

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

Abbreviations used in this section:

ARCBS Australian Red Cross Blood Service
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*

Supply & Distribution Questions and Answers

Introduction

The following answers have been prepared and endorsed by the Australian Red Cross Blood Service.

- 1. How will Australia maintain national self-sufficiency for Rh (D) immunoglobulin?*
- 2. Is there a difference in yield between male and female Anti-D donors?*
- 3. With the introduction of the 250 IU Rh (D) immunoglobulin, how many 625 IU Rh (D) immunoglobulin doses are expected to be saved?*
- 4. If the UK dose of Rh (D) immunoglobulin is 500 IU, why not alter the 625 IU to this dose and save this precious resource?*
- 5. How can I order Rh (D) Immunoglobulin products?*
- 6. What intravenous Rh (D) immunoglobulin product is currently available in Australia and how can I access it?*

- 1. How will Australia maintain national self-sufficiency for Rh (D) immunoglobulin?*

One of the most successful medical advances has been the prevention of Haemolytic Disease of the Newborn (HDN) by the discovery, introduction and clinical usage of Rh (D) immunoglobulin. In 1968, Australia became the first country in the world to be self-sufficient in production of Rh (D) immunoglobulin. As a result, we have seen a dramatic decline in mortality rates among unborn and newborn Rh (D) positive children of Rh (D) negative mothers.

There have been several challenges in maintaining and increasing the supply of Rh (D) immunoglobulin including:

- the progressive retirement of the original cohort of Rh (D) plasmapheresis donors, primarily on the grounds of age
- declining levels of Rh (D) antibody in Rh (D) plasmapheresis donors, which occurs over time
- a reduction in the number of potential donors with Rh (D) antibodies due to a fall in the number of women immunised during pregnancy (because of the success of the HDN prevention program in recent decades) and less people receiving Rh (D) incompatible transfusions due to an improvement in the supply of Rh (D) negative blood
- ethical considerations associated with increasing the Rh (D) antibody levels in blood donors by primary immunization and boosting, as this requires a small transfusion of incompatible blood
- the significant effect on input if any donor withdraws from the program, as we rely on a small number of Rh (D) plasmapheresis donors across Australia.

With the introduction of antenatal prophylaxis programs, the Australian demand for Rh (D) immunoglobulin has also considerably increased. To ensure that the Australian demand for Rh (D) Immunoglobulin can be met from domestic supply, ARCBS runs a special blood donor program. The purpose of this program is to maintain and increase the Australian supply of Rh (D) immunoglobulin as required. This involves actively recruiting new donors for Rh (D) primary immunisation and boosting to increase the pool of donors contributing to the supply of plasma for the production of Rh(D) Immunoglobulin. The pool of Rh (D) plasmapheresis donors has increased to over 200. ARCBS is also regularly boosting the levels of anti-D in existing donors.

Blood banks, hospitals or pathology laboratories can also assist by identifying people with high levels of anti-D antibodies due to previous transfusion or pregnancy and asking whether they are interested in joining the ARCBS Rh (D) Plasmapheresis Donor Program.

2. *Is there a difference in yield between male and female Anti-D donors?*

There is no known sex difference in the yield from immunised donors. Historically prior to the advent of primary immunisation programs the majority of donors with high levels were women who had multiple pregnancies.

3. *With the introduction of the 250 IU Rh (D) immunoglobulin, how many 625 IU Rh (D) immunoglobulin doses are expected to be saved?*

The 1999 National Health and Medical Research Council (NHMRC) *Guidelines on the Prophylactic Use of Rh (D) Immunoglobulin (Anti-D) in Obstetrics* suggested ways in which to balance best practice in the use of Anti-D with a limited national supply. One recommendation was to introduce a 250 IU dose of anti-D for first trimester indications. The NHMRC Report (1999) estimated that if the 250 IU dose is used appropriately, 12,000 additional doses of the 625 IU could be made available for antenatal prophylaxis.

Subsequently CSL Limited, in addition to its continued supply of the 625 IU dose, was contracted to develop a 250 IU dose of Anti-D for first trimester use.

4 *If the UK dose of Rh (D) immunoglobulin is 500 IU, why not alter the 625 IU to this dose and save this precious resource?*

Recommended doses vary internationally from 500 IU to 1500 IU. There are no comparative studies of one manufacturer's product versus another. To reduce the dose would require additional efficacy studies. This would be a lengthy and expensive exercise.

5. *How can I order Rh (D) Immunoglobulin products?*

Approved health providers can place orders for Rh (D) immunoglobulin (ARCBS/CSL 250, 625 IU) from the Australian Red Cross Blood Service.

6. *What intravenous Rh (D) immunoglobulin product is currently available in Australia and how can I access it?*

A quantity of WinRho SDFTM is available in reserve where access to an intravenous preparation is warranted. This product may be accessed via the Australian Red Cross Blood Service. Contact the ARCBS Transfusion Medicine Specialist in your capital city.

References: *Approved Product Information for WinRho SDFTM*