Public Health Nurse Administration of Intramuscular Immunoglobulin (Ig) Final

Provincial Population & Public Health Guideline

Regional and Clinical Supports, Population and Public Health

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1. Abbreviations

AEFI Adverse events following immunization

lg Immunoglobulin

IM Intramuscular

IV Intravenous

IVIg Intravenous Immunoglobulin

IMIg Intramuscular Immunoglobulin

2. Purpose

To provide recommendations and best practice guidance regarding the intramuscular (IM) administration of immunoglobulin (Ig).

3. Scope

This guideline applies to public health nurses managing communicable disease investigations. It assists in informing practice regarding public health nurse IM administration of Ig to susceptible contacts.

The scope of practice for Registered Nurses includes the administration of IMIg without the need for an order. For additional details, please visit: https://crnm.mb.ca/wp-content/uploads/2022/01/ScopeofPractice.pdf

4. Background

Ig is made from donated human blood plasma that contains antibodies to protect against infections (e.g., Hepatitis A and Measles). Ig can provide immediate, short-term protection when given within the indicated time frame. It can prevent infection or make the illness less severe.

Ig is generally given to persons who are unable to receive the vaccine, and/or individuals at higher risk of complications from diseases such as infants, pregnant individuals, and persons with weakened immune systems.

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5. Procedure

Administering intramuscular immunoglobulin (IMIg) requires adherence to specific procedures to ensure safety and efficacy. The process outlines indications for use of Ig, informed consent, contraindications, precautions, Ig ordering processes and Ig administration.

5.1. Indications for use of immunoglobulin Preparations

Indications for use of Ig preparations may include factors such as the patient's medical condition, immune status, and specific indications for treatment.

Refer to the communicable disease protocols below for indications of Ig use.

Note: Product monographs in the links provided below are examples of various Ig preparations. Confirmation of product in stock is required.

Immunoglobulin (lg):

- Manitoba Health Seniors and Long-Term Care Communicable Disease Protocol Measles (Rubeola)
 www.manitoba.ca/health/publichealth/cdc/protocol/measles.pdf
- Manitoba Health Seniors and Long-Term Care Communicable Disease Protocol Hepatitis A www.gov.mb.ca/health/publichealth/cdc/protocol/hepa.pdf
- GamaSTAN® S/D Product Monograph <u>Microsoft Word -</u>
 <u>~db5_Oc75c934e33e242f8bacd777dd92926ec.doc (hres.ca)</u>

Hepatitis B Immunoglobulin (HBIg):

- Manitoba Health Seniors and Long-Term Care Communicable Disease Protocol Hepatitis B www.gov.mb.ca/health/publichealth/cdc/protocol/hepb.pdf
- Post-exposure Prophylaxis for HIV, HBV and HCV INTEGRATED PROTOCOL FOR MANAGING EXPOSURES TO BLOOD AND BODY FLUIDS IN MANITOBA www.manitoba.ca/health/publichealth/cdc/protocol/hiv_postexp.pdf#page=23
- HyperHEP B® 00062962.PDF (hres.ca)



Tetanus Immunoglobulin (TIg):

- Manitoba Health Seniors and Long-Term Care Communicable Disease Protocol Tetanus www.gov.mb.ca/health/publichealth/cdc/protocol/tetanus.pdf
- HYPERTET® S/D PRODUCT MONOGRAPH (hres.ca)

Varicella Immunoglobulin (Varlg):

- Manitoba Health Seniors and Long-Term Care Communicable Disease Protocol Varicella www.gov.mb.ca/health/publichealth/cdc/protocol/varicella.pdf
- VariZIG® Microsoft Word ~db5 Od53fa375ad7640c79884fed5192374da.docx (hres.ca)

Rabies Immunoglobulin (Rablg)

- Manitoba Health Seniors and Long-Term Care Communicable Disease Protocol Rabies pdf.hres.ca/dpd pm/00062278.PDF
- HYPERRAB® S/D pdf.hres.ca/dpd_pm/00036488.PDF

5.2. Informed Consent

Informed consent is a crucial aspect of medical treatment, including Ig therapy. It involves providing clients with comprehensive information about the treatment, including its purpose, potential benefits, risks, alternatives, and any uncertainties involved. Clients are given the opportunity to ask questions and make an informed decision about whether to proceed with the treatment. For further information on Manitoba Health Seniors and Long-Term Care Informed consent guidelines:

www.manitoba.ca/health/publichealth/cdc/protocol/consentguidelines.pdf

For written consent documentation, if needed:

Child Adolescent Immunization Consent Form (gov.mb.ca)

Adult Immunization Consent Form (gov.mb.ca)

5.3. Contraindications

Identifying any contraindications to Ig administration is crucial to ensure patient safety. Prior to Ig administration, assess the client's past medical history in the following areas:

 History of anaphylactic reaction to a previous dose of any Ig product or any components (2).

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History of isolated IgA deficiency. (1,4) Such persons have the potential for developing antibodies to IgA and could develop anaphylactic reactions to subsequent administration of blood products that contain IgA.1(1,4).

For those with underlying health conditions, consultation with the MOH and/or the client's health care provider may be required to rule out any contraindications (1).

5.4. **Precautions**

Human Ig preparations are among the safest blood-derived products available.

Ig is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, and theoretically, the Creutzfeldt-Jakob (CJD) agent that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, testing for the presence of certain current viral infections and inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease (4).

5.5. Immunoglobulin Ordering Procedures

The following procedure for ordering Ig ensures timely availability and appropriate utilization of this therapy.

- Orders for Ig can be placed using the Vaccine and Biologics Order Form available at:
 - www.gov.mb.ca/health/publichealth/cdc/protocol/vaccinebiologics.pdf or via PHIMS as an URGENT order.
- For After hours, contact the Provincial Distribution Warehouse at 204-948-1333 or Toll-free at 1-855-683-3306 and advise the customer service representative of order/requisition number, Medical Officer of Health (MOH) authorizing order and that the order is urgent.

Note: Varicella immunoglobulin (Varlg) is obtained through Canadian Blood Services. Contact: 204-789-1034

Immunoglobulin Administration 5.6.

Ig Administration involves the proper delivery of Ig therapy to patients. The process includes the following steps:



5.6.1. 7 Rights

The "7 Rights" of medication administration are a set of principles designed to ensure the safe and accurate administration of medications. They include:

Right Client: Ensuring that the medication is administered to the correct client by verifying their identity using at least two unique identifiers (e.g., name and date of birth).

Right Time/ schedule: Ensuring that the medication is administered at the correct time according to the prescribed schedule. This involves adhering to specific timing instructions, such as time since exposure to infectious agent.

Right Medication: Confirming that the medication being administered is the right medication prescribed for the client. This involves checking the medication label against the medication order.

Right Dose: Administering the correct dose of medication as prescribed by the healthcare provider. This includes verifying the dosage calculations if necessary.

Right route/ needle/ technique: Administering the medication via the correct route as specified in the prescription or order (e.g., intramuscular, etc.).

Right injection site: The right injection site is crucial for the safe and effective administration of Ig therapy. The choice of injection site depends on the specific product being administered and volume of Ig required,

Right Documentation: Recording the medication administration accurately and promptly in the patient's medical record e.g., PHIMS. This includes documenting the medication name, dose, route, time, and any relevant observations or patient responses.

Adhering to these "7 Rights" helps minimize medication errors, ensure patient safety, and promote effective medication management practices in healthcare settings.

5.6.2. Site Selection

Use clinical judgment to select the appropriate injection site and needle size. This assessment is based upon:

- client's age
- volume of biological product to be administered.
- viscosity of biological product
- adequacy of muscle mass
- recommended route of administration for the biological product
- number of products to be administered.



Immunoglobulin Preparations (HBIg, Ig, TIg, VarIg, RabIg) (3)

(Table adapted from BC Communicable Disease Manual Chapter 2- Immunization Part 4 Biologics Products)

Client Age	Needle Length	Size (Gauge)	Site	Route	Maximum Volume Per Site
Infants under 12 months	7∕8" - 1"	25	Ventrogluteal ¹ , ² Vastus lateralis	IM IM	1 mL 1 mL
Children 12 months to 4 years (inclusive)	1"	22-25	Ventrogluteal ^{2,3} Vastus lateralis Deltoid	IM IM IM	1 mL 2 mL 1 mL
Children 5 years to 18 years	1" - 1½" 1" 1" - 1½" 1" - 1½"	20-25 22-25 20-25 20-25	Ventrogluteal ^{2,3} Deltoid ⁴ Vastus lateralis Dorsogluteal ⁵	IM IM IM	3 mL 1 mL 3 mL 3 mL
Adults 19 years and older	1" – 1½"	20-22 20-22 20-22 20-22	Ventrogluteal ^{2,3)} Deltoid ⁴ Vastus lateralis Dorsogluteal ⁵	IM IM IM IM	4 mL 2 mL 5 mL 5 mL

Intramuscular Injections

<u>Ventrogluteal Site</u>: https://canvax.ca/intramuscular-injection-ventrogluteal-site (5,6,7,12)

The ventrogluteal site is the preferred site for the IM injection of large volumes of Ig preparations.

- This site can be used in those 7 months of age and older.
- This muscle is accessible in the supine, prone, and side-lying position.
- The right hand is used for locating the site on the left hip; the left hand is used for locating the site on the right hip.
- Place heel of the hand over the greater trochanter of the client's hip with wrist almost perpendicular to the femur. Point the thumb toward the client's groin and the fingers toward the client's head. Point index finger to the anterior superior

¹ The ventrogluteal site can be used in children 7 months of age and older.

² The ventrogluteal muscle is the preferred site for administration of all immunoglobulin preparations to children and adults.

³ Alternate sites for the administration of immunoglobulin preparations are the deltoid and vastus lateralis; in exceptional circumstances, the dorsogluteal site may be used.

⁴ The deltoid is not to be used for the administration of Rablg. Its use should be reserved for the administration of rabies vaccine.

⁵ Use of the dorsogluteal site is only recommended when the ventrogluteal and vastus lateralis sites have had maximum volumes of an immunoglobulin preparation injected and an additional volume still needs to be administered. This is due to the possibility of sciatic nerve injuries when the injection is done in the dorsogluteal site.



iliac spine and extend the middle finger back along the iliac crest toward the buttock. The index finger, the middle finger, and the iliac crest form a V-shaped triangle. The injection site is the center of the triangle.

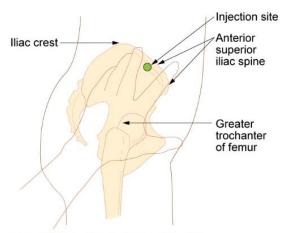


Figure 18.31 Locating the Ventrogluteal Site

<u>Deltoid Site</u>: <u>Intramuscular and Subcutaneous Injections: A guide for Pharmacists | CANVax</u> (5,6,12)

- The deltoid muscle injection site is 4 cm below the acromion process for adults.
 In children 3-18 years of age injections should be given 3-5cm below the acromion process.
- The injection site is typically about 2 to 3 finger-widths below the acromion process.

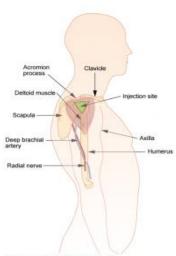


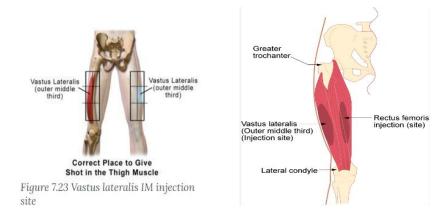
Figure 7.24 Deltoid intramuscular injection site

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<u>Vastus Lateralis (Anterolateral Thigh) Site Intramuscular Injection</u>: <u>Intramuscular Injection</u>: <u>Int</u>

- Define the site by dividing the space between the trochanter major and the femur and the top of the knee into three parts; draw a horizontal median line along the other surface of the thigh.
- The injection site is in the middle third, just above the horizontal line.



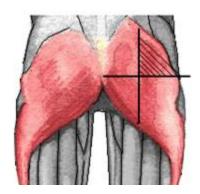
<u>Dorsogluteal Site Intramuscular Injection</u>: <u>Intramuscular Injection: Dorsogluteal Site | CANVax (</u>5,6,9,12)

The dorsogluteal site is only to be used for the IM injection of large volumes of Ig preparations when the ventrogluteal and vastus lateralis sites have had maximum volumes of an Ig preparation injected, and an additional volume still needs to be administered. This is due to the possibility of sciatic nerve injuries when the injection is done in the dorsogluteal site.

- This site should only be used in individuals over 5 years of age.
- Place client in a prone, side lying, or standing position.
- Encourage a posture that will provide muscular relaxation and reduce discomfort (i.e., turning toes inward when prone, flexing the upper leg at hip and knee when lying on the side, flexing knees, and leaning the upper body against a support when standing).
- Define the site by dividing the buttock into 4 quadrants. The injection site is the centre of the upper outer quadrant.
- Direct the needle anteriorly (i.e., if the client is lying prone, direct the needle perpendicular to the table's surface, not perpendicular to the skin plane).

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5.6.3. Considerations for Intramuscular Immunoglobulin Administration

Before administering parenteral drug products, it's essential to visually inspect them for expiry date, particulate matter, and any signs of discoloration. Refer to examples of product monographs in section 5.1 for detailed product descriptions.

When administering Ig and a vaccine simultaneously, separate limbs must be used in order to prevent any potential interference between the two substances.

Note:

- When determining the dose for Ig administration, it's crucial to carefully consider the route of administration, especially regarding maximum volumes for IM versus IV administration routes and the maximum volume per IM site (refer to section 5.6.2).
- Infiltrating a bite wound with rabies Ig (RabIg) is a standard recommendation for preventing rabies infection following exposure to the rabies virus. Generally, RabIg wound infiltration administration is done within an acute care setting, however PHNs are able to administer RabIg IM for non-complicated wounds where wound infiltration is not required, consultation with an MOH is recommended.

5.6.4. Pain & Anxiety Control

Pain and anxiety control are important considerations during Ig administration, especially for patients who may require repeated injections or infusions.

Encourage comfort and relaxation (14).



- Encourage slow deep breathing.
- Some clients may benefit from having a support person attend the appointment with them.
- If client reports a history of fainting with needles or feeling dizzy, ensure they are lying down when receiving the injection and remain lying down for a few minutes post-immunization.

Distraction (14)

- Redirect the client's attention away from the needle. Talk with them or ask them
 questions about a subject other than immunization, encourage them to read,
 play a video game, watch a video on their phone, play music, practice slow deep
 breathing, or rub their arm.
- · Comfort techniques for younger children and infants, i.e. breastfeeding.

Topical Anesthetics (14)

Clients may attend an immunization clinic with a numbing cream, patch, spray or
other agent that has been applied prior to arriving at the clinic. These agents
numb the surface of the skin so the individual will feel little to no pain with the
injection. Whenever a topical anesthetic is applied, it must be removed before
proceeding with the immunization.

5.6.5. Monitoring for Adverse Events Following Intramuscular Immunoglobulin Administration

Local pain and tenderness at the injection site are common, urticaria, and angioedema may occur. Other side effects of Ig can include flushing, headache, chills, nausea, feeling unwell, fever and pruritus. Anaphylactic reactions, although rare, have been reported following the injection of human Ig preparations.

Patients should be closely monitored for at least 15 minutes after IMIg administration for immediate adverse reactions such as syncope or anaphylaxis.

Vasovagal Syncope or Fainting,

Is an event that can occur within the context of giving immunizations with rapid onset and recovery. It is common in those who have anxiety when receiving immunizations. Some of the common signs and symptoms may include some or all of the following:

- complaint of feeling faint or light-headed
- pallor
- loss of consciousness which may be accompanied by brief clonic seizure activity



- salivation
- low pulse
- nausea and vomiting
- diaphoresis (sweating), cool clammy skin
- respiratory rate is normal and not labored but may be shallow
- cardiovascular signs include bradycardia and faint peripheral pulses but usually the carotid pulse is strong

Vasovagal Syncope Management

- If conscious, place the client in a supine (lying on their back) position and elevate the lower extremities.
- If loss of consciousness or vomiting has occurred or is imminent, position the client lying on one side.
- Pregnant clients should be positioned on their left side.
- Apply a cool pack to back of neck to assist with diaphoresis. Recovery of consciousness and resolution of limb jerking usually occurs within a minute or two.
- The client may remain pale, diaphoretic, and mildly hypotensive for several minutes.
- Continue monitoring and providing support to the client who has fainted until signs and symptoms have stabilized.
- If client has fallen and sustained an injury (e.g., concussion) they may need to be further assessed by a health care practitioner.

Anaphylaxis

Every provider should be familiar with the signs and symptoms of anaphylaxis and be prepared and equipped with an anaphylaxis kit to act quickly.

Refer to your regions or site's specific anaphylaxis training requirements, protocols, and clinical practice guidelines.

For additional resources: Anaphylaxis and other acute reactions following vaccination: Canadian Immunization Guide www.canada.ca/en/public-

health/services/publications/healthy-living/canadian-immunization-guide-part-2-vaccinesafety/page-4-early-vaccine-reactions-including-anaphylaxis.html



Key Distinguishing Features of Anaphylaxis and Vasovagal Syncope (13)

Clinical	Anaphylaxis	Vasovagal Syncope
features		
Onset from time of immunization	 rapid onset and progression of symptoms occurs minutes to hours after exposure to trigger recovery dependent on response to treatment 	 sudden onset occurs before, during or shortly after trigger (e.g., sight of the needle) recovery occurs within 1- 2 minutes
Skin	 flushed, red blotchy areas (not necessarily itchy) itchy, generalized hivelike rash and/or swelling and hives at the injection site tingling sensation often first felt about the face and mouth progressive, painless swelling about the face, mouth, and tongue 	 pale excessive perspiration cold, clammy
Respiratory	 labored breathing - hoarse voice, throat tightness, rapid breathing, wheezing, coughing, nasal flaring, nasal and chest congestion rhinitis (stuffy or runny nose, itchy watery eyes and sneezing) shortness of breath, stridor, retractions, chest pain and cyanosis 	breathing normal or shallow, irregular, laboured
Cardiac	 weak and rapid pulse hypotension alone after exposure can represent anaphylaxis. hypotension is less common in children. shock 	slow, steady pulseHypotension



Neurologic	 sense of severe anxiety and distress loss of consciousness-no improvement once supine or in head down position 	 fearfulness light-headedness dizziness numbness, weakness spasm in the hands and feet associated with
	position	hyperventilation

5.6.6. Adverse Reactions Following Administration of **Passive Immunizing Agent**

An adverse reaction following administration of a passive immunization agent is any untoward medical occurrence (e.g., anaphylaxis) in a recipient which follows administration.

Of particular interest are those reactions which meet one or more of the following criteria:

- a. Is of a serious nature.
- b. Requires urgent medical attention.
- c. Is an unusual or unexpected event.

Any suspected adverse reaction to a passive or diagnostic agent can be reported to the Canada Vigilance Program by:

Telephone

Call a Canada Vigilance Regional Office at 1-866-234-2345 (toll-free).

Download and print the Canada Vigilance Adverse Reaction Reporting Form. Complete the form and send it by fax at 1-866-678-6789.

Mail

Download and print the Canada Vigilance Adverse Reaction Reporting Form and the postage-paid label.

Complete the form and mail it to a Canada Vigilance Regional Office, using the postage-paid label.

Online

Complete a report online.

Adverse events following immunization (AEFI) form can be used if administering an active and passive immunizing agent concomitantly.

Review the following resources:



- Report of Adverse Events Following Immunization <u>www.gov.mb.ca/health/publichealth/cdc/docs/mhsu_2334_20161115_aefi.pdf</u>
- User Guide for the Completion and Submission of the AEFI Reports for definitions of a serious AEFI and how to complete the form.
 www.gov.mb.ca/health/publichealth/cdc/protocol/aefi.html

6. Blood Products, Immunoglobulin and Timing of Immunization

Administration of Ig preparations and certain blood products can interfere with the immune response to parenteral live virus vaccines if given concomitantly with or shortly before or after the vaccine. Refer to the following section of the Canadian Immunization Guide for minimum intervals: Blood products, human immunoglobulin and timing of immunization: Canadian Immunization Guide - Canada.ca

7. Documentation In PHIMS

All active and passive immunization agents are to be documented in PHIMS phimsmb.ca. When recording an immunization that was administered in multiple sites, enter the immunization as one immunization and type in the total dose (to assure proper auto decrement of stock), document the site as "Other" and in the comments section, record the sites that were used, and the specific dosage or volume administered at each site.

For further information see the following links:

phimsmb.ca/files/provider-recorded.pdf

phimsmb.ca/files/2016-09-phims-su.pdf

8. Resources

Provincial Immunization Competency Guideline www.manitoba.ca/health/publichealth/cdc/div/manual/docs/immcomp.pdf

Infection prevention and control guidelines https://www.gov.mb.ca/health/publichealth/cdc/ipc.html

PPE guidelines

sharedhealthmb.ca/files/routine-practices-protocol.pdf



9. References

- Manitoba Health Seniors and Long Term Care Communicable Disease Protocol Measles (Rubeola)(2019)
 www.manitoba.ca/health/publichealth/cdc/protocol/measles.pdf
- 2) BC CDC Immunization Manual Part 4: Biological Products (Vaccines & Immune Globulins) www.bccdc.ca/health-professionals/clinical-resources/communicable-disease-control-manual/immunization/biological-products
- 3) BC CDC Immunization Manual Ig preparations www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Chapter%202%20-%20Imms/Part4/Ig.pdf
- 4) GamaSTAN® S/D immunoglobulin (Human) PRODUCT MONOGRAPH <u>Microsoft Word - ~db5_Oc75c934e33e242f8bacd777dd92926ec.doc (hres.ca)</u>
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- 6) Thompson River University, Pressbooks BC Campus (2018). Clinical Procedures for Safer Patient Care. Chapter 7.5 Intramuscular Injections.

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- 8) Intramuscular and subcutaneous injections: A guide for Pharmacists CANvax (2018)_ www.canvax.ca/intramuscular-and-subcutaneous-injections-guide-pharmacists
- 9) CANvax (2018) canvax.ca/intramuscular-injection-vastus-lateralis-site
- 10)Intramuscular Injection: Dorsogluteal Site CANvax (2014) canvax.ca/intramuscular-injection-dorsogluteal-site
- 11) Manitoba Health Seniors and Long-Term Care Communicable Disease Protocol Hepatitis A www.gov.mb.ca/health/publichealth/cdc/protocol/hepa.pdf
- 12) BC CDC Communicable Disease Control Manual Chapter 2: Immunization Appendix B Administration of Biological Products (2022)

 www.bccdc.ca/resourcegallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manual
 s/Epid/CD%20Manual/Chapter%202%20%20Imms/Appendix B Administration.pdf



13)BC CDC Communicable Disease Control Manual Chapter 2: Immunization Part 3
- Management of Anaphylaxis in a Non-Hospital Setting (2019)

www.bccdc.ca/resourcegallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manual

gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manual s/Epid/CD%20Manual/Chapter%202%20-%20Imms/Part_3_Anaphylaxis.pdf

14)BC CDC Communicable Disease Control Manual Chapter 2: Immunization Appendix D - Reducing Immunization Injection Pain (2018)

www.bccdc.ca/resourcegallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manual
s/Epid/CD%20Manual/Chapter%202%20-%20Imms/Appendix D RIIP.pdf