

## Rh D Immunoglobulin (Anti-D)

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**Functional Sub group** Clinical/ Patient Services - Maternity  
Clinical/ Patient Services - Medical Treatment  
Population Health - Health Promotion

**Summary** The policy advises health professionals that Australia is now self-sufficient in its supply of Rh D immunoglobulin (Anti-D) and provides guidelines for the use of this product in obstetrics. The emergency 24 hour hot line is (02) 9229 4000.

**Replaces Doc. No.** RH D Immunoglobulin (Anti-D) [PD2005\_524]

**Author Branch** Clinical Policy

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**Applies to** Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations - Non Declared, Affiliated Health Organisations - Declared, Community Health Centres, Divisions of General Practice, Government Medical Officers, Public Hospitals

**Audience** Medical staff, midwives and nurses

**Distributed to** Public Health System, Community Health Centres, Divisions of General Practice, Government Medical Officers, Health Associations Unions, Health Professional Associations and Related Organisations, NSW Ambulance Service, NSW Department of Health, Public Health Units, Public Hospitals, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

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**Status** Active

**Director-General**

**Compliance with this policy directive is mandatory.**

## Rh D IMMUNOGLOBULIN (ANTI-D)

This Policy Directive replaces Policy Directive 2005\_524, *Rh D Immunoglobulin (Anti-D)*. The intended users of the Policy Directive are medical staff, midwives and nurses involved in obstetric care.

### BACKGROUND

Rh D immunoglobulin is used to protect against Haemolytic Disease of the Newborn, which has the potential to occur in children born to women with Rh D negative blood.

In 1999 a Working Party of the National Health and Medical Research Council (NHMRC) issued evidence-based guidelines for the prophylactic use of Rh D immunoglobulin in obstetrics. The Working Party concluded that the product should be used for (1) potentially sensitising antenatal events, (2) antenatal prophylaxis and (3) postpartum prophylaxis. The Working Party acknowledged that routine administration of Rh D immunoglobulin to all Rh D negative women at 28 and 34 weeks gestation represented best practice for antenatal prophylaxis but was unable to recommend this because there was shortage of Rh D immunoglobulin in Australia at that time.

By 2001, the supplies of Australian produced Rh D immunoglobulin had increased and an imported product (WinRho SDF™) had been registered with the Therapeutic Goods Administration. As a consequence, the NHMRC Working Party reviewed and amended the guidelines to include a three-staged antenatal anti-D prophylactic program:

Stage 1: This stage provided for the use of Australian produced Rh D immunoglobulin for routine antenatal prophylaxis for Rh D negative women having their first baby and reaching at least 28 weeks gestation. In Stage 1 the local product was to be used for potentially sensitising antenatal events. The imported product was to be used for postnatal prophylaxis.

Stage 2: This stage provided for the use of Australian produced Rh D immunoglobulin for routine antenatal prophylaxis for ALL Rh D negative women who did not have preformed anti-D antibodies. The local product was to be used for potentially sensitising antenatal events and the imported product was to be used for postnatal prophylaxis.

Stage 3: This stage provided for the use of Australian produced Rh D immunoglobulin for routine antenatal and postnatal prophylaxis for all Rh D negative women without preformed anti-D antibodies.

The different stages of the program were to be implemented as the supplies of Australian produced Rh D immunoglobulin increased. Stages 1 and 2 of the program were implemented in late 2002 and 2004, respectively. Australia is now self-sufficient in its supply of Rh D immunoglobulin and Stage 3 of the program was implemented at the end of March 2006.

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## PRODUCT INFORMATION, ORDERING AND DISTRIBUTION

Australian Rh D immunoglobulin is produced by CSL Limited and is distributed by the Australian Red Cross Blood Service (ARCBS). The ARCBS no longer routinely issues the imported product, WinRho SDF™ but it holds a stock in reserve for when the intravenous preparation is required, for example, following massive fetomaternal haemorrhage.

Enquiries about either of the products should be directed to the ARCBS (NSW) Transfusion Medical Officer on (02) 9229 4347 or 24 -hr line (02) 9229 4000.

For ordering requirements contact the Distribution Department of the ARCBS on (02) 9229 4000.

For information on handling and storage of the Australian produced Rh D immunoglobulin and WinRho SDF™ please refer to the respective product information sheets and the NSW Health Policy Directive PD2005\_261 - *Management of Fresh Blood Components*.

## SUMMARY OF THE REVISED RECOMMENDATIONS FOR USE OF ANTI-D (SEE ALSO TABLE 1)

These recommendations are in line with the *NHMRC Guidelines on the prophylactic use of Rh D Immunoglobulin (anti-D) in Obstetrics (1999)*.

Rh D immunoglobulin should be used for the following:

### POTENTIALLY SENSITISING EVENTS

(A) In the **first trimester** (less than 12 weeks):

- Single pregnancies: 250 IU Rh D immunoglobulin.
- Multiple pregnancies (such as twins): 625 IU Rh D immunoglobulin.

(B) In the **second and third trimester**:

- 625 IU Rh D immunoglobulin with additional doses as indicated from the results of assessment of the extent of fetomaternal haemorrhage (FMH).

### ANTENATAL PROPHYLAXIS

All Rh D negative **women who do not have preformed anti-D antibodies**:

- 625 IU Rh D immunoglobulin at 28 and 34 weeks gestation.

### POSTNATAL PROPHYLAXIS

- 625 IU Rh D immunoglobulin with additional doses as indicated from the results of assessment of the extent of FMH within 72 hours of the birth.

## ADMINISTRATION OF RH D IMMUNOGLOBULIN

All pregnant women, both Rh D positive and Rh D negative, should be tested in the first trimester for blood group and clinically significant red cell antibodies. Repeat testing of Rh D negative women at 28 weeks prior to administering Rh D immunoprophylaxis is becoming the accepted protocol in most Australian centres, as is the elimination of the antibody screen at 34-36 weeks. Further information on the protocol for antibody screening in Rh D negative women during pregnancy, is given in the *Guidelines for Blood Grouping & Antibody Screening in the Antenatal and Perinatal Setting* published by the Australian & New Zealand Society of Blood Transfusion (March 2004) available at <http://www.anzsbt.org.au/publications>.

### 1. POTENTIALLY SENSITISING EVENTS

Potentially sensitising events include ectopic pregnancy, miscarriage, termination of pregnancy and ultrasound guided procedures such as chorionic villus sampling, amniocentesis, cordocentesis & fetoscopy as well as abdominal trauma considered sufficient to cause fetomaternal haemorrhage, external cephalic version, antepartum haemorrhage and normal delivery.

In the event of potentially sensitising events during the first trimester of pregnancy, Rh D immunoglobulin should be administered as soon as possible after the sensitising event and always within 72 hours. If Rh D immunoglobulin has not been offered within 72 hours, a dose offered within 9-10 days may provide protection.

In the event of potentially sensitising events that occur after the first trimester, blood should be taken prior to the administration of Rh D immunoglobulin to determine the extent of possible FMH. Additional doses of Rh D immunoglobulin should be administered as indicated from the results of testing. There are a variety of methods to assess FMH. For further information see *Guidelines for Laboratory Assessment of Fetomaternal Haemorrhage, 2002*, Australian & New Zealand Society of Blood Transfusion website: <http://www.anzsbt.org.au>

### 2. ANTENATAL PROPHYLAXIS

Before administration of Rh D immunoglobulin, the midwife, registered nurse or medical practitioner should check against the pathology result form to confirm the mother's blood group and red cell antibody status i.e. that there were no preformed anti-D antibodies. Findings should be documented and placed on the patient file. Whether or not the patient is given antenatal Rh D immunoglobulin prophylaxis should also be documented.

**Rh D immunoglobulin should be administered at weeks 28 and 34 only if the mother is Rh negative and had no preformed anti-D antibodies.** If Rh D immunoglobulin was given for a potentially sensitising event, antenatal

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prophylaxis doses should still be given. Refer to Table 1 for appropriate dosage and route of administration of Rh D immunoglobulin.

### 3. POSTNATAL PROPHYLAXIS

Before postnatal administration of Rh D immunoglobulin, the blood groups of the mother and baby must be checked and confirmed by two staff members (midwives, registered nurses or medical practitioners). The members of staff responsible for checking this information must sign that the information is correct.

Rh D immunoglobulin should be administered to the mother if the:

- mother is Rh D negative, and
- baby is Rh D positive

**even if maternal antibodies are detected at birth unless it has been clearly documented that she was already alloimmunised.**

If cord blood cannot be obtained from the baby, the baby should be considered Rh D positive and Rh D immunoglobulin should be administered to the mother.

#### **Post birth tests and recommended dose(s) of Rh D immunoglobulin to be used**

As soon as possible after birth, the antibody status of the mother should be determined and a Kleihauer-Betke test (FMH test) should be carried out to determine the dose of Rh D immunoglobulin to be given. **Unless it is clearly documented that the mother is already alloimmunised**, the mother should receive **625 IU anti-D plus additional doses as indicated from the Kleihauer-Betke test. 625 IU anti-D should afford protection against a FMH of 6ml (12 ml whole blood) of Rh D positive red cells.**

It should be noted that the tests for antibody status and the Kleihauer-Betke test do not distinguish between antibodies that are due to passive administration or due to alloimmunisation. If there is doubt as to whether the mother has been alloimmunised, Rh D immunoglobulin should be administered (see *ANZSBT Guidelines for Blood Grouping & Antibody Screening in the Antenatal and Perinatal Setting (2004)*).

#### **Documentation of postnatal prophylaxis**

A copy of the documented blood groups for both mother and baby should be placed on the patient's medical record and must have been signed by two members of staff (midwives, registered nurses or medical practitioners) when they checked to ensure that the information was correct.

On leaving the hospital, the midwife, registered nurse or medical practitioner responsible for discharging the mother and baby should check the blood group pathology reports to ensure that the mother has been given Rh D

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immunoglobulin. Upon confirmation, the midwife, registered nurse or medical practitioner responsible for discharge, should sign the patient notes.

## **CONSENT TO TREATMENT**

As part of informed consent to medical treatment, a patient must be given a clear explanation of the potential risks and benefits of receiving Rh D immunoglobulin because it is a human blood product. The discussion should be documented in the patient's notes and the consent form completed. If a patient declines treatment, this should be recorded on the patient's notes. For further information about consent to treatment please refer to the NSW Health Policy Directive PD2005\_406 *Consent to medical treatment – Patient Information*.

Please note that the information in NSW Health Policy Directives is applicable to public health institutions only. Private obstetricians OR private health providers are encouraged to check with their indemnity organisation to determine what the legal requirements are in relation to private health providers and whether or not the NSW Health consent forms will cover private health providers, if they wish to use them.

## **SUPPORTING INFORMATION**

The Australian Red Cross Blood Service (ARCBS) site <http://www.transfusion.com.au/RhD> provides up-to-date information for health professionals and relevant support materials for consumers on the use of Rh D immunoglobulin. These materials include:

*You & Your Baby: Important information for Rh (D) Negative Women*

*Important Information for Rh (D) negative women: Prevention of Haemolytic Disease of the Newborn*

*Guidelines for the Use of Rh (D) immunoglobulin – Wall Poster (500 x 340mm)*

*Frequently Asked Questions about the use of Rh (D) immunoglobulin*

Selected materials can be ordered by completing a 'Material Fax Request Sheet', downloadable in pdf format, at the same address and there is also a facility to enable specific questions to be answered.

In addition to information on the ARCBS website, information on Rh D immunoglobulin is available on the NHMRC site: <http://www.nhmrc.gov.au>

Robyn Kruk  
**Director-General**

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**TABLE 1: USE OF RH D IMMUNOGLOBULIN IN OBSTETRICS**

|   |  |   |   |
|---|--|---|---|
| <p><b>POTENTIAL ANTENATAL SENSITISING EVENTS</b></p> <p>These include ectopic pregnancy, miscarriage, termination of pregnancy and ultrasound guided procedures such as chorionic villus sampling, amniocentesis, cordocentesis &amp; fetoscopy as well as abdominal trauma considered sufficient to cause fetomaternal haemorrhage, external cephalic version, antepartum haemorrhage and normal delivery.</p>   |  | <p><b>PROPHYLAXIS</b></p>   |   |
| <p><b>1<sup>st</sup> Trimester<br/>(less than 12 weeks gestation)</b></p>   | <p><b>2<sup>nd</sup> and 3<sup>rd</sup> Trimester<br/>(week 12 &amp; beyond)</b></p>   | <p><b>Antenatal</b></p>   | <p><b>Postnatal</b></p>   |
| <p><b>Indication:</b></p> <p>Potential sensitising event</p>  | <p><b>Indication:</b></p> <p>Potential sensitising event</p>   | <p><b>Indication:</b></p> <p>All Rh D negative women with no preformed anti-D antibodies</p>                    | <p><b>Indication:</b></p> <p><b>All Rh D negative women who deliver a Rh D positive baby unless it has been clearly documented that they are already alloimmunised.</b></p>             |
| <p><b>Product &amp; Dose</b></p> <p>CSL Rh D immunoglobulin<br/><b>250 IU</b><br/>(625 IU for multiple pregnancies ie. twins etc)</p>   | <p><b>Product &amp; Dose</b></p> <p>CSL Rh D immunoglobulin<br/><b>625 IU</b>. Additional doses to be given as indicated from results of assessment of fetomaternal haemorrhage.</p> | <p><b>Product &amp; Dose</b></p> <p>CSL Rh D immunoglobulin<br/><b>625 IU</b> at 28 and 34 weeks gestation.</p> | <p><b>Product &amp; Dose</b></p> <p>CSL Rh D immunoglobulin<br/><b>625 IU</b>. Additional doses to be given as indicated from the results of assessment of fetomaternal haemorrhage</p> |
| <p><b>Route of administration</b></p> <p>Given slowly by deep intramuscular injection</p>   | <p><b>Route of administration</b></p> <p>Given slowly by deep intramuscular injection</p>  | <p><b>Route of administration</b></p> <p>Given slowly by deep intramuscular injection</p>                       | <p><b>Route of administration</b></p> <p>Intramuscular injection</p>  |
| <p><b>N.B.</b></p> <p><b>In some circumstances, intravenous administration of Rh D immunoglobulin may be warranted in which case the intravenous preparation of Rh D immunoglobulin (WinRho SDF™) should be used. Contact the ARCBS for further information.</b></p>  |  |   |   |
| <p><b>CONTRAINDICATIONS</b></p> <p>Rh D immunoglobulin should not be given to individuals:</p> <ul style="list-style-type: none"> <li>▪ With preformed anti-D antibodies, except where the preformed antibodies are due to antenatal administration of Rh D immunoglobulin;</li> <li>▪ Who are Rh D positive;</li> <li>▪ Who are immunoglobulin A deficient, unless they have been tested and shown not to have circulating anti-IgA antibodies; or</li> <li>▪ With a history of anaphylactic or other severe systemic reaction to immunoglobulins.</li> </ul> <p>For individuals with severe thrombocytopenia or a coagulation disorder that contraindicates intramuscular injection, the intravenous preparation of Rh D immunoglobulin should be used.</p> |  |   |   |