ANTI-D IMMUNOGLOBULIN (ANTI-D) FOR THE PREVENTION OF HAEMOLYTIC DISEASE OF THE NEWBORN - CLINICAL GUIDELINE V1.1
**Summary.**

Booking bloods confirm that woman has Rh D negative blood group with no evidence of Anti-D (allo) antibodies

### Sensitising event

- Miscarriage/abortion
- Amniocentesis
- Ectopic pregnancy
- Abdominal trauma/fall
- Any other potential sensitising event

#### <12 weeks gestation

Give Anti-D with significant bleeding (with pain), ectopic & molar pregnancy and therapeutic TOP

#### >20 weeks gestation

12-20 weeks gestation

Within 72 hours of event take blood sample for antibody screen prior to administration of 1500i.u. anti-D

If there is ongoing intermittent bleeding Anti D 1500IU should be administered at 1st bleed and 2nd bleed (irrespective of time) and from the 3rd bleed (now classified as recurrent bleeding) 6 weekly intervals thereafter

If woman has made her own Anti-D (allo) antibodies, do not give prophylactic anti-D. Blood samples to be sent to NBS/NHSBT monthly until 28 weeks and at 2 weekly intervals until delivery

### Prophylactic Anti-D

Regardless of any sensitising events during pregnancy routine prophylaxis should still be offered at 28 weeks gestation

At 16/40 midwife makes written request to blood transfusion for 28/40 prophylactic Anti-D appointment

Midwife takes blood at 28 week appointment for antibody levels followed by administration of prophylactic Anti-D 1500IU

#### Delivery

Send cord and maternal blood to blood transfusion

Baby RhD positive

Baby RhD negative Anti D not required

Within 72 hours of event 1500IU Anti-D to be offered to the mother. Do not wait for the result of the Kleihauer test before administering Anti-D. If further anti-D is required blood transfusion will contact the on call midwife. Can be up to 10 days post sensitising event if 72 hour window is missed.

For further advice contact 01872 252500
1. **Aim/Purpose of this Guideline**

1.1. To provide Midwives and Obstetricians with guidance on the utilization of Anti-D immunoglobulin (Anti-D). Anti-D is administered to prevent sensitization to the RhD antigen in RhD negative women to prevent Haemolytic Disease of the Newborn (HND).

1.2. Anti D immunoglobulin should be offered to RhD negative women:
   - Following a potentially sensitizing event in pregnancy
   - At 28 weeks as antenatal prophylaxis
   - Postnatally to those who have given birth to a RhD positive baby

1.3. The British Committee for Standards in Hematology (BCSH) (2014) and the National Institute for Clinical Excellence (NICE) (2008) has recommended that routine antenatal Anti-D prophylaxis (RAADP) is offered to all non sensitised pregnant women along with antenatal Anti-D prophylaxis (AADP) for potentially sensitizing events.

1.4. NICE (2008) considered the use of single-dose and two-dose regimens. There was no evidence of a difference in effectiveness between the regimens. Royal Cornwall Hospitals Trust has chosen to utilize the 1500IU dose.

2. **The Guidance**

2.1. **Contraindications**
   - Previous allergy to Anti-D. Caution should be exercised in women who have had severe allergic reactions to other blood products or medication. Refer to Consultant for advice.
   - Women who are already sensitized to the D antigen. Women with other RBC antibodies should still be offered Anti-D.
   - Caution should be exercised in women suffering from severe thrombocytopenia or any major inherited bleeding disorder that would contraindicate intramuscular injections. For women diagnosed with gestational thrombocytopenia, please refer for haematological opinion, if platelet count < 100 x 10⁹/L, prior to administration of Anti-D. Although less effective, Anti-D can be given subcutaneously.

   **DISCUSS WITH CONSULTANT AND BLOOD TRANSFUSION LABORATORY IF YOU HAVE ANY CONCERNS**

2.2. **Side Effects**
   - Short term discomfort at injection site
   - Occasionally; fever, malaise, headache, cutaneous reactions, chills
   - Rarely: nausea, vomiting, hypotension, tachycardia, allergic anaphylactic type reactions, dyspnoea and shock
   - Anaphylactic reactions may occur in patients who have antibodies to IgA, or patients who have had an atypical reaction to blood transfusions or treatment with plasma derivatives.
2.3. Anaphylactic Reactions
Administer both antenatal and postnatal Anti D early in the consultation to allow time for the development of any allergic reactions. Advise women to wait for 20 minutes and report any adverse effect.

2.4. Routine Antenatal Anti-D Prophylaxis at 28 Weeks Gestation
This prophylaxis dose is given, in addition to any sensitizing event during pregnancy, at 28 weeks gestation

2.4.1. At 16 Weeks
- Order Anti-D for 28 weeks following discussion, information leaflet and consent being obtained. Document in notes that it has been ordered. All Anti-D is issued on a named patient basis.
- Document the date you ordered the Anti-D on the Anti-D Audit pro forma held in front of the case loading notes

2.4.2. At 28 Weeks
- Give Anti-D 1500IU AFTER taking blood for antibody screen
- Prior to administration check woman’s notes clarifying she is RhD negative and fulfills criteria for administration. Check the woman’s identify: full name and date of birth.
- Obtain and document consent
- Ensure an Anaphylaxis pack is available in the event of an anaphylactic reaction
- Administer Anti-D intramuscularly into the deltoid (upper arm)
- Document in woman’s notes hospital number, time and date of administration, batch number, expiry date (utilizing the sticker on the box), and signature. This enables traceability of Anti-D administration.
- Document on Anti-D Audit proforma held at front of case loading file
- Any unused doses need to be returned to Blood Transfusion Laboratory, identifying reason for non-administration

2.5. Women who Present for Booking Later than 28 Weeks
If an RhD negative woman, presents after 28 weeks she should be offered Anti-D prophylaxis. If in doubt discuss with Blood Transfusion Laboratory.

2.6. Transfer of Care
If a woman transfers into Cornwall before 34 weeks and she had previously started a two dose regime of 500IU Anti-D immunoglobulin at 28 weeks a second dose of Anti-D immunoglobulin, 1500IU should be given when possible.
If in doubt discuss with Blood Transfusion Laboratory Ext. 2500.

2.7. Women who Decline Blood Products
All women who decline blood products and JWs should be seen in the anaesthetic clinic early in the second trimester of their pregnancy. The Advance Directive should be discussed and their wishes regarding minor fractions, cell salvage and Anti D documented. Please see “women who decline blood products “ guideline (New 2018)
- The majority of Jehovah’s Witness women accept Anti-D but may still decline as it is a blood product. Ensure that a discussion with information
leaflet is documented with her decision in her hand held notes and Anti-D proforma.

- The partner may wish to make an appointment at the GP to have his RhD factor identified (this is a private test and there will be a charge).

2.8. Women who decline Anti-D
Any decline of Anti D should be clearly documented in the woman’s notes.

2.9. Anti-D Prophylaxis Following Sensitising Events in Pregnancy
Anti-D should be given as soon as possible after the sensitising event within 72 hours. If more than 72 hours has elapsed, discuss with Blood Transfusion Laboratory.

2.9.1. Anti-D 1500IU given < 12 weeks gestation to:
- Termination of pregnancy (TOP)
- Evacuation of retained products of conception (ERPC)
- Ectopic pregnancy
- If bleeding is heavy, repeated or there is significant pain
- Conservative management of missed miscarriage or an embryonic pregnancy

2.9.2. Anti-D is not required at < 12 weeks gestation in women who present with:
- Conservatively managed incomplete or complete miscarriage
- A threatened miscarriage (viable pregnancy seen on scan)

2.9.3. Anti-D 1500IU is given > 12 weeks gestation following sensitising events e.g. spontaneous miscarriage complete or incomplete, threatened miscarriage, ERPC.

If there is ongoing intermittent bleeding Anti D 1500IU should be administered at 1st bleed and 2nd bleed (irrespective of time) and from the 3rd bleed (now classified as recurrent bleeding) and 6 weekly intervals thereafter.

This is in ADDITION to the 28 week prophylactic dose.

For any sensitising events after 20 weeks perform a Kleihauer test.

IF IN DOUBT DISCUSS WITH BLOOD TRANSFUSION LABORATORY Ext 2500

2.9.4. Other Sensitising Events Requiring Anti-D
- Invasive prenatal diagnosis – CVS, amniocentesis, embryo reduction, fetocide for late medical TOP
- Antepartum haemorrhage
- External cephalic version
- Abdominal trauma (Road Traffic Accident)
- Intrauterine death
- Placenta Percreta RhD negative mothers should have Kleihauer test if no vaginal bleeding to detect silent feto-maternal bleed
- Delivery
2.10. Postnatal Anti-D Prophylaxis

2.10.1. At Delivery
All Rh D negative women should have cord blood sample sent for ABO testing. If the baby is Rh D positive, Anti-D 1500IU should be given within 72 hours of delivery. A maternal sample should be sent for Kleihauer testing to determine the extent, if any, of feto-maternal haemorrhage and whether sufficient Anti-D has been given. If the woman has received cell salvage blood the Kleihauer sample should be taken 45 minutes after the completion of the re-infusion of cell salvage blood. If the woman is discharged from hospital prior to the result being available ensure the Community Midwife is informed that she needs to follow up the result and the necessity or not for Anti-D. **(New 2018)**

Measles, Mumps and Rubella vaccination (MMR) can be given at the same time but should be administered in the other arm. Please be aware that the efficacy of the vaccine may be reduced for up to 3 months if administered in association with Anti-D.

Please ensure that women who deliver at home or in a Birth Centre may be required to transport bloods or collect Anti-D from RCHT over weekends and Bank Holidays.

2.10.2. Stillbirth or Intrauterine Death
If the blood group of the baby cannot be determined, as is often the case, Rh D negative mothers should always have a Kleihauer sample taken and given Anti-D. If more than 72 hours have lapsed following a sensitizing event 1500IU Anti-D should be given as there is some benefit for up to 10 days. Blood should be taken for antibodies 6 months later by GP and referral if required.

2.11. Non Compliance
DATIX when the 72 hour window for administration has been missed or an inappropriate administration of Anti-D has been given. These will be reportable to Serious Hazards of Transfusion and follow up samples may be required 6 months later to determine if immune anti-D is present.

2.12. Women with Atypical Antibodies
Discuss with Blood Transfusion Laboratory and refer to Consultant Obstetrician if indicated.
3. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Frequency</th>
<th>Reporting arrangements</th>
<th>Acting on recommendations and Lead(s)</th>
<th>Change in practice and lessons to be shared</th>
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<tr>
<td>Lead</td>
<td></td>
<td>Supervisors of Midwives</td>
<td>Individual Supervisor of Midwives to be informed if staff member is non-compliant</td>
<td>Supervisor of Midwives Newsletter</td>
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<tr>
<td>Tool</td>
<td></td>
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<td>Action leads will be identified and a time frame for the action to be completed</td>
<td>Maternity Patient Safety Newsletter</td>
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<td>The action plan will be monitored by the Maternity Patient Safety Midwife</td>
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</table>

- Documentation of the ordering and administration of Anti-D

- During Supervisory annual review the supervisor of midwives will review the midwives’ Anti-D audit proforma
- Was the Blood group clearly documented in the Maternal Handheld notes
- Did the patient have a sensitizing event
- If so, did they receive prophylactic Anti D within 72 hours of the sensitizing event
- Did the patient receive prophylactic Anti D at 28 weeks
- Did the patient receive Anti D following delivery if required, within 72 hours of delivery

- Annually for each community midwife
- 1% or 10 sets, whichever is the greater, of all health records of women who have delivered will be audited over the 3 year lifetime of this guideline or sooner if indicated

- Supervisor of Midwives Forum
- During the process of the audit if compliance is below 75% or other deficiencies identified, this will be highlighted at the next Obstetric Patient Safety Forum or Clinical Audit Forum and an action plan agreed

- Individual Supervisor of Midwives to be informed if staff member is non-compliant
- Action leads will be identified and a time frame for the action to be completed
- The action plan will be monitored by the Maternity Patient Safety Midwife

- Supervisor of Midwives Newsletter
- Maternity Patient Safety Newsletter

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ‘Equality, Diversity & Human Rights Policy’ or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.
### Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>ANTI-D IMMUNOGLOBULIN (ANTI-D) FOR THE PREVENTION OF HAEMOLYTIC DISEASE OF THE NEW-BORN - CLINICAL GUIDELINE V1.1</th>
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<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td>16th January 2018</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>16th January 2018</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>16th January 2021</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Nicki Jannaway</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 253093</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>To provide Midwives and Obstetricians guidance on the utilization of Anti-D immunoglobulin (Anti-D) to prevent Haemolytic Disease of the Newborn (HND).</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>Anti-D, Rh, negative, HND, Haemolytic disease, new-born, anaphylaxis, immunoglobulin, MMR, antibodies, blood</td>
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<tr>
<td>Target Audience</td>
<td>RCHT</td>
</tr>
<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Date revised:</td>
<td>4th January 2018</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>ANTI-D IMMUNOGLOBULIN (ANTI-D) FOR THE PREVENTION OF HAEMOLYTIC DISEASE OF THE NEW-BORN - CLINICAL GUIDELINE V1.0</td>
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<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Maternity Guidelines Group Obs and Gynae Directorate Divisional Board for noting</td>
</tr>
<tr>
<td>Divisional Manager confirming approval processes</td>
<td>David Smith</td>
</tr>
<tr>
<td>Name and Post Title of additional signatories</td>
<td>Not required.</td>
</tr>
<tr>
<td>Name and Signature of Divisional/Directorate Governance</td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td>Lead confirming approval by specialty and divisional management meetings</td>
<td>Name: Caroline Amukusana</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Signature of Executive Director giving approval</td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td>
<td>Internet &amp; Intranet  ✔️ Intranet Only</td>
</tr>
<tr>
<td>Document Library Folder/Sub Folder</td>
<td>Clinical/Midwifery and Obstetrics</td>
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<tr>
<td>Links to key external standards</td>
<td>None</td>
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</table>

**Related Documents:**

- BSCH guideline for the use of anti-D immunoglobulin for the prevention of haemolytic disease of the fetus and new-born (2014) British Blood Transfusion Society
- The British Committee for Standards in Haematology (BCSH) (2014)
- NICE (National Institute for Clinical Excellence) (2008) Routine Antenatal Anti-D Prophylaxis for women who are RhD negative. Guidance 41
- RCOG (Royal College of Obstetricians & Gynaecologists) (2001) Use of Anti-D immunoglobulin for Rh Prophylaxis. Guideline No 22

**Training Need Identified?**  No

**Version Control Table**

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
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<tbody>
<tr>
<td>17th July 2015</td>
<td>V 1.0</td>
<td>Initial document</td>
<td>Sandra Whitehall, Specialist Midwife for Women with Complex Needs</td>
</tr>
<tr>
<td>16th January 2018</td>
<td>V 1.1</td>
<td>Updated 2.7 JW to be seen in anaesthetic clinic early in second trimester. Advanced directive to be discussed. 2.10 reminder re kleihauer</td>
<td>Nicki Jannaway, transfusion team</td>
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</table>
Appendix 2. Initial Equality Impact Assessment Form

This assessment will need to be completed in stages to allow for adequate consultation with the relevant groups.

| Name of Name of the strategy / policy / proposal / service function to be assessed | DIRECTORATE AND SERVICE AREA: Obs & Gynaecology Directorate | IS THIS A NEW OR EXISTING POLICY? | EXISTING |
| Name of individual completing assessment: Nicki Jannaway | Telephone: 01872 253093 |

1. **Policy Aim***
   
   Who is the strategy / policy / proposal / service function aimed at?
   
   To provide Midwives and Obstetricians with guidance on the use of Anti-D immunoglobulin as immunoprophylaxis to prevent sensitisation to the D antigen during pregnancy and delivery

2. **Policy Objectives***
   
   To prevent Haemolytic Disease of the New-born

3. **Policy – intended Outcomes***
   
   To ensure rhesus negative women receive appropriate immunoprophylaxis to prevent sensitisation to the D antigen

4. *How will you measure the outcome?*
   
   Compliance Monitoring Tool.

5. Who is intended to benefit from the policy?
   
   All pregnant women and their babies

6a Who did you consult with?

<table>
<thead>
<tr>
<th>Workforce</th>
<th>Patients</th>
<th>Local groups</th>
<th>External organisations</th>
<th>Other</th>
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</thead>
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<tr>
<td>X</td>
<td></td>
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</tbody>
</table>

   **Please record specific names of groups**
   
   Clinical Guideline Group
   
   Obstetric and Gynaecology Directorate

What was the outcome of the consultation?

Guideline agreed
7. The Impact
Please complete the following table. **If you are unsure/don’t know if there is a negative impact you need to repeat the consultation step.**

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
<th>Rationale for Assessment / Existing Evidence</th>
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<tbody>
<tr>
<td>Age</td>
<td>X</td>
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<td></td>
<td>All pregnant women and their babies</td>
</tr>
<tr>
<td>Sex (male, female, trans-gender / gender reassignment)</td>
<td>X</td>
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<td></td>
<td>All pregnant women and their babies</td>
</tr>
<tr>
<td>Race / Ethnic communities /groups</td>
<td>X</td>
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<td></td>
<td>All pregnant women and their babies</td>
</tr>
<tr>
<td>Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.</td>
<td>X</td>
<td></td>
<td></td>
<td>All pregnant women and their babies</td>
</tr>
<tr>
<td>Religion / other beliefs</td>
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<td>All pregnant women and their babies</td>
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<tr>
<td>Marriage and Civil partnership</td>
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<td>All pregnant women and their babies</td>
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<td>Pregnancy and maternity</td>
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<td>All pregnant women and their babies</td>
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<td>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</td>
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<td>All pregnant women and their babies</td>
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</tbody>
</table>

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation- this excludes any policies which have been identified as not requiring consultation. or
- Major this relates to service redesign or development

8. Please indicate if a full equality analysis is recommended. | Yes | No |
<table>
<thead>
<tr>
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<tbody>
<tr>
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<td>X</td>
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</table>

9. If you are **not** recommending a Full Impact assessment please explain why.

No areas indicated
Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa,
Truro, Cornwall, TR1 3HD

This EIA will not be uploaded to the Trust website without the signature of the
Human Rights, Equality & Inclusion Lead.

A summary of the results will be published on the Trust’s web site.

Signed Sarah-Jane Pedler

Date 16th January 2018