



**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 This is to avoid the risk of out of date printed versions of the document.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.*

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## 1. Executive Summary

All Rh (D) Negative women who carry a Rh(D) antigen positive fetus are at risk of being sensitised to produce immune anti-D following a feto-maternal haemorrhage (FMH). Rh Haemolytic disease of the fetus and newborn (Rh-HDFN) occurs when the maternal immune anti-D crosses the placenta resulting in haemolysis of the fetal red cells with subsequent anaemia and kernicterus. <sup>1</sup>

Antenatal and Post-partum immune-prophylaxis using anti- D immunoglobulin (anti-D Ig) began in the UK in 1969. The programme has been an astounding success: deaths attributed to Rh-HDFN fell from 46/100 000 births before 1969 to 1.6/100 000 in 1990. (AADP) <sup>2</sup>

In 2008 the National Institute for Clinical Excellence (NICE) produced guidance on the use of Routine Antenatal Anti-D Prophylaxis (RAADP) for Rh(D) negative women. NICE recommended that RAADP should be a treatment option for all pregnant women who are Rh(D) negative and who are not known to be sensitised to the Rh(D) antigen. <sup>3</sup>

### 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 (possibly 6 months or more). <sup>2</sup>

There is no method to distinguish between prophylactic and immune anti-D. As current guidelines recommend that all patients with positive antibody screens must be excluded from the 'Electronic Issue' method of providing compatible red cells such patients must be serologically cross-matched to ensure compatible blood is provided. <sup>4</sup>

In clinical terms this means it will take longer for compatible blood to be made available. It will take at least 45 minutes to fully cross-match a patient who still has detectable prophylactic anti-D in her circulation.

In an emergency situation O Rh(D) negative red cells may be issued - on the responsibility of the requesting clinician, until group specific and antibody compatible blood can be provided.

## 1.2 Scope of policy

The scope of this policy applies to **all non-sensitised Rh(D) negative** women who are pregnant.

If it is found that a woman has been sensitised to the Rh(D) antigen then this policy does not apply and guidance must be sought from a consultant obstetrician.

## 1.3 Essential Implementation Criteria

- ∇ Identification of Rh(D) negative women at booking
- ∇ Appropriate management of sensitising events in the antenatal period.
- ∇ Administration of RAADP at 28 weeks to all non-sensitised Rh(D) negative women who are pregnant.
- ∇ Appropriate post partum prophylaxis if the woman has a Rh(D) positive baby.

The following documents have been used to inform this Policy.

**The use of Anti-D Immunoglobulin for Rhesus D Prophylaxis:** Green-Top Guideline No 22: Royal College of Obstetricians and Gynaecologists.

**Routine ante-natal anti-D prophylaxis for women who are rhesus D negative:** National Institute for Health and Clinical Excellence.

**Guidelines for the use of prophylactic anti-D immunoglobulin:** Working party of the British Committee for Standards in Haematology.

See page 16 for full list of references.

This policy has undergone an equality impact assessment screening process using the toolkit designed by the NHS Centre for Equality & 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 to midwives, nurses and doctors in the management of Rh(D) negative women. This will ensure:

- ∇ That all Rh(D) negative pregnant women 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 to the Rh(D) antigen during the antenatal and post- partum period is reduced.
- ∇ That there is appropriate requisition, storage, administration and audit control of anti-D immunoglobulin. <sup>9</sup>

## **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.

Correct patient identification, accurate documentation and clear communication are fundamental to the safe implementation of this policy. <sup>5</sup>

### **Ante-natal / Obstetric Staff:**

- Clinical management
- Informed consent (See Appendix B)
- Appropriate requesting of prophylactic anti-D
- Safe product handling
- Appropriate administration of prophylactic anti-D
- Traceability of the product
- Return of unused products
- Reporting of errors and incidents

### **Blood Bank staff:**

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

### **Transfusion Practitioners and Transfusion Link Nurses:**

Training and Incident Investigation

## **4. THE ADMINISTRATION OF PROPHYLACTIC ANTI-D** 2, 3, 6

### **A: General principles whenever prophylactic anti-D is administered:**

#### **A1: Contraindications:**

- ∇ Consent not given
- ∇ Previous sensitisation resulting in presence of immune anti-D
- ∇ Allergy to human immunoglobulins or human albumin.
- ∇ Known low IgA.

**A2:** NB: Anti-D must not be administered intra-muscularly if there is a history or evidence of:

### **Thrombocytopenia Any other coagulation disorder**

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

#### **A3: Interaction with other medicines:**

MMR vaccine may be given with anti-D (Rh0) immunoglobulin injection provided that separate syringes are used and the products are administered into different limbs. If not given simultaneously, MMR should be given 3 months after anti-D (Rh0) immunoglobulin.

If anti-D is given within 2 - 4 weeks of receiving a **live vaccine** such as Yellow Fever, Rubella, BCG or oral Polio, the efficacy of these vaccines may be reduced. <sup>3</sup>

#### **A4: Possible Side effects:**

- ∇ Headache
- ∇ Fever (pyrexia)
- ∇ Skin reactions such as a rash and itch
- ∇ A general feeling of unwell (malaise)
- ∇ Pain, soreness or bruising at the injection site

#### **A5: Omission or late Administration:**

All cases of late or missed administration should be reported 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.

#### **A5: Common principles and procedures: <sup>2, 6</sup>**

##### **A5.1 Request for anti-D:**

Transfusion request forms and samples must be completed in accordance with the Blood Transfusion Sample Acceptance / Rejection Policy. There is an all Wales Zero tolerance policy for discrepancies in transfusion requests and clinical staff are responsible for performing positive patient identification and accurate labelling of samples.

Mis-labelled requests constitute a breach of best practice and may delay treatment or result in a serious adverse event. (See Section 5. Training p15).

##### **A5.3 Dosing:**

Dosing is assessed routinely by the Kleihauer Acid Elution Test for sensitising events post 20 weeks gestation. Where a FMH of greater than 4ml is estimated the sample will be referred for Flow Cytometry.

If confirmed a follow-up maternal sample 72 hours after the intramuscular administration of anti-D (48 hours if anti-D is given intravenously) should be tested to assess the removal of fetal cells following a feto-maternal Haemorrhage of >4mL. More anti-D may be necessary if fetal cells remain <sup>6</sup>

### **A5.2 Deadline for optimum effect:**

The appropriate dose of anti-D should be administered **within 72 hours** of the sensitising event. However, anti-D may be partially effective if given up to 10 days following a sensitising event. <sup>7</sup>

RAADP and non-routine anti-D prophylaxis for sensitising events should be viewed as completely separate entities. Anti-D prophylaxis must be considered for all sensitising events either side of the 28 weeks RAADP period. <sup>2</sup>

### **A5.3 Administration:**

Anti-D should always be given in accordance with the manufacturer's instructions and the ABHB policy for the administration of medicines.<sup>5</sup> Links to product administration leaflets are given in **Appendix A**.

### **A5.4 Post administration observation:**

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

### **A5.6 Traceability:**

The procedure implemented by the supplying Blood Bank to confirm final fate of the product must be followed. All unused products must be returned to the supplying Blood Bank by the agreed route.

### **A5.7 Error and Incident Reporting:**

Errors in the storage, issue, collection and administration of prophylactic anti-D must be appropriately reported in a timely fashion and corrective and preventative actions implemented as deemed necessary following root cause analysis.



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**B: Routine Antenatal Anti D prophylaxis (RAADP) at 28 weeks<sup>2, 3</sup>**

NB: This Process starts at booking

The product currently used within ABHB for RAADP is Rhophylac Ig 1500 IU (300 micrograms / 2 ml), solution for injection in pre-filled syringe.

B1 It is recommended that RAADP is offered to all non-sensitised pregnant women who are Rh(D) negative.

**At Booking:**

B2 Blood should be taken at booking for ABO Blood Group, Rh(D) status and antibody screen.

B3 Women will be informed, via letter, of their ABO and Rh(D) status.

This usually happens within 15 working days of their sample being taken.

B4 If a woman is Rh(D) negative she will be sent information on RAADP and a clinic appointment for an anti-D clinic at 28 weeks gestation.

Written information should be given in the woman's first language where ever possible.

B5 All Rh(D) negative women will receive verbal and written information to enable them to make an informed choice about treatment.

B6 Rh(D) negative women who do not wish to have anti-D prophylaxis administered must have their wish respected. A record of the discussion with the woman should be made in the woman's hand held records and hospital obstetric notes.

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### **At 28 weeks:**

**B7** Anti-D must be requested on an individual named patient basis from blood bank by a written request at least 24 hours before the woman is due for her 28 week appointment.

N.B: If the anti-D clinic is held on a Monday, then all requests must be received by Friday of the previous week for delivery of anti-D on Monday morning. Bank Holidays must also be taken into account.

**B8** At 28 weeks the midwife should verbally discuss the benefits and risks of RAADP with the woman. If she agrees to have RAADP then a consent form must be signed (see **Appendix B**)

If a woman decides not to have RAADP then a note of this and the discussion had must be made in the woman's hand held notes and hospital obstetric notes.

**B9** Blood must be taken for full blood count (FBC) and a Group and Antibody Screen at least **ONE WEEK BEFORE BY THE COMMUNITY MIDWIFE BEFORE the anti-D injection is administered.**

This is to check for the presence of immune anti-D due to a silent or undisclosed sensitising event.

It is important to indicate on the blood bank request form whether the woman has already received anti-D earlier in the pregnancy and when.

**B10** RAADP should still be offered to all Rh(D) negative pregnant women who have received anti-D earlier in pregnancy. Please contact the Blood Bank for further information if required.

**B11** A 1500 IU dose will be supplied by the Blood Bank on a named patient basis. A Traceability Tag with the woman's details and anti-D batch number will be attached.

**B12** When delivered to the clinic area Anti-D must be kept at room temperature. **Do not store in the clinic fridge.**

**B13** The anti-D should be given by deep intra-muscular route. If patients BMI are 30 or less then route is im into thigh if BMI over 30 then must be given into the deltoid. **Please refer to contra-indications in section 8**

**B14** The woman must remain in the clinic for 20 minutes post injection to observe for signs of adverse effects.

- B15** A record of administration must be documented in the all Wales maternity notes, the drug chart and PROTOS.
- B16** The Traceability Record must be completed and returned to the supplying Blood Bank by the agreed route.
- B17** If the woman does not attend clinic then the anti-D must be returned to Bank as soon as possible and within 24 hours.
- B18** Women who fail to keep their 28 week appointment will be reappointed for a second invite. Depending on gestation:

1500 IU should be offered up to 36 weeks gestation.

500 IU should be offered over 36 weeks gestation.

This protects late bookers, transfers, or women who may have DNA.

- B19** For women who have transferred into ABHB and have commenced a two dose regime that some other Health Boards and NHS Trusts use:

Give 1500 IU of anti D at the time the second dose was due on the two dose regime - this is usually at 34 weeks.

**NB: RADDP does NOT exclude the need for additional prophylactic Anti-D to cover subsequent sensitising events regardless of the time interval since previous administration.<sup>2</sup>**

**C Non-routine Antenatal Anti-D Prophylaxis (AADP)<sup>2, 6</sup>**

These procedures apply where sensitising events occur during different stages of pregnancy.

**C1 AADP before 12<sup>+0</sup> weeks gestation:**

Standard dose is 500 International units (IU) currently supplied as D-Gam Ig 500IU.

A Kleihauer Screen is not required if gestation is less than 20 weeks.

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### **C1.1 Therapeutic termination of pregnancy**

Anti D Ig should be given to all Rh D negative women having a therapeutic termination of pregnancy, whether by surgical or medical methods and regardless of gestational age.

### **C1.2. Miscarriage**

Anti D is not required for spontaneous miscarriage before 12<sup>+0</sup> weeks of gestation, provided there is no instrumentation of the uterus.

**Anti-D should only be given to RhD negative women before 12<sup>+0</sup> weeks gestation if the pregnancy has been terminated by surgical evacuation of the uterus.**

Gynae staff must liaise with ANC so that 28 week Anti D clinic OPA can be cancelled preventing unnecessary stress caused to patient by clinic contact.

### **C1.3. Threatened Miscarriage**

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<sup>2</sup> although there are rare examples<sup>3</sup>, administration of anti D Ig is therefore not recommended in these cases.

**Anti-D Ig may be considered prudent** in Rh(D) negative women if there is heavy or repeated bleeding or associated abdominal pain as gestation approaches 12<sup>+0</sup> weeks. However, the period of gestation should be confirmed by ultrasound in these circumstances.

### **C1.4. Ectopic pregnancy**

Anti D Ig should be given to all Rh(D) negative women who have an ectopic pregnancy, regardless of management.

## **C2 AADP after 12 weeks and before 20 weeks gestation:** <sup>2, 6</sup>

Standard dose is 500IU.

The product currently used in ABUHB is D-Gam Ig 500 IU.

A Kleihauer Screen is not required if gestation is less than 20 weeks.

**C2.1 Indications:** The following are potentially sensitising events:

- Spontaneous complete or incomplete miscarriage
- Threatened miscarriage:
- Ectopic pregnancy
- Therapeutic termination (surgical or medical) of pregnancy
- Invasive procedures: chorion villus sampling, amniocentesis, cordocentesis and intrauterine transfusion
- Vaginal bleeding and antepartum haemorrhage
- Trauma to the abdomen (direct/indirect, sharp/blunt, open/closed)
- Other intrauterine procedures (insertion of shunts, embryo reduction and laser)
- Fetal death

**A woman in whom bleeding continues intermittently after 12 weeks of gestation should be given 500 IU anti D Ig at 6 weekly intervals.**

**C3 AADP after 20 weeks gestation: <sup>2, 6</sup>**

Minimum (Standard) dose is 500 IU anti D Ig  
The product currently used in ABHB is D-Gam Ig 500 IU.

A Kleihauer Screen is required for gestations of 20 weeks or greater.

The Blood Bank will advise the appropriate dose in the report.  
This is based on 125 IU anti-D being effective for a FMH of 1 ml red cells.

**C3.1 Indications: As for C2.1 above.**

**D. Post-delivery Anti-D Prophylaxis: <sup>2, 6</sup>**

Minimum (Standard Dose is 500 IU anti-D Ig

The product currently used in ABHB is D-Gam Ig 500 IU.

- D1 Cord and Maternal samples are required.**
- D2** Following delivery, a cord blood sample should be taken from the baby of a Rh(D) negative woman to establish the ABO and Rh(D) group. The sample should be taken with a syringe and needle from an umbilical cord blood vessel wherever possible.
- D3** If cord blood is unavailable, then consideration should be given to obtaining another sample for blood grouping. **If this is not possible, then it should be assumed that the baby is Rh(D) positive for the purposes of FMH determination, and administration of anti-D immunoglobulin prophylaxis.**
- D4** The maternal sample must be collected 30-45 minutes after delivery.
- D5** Strict adherence to the **ABHB Blood Transfusion Sample Acceptance /Rejection Policy**<sup>10</sup> is required for Maternal and Cord samples. The samples must be handwritten and clearly marked as Maternal or Cord.
- D6** Where a registration number is available for the newborn it must be used on the request form and sample. If it is not available the fields must be left blank - **do not use the mother's number on the cord/baby's request form or sample.**

The identifiers required for both mother and cord or mother and baby sample are:

<b>Maternal</b>	<b>Cord (Infant)</b>
∇ First name	First name
∇ Last name	Last Name
∇ Date of birth	Date of birth
∇ First line of the address	First line of address
∇ Hospital number or NHS number	whichever is available

In the absence of a baby's forename the sample must be clearly labelled with the words '**infant SURNAME 'female infant SURNAME '** or '**male infant SURNAME '**.

**The date of birth on the sample must be that of the baby and not the mother.** <sup>10</sup>

- D7** If the baby is confirmed as being Rh(D) positive at least 500 IU of anti-D is recommended to be administered to the mother.

500 Ig of anti-D will cover up to 4 mls of feto-maternal haemorrhage; however, depending on the result of the Kleihauer Screen, additional doses may be required.

If the delivery is by caesarean section and the patient has had autologous blood via intra operative cell salvage they should be given 1500IU and then additional anti-D if indicated by the Kleihauer result.

All anti-D must be administered within 72 for optimum protection

- D8** If a sample cannot be obtained from the infant or the mother refuses to have a sample collected from the infant, then it should be assumed that the infant is Rh(D) Positive and the mother offered anti-D at the dose indicated by the Kleihauer screen. <sup>8</sup>

The Clinician in charge of the patient MUST provide counselling before a decision is taken by the patient to have anti-D without an infant group as she is being offered a product of human origin which she may not require.

The Clinician must document this discussion and consent in the hospital obstetric notes. If the woman also refuses anti-D Ig at this point, this must also be documented in the hospital obstetric notes

- D9** **If anti-D is not administered within the 72 hour time period a dose given within 10 days may offer some protection and therefore must be offered.** <sup>7</sup>

## **5 Training:**

Initial training will be provided by Rhophylac on each main site (NHH, RGH, YYF) prior to the introduction of RAADP.

Safe transfusion and anti-D administration theory sessions are provided by the transfusion practitioners or a blood transfusion link nurse.

Anaphylaxis training must be undertaken and kept up to date by those involved running the Ant D clinics.

These sessions are available to book on the ABHB intranet and updates are then adequate by accessing on line learning.

Records for the training will be held by the transfusion practitioners and also by the midwifery leads.



## **6 References:**

- 1 Mollinson PL, Engelfriet CP, Contreras M. Haemolytic disease of the fetus and the newborn. In: Mollinson PL, editor. *Blood transfusion in clinical medicine*. 10<sup>th</sup> edition. Oxford: Blackwell Scientific
- 2 RCOG (2011). Royal College of Obstetricians and Gynaecologists. *Use of Anti D Immunoglobulin for Rhesus Prophylaxis*.
- 3 NICE 2008: National Institute for Health and Clinical Excellence. *Routine ante-natal anti-D prophylaxis for woman who are rhesus D negative* (TA156). London:
4. BCSH; 2006: British Committee for Standards in Haematology, Blood Transfusion Task Force. *The specification and use of Information Technology (IT) systems in Blood Transfusion Practice*.
5. Blood Component Transfusion Policy: ABHB / Clinical / 0048
6. BCSH; 2006: Working Party of the British Committee for Standards in Haematology, Transfusion Taskforce.. *Guidelines for the use of prophylactic anti-D immunoglobulin*. London:
7. SHOT Annual Report, 2010. *Available at:*  
<http://www.shotuk.org/wp-content/uploads/2011/07/SHOT-2010-Report1.pdf>
8. BCSH; 2009: Working Party of the British Committee for Standards in Haematology, Transfusion Taskforce. *Guidelines for the Estimation of Fetomaternal Haemorrhage*. London:
9. The European Parliament and the Council of the European Union. 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 and blood components and amending Directive 2001/83/EC. Official Journal of the European Union 2003;46:30-40

**10. ABHB Blood Transfusion Sample Acceptance / Rejection**  
Policy: ABHB/Clinical/0269

## **7 Appendices:**

### **Appendix A:**

#### **Administration of medicines leaflet links**

##### **D gam anti-D:**

<http://www.medicines.org.uk/emc/medicine/14629/PIL/D-GAM+Human+Anti-D+Immunoglobulin/>

##### **Rhophylac anti-D:**

[http://www.medicines.org.uk/emc/medicine/12087/SPC/Rhophylac+300+\(1500+IU\)/](http://www.medicines.org.uk/emc/medicine/12087/SPC/Rhophylac+300+(1500+IU)/)

**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: .....

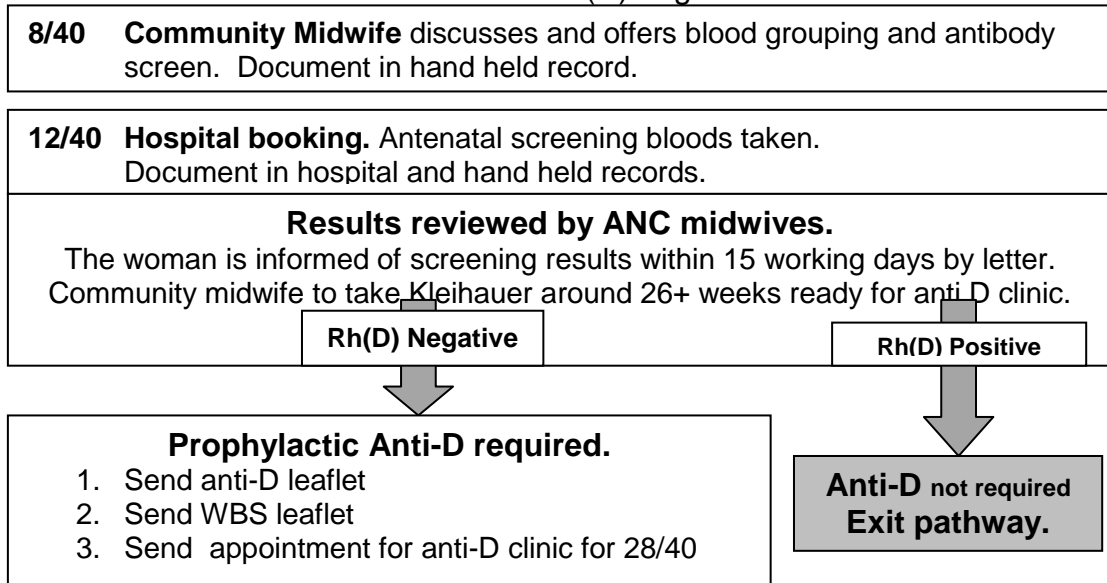
.....

Date: .....

Please place this consent form into patient's case notes.

**Appendix C: ROUTINE ANTENATAL ANTI-D PROPHYLAXIS (RAADP)**

For all non-sensitised Rh(D) negative women



**24 hours prior to Anti D clinic:** Check the clinic list to ensure the pregnancy is ongoing. Anti-D must be ordered on an individual named patient basis from blood bank 24 hours before the patient attends clinic.

**Anti D Clinic at 28/40 weeks**

- Results of blood group, Rh factor and antibody status checked.
  - Discuss Anti-D again and obtain written consent for the administration of prophylactic Anti-D (RAADP). **If declined document this decision in the hospital and hand held records.**
  - Ensure no history of thrombocytopenia, bleeding disorders, known IgA deficiency or allergies to human immunoglobulin or human albumin
  - **Take Full Blood Count and antibody screen BEFORE Anti-D administration if not taken by community midwife already**
  - Check the patient's identifiers before administration – Full name, 1st line of address, date of birth and hospital number.
  - Administer anti-D 1500 IU via deep IM injection NB site depending on BMI - unless this site contra-indicated (See Section 4A.2 p6)
  - Complete and place Anti-D traceability sticker in hospital record. Also complete and tear off perforated portion and return to blood bank. Record administration of anti-D in hand held records, hospital notes and on medication chart.
- Document on **PROTOS**  
 Woman advised to remain in ANC for 20 minutes following administration – **urgent medical assistance must be sought if symptoms of an allergic reaction are observed**
- Defaulters**
- Contact woman to confirm that they have declined anti-D (document in notes) or 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 clinic.
  - If 2<sup>nd</sup> appointment defaulted, **no further appointment sent.**
  - **(Anti-D given following any sensitizing event must be noted on request)**