

OFF-SITE IMMUNIZATION POLICY FOR COVID-19 VACCINE ADMINISTRATION BY PHARMACISTS

As Alberta continues to work towards achieving an immunization goal of at least 70% of all eligible Albertans being fully immunized as soon as possible, there has been an increasing number of requests from pharmacies and individual Albertans to facilitate the provision of COVID-19 vaccines off-site. This is particularly critical for rural communities where individuals may not be able to readily access Alberta Health Services Immunization Clinics or a community pharmacy.

When considering provision of off-site immunization services, planning and operationalization should focus on the scope and quantity of expected individuals requesting immunization.

Off-Site for Individuals or Small Groups (5 individuals or less): use of Prefilled Syringes (PFS) may be preferred in order to minimize vaccine wastage and the need to immunize vulnerable people who are not able to attend an immunization site (AHS clinic or pharmacy). Situations where this may be warranted include, but are not limited to;

1. Home visits for homebound individuals
2. Congregate care sites for a small number of residents who missed the previous immunization clinic(s)

When operationalized, off-site immunization can increase the capacity of all partners and increases immunization access to Albertans as it allows:

- The health care system to collaborate and connect with individuals that may be hard to reach, be hesitant to receiving the vaccine or have other barriers (e.g., lack of trust in government, transportation, English as a second language, other) that decrease their likelihood of accessing immunization services.

Mandatory Requirements

The following guidelines **MUST** be adhered to for any off-site immunization. The safety of Albertans and the integrity of vaccine are of the utmost importance.

- This policy **does not support the movement of any COVID-19 vaccine vials**.
- COVID-19 vaccine which has been punctured can **ONLY** be moved to another location if it is in a **pre-filled syringe (PFS)** and adheres to the transport and safety requirements for pre-filled syringes.
- Maintenance of cold chain with temperature monitoring devices (TMD) **MUST** be maintained at all times for any vaccine moved off-site. Documentation and maintenance of a temperature log is **mandatory** and these records must be kept for 3 years.
- ALL public health guidelines in effect at the time of the off-site immunization clinic (i.e. masking, social distancing, building capacity, etc.) **must** be adhered to at all times.
- **There must be one responsible individual assigned** who is the key contact for the off-site immunization and is responsible for ensuring all requirements are met before, during and after the off-site immunization. This includes daily AVI reconciliation and Alberta Blue Cross (ABC) claim submissions. **The responsible individual must be either a pharmacist or regulated pharmacy technician.**

Consult the Alberta COVID-19 Immunization Policy (ACIP) and the Alberta COVID-19 Pharmacy Immunization Program (ACPIP) for general guidance and information.

It is critical that prior to conducting any immunization, including off-site immunizations, pharmacy partners review the requirements in the ACIP and ACPIP by reviewing the most current versions posted by Alberta Health.

[Alberta COVID-19 Immunization Policy \(ACIP\)](#)

[Alberta COVID-19 Pharmacy Immunization Program \(ACPIP\)](#)

COVID-19 Vaccine Reporting and Data Requirements

All requirements in the [Alberta Immunization Regulation](#) as well as the ACIP and ACPIP related to immunization reporting, adverse event reporting, cold chain breaks, AVI reconciliation and others **MUST** be adhered to for any off-site immunization.

- NETCARE/ImmARI reporting access is readily available to confirm immunization history and to pre-screen eligibility for individuals.
- Ensure individuals have valid Alberta Health Care, if not refer to AHS for immunization services.

- Ensure vaccine temperature monitoring is documented regularly throughout the duration of the clinic, and that cold chain temperature is maintained until administration of the vaccine.
- Ensure appropriate documentation and reporting if an [Adverse Event Following Immunization \(AEFI\)](#) occurs.
- Immunization claims to be submitted to ABC to meet same day submission requirements.
- Alberta Vaccine Inventory (AVI) reporting and reconciliation to be submitted to AVI to meet same day requirements for reporting.
- Documented informed consent was collected in either print or electronic records.
- Providing a record of immunization for proof of immunization.

Ordering Vaccine and Compensation

- Alberta Health will provide COVID-19 vaccine, injection supplies and ancillary supplies at no cost to pharmacies wishing to provide off-site immunization services.
- For off-site immunization for Individuals or Smaller Groups, vaccine supply should be used from the current inventory in the pharmacy that is used for the general public.
- Claims for the Assessment and Administration of COVID-19 Vaccine may be submitted to ABC as per the ACPIP guidelines when an off-site immunization is conducted.

Off-Site Immunization for Individuals or Small Groups (5 individuals or less)

Key Considerations

When considering the design and operationalization for off-site immunization of individuals or small groups, it is important to address the following:

- **Administration of Vaccine:** Vaccine may only be administered by practitioners who are authorized/enabled to do so.
- **Immunization Logistics:** Processes need to be in place for checking immunization records prior to booking appointments and immunizing off-site and all public health measures in place at that time must be adhered to (i.e. masking, social distancing, etc.).
- **Immunization Supplies/Materials:** Ensure that a complete and up-to-date anaphylaxis kit is on-hand at all times during the off-site immunization. Ensure there is appropriate ancillary supplies (i.e. PPE, diluent, syringes/needles, alcohol swabs, etc.) and information materials to support vaccine administration and education.
- **Vaccine Supply and Distribution:** Determine the quantity of vaccine required for off-site immunization, how much of the current vaccine inventory in the pharmacy will be used, and how the vaccine will be transported to the off-site location.
 - Ensure all vaccine doses are planned to be administered within 30 days once vaccine is removed from freezer for vials that have not been punctured.

- **Vaccine Storage and Handling:** Adhere to the policies and protocols for COVID-19 vaccine PFS as well as the [Alberta Health Vaccine Storage and Handling for COVID-19 Vaccine](#) policy, determine how the vaccine is to be stored in cold-chain to remain viable off-site, and what temperature monitoring system will be utilized.
- **Vaccine Wastage Mitigation Strategies:** Establish a plan if there are fewer than expected individuals than anticipated for immunization, so that excess vaccine is managed given that it cannot be moved again.
- **Establish a plan for the off-site immunization to be repeated to support second dose administration (if required).**

Physical Environment

Off-site immunization for individuals or small groups away from the pharmacy requires consideration of the physical set-up and surrounding areas.

- Waste Management for personal protective equipment (PPE), injection supplies (i.e. needles/syringes), other waste generated and the proper disposal thereof.
- A private space to accommodate the set-up and administration of the vaccines, including:
 - Required furniture for immunization station(s), including tables and chairs;
 - Appropriate area and adequate spacing for individuals waiting 15-minutes following immunization;
 - Appropriate space for storing vaccine and handling equipment
 - Appropriate temperature monitoring devices.

COVID-19 Vaccine Pre-Filled Syringes (PFS) – Policy and Protocols

This policy is needed to allow the immunizer to pre-fill syringes with COVID-19 vaccine for single use and allow for appropriate transportation of these pre-filled syringes of COVID-19 vaccine when a full vial is not required.

The pre-filled syringes must be administered within the stipulated time of the vaccine vial being punctured and/or reconstituted depending on whether preparation was done in a sterile or non-sterile environment.

In addition to the Alberta *Immunization Regulation*, regulatory and employer requirements, immunizers must:

- Label the prefilled COVID-19 vaccine syringe with the vaccine type, vaccine lot number, and date and time the vial was first punctured and/or reconstituted, and
- Only administer the COVID-19 vaccine that they have drawn up and labelled themselves.

Individuals who are to receive COVID-19 vaccine from a PFS must provide informed consent.

Suggested informed consent script:

“Due to challenging vaccine storage and handling requirements, the best way to transport the vaccine to your home is in a prepared syringe. It is important to understand that transporting the vaccine this way has not been broadly studied and there is limited data regarding the stability of the vaccine transported in this way. Would you like to proceed with receiving an immunization from a prepared syringe for COVID-19 vaccine?”

Stability of COVID-19 Vaccine PFS

Syringes must be of a polycarbonate or polypropylene type with a stainless steel needle. These are the most commercially available syringes approved for PFS use.

Use aseptic technique in a **sterile** environment (PEC certified fume hood or other device which maintains ISO Class 5 air quality or better) during vaccine preparation to ensure the quality and safety of the vaccine products. Follow manufacturer instructions for vaccine preparation. Prefilled syringes prepared in this manner must be administered within **6 hours** of initial preparation.

Note: if prefilled syringes are prepared using aseptic technique in a **non-sterile** environment (countertop), then the time for the administration of the vaccine from preparation is **only ONE HOUR**.

This is in alignment with Alberta College of Pharmacy Model Standards for Practice for Non-Hazardous Sterile Preparations, specifically standards 6.1.3 to 6.1.5 which consider sterility parameters for pharmacists and pharmacy technicians.

The syringe stability information for the Pfizer-BioNTech and Moderna vaccines are based on physical and chemical stability studies conducted by the manufacturers.

Pfizer: Vaccine in the prefilled syringe must be administered within **6 hours** of initial vial dilution. All remaining doses from the vial used to prepare the prefilled syringe must also be administered within 6 hours of initial vial puncture/dilution, stored at 2°C to 25°C, keep out of direct sunlight.

Pfizer has conducted physical and chemical stability studies which have shown that the vaccine maintains all its measured quality attributes when diluted vaccine is stored in polycarbonate and polypropylene syringes with stainless steel needles for 6 hours at 2°C to 25°C after the source vial is diluted.

Microbiological risk was assessed through a microbiological challenge study which showed that microbiological growth has a greater potential to occur after 6 hours.

Moderna: According to the Chemistry, Manufacturing and Control (CMC) department at Moderna, prefilled syringes can be stored in the refrigerator to ambient room temperature at 2°C to 25°C.

Moderna vaccine in the prefilled syringe must be administered within **6 hours** of initial vial puncture, keep out of direct sunlight.

Labelling of COVID-19 Vaccine PFS

Label each PFS prepared for administration with legible, identifying information to prevent errors during storage, dispensing, transport and administration.

Label each of the COVID-19 vaccine PFS with the vaccine type, vaccine lot number, and date and time the vial was first punctured, exact beyond use date and time, and preparer's name or initials.

Examples of pre-drawn syringe labels

Pfizer-BioNTech COVID-19 Vaccine (30 mcg / 0.3 mL) IM suspension

Date & Time to discard (6 hours after dilution):

Lot #:

Initials of preparer:

Moderna COVID-19 Vaccine (100 mcg / 0.5 mL) IM suspension

Date & Time to discard (6 hours after puncture):

Lot #:

Initials of preparer:

Packaging and Transportation of COVID-19 Vaccine PFS

To ensure vaccine viability, you must select a suitable storage option for off-site immunizations. Vaccine carriers, portable storage units, hard-sided insulated or Styrofoam container(s) are all options. A soft-sided container can also be considered if it is a qualified container or packout.

A thick barrier (at least 1 inch) of bubble wrap or corrugated cardboard box may be utilized as a barrier between the transport container cooling agent (frozen gel pack, ice packs, etc.), and the container with prefilled syringes. This is to prevent direct contact between prefilled syringes and the cooling agent that may cause the vaccine to freeze or deviate from appropriate cold chain.

Wrap each of the prefilled syringes in preconditioned bubble wrap, cardboard or other material in a manner that would prevent downward pressure on the syringe plunger resulting in wastage

and that will minimize any vibration or shock to the vaccine. The temperature monitoring device probe must be placed with the vaccine and not by the cooling agent.

Transport vaccine in prefilled syringes at a temperature between 2°C to 8°C, with constant temperature monitoring by a digital TMD that can be read without opening the transport container.

The temperature in the transport container will be recorded every time the transport container is opened and/or at least three times a day.

The immunizer/transporter must be aware of their role in maintaining the cold chain.

- The temperature within the vehicle should not be outside room temperature 15°C to 20°C and minimizes movement of the vaccine.
- Implement special precautions to prevent excessive movement/ “jostling” of the vaccine including conducting ground transport on paved or smooth gravel/dirt roads.
- The vaccine will be handled with care to avoid shocks, drops and vibration as much as possible.
- The vaccine will not be exposed to extreme heat or cold during transport.
- Vaccine in insulated transport containers should be placed in the area of the vehicle that maintains room temperature, i.e. not the trunk of the car.
- The vaccine can be transported from home to home and should not be left unattended at any time.

Discard any remaining vaccine in prefilled syringes at the end of the workday.

Never transfer prefilled, reconstituted vaccine back into a vial for storage.



Examples of approved barrier boxes, wrapping/cushioning for prefilled syringes of vaccine, and temperature monitoring device to be packed directly with prefilled syringes. The packed barrier box containing the temperature monitoring device and prefilled syringes would then be placed in the larger transport box with the cooling agent.