

TITLE: Pre-Loading Syringes with Vaccine for Mass Immunization Clinics

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1.0 PURPOSE

1.1 To provide guidance regarding the limited practice of pre-loading syringes with vaccine in controlled mass immunization settings as a part of a strategy to improve clinic efficiency while maintaining safe and appropriate practice standards.

2.0 SCOPE & GOAL

- **2.1** To provide guidance on the immunization practice of pre-loading vaccine syringes to facilitate client flow at mass immunization clinics.
- **2.2** To ensure staff involved in preparing the pre-filled syringes follow consistent technique for this procedure, are trained in aseptic technique, and adhere to WRHA policies related to vaccine storage and handling, e.g., cold chain maintenance.
- **2.3** This practice guideline outlines the process for pre-loading syringes that occurs by another designated/trained health professional. This does not preclude an immunization provider from setting up his/her own immunization station and pre-drawing doses that he/she will be administering at that station in a short timeframe.

BACKGROUND

3.0 POSITION ON PRE-LOADING SYRINGES WITH VACCINE

- **3.1** Pre-loading syringes with vaccine in advance of administration is strongly discouraged as a routine practice for the following reasons:
 - Potential (unknown) risk of vaccine potency being altered as a result of interaction of the vaccine with the plastic of the syringe. There is a lack of scientific evidence describing this potential risk.
 - Risk of breaking the cold chain may increase if pre-drawn, e.g., vaccine temperature may fall outside of recommended temperature range of +2°C to +8°C.
 - The risk of medication errors may increase if more than one type and brand of vaccines are being used at an immunization clinic.
 - Risk of possible bacterial growth if contaminated during preparation and vaccine left to sit prior to administration.
 - Risk of wastage when more vaccine is pre-drawn than can be used in the recommended time frame.



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4.0 ADMINISTRATION OF A PRE-LOADED SYRINGE BY A REGISTERED NURSE – **EXCEPTIONS:**

- The only exception that can be considered whereby a Registered Nurse can 4.1 administer a vaccine that has been pre-loaded by another health professional is as follows:
 - this practice occurs within the context of a regional clinic that is specifically using • pre-loaded syringes of vaccine as a part of a mass immunization clinic (i.e. mass influenza immunization clinic) where pre-loading is being used as a method to facilitate client flow through a clinic and
 - provided the identified quality assurance supports are in place.

The person drawing up the vaccine is;

- a pharmacist (or pharmacy technician/ pharmacy student under the direction of the • pharmacist)
- a Registered Nurse
- a Licensed Practical Nurse
- a health professional student (nursing, pharmacy, medicine) under the supervision of a clinical advisor/educator]

Professional pharmacy standards for the pre-loading of syringes are to be followed in keeping with site specific or regional pharmacy guidelines related to documentation, monitoring and other relevant guality assurance practices.

QUALITY ASSURANCE 5.0

5.1 All of the following quality assurances need to be met:

- 5.1.1 This practice may only be considered if only one vaccine is being pre-drawn (to minimize the risk of medication error), which will be pre-determined by the WRHA Population and Public Health immunization program.
- 5.1.2 All WRHA staff participating in the pre-loading activities must demonstrate the competencies and supervision required for the pre-filling of syringes according to accepted best practices in medication preparation, aseptic technique and specifically in vaccine preparation, handling, and maintenance of cold chain.



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- 5.1.3 The following groups of health professionals have authorization to participate in the pre-loading processes: Registered nurses, LPNs, Pharmacists and Pharmacy Technicians, and Health Professional Students (nursing, pharmacy, and medicine) with clinical supervision (under academic agreements) who have demonstrated required competencies.
- 5.1.4 A clearly documented system for tracking accountability must be implemented, e.g., the health professional preparing the vaccine (drawing up) must sign off on the medication preparation procedure, indicating they have prepared the medication according to organizational protocols (see appendix A).
- 5.1.5 The zip lock bags containing the syringes must be labeled with the following information:
 - Name of vaccine
 - Manufacturer
 - Dosage
 - Lot number
 - Time drawn up
 - Expiry time (e.g., for influenza vaccine, within 4 hours of being drawn up)
 - Name/initials of vaccine preparer
 - Name/initials of the person who inspected the syringes (if vaccine preparer is a pharmacy tech or pharmacy student)
- 5.1.6 A qualified pharmacist or RN or LPN must assess the syringe prior to it being made available for use by the RN or LPN administering vaccine.
- 5.1.7 All workers involved in the chain of custody of the vaccine being prepared must be educated/trained/oriented on the WRHA cold chain protocol and specifically be aware of expiry time limits.
- 5.1.8 The syringes contained within the zip lock bags should not be removed until just before administration. No syringes should be added to the bag after the preloading is completed in the pharmacy area. Syringes in the zip lock bags should be used by one immunization provider and not shared between multiple providers.
- 5.1.9 Ideally all pre-loaded syringes contained in the zip lock bag with the empty vial and labels should be administered by one nurse. If circumstances occur that this nurse is not able to complete administering all doses within the bag, a transfer of custody can occur once if all the following criteria are met. The receiving nurse should :
 - Ensure the vaccine is still within the pre-determined time frames approved for administration from when it was drawn up.



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- Ensure cold chain has been maintained since leaving the pharmacy area.
- Affirm with the originating immunization provider that the remaining syringes have not been removed from the zip lock bag during the process, nor have any syringes been added to the bag.
- Ensure the lot # on the vial matches the lot # number on the label on the zip-loc bag and the labels in the bag.
- **5.1.10** Nurses who administer the pre-loaded vaccine must perform the last check to ensure they are giving the right dose of the right drug to the right person at the right time (check expiry) via the correct route, as per standard nursing practice.

VALIDATION 6.0

This guideline for pre-loading influenza vaccine for mass immunization has 6.1 been developed in discussion with and with the support of the College of Registered Nurses of Manitoba (CRNM).

7.0 **RECOMMENDED READING**

7.1 Canadian Immunization Guide, Seventh Edition, 2006

8.0 **APPENDICES**

8.1 Appendix A – Vaccine Preparation Process

8.1.1 Proper vaccine handling and preparation is critical in maintaining the integrity of the vaccine during transfer from the manufacturer's vial to the syringe and ultimately to the patient.

8.2 Pre-loading Syringes

8.2.1 Pre-loaded syringes should be administered preferably within 1 hour of being drawn up, and should be discarded if not used within 4 hours of being drawn up.

8.2.2 For WRHA influenza clinics the following labeling processes will be used: A zip lock bag will have the following labeling notation (see label sample below):

8.2.2.1 Vaccine name

8.2.2.2 Manufacturer



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- 8.2.2.3 Lot #
- 8.2.2.4 Dosage
- **8.2.2.5** Vaccine Preparer Name, designation and initials
- 8.2.2.6 Time vaccine drawn up
- 8.2.2.7 Time vaccine must be discarded by

8.2.2.8 Pharmacy Lead - Name designation and initials [pharmacist/registered nurse who inspected the loaded syringe prior to it being administered]

8.3 Process

8.3.1 Immunization providers must always consult the manufacturers' product monograph(s) for information about vaccine use, dosage, storage and handling, and be familiar with and follow existing WRHA guidelines and practices on same.

8.3.2 Place a labeled zip lock bag on a clean work surface. Each zip lock bag is for single use only.

8.3.3 Inspect the vial of vaccine:

8.3.3.1 Each vaccine vial will be carefully inspected for damage or contamination prior to use.

8.3.3.2 The expiration date printed on the vial or box will be checked.

8.3.3.3 Vaccine can be used through to the last day of the month indicated by the expiration date unless otherwise stated on the package labeling.

- **8.3.3.4** Expired vaccine should never be used.
- 8.3.4 Line a work basket with a clean towel.
- **8.3.5** Note time that vaccine preparation began and document on label.

8.3.6 Follow the procedure for the drawing up a product for injection using aseptic technique.

8.3.7 Syringes should be removed from the outer wrap just prior to drawing up doses. Vaccine should be drawn up into the syringe within 15 minutes of removing the outer wrap.

8.3.8 One at a time, draw vaccine into each syringe and then place it in the work basket.

8.3.9 Place the empty vial in the work basket with the filled syringes.



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8.3.10 Complete all relevant sections on the label (see label below) of the zip lock bag.

8.3.11 Have syringes inspected by pharmacy area leader.

8.3.12 Pharmacy area leader to complete the "inspected by" section.

8.3.13 Place all syringes and the empty vial into the prepared zip lock bag.

8.3.14 Double check the vaccine manufacturer, trade name and lot # to ensure they match with the vial and the label on the zip lock bag.

8.3.15 Ten corresponding labels are to be prepared and enclosed in the zip lock bag with the pre-drawn syringes. These are to be placed on client record (consent form) as part of the documentation when vaccine is administered.

8.3.16 Place prepared zip lock bag in monitored cooler/fridge to maintain cold chain until needed for use.

8.3.17 All prepared syringes originating from the vial should remain in the same zip lock bag, to ensure there is access to the original vial of vaccine to confirm the contents of the syringe.

| | Sample label for Pre-Loaded Vaccine | | | |
|----------------------|-------------------------------------|--|--|--|
| Vaccine Name: | | | | |
| Manufacturer: | | | | |
| Lot #: | | | | |
| Dose: | | | | |
| Vaccine Preparer: | | | | |
| Designation/Initial: | | | | |
| Time Drawn up | | | | |
| Time Expired | | | | |
| Inspected By: | | | | |
| Designation/Initial: | | | | |