Policy Clinical Guideline

Anti-D Prophylaxis

Policy developed by: SA Maternal & Neonatal Community of Practice Approved SA Health Safety & Quality Strategic Governance Committee on: 19 April 2016 Next review due: 19 April 2019

Summary Guideline for the management of women with Anti-D Prophylaxis Keywords clinical guideline, anti d prophylaxis, rh d immunoglobulin, anti d antibodies, threatened miscarriage, miscarriage, termination of pregnancy, ectopic pregnancy, chorionic villus sampling, amniocentesis, cordocentesis, fetomaternal haemorrhage Policy history Is this a new policy? N Does this policy amend or update an existing policy? Y v3.0 Does this policy replace an existing policy? N If so, which policies? Applies to All SA Health Portfolio Staff impact All Clinical, Medical, Nursing, Allied Health, Emergency, Dental, Mental Health, Pathology

PDS reference CG148

Version control and change history

Version	Date from	Date to	Amendment
1.0	13 Sept 04	19 Mar 07	Original version
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Note

This guideline provides advice of a general nature. This statewide guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

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Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient's medical record, the decision made, by whom, and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for discussing care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes:

- The use of interpreter services where necessary,
 - Advising consumers of their choice and ensuring informed consent is obtained,
- Providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct, and
 - Documenting all care in accordance with mandatory and local requirements

Explanation of the aboriginal artwork: The aboriginal artwork used symbolises the connection to country and the circle shape shows the strong relationships amongst families and the aboriginal culture. The horse shoe shape design shown in front of the generic statement symbolises a woman and those enclosing a smaller horse shoe shape depicts a pregnant women. The smaller horse shoe shape in this instance represents the unborn child. The artwork shown before the specific statements within the document symbolises a footprint and demonstrates the need to move forward together in unison.

Australian Aboriginal Culture is the oldest living culture in the world yet Aboriginal people continue to experience the poorest health outcomes when compared to non-Aboriginal Australians. In South Australia, Aboriginal women are 2-5 times more likely to die in childbirth and their babies are 2-3 times more likely to be of low birth weight. The accumulative effects of stress, low socio economic status, exposure to violence, historical trauma, culturally unsafe and discriminatory health services and health systems are all major contributors to the disparities in Aboriginal maternal and birthing outcomes. Despite these unacceptable statistics the birth of an Aboriginal baby is a celebration of life and an important cultural event bringing family together in celebration, obligation and responsibility. The diversity between Aboriginal cultures, language and practices differ greatly and so it is imperative that Perinatal services prepare to respectively manage Aboriginal protocol and provide a culturally positive health care experience for Aboriginal people to ensure the best maternal, neonatal and child health outcomes.

Indications

> RhD immunoglobulin is indicated for the prevention of RhD sensitisation in RhD negative women

Contraindications

- > In the obstetric setting RhD immunoglobulin should **NOT** be given to:
 - > A RhD positive woman
 - > A RhD negative woman with preformed anti-D antibodies **Note:** RhD immunoglobulin must not be given to the baby

Dosage

Summary of current dosing recommendations for RhD negative pregnant women



	RhD immunoglobulin
Obstetric conditions	
Sensitising events in the first trimester	250 IU
Sensitising events beyond the first trimester	625 IU
Sensitising events in multiple	625 IU
pregnancy	
Pregnancy	
Antenatal prophylaxis	625 IU
(28 and 34 weeks)	
Postpartum	
Birth of Rh Pos Baby	625 IU**

**The dose is dependent on the result of the fetomaternal [FMH] screen (administer one vial 625 IU whilst awaiting result of FMH screen) A postpartum FMH screen is considered optimal care and should be performed routinely following birth

General

- > For successful immunoprophylaxis, RhD immunoglobulin should be administered as soon as possible after a sensitising event, but always within 72 hours. If RhD immunoglobulin has not been offered within 72 hours, a dose given within up to 9-10 days may provide protection
- > RhD immunoglobulin should be given slowly by deep intramuscular injection, using an appropriately sized needle. If a large dose (more than 5 mL) is required, it is advisable to administer it in divided doses at different sites. Alternatively, intravenous RhD immunoglobulin (Rhophylac[®]) may be given. Repeat testing should be performed at 48 hours due to the rapid absorption of IV Rhophylac[®]
 - > For women with a BMI >30, particular consideration should be given to factors which may impact on the adequacy of the injection, including the site of administration and the length of the needle used.
 - In their Frequently Asked Questions about the use of RhD Immunoglobulin, The Australian Red Cross Blood Service recommend the deltoid muscle or anterolateral thigh as the best site for administration of RhD Immunoglobulin, with avoidance of the buttocks
 - > No specific additional testing is required because a woman has a BMI >30. Routine post-administration testing is not required unless there has been a large fetomaternal haemorrhage (FMH of greater than 6 mL); in which case, testing should be in accordance with the recommendations below
- > RhD immunoglobulin is a blood product and the minimum requirement is for informed consent to be documented in the woman's medical record
- > It is ESSENTIAL that the 28-WEEK antibody screening BLOOD SAMPLE is taken BEFORE the first routine prophylactic injection is given at 28 weeks



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Sensitising events in the first trimester (up to and including week 12 of gestation)

- > A dose of 250 IU CSL RhD immunoglobulin (minidose) should be offered to every RhD negative woman with no preformed anti-D antibodies to ensure adequate protection against immunisation with the following indications:
 - > Miscarriage
 - > Termination of pregnancy
 - > Ectopic pregnancy
 - > Chorionic villus sampling
- > There is insufficient evidence to suggest that bleeding before 12 weeks gestation in an ongoing pregnancy (threatened miscarriage) necessitates anti-D³. However, if the pregnancy then miscarries, Rh D immunoglobulin should be given²
- If the gestational age is not known with certainty and the possibility exists that the gestational age is 13 weeks or more, then a larger dose [625 IU] should be given
- > If it is known that there is a multiple pregnancy the larger dose [625 IU] is recommended
- > A dose of 250 IU CSL RhD immunoglobulin (minidose) is sufficient to prevent immunisation in fetomaternal haemorrhage [FMH] with 2.5 mL of fetal red cells (5 mL fetal whole blood)

Sensitising events beyond the first trimester (after week 12 of gestation)

- > A dose of 625 IU CSL RhD immunoglobulin should be offered to every RhD negative woman with no preformed anti-D antibodies to ensure adequate protection against immunisation for the following indications:
 - > Genetic studies (chorionic villus sampling, amniocentesis and cordocentesis)
 - > Abdominal trauma considered sufficient to cause fetomaternal haemorrhage [FMH]
 - > Each occasion of revealed or concealed antepartum haemorrhage (where the patient suffers unexplained uterine pain, the possibility of concealed antepartum haemorrhage should be considered, with a view to immunoprophylaxis)
 - > External cephalic version (performed or attempted)
 - > Miscarriage or termination of pregnancy
 - > Intrauterine death
- > Evidence for the efficacy of this dose for these indications is not available. It is therefore recommended that the magnitude of fetomaternal haemorrhage [FMH] be assessed when there is a likelihood of a significant FMH, such as severe abdominal trauma, abruption, transplacental puncture or puncture of fetal blood vessels. Further doses of RhD immunoglobulin need to be administered for FMH in excess of 6 mL fetal red blood cells (12 mL fetal blood)

Antenatal prophylaxis (at weeks 28 and 34 of gestation)

> Universal prophylaxis with RhD immunoglobulin is recommended for pregnant women who are RhD negative without preformed anti-D antibodies



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- > RhD immunoglobulin in the form of 625 IU CSL RhD immunoglobulin, should be offered at 28 and again at 34 weeks, to all RhD negative women who have no preformed anti-D antibodies
- It is essential that women are screened again for pre-existent anti-D before the prophylaxis is given at 28 weeks and that the blood sample is taken before administration of the RhD immunoglobulin. The result of the test does not need to be available before administration of the RhD Immunoglobulin as the dose is not dependent on the result
- > No repeat screening is necessary before the second administration at 34 weeks (in cases where no sensitising events have occurred)

Postpartum

- > A dose of 625 IU should be offered to every RhD negative woman giving birth except when the baby is RhD negative
- > RhD immunoglobulin should not be given to women with pre-existing anti-D antibodies, except where this is known to be due to the presence of antenatally administered RhD immunoglobulin
- If it is unclear whether the anti-D detected in the mother's blood is passive from the administered anti-D or preformed, the treating clinician should be consulted. If there is continuing doubt, RhD immunoglobulin should be administered
- > The magnitude of fetomaternal haemorrhage [FMH] should be assessed by a method capable of quantifying a haemorrhage of > 6 mL of fetal red blood cells (12 mL of fetal whole blood). The recommended method for this is flow cytometry. For FMH of 6 mL packed fetal red blood cells or greater, further doses should be administered sufficient to prevent maternal immunisation
- > A dose of 625 IU will protect against a fetomaternal haemorrhage of up to 6 mL of RhD positive fetal red blood cells (approximately 12 mL of fetal whole blood). Further doses of RhD immunoglobulin need to be administered for FMH in excess of 6 mL packed fetal red blood cells (approximately 12 mL fetal whole blood)
 - > For example: A haemorrhage greater than 6 mL, the recommended dose is 100 IU per extra mL RhD positive packed red blood cells in excess of 6 mL (i.e. 50 IU per mL of fetal whole blood in excess of 12 mL fetal whole blood)



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References

- 1. Current product information sheet(s)
- 2. National Blood Authority. "Guidelines on the prophylactic use of RhD immunoglobulin (anti-D) in obstetrics". 2003.
- 3. Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG). Guidelines for the use of Rh (D) immunoglobulin (anti-D)in obstetrics in Australia. C-Obs 6. 2012. Available from URL: <u>www.ranzcog.edu.au</u>
- 4. Directive from Chief Medical Officer, Commonwealth of Australia to Product User RhD Immunoglobulin (anti-D) in Obstetrics 4.11.02.
- 5. Transfusion Medicine Manual 2003- Australian Red Cross Blood Service
- Brennand J, Cameron A. Red cell alloimmunization. In: Kilby MD, Oepkes D, Johnson A, editors. Fetal therapy: Scientific basis and critical appraisal of clinical benefits. Cambridge: Cambridge University Press; 2013. p. 55-66.
- 7. Daniels G. Human blood groups. Chapter 5 Rh blood group system. Oxford: Blackwell Science; 1995.
- 8. Avent ND, Reid ME. The Rh blood group system: A review. Blood 2000; 95: 375-87.

Useful websites:

www.anzsbt.org.au www.ranzcog.edu.au www.arcbs.redcross.org.au www.csl.com.au

Abbreviations

CSL	Commonwealth serum laboratories		
FMH	Fetomaternal haemorrhage		
IU	International units		
mL	Millilitre(s)		
RANZCOG	Royal Australian and New Zealand College of Obstetricians and		
	Gynaecologists		
Rh	Rh blood group		

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