Manitoba
Health
Population Health Division
Assistant Deputy Minister
3rd Floor - 300 Carlton Street
Winnipeg, Manitoba R3B 3M9

March 21, 2022

Ms. Rebecca Hume
8 – 149 Langside Street
Winnipeg, Manitoba R3C 1Z5

Dear Ms. Hume:

Re: Your request for access to information under Part 2 of *The Freedom of Information and Protection of Privacy Act* [Our File Number 020-22].

On January 26, 2022 Manitoba Health (MH) received your request for access to the following records:

> *I am requesting copies of all policies and procedures concerning the roll-out of the first and second doses of vaccines in correctional intuitions in Manitoba. Please note: I have already made this request via Department of Justice, who recommended I refile for records in Health, incl. Regional Health Authorizes. Date Range: January 1, 2021 to November 1, 2021*

We note that in your request you have included Regional Health Authorities. MHSC response is limited to records in the custody and control of MHSC and does not include records in the custody and control of other public bodies. Based on this clarification, access is granted in full to the attached record. Initially, the roll out of vaccinations in corrections was done by regional focused immunization teams (FIT). Later on all provincial corrections sites transitioned over to the Independent Immunization Partner Channel and the guide can be access in the following link: http://www.gov.mb.ca/asset_library/en/covidvaccine/iipc-program-guidelines.pdf

If you have any questions concerning this matter, please contact the Department's Access and Privacy Coordinator, Michelle Huhtala at (204) 786-7237.

Sincerely,

Avis Gray
Access & Privacy Officer

Attachment.

c: M. Huhtala

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Manitoba COVID-19 Immunization Campaign Operational Manual

Focused Immunization Team (FIT) Clinics

Personal Care Home & other Congregate Settings

CAUTION: Please note this manual is updated on an ongoing basis. It is recommended that you access this document from the Share Point as needed to ensure you have the most up to date information available for reference.

Disclaimer: The information therein is accurate as of the date posted, but can change over time as new information becomes available and to reflect regulatory changes. If you require access to an online version of this manual or other clinic documents, or if there are any changes required to this document, please contact the Vaccine Implementation Task Force: VITF@gov.mb.ca.

Record of Change Log

Change Date	Summary of Revisions
February 26, 2021	Original version (1.0)
March 17, 2021	Version update (1.1) • 2.5.1 Added reference to IP&C other congregate settings • 3.2.3 and 3.3.4 updated consent and removed enhanced consent • 3.3.5 Added SOP for Non-Safety Engineered Needle Use and Safety and Provincial Anaphylaxis Protocol • Updated hyperlinks throughout document • Removed Appendix A Vaccine Specific Information and in 2.1 added reference to COVID -19 vaccines authorized for use in Canada • Removed Appendix B IP&C requirements • Removed Appendix C IP&C cleaning products and schedule • Removed Appendix D • Posted all appendices on the SharePoint site
April 6, 2021	Version update (1.2) • 2.1 Updated Product Monograph links for Astra Zeneca and Covishield • 2.5.2 Updated Enhanced Cleaning section • 2.9.1 Updated Biomedical Waste • 3.1.8 Updated Transportation and Accommodation • 3.3.2 Updated Clinic Flow • 3.3.4 Updated Informed Consent • 3.3.5 Updated Vaccine Administration including AZ clinic reference
April 26, 2021	• 2.2 Added Janssen Product Monograph hyperlink • 2.7.2 NEW Media Relations section • 3.1.5 Updated staffing with roles of volunteer navigators and hyperlink to Volunteer Incident report
May 14, 2021	• 3.3.1 Added Client Identification section • 3.3.4 Added link to SOP Obtaining Consent for Minor's Presenting to COVID-19 Immunization Clinics
May 21, 2021	• 3.1.7 Updated Table 2 Training and Orientation by role
May 28, 2021	• Updated IP&C Protocol for FIT for Other Congregate and Pop-up sites. • Added protocol on clothing and shoes, amended protocol on clients and wearing masks
June 2, 2021	• 2.8 Added diagram for packing Pfizer for Transport
June 27, 2021	• 2.6 Added French Language Services • 3.3.5.Add COVID-19 Second Dose Interval Quick Reference
June 28, 2021	• Updated IP&C protocol for FIT for Other Congregate and Pop-up sites.

Table of Contents

1 Introduction

The purpose of the Focused Immunization Team (FIT) Operational Manual is to provide guidance for Service Delivery Organizations (SDOs) and Personal Care Homes and other Congregate Living settings to leverage available assets and implement immunization clinics within their sites in Manitoba. It offers tactical guidelines for setting up clinics to deliver COVID-19 vaccine, including vaccine and clinic information, staffing details and responsibilities, supplies, and reporting mechanisms.

The contents within are informed by the Government of Canada's Planning Guidance for the Administration of COVID-19 Vaccine and Planning Guidance for Immunization Clinics for COVID-19, as well as standard provincial immunization processes in Manitoba that have been adapted to the COVID-19 context.

This Operational Manual is a guiding document for Manitoba's COVID-19 immunization campaign and is designed to support the overall goal to minimize serious illness and overall death due to SARS-CoV-2 infection while minimizing societal disruption as a result of the COVID-19 pandemic.

Note:

- This manual along with the links to forms, standard operating procedures (SOPs), and protocols for Focused Immunization Teams are located on the SharePoint site hosted by Manitoba eHealth.
- Members of the public may be referred to as client, patient or resident throughout this document.
- The Department of Health, Seniors and Active Living has changed to Manitoba Health and Seniors Care (MHSC). Any document reference to MHSAL is now MHSC.

2 Standard Information

2.1 COVID-19 Vaccine Product Details

Health Canada (HC) Biologics and Genetic Therapies Directorate (BGTD) is responsible for regulation of vaccines for human use under the Food and Drugs Act and Food and Drugs Regulations. Vaccines must meet the regulatory requirements for safety, efficacy and quality before they can be approved for use in Canada.

Refer to Clinic Reference on Preparation(s) of COVID -19 vaccines authorized for use in Canada

The guidance documents from the National Advisory Committee on Immunization (NACI for COVID-19 provide further details on the vaccines available to Manitobans. For additional vaccine specific information, consult the vaccine product leaflet or information contained within the product monographs. Product monograph for the vaccine product being used MUST be physically on-site at each clinic.

Pfizer-BioNTech COVID-19 Vaccine Product Monograph
Moderna COVID-19 Vaccine Product Monograph
AstraZeneca COVID-19 Vaccine Product Monograph
COVISHIELD COVID-19 Vaccine Product Monograph
Janssen COVID-19 Vaccine Product Monograph

2.2 Vaccine Cold Chain Storage Requirements

Proper storage and handling practices are critical to minimize vaccine loss and limit the risk of administering COVID-19 vaccine that is less effective. Appropriate storage temperatures and light requirements must be maintained at each step.

The cold chain requirements for certain vaccine products require storage and distribution in a frozen state unless otherwise specified. Limiting the movement of product is preferential to reduce cold chain excursions. Due to the sensitivity of these products emergency backup power supplies and alternative storage locations are required in the event of a power or freezer failure.

The vaccines require thawing before use and cannot be frozen a second time. There are specified periods of time where the vaccines can be stored in the refrigerator, between 2° to 8° Celsius prior to use. There are also limited periods of time that vaccines can be used once mixed with diluent or adjuvant, once the vial is punctured and/or when pre-loaded into a syringe. Therefore, sufficient supply to accommodate the anticipated needs of the clinic should be available on site. The Immunization Clinical Lead must have a plan to minimize additional thawed vaccine on hand at the end of each day's clinic operation. The date the product is thawed and the date which it must be used by should be clearly marked on the vial and/or outer package.

Established protocols must be followed for monitoring and recording the vaccine storage temperature at designated frequencies during the operation of a clinic and after hours. These protocols are intended to help avoid vaccine temperature excursions and to identify when and how they may have occurred so they can be understood and subsequent occurrences minimized. The Immunization Clinical Lead or designate shall monitor and record vaccine temperatures at specified frequencies twice daily at minimum, including upon receipt and periodically during the clinic until the supply is exhausted.

If a cold chain break is identified after a vaccine has been administered, inform the Immunization Clinical Lead or designate for immediate reporting and mitigation.

A plan is necessary to prevent the vaccine from exposure to direct UV or fluorescent light, as described in the vaccine(s) product monograph.

2.2.1 Dry Ice

There is a possibility that Pfizer-BioNTech COVID-19 vaccine could be shipped in frozen state to congregate setting. Should this happen, dry ice will be required.

Refer to Vaccine Dry Ice Storage and Usage SOP
Refer to ULT Freezer Product Handling SOP

2.3 General Cold Chain Protocols

In the absence of specific protocols for COVID -19 vaccines please refer to the MHSC cold chain protocol for further guidance or the current National Vaccine Storage and Handling Guidelines for Immunization Providers for information on cold chain management, vaccine storage, temperature monitoring and transportation requirements.

2.4 Vaccine Distribution and Redistribution

Manitoba will use a mixed provider delivery model for the Manitoba COVID-19 Immunization Program. Vaccine distribution will be managed by Material Distribution Agency (MDA).

Redistribution:

If any unopened vials remain at the end of a clinic, they can be can be transported, following vaccine specific guidelines. There may be situations where a full vial of mRNA vaccine is not required and it may be feasible to use the remaining dose to immunize underserviced people who qualify for SARS-CoV-2 mRNA vaccine, but are unable to attend an immunization clinic. Under regional direction, pre-filled syringes may be utilized and transported adhering to guidelines developed.

Refer to SOP on Pre-Filled mRNA Vaccine Transport

2.5 Health and Safety Procedures

2.5.1 Infection Prevention & Control

Refer to Infection Prevention & Control Requirements for Planning COVID-19 Vaccine FIT - PCH Program.

Refer to Infection Prevention & Control Requirements for Planning COVID-19 Vaccine FIT - Other Congregate settings.

2.5.2 Enhanced cleaning

Some FIT clinic sites will have their own approved list of cleaning products, disinfectants and cleaning schedules. If the chosen site does not provide cleaning service, cleaning and disinfection of the site will be contracted out.

Refer to the Vaccine Clinic Approved Disinfectant and Cleaners list and follow the Covid-19 vaccine site cleaning service cleaning frequency schedule.

Protocol on IP&C Approved Disinfectants and Cleaners
Protocol on IP&C Cleaning Schedule

2.6 French-Language Services

French-Language services need to be incorporated into the planning and delivery of COVID-19 Immunization clinics.

Refer to SOP French-Language Services Procedure

2.7 Accessibility

Planning a clinic must incorporate methods to improve access as well as accessibility, per the Accessibility for Manitoban's Act.

2.8 Communications

Manitoba's COVID-19 Vaccine webpage includes information for Manitobans about the COVID-19 vaccines as well as Manitoba's plan for delivering the COVID-19 vaccine to its population. Clinic resources can be found on the Resources page, for both the public and health care providers (e.g., product monograph, factsheets, and consent forms). Regularly check this website for the most up-to-date resources and information, and please encourage others to access this website to mitigate the spread of misinformation.

2.8.1 Vaccine Confidence

Health care providers should refer to evidence-based resources tailored to a range of socio-cultural groups, to increase vaccine confidence, including:

- Factsheets.
- Product monographs.
- Information on Health Canada's regulatory and approval process for vaccines.

The resources and links to the information can be found on the COVID-19 Vaccine webpage.

Refer to PowerPoint Presentation Indigenous Canada Vaccine Confidence

2.8.2 Media Relations

Staff should redirect all media inquiries to Communications Services Manitoba, to the attention of Lenore Kowalchuk (204-945-7123 or lenore.kowalchuk@gov.mb.ca). Comments or interviews should only be provided by designated spokespeople.

2.9 Supply Management

The required and recommended list of supplies to operate a COVID-19 Immunization Clinic will vary from site to site depending on availability. Given the nature of the items required to operate a clinic, the items will be ordered through MDA. Additionally, where possible some items that can be more easily provided by the site (e.g. tables) should only be ordered where this option is not available.

The Immunization Clinical Lead will be responsible for ordering all supplies including vaccine.

Refer to Vaccine Clinic Supply Order Forms PCH

Refer to Vaccine and Supplies Order Process Map
Refer to Vaccine Supply and Distribution PCH SOP
Refer to Pfizer Packing for Transport diagram

All supply orders use the following procedures:

- All items are entered into the Vaccine Clinic Supply Order form and submitted to MDAPPEOI@gov.mb.ca and copy kathleen@pahkala@gov.mb.ca. For product information or concerns and the most up to day supply order from contact Kathleen Pahkala 431-338-2330 or kathleen.pahkala@gov.mb.ca.

- Supplies are to be ordered a minimum of one week prior to FIT immunization clinic with confirmation of number of vaccines required at least 3 business days prior to that clinic (number of completed consent forms received).

- For "On Demand" items the Immunization Clinical Lead should contact the location of the clinic in order to determine which items are already on location or can be provided by the venue. This can be collected by using the Request for Information sheet RFI Form.

- When ordering vaccine and other supplies, you must ensure contact person who is available to receive the supplies is listed on the MDA order form. The first and last name as well as their cell phone number must be present and ensure the recipient is available during the delivery timeframe. An alternate contact's information also needs to be provided.

- Supplies should be ordered in sufficient quantities to last for the duration of the clinic. Immunization supplies will be delivered daily along with the vaccine in Winnipeg. For rural clinics, MDA will ship the vaccine and supplies two days in advance. The clinic location will not be expected to store immunization supplies on site in advance of the clinic date.

- PCHs and other congregate settings are asked to provide gowns, gloves, rolling carts, a supply room, and vaccine storage options if available. Where available, they will also be asked to provide one site nurse (RN, LPN, RPN) for each immunization clinic. Regional Managers or Clinic Leads are responsible for coordinating with each site to determine supplies and resources available for use.

- The same process is to be followed for ordering supplies and vaccine for second dose.

2.10 Security and safety plans

This section contains the security and safety plans for vaccines, supplies, staff, members of the public, and biomedical waste.

2.10.1 Biomedical Waste

For safety and security purposes, vaccine and vaccine packaging MUST be disposed of in accordance to the criteria below:

1. Used vials must have their labels removed and be discarded with medical waste. Labels must be shredded or ripped up;

2. Vaccine packaging (boxes) must have the producer's label removed from the box and shredded or ripped up. The cardboard box can be recycled.

Refer to regional policy for additional information on safe handling biomedical waste.

2.10.2 Vaccine Security on Site

Soft security on site for any facility holding vaccine regardless of amount. Each Regional Manager/Immunization Clinical Lead is to coordinate on site with security providers (i.e. both internally and externally arranged providers) the practical placement of security personnel and/or devices as appropriate.

It should also be understood that public safety must be provided concurrently with vaccine safety at immunization clinics so Regional Manager/Immunization Clinical Lead must work with the VITF security procurement team to determine the resourcing needs and sources.

2.10.3 Vaccine Security in Transit

COVID-19 vaccines transported from location to location (including those carried by Focused Immunization Teams "FITs" and Pop-up Clinics) shall be provided security as per currently approved VITF practice.

- Contact vaccine implementation task force: Gino Bucci, phone: 204-806-3093, email: gino.bucci@gov.mb.ca.

3 Immunization Clinic Framework

3.1 Coordination

Planning and implementation of immunization clinics requires experienced leadership and the coordination of many community groups and individuals. Clinic leadership will provide overall management, planning and coordination of clinic operations, as well as knowledge of public health practices and infection prevention and control to prevent the transmission of COVID-19.

3.1.1 Provincial government

The provincial government provides primary leadership and coordination for planning clinic delivery models and developing the pool of human resources for key clinic roles. Agreements for facilities, parking, security, transportation, are negotiated in advance. The provincial government also manages procurement, storage and distribution for all the vaccines and required supplies to the immunization clinics.

Provincial COVID-19 Immunization Workforce Director

- Responsible for the overall coordination of vaccine administration in Manitoba, working with the six Service Delivery Organization (SDOs) across the province: Interlake-Eastern Health Authority; Northern Regional Health Authority, Prairie Mountain Health, Southern Health Santé Sud, Winnipeg Regional Health Authority, and Shared Health
- Leads and manages a flexible and collaborative team with a culture of client service to prepare and oversee vaccine administration in Manitoba
- Direct authority and accountability for COVID-19 immunization clinics
- Accountable for the delivery on all service level commitments for:
    - Human resources
    - Financial management
    - Inventory control and distribution
    - Contracts with external companies
    - Reporting
    - Ensuring client satisfaction
    - Operations and policy development

3.1.2 Service Delivery Organizations (SDOs)

Service Delivery Organizations (SDOs) or other service providers such as FNIHB or First Nations are responsible for the management and oversight of service delivery within their jurisdiction. SDOs are responsible for identifying appropriate staff, developing a staffing plan, and ordering all necessary supplies to implement immunization clinics in their region. If further resources are required, they can secure more staff from the pool of provincially hired Shared Health staff. Regional managers will adapt the details for clinic planning within this manual to accommodate their specific needs.

3.1.3 Clinic implementation

Regional managers will be responsible for the oversight of the clinics. Core staff and their roles and responsibilities are identified in the staffing section of this manual.

3.1.4 Clinic assumptions

Clinic planning begins with determining the number of people to be immunized which is based on vaccine supply and eligibility screening criteria. This number is then used to determine the number of staff required at each clinic.

Factors to consider:

- Vaccine allocation, timing of distribution, and eligibility criteria impact the number of people who can be immunized
- Process to obtain informed/enhanced consent
- Staffing needs are based on vaccine supply, clinic size, and resource constraints may allow for roles to be consolidated
- Immunization rates are impacted by time taken when administering to people with language or cultural barriers, those requiring special assistance, and receiving consent
- If running clinics more than five days per week, it is optimal to provide each full time staff member with two consecutive days off per week, if possible
- Use same location to administer first and second dose to avoid confusion and control volumes

3.1.5 Staffing

The following five (5) roles in Table 1 are deemed an essential part of immunization clinics. The Manitoba Government is generating a pool of human resources for these key roles. FTEs may change based on clinic size.

Table 1: Key roles for FIT immunization clinics

Position	Main Tasks
Regional Manager	Lead clinic planning, manage media issues, occurrences, complaints, staffing or logistical issues.
Immunization Clinical Lead	Primary focus on clinical services, informed consent, adverse reactions management & reporting, clinical practice, post immunization observation area, ordering clinic supplies, vaccine inventory management
Immunization Team Member (clinical)	Verify informed consent. Draw up and administer vaccine and document the immunization
Site Point Person	Site orientation, management of site supplies, welcome the immunization team, manage and problem solve residents/clients/patient issues. Liaise with staff, clients and family members.
Site Clinical Staff	Assist in welcoming, prepping and identifying residents/clients/patients. Site clinical staff with experience in immunizations and with completion of Red River non-credentialed training, can draw up and administer vaccine and record immunization. Site clinical staff observe the residents/clients/patients after immunization for the recommended time based on the vaccine administered and respond to any immediate reactions or medical emergencies and/or answer any health questions. Site clinical staff also respond if there are any non vaccination related medical emergencies.
Volunteer (if applicable):	Welcoming, orienting and directing clients attending the immunization clinic; assist with screening, greet and assist with traffic flow throughout the clinic, direct clients to use hand sanitizer throughout the clinic, identify clients who require an interpreter or additional physical assistance, assist with sanitizing clipboards and pens in the informed consent area. Please refer to Volunteer Incident Report Form in the event volunteer has an incident (ex. fall).

NOTE: Other required positions may include a data entry clerk, Custodial staff, Cleaning/disinfection services, Security

Position descriptions for key roles and other critical roles/services have been developed. See https://sharedhealthmb.ca/covid19/providers/jobs/.

3.1.6 Staffing models

Two different staffing models will be utilized in delivering COVID-19 FIT programs within the PCH and other congregate settings.

1. Focused Immunization Team
2. Blended Delivery

Focused Immunization Team

Designated team will travel to each location to deliver the immunization program. Each Focused Immunization Team (FIT) will be comprised of the following personnel and will be scaled up as needed:

- 1 x Immunization Clinical Lead
- 1 x Immunization Team Member
- 1 x Site Point Person

Each region will draw from 3 categories of staff:

1. Existing staff – casual immunization nurses, public health nurses, and primary care nurses
2. New hires through Shared Health
3. Private organizations

PCH

It is recommended that regions draw on experienced immunizers. One nurse (RN, RPN, LPN) from the site (Site Point Person) will be dedicated to the immunization clinic to assist with navigation throughout the site. This nurse will not be tasked with immunizing unless there are residents identified with reactive behaviours where use of a familiar nurse would improve the immunization experience.

Other Congregate Settings

It is recommended that one contact person from the site be present and available to assist the team with Navigation throughout the site.

Blended Delivery

Site will be responsible to deliver the immunization program with the support of a FIT Immunization Clinic Lead and other FIT members as necessary. Each Blended Delivery Clinic will be comprised of the following personnel and will be scaled up as needed:

- 1 x FIT immunization Clinical Lead
- 1 x Site Point Person
- 1 x Site Clinical Staff (Immunization Team Member)
- Additional FIT Immunizers as indicated if site staff unavailable

Each site will draw on existing site clinical staff that have received training.

3.1.7 Training and Orientation

A comprehensive training and orientation package for clinic staff has been developed. Please see table below for further details.

Table 2: Training/orientation required by role

Role	Training materials
Immunization Clinical Lead	• RRC Micro-Credential Course (theory and practical) or Non-Credential Immunization Training (self learning) - depending on previous immunization and PHIMS experience required • PHIMS Training specific to Clinic Lead role • PHIMS Practical Training provided first shift by experienced clinic lead

	• LMS Training (PHIA, Fire Safety, Hand Hygiene, PPE, WHIMS) required if Shared Health employee • Clinic Orientation offered first shift by regional manager
FIT Immunizers	• RRC Micro-Credential Course (theory and practical) or Non-Credential Immunization Training (self learning) - depending on previous immunization and PHIMS experience required • PHIMS COVID 19 Immunizer Course LMS-1601 • LMS Training (PHIA, Fire Safety, Hand Hygiene, PPE, WHIMS) required if Shared Health employee • Clinic Orientation offered first shift by clinic manager/clinical lead
Site Immunizers	• RRC Non-Credential Immunization Course • Clinic Orientation offered first shift by Immunization Clinical Lead

3.1.8 Transportation and Accommodation – For FIT Team Members

Travel within a region

Where possible staff should be encouraged to use their own vehicle to travel to targeted sites to ensure physical distancing. Staff shall record their mileage for reimbursement at the current government rate.

If travel is required to locations where the use of a personal vehicle is not feasible, then transportation should be arranged by the regional manager that allows for staff to maintain physical distancing. Procedure masks must be worn by all staff who are being transported in the same vehicle.

In the event the FIT requires staff to be away from their residence overnight, it is the responsibility of the regional manager to ensure appropriate accommodations are secured. Meal costs will be reimbursed based on the current government allowances. Food may be available from a central kitchen depending on location.

Travel outside of a region

Shared Health immunization employees will be reimbursed for travel related expenses if assigned from one region to another (designated as a "Travelling Immunizer or Navigator"). Provincial Director can provide details on the Travelling Immunizer and Navigator Travel Expense Claim Policy.

3.2 Documentation & Reporting

The following will be recorded in PHIMS: Immunizations administered, consent obtained, immunization errors (e.g., injection too high up the arm, administration of vaccines found to have been involved in incidents of adverse storage conditions, etc.) and adverse events following immunization (AEFI).

3.2.1 Data Entry

Every health care provider and facility in Manitoba **MUST ACCOUNT FOR EVERY DOSE OF VACCINE ORDERED AND ADMINISTERED.** Immunizations are entered into a client's electronic public health record via the Manitoba Immunization Registry - Public Health Information Management System (PHIMS). PHIMS is a secure, integrated electronic public health record that contains important public health information maintained by Manitoba Health and Seniors Care (MHSC).

Data entry by PHIMS users is described below.

- Generally, public health providers enter the immunization data directly into PHIMS and can review a client's immunization history and forecaster. For vaccines administered by non-public health providers, immunization data will be received into PHIMS via electronic interfaces from Physician billing.
- PHIMS sends Manitoba client's immunizations data into eChart Manitoba. Most non-public health providers view a client immunization history by accessing a client's immunization (line list) in eChart Manitoba. Only immunization records on clients with a Manitoba Health Personal Health Information Number (PHIN) are sent to eChart Manitoba.

Clients who are not in the PHIMS client registry, (e.g. the client does not have a PHIN, the client is from out of province or country but is seeking services in Manitoba), their record in PHIMs will need to be manually created following the "create client" process. Clients should be advised that if they are not in the PHIMS client registry their health care provider will not be able to see their immunization record in eChart.

The COVID-19 Immunization Consent Form as well as the Request to Create Client in PHIMS form will need to be completed for this client. A minimum of 5 client identifiers are required to create a client in PHIMS. Please refer to PHIMS Training and Support Tools, Managing Client Records – 1.0 Creating a Client.

NOTE: PHIMS users should continue to refer to the PHIMS Training and Support Tools website for reference documents, training and support tools, tip sheets, FAQs and other materials related to immunization and inventory management.

3.2.2 Digital Health

PHIMS users should follow these steps for access issues, account requests, and downtime procedures.

System Access Issues

If users encounter internet related issues, speak with your immunization clinical lead or regional manager to determine if it's a local issues. If users can access the internet but are encountering system access issues (for example they are unable to access the PHIMS or they are experiencing email access issues), contact the Shared Health Service Desk. If your issue is urgent you must call 204-940-8500 and stay on the line to speak with an agent. For non-urgent requests or issues you may also alternatively email servicedesk@sharedhealthmb.ca.

User Account Requests

To get a user set up on the PHIMS complete and submit the Digital Health ACMT (Add Change Move Transfer) form, and the Authentication Questions. Both forms can be obtained from digital health to grant them access to the system or obtain forms from the Forms folder. The ACMT form must be approved and submitted by a pre-authorized Manager or Director.

Please note the hyperlink provided above is located on an intranet (internal) website, therefore, not accessible from public internet or those that may be attempting to access external to the Provincial Data Network.

Downtime Procedures

Downtime refers to a point in time when a specific system such as PHIMS is not available (or not working as expected) and workflow procedures must be changed to continue working without the system. Downtime can be either scheduled or unscheduled.

Refer to Digital Health Operational Manual.

3.2.3 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.

A reportable AEFI is an event that:

- is temporally associated with a vaccine, and
- has no other clear cause at the time of reporting.

An AEFI is considered "unexpected" if either of the following criteria is met:

- is not listed in the most current Health Canada-approved product monograph for vaccines marketed in Canada, and
- listed in the product monograph but is different in nature, severity, frequency, specificity or outcome.

Information contained in the AEFI User Guide will provide immunization providers with direction for how to correctly complete and submit either in PHIMS or by using the pdf reporting form. Please see PHIMS Training and Support Tools - COVID Immunizer Resources for information on documenting an AEFI. For providers without access to PHIMS there are instructions at the bottom of the pdf reporting form for how and where to submit when completed (submit to Medical Officer of Health (MOH) in your Regional Health Authority). Any reported AEFI is routinely reviewed and, if needed, investigated further. In all cases, recommendations with respect to future immunizations is provided by a Medical Officer of Health.

In accordance with 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 (as per section 59 of The Act). 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. Regions are responsible for running regional AEFI reports on a regular and ongoing basis. Please refer to PHIMS Training and Support Tools for guidance on Generating an AEFI Report.

For more information on AEFI, visit Manitoba Public Health online.

3.2.4 Cold chain reporting

Please refer to the MHSC Cold Chain Protocol for further information. COVID-19 specific protocols are still under development.

3.2.5 Wastage

Industry standard for vaccine wastage is approximately 5%. All wastage must be tracked in PHIMS. Refer to PHIMS link on Documenting Vaccine Wastage and refer to section on Vaccine Securities, Tracking and Inventory Reconciliation in PHIMS.

3.2.6 Evaluation

To ensure immunization clinics are running as efficiently and optimally as possible, the Province is developing an evaluation process and will be implemented in the coming weeks. The information collected will be recorded and used by the Province of Manitoba for the sole purposes of improving the efficiency and effectiveness of the immunization clinics.

3.3 Operations

3.3.1 Appointment Booking

Each region will be responsible for scheduling appointments following Manitoba standards on dosing intervals.

PCH and other congregate settings are to track new admissions and clients who did not receive immunization during previous clinic visit. Regions will partner with PCH and other congregate settings to develop customized plans to identify how and when individuals will receive first dose and second dose. Clinics are scheduled when a minimum number of residents are available to receive the vaccine.

3.3.1 Client Identification

Clients are asked to provide one (1) form of client identification (ID) prior to receiving their immunization. Clients will be reminded by appointment booking call centre or by online scheduling portal to bring ID to their scheduled immunization appointment.

The preferred form of client ID is the Manitoba Health Card (Registration Certificate). If the client does not have a Manitoba Health Card or Personal Health Identification Number (PHIN), other examples of acceptable ID include birth certificate, employee identification, gun registration, immigration card/document, passport, student card, treaty status card, vehicle license, etc.
If client is unable to present one form of physical ID, proceed to verify client ID by searching client in the Public Health Management System (PHIMS). Use two client identifiers (e.g. name and date of birth). If client record is found in PHIMS, and immunization history verifies client is eligible to receive vaccination, proceed with immunization. If unable to locate client in PHIMS, consult with Clinic Lead or Clinic

Manager and attempt to gather five client identifiers and proceed with manually creating a client in PHIMS following the "create client" process.

3.3.2 Clinic flow

Each site is requested to identify a site point person for the day of the on-site campaign to assist the immunization team to navigate the site, problem solve any changes, assist with post immunization observation.

Site assistance requested from Site Point Person/Site Clinical Person:

- Identify an area where supplies can be safely stored during clinic day
- Assist the FIT in securing supplies required for the clinic day (e.g. carts to transport supplies and vaccine through the site, etc.)
- Assist the immunization team with any problem solving required
- If site clinical person, assist with post immunization observation and participate as part of the immunizing team if required

Three different vaccine administration models may be considered; Cart to room delivery, with administration of vaccine taking place in the residents/clients/patients room; Fixed point of administration, with all residents/clients/patients going to one location to receive the vaccine, or a hybrid of the two aforementioned models.

- The preferred approach for PCH immunization is cart to room.
- If a site is in an outbreak, the immunization process is to occur in a cart to room fashion working from non-outbreak units to outbreak units.
- If a site is not in an outbreak, immunization in a congregate setting is an option. If a site is looking to plan for a centralized vaccine clinic, they must engage their site IP&C representative in the planning and consider how the observation period will be monitored
- Hybrid models may be used where congregate is suited for some residents/clients/patients but not others.

Post Immunization Observation Period

Clients require a post observation period of 15-30 minutes post immunization to be monitored for adverse reactions. FIT team, in collaboration with the site, will determine the process for monitoring clients and responding to adverse events. On occasion a client may feel faint, show signs of allergy or any other health issue (before or after the immunization). These clients require treatment as appropriate and 911/emergency response should be initiated as needed.

Refer to Provincial Anaphylaxis Protocol: Community Health Immunization for suspect allergy or anaphylaxis response during an immunization clinic.

3.3.3 Eligibility Criteria

A complete vaccine series of COVID-19 vaccine may be offered to individuals who meet province of Manitoba eligibility criteria. Please refer to Manitoba's COVID-19 Vaccine website for information on provincial eligibility criteria.

PCH

All residents are eligible to receive vaccination unless otherwise contraindicated, despite previous disease. Residents with previous COVID-19 infection can be vaccinated if they are no longer symptomatic and are clinically feeling better. Residents should not be vaccinated if they have any symptoms that could be due to COVID-19. Refer to current provincial guidance on whether staff are eligible to receive vaccine in instances where unused vaccine may be subsequently wasted at the end of a clinic.

Other Congregate Settings

All adult clients residing in other congregate setting where FIT is delivering the COVID-19 immunization program are eligible to receive vaccination unless otherwise contraindicated. Refer to current provincial guidance on whether staff are eligible to receive vaccine in instances where unused vaccine may be subsequently wasted at the end of a clinic.

3.3.4 Informed Consent

As per MHSC Informed Consent Guidelines for Immunization, verbal or written consent must be obtained prior to immunization and must be documented. Documentation can be done on the COVID-19 Immunization Consent form, within PHIMS, within the client health record, or within any other approved charting system. Signed consent forms are valid for one year from the time of signing.

Refer to SOP Obtaining Consent for Minor's Presenting to COVID-19 Immunization Clinics for additional requirements related obtaining informed consent in clients under the age of 18.

Please see the Clinical Practice Guidelines for Immunizers and Health Care Providers regarding 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; or people who should not be immunized and require further consultation.

Individuals who are pregnant, planning to become pregnant or breastfeeding; immunosuppressed due to disease or treatment and/or have an autoimmune condition, need to only complete one consent form.

PCH
Two weeks prior to the immunization clinic date, PCHs should access the current version of the COVID-19 Immunization Consent Form and Factsheets. PCH staff are responsible for obtaining informed consent by working with the residents, legal decision maker, Public Guardian, and/or Trustee.

Per PCH practice, a prescriber order is also obtained. The number of completed consent forms are to be sent to the FIT Immunization Clinical Lead 72 hours prior to the immunization clinic. Residents who refused vaccination are not to be included in the number to the FIT Immunization Clinical Lead.

PCHs will work with residents and legal decision makers to obtain informed consent by phone/virtual for verbal consent, or fax for written consent. Email is not an accepted means of obtaining consent. Consent forms will be valid for one year from date signed to accommodate for the second dose of vaccine, a second consent form is not required. Consent is entered into PHIMS will need to reflect this time frame. Once both doses of the vaccine are administered, the original consent form(s) are to be filed in the residents' health record.

Other Congregate Settings
Region and other congregate sites will determine best method to obtain Informed Consent. Process to provide site with consent forms and applicable fact sheets, as well as a mechanism to confirm number of clients consenting to vaccination prior to clinic date should be established to ensure supplies and vaccine ordered and brought to site coincide with the number of clients receiving vaccine.

3.3.5 Vaccine Administration

COVID 19 immunizations are administered by immunization teams at a variety of sites in Manitoba. Vaccine product used for first dose will be determined by clinic location, availability, and current eligibility criteria. Clients must receive the correct COVID-19 vaccine product for subsequent dose administration in the correct dosing interval.

Refer to SOP on Vaccine Product Dose Interval for Immunizer
Refer to COVID-19 Second Dose Interval Quick Reference

The Immunizer is responsible for drawing up their own immunizations prior to administration. Direction is not to reconstitute and pre-draw vaccine for someone else to administer. For quick a reference on administering COVID-19 vaccines, please see the following clinic reference sheets:

Refer to Clinic reference Pfizer for Immunizers
Refer to Clinic reference Moderna for Immunizers
Refer to Clinic reference AstraZeneca for Immunizers

Using a non-safety engineered needle and/or syringe is a procedure outside of the norm, and would be utilized only when safety engineered 1 mL needles and/or syringes cannot be procured as the primary choice for immunization clinics.

Refer to SOP for Non-Safety Engineered Needle Use and Safety

Immunizers using Pfizer vaccine can draw six (6) doses for administration.

Refer to SOP for Pfizer Drawing 6 Doses Recommended Practice

Dead-volume (aka dead space) is the amount of fluid remaining within the syringe and needle after an injection is completed. Low dead-volume syringes and needles are designed to reduce this wastage.

Refer to Pfizer Reference for Low Dead Volume Syringes

3.3.6 Vaccine Securities, Tracking and Inventory Reconciliation in PHIMS

Since the supply of vaccine may be limited and the demand may be extremely high, care must be taken to protect the vaccine supply from theft and fraud. Every vaccine and vial must be accounted for at the start and end of each immunization clinic data entry day.

It is expected that the Immunization Clinical Lead would ensure that the following actions are completed by their team(s) in PHIMS within the specified time frame indicated for each:

When product physically arrives at the site:

- After physical receipt of inventory at the site, the requisition in PHIMS should be received into the proper Holding Point Location on the same day that the product arrived (preferably within 2 hours). Refer to QRC 4.4 Receiving a Requisition.

Entering immunizations in PHIMS, through a Mass Immunization Event (or other method of entry):

- Immunizations administered by FIT teams are expected to be entered into PHIMS within 24 hours of the actual clinic date, if possible by the end of the next business day.

- Users must ensure that the organization selected allows them to access the appropriate holding point and that the Service Delivery Location (SDL) selected is correct. Please select the appropriate SDL in PHIMS for PCHs (Refer to Mass Immunization Events Guide for COVID-19-PCH) and for correctional facilities (Refer to Mass Immunization Events Guide for COVID-19-Congregate Settings).

- The following global Service Delivery Locations (SLDs) have been set up for FIT Immunization Clinics where an SDL does not already exist in the system:

  First Nation Focused Immunization Team Site
  Interlake-Eastern Focused Immunization Team Site
  Northern Focused Immunization Team Site
  Prairie Mountain Focused Immunization Team Site
  Southern Focused Immunization Team Site
  Winnipeg Focused Immunization Team Site

Documenting Wastage in PHIMS:

- Any doses wasted during immunization clinics should be documented within the same time period, preferably immediately after the data entry for doses administered has been completed. Refer to PHIMS link on Documenting Vaccine Wastage. Industry standard for vaccine wastage is approximately 5% and Manitoba is aiming to fall well below that benchmark.

Reconciling Inventory on Hand in PHIMS:

- Once all doses administered and wasted have been documented, and before inventory is removed for the next clinic, complete a physical inventory count in PHIMS to ensure that the inventory on hand in the system reflects the actual inventory in the refrigerator/freezer using QRC 4.8 Physical Count.

- Physical counts should be completed in PHIMS on a weekly basis at a minimum, but preferably at the end of each day where immunization clinic data and wastage is entered.

3.3.7 Vaccine Usage

Due to limited vaccine supply during early phases of the COVID-19 immunization program, limiting vaccine wastage is critical. The site will make every effort to provide as accurate a number of people to be immunized as possible. However, since consenting clients may be ill on the date of the clinic, it is understood that fewer people than planned may be available to be immunized. The number of doses of vaccine brought to the site is determined by the following:

- Consenting clients+ 5% rounded up to the nearest vial to account for vaccine wasted

Vaccine will be transported based on consenting client numbers. The process is to check in with the site same day or day before to confirm the actual numbers of consents. This number may vary from the number of clients to take into account deaths, symptomatic residents, clients transferring in and out of the congregate setting, and refusal of immunization. A tracking tool may be used to manage clients moving in and out of congregate settings.

Refer to PCH Resident Vaccination Tracking Tool to assist in monitoring clients moving in and out of congregate settings.

Refer to SOP on Process to limit vaccine wastage in PCH.

Unopened vials should be dated and transported back to the base office for future FIT team use before they expire. Adjust your order for the next clinic accordingly.

3.4 Data management

Paper consent forms will be the standard practice utilized at PCH and other congregate settings and there will be no requirements for direct entry into PHIMS. PCH and other congregate setting will provide line listing of consenting resident information to FIT Immunization Clinical Lead 72 hours prior to immunization clinic. Sites may scan, email, collect, or fax completed consent forms to the FIT Immunization Clinical Lead. This information will be used to set up a mass immunization event in PHIMS (refer to the Mass Immunization Events Guide for COVID-19 – PCH). PLEASE NOTE: it is extremely important to ensure that the correct Service Delivery Location, Holding Point Location and Reason for Immunization is selected when creating the Mass Immunization Event. It is also important to ensure that the Auto Decrement function is checked. The FIT Immunization Clinical Lead will upload the information into the immunization event and print a Mass Immunization Event Data Event Worksheet Report with the clients' or residents' information for the upcoming clinic. For PCH information required to establish a mass immunization event may be successfully downloaded from the Long Term Care (LTC) database. **IF** there are clinics with full connectivity and **IF** the immunizers are trained in PHIMS then direct entry into PHIMS can occur.

During the immunization clinic:

- If using direct entry into PHIMS, doses administered should be entered in real time using the appropriate Mass Immunization event (refer to Documenting COVID-19 Immunizations).
- Should wastage occur, document directly in PHIMS using the Documenting Vaccine Wastage guideline.

  PLEASE NOTE: it is extremely important to ensure that the correct Service Delivery Location as well as the appropriate Reason for Wastage is selected when documenting wastage in PHIMS.

- If direct entry into PHIMS is not possible at the time of wastage, ensure to track the number of doses as well as the reason for wastage to ensure that the correct information may be entered in PHIMS at the end of the clinic day.
- At the end of the event, ensure all clients on the mass immunization worksheet have a status recorded. E.g.: "immunized", "absent" (no shows) or "deferral" (clients unable to be immunized).

PCH

Once the immunization clinic is complete, the original consent form is to be left at the PCH and will need to be available for second dose administration. A copy will be provided to the FIT Immunization Clinical Lead to be entered into PHIMS. FIT Immunization Clinical Lead will be responsible for meeting the requirements of data entry into PHIMs within 24 hours. This may be done in partnership with local Public Health office. When entering immunizations into PHIMS, if the immunizer has not been added as a provider within PHIMS, assign the immunization to "other provider". Please refer to Mass

Immunization Events Guide for COVID-19-PCH document for detailed instructions on how to add "other provider" to immunizations given by non-PHIMS providers.

Any consent forms for staff that receive immunization due to extra doses post immunization clinic should be brought back to the Public Health office by the FIT Immunization Team Lead for data entry into PHIMS. Staff cannot be added to the Mass Immunization Event, and must be entered as individual immunizations in PHIMS. The FIT Immunization Clinical Lead is to ensure staff consent forms are brought back to the PCH for second dose administration. Once the second dose is complete and entered into PHIMS, consent forms would be stored and/or disposed of as per regional policy.

Other Congregate Settings

Once the immunization clinic is complete, the region and other congregate sites will determine if a copy of the consent form is required to stay onsite in a client medical file/record. A copy will need to be provided to the FIT Immunization Clinical Lead to be entered into PHIMS. FIT Immunization Clinical Lead will be responsible for meeting the requirements of data entry into PHIMs within 24 hours. A plan to bring consent forms back to the site for the second dose will be determined by the region and congregate setting.

3.5 Quality Assurance and Continuous Quality Improvement

An integral part of our ability to improve our service delivery of vaccines to Manitobans is a robust risk management and lessons learned process. The identification and reporting of risks and lessons learned should be integrated into day to day operations. Everyone working to deliver vaccines to Manitobans should be encouraged to identify and report potential risks and lessons learned. The following paragraphs describe Risk Management and LEAN/Lessons Learned.

3.5.1 Risk Management

Risk management is the identification, assessing and controlling of risks and making decisions that balance risk costs with the task benefits. Team members at all levels can and should identify what may be considered risks that would hamper the ability to deliver vaccines to Manitobans.

Team members can do this by:

- Identifying a potential risk.
- Describing the risk.
- Identifying the impact/consequence if the risk is not addressed.
- Assessing whether the risk has a minimal, minor, moderate, significant or severe impact.
- Assessing whether the risk has rare, unlikely, possible, likely or almost certain probability of happening.
- Proposing a plan to mitigate the risk.

Once a risk has been identified it should be forwarded to the Quality Assurance Workstream, attention Dennis Tabbernor at Dennis.Tabbernor@gov.mb.ca or at 204-945-4241.

3.5.2 LEAN, process improvements, and lessons learned

LEAN approaches for vaccine programs include the following:

1. When vaccine supply is stable, staffing levels need to align more closely to the number of appointments/day
    - A policy of regular overstaffing provides safety, but it also hides process problems
2. Signage is crucial to remove friction from the client experience and improve process flow
3. Creating regularly restocked immunizer supply kits to shorten the vaccine reconstitution and pre-draw steps
    - 24% of current Pfizer immunization cycle time is tied up with these steps
4. Develop consistent process for tracking immunized clients in mobile site settings during post-immunization recovery period
    - For example, placing sticker on the immunized resident with a time stamp of when their observation period ends
5. Consider shipping vaccine directly to the PCH/mobile site rather than requiring a FIT team member to pick-up at a storage facility
    - Will free-up a significant amount of FIT Lead's time to focus on immunizing and other related tasks
6. Identify and train up PCH staff to immunize PCH residents
    - Will improve process efficiency and reduce number of FIT team members required

7. Streamline data-entry processes to reduce duplication of information
    - Continue with 'mass event' lot numbers; review other data entry tasks

Process Improvements: Process Flow Value Stream Maps are used to determine total client processing time, non-productive time, turnaround time, wait time, immunization time, and reconstitution time.

Calculations are used to determine **TAKT** = the pace of customer demand for a day:

$$TAKT = \frac{\#\ of\ available\ work\ minutes\ per\ day}{Total\ \#\ of\ doses\ per\ day}$$

Calculations are used to determine **Cycle Time** = the time from the one point in a process until the same point in the next cycle:

$$Cycle\ Time\ (C/T) = \frac{P/T}{\#\ of\ Immunizers}$$

Calculations are used to determine **Process Time**: measured time from when a client presents in front of immunizer until next client presents in front of immunizer:

$$Total\ Avg\ Vacc'n\ Proc\ Time = Observed\ Average\ P/T + Average\ Recon/dose$$

$$Average\ Recon\ time/dose = \frac{Average\ Reconstitution\ Time/vial}{6\ doses/vial}$$

$$Target = \frac{Ratio\ Average\ Vacc'n\ Cycle\ Time}{TAKT}$$

Refer to Vaccination Sites Lean Guidelines document for details on calculating TAKT, Cycle Time, Process Time.

Lessons Learned: A dedicated Lessons Learned Champion for mobile/congregate sites is responsible for regularly collecting feedback from staff, recording staff improvement ideas and assists with implementation of solutions as required. This Champion reports directly to the Clinic or Regional Manager as appropriate.

Refer to Vaccination Sites Lean Guidelines document for continuous process improvement overview, huddle templates, lessons learned tracking sheet, lessons learned log, and communication structure.