

PANDEMIC INFLUENZA RESPONSE PLAN

SECTION NINE - VACCINES TABLE OF CONTENTS

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VACCINES

Target Audience

Immunization providers such as public health nurses, registered nurses, physicians and other staff in facilities may be responsible for storage, handling and transportation (i.e. pharmacist, pharmacy technician, EMS, maintenance, administrative support).

Introduction

Influenza immunization has been considered the cornerstone of influenza prevention and control and will also serve as the central preventive strategy during the next pandemic.

The objectives of the pandemic vaccine program (as stated in the Canadian Pandemic Influenza Plan) are to:

- Provide a safe and effective vaccine program to all Canadians as quickly as possible
- Allocate, distribute and administer vaccine as rapidly as possible to the appropriate groups of people
- Monitor the safety and effectiveness of vaccination programs

Pandemic vaccine programs should be flexible and continue to evolve based on the best information available at any given time.

Assumptions:

In order to plan for an event that in many ways is unpredictable the Canadian Pandemic Plan provides a set of assumptions that have specific implications for pandemic vaccine programs.

- The next pandemic will first emerge outside of Canada
 - *The virus to be used for the pandemic vaccine will be isolated outside of Canada and sent to the manufacturer as a “primary seed lot.” The government does not have control over when this will occur.*
- The next pandemic virus will be present in Canada within three months after it emerges in another part of the world, but it could be much sooner because of the volume and speed of global air travel.
 - *There will likely be cases of pandemic influenza in Canada prior to the availability of vaccine.*
- The first peak of illness in Canada could occur within two to four months after the virus arrives. The first peak in mortality is expected to be approximately one month after the peak in illness.
 - *There will likely be deaths due to pandemic influenza in Canada before the availability of vaccine.*

- The impact of the pandemic in terms of severity, age distribution and extent of spread may be different from annual influenza; however, this will not be known until the novel virus starts spreading efficiently in the human population.
 - *It will not be possible to identify in advance of the pandemic the individual risk factors for poor outcome of infection with the specific pandemic influenza virus.*
- Individuals who recover from illness caused by the pandemic strain will be immune to further infection by that strain.
 - *Those with a history of illness attributed to the pandemic virus may be considered at lower priority for immunization if prioritization is necessary.*
- A pandemic vaccine will become available in time to have an effect on the impact of the pandemic in Canada. The extent of the effect will largely depend on the timing of vaccine availability in comparison to the pandemic activity in Canada.
- Two doses of vaccine may be needed in order to optimize protection. The two doses would be given approximately one month apart.
- Because of cross-protection, a vaccine developed from a strain isolated early in the pandemic will still be beneficial should the pandemic virus “drift” over the course of the pandemic.
- The new pandemic vaccine is not likely to be 100% effective, but even a vaccine with relatively low efficacy (e.g. 30%) will help curb the effect of the pandemic.
- There will be limited information regarding vaccine safety before the rollout of the immunization campaign.
- Concern regarding vaccine safety and reactogenicity will likely be inversely proportional to the severity of the pandemic in Canada.
- Depending on the timing of the pandemic and availability of the pandemic vaccine, seasonal influenza immunization programs may not be initiated or completed, as the pandemic vaccine program is the priority.

Prioritization

It is expected to take several months to develop and produce a pandemic vaccine and it is anticipated that the vaccine will become available in lots. This requires that decisions will need to be made regarding how these doses will be distributed across Canada and whether to prioritize certain subgroups of the population ahead of others.

At this time, according to the Canadian Pandemic Plan there is no policy decision regarding distribution of the first doses of vaccine across Canada. The Canadian Pandemic Plan identifies population subgroups, with definitions of each and examples of who might be included in each group. Determining the order in which these subgroups would receive vaccine must take into consideration several factors, many of which will not be known until the pandemic occurs. Some of these factors may be:

- Impact on pandemic goals (i.e. minimizing serious illness, overall deaths and societal disruption)
- Operational considerations (i.e. size of group, ease of identification and accessibility)
- Severity/epidemiology of the pandemic
- Difference in vaccine effectiveness between groups
- Timing of vaccine availability
- Public opinion and risk perception as a consideration (e.g. perceived severity of the pandemic and risks of the vaccine)

When available it is important that the vaccine be distributed in an equitable, efficient, consistent, secure and timely manner across the region.

Mass Immunization

Mass immunization clinics are the most cost effective method for providing immunization to a large number of people over a short time period. It is expected that planning for mass clinics will be based on:

- Directives from Public Health Agency of Canada or Manitoba Health for priority group immunization.
- The annual ARHA influenza program.
- The availability of vaccine distribution and storage.
- The ARHA Quality Framework.

Planning should consider whether (and how) one dose of vaccine could be administered to the entire population within one month (dependent upon vaccine availability). If this is not feasible, determine what the fastest achievable and sustainable administration rate is for the region when human and other resources may be limited. Planners should develop methods of identifying the numbers for each population subgroup, as well as how to identify and target these individuals. They must also be prepared to implement both a non-prioritized and prioritized pandemic immunization program.

This plan will also work for mass prophylaxis clinics, where antivirals may be distributed to target populations. An overview of the guidelines for setting up and managing a mass clinic is given in Appendix A, Section 9 ARHA Pandemic Influenza Response Plan. (Secure access, password required).

Communication

Communication plans need to be developed to ensure communication channels are in place to:

- Update key players at local levels
- Provide health care workers with current information
- Provide the public with information
- Facilitate implementation of the program
- Mobilize resources required to rapidly implement mass immunization clinics
- Inform key participants of decisions that are made on a daily basis (**Tool 9.1 – ARHA Vaccine Delivery Decision Checklist**). Please refer to Section 7 – Communications for more detail.

Vaccine Uptake

It is important to be prepared to immunize 100% of the population; however, the actual proportion of the population that will voluntarily seek vaccination will depend on public perception of the risk and the severity of the disease. Therefore, it would be prudent to prepare for an initial demand of 75% of the target population.

Vaccine Management

The objectives of vaccine management are:

- To track, store, distribute, allocate and administer vaccine/prophylaxis and supplies safely, securely, efficiently and appropriately.
- To monitor vaccination rates by population subgroups.
- To monitor unusual/adverse events following immunization.

Vaccine Distribution

Manitoba has a vaccine distribution system in place to support all existing immunization programs in the province. When a pandemic vaccine becomes available the federal government will secure supplies of the vaccine and distribute it to provinces and territories on an equitable basis. Manitoba Health will maintain the provincial vaccine depot and distribute the vaccine to regional health authorities. *(In the ARHA the regional receiving depot/s may distribute vaccine within the region as needed. Refer to Appendix A).* Please refer to Section 11 - Safety & Security / Materials Management (Secure access, password required) for Vaccine transportation.

Vaccine Security Plan

Safety and security are vital considerations in a pandemic situation where supplies may be limited and fear and anxiety may be widespread. All mass vaccination campaigns require security measures to address the safety of staff, clients and supplies. Vaccine security is also needed during transport and storage. See Safety and Security / Materials Management Section 11 (Secure access, password required).

Inventory and Tracking

Once pandemic vaccine arrives in the region, each dose must be accounted for from its arrival at the regional depot until administration to the client.

Once received the regional depot pharmacist will enter the name of the vaccine, the lot numbers and the quantity of vaccine received on this form. When vaccine is distributed to sites across the region, pharmacy will record the location sent, number of doses shipped and lot numbers.

Influenza Vaccine/Anaphylaxis Medications Pharmacy Order/Return Form - Tool 9.2

The PHN will fill out and fax this form to order from/return vaccine to the regional pharmacy depot. This form will accompany all shipments. Upon receipt of vaccine signature is required to verify inventory received and temperature monitoring.

At the community clinics the following forms will be used to monitor / communicate vaccine supply.

Vaccine Inventory Supply Log - Tool 9.3

Clinic Vaccine Summary Form – Tool 9.4

Appointment/Staffing/Vaccine Tracking Document - Tool 9.5

Tracking/Recall for two-dose system (if recommended):

It is assumed that for a two-dose program, completion of the second dose (approximately one month after the first) should be carried out as soon as possible to effect immunity. Administration of the second dose should not wait until after every priority group has received a first dose. This strategy will require extensive planning that involves record-keeping, tracking and recall mechanisms. These strategies should be developed with input from IT and MIMS clerks.

Vaccine Storage, Handling and Monitoring “Cold Chain” Procedure

Refer to **ARHA Public Health Practice Manual - HP 3.2.13**

Safe and immunogenic vaccine products will be provided to clients by all vaccine providers in the region. Quality control measures will be implemented in accordance with the National Guidelines for Vaccine Storage and Transportation and the ARHA Vaccine Storage, Handling and Monitoring “Cold Chain” Procedure.

Informed Consent and Documentation for Immunization

Refer to **ARHA Public Health Practice Manual - HP 3.2.1**

All immunizations are voluntary in Manitoba. The process of obtaining informed consent is a requirement supported by the Canadian National Advisory Committee on Immunization (NACI), the College of Physicians and Surgeons of Manitoba, College of Registered Nurses of Manitoba, College of Registered Psychiatric Nurses and the College of Licensed Practical Nurses and in accordance with the Assiniboine Regional Health Authority, Informed Consent for Health Care Intervention (ADM-XII-310).

Pandemic Client Surveillance Form Tool 9.6

Procedure for Immunization Administration

Refer to **ARHA Public Health Practice Manual - HP 3.2.7**

The Registered Nurse/Immunization Provider will, when giving any vaccine, ensure safe and accurate administration. All clients will be assessed prior to vaccine administration. Vaccines will be administered using the recommended injection technique and the appropriate supplies and equipment.

Adverse Event Following Immunization (AEFI) Reporting

Refer to **ARHA Public Health Practice Manual - HP 3.2.11**

All adverse events following immunization occurring in the Assiniboine Regional Health Authority will be appropriately recorded by health care providers and submitted to the Regional Medical Officer of Health who will review and forward to the Division of Immunization of the Bureau of Infectious Diseases of Health Canada via Manitoba Health.

An enhanced plan may need to be developed and in place to monitor vaccine safety and to ensure the timely communication of any potential adverse event following immunization during the pandemic.

Documentation Tools

Tool 9.1	ARHA Vaccine Delivery Decision Checklist
Tool 9.2	Influenza Vaccine/Anaphylaxis Medications Pharmacy Order/Return Form
Tool 9.3	Vaccine Inventory Supply Log
Tool 9.4	Clinic Summary Sheet
Tool 9.5	Appointment/Staffing/Vaccine Tracking System
Tool 9.6	ARHA Pandemic Client Surveillance Form (or MB Health Consent form)

Resources:

- BC Pandemic Influenza Preparedness Plan
- Canadian Pandemic Influenza Plan
- Vancouver Coastal Health Pandemic Influenza Plan
- Ontario Health Plan for an Influenza Pandemic
- Toronto Pandemic Influenza Plan 2005
- Manitoba Health

Tool 9.1

Vaccine Delivery Decisions Checklist

ISSUED BY:

DATE: **TIME:**

DECISION(S):

Task	Resp	Comments
<input type="checkbox"/> Adjust Health Suite (adding vaccine spots/stop booking)		
<input type="checkbox"/> Make necessary changes in delivery & amount of vaccine ne		
<input type="checkbox"/> Maureen to change/book nurses		
<input type="checkbox"/> Melanie to obtain supplies		
<input type="checkbox"/> Notify DCs to obtain EMS support as needed		
<input type="checkbox"/> Notify Call Centre staff		
<input type="checkbox"/> Change Call Center script		
<input type="checkbox"/> Change call centre message mailbox		
<input type="checkbox"/> Public communication		
<input type="checkbox"/> Commincate decision to Clinic Managers/Team Leaders		
<input type="checkbox"/> Communicate decision to front line clinic staff		
<input type="checkbox"/> Other		

Tool 9.2 Influenza Vaccine / Anaphylaxis Medications Pharmacy Order/Return Form

To be used when ordering or returning Influenza Vaccine and Anaphylaxis Medications from/to the Regional Pharmacy Depot FAX 476-2901; Phone 476-7824. Please include in shipping box.

Facility: _____

Date: _____

Address: _____

Contact Person: _____

Order No. (completed by Pharmacy): _____

Telephone: _____

Product Requested from Depot

Fax: _____

Product Returned to Depot

Product	# Vials Ordered	# Vials Sent	Lot Number		# Vials Returned	Lot Number	Comments
Vaccine: Vaxigrip (10 doses per vial)							
Vaccine:Fluviral (10 doses per vial)							
Epinephrine 1:1000							
Diphenhydramine 50 mg/mL							

SENDING	TRANSPORT	FINAL DESTINATION
Name: _____ Date: ___/___/___ Time:__:__ hrs Current Fridge Temp. when Vaccine Packed: _____ Packed with Thermometer _____ OR Cold/Warm Marker Indicator: _____ Signature: _____	Name: _____ Date: ___/___/___ Time:__:__ hrs Temp: Min _____ Max _____ Cold/Warm Marker Indicator: _____ Signature: _____	Name: _____ Date: ___/___/___ Time:__:__ hrs Temp: Min _____ Max _____ Cold/Warm Marker Indicator: _____ Signature: _____

Signature demonstrates accurate receipt /acceptance of product.

Tool 9.3 Vaccine Inventory Supply Log (2 pages)

Date: _____ **Clinic:** _____ **Nurse Signature:** _____

Lot #	Doses Administered	Doses Wasted	Doses Remaining	Nurses Initials

Hand in Inventory Supply Log for Vaccine to Immunization Team Leader at end of shift.

Tool 9.3 Vaccine Inventory Supply Log (2 pages)

To be completed by Immunization Team Leader or Clinic Manager at the beginning and end of each clinic shift (i.e. 9:00am to 3:00pm; 3:00pm to 9:00pm)

Date: _____ **Time:** _____

Community Clinic: _____ **Location:** _____

Immunization Team Leader / PHN: _____

Vaccine Inventory:

Time	Lot #	# of Vials brought to clinic	# of Vials Added during clinic	# of Vials returned at end of clinic	Nurses Signature

Tool 9.4 CLINIC SUMMARY SHEET

Date: _____

Community: _____ Location: _____

VACCINE – Doses Given

1. Total number immunized with _____ vaccine.
Total for Day _____
2. # of health care workers immunized _____
2a. of which were ARHA employees _____
3. # of high-risk and/or chronic (including 65>) _____
4. # of household contacts/volunteers _____

NOTE: (Lines 2, 3 and 4 should equal Line 1)

Number of adverse events following immunization occurring at clinic (AEFI) _____

At end of clinic day Fax this form to:

- **MIMS Clerk**
- **ARHA Regional Office**

At end of clinic Phone (re: vaccine quantities):

- **Vaccine Inventory Manager**

Clinic Manager _____

Tool 9.6 Pandemic Client Surveillance Form
Receptionist

_____ **Community Clinic**
_____ **Date**

Client Information:

Surname _____ Legal First Name _____ Initial _____ Date of Birth _____
yyyy / mm / dd PHIN _____

Client Phone Number: _____ Receptionist Initials _____

Identification Document(s)

- | | |
|---|---|
| <input type="checkbox"/> Drivers License _____ | <input type="checkbox"/> Student Card _____ |
| <input type="checkbox"/> Manitoba Health Card _____ | <input type="checkbox"/> Passport _____ |
| <input type="checkbox"/> Birth Certificate _____ | <input type="checkbox"/> Other _____ |

Nursing Assessment

Reason for Immunization: Priority Group

- 1 2 3 4 5 6

Health History Review:

- Have you had a flu shot before? Yes No
Are you well today? Yes No, If NO explain _____
Do you have any allergies? No Yes, If YES _____
Are you currently on antibiotics for an infection? No Yes, If YES _____
Have you had a reaction to a vaccine in the past? No Yes, If YES, _____

- Reviewed contraindications and side effects; explained how to manage side effects.

Refer to Medical: Reason _____

Informed Consent Obtained

- Yes**, I do consent to the person named above receiving the vaccine.
 No, I do not consent to the person named above receiving the vaccine.

Alternate Decision Maker: Signature _____ Relationship _____

RN Signature: _____ **Refer to Immunization Nurse:**

Immunization Nurse

Dose 1 <input type="checkbox"/> Date _____	Dose 2 <input type="checkbox"/> Date _____
Vaccine: _____ Lot # _____	Vaccine: _____ Lot #: _____
Dose: <u>Circle:</u> 0.5 mL IM (for 3 yrs & older) <u>or</u> 0.25 mL IM (for children 6-35 mths)	Dose: <u>Circle:</u> 0.5 mL IM (for 3 yrs & older) <u>or</u> 0.25 mL IM (for children 6-35 mths)
Site: <u>R or L</u> <input type="checkbox"/> Deltoid <input type="checkbox"/> Vastus Lateralis	Site: <u>R or L</u> <input type="checkbox"/> Deltoid <input type="checkbox"/> Vastus Lateralis
RN Signature: _____	RN Signature: _____

MIMS Data Entry

Immunization(s) entered into MIMS Dose #1 _____ Dose #2 _____
Date/Initial Date/Initial

Medical Assessment: _____

Physician Signature _____ **Date:** _____