

Resources for Midwives

Version 2
Updated March 2017



Inspiring and facilitating best
transfusion practices in Ontario.



Table of Contents

Acknowledgements	3
Disclaimer	3
Introduction	4
Scope	4
Abbreviations and Glossary of Terms.....	5
<u>Midwives</u>	
Tips for Management of Rh(D) negative Clients and the Use of Rh Immune Globulin	7
Hemolytic Disease of the Fetus and Newborn and its Prevention with Rh Immune Globulin- Information for Midwives.....	8
Transfusion Medicine Topics for Midwives	10
<u>Clients</u>	
Answers About Rh Immune Globulin	11
<u>Technical</u>	
Memorandum of Understanding	15
Rh Immune Globulin: Documentation of Informed Choice Discussion	18
RhIG Transportation	19
Record of Rh Immune Globulin Storage and Transport.....	20
Record of Rh Immune Globulin Administration.....	21
Standards for Blood and Blood Components, CSA Z902-15 Canadian Standards Association Excerpts for Midwives	22
Standards for Hospital Transfusion Services, version 3, 2011 Canadian Society for Transfusion Medicine (CSTM) Excerpts for Midwives	25
References	29



Acknowledgements

The Ontario Regional Blood Coordinating Network (ORBCoN) gratefully acknowledges the funding support provided by the Ministry of Health and Long-Term Care (MOHLTC).

ORBCoN would like to recognize the efforts and feedback from the following experts:

- Dr. Lani Lieberman
- Jenna Robertson, MA, RM (Association of Ontario Midwives)
- Leanne McInall, BA, BHSc, RM (Thames Valley Midwives)
- Claire Osepchook, BHSc, RM (Seventh Generation Midwives)

Disclaimer

The contents and templates in the *Resources for Midwives* are not intended to replace any processes, policies or procedures already implemented at a hospital. The resource is provided solely as an example of the various standards and responsibilities for RhIG administration process for the Midwife Practice Group (MPG) and their local hospital (with a focus on the Transfusion Medicine Laboratory) and examples of documents to support relevant information. The resource may be used in its entirety or modified to suit the purpose of the Midwife Practice Groups and hospitals. The information contained in this document is believed to be true and accurate at the time of publication, neither the authors nor the publishers can accept legal responsibility for any errors or omissions that may have occurred.



Introduction

In 2006, the Ministry of Health and Long-Term Care (MOHLTC) launched a new initiative, the Ontario Regional Blood Coordinating Network (ORBCoN). ORBCoN was mandated to engage Ontario hospitals with Transfusion Medicine Laboratories (TML) to institute educational opportunities and provide support to hospitals with utilization improvement and inventory management tools to facilitate best practices and client safety.

The Resources for Midwives is intended to assist Ontario midwives with administering Rh Immune Globulin (RhIG). Midwifery care is growing in Ontario. According to Ontario's Better Outcomes Registry & Network (BORN), midwives provided care to about 17.9% clients of Ontario's childbearing families in the 2013-2014 fiscal year (19,417 clients). Midwives are autonomous primary care providers who provide complete antenatal, intrapartum and postpartum care, including well-baby care for 6 weeks postpartum.

The administration of RhIG is regulated by the following national standards:

- Canadian Standards Association (CSA) Standards of Blood and Blood Components
- Canadian Society for Transfusion Medicine (CSTM) Standards for Hospital Transfusion Services

The process of administration of RhIG involves collaboration with a multidisciplinary team. The Transfusion Medicine Laboratory (TML) provides the product for the midwife. The TML and the midwife have shared responsibilities while handling or preparing RhIG (CSA 2015, College of Midwives of Ontario 2014).

Scope

The Resources for Midwives was developed to provide all Ontario midwives responsible for clients in the antepartum and postpartum period, with a resource that outlines the process of RhIG administration and includes documents that may be utilized to ensure that national and provincial standards are met.

The toolkit provides educational resources for both midwives and clients. There are frequently asked questions, articles, and a comprehensive power point presentation encompassing:

- Hemolytic disease of the fetus and newborn
 - red blood cell antibodies, including anti-D
- Prenatal laboratory testing
 - the significance of passive anti-D
- The use of Rh Immune Globulin (RhIG)
- Informed choice
- Weak D blood types and their significance

The Resources for Midwives contains forms for documentation of storage, transportation and administration of RhIG, standards and infusion guidelines.

This toolkit may be used in its entirety or may be modified as needed based on existing protocols and systems already used by midwife practice groups and their hospitals.



Abbreviations and Glossary of Terms

Abbreviations

AABB	American Association of Blood Banks
AOM	Association of Ontario Midwives
BORN	Better Outcomes Registry & Network
CBS	Canadian Blood Services
CMO	College of Midwives of Ontario
CSA	Canadian Standards Association
CSTM	Canadian Society for Transfusion Medicine
G&S	Group and Screen
HDFN	Hemolytic Disease of the Fetus and Newborn
IgG	Immunoglobulin G
IgM	Immunoglobulin M
MOHLTC	Ontario Ministry of Health and Long -Term Care
MPG	Midwife Practice Group
PPP	Plasma Protein Products
RBC	Red Blood Cells or “red cells”
RhIG	Rh Immune Globulin (brand name: WinRho®)
SOP	Standard Operating Procedure
TML	Transfusion Medicine Laboratory, “blood bank”
T&S	Type and Screen

Glossary

Administration group/health care professional: A group or person that receives and administers (without storing) RhIG for a specific client from a transfusion medical laboratory.

Blood component: Parts of a whole blood donation, obtained by separating the whole blood into its component parts – red cells, plasma, and platelets. Cryoprecipitate, a part of the plasma, is also considered a blood component.

Blood product: any therapeutic product, derived from human blood or plasma, and produced by a manufacturing process that pools multiple units e.g.: Rh Immune Globulin (RhIG), Intravenous Immune Globulin (IVIg), Albumin

Client: a person who receives antenatal, intrapartum, and postpartum care from a midwife

Dispensary facility: Any facility that receives, stores, distributes and administers blood components and/or products from a transfusion medical laboratory.

Group and Screen: Laboratory tests to determine a person’s blood group (blood type) and to screen the plasma for unexpected red cell antibodies. Same as a Type and Screen.



Informed Choice: Informed choice is a collaborative information exchange between a midwife and her client that supports client decision-making (CMO, 2014)

Midwife: Autonomous primary care providers who provide complete antenatal, intrapartum and postpartum care, including well-baby care for 6 weeks postpartum.
A person who has successfully completed a midwifery education program that is duly recognized in the country... (ICM, 2011)

Titre: A measurement of the concentration of an antibody in plasma. The higher the titre, the higher the concentration of antibody.

Transfusion Medicine Laboratory: A licensed hospital laboratory transfusion service that is providing blood components and/or products that are received from Canadian Blood Services (CBS) to another facility either for storage or administration.

Type and Screen: Laboratory tests to determine a person's blood type (blood group) and to screen the plasma for unexpected red cell antibodies. Same as a Group and Screen.



Tips for Management of Rh(D) negative Clients and the Use of Rh Immune Globulin

1. RhIG is used in Rh(D) negative clients only, to prevent hemolytic disease of the fetus and newborn (HDFN) due to anti-D antibody. RhIG is not indicated or effective in an Rh negative client who has already formed immune anti-D.
2. Some clients will have an unusual Rh blood type called 'weak D positive' or 'weak D'. There are many genetically-determined types of weak D. Most of these clients will not form anti-D when exposed to Rh positive blood, and are managed the same way as Rh positive clients, while others may form anti-D and are managed the same way as Rh negative clients. The only way to determine whether a weak D positive client is a candidate for RhIG is to perform genotyping. This is done at a Canadian Blood Services reference laboratory, and can be arranged through consultation with your local Transfusion Medicine Laboratory (TML).
3. HDFN can be caused by red cell antibodies other than anti-D, in both Rh positive and Rh negative clients. The most common of these antibodies are anti-K, anti-c, and anti-E. RhIG does not prevent HDFN due to any antibody other than anti-D. Follow the CMO Standards regarding Consult and Transfer of Care for these clients, who should be referred to a high-risk obstetrical unit. On the other hand, some red cell antibodies such as anti-Le, anti-Lu, and others do NOT cause HDFN.
4. All clients should have a blood group (also known as blood type) and antibody screen done at the first prenatal visit, and again at 28 weeks gestation. **RhIG must not be given** before the first group and screen is done (see next tip). At 28 weeks gestation, a blood sample for a second group and screen should be taken **before** giving RhIG.
5. When requesting a Group and Screen, always indicate if RhIG has been given, and when. This helps to differentiate between passive anti-D (present in RhIG) and immune anti-D (formed by the client's own immune system and capable of causing HDFN). RhIG administration can cause a positive antibody screen, which persists for weeks to months. A TML may be able to help you determine whether your client's anti-D is passive or immune. When in doubt, give RhIG if the client is otherwise a candidate for it.
6. When an Rh negative client delivers, the baby's blood group should be determined from a sample of cord blood. If the baby is Rh negative, RhIG is not necessary. If the baby is Rh positive, weak D positive, or of unknown Rh group, a Kleihauer-Betke or flow cytometry test is done on the client's blood to estimate the volume of fetal maternal hemorrhage during parturition, and to determine if more than one 300µg vial of RhIG is needed.
7. RhIG must be stored according to the manufacturer's directions and in compliance with national standards. The product must be stored in a temperature-monitored fridge connected to emergency power, with an alarm that is continuously monitored. It is usually stored at the local TML, where these standards can be met.
8. National standards require that every dose of RhIG be traceable to the individual client, in case of a product recall. A log sheet helps to keep track of which clients received which lot number of RhIG.



Hemolytic Disease of the Fetus and Newborn and its Prevention with Rh Immune Globulin- Information for Midwives

Hemolytic Disease of the Fetus and Newborn

Hemolytic Disease of the Fetus and Newborn (HDFN) is caused by maternal IgG antibodies directed against fetal red blood cell (RBC) antigens inherited from the father or sperm donor and absent from the mother's RBCs. Although most HDFN is caused by anti-D antibody formed by Rh(D) negative clients, RBC antibodies directed against other RBC antigens can cause HDFN, which means that Rh positive clients may also be at risk of HDFN. The most commonly implicated antibodies, other than anti-D, are anti-K, anti-c, and anti-E. Some RBC antibodies do NOT cause HDFN, such as anti-Le, anti-Lu, and others. HDFN may not be apparent in a first pregnancy due to low levels of maternal antibody, but may occur in a second or later pregnancy due to antibodies formed during the first pregnancy.

Prenatal Testing

At the first prenatal visit a Group/Type and Screen is performed on the client's blood. Her blood is grouped for ABO and Rh, and screened for unexpected antibodies to RBCs, such as anti-K, anti-c, anti-E, and others. Because antibodies other than anti-D can cause HDFN, the antibody screen is important. If a client is Rh negative, and has not previously formed anti-D, she will require Rh Immune Globulin (RhIG) to prevent HDFN in case her baby is Rh positive. The Group/Type and Screen is repeated at week 28 to determine if the client has formed any new RBC antibodies since the first group and screen. Clients who have already formed anti-D, and clients who have antibodies other than anti-D, will not benefit from RhIG. If RhIG is to be used, it is important to perform the first prenatal group/type and screen and the 28-week Group/Type and Screen before the first dose. This will avoid confusion in interpretation of a Group/Type and Screen post RhIG due to passive anti-D (see below).

Rh Immune Globulin

Rh Immune Globulin (RhIG) is a blood product derived from human plasma, and contains IgG antibody to the D antigen. It is used to prevent HDFN in Rh negative clients who have not formed anti-D. The mechanism of action is not fully understood. Given at 28 weeks of pregnancy, after potentially immunizing events such as abdominal trauma, abortion or vaginal bleeding, and again within 72 hours of delivery of an Rh positive baby, RhIG reduces the client's risk of immunization to the D antigen by 99.9%. If RhIG cannot be given within 72 hours of delivery it should be given as soon as possible, up to 28 days post-delivery. Without RhIG, the risk of immunization is 12-16%, and the risk increases with each pregnancy. RhIG does not prevent HDFN caused by RBC antibodies other than anti-D. There are no alternatives to RhIG for prevention of HDFN due to anti-D.

RhIG is effective for about 12 weeks. One 300µg dose of RhIG protects the client from a transplacental bleed of 30 mL of fetal blood (=15 mL of fetal RBCs). After delivery, a test is performed on the client's blood to determine if there was a bleed of greater than 30 mL, which would therefore require additional dose(s) of RhIG. This testing is done either by the Kleihauer-Betke method, or by flow cytometry, and is required for all Rh negative clients who deliver an Rh positive or weak D positive baby, or a baby whose Rh group is unknown.



RhIG must be stored according to the package insert, at 2° to 8°C. If not properly stored, it may lose its effectiveness or harm the recipient. National standards for the storage of blood products are very strict. For example, if RhIG is stored in a fridge, the fridge must be connected to an emergency power supply, there must be a method of monitoring the fridge temperature, and the temperature monitor must have an alarm that can be responded to at any time of the day or night, including weekends. There are alternatives to temperature-monitored fridges, such as validated transport boxes that will maintain the required internal temperature for several hours. National standards are also very strict about documenting the validation and maintenance of blood product storage containers, and documentation must be kept for specified time periods e.g. 5 years. Due to these requirements, RhIG is usually distributed from hospital blood banks which are able to maintain these standards.

All injections must be documented using a log sheet or other method so that, in the event of a product recall by the manufacturer, all doses, including their lot numbers, can be traced with certainty to individual recipients.

Documentation of Informed Choice Discussion

RhIG is a blood product. An informed choice discussion with the client must take place and be documented before RhIG is used.

Passive anti-D

If a client has received an injection of RhIG, her antibody screen may be positive (showing the presence of the anti-D antibody) for weeks or months following the injection. When ordering a Group/Type and Screen, it is very important to provide the testing laboratory with the clinical history of any RhIG injections, including the date. Without this history, it may not be possible to tell whether the anti-D is immune (actively formed by the client's immune system) or passive (due to the presence of RhIG). This may have significant implications for client management.

Weak D

Occasionally, a client will test as Rh negative at one laboratory and Rh positive at another. This may be due to the fact that different testing reagents or different test methodologies are used at different laboratories. If there are conflicting results, further testing is required to determine if the client's blood type is weak D instead of Rh positive or Rh negative. This means that she has a genetic variant of the D antigen, of which there are many.

Most people who type as weak D do not form anti-D, and may be managed in the same way as Rh positive clients, in that RhIG is not required or beneficial. The only way to be sure of the reason for the weak D blood test result is to perform genetic analysis (genotyping) of the client's DNA. Genotyping is offered by Canadian Blood Services (CBS) and will require consultation with a hospital blood bank.



Transfusion Medicine Topics for Midwives

Ontario Regional Blood Coordinating
Network (ORBCoN)



Answers About Rh Immune Globulin

What does it mean to be Rh or D negative?

If you are Rh negative, your red blood cells do not have a marker called Rh factor on them. If you are Rh positive, your blood cells do have this marker. If your blood is exposed to blood with this marker (D positive blood), your immune system will react to the Rh factor by making antibodies to destroy the blood cells carrying it. In Canada, about 85% of people are Rh positive and 15% are Rh negative.

What is Rh sensitization?

If your baby's father or the person who provided you with sperm for this pregnancy is Rh negative, your baby will also have Rh negative blood and there is no possibility of becoming Rh sensitized. But if the baby's father or the person who provided sperm to you is Rh positive, there is a possibility of having an Rh positive baby. If you are Rh negative and your baby is Rh positive you can become sensitized to Rh positive blood. This means that cells in your immune system make antibodies to fight Rh positive blood in the same way they can make antibodies to fight germs. Most of the time your blood and your baby's blood do not mix. But, sometimes your baby's cells can get into your blood stream and cause you to become Rh sensitized. There is about a 12-16% chance of becoming Rh sensitized during pregnancy. It can take as little as 0.01 mL of blood for sensitization to occur. Certain things put you at a higher risk of becoming sensitized, such as:

- Physical trauma (such as a car accident or other injury)
- Invasive genetic testing such as chorionic villus sampling (CVS) or amniocentesis
- Miscarriage
- Abortion
- Turning a breech baby (external cephalic version)
- Placental abruption (bleeding in the uterus)
- Giving birth

What are the risks to my baby if I become Rh sensitized?

Becoming Rh sensitized during your first pregnancy isn't usually a problem for the baby. But, if you get pregnant again with another Rh positive baby, your immune system can start attacking that baby's red blood cells. This can make your baby sick with something called Rh disease or Hemolytic Disease of the Fetus and Newborn. Rh disease can cause anemia, jaundice or, in some cases, very serious problems such as brain damage or even death. If you are at risk, Rh sensitization can almost always be prevented. If you are already Rh sensitized, treatment is available for Rh disease.



How do I know if I am Rh sensitized?

A blood test is the only way to check your blood type and find out if you are Rh sensitized. Your midwife will test your blood during one of your first appointments and then again at 28 weeks. If you are Rh negative you will also be offered a blood test after birth to check for Rh antibodies.

Can Rh sensitization be prevented?

Rh sensitization can be prevented with Rh Immune Globulin (sometimes called WinRho®). Rh Immune Globulin is a human blood product that has been used in Canada since 1968 to prevent Rh disease. It is a shot (injection) that contains Rh antibodies.

When your immune system makes its own antibodies to fight a germ, cells in your immune system ‘remember’ the germ. If you ever come in contact with that germ again, your immune system is ready to fight it. A similar immune response occurs if you are Rh negative and are exposed to Rh positive blood. But, if your midwife gives you shots with Rh antibodies in them, your immune system is “fooled” and it doesn’t make antibodies of its own. The Rh antibodies your midwife gives you won’t stay in your blood forever. So, the next time you have an Rh positive baby, your body won’t recognize the Rh positive blood and won’t attack the baby’s red blood cells. Getting the shot of Rh Immune Globulin is 99.9% effective in preventing Rh sensitization. During every pregnancy your midwife will offer you a shot of Rh Immune Globulin:

- at 28 weeks of pregnancy
- within 72 hours after you give birth if your baby is Rh positive
- following miscarriage, therapeutic abortion, amniocentesis, chorionic villous sampling, and trauma (like a car accident or a bad fall while pregnant)

What are the Risks of Rh Immune Globulin?

Because Rh Immune Globulin is made from human blood, there is always a small risk of being exposed to viruses that the blood donor may have carried. However, in Canada all blood donors are screened for infection and all the Rh Immune Globulin is chemically treated and mechanically filtered to kill and remove viruses.

What are the possible side effects of getting the Rh Immune Globulin shot?

Most people who receive Rh Immune Globulin don’t experience any side effects. Usually your midwife will stay with you for about a half hour after giving you the shot to make sure you don’t experience any immediate problems. Some possible side effects include:

- Pain and swelling where you received the shot
- Slight fever
- Feeling unwell (malaise)



- Headache
- Mild allergic reaction (hives)
- With any blood product, there is a small risk of anaphylaxis (a severe allergic reaction that can make it difficult to breathe)

What happens if I choose not to get Rh Immune Globulin?

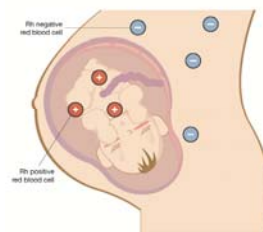
Some people are not comfortable receiving any human blood products (such as Rh Immune Globulin or blood transfusions). Or, you may have other concerns about receiving this shot. You are always free to refuse any intervention that your midwife offers to you. It is important to understand that:

- Without Rh Immune Globulin, there is a 12 to 16% chance that your body will form Rh antibodies. If you become Rh sensitized and become pregnant again, there is a risk that your next baby will become very sick or that the pregnancy will not be able to be carried to term.
- The problems related to Rh disease tend to get worse with each Rh positive pregnancy you have.
- There are no effective alternative treatments to prevent Rh disease. Rh Immune Globulin is the only way to prevent Rh disease in babies.

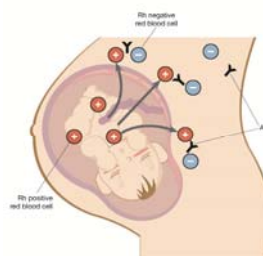
If you have any questions after reading this handout, talk to your midwife. If it helps, you can write down any questions you may have and bring this sheet with you to your next appointment.

Rh Sensitization

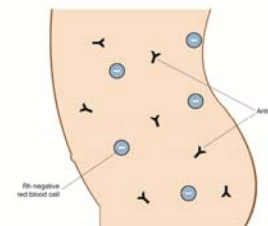
Rh negative (-) woman with Rh positive (+) baby.



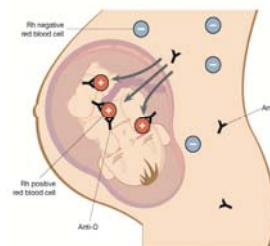
Baby's cells enter the woman's blood stream and she may become sensitized. This means the woman's body makes antibodies (Y) to fight the baby's Rh positive (+) red blood cells.



The woman's body will keep a memory of these antibodies (Y) in case Rh positive blood cells enter her bloodstream again in the future.



If the woman becomes pregnant again with an Rh positive (+) baby, her body may make large amounts of antibodies (Y) to attack the baby's blood cells. This can make the baby very sick with a disease called Rh disease or Hemolytic Disease of the Fetus and Newborn.



Memorandum of Understanding

Between

Enter Hospital.

And

Enter Midwife Practice Group Name.

For

Hospital Transfusion Medicine Laboratories (TML) and Midwife Practice Group (MPG) PURPOSE

The purpose of this agreement is to establish responsibility and accountability of the two parties named herein to provide safe and effective access to and administration of Rh Immune Globulin (RhIG) for clients in Ontario.

GOALS AND FORMS OF COOPERATION

The main interests of this partnership are to:

- Mitigate risk and maximize client safety through compliance with established, evidence based national standards RhIG.
- Understand the respective roles, responsibilities and expectations of the licensed TML that provide RhIG and the MPG that receives and administers the RhIG.
- Outline the relationship and expectations of each party for ongoing consultation, and support as well as policy and procedure development in order that the standards may be met and continuously maintained.
- Determine the expectations of voluntary accreditation requirements for the MPG.

COORDINATION

The medical, technical and administrative coordination of this agreement is appointed to the following facility and group : < insert facility name(s) >

The medical, technical and administrative coordination shall address and resolve logistical and administrative issues that may arise during the term of this agreement, and shall supervise and report on the activities conducted within the framework hereof.



CLAUSE

A. Definitions

Transfusion Medicine Laboratory: A licensed hospital laboratory transfusion service that provides blood components and/or products that are received from Canadian Blood Services (CBS) to another facility either for storage or administration.

Dispensary facility: Any facility that receives, stores, distributes and administers blood components and/or products received from a Transfusion Medicine Laboratory.

Examples:

- Acute care facilities that do not have licensed laboratories on site that keep an emergency supply of any blood and blood components/products
- Midwife Practice Group (MPG) that administers Rh Immune Globulin (RhIG)

Administration group/health care professional: A group or person that receives and administers (without storing) RhIG for a specific client from a Transfusion Medicine Laboratory.

Examples:

- Midwife Practice Group/Midwife that administers RhIG which has been supplied by a Transfusion Medicine Laboratory.

Blood product: any therapeutic product, derived from human blood or plasma, and produced by a manufacturing process that pools multiple units e.g.: Rh Immune Globulin (RhIG), Intravenous Immune Globulin (IVIg), Albumin

B. Roles and Responsibilities

General Responsibility: (All Parties)

- To the extent possible, the participating institutions will ensure that RhIG products are handled, stored, distributed, transported and administered in a manner that prevents damage, limits deterioration, maximizes client safety and meets requirement standards. (Refer to: CSA Standards for Blood and Blood Components, CMO Standards for Midwives, and CSTM Standards for Hospital Transfusion Services)
- Enter other responsibilities as agreed by the participating institution members; e.g. may include responsibilities for training, competency assessment, document development, record transport, storage and administration logs, and/or management of adverse reactions etc.

Transfusion Medicine Laboratory: <Examples of responsibilities: Develop operating procedures for the receipt, handling, storage, preparation for administration, and administration of products>

- Document receipt, storage and issuing
- Management of recall information received from blood product supplier (Canadian Blood Services)



- Enter other responsibilities as agreed by the participating institution members.

Midwife Practice Group: <Examples of responsibilities>

- Document receipt and administration of RhIG from TML, product name, lot number, expiry dosage, date and time administered, who administered the RhIG, recipient name and identification number
- Upon receipt of RhIG, transport RhIG in a secure and validated transport bag
- Discuss and obtain documentation of informed choice from client
- Enter other responsibilities as agreed by the participating institution members.

C. Timelines

- Expectations for Completion
- Expiry date of MOU

IN WITNESS WHEREOF, each of the undersigned parties represents and warrants that it has the full authority to sign and enter into this agreement on behalf of the institution that each purports to represent.

SIGNATORIES

<p>Enter Hospital Name.</p> <p>Name: _____</p> <p>Title _____</p> <p>Date: _____</p>	<p>Enter Midwife Practice Group Name.</p> <p>Name: _____</p> <p>Title _____</p> <p>Date: _____</p>
---	---



Rh Immune Globulin: Documentation of Informed Choice Discussion

Client Name: _____

Health Card Number: _____

D.O.B. (DD/MM/YYYY): _____

Date (DD/MM/YYYY): _____ Time: _____

1. I have been informed by _____ or his/her designate, that I may need Rh Immune Globulin (RhIG) during my pregnancy or after delivery of my baby.
2. The benefits and risks of RhIG have been explained to me.
3. The alternatives to RhIG have been explained to me.
4. The consequences of not receiving RhIG have been explained to me.
5. I have had the opportunity to ask questions about my care. All of my questions have been answered to my satisfaction.

I choose to use Rh Immune Globulin as part of my care.

I choose **not** to use Rh Immune Globulin as part of my care.

Signature of client

Signature of midwife

Name of midwife (printed)

Date (DD/MM/YYYY) and Time



RhIG Transportation

RhIG must be stored according to the manufacturer's package insert directions (2°-8°C).

RhIG will remain stable at the temperature until the stated expiry date.

When RhIG is transported from the dispensing facility, it should remain in a controlled environment.

A nationally accepted shipping container was selected based on innovation, ruggedness, durability and ease of use. The shipping container was validated both in lab and in field. The validation was performed in collaboration with Ontario and Newfoundland for the entire country and is available for reference on www.transfusionontario.org.

These shipping containers, named Credo Promed are available for purchase at http://www.pelicanbiothermal.com/sites/default/files/9-credo_promed_v6_0915.pdf and must have a mini validation performed prior to implementation into the transport program.

ORBCoN is available as a resource to provide guidance, support, and Standard Operating Procedures for the initial mini validation. Temperature checks must be performed annually as defined by the specific midwife user group in order to meet standards.



Midwife Practice Group

Address

Record of Rh Immune Globulin Storage and Transport

Product Name	Lot Number	Expiry Date dd/mm/yyyy	Dispensing Facility	Person dispensing RhIG	Issued in controlled container? Y/N	Packing Configuration intact? Y/N	Receiving Midwife



Midwife Practice Group

Address

Record of Rh Immune Globulin Administration

Client Name (Last, First)	Date of Birth (DD/MM/YYYY)	Health Card Number	Product Name	Product Lot number	Expiry date	Dose (µg)	Date Given (DD/MM/YYYY)	Given by Print name (initials)



Standards for Blood and Blood Components, CSA Z902-15 Canadian Standards Association Excerpts for Midwives

The following list contains only edited excerpts from this Standard, and is not intended to be exhaustive. The complete Standard is copyrighted by and can be purchased from the Canadian Standards Association at www.csagroup.org. The CSA Standard is referenced to several other publications, including the Canadian Society for Transfusion Medicine (CSTM) *Standards for Hospital Transfusion Services*. Excerpts from the CSTM Standards are provided in a separate document.

The CSA Standard applies to facilities that collect, process, store, and use blood components (e.g. red blood cells, plasma, platelets, and others) for transfusion. Rh Immune Globulin is a blood product, not a blood component. While the CSA Standard does not specifically apply to organizations that manage blood products but not blood components, these organizations are encouraged to review the relevant requirements for blood products and incorporate them as appropriate into their procedures. An organization, such as a hospital, that supplies midwives with RhIG may require compliance with relevant CSA Standards before supplying RhIG. The language used in this Standard may differ from language usually used by midwives.

11.2 Information to recipients, including Informed consent

11.2.1 An operating procedure shall be in place for obtaining informed consent of the recipient prior to the administration of blood products. Information shall include: a) a description of the blood product; b) the associated risks and benefits, including life-threatening risks; and c) alternatives, if appropriate, including benefits and risks.

11.4 Transfusion

11.4.12 For the administration of blood products, the blood product manufacturer's instruction for preparation shall be consulted.

11.9 Rh-Immune Globulin (RhIG)

11.9.1 All women undergoing delivery, abortion, or invasive obstetric procedures shall have their Rh group determined. A policy shall be in place regarding the administration of Rh-Immune Globulin (RhIG) to women in whom the result for weak D is found to be positive.

11.9.2 The record of administration of RhIG shall include the lot number of the product.

11.9.4 There shall be written procedures for the administration of RhIG. All Rh-negative women should receive Rh-Immune Globulin at 28 weeks gestation and within 72 h after delivery, abortion, amniocentesis, or any other event or procedure that can cause fetomaternal hemorrhage. Exceptions shall be a) if the fetus or neonate is confirmed Rh-negative (including a weak D test); or b) if there is evidence of immunization to D not related to RhIG therapy.



11.9.5 If 72 h have passed after delivery, the RhIG may be given up to 28 days after delivery.

11.9.6 A postpartum maternal blood sample from Rh-negative women at risk shall be tested by a method that will detect a significant fetomaternal hemorrhage requiring more than a single dose of RhIG for effective prophylaxis.

14 Transfusion service responsibilities regarding blood products used in the facility

14.1.1 The manufacture, labelling, and commercial distribution of blood products are covered by federal legislation and oversight in Canada. Once they enter the health care facility, blood products become the responsibility of the transfusion service or the pharmacy, depending on the facility's policies for each product. This Clause establishes requirements for transfusion services that store and issue blood products and is intended to align the facility's procedures for blood products with its procedures for blood components.

14.1.2 If a transfusion service is responsible for blood products, it shall have operating procedures for the receipt, handling, storage, preparation for administration (if applicable), and administration of those products. The procedures shall be designed to ensure that the blood product manufacturer's instructions are followed for each of the functions performed in the facility and that the performance of these functions is documented.

14.2 Records

The facility shall document the following activities as they apply to the blood products it handles: a) receipt; b) additional labelling as required to maintain traceability; c) storage; d) requests; e) preparation for administration (if done in the facility); f) administration; g) destruction or return to manufacturer of unused product; and h) adverse events.

14.5 Administration

At the time of administration, the recipient's medical chart shall be updated with the a) lot number or identification number traceable to the lot number; b) name of the product administered and volume/dose; c) date and time of the administration (both start and finish) and; d) identity of the person who administered the product.

14.6 Storage and transportation

14.6.1 Blood products shall be stored and transported in accordance with the environmental and handling conditions specified in the manufacturer's instructions. Blood products shall not be used after their expiration date unless it is with the written approval of a physician.

14.8 Adverse events

The facility's operating procedures shall include provisions for documenting, reporting, evaluation, and follow-up of all adverse events relating to the blood products it handles, including the necessary notifications of the distributor, manufacturer, and regulatory authorities.



20.6.3 Records of Recipients

20.6.3.3 Investigations and reports of the following recipient events as related to the safety of the product shall be retained for 10 years: a) errors and accidents that could lead to serious adverse reactions; or b) unexpected or serious adverse events.

22 Buildings and facilities

22.1.7 There shall be access to an emergency power source for critical equipment in the event of a power failure.

23 Mechanical equipment

23.1.2 All mechanical equipment used by the facility shall be a) appropriate for its intended use; b) properly installed and tested; and c) calibrated and maintained in accordance with the manufacturer's instructions.

23.3.4 Records of calibration and performance verification of equipment shall be retained for 3 years, or in accordance with the manufacturer's instructions, whichever is greater. Records should indicate actual results observed. The format of the records should indicate the criteria for acceptable ranges in a way that is clear to the person making the entry.

Record Retention Requirements (Table 4) (Z902-15 CSA page 130)

- A-24 Documentation of calibration and performance verification of critical equipment – 3 years minimum



Standards for Hospital Transfusion Services, version 3, 2011 Canadian Society for Transfusion Medicine (CSTM) Excerpts for Midwives

The following list contains only edited excerpts from this Standard, and is not intended to be exhaustive. The complete Standard is copyrighted by and can be purchased from the Canadian Society for Transfusion Medicine at www.transfusion.ca.

The CSTM Standard applies to hospital transfusion services. While the Standard does not specifically apply to organizations that manage blood products (e.g. RhIG) but not blood components (e.g. red blood cells, plasma, platelets, and others), these organizations are encouraged to review the relevant requirements for blood products and incorporate them as appropriate into their procedures. Rh Immune Globulin is a blood product, not a blood component. An organization, such as a hospital, that supplies midwives with RhIG may require compliance with relevant CSTM Standards before supplying RhIG. The language used in this Standard may differ from language usually used by midwives.

3.2 Blood Component and Blood Product Storage

3.2.1.1 Equipment used for blood component and blood product storage, including that situated outside the transfusion service, shall be connected to an emergency power supply. The power supply system shall be checked at defined intervals to ensure an immediate switch to emergency power.

3.2.1.2 Equipment for blood component and blood product storage shall maintain a temperature within the appropriate temperature range.

3.2.1.3 There should be a system in place to continuously monitor and record the temperature of all storage devices.

3.2.1.4 There shall be a documented record of temperature at least every four hours for storage devices without a continuous recorder.

3.2.1.5 The transfusion service (TS) shall perform a daily review of the temperature monitoring system to ensure it is operating correctly.

3.2.1.6 When a daily temperature check is not possible, the laboratory shall implement a process to ensure that the storage device has maintained an appropriate temperature between visual checks. This shall be documented prior to the use of the blood products.

3.2.2.1 Refrigerators and freezers for blood component and blood product storage shall be validated to maintain an appropriate temperature throughout the storage area.



3.2.2.2 Refrigerators and freezers when in use for storage of blood components and blood products shall have an audible temperature alarm with a back-up power supply. The alarm and back-up power supply for the alarm shall be checked at least monthly, and the check shall be documented. The alarm warning shall signal in a place that is continuously monitored or staffed so immediate corrective action can be taken.

3.2.2.3 Refrigerator and freezer alarm activation points shall be set at temperatures that allow for corrective action to be taken prior to the blood products reaching unacceptable temperatures. The activation points shall be verified according to the manufacturer's recommendation or at least annually.

3.2.2.4 All thermometers used in refrigerators and freezers that store blood components and blood products shall be checked against a certified calibrated thermometer at least annually, and the check shall be documented. Appropriate corrective action shall be taken if required and documented.

5.1 Blood Components and Blood Products

5.1.1.1 Policies, processes and procedures shall be established to maintain traceability of all blood components and blood products from the issuing facility to the final disposition at the receiving facility.

5.1.2 Storage

5.1.2.1 Blood components and blood products shall be stored under optimal temperature conditions as recommended by the blood supplier and/or manufacturer.

5.1.2.2 A process shall be in place to ensure the maintenance of storage conditions in the event of a power failure or other disruption.

5.1.2.3 Blood components and blood products shall be stored separately from all other substances...This may involve the use of clearly segregated areas within the same storage equipment.

5.4.5 Rh Immune Globulin (RhIG)

5.4.5.1 Policies, processes and procedures shall be established to ensure that all potential candidates for RhIG therapy shall have their Rh type and antibody screen determined.

5.4.5.2 A policy shall be established regarding the administration of RhIG to women who type as weak D positive.



5.4.5.3 RhIG should be administered to each Rh negative woman not known to be immunized to the D antigen, in the following situations: a) at 28 weeks gestation; b) following delivery of an Rh positive neonate (including weak D positive or Rh unknown); c) following spontaneous or therapeutic abortion; d) following amniocentesis; e) following any procedure or event known to be associated with increased risk of Rh immunization due to fetomaternal hemorrhage.

5.4.5.4 RhIG should be administered within 72 hours of delivery or other possible immunizing event. If 72 hours have passed after delivery, the RhIG should be given up to 28 days. The dosage schedule shall be as recommended by the manufacturer.

5.4.5.5 When a weakly reactive anti-D is detected in an Rh negative woman, a determination should be made as to whether she received RhIG during her pregnancy. If receipt of RhIG cannot be established, the woman shall be treated as in 5.4.5.4.

5.4.5.6 A test shall be performed to determine the amount of fetomaternal hemorrhage in an eligible candidate. If a fetal bleed is detected, an appropriate dose of RhIG shall be given according to the manufacturer's recommendations.

5.6.1 Transportation

5.6.1.5 Blood components and blood products shall be transported in a manner that will ensure that the specified conditions (Appendix B) are maintained at all times. Blood components and blood products shall be shipped in a validated shipping container, or evidence that the transportation conditions were in compliance shall be documented. Transportation time shall not exceed the limit of the validated transport container.

5.6.1.7 Blood products with a specified storage temperature of 1-6°C shall be maintained during transport at a temperature of 1-10°C for no longer than 24 hours.

5.7.5 Issuing Records

5.7.5.3 For each blood product issued, a record keeping system shall be in place which documents: a) recipient's family and given names; b) recipient's identification number; c) name of blood product; d) lot number; e) volume and/or potency; f) manufacturer; g) dosage/vials used; h) visual inspection; i) date and time of issue; j) identity of the person issuing the blood product; k) identity of the person transporting the blood product to the recipient's location.

5.7.5.4 The record system shall ensure that a copy of all the information relating to the recipient and the transfused blood component or blood product forms a permanent transfusion record for the recipient. The record keeping system shall be designed to make it possible to trace the blood product.



6.6 Retention of Other Records

6.6.5 The temperature monitoring records for storage of blood components and blood products shall be retained for 5 years.

6.6.9 Equipment records shall be retained for the life of the equipment post decommissioning plus 5 years. Records shall include: a) validation protocols, results and conclusions; b) calibration results, indicating the observed result and the acceptable range; c) preventive maintenance; d) malfunction, service, and repair, including the activities performed, the name of the contractor, and any deviations from specification; e) disposal records.

10.15 Food and beverage shall not be stored in areas designated for the storage of blood components, blood products, reagents, and blood samples.

Record Retention Requirements (Appendix A) (CSTM Version 3 page 83)

Indefinitely: Blood component and blood product final disposition (6.3.5), serious adverse transfusion events (6.5.5), lookback and traceback documents (6.6.1), blood supplier correspondence related to blood components and blood products (6.4.5).

5 years: temperature monitoring of blood storage devices (6.6.5), minor adverse transfusion events



References

1. BORN Ontario. www.bornontario.ca. [Online].; 2016 [cited 2016 February 1. Available from: <https://www.bornontario.ca/assets/documents/FINAL%20English%20Jan%202016.pdf>.
2. College of Midwives of Ontario. www.cmo.on.ca. [Online]. Toronto; 2014 [cited 2015 November 17. Available from: <http://www.cmo.on.ca/wp-content/uploads/2015/07/Informed-Choice.pdf>.
3. International Confederation of Midwives. www.internationalmidwives.org. [Online].; 2014 [cited 2015 November 17. Available from: <http://www.internationalmidwives.org/who-we-are/policy-and-practice/icm-international-definition-of-the-midwife/>.
4. Canadian Standards Association (CSA) Group. Z902-15 Blood and blood components. 2015. Z902-15.
5. Canadian Society for Transfusion Medicine. Standards for Hospital Transfusion Services. 2011 February.
6. Maynard K. Administration of Blood Components. In Fung MK, Grossman BJ, Hillyer CD, Westhoff CM. Technical Manual 18th Edition. Bethesda: AABB; 2014. p. 545.
7. Qureshi H, Massey E, Kirwin D, Davies T, Robson S, White J, et al. Transfusion Medicine-Official Journal of the British Blood Transfusion Society. [Online].; 2013 [cited 2015 October. Available from: <http://onlinelibrary.wiley.com/doi/10.1111/tme.12091/pdf>.
8. Association of Midwives. www.ontariomidwives.ca. [Online].: Association of Ontario Midwives; 2015. Available from: http://www.ontariomidwives.ca/images/uploads/newsletter/Ontario_Midwife_Fall_2015_Web.pdf.
9. Canadian Blood Services. Clinical Guide to Transfusion. 2013. CBS.
10. American Association of Blood Bankers. Guidelines for Prenatal and Perinatal Immunohematology. 2005. AABB.
11. Flegel WA. Molecular genetics and clinical applications for RH. Transfusion and Apheresis Science. 2011; 44: p. 81-91.
12. Sandler S. G., Flegel W.A, Westhoff C.M., et al. It's time to phase in RHD genotyping for clients with a serologic weak D phenotype. Transfusion. 2015 March; 55: p. 680-689.

