



RhoGAM Informed Consent for RhD-Negative Women

RhD-negative women who deliver a D-positive baby or who are otherwise exposed to D-positive red cells are at risk of developing anti-D antibodies. D-positive fetuses/neonates of these mothers are at risk of developing hemolytic disease of the fetus and newborn (HDFN), which can be associated with serious morbidity or mortality.

Implementation of programs for antenatal and postnatal anti-D immune globulin prophylaxis has led to a significant reduction in the frequency of D alloimmunization and associated fetal/neonatal complications. However, D alloimmunization with serious sequelae in offspring still occurs, particularly in low resource countries where anti-D immune globulin is not widely available. Where appropriate monitoring and intervention are available, HDFN can be treated successfully in most cases.”

When a woman has an Rh- blood type (no rhesus factor on the surface of their red blood cells) and there is a possibility that she may be carrying an Rh+ baby (father of baby has a positive blood type), administration of Rhogam (anti-D immune globulin) at 28 weeks and within 72 hours of birth is recommended. This is because blood mixing can occur during pregnancy and through the process of birth. If blood with the rhesus factor enters the bloodstream of the woman with a Rh- blood type, the body may develop anti-D antibodies resulting in isoimmunization.

What is Isoimmunization?

Isoimmunization, also called Rh sensitization, hemolytic disease of the fetus, or Rh incompatibility results in the mother's immune system producing antibodies that fight and destroy the baby's Rh+ cells. Red cell destruction can lead to miscarriage and make the baby anemic well before birth. Isoimmunization impacts the baby in the following manner:

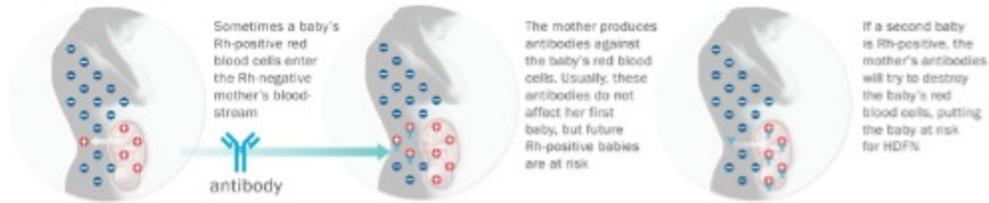
- Blood production in the fetus begins at about 3 weeks and Rh antigen has been identified in the red cell membrane as early as 38 days after conception.
- Re-exposure to the antigen produces a rapid immunological response usually measured in days.
- The sensitized mother produces IgG anti-D (antibody) that crosses the placenta and coats D-positive fetal red cells which are then destroyed in the fetal spleen.
- Mild to moderate hemolysis (red cell destruction) manifests as increased indirect bilirubin (red cell pigment).
- Severe hemolysis leads to red blood cell production by the spleen and liver.
 - Subsequently, hepatic circulatory obstruction (portal hypertension) with placental edema interferes with placental perfusion and ascites develops.
 - Hepatomegaly increased placental thickness, and polyhydramnios often precede the development of hydrops (fetal heart failure).
 - As liver damage progresses decreased albumin production results in the development of anasarca (extreme generalized edema), and effusions (fluid buildup in chest and lungs).
- Overall, 16% of Rh-negative women will become sensitized after their first pregnancy if not given Rhogam.

What is RhoGAM or anti-D immunoglobulin?

RhoGAM is a prescription medicine that is used to prevent Rh immunization, a condition in which an individual with Rh-negative blood develops antibodies after exposure to Rh-positive blood. RhoGAM is administered by intramuscular (IM) injection

RhoGAM is purified from human plasma containing anti-Rh (anti-D). Plasma for RhoGAM is sourced from a single donor center owned and operated by KEDPLASMA, LLC. All donors are carefully screened and tested for blood-borne pathogens. Donated plasma may still carry a risk of transmitting infectious agents.

How HDFN develops:



How RhoGAM works:



Is RhoGAM effective at preventing isoimmunization?

Overall, 16% of Rh-negative women will become sensitized after their first pregnancy if not given Rhogam. This rate fell to 1 to 2 percent with routine postpartum administration of a single dose of anti-D immune globulin and was further reduced to 0.1 to 0.3 percent with the addition of routine antenatal administration in the third trimester. D alloimmunization has not been completely eliminated because of failure to administer anti-D immune globulin in accordance with published guidelines and because of unsuspected fetomaternal bleeding early in gestation, before administration of third-trimester prophylaxis.

What are the risks of the RhoGAM injection?

“There is no evidence that maternal administration of anti-D immune globulin results in any significant risk of fetal anemia, enhancement of maternal primary immune response to D-positive red blood cells, adverse obstetric outcome, reduced maternal response to postpartum rubella immunization, or short- or long-term harm to the fetal immune system.

Serious adverse reactions are rare: From 1990 to 2000, 2.9 million doses of one manufacturer's anti-D immune globulin were administered, and the manufacturer received only 11 reports of adverse events possibly related to the drug.”

Based on the information above, I desire to:

- Have my partner tested to determine his blood type. If he is negative, I choose to decline Rhogam.
- My partner is a positive blood type and I desire to:
 - Receive RhoGAM prophylaxis at 28 weeks.
 - Decline RhoGAM prophylaxis at 28 weeks.
 - Receive RhoGAM prophylaxis within 72 hours of childbirth.
 - Draw cord blood immediately after birth to determine my child's blood type. I understand the lab may not produce results within 72 hours of birth. Based on the results, I will decide on whether I want RhoGAM prophylaxis at this time.
 - Decline RhoGAM prophylaxis after birth.

Client's Signature

Client's Name

Date

Midwife's Signature

Midwife's Name

Date

1. Overview of RhD Alloimmunization in Pregnancy by Moise: https://www.uptodate.com/contents/overview-of-rhd-alloimmunization-in-pregnancy?topicRef=6773&source=see_link
2. Isoimmunization: [https://health.usf.edu/care/obgyn/services-specialties/mfm/isoimmunization#:~:text=Isoimmunization%20\(Sometimes%20called%20Rh%20sensitization,destroy%20the%20baby's%20blood%20cells.](https://health.usf.edu/care/obgyn/services-specialties/mfm/isoimmunization#:~:text=Isoimmunization%20(Sometimes%20called%20Rh%20sensitization,destroy%20the%20baby's%20blood%20cells.)
3. Management of Rh Disease and Isoimmunization: <http://perinatology.com/Archive/Isoimmunization.htm>
4. <http://www.rhogam.com/patients/about-rhogam/>
5. Management of Rh Disease and Isoimmunization: <http://perinatology.com/Archive/Isoimmunization.htm>
6. Prevention of RhD alloimmunization in Pregnancy:
7. <https://www.uptodate.com/contents/prevention-of-rhd-alloimmunization-in-pregnancy?csi=87ab641e-d680-4076-b13e-dd14ff97a711&source=contentShare>
8. Prevention of RhD alloimmunization in Pregnancy:
9. <https://www.uptodate.com/contents/prevention-of-rhd-alloimmunization-in-pregnancy?csi=87ab641e-d680-4076-b13e-dd14ff97a711&source=contentShare>