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#### Introduction

Welcome to the *Manitoba Module: Administration of Injections*. Successful completion of this module is one of the requirements for pharmacists applying for authorization to administer drugs and vaccines by injection from the College of Pharmacists of Manitoba (College). This module was developed in partnership by the College of Pharmacists of Manitoba, and the University of Manitoba College of Pharmacy.

#### **Learning Objectives**

Upon successful completion of this module, the pharmacist will be able to:

- Describe the applicable sections of the *Pharmaceutical Act* and Regulations and integrate the College of Pharmacists of Manitoba's practice direction related to administering injections into his/her practice;
- 2. Explain the recommended immunization schedule in Manitoba;
- 3. Examine the administration of drugs that are not vaccinations;
- 4. Explain proper procedures when reconstituting and preparing medications for injection;
- 5. Discuss the key sites and factors affecting needle choice for intramuscular, subcutaneous, and intradermal routes of administering injections;
- 6. Identify and manage adverse events following an injection, including anaphylaxis, and report them to the appropriate agencies; and
- 7. Describe requirements for storage and handling of vaccines.

## **Recognition of Pharmacist Injection Training Programs**

The Council of the College of Pharmacists of Manitoba made several motions in 2013 and 2014 that affect injection training program recognition in Manitoba as follows:

The College recognizes injection training programs in Canada that have current
 Canadian Council on Continuing Education in Pharmacy (CCCEP) stage 2 competency-mapped accreditation. See the CCCEP website for more information:
 <a href="https://www.cccep.ca/">https://www.cccep.ca/</a>.

- The College will recognize a pharmacist's authorization to administer injections from another Canadian jurisdiction if that province has the same CCCEP Stage 2 injection training accreditation requirement and that pharmacist's authorization is current/active at the time of application.
- All pharmacists applying for injection authority in Manitoba are required to complete this module, the *Manitoba Module: Administration of Injections*.

#### Pharmacist Authorization to Administer Injections in Manitoba

The successful completion of an injections training program does not grant pharmacists authorization to administer injections. Pharmacists must apply for and receive authorization from the College of Pharmacists of Manitoba in order to administer injections. The "Application for Authorization to Administer Drugs and Vaccinations by Injection" is available on the College website to those members who have successfully completed all requirements for the administration of drugs and vaccines. Please see the <u>College website</u> more information.

To be eligible to apply for certification of authorization to administer drugs by subcutaneous, intradermal and intramuscular injections, a pharmacist must:

- be a licensed, practicing member with the College of Pharmacists of Manitoba;
- have successfully completed an education program approved by Council on the administration of drugs by injection;
- have successfully completed the Manitoba Module: Administration of Injections; and
- possess valid and current certification in CPR Level C or Level HCP and Emergency or Standard First Aid from an in-person training program, that is recognized as an approved first aid training agency/program/provider by the Workplace Safety and Health (WSH) Branch of the Manitoba government. This certification must be kept current for the duration of the certification of authorization to administer drugs by injection. Pharmacists must notify the College if they do not renew their certification. A list of all WSH approved programs can be found here by selecting the "First Aid" tab on the list: <a href="https://www.gov.mb.ca/labour/safety/training.html">https://www.gov.mb.ca/labour/safety/training.html</a>. Please ensure that the agency

where you complete your certification or re-certification is delivering one of the approved training programs found on the WSH Branch list.

A member cannot administer injections until he/she has received confirmation from the College that his/her application has been reviewed and approved, and the member has thoroughly read and understood the practice direction entitled, "Standard of Practice # 5: Administration of Drugs including Vaccines."

Please note that a pharmacist with injection authorization may only administer an intradermal injection if the training program he/she completed included an intradermal injection component and the pharmacist is competent.

## Recertification and Retraining Requirements

The Council of Pharmacy Registrars of Canada (CPRC) came to a consensus on recommendations for injection recertification and/or retraining requirements. In April 2014, the College Council decided on the following requirements:

- Self-declaration of proficiency of knowledge and skills as part of annual license renewal;
- Retraining in a full CCCEP Stage 2 competency mapped injection course if an injection has not been given in the preceding three years;
- Retraining in a full CCCEP Stage 2 competency mapped injection course if an injection
  has not been given within one year after completion of the initial training course; and
- A pharmacist must apply and receive certification of injection authorization from the
  College of Pharmacists of Manitoba within one year of completing the required training
  or within one year of graduating from a Faculty of Pharmacy in Canada, or will need to
  retrain in a full CCCEP Stage 2 competency mapped injection course.

Although these are the minimum requirements, pharmacists must ensure that they are competent and confident in administering drugs and vaccines. As such, they may need to administer injections more often than the minimum required.

The *Pharmaceutical Act* and Regulations

The *Pharmaceutical Act* in Manitoba was passed and received Royal Assent on December 7th, 2006. The legislation was proclaimed by the government and came into effect on January 1,

2014. The *Pharmaceutical Act* can be viewed <u>here</u>.

It is imperative that injection pharmacists are knowledgeable on the applicable sections of the Pharmaceutical Regulation to the *Pharmaceutical Act*. The full document can be viewed here and the sections related to administration of drugs and injections are highlighted below<sup>1</sup>.

An amendment to the Regulation came into force in November 2022 to update the name of the provincial immunization database and to expand Schedule 2 to permit the ongoing administration of COVID-19 vaccines by pharmacists. The amendment can be viewed here.

Pharmacists should refer to the CPhM website for any applicable updates.

Part 14

ADMINISTRATION OF DRUGS BY MEMBERS

Definition of "advanced method"

**107** In this Part, "advanced method" means any of the following methods for administering a drug:

- (a) through intradermal, subcutaneous or intramuscular injection;
- (b) intravenously through an established central or peripheral venous access device;
- (c) rectally.

MEMBERS MAY ADMINISTER DRUGS

Administration of drugs — all members

**108(1)** A member or an intern may administer a prescription drug or a non-prescription drug to a patient by the following means:

- (a) orally, including sublingual and buccal;
- (b) topically, including ophthalmic, otic and intranasal;

(c) via inhalation.

**108(2)** Despite subsection (1), a vaccine may not be administered to a patient who is under the age of seven.

#### Administration of drugs — certified members

**109(1)** A member may administer a drug using an advanced method only if he or she holds a current certification in that method under section 114.

**109(2)** A member who is completing a course or program of study for certification in an advanced method may administer a drug using that method if, while doing so, he or she is under the direct supervision of

- (a) a member who is certified in that method; or
- (b) another health care professional who is legally permitted and competent to administer a drug using that method.

#### Drugs that may be administered by certified members

**110** A member who is certified in an advanced method may use that method to administer any of the following drugs:

- A member may administer a vaccine that is prescribed by an authorized practitioner to a
  person who is at least seven years of age, using an advanced method described in clause
  107(a) or (b).
- 2. A member may administer a drug other than a vaccine that is prescribed by an authorized practitioner to a person over the age of five years.
- 3. A member may administer a vaccine listed in Schedule 2 to this regulation, which is provided under a provincial immunization program free of charge to patients who meet provincial criteria, as long as the member complies with the program requirements.

#### **Notes:**

- Section 110(3) is not limited by the age restrictions outlined for other vaccines but is set by provincial policy.
- Please see the Manitoba Health website or <u>Immunization Program Manual</u> for updates on age of administration for publicly funded vaccines such as influenza and COVID-19 vaccines.

#### Reporting about vaccine administration

**111** A member who administers a vaccine to a patient must report the details of the administration (which may include personal health information as that term is defined in The Personal Health Information Act) to the Manitoba Immunization Monitoring System maintained by the Department of Health the electronic public health information network that is operated by the Department of Health. The report must be in the form and be provided at the time that the minister requires. (Updated Nov. 2022).

#### Collaborative practice required for intravenous administration

**112** A member who is certified to administer a drug intravenously through an established central or peripheral venous access line may use that advanced method only when

- (a) he or she is practising in a collaborative practice with other regulated health professionals, including one or more physicians or registered nurses (extended practice); and
- (b) the practice meets requirements approved by the council.

#### DRUG ADMINISTRATION RECORD DOCUMENTS

#### **Drug administration record**

**113** A member who administers a drug to a patient must make and retain a record in the pharmacy of the following:

- (a) the patient's name and address;
- (b) the name of the drug and total dose administered;

- (c) for an advanced method or vaccination by any method, identification of the manufacturer, lot number and expiry date of the drug;
- (d) for an advanced method, the route of administration and the location on the body where the drug was administered;
- (e) the name of the member administering the drug;
- (f) the date and the time of administration;
- (g) any adverse events;
- (h) the price, if there is a charge for administration.

#### Notes:

- The Manitoba Immunization Monitoring System was replaced by the Public Health Information Management System (PHIMS), formerly known as Panorama.
- The drug administration record can be recorded and retained in a readily retrievable manner electronically or written.
- In the case of an immunizing agent, the pharmacist must record the info on the patient's health record as stated in Section 5 of the Immunization Regulation to the *Public Health Act* (and that information is already included in the above list). <sup>2</sup>

#### CERTIFICATION OF MEMBERS IN ADVANCED METHODS

#### Certification of members in advanced methods

- 114(1) A member who wishes to be certified in an advanced method must
  - (a) establish that he or she has successfully completed the education and training requirements approved by the council;
  - (b) apply to the registrar in the form approved by the council; and
  - (c) pay the fee provided for in the by-laws.
- **114(2)** The registrar may certify a member in an advanced method subject to any conditions the registrar considers advisable.

**114(3)** If an application for certification in an advanced method is not approved, or is approved subject to conditions, the registrar must

- (a) give notice to the applicant in writing with reasons for the decision; and
- (b) inform the applicant of their right to appeal the decision to the council.

Sections 21 and 22 of the Act apply with necessary changes to an appeal.

#### Renewal of certification

**115(1)** A certification under section 114 must be renewed annually in accordance with the bylaws.

**115(2)** A member must apply for renewal within the time period provided in the by-laws, pay the renewal fee provided in the by-laws and meet the continuing competency requirements approved by the council.

**115(3)** If an application for renewal is not approved because the applicant has not met the continuing competency requirements, subsection 114(3) applies, with necessary changes.

#### Cancellation or suspension of certification

**116** Sections 23 to 25 of the Act apply to the cancellation and suspension of a certification, with necessary changes.

#### REPRESENTATION AS A CERTIFIED MEMBER

#### No representation as certified unless certified

**117** No member may represent that they are certified in an advanced method unless they hold current certification under this Part.

## Authorized Practitioners and Schedule 2 to the Pharmaceutical Regulation

Section 110 of the Pharmaceutical Regulation often generates some confusion. It states:

**110** A member who is certified in an advanced method may use that method to administer any of the following drugs:

- 1. A member may administer a vaccine that is prescribed by an authorized practitioner to a person who is at least seven years of age, using an advanced method described in clause 107(a) or (b).
- 2. A member may administer a drug other than a vaccine that is prescribed by an authorized practitioner to a person over the age of five years.
- 3. A member may administer a vaccine listed in Schedule 2 to this regulation, which is provided under a provincial immunization program free of charge to patients who meet provincial criteria, as long as the member complies with the program requirements.

#### **Authorized Practitioner**

A pharmacist is <u>not</u> considered an authorized practitioner. Only medical practitioners or physicians, dentists and nurse practitioners are included in the definition of authorized practitioner as it applies to the practice of pharmacy in Manitoba. Therefore, for an advanced method, a prescription is required from an authorized practitioner for the drug or vaccine to be administered by a pharmacist, apart from the publicly funded vaccines included in Schedule 2 to the Pharmaceutical Regulation. This does NOT mean NAPRA schedule 2 vaccines.

## Schedule 2 to the Pharmaceutical Regulation

Currently, vaccines that a member may administer, without a prescription from a practitioner, as part of the provincial program include:

- human papillomavirus (HPV) vaccine
- influenza vaccine
- pneumococcal polysaccharide (Pneu-P-23) vaccine
- tetanus-diphtheria-acellular pertussis (Tdap) vaccine

• tetanus-diphtheria (Td) vaccine

severe acute respiratory syndrome coronavirus 2 (COVID-19) vaccine

Schedule 2 to the Pharmaceutical Regulation was amended in 2016 to include the tetanusdiphtheria vaccine and in 2022 to include COVID-19 vaccines that a member may administer as part of the provincial program.

## Practice Direction Standard of Practice #5: Administration of Drugs Including Vaccines

The Pharmaceutical Act December 2006, defines a "practice direction" as follows:

"Practice direction" means a written statement made by the council for the purpose of giving direction to members and owners about the conduct of their practices or pharmacy operations.

Practice Directions carry similar legal significance to regulations, and thus it is required that members who will be administering injections are familiar with the Administration of Drugs Practice Direction.

The Practice Direction Standard of Practice #5: Administration of Drugs including Vaccines, was updated in Dec. 2013 and came into effect on January 1, 2014. Revisions were approved by Council in May 2022. The Practice Direction must be reviewed and can be found <a href="https://example.com/here.2">https://example.com/here.2</a>

## The Public Health Act and the Immunization Regulation to the Public Health Act

There are several requirements of *The Public Health Act* and the Immunization Regulation respecting immunizations. Areas to focus on are the consent requirements (i.e., the information to be provided to the patient as specified in the legislation), the records to be kept, and the requirement to report adverse events.

These requirements need to be reviewed and can be accessed through the following links:

The Public Health Act - See sections 57 to 59

http://web2.gov.mb.ca/laws/statutes/ccsm/p210e.php

The Public Health Act Immunization Regulation - Read entire document

http://web2.gov.mb.ca/laws/regs/current/ pdf-regs.php?reg=36/2009

Manitoba Health Informed Consent Guidelines for Immunizations

http://www.gov.mb.ca/health/publichealth/cdc/protocol/consentguidelines.pdf

#### **Post-Injection Adverse Events**

#### Management

It is extremely important that the pharmacist who is administering injections is knowledgeable on the management of post-injection adverse events. The following two websites need to be reviewed, in addition to completing and maintaining current CPR and First Aid requirements:

Anaphylaxis vs Vasovagal Reaction – A Comparison of Signs and Symptoms
<a href="http://www.wrha.mb.ca/professionals/immunization/files/AnaphyvsVasReactionTable.pdf">http://www.wrha.mb.ca/professionals/immunization/files/AnaphyvsVasReactionTable.pdf</a>

#### **Management of Anaphylaxis in Non-Hospital Settings**

https://professionals.wrha.mb.ca/old/extranet/publichealth/files/mgmt-suspected-anaphylaxis-pph.pdf

#### Reporting

Health care providers need to report adverse events to the appropriate Medical Officer of Health at Manitoba Health. These reports are forwarded to the Public Health Agency of Canada's Canadian Adverse Events Following Immunization Surveillance System (CAEFISS).

Please review the following website and associated links for information on adverse events following immunization including the information on reporting requirements and the form:

Adverse Events Following Immunization (AEFI)

https://www.gov.mb.ca/health/publichealth/cdc/div/aefi.html

## Safety-Engineered Needles

In accordance with the <u>Workplace Safety and Health Amendment Act</u>, when administering injections to patients using hollow-bore needles, pharmacists must use safety-engineered needles. This is extremely important in preventing needle stick injuries. Post-exposure to a patient's blood via a needle stick injury is a serious health concern for pharmacists providing injections. There are rare cases where the use of safety-engineered needles may not be reasonably practicable (such as when administering manufacturer pre-filled syringes).

# Administration of Drugs including Vaccines Policy and Procedure Manual Template and Needle Stick Injury Guidelines

Pharmacies that administer injections must have a policy and procedure manual that includes information on the administration of drugs, including vaccines, and emergency response protocols. The College has created an <u>Administration of Drugs including Vaccines Policy and Procedure Manual Content Template document</u>. Pharmacy managers should use this when developing their own manual. This resource document also has a section on needle stick injury protocol.

It is required that pharmacy managers ensure all employees at risk of injury are educated in needle stick prevention and the protocol to follow, should an injury occur. To offer pharmacies further guidance on needle stick injury protocols, the College has developed a <a href="Needle">Needle</a> Stick Injury Guidelines document that needs to be reviewed in its entirety.

## Injecting Drugs other than Vaccines

Pharmacists in Manitoba have the authority to administer drugs other than immunizations (see the Pharmaceutical Regulation for more detail). Pharmacists can find the recommended route of administration of specific medications in the drug monographs located in the *Compendium of Pharmaceuticals and Specialties* from the Canadian Pharmacists Association or by visiting the Health Canada Drug Product Database webpage. The recommended routes of administration are provided by the drug product manufacturer.

It is CPhM Council policy that the administration of drugs is for the purposes of pharmaceutical care, drug therapy management or, in other words, connected with drug therapy of the patient. Drug administration is not intended for other purposes such as cosmetic, nor are pharmacists authorized to administer cosmetics or cosmetic drugs. For more information, please see the Position Statement on Injections of Neuromodulators and Dermal Fillers.

#### Pharmacist administration of hazardous medications

Hazardous and/or cytotoxic drugs such as testosterone or methotrexate are medications that pose a potential health risk from exposure in the workplace. Information and a list of hazardous drugs in healthcare settings can be found here: <a href="National Institute for Occupational Safety and Health (NIOSH)">National Institute for Occupational Safety and Health (NIOSH)</a> List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016. A pharmacist must check the list as well as the product's safety data sheet and monograph prior to administering a product. The pharmacist must determine whether additional precautions need to be taken and ensure those requirements are met.

The current legislation and practice directions do not prevent a pharmacist from administering these drugs if this is indicated in the product monograph and/or approved by the product manufacturer. However, the pharmacist must have the required knowledge, skill, and competence, and follow the appropriate procedures and precautions for the safe preparation and administration in order to protect and prevent contamination to the pharmacist, patient or other staff. Safe drug administration policies and procedures must be in place, including precautionary measures for safe transport, disposal of the hazardous product, management of an accidental spillage, and measures for handling any adverse reactions that may arise after administration.

The authorization to administer drugs by injection does not automatically mean that a pharmacist is trained and competent to inject all types of drug products. Hazardous drugs pose different considerations and safety precautions. A risk assessment must be performed, and training undertaken as needed.

CPhM does not currently have a guideline regarding injections of hazardous drugs by pharmacists, but the Alberta College of Pharmacists (ACP) has published <u>Guidelines for Medication and Vaccine Injection Safety</u>. This guidance should be followed by Manitoba pharmacists administering hazardous medications. It states:

If hazardous drugs are administered in the practice setting, they are stored, handled and used safely.

- a. A written procedure is in place for the management of hazardous drugs
- b. Hazardous drugs are stored separately from other medications if possible.
- c. Employees and others at risk from handling hazardous drugs are identified and provided with adequate training and equipment.
- d. Cytotoxic spill kits are available, and staff are trained in spill management.
- e. Adequate personal protective equipment including but not limited to gloves, disposable gowns and facial protection is worn for administration of hazardous drugs.
  - i. Additional personal protective equipment is used where there is potential for splash, spill or aerosolization.
  - ii. Personal protective equipment is disposable where possible.
- f. Hazardous drug waste and equipment is disposed at point-of-use into a cytotoxic waste container with minimal manipulation (e.g., needles and syringes are left intact).

In summary, it is not outside of a pharmacist scope of practice to administer hazardous medications, however the necessary policies and procedures, equipment and additional knowledge, skill, and training need to be in place.

## Administering Injections to Children Two Years of Age and Older

In September 2022, pharmacists who had certification of authorization to administer drugs and vaccines by injection were authorized by Manitoba Health to administer COVID-19 and seasonal influenza (flu) vaccines to individuals two (2) years of age and older. As of December 2022, the minimum age for pharmacist administration of all other vaccines remains at seven (7) years of

age and older. Please check on the College <u>website</u>, Manitoba Health website or <u>Immunization</u>

Program Manual for Immunization <u>Providers in Manitoba</u> for any further updates.

The College strongly encourages all injection-certified pharmacists and interns to review the following resource list to support the safe and effective administration of vaccines to children two years of age and older: <a href="https://cphm.ca/resource/administration-of-injections-to-young-children-ages-2-5-resource-list/">https://cphm.ca/resource/administration-of-injections-to-young-children-ages-2-5-resource-list/</a>.

As always, pharmacists must practice within the scope of their competence, skill and knowledge. Additionally, pharmacists must review the following resource on preventing vaccine incidents and reducing the chances of patient

harm: <a href="https://cphm.ca/resource/medication-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-incidents-in-covid-19-vaccine-administration-in-covid-19-vaccine-

#### Immunization in Manitoba

Pharmacists who are providing vaccinations in Manitoba must be familiar with Manitoba's immunization program and schedule. Each province has its own routine immunization schedule. Pharmacists are also responsible for complying with the applicable Manitoba Health guidelines related to administration of immunizing agents. All this information can be found and reviewed on the "Communicable Disease Control" section of Manitoba Health's website.

The documents on the following webpages should be reviewed thoroughly by pharmacists who will be providing vaccinations in Manitoba:

- Immunization Program Manual for Immunization Providers in Manitoba http://gov.mb.ca/health/publichealth/cdc/div/manual/index.html
- Immunization (Vaccination)
   <a href="http://www.gov.mb.ca/health/publichealth/cdc/div/index.html">http://www.gov.mb.ca/health/publichealth/cdc/div/index.html</a>
- Questions & Answers: Reporting of all Vaccines via DPIN
   http://gov.mb.ca/health/publichealth/cdc/div/manual/docs/qa\_dpinvaccinereporting.p
   df

As Manitoba Health looks to make processes more efficient, they regularly update the <a href="Immunization Program Manual for Immunization Providers in Manitoba">Immunization Program Manual for Immunization Providers in Manitoba</a>. Pharmacists are reminded to review information at the above link regularly for updated information on immunization and to ensure their pharmacy is using the most up-to-date forms and processes. Please ensure your pharmacy is only using forms indicated for pharmacies and in the timelines indicated.

#### **Immunization Schedules**

It is important for an injection pharmacist to know which immunizations are included and not included in Manitoba's Immunization Schedule. Updated charts of the schedules must be reviewed on the Manitoba Health website by clicking <a href="here">here</a>. Regardless of the schedule, a pharmacist must be aware of the age restrictions for pharmacist administration of injections.

#### Becoming an Immunization Provider

Information on how to become an immunization provider in Manitoba, including the application, processes and procedures for requesting client immunization history and for reporting immunizations are updated periodically and can be found on the Manitoba Health website on the "Immunization Program Manual for Immunization Providers in Manitoba" page. Documents on this webpage include the new immunization provider application form, how to order publicly funded vaccines from the Provincial Vaccine Warehouse, how to report vaccines, how to report vaccines given to a client without a valid PHIN, and how to get reimbursed for administration of the included publicly funded vaccines.<sup>3</sup>

In June 2019, Manitoba Health announced that, effective immediately, pharmacists are no longer required to invoice them for doses of publicly funded vaccines that have been administered to patients with valid PHINs. Instead, pharmacies will receive payment for these doses on a quarterly basis according to the entry of the two-letter PS code (which should be used for all pharmacist-administered vaccines, whether they are publicly funded) into DPIN. Only DPIN data with the PS code gets uploaded into Manitoba's provincial immunization registry and the patient's immunization record.

For information on becoming a COVID-19 vaccination provider, please see the Manitoba Health webpage "COVID-19 Vaccine – Physician and Pharmacist Vaccination Partners".

#### Off-site immunization clinics

Manitoba Health has instructed that pharmacies planning to hold off-site immunization clinics lead by a pharmacy team need to provide advance notice of the date and location of the clinic to the local Regional Health Authority (RHA) Public Health office. By contacting the RHA office in advance, the pharmacy can ensure that immunization efforts are not duplicated and if necessary, an alternate day or location can be arranged in order to maximize immunization efforts. A list of the RHA Public Health Offices and contact information can be found here: <a href="https://www.gov.mb.ca/health/publichealth/offices.html">https://www.gov.mb.ca/health/publichealth/offices.html</a>.

The pharmacy holding an offsite immunization clinic must also be registered with Manitoba Health as an immunization provider, the pharmacists providing the injections must be certified by the College to provide injections, and the offsite immunization clinic must meet the requirements of proper procedures and patient care as outlined in the legislation and applicable Practice Directions.

## Vaccine Storage

Appropriate storage temperatures and light requirements must be maintained at each step of the way in order to ensure that the products used in immunization will provide the client with the expected protection.<sup>6</sup>

To ensure proper storage and handling of vaccinations, a process referred to as "cold chain" is adopted. Cold chain refers to "the process used to maintain optimal conditions during the transport, storage, and handling of vaccines, starting at the manufacturer and ending with the administration of the vaccine to the client"<sup>6</sup>. To briefly summarize, the proper execution of the

cold chain protocol involves three parts, namely, trained personnel, proper transportation and storage equipment, and efficient vaccine management procedures<sup>6</sup>.

It is important that all pharmacies have detailed protocols in place to address the following:

- a) Routine vaccine storage and handling
- b) Urgent vaccine storage and handling (e.g., power outages)
- c) Management of inappropriate vaccine storage conditions

Please review the following resources on vaccine storage:

- Read the following document:
  - Canadian Immunization Guide Storage and handling of immunizing agents
     https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-9-storage-handling-immunizing-agents.html
- Review the following websites:
  - Manitoba Health Cold Chain Protocol Vaccines and Biologics, available at http://www.gov.mb.ca/health/publichealth/cdc/coldchain/protocol.html
  - Manitoba Health: Vaccine Biologics- Packing, Storage and Handling for Off-Site
     Immunization Clinics
    - http://www.gov.mb.ca/health/publichealth/cdc/coldchain/protocol7.html

## Summary of Infection Control and Routine Practices 7,8

The following information is taken from the Canadian Immunization Guide.

Vaccine providers should incorporate routine infection control practices into all immunization procedures as follows:

- Hand hygiene should be performed before vaccine preparation, between vaccine recipients, and whenever the hands are soiled. Alcohol-based hand sanitizers are an alternative to hand washing with soap and water when hands are not visibly soiled. Hand hygiene should be performed after removing gloves.
- Glove use during immunization is not routinely recommended unless the skin on the vaccine provider's hands is not intact or when administering Bacille Calmette-Guérin (BCG) or smallpox vaccine. If there is a risk of bleeding, or if the patient's condition requires contact or Acute Respiratory Illness (ARI) precautions, gloves are to be worn. If gloves are worn, they should be changed between vaccine recipients. Hands should be washed before putting on new gloves.
- Prior to withdrawal of vaccine into the syringe, the vaccine vial should be uncapped, the stopper wiped with a suitable disinfectant (e.g., isopropyl alcohol) and the stopper allowed to dry.
- Before injection, the skin should be cleansed with a suitable antiseptic such as an alcohol swab and allowed to dry.
- A separate sterile needle and syringe should be used for each injection.
- Vaccines should be withdrawn from the vial by the immunizer administering the vaccine.
- Policies and procedures should be developed and implemented regarding accidental
  exposure to blood or body fluids, including needle stick injuries, and vaccine providers
  should be educated about these policies and procedures.
- Refer to <u>Immunization of Workers</u> in Part 3 for more information about vaccines recommended for health care workers.

In addition to the recommendations above, the following practices should be observed:

- The needle should not be changed between withdrawing vaccine from the vial and administering the vaccine unless the needle is contaminated or damaged. If the needle is a blunt fill or large bore needle, it should be changed as well. Studies have shown that changing the needle tip, significantly reduced pain intensity, as the tip of the needle is sharp and free of medication residue. However, certain brands of syringes, don't allow the needle to be changed. In this situation, it is discouraged to insert the needle multiple times into the rubber stopper to draw up medication.
- Needles should not be recapped after use.

- Used syringes and needles should be immediately and carefully disposed of in a container designed for this purpose; used syringes and needles should never be placed on the work surface.
- Whenever possible, Safety Engineered Sharp devices should be used. Engage the safety mechanism on needles immediately following administration of vaccine.
- Used cotton balls can be discarded into the regular garbage, however, if saturated with blood, dispose into sharps container.
- Empty or expired vaccine vials should be disposed of according to local waste management legislation or guidelines.
- Safe Injection Mantra "One needle, One syringe, only one time!"

Additional information on infection prevention and control guidelines is available in <u>Routine</u>

<u>Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare</u>

Settings.

## Injection Equipment Introduction<sup>9,10</sup>

#### **Definitions:**

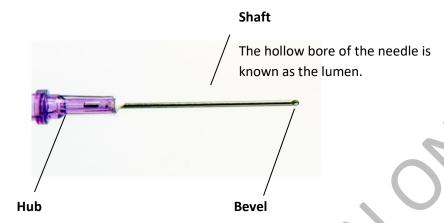
**Needle Length:** Needles come in many different lengths. Choosing the correct length of needle for the injection being done is essential. A shorter needle is required for a subcutaneous injection than an intramuscular injection. Incorrect needle length can result in incorrect route of administration.

Appropriate needle selection is important because the immunizing agent needs to reach the appropriate tissue site (dermis, subcutaneous tissue or muscle) to optimize the immune response and to reduce the risk of injection site reactions. Appropriate needle selection is important for all drugs and vaccines. The length must be long enough to reach the specific tissue site but not hit the underlying bone. Longer needles used for Intramuscular injection are correlated to less redness at the injection site, and less swelling.

To select the right needle, one must base it on the route of administration, the recipient's muscle mass, as well as the viscosity of the vaccine.

**Needle Gauge:** Gauge refers to the diameter of the needle. A larger number gauge is a smaller diameter needle. A 25G needle is typical for immunizations. Larger diameter needles can be used for more viscous medications. Very fine and short needles are usually used for insulin administration (example: 5mm 30G).

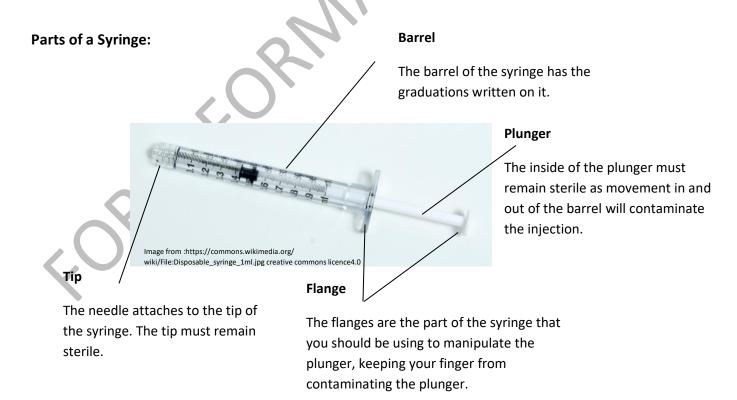
#### Parts of a Needle



The hub of a needle is colour coded to coincide with the gauge of the needle. These colours are universal

When administering an intradermal injection, particular attention is paid to the insertion of this pointed end of the needle

\*The needle must remain sterile through an injection preparation and administration.





Syringes come in many different sizes. When choosing a syringe for injection, it is recommended that you choose a syringe close to the volume being administered. It is common practice to use the closest syringe size to the volume being administered, unless it is the maximum volume of that syringe. Example: for 1 mL or 2 mL, use a 3 mL syringe. Use a 5 mL syringe for a 3 mL injection.



Insulin syringes have orange caps and are calibrated by insulin units rather than mL. Insulin is only to be administered with an insulin syringe, and only insulin should be administered in an insulin syringe. The needle on an insulin syringe is permanent.

## Pain Management Techniques<sup>7,10,11</sup>

The following pain management techniques can be used when appropriate or necessary:

- Manual pressure on the injection site for 10 seconds before needle insertion, to reduce pain
- Larger-bore needles reduce pain and swelling/redness after injection as less pressure is required to depress the plunger
- Injection of vaccines without aspiration
- Injecting vaccines that cause the most injection site pain after other vaccines
- Topical anesthetics prior to vaccine injection
- Presence of parent/caregiver during vaccine injection (≤ 10 years of age)
- Presence of a support person for those recipients with heightened anxiety
- Sitting up during vaccine injection or if high risk of fainting, immunize while lying down
- Distraction techniques
- Deep breathing
- Positioning to relax the muscle

Administration of oral analgesics (such as acetaminophen or ibuprofen) to children to reduce pain prior to or at the time of vaccine injection is not recommended, as there is no evidence of a benefit from this intervention.<sup>7</sup>

## **Intramuscular Injection Practice Notes**

The following serves as a short summary on intramuscular (IM) injections.

#### Site and Needle Choices<sup>7,9,10,11,12</sup>

IM vaccination in patients <12 months are done in the vastus lateralis (VL) site.

\*Reminder to pharmacists to review the age restrictions\*

IM vaccination in patients 12 months and older is done in the deltoid unless there is a particular reason to continue to use the VL.

Needle choice for an IM injection should ensure that the injection will go deep enough to penetrate muscle and not deposit the medication in the subcutaneous layer. Site and needle length are important to ensure that underlying structures are not damaged. It is a common misconception that a shorter needle decreases injection pain. Administration of medications through the wrong route can result in increased pain, reduced immune response, and abscess.<sup>7,11,12</sup>

Although one should always try to avoid hitting bone, if this happens, the administrator should pull back slightly on the syringe/needle to move the needle tip into the muscle and then inject. Most often the patient will be unaware that bone was contacted if the administrator does not react to it.

Needle choices are made based primarily on the length of the needle rather than the gauge. A 22-25G needle is appropriate for IM injections. Viscous medications must be administered with a wider needle (for example: 21G).<sup>7, 9</sup>

Larger muscles can accommodate larger volume injections. Typically, the deltoid is used for only 1mL injection, but is sometimes used for up to 2mL in a well-developed deltoid. The vastus lateralis can be used for up to 5 mL injections in adults and 1 - 3 mL for children.<sup>11</sup>

#### IM Needle Selection Guidelines from the Canadian Immunization Guide<sup>7</sup>:

Age of recipient	Needle Gauge	site	Needle length
>3-12 years	22-25g	Deltoid (1st choice site)	1.6 cm-2.5 cm
			(% inch − 1 inch)
		Anterolateral thigh	2.5 cm- 3.2 cm
			(1 inch -1¼ inch)
Adolescents and adults	22-25g	Deltoid muscle	For those weighing
(>12 years))			<130 lbs (<60kg):
` ' "			1.6 cm – 2.5 cm
			(⅓ inch– 1 inch)
			Males weighing 130-
			260 lbs (60-118kg)
			and females weighing
			130-200 lbs (60-90kg):
			2.5 cm (1 inch)
			Males weighing
			>260lbs (118kg) and
			females weighing
			>200lbs (90kg):
			3.8 cm (1½ inch)

#### Footnote 1

A range of needle lengths are listed, as clinical judgment should be used when selecting needle length for IM injections. Consideration should be given to recipient's weight, gender and age. These recommendations are based on the practice of having the skin stretched flat (between thumb and forefinger) at the time of administration.

#### Footnote 2

A larger gauge needle (e.g., 22 gauge) may be required when administering viscous or larger volume products such as immune globulin.

#### Footnote 3

The deltoid site is often selected for toddlers and young children as temporary muscle pain post-injection in the anterolateral thigh muscle may affect ambulation.

## Preventing shoulder injuries

Serious shoulder injuries can occur when health care providers inaccurately administer intramuscular vaccines in the deltoid. Pharmacists should review this helpful resource on page 8 of the Fall 2021 CPhM Newsletter by clicking <a href="here">here</a> to help prevent shoulder injuries when administering intramuscular injections.

## Skin Prep<sup>7,11,12</sup>

Much research now indicates that cleansing the skin with a disinfectant is unnecessary. Although it decreases bacteria on the skin prior to injection, it does not change the rate of post injection infection. In many policies, current recommendation is to cleanse the site with soap and water if visibly soiled. This is true of subcutaneous injections, intradermal injections, and intramuscular injections. Although not a necessity, cleansing the injection site with alcohol is still widespread practice.

## Aspiration<sup>7,11,12</sup>

Historically, intramuscular injection technique has involved the practice of aspiration – pulling back on the plunger to ensure that you will not inadvertently be injecting into a blood vessel. More recent studies have determined that evidence for the effectiveness of this practice is questionable due to a combination of reasons. Common consensus now is that only with the dorsogluteal (DG) site might this be valuable. The DG is no longer a recommended administration site for ANY IM injections and is NEVER an appropriate site for immunization. In some environments, the syringes used for vaccination are incapable of aspirating. Given the lack of evidence of benefit of aspirating and the fact that it prolongs the procedure, increasing patient anxiety and discomfort, omitting this step is now recommended practice.

#### **Subcutaneous Injection Practice Notes**

The following serves as a short summary on subcutaneous injections.

#### Site and Needle Choice 7,10,12,13

For all injection site choices, assess the skin to find an area that is correctly landmarked, and free of lesions, inflammation, swelling, bruising, scarring and tenderness, and which has not been often injected. These conditions can decrease absorption and increase discomfort.

The upper outer aspect of the arm is often the site of choice for vaccines, and other subcutaneous medications are often administered in the leg or abdomen.<sup>9,10</sup>

A short needle is required. Needle choice is made initially by length. Typically a 25G 5/8" needle is used. A shorter needle could be appropriate if available. There is no evidence that longer needles are required for larger people for subcutaneous injections.<sup>13</sup>

The practitioner must make every effort to avoid inadvertently administering the subcutaneous injection intramuscularly (IM) or intradermally (ID). By far, the greater risk is accidental IM injection. The dermis and epidermis are only 1-3 mm deep, so it is very unlikely that the needle is injected so shallow that the subcutaneous injection goes ID.

For people who have very little subcutaneous tissue, the risk of going IM is significant. For these patients, the tissue must be pinched up during needle insertion and this pinch can be maintained if there is serious concern about going IM. 10,12,13

#### **Intradermal Injection Practice Notes**

The following serves as a short summary on intradermal injections.

#### Site and Needle Choice 7

The flexor surface of the forearm is most used for intradermal injections. This area can be found about a hand's width above the wrist and three to four finger widths below the antecubital space. For some medications, the upper arm beneath the insertion of the deltoid is recommended. Review the product monograph of the drug that you are injecting for guidance. With this route of administration, your needle choice relies more on gauge than needle length. The entire length of the needle is not inserted. A very fine needle such as a 29G is used and inserted at a 10-15 degree angle. The medication is injected, resulting in a visible bleb. If no bleb is seen, the injection was too deep and was administered subcutaneously and will need to be readministered.

Some intradermal vaccines come with a special administration device. Check product monograph for administration details.

#### **Additional Resources**

Pharmacists must review the following articles and resources:

- Canadian Immunization Guide Public Health Agency of Canada
  - http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php
- Effective communication about immunization (benefits and risks)
  - https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-5-communicating-effectively-immunization.html
  - http://www.wrha.mb.ca/professionals/immunization/03-01.php
- Immunization Competencies for Health Professionals Public Health Agency of Canada
  - o http://www.phac-aspc.gc.ca/im/pdf/ichp-cips-eng.pdf
- Informed consent guidelines and documentation

- http://www.gov.mb.ca/health/publichealth/cdc/div/info.html (under Provincial Informed Consent Guidelines)
- Injection-related pain and anxiety reduction techniques
  - http://www.wrha.mb.ca/professionals/immunization/03-03.php (under Pain Management)
- Manitoba Health Communicable Disease Control website on Immunizations
  - o <a href="http://www.gov.mb.ca/health/publichealth/cdc/div/index.html">http://www.gov.mb.ca/health/publichealth/cdc/div/index.html</a>

Pharmacists should also be familiar with policies and guidelines applicable to the administration of injections that may be in place within your place of employment or organization. As well, pharmacists should explore the immunization publications available for patients on the Government of Canada website.

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