld record. Complete and tear off perforated portion and return to Blood Bank. Record administration of anti-D in handheld/ electronic records and prescription charts. **All anti-D must be kept in the fridge until administration.**
- **Patient advised to remain in antenatal clinic for 20-minutes following administration- urgent medical assistance must be sought if symptoms of an allergic reaction are observed.**

Defaulter pathway

- Contact woman to confirm that they have declined anti-D (document on CWS) and offer another appointment if they wish to have anti-D.
- Anti-D issued for non-attendees to be returned to Blood Bank by the end of the clinic.
- If 2nd appointment defaulted, not further appointment sent.
- **Anti-D given following any sensitizing event must be noted on request.**

9.4. Appendix D: Summary of Anti-D Administration form

Name

Address

D.O.B.

Administration of Routine Anti-D (RAADP)

@ 28-29 Weeks accepted/ declined

Date given …… Signature ……

Administration of Anti-D for sensitizing event (AADP)

1. Gestation …… Date given …… Signature ……
2. Gestation …… Date given …… Signature ……
3. Gestation …… Date given …… Signature ……
4. Gestation …… Date given …… Signature ……
5. Gestation …… Date given …… Signature ……

Post Partum administration of Anti-D

Date given …… Signature ……