SOUTHAMPTON UNIVERSITY HOSPITALS NHS TRUST

APPROVED **PATIENT GROUP DIRECTION**

PROFORMA

Title of document:		Midwife administration of Human anti-D Immunoglobulin (antenatal and postnatal)	
Author: (Name & Position)		Sally Boxall Consultant Nurse in Prenatal Diagnosis and Family Support	
Keywords:		Anti-D; prophylaxis; Rhesus; Antenatal; Postnatal	
Description:		Patient group direction for the midwife administration of Anti-D immunoglobulin to women both antenatally and postnatally	
Final Validation Committee:		Drugs Committee	
Date agreed: (*can be manually added when document validated*)	January 2004	**Date sent to Policy Administrator:** (*can be manually added when document validated*)	October 2007
Accountable Officer: (Name & Position)		David Howe CSD	
Responsible Officer: (Name & Position)		Sally Boxall, Consultant Nurse in prenatal diagnosis and family support	
Directorates who use the document:		Obstetrics and Gynaecology	
Highlighted to:		All relevant staff	
Date doc. implemented: (*i.e. becomes a live document*)	January 2004	**Date of next review:**	June 2009
Date doc. loaded on SUHTranet:	22/10/2007	**Date archived:**	
Date(s) Reviewed (*if applicable*):		January 2004; January 2006; August 2007	
Details of most recent review: (*Outline main changes made to document*)		3.4, 3.6 & 3.7 Additional doses have been added to allow use of *Partobulin SDF* brand of Anti-D.	

Signature of Chairman of Validation Committee: D Waller
Print Name: D Waller
Post Held: Chair SUHT Drugs Committee

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Southampton Drugs Committee: Summary Sheet for Patient Group Directions

For submission for final approval the Drugs Committee requires this sheet to be completed and included with the full Directions.

<table>
<tr><td colspan="3">Patient Group Direction Title: Midwife administration of Human anti-D Immunoglobulin (antenatal and postnatal)</td></tr>
<tr><td colspan="3">Summary of purpose: To facilitate appropriate and timely prophylaxis with anti-D Immunoglobulin to rhesus-negative women for prevention of Rh (D) sensitisation by midwives</td></tr>
<tr><td colspan="3">Drugs involved: Anti-D Immunoglobulin Injection</td></tr>
<tr><td colspan="3">Where will this be used: Within SUHT and community</td></tr>
<tr><td colspan="3">How will initial training and continuing education be dealt with?
Regular education as part of annual update
2hr mandatory PGD education session
Induction session for midwives new to the trust</td></tr>
<tr><td colspan="3">Directorate(s): Obstetrics and Gynaecology</td></tr>
<tr><td colspan="3">Supported by:

David Howe
Clinical Service Director

Sally Boxall
Senior Clinical Nurse or relevant professional lead

Christina Nurmahi
Directorate Pharmacist

(please continue on a separate sheet if multiple directorates)</td></tr>
<tr><td colspan="2">Approved by:

S Bassan
Chief Pharmacist

Date: 24/08/2007</td><td>Sally Boxall
Nursing/Midwifery Group or lead professional if nurses not involved

Date: 11/09/2007</td></tr>
</table>

Available in electronic form from Chief Pharmacist's office

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PATIENT GROUP DIRECTION

Name of specific Patient Group Direction: Midwife administration of Human Anti-D Immunoglobulin

Clinical Department/ Service: Obstetrics and Gynaecology

1. Clinical Condition

1.1	Define situation/condition	➢ All non-sensitised Rh (D) negative women should be offered routine immunoprophylaxis with anti-D Immunoglobulin at 28 and 34 weeks of pregnancy in an attempt to prevent women producing anti-D physiologically which can cause haemolytic disease of the newborn (HDN) ➢ Additionally anti-D should be given to non-sensitised Rh (D) negative women within 72 hours of a sensitising event during pregnancy ➢ Anti-D should be offered to women following the birth of a Rh (D) positive baby.
1.2	Criteria for inclusion	All non- sensitised Rh (D) negative women who are pregnant or who have given birth to a Rh (D) positive child within the previous 72 hours are eligible for inclusion. Women who experience a potential sensitising event are also eligible for inclusion i.e. ➢ Pregnancy loss involving uterine evacuation or termination at any gestation ➢ Threatened or complete miscarriage after 12 weeks gestation ➢ Ectopic pregnancy ➢ Invasive antenatal diagnosis or other intrauterine procedures ➢ Antepartum haemorrhage (PV bleeding) ➢ External cephalic version ➢ Abdominal trauma ➢ Abdominal pain with reasonable grounds for suspicion of abruption ➢ Intrauterine death

1.3	Criteria for exclusion	• Women who do not meet the inclusion criteria • Women who are Rh (D) positive • Women who decline anti-D • Known hypersensitivity to any of the components of the injection
1.4	Cautions	Women who have antibodies against immunoglobulin A (IgA) Women who have atypical reactions following receipt of a blood transfusion or blood products.
1.5	Action if patient excluded	If a woman is excluded from having anti-D, this should be recorded in her notes and medical advice sought if appropriate
1.6	Action if patient declines	If a woman declines anti-D the discussion should be documented in her notes.

2. Characteristics of staff

2.1	Class of Health Professional for whom PGD is applicable	Registered midwives employed by SUHT
2.2	Additional requirements considered relevant to the medicines used in the protocol	Named individuals assessed as competent by this Trust and authorised to supply and administer drugs under this Patient Group Direction
2.3	Continued training requirements	Maintains own level of competence with evidence of continued professional development (PREP requirements)

3. Description of Treatment

3.1	Generic Name of Medicine and Form e.g. tablets	Anti-D Immunoglobulin Injection (*D-Gam* and *Partobulin SDF* brands)
3.2	Legal status Prescription Only Medicine (POM)/Pharmacy Only (P)/General Sales List	POM
3.3	Licensed or unlicensed (state rationale for use)	Licensed
3.4	Dose(s) (Where a range is applicable include criteria for deciding on a dose)	Routine Immunoprophylaxis ***For D-Gam*** 500iu IM for women at 28 and 34 weeks gestation of pregnancy **For *Partobulin SDF*** brand, dose is 1250iu given as above. Antenatal ***For D-Gam*** 250iu IM for women before 20 weeks gestation ***For D-Gam*** 500iu IM for women of 20 weeks or greater gestation **For *Partobulin SDF*** brand, give 1250iu throughout gestation (this is unlicensed dose for gestation less than 12 weeks). Postnatal (if fetus Rh (D) positive) ***For D-Gam*** 500iu IM for feto-maternal haemorrhage (FMH) less than 4mls red cells **For *Partobulin SDF***, dose is 1250iu. Give 125iu for each ml of red cells above 4mls (indicated by Kleihauer and after discussion with blood transfusion department)
3.5	Route/Method of Administration	Intramuscular injection into deltoid muscle

3.6	Frequency of Administration	**For *Ð Gam*** 500iu at both 28 weeks and 34 weeks for antenatal prophylaxis. **For *Partobulin SDF*** brand, dose is 1250iu given as above. **For *D-Gam*** Antenatal 250iu following potential sensitising event before 20 weeks gestation ***For D-Gam*** Antenatal 500iu following potential sensitising event after 20 weeks gestation **For *Partobulin SDF*** brand, give 1250iu throughout gestation (this is unlicensed dose for gestation less than 12 weeks). **For *D-Gam*** Post delivery one 500iu dose within 72 hours unless FMH>4mls, in which case further doses may be advised by blood transfusion department. **For *Partobulin SDF*** brand, dose is 1250iu.
3.7	Total dose and number of times treatment can be administered over what time	For routine prophylaxis: **For *Ð Gam*** a total of two 500iu doses are required i.e. at 28 and 34 weeks gestation. ***For Partobulin SDF*** dose is1250iu given as above. Post delivery: ***For D-Gam*** one 500iu dose should be given, with a further 500iu dose being given if advised by haematology. ***For Partobulin SDF,*** dose is 1250iu. If still further doses are required following discussion with haematology, medical advice should be sought. Additional doses may be given following sensitising events as previously described and as advised by haematology.
3.8	Side effects of drugs (to include potential adverse reactions) and any monitoring required	• Pain and inflammation at injection site • Risk of infection from product produced from human blood • Sensitivity reactions – including shortness of breath, shaking, dizziness, chest pain, swelling of face, tachycardia and allergic or anaphylactic reactions • The woman should be observed for at least 20 minutes after

		administration.
3.9	Procedure for reporting Adverse Drug Reaction's (ADR') to Doctor	• All suspected adverse events should be recorded in the patient notes and medical advice sought where appropriate • To be reported to woman's doctor and GP after review • Any adverse event is to be recorded in the woman's notes and reported using SUHT's reporting forms
3.10	Information on follow up treatment if needed	24 hour contact numbers on patient information leaflet
3.11	Written/verbal advice for patient/carer before/after treatment.	Give the woman specific patient information leaflet (you, your baby and the Rhesus factor) and documentation produced by HICCS
3.12	Specify method of recording supply/administration, names of health professional, patient identifiers, sufficient to enable audit trail.	Anti-D is supplied by SUHT blood transfusion department to Bitterne Health Centre, birthing centres and the Princess Anne Hospital. It is required to be kept in a locked refrigerator between 2 and 8 °C and rigorous monitoring of temperature is essential. An individual form is supplied with each vial of anti-D. This should be completed with the woman's details and date of administration, and returned to SUHT blood transfusion department. This will maintain the audit trail. The details of the batch number, date of administration and person administering the drug should be entered in the woman's hand held notes using a sticky label specifically for use with a PGD

4. Management of Patient Group Directions

a. Group Direction developed by: Sally Boxall, Consultant Nurse in Prenatal Diagnosis and Family Support

Christina Nurmahi, Directorate Pharmacist

b. Supported by:

To be signed by all where indicated –

- Clinical Service Director **David Howe** Date 24/08/2007
- Senior Clinical Nurse or relevant professional lead **Sally Boxall** Date 11/09/2007

  Job title of the above **Consultant Nurse in Prenatal Diagnosis**
- Directorate Pharmacist **Christina Nurmahi** Date 24/08/2007

c. Authorised for SUHT by:

- Chief Pharmacist **Surinder S Bassan** Date 24/08/2007
- Signature for Nursing/ Midwifery Group or lead professional if nurses not involved:
- **Carla Hartnell** Date 24/08/2007

  Job title of the above Head of Nursing & Professions
- Signature of Drugs Committee Chair **D Waller** Date 06/09/2007
- Review Date: *(Maximum of 2 years)* **June 2009**

  Job title of person responsible for reviewing…….

d. Acceptance by Individual

- The direction must be read, agreed to and signed by each professional who works within it.
- **This signed copy should be retained by the individual. The department/service in which the PGD operates should use the appendix overleaf to keep a master list of authorised users.**
- All professions must act within their appropriate Code of Professional Conduct.

I have read the PGD and agree to work within its parameters:

Name of professional……....

Title of professional……

Signature of professional……...Date ……..

e. Departmental Record of Signatories

This is the departmental list of all those who have read and agreed to act within the parameters of this PGD. Each individual has kept a copy of the PGD signed at (d) above for his/herself.

Print Name	Sign	Date