

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

Abbreviations used in this section:

IU- International Units

NHMRC Report (1999): National Health and Medical Research Council (NHMRC) *Guidelines on the prophylactic use of Rh D immunoglobulin (Anti-D) in obstetrics 1999*

NHMRC Report (2003): National Health and Medical Research Council (NHMRC) *Guidelines on the prophylactic use of Rh D immunoglobulin (Anti-D) in obstetrics 2003*

Policy Questions & Answers

Introduction

The following answers to frequently asked questions are intended for use by healthcare professionals and have been endorsed by the National Blood Authority.

Policy Questions

1. *What is the Australian policy regarding Rh (D) antenatal immunoprophylaxis?*
2. *Where do I obtain further information on anti-Rh (D) immunoglobulin?*
3. *When will the expected implementation of stage III occur?*
4. *Am I able to access an intravenous Rh (D) immunoglobulin preparation?*

Questions and Answers

1. *What is the Australian policy regarding Rh (D) antenatal immunoprophylaxis?*

In 1999, the National Health and Medical Research Council (NHMRC) published guidelines aiming to balance best practice in the use of Rh (D) immunoglobulin with limited supply. While the Working Party found that universal prophylaxis with Rh (D) immunoglobulin to Rh (D) negative women at 28 and 34 weeks gestation is generally regarded as best practice, it was unable to recommend antenatal prophylaxis due to supply constraints at the time.

Since the 1999 guidelines were issued, there have been a number of developments which have increased the supply of Rh (D) immunoglobulin in Australia, including

- the introduction of a 250IU dose of Rh (D) immunoglobulin in May 2001 and its use in potentially sensitising events in the first trimester,
- approval was obtained for the use of an overseas Rh (D) immunoglobulin product in October 2002 to ease the pressure on the domestic supply until self-sufficiency could be reached,

- notwithstanding the above, Governments are developing a supply risk mitigation strategy to ensure continuity of supply for any product in the event of an inability to supply; and
- additional funding was provided by Governments to the Australian Red Cross Blood Service (ARCBS) to recruit more anti-D donors, and to conduct primary immunisation and boosting of existing donors.

In 2001 the Working Party was reconvened to review the guidelines, particularly in regard to antenatal prophylaxis. Based on the results of an updated literature review and assessment of progress towards self-sufficiency in Rh (D) immunoglobulin, the Working Party recommended a staged implementation of full antenatal prophylaxis as follows:-

- Stage 1 provided for routine antenatal prophylaxis at 28 and 34 weeks gestation for Rh (D) negative women without preformed anti-D having their first baby reaching at least 28 weeks gestation. During this stage, an overseas Rh (D) immunoglobulin product, WinRho SDFTM was used for postnatal prophylaxis. This stage commenced in November 2002 and is now complete.
- In Stage 2, routine antenatal prophylaxis at 28 and 34 weeks' gestation was extended to all Rh (D) negative women without preformed anti-D and still required the use of WinRho SDFTM for postnatal prophylaxis. Stage 2 of the program commenced in January 2005.
- Stage 3 is the final stage of the program during which both antenatal and postnatal Rh (D) immunoprophylaxis will be fully supported by Australian sourced Rh (D) immunoglobulin. The NBA has put in place arrangements to ensure that anticipated demand for Rh (D) immunoglobulin from 31 March 2006 is met through Australian sourced products.

Arrangements are also being put in place to ensure there is sufficient Rh (D) immunoglobulin available in Australia in the case of unexpected events.

For Stage 3, the available Rh (D) immunoglobulin products should be used as indicated below:

- First trimester sensitising events¹ (<12 weeks): Rh (D) Immunoglobulin 250 IU
- First trimester sensitising events¹ (multiple pregnancies <12 weeks): Rh (D) Immunoglobulin 625 IU
- Second and third trimester sensitising events¹ (<12 weeks): Rh (D) Immunoglobulin 625 IU
- All Rh (D) negative women without preformed Anti-D: Rh (D) Immunoglobulin 625 IU at 28 and 34 weeks' gestation
- Postnatal prophylaxis: Rh (D) Immunoglobulin 625 IU

Note 1: Sensitising events include ectopic pregnancy, miscarriage, termination of pregnancy and ultrasound guided procedures such as chorionic villus sampling, amniocentesis, cordocentesis and fetoscopy, as well as abdominal trauma considered sufficient to cause fetomaternal haemorrhage, external cephalic version, antepartum haemorrhage and normal delivery.

2 *Where do I obtain further information on anti-Rh (D) immunoglobulin?*

Further information is available from the ARCBS website www.transfuse.com.au/RhD and the CSL website www.csl.com.au

3 *When will the expected implementation of stage III occur?*

National implementation of stage III will commence on 31 March 2006. By this date arrangements will be in place to ensure that all healthcare providers (or approved recipients) will be able to receive domestically produced anti-D immunoglobulin for routine prophylaxis. However, any WinRho already in inventory should be used up rather than wasted.

4 *Am I able to access an intravenous Rh (D) immunoglobulin preparation?*

In some circumstances, access to an intravenous Rh (D) immunoglobulin preparation may be warranted. A quantity of intravenous Rh (D) immunoglobulin will be made available for this purpose. This product may be accessed via the Australian Red Cross Blood Service.

It should be noted that the NBA has only approved the use of intravenous Rh (D) immunoglobulin for the following indications within Australia:

- Postnatal prophylaxis
- To prevent alloimmunisation in Rh (D) negative females of child-bearing age who have been transfused with Rh (D) positive red cells or blood components.

Specifically, intravenous Rh (D) immunoglobulin is not authorised for use in immune thrombocytopenic purpura (ITP) within Australia.

Reference: *Approved usage of WinRho SDFTM within Australia*, Medilink – A Newsletter for Clinical and Scientific Professionals, Australian Red Cross Blood Service, October 2004; Volume 7 Issue 2 Page 4