Independent Immunization Partners Channel Program Guide

The purpose of this guide is to provide an overview of the Independent Immunization Partners Channel (IIPC) program requirements as well as the responsibilities of Independent Immunization Partners (IIPs) once they are approved. The IIPC team will provide further detail to IIPs once they are approved in the program.

CONTENTS

General Information

1 SCOPE

Administration of COVID-19 vaccine within the Independent Immunization Partners Channel (IIPC). This is a separate channel from other provincial Vaccine Implementation Task Force (VITF) systems (i.e., Supersites, Pop-Up clinics, Focused Immunization Teams (FITs), Distributed Channel).

2 PRINCIPLES

- Increase accessibility of COVID-19 vaccine to strategically reach priority populations in a more timely and less resource-intensive approach
- Vaccine distributed through this channel must be used within 1 week of receipt (with the exception of sites without temperature-monitored fridges where vaccine must be used the same day of delivery)

3 PARTICIPATING INDEPENDENT IMMUNIZATION PARTNERS (IIPs)

- Hospitals, Personal Care Homes (PCHs), Regional Health Authority Home Care, Mental Health and Public Health Programs, Correctional facilities, Occupational Health and Safety for Health Care Workers, and other sites where strategically administering COVID-19 vaccine through the site can provide more timely access and reduce FIT requirements are eligible to apply.
- The program will operate in phases as each site completes the preparation/application process.
- Some sites may not be prepared to participate as a member of this strategy and instead may continue to be supported by the regional FIT.
- Each participating IIP will be asked to identify an Immunization Coordinator for the site who can liaise with the IIPC and Vaccine Implementation Task Force team on vaccine allocation, inventory and PHIMS data entry.

Program Requirements

1 ORDERING VACCINE ALLOCATIONS, COLD CHAIN STORAGE, INVENTORY

1.1 Submitting allocation requests

Once approved through the application process, IIPs will submit vaccine requests to IICP (*the specific form/process will be will be provided to IIPs as part of post-approval package).* After receiving and reviewing the requests, the IIPC team will email IIPs indicating the approved vaccine allocations. Material Distribution Agency (MDA) will be informed of the approved allocations (in preparation for the ordering process).

1.2 Ordering

Once IIPs receive their vaccine allocation confirmation email, they will be responsible for ordering the approved amount of vaccine and supplies from MDA, using the online order form*. (A link to the MDA online order form will be provided to IIPs as part of post-approval package).* Forms must be submitted a minimum of three business days prior to when the vaccine or supplies are required.

1.3 Cold Chain Storage[1]

IIPs will be responsible for administering received doses within the day of delivery or within the week of delivery, depending on their storage capacities:

A. IIPs that meet the cold storage requirements and have a vaccine rescue plan in place can store and use vaccine allocation within the week of delivery.
B. IIPs that do not meet the cold storage requirements will have vaccines delivered the same day they plan to administer the vaccine.

Refrigerator/freezer features

Refrigerators used for vaccine storage must have the following features:

- maintain the required vaccine storage temperatures through all seasons
- equipped with a calibrated temperature-monitoring device inside each storage compartment (such as a continuous temperature monitor or minimum/maximum thermometer. Household mercury-styled thermometers are **NOT** acceptable)
- recommend that the fridge be dedicated to the storage of vaccines only (if possible, store medications in separate fridge); **NO** food or drinks can be stored in the same fridge
- placed in a secure location away from unauthorized and public access
- located on a dedicated circuit; recommend that the fridge be plugged into an outlet with an emergency power supply, if possible

Types of refrigerators for vaccine storage

A. BEST: **A purpose-built vaccine refrigerator** (also referred to as a pharmacy, lab-style, or laboratory grade refrigerator) is the best type for storing all inventories of vaccines. It has been shown to have the least temperature variations, maintaining temperatures more reliably within the desired range. The defrost mechanism and fan-forced air circulation (see *Section 3.4.3: Refrigerators Appropriate For Use*) differentiate this type of refrigerator from domestic refrigerators, making it more suitable for vaccine storage.
B. ACCEPTABLE: A combination of domestic refrigerator and freezer unit (domestic frost-free refrigerator) is acceptable but requires significant modifications to store vaccines. The refrigerator and freezer compartments must have separate external doors, and the unit must meet the criteria set out in these guidelines.
C. NOT RECOMMENDED: Manual and cyclic defrost refrigerators are not recommended for vaccine storage because of the significant temperature variations and the risk of vaccines freezing. Generally, while the compressor is running, the area near the evaporator can be very cold whereas other areas are much warmer.
D. NOT RECOMMENDED: Any style of small, domestic-use bar fridge is unpredictable in terms of maintaining temperatures and must not be used. With combined refrigerator and freezer units, the freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store freezer-stable vaccines.

[1] **Note:** IIPs may collaborate with local Hospitals or health providers for shared access to refrigerators either as primary storage location or as part of the vaccine rescue plan.

Please see Cold Chain Protocol – Vaccines and Biologics | Health and Seniors Care | Province of Manitoba and the National Vaccine Storage and Handling Guidelines for Immunization Providers for more information

1.4 Temperature recording and monitoring

Regular and accurate temperature monitoring is imperative to ensure that the products have been stored at the manufacturer's recommended storage temperatures. Refrigerators that contain vaccines or biologics must have an appropriate temperature-monitoring device.

IIPs will be responsible for recording refrigerator temperatures twice daily, 7 days a week, and report cold chain excursions per the provincial Cold Chain Protocol for Vaccines and Biologics.

Types of temperature recording devices

The only temperature recording devices recommended for monitoring refrigerator temperatures for vaccines and biologics are:

A. Continuous Temperature Monitors (Data Loggers):
   - stand-alone temperature monitors that can record multiple temperatures
   - accompanied by computer software that allows for downloading data
   - provide an accurate picture of minimum and maximum temperatures and the time spent at each temperature

B. Digital Min/Max Thermometers:
   - several types are available on the market with slightly different operating instructions
   - follow and monitor the installation instruction from the unit manufacturer

Fluid-filled biosafe liquid thermometers, bi-metal stem thermometers, and household mercury thermometers are NOT recommended for the temperature monitoring of refrigerators containing vaccines and biologics.

Room temperature can be taken using a standard household thermometer.

In settings where continuous temperature monitoring devices are not being used, Manitoba Health and Seniors Care recommends the use of calibrated digital min/max thermometers.

- They show the current temperature and the minimum and maximum temperatures that have been reached since the last time the thermometer was reset.
- It is important to manually reset the min/max thermometer each time the temperatures are recorded.
- A limitation to min/max thermometers is that the readings do not indicate when the exposure occurred and the exact length of time of exposure.

Required actions for daily temperature monitoring

A. Take the fridge(s) temperature twice daily (including units with continuous temperature monitoring and recording devices).
B. For IIPs that do not have staff 24/7, some options to consider are:
   - Train security that is on site, if available, to conduct the temperatures on non-work days.

- Use a continuous temperature monitoring device (data logger) as it can better indicate the time and length of any exposures.
- Have the refrigerator(s) hooked up to a central alarm system that will go off when temperatures are outside of the set temperatures. Designated staff or security would be required to assess the situation if an alarm goes off and know the steps required to protect the vaccines and biologics.

C. Document temperatures on a temperature log (Resource 3: Temperature Log for Vaccines and Biologics), including the:
   - current refrigerator temperature
   - minimum temperature since last reading
   - maximum temperature since last reading
   - room temperature (to establish effect of ambient temperatures on storage)

   Note: If a temperature reading is missed, the log entry should remain blank.

D. Take **immediate action** when the temperature in the fridge is outside the required range or if there is an equipment or power failure. Actions taken should be recorded (Resource 4: Storage Trouble Shooting Record).

The Vaccine Coordinator or back-up will be responsible for:

A. reviewing the *Temperature Log for Vaccines and Biologics* **weekly** to ensure proper storage temperatures are being maintained
B. reviewing the *Temperature Log for Vaccines and Biologics* and *Vaccine Storage Trouble Shooting Records* **monthly** to note trends in storage temperatures and potential storage issues
C. keeping the *Temperature Log for Vaccines and Biologics* and *Vaccine Storage Trouble Shooting Records* for a period of **three (3) years** (to monitor historical and seasonal patterns)

To help prevent substantial losses of vaccines and biologics facilities storing large inventories should install continuous monitoring temperature alarm systems with round-the-clock notification to appropriate personnel.

See Temperature Monitoring – Cold Chain Protocol | Health and Seniors Care | Province of Manitoba

1.5 Vaccine rescue plan

IIPs are responsible to have a vaccine rescue plan in place if vaccine storage temperatures go outside of the required range that includes plans for alerting a designated person and steps to protect the vaccines and biologics. If the facility is not managed/monitored 24/7, ensure the refrigerator is connected to a central alarm system that will go off when temperatures are outside of the set temperature range. If an alarm goes off, the designated person, or the alarm-monitoring provider, would be required to assess the situation and follow the required steps to protect the vaccines and biologics. See Managing Cold Chain Problems | Health and Seniors Care | Province of Manitoba (gov.mb.ca) for information.

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2 ASSESSING PATIENT/CLIENT ELIGIBILITY

2.1 Assessing client eligibility

IIPs are required to only provide immunization to those that meet the current Manitoba's COVID-19 vaccine eligibility criteria.

2.2 Checking immunization history

Prior to administering any vaccine, IIPs are to review client immunization records to view COVID-19 immunization history, ensure minimum intervals between doses have been met, and select the appropriate second/subsequent product.

Recommended approach

1. Sites with access to PHIMS: review client's immunization record in PHIMS to confirm dosing interval and product.
2. Sites without access to PHIMS: review client's immunization records in eChart to confirm dosing interval and product.
3. If (1) and (2) are not feasible: IIPs can ask clients/patients to view their COVID-19 vaccine record per the website Shared Health Manitoba - COVID-19 Results (e.g., sites are encouraged to have a computer station with printer available for client/patients/residents to access Shared Health website and to print record for personal file).
4. If none of the options listed above are feasible: IIPs may partner with FIT/Public Health/Primary Health Care/Regional Programs to access immunization records.

2.3 Obtaining and documenting informed consent

Per MHSC Informed Consent Guidelines for Immunization, verbal or written consent must be obtained prior to immunization and must be documented.

A provincial COVID-19 Vaccine Consent Form is available for immunizers and health care providers to use for the purposes of obtaining and documenting informed consent from clients/patients/residents. Informed consent can be given verbally or in writing and must be documented.

A consent form or client/patients medical chart or electronic health record may be used to document informed consent. Signed consent forms are valid for one year from the time of signing. For more information, review the provincial Informed Consent Guidelines for Immunization. It is recommended that a consent form be used for the administration of both dose one and dose two. Consent forms are to be collected and stored per site policy and in accordance to *Government of Manitoba Personal Health Information Act (PHIA).*

Obtaining consent from special populations

Refer to the Clinical Practice Guidelines for Immunizers and Health Care Providers regarding considerations related to immunizing special populations including individuals who are pregnant, planning to become pregnant or breastfeeding; immunosuppressed due to disease or treatment and/or

have autoimmune conditions; those with allergies; or people who should not be immunized and require further consultation.

3 VACCINE ADMINISTRATION AND DOCUMENTATION

3.1 Administering

IIPs are responsible for ensuring vaccine administration is provided according to provincial eligibility guidelines and administered by individuals who have vaccine administration within their normal scope of practice and those who meet all training requirements. It is recommended that individuals who do not have vaccine administration within their normal scope of practice consult with their professional regulatory body to determine their ability to perform this reserved act.

3.2 Reporting of administered doses

All administered COVID-19 vaccine doses must be documented in PHIMS, ideally in real time and at a maximum within 24 hours after administration.

Documentation of vaccines administered (data entry) options

A. IIPs with PHIMS access/capacity will be responsible for entering vaccine administration into PHIMS and for adhering to the following guidelines:

- All client/patient/resident immunization records must include (at minimum) the client/patient/resident personal health identification number (PHIN) [unless unavailable, in which case see below], the location of administration, the immunization provider, date of administration, vaccine product, manufacturer, lot number, reason for immunization, dosage and site.

NOTE: PHIMS users should continue to refer to the internal https://phimsmb.ca/resources/non-public-health/ reference documents, training and support tools, tip sheets, FAQs and other materials related to immunization.

B. IIPs without PHIMS access/capacity may continue with their current processes for immunization data entry (e.g., partnering with FIT or Public Health). Over the longer term, the IIPC team can support these sites in acquiring the PHIMS access and the training required to manage data independently.

- IIPs who are partnering with public health or FIT for data entry are responsible for ensuring client/patient/resident consent forms are transported to FIT/public health for PHIMS entry within 24 hours of vaccine administration.

Documentation for doses administered to clients without a PHIN

- Doses administered to persons without a PHIN will need to documented and submitted according on the COVID-19 Vaccine Inputting Form for IIPs for Clients without a Manitoba PHIN.
- With the exception of IIPs with full PHIMS provisioning (e.g., public health offices) who can create new clients and have inventory function, all IIPs must submit this form to public health.
- Clients without PHINs should be advised that their health care providers will not be able to see their immunization record in eChart.

3.3 Reporting wastage

With the exception of IIPs with full PHIMS provisioning (e.g., public health offices) who can create new clients and have inventory function, all IIPs submit a weekly wastage log report to public health. (*the reporting form/process will be confirmed as part of post approval package to IIPs*).

3.4 Information Technology systems

IIPs entering data into PHIMS are responsible for ensuring appropriate information technology systems are in place (see phimsmb.ca/getting-access/readiness/).

3.5 Post immunization emergencies: Anaphylaxis and other acute reactions

Each immunization clinic must be prepared to manage post immunization emergencies (i.e. anaphylaxis) according to their site protocols. If no site protocol exists, the Manitoba Provincial Anaphylaxis Protocol: Community Health Immunization[2] can be implemented *(a copy of this protocol will be provided to IIPs as part of post-approval package).*

All patients/clients/residents must be observed for a minimum of 15 minutes after the vaccine is administered. If there is a specific concern about a possible allergy to a component of the COVID-19 vaccine, an extended period of observation post-vaccination of 30 minutes may be warranted.

IIPs must ensure anaphylaxis management equipment and anaphylaxis medication (e.g., epinephrine/Epi-Pen) are on site at all times and staff on site have the appropriate training to respond in the event of post immunization reaction (e.g., recent BLS/CPR).

3.6 Adverse Events Following Immunization (AEFI)

An AEFI is any untoward medical occurrence in a vaccine that follows immunization and that does not necessarily have a causal relationship with the administration of the vaccine. The event may be any unfavourable and/or unintended sign, abnormal laboratory finding, symptom or disease.

In accordance with section 59 of The Public Health Act, all AEFIs are to be reported to the regional Medical Officer of Health (MOH) within seven days of becoming aware of the AEFI. For all serious AEFI's, health care providers must report to the Regional MOH within one business day, which can be done by telephone, followed by the complete report within 72 hours.

A **reportable** AEFI is an event that: (1) is temporally associated with a vaccine, and (2) has no other clear cause at the time of reporting.

Of particular interest are AEFIs that are serious, unexpected and/or of special interest. But ALL AEFIs that meet (1) and (2) above should be reported, unless they are only mild local reactions that are not overly concerning to the vaccine recipient.

- See User Guide for the Completion and Submission of the AEFI Reports for definition of **serious** AEFI.
- An AEFI is considered **"unexpected"** if either of the following criteria is met: it is not listed in the most current Health Canada-approved product monograph for vaccines marketed in Canada; or, it

[2] Current provincial guidance reflect the Canadian Immunization Guide.

is listed in the product monograph but is different in nature, severity, frequency, specificity or outcome.

Process for reporting AEFI

Immunization administrators must complete and submit AEFI reports in one of the following manners:

A. IIP with PHIMS access: report AEFI via PHIMS – see Generating an AEFI Report. Refer to PHIMS Training and Support Tools - COVID Immunizer Resources for additional information on documenting an AEFI.
B. IIP without PHIMS access: report AEFI via the PDF reporting form and follow instructions listed on the form for submitting to the Regional Medical Officer of Health.

Information contained in the User Guide for the Completion and Submission of the AEFI Reports provides direction for how to correctly complete and submit in either manner described above.

Report death outcomes that meet the following criteria:

- death occurred within 30 days of vaccination AND
- the antecedent AEFI or medical condition that led to the demise itself is reportable. If no antecedent AEFI is identified, the death itself is the AEFI and should be reported as such if occurred within 30 days

For more information on AEFI, visit Manitoba Public Health.

3.7 Vaccine wastage mitigation strategies

IIPs are responsible for developing and maintaining vaccine wastage mitigation strategies, such as:

- review appointment flow to help inform vaccine preparation requirements.
- only order/pull the amount of vaccine required for each clinic.
- monitor vaccine preparation and pre-loading to match the rate of the remaining appointments for that clinic nearing the end of a clinic
- decrease the number of staff preparing vaccine at the end of a clinic to better manage the number of doses prepared
- doses remaining at the end of a clinic should be less than the amount of vaccine in one vial (e.g. 5 doses of Pfizer, 9 or 13 doses of Moderna, depending on how it is supplied)

If unused vaccine doses do remain in an open vial at the end of an immunization clinic, doses may be offered to clients/patients/residents or staff who were not scheduled to receive their vaccination on that day. This option should only be available for vaccine that would otherwise be discarded at the end of a clinic. All processes for an individual to receive vaccine still apply (i.e. consent form completion, informed consent obtained, observation period observed, etc.).

Administration of additional doses will be prioritized as follows:

1. Clients/patients/residents who are eligible for their first dose of COVID-19 vaccine and have not yet received their first dose.
    - If there are more clients/patients/residents identified than vaccine doses available, immunization will be offered in the order of those who would have been eligible first.

2. Staff who are eligible for their first dose of COVID-19 vaccine and have not yet received their first dose.
    - If there are more staff identified than vaccine doses available, immunization will be offered in the order of those who would have been eligible first.
3. Clients/patients/residents who are eligible for their second dose of COVID-19 vaccine and have not yet received their second dose.
    - If there are more clients/patients/residents identified than vaccine doses available, immunization will be offered in the order of those who would have been eligible first and then in order that they received their first dose of COIVD-19 vaccine.
4. Staff who are eligible for their second dose of COVID-19 vaccine and have not yet received their second dose.
    - If there are more staff identified than vaccine doses available, immunization will be offered in the order of those who would have been eligible first and then in order that staff received their first dose of COIVD-19 vaccine.

If additional doses remain at the end of the clinic and there are no staff interested or eligible for immunization, those additional doses should be wasted according to policy.

4 COMPETENCY AND TRAINING

Participating IIPs are responsible to ensure all staff involved in mRNA immunization administration have the required competency and training prior to administering COVID vaccines.

Any provider that will be administering mRNA vaccine MUST complete necessary training materials per the VITF. mRNA vaccines fall under a new vaccine technology platform that comes with unique storage and handling requirements. Please see Appendix A for further detail regarding training requirements.

RESOURCES

See the following resources for up-to-date information

- Clinical Practice Guidelines for Immunizers and Health Care Providers
- Non Public Health - PHIMS (phimsmb.ca) COVID-19 Resources and Consent Forms (Province of Manitoba)
- COVID-19 Information for Health Care Professionals (Province of Manitoba)
- Manitoba Public Health: Vaccine Safety
- Resources for Health Care Professionals (Shared Health Manitoba)
- Cold Chain Protocol – Vaccines and Biologics (Province of Manitoba)

APPLICATION AND REGISTRATION PROCESS

A. Review program inclusion requirements
B. Complete and submit the IIPC Application form
    - an IIPC team member will be in contact if any requirements are outstanding
    - complete applications will be reviewed/approved by the VITF
    - an IIPC team member will confirm approvals and provide the post-approval package along with instructions about next steps
C. Submit requests for vaccine allocations to the IIPC liaison
D. Order vaccine and supplies through MDA once vaccine allocations are confirmed
    - order only the amount of vaccine confirmed to be used within the prescribed timeframe
E. Administer immunization program according to all requirements as outlined above
F. Maintain inventory tracking processes and provide weekly reports to IIPC
G. Maintain ongoing communication with IIPC liaison

Appendix A Training Requirements

For applicants or staff members that have recent immunization or intramuscular (IM) injection experience (within the past two years), training requirements required include the **IIPC Non-Credential-Theory Only course** This is theory based self-directed study module. After registering for training, the Corporate Services Training Team will send the applicant or staff member an email with information and the self-directed study course material. After completing the training, users are asked to confirm their completion by clicking on a link to a survey. This signals to the training team that the individual has completed their training.

For applicants or staff members that have no or no recent immunization or IM injection experience (within the past two years), training requirements include the **Red River College Micro-Credential course** which includes a hands-on immunization **lab**.

For all training related questions and to register for training please contact VITFtraining@sharedhealthmb.ca.

Please note: at this time, IIPs will continue to maintain their current data entry into PHIMS practice (i.e. additional PHIMS data entry training will not be offered at this time). The IIPC liaison will notify IIPs once PHIMS training and provisioning is available.