

Guidance for Clinical Management of Patients with Influenza-Like-Illness (ILI) in the context of pandemic (H1N1) 2009 in Remote and Isolated Communities

This guidance document is being provided by the Public Health Agency of Canada in response to the pandemic (H1N1) 2009 influenza virus. The guidance and recommendations are based on current available scientific evidence about the pandemic (H1N1) 2009 influenza, as well as expert opinion where scientific evidence is incomplete, and is subject to review and change as new information becomes available.

The following guidance should be read in conjunction with relevant provincial and territorial guidance documents. The Public Health Agency of Canada will be posting regular updates and related documents at www.phac-aspc.gc.ca.

Introduction

The purpose of this document is to provide specific recommendations to clinicians to support the clinical management of patients presenting with influenza-like illness (ILI) to health facilities in remote and isolated communities in the context of pandemic (H1N1) 2009 influenza (hereafter referred to as pH1N1). This document addresses the unique aspects of the clinical management in these settings, especially where there are issues related to remote and isolated communities that are not addressed in existing guidance documents. For further background, context and definitions, the reader is referred to the PHAC document *Remote and Isolated (RI) Communities in the context of the pandemic (H1N1) 2009 outbreak* (to be published soon).

Detecting Pandemic Influenza

Surveillance of ILI in remote and isolated communities, as in any other community, is important in order to monitor the entry or circulation of pH1N1 in the community. Surveillance will also contribute to the evaluation of the effectiveness of antiviral treatment by identifying strains of the virus resistant to antiviral therapy. Testing (nasopharyngeal swabs) should be undertaken when patients are suspected to have an influenza-like illness if there is limited or no known transmission of the virus in the community. Once the pandemic strain is confirmed in a community, routine testing of patients, other than those with atypical presentation, or with those at high risk of developing severe respiratory illness, should not likely be necessaryⁱ.

Current [case definitions for pH1N1](#) (confirmed and probable) for surveillance purposes are available [online](#).

Infection Prevention and Control

There are no identified differences in Infection Prevention and Control in a health care facility in a remote and isolated community than in other communities. However, consideration should be given to increasing stockpiles of supplies and equipment for infection prevention and control due to potential disruption in transportation routes. Clinic managers might consider maintaining a 4 week supply of clinic stock including personal protective equipment for health care workers (e.g. gowns, masks, gloves, and cleaning products).

For general information refer to [Guidance for Ambulatory Care of Influenza-Like Illness in the context of H1N1 influenza virus](#).

Diagnosing and Treating Pandemic Influenza

The following screening criteria for ILI can be used to determine the need for infection prevention

and control measures and for patient assessment.

ILI Screening criteria for clinical purposes in the context of pH1N1ⁱⁱ

- Sudden onset of fever $>38^{\circ}\text{C}$ (100.4°F)¹ and new or worsening cough.
- One or more of the following symptoms are common:
 - Sore throat
 - Coryza (runny nose, congestion)
 - Fatigue/malaise/prostration
 - Myalgias/althralgias (Muscle/joint aches)
 - Headache
 - Decreased appetite
- Nausea, vomiting and diarrhea are sometimes present (rare in people over 65 years of age)

Clinical algorithms and medical directives, where permissible, can assist health professionals in remote and isolated communities with clinical management.

Inclement weather, geographic distances and limited transportation infrastructure may impact timely access to accurate laboratory results therefore **treatment decisions for patients with ILI may be made based primarily on clinical assessment at the local health facility.**

Point of care testing should not be used as the sole basis for clinical decisions as it has low sensitivity (15-60%) and the potential for false positive tests results occurring. If it is used to assess influenza, results should be interpreted in consideration of the test limitations and confirmed by standard methods at a public health laboratoryⁱⁱⁱ.

Due to existing limitations with internet access and other technological challenges in some remote and isolated communities, clinicians in these communities might consider having access to alternate means of communication such as satellite phones for consultation with medical experts.

For general information on clinical assessment and laboratory guidelines, clinicians in remote and isolated communities should refer to their specific jurisdictional pandemic plans as well as the guidance documents available on the PHAC website at www.fightflu.ca.

Treatment with Antivirals

In comparison to the general Canadian population, aboriginal populations have higher rates of hospitalizations and greater risk of severe outcomes (ICU admissions and deaths) from pH1N1 2009 influenza^{iv}. Since the majority of Canada's remote and isolated communities are aboriginal and there are geographical, transportation and health services access issues to consider, planners or clinicians may consider modifying current antiviral treatment recommendations for the remote and isolated context, as follows:

Once pH1N1 is detected in a remote and isolated community all individuals with influenza-like illness should be offered early treatment with antivirals regardless of disease severity or the presence of risk factors for severe disease.

For general guidelines related to the use of antiviral drugs refer to [Annex E of the Canadian Pandemic Influenza Plan](#), and the *Guidance for Ambulatory Care of Influenza-Like Illness in the context of H1N1 influenza virus*.

Antiviral use in children under 1 year of age

All healthy children under 24 months of age and children with certain chronic health conditions are at increased risk of influenza-related complications and hospitalization from pH1N1^{vi}. As such, the emergency use of oseltamivir in children <1 year of age has been authorized through Health

Canada's *Interim Order Respecting the Sale of Oseltamivir Phosphate - Expanded Use for Children Under One Year of Age*^{vii} in the context of pH1N1.

Normally children less than one year of age infected with pH1N1 would be managed in an acute care facility in consultation with pediatric infectious disease specialists. However, in a remote and isolated community where there may be delays in access to acute care and early treatment, consideration should be given for antiviral treatment of these children while still in the community awaiting transfer. This should be done in collaboration with a physician or pediatric infectious disease specialist, if possible.

For information on antiviral use in children under the age of 1 year, including dosing recommendations, refer to *Interim Guidance for Emergency Use of Oseltamivir in Children under 1 year of age in the context of pandemic (H1N1) 2009*.

Pregnant, post-partum and breastfeeding women

The increased risks associated with influenza infection during pregnancy (especially in the 2nd and 3rd trimester) and women within six weeks post-partum have been noted in the current influenza pandemic^{viii,ix}. Clinicians and pregnant women in remote and isolated communities should be made aware of the increased risk associated with pregnancy and have ready access to antivirals for treatment of those women who present with influenza-like illness. Clinicians might consider maintaining rosters of the women who are pregnant, breastfeeding, or within 6 weeks post-partum to facilitate identification of this high risk group if required.

For general recommendations on managing the pregnant and post-partum/breast feeding woman, refer to *Clinical Guidance for Pregnant and Breastfeeding Women with Influenza-Like Illness in the context of the Pandemic H1N1 2009 Virus*.

Adverse Event Reporting

Adverse event reporting is no different in a remote and isolated community than in any other community however, telecommunications can be a challenge for many of these communities especially at certain times of the year.

The following three methods are acceptable ways to report adverse events.

- Call toll-free at 1-866-234-2345
- Report online at www.healthcanada.gc.ca/medeffect
- Complete a Canada Vigilance Reporting Form^x which can be sent by fax toll-free to 1-866-678-6789

Alternatively, the Canada Vigilance Reporting Form can be sent by postage paid mail.

The [form and postage paid label](http://www.healthcanada.gc.ca/medeffect) are available at www.healthcanada.gc.ca/medeffect or by calling 1-866-234-2345. The adverse reaction reporting form is also available for health professionals at the back of the Compendium of Pharmaceuticals and Specialties (CPS).

More information on Adverse Events is available at *Reporting Adverse Reactions to Antiviral Drugs during an Influenza Pandemic – Guidelines for Health Professionals and Consumers*.

Other Antiviral Considerations

Prepositioning

The availability and accessibility of antivirals in remote and isolated communities is an important consideration for clinicians. To ensure the maximum benefit from antiviral treatment, it is essential to take the medication within 48 hours of onset of symptoms^{xi,xii}. Many remote and isolated communities, especially during the usual flu season (Oct-April), have challenges with transport of goods including medications.

It is recommended that antivirals be prepositioned in each remote and isolated community in an amount sufficient to treat a minimum of 17.5% of their total population².

It is possible that pH1N1 could spread rapidly in some remote and isolated communities and there may be a need for additional antivirals (beyond the 17.5%). Consideration should be given to increasing the antiviral stockpile where delays of more than 48 hours can be expected. Once the antiviral has been positioned in a community, it is recommended to undertake regular inventory maintenance, stock replenishment, and return/rotation of expiring stock.

In addition to monitoring antiviral depletion, attention should be paid to the amount of remaining compounding vehicle (Ora-Sweet SF) and replenish as required.

Storage space and security should be regularly monitored.

Prescribing and dispensing antivirals in remote and isolated communities

Many remote and isolated communities do not have consistent access to physicians for prescription purposes. Alternative measures should be considered, such as expanding the role of other health care providers or non-regulated personnel, as appropriate.

The use of medical directives and treatment protocols can facilitate a consistent approach to the assessment and treatment (including antiviral medications) of pH1N1.

It is recommended that provinces and territories encourage the use of medical directives where permissible. This could allow nurses to prescribe and dispense antivirals in remote and isolated communities under medical delegation and/or oversight appropriate to the jurisdiction.

The Society of Obstetrics and Gynaecology of Canada in their document *H1N1 Recommendations in Pregnancy* recommends providing pregnant women with a prescription for Tamiflu® (75mg bid for 5 days) during their antenatal visit, to be used when a suspected H1N1 infection occurs^{xiii}.

This standard might be considered for addressing other high risk groups. That is, when a prescribing clinician is available in the community, prescriptions could be provided to be used when a suspected pH1N1 infection occurs. The prescription would only be filled if the clinical criteria for ILI are met and there is a high likelihood that pH1N1 is present in the community.

As with all communities, provinces and territories may recommend tracking the prescribing and use patterns (e.g. patient demographics, presenting symptoms, time of treatment initiation related to symptom onset) of antivirals throughout the course of the pandemic.

For further information, refer to [Guidance for Ambulatory Care of Influenza-Like Illness in the context of H1N1 influenza virus](#).

Compounding of an oral suspension from TAMIFLU® capsules

Remote and isolated communities may not have access to Health Canada-approved, commercially manufactured Tamiflu® for oral suspension. Most remote and isolated communities will not have a pharmacist available to prepare an oral suspension, and therefore clinicians may be required to prepare an emergency compound for oral suspension. In those situations provinces and territories may choose to extend the right to prepare and dispense medications to other licensed health care providers, if feasible.

For details on emergency compounding of oseltamivir for an oral suspension, see [Appendix A](#) of this guidance.

Antiviral prophylaxis

Despite the numerous factors that put people living in remote and isolated communities at higher risk for influenza transmission and severe illness, prophylaxis (prevention) of pandemic influenza with antivirals is not recommended as a general strategy for its control.

Occupational Considerations

It is important to consider that shortages of health care workers and essential service workers could have a severe impact on health services in remote and isolated communities. It is recommended that remote and isolated communities identify essential service workers and ensure they know how to access early antiviral treatment should they develop ILI.

Occupational considerations are discussed in the *Guidance: Infection prevention and control measures for Health Care Workers in Acute Care Facilities* and the *Guidance: Infection Prevention and Control Measures for Prehospital Care*.

Outbreaks of pH1N1 influenza in remote and isolated communities have the potential to significantly increase the demand on the supplies in health care facilities. Clinic managers might consider maintaining a 4 week supply of clinic stock including personal protective equipment for health care workers (e.g. gowns, masks, gloves), laboratory supplies (NP swabs) and essential medical supplies including oxygen.

For guidelines related to health services considerations in remote and isolated communities, including storage and security of supplies, refer to *Guidance for Health Services Planning in Remote and Isolated Communities in the Context of Pandemic (H1N1) 2009* (to be published soon).

Appendix A

Emergency Compounding of an Oral suspension from TAMIFLU capsules^{xiv}

Compounding an oral suspension with this procedure will provide one patient with enough medication for a 5-day course of treatment or a 10 day course of prophylaxis.

Commercially manufactured TAMIFLU for Oral Suspension (12 mg/ml) is the preferred product for paediatric and adult patients who have difficulty swallowing capsules or where lower doses are needed. In the event that TAMIFLU for Oral Suspension is not available, the pharmacist may compound a suspension (15 mg/ml) from TAMIFLU (oseltamivir phosphate) Capsules 75 mg using the vehicle Ora-Sweet SF (Paddock Laboratories). Other vehicles have not been studied.

First, calculate the Total volume of an oral suspension needed to be compounded and dispensed for each patient. The total volume required is determined by the weight of each patient (see table 1).

Compounding an oral suspension with this procedure will provide one patient with enough medication for a 5-day course of treatment or a 10-day course of prophylaxis^{xv}.

Table 1: Volume of an Oral Suspension (15mg/ml) Needed to be compounded Based upon the patient's weight

Body Weight (kg)	Body weight (lbs)	Total Volume to Compound per patient (mL)
< 15 kg	< 33 lbs	30 ml
16 to 23 kg	34 to 51 lbs	40 ml
24 to 40 kg	52 to 88 lbs	50 ml
> 41 kg	> 89 lbs	60 ml

Second, determine the number of capsules and the amount of vehicle (Ora-Sweet SF) needed to prepare the Total Volume (calculated from Table 1: 30 ml, 40 ml, 50 ml, or 60 ml) of compounded oral suspension (15 mg/ml) Refer to table 2.

Table 2: Number of TAMIFLU 75 mg Capsules and Amount of Vehicle (Ora-Sweet SF) Needed to prepare the Total Volume of a Compounded oral suspension (15 mg/ml)

Total volume of Compounded Oral suspension to be prepared	30 ml	40 ml	50 ml	60 ml
Required number of TAMIFLU 75 mg capsules	6 Capsules (450 mg oseltamivir)	8 Capsules (600mg oseltamivir)	10 capsules 750 mg oseltamivir	12 capsules (900 mg oseltamivir)

Required volume of vehicle Ora-Sweet SF (Paddock Laboratories)	29 mL	38.5 mL	48 mL	57 mL
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Third, follow the procedure below for compounding the oral suspension (915 mg/mL) from TAMIFLU Capsules 75 mg:

1. Carefully separate the capsule body and cap and transfer the contents of the required number of TAMIFLU 75 mg Capsules into a clean mortar.
2. Triturate the granules to a fine powder.
3. Add one-third (1/3) of the specified amount of vehicle and triturate the powder until a uniform suspension is achieved.
4. Transfer the suspension to an amber glass or amber polyethyleneterephthalate (PET) bottle. A funnel may be used to eliminate any spillage.
5. Add another one-third (1/3) of the vehicle to the mortar, rinse the pestle and mortar by triturating motion and transfer the vehicle into the bottle.
6. Repeat the rinsing (step 5) with the remainder of the vehicle.
7. Close the bottle using a child-resistant cap.
8. Shake well to completely dissolve the active drug and to ensure homogeneous distribution of the dissolved drug in the resulting suspension. (Note: the active drug, oseltamivir phosphate, readily dissolves in the specified vehicle. The suspension is caused by some of the inert ingredients of TAMIFLU capsules which are insoluble in the vehicle.)
9. Put an ancillary label on the bottle indicating "shake gently before use". (This compounded suspension should be gently shaken prior to administration to minimize the tendency for air entrapment.)
10. Instruct the parent or guardian that any remaining material following completion of therapy must be discarded by either affixing an ancillary label to the bottle or adding a statement to the pharmacy label instructions.
11. Place an appropriate expiration date label according to storage condition.

Storing the Pharmacy-compounded suspension

Compounded with Ora-Sweet SF: stable for 5 weeks (35 days) when stored at 25°C.

References

ⁱ Public Health Agency of Canada (PHAC) (pending approval). *Interim guidelines for the laboratory diagnosis of pandemic H1N1 (2009)*.

ⁱⁱ Public Health Agency of Canada (PHAC). (2009, October). *Clinical recommendations for patients presenting with respiratory symptoms during the 2009-2010 influenza season*. Retrieved from http://www.phac-aspc.gc.ca/alert-alerte/h1n1/pdf/H1N1_DecisionTree_oct23_e.pdf

ⁱⁱⁱ Public Health Agency of Canada (PHAC) (pending approval). *Interim guidelines for the laboratory diagnosis of pandemic H1N1 (2009)*.

^{iv} Public Health Agency of Canada (PHAC) (October 4-October 10, 2009). *FluWatch*. Retrieved from http://www.phac-aspc.gc.ca/fluwatch/09-10/w40_09/index-eng.php

^v Public Health Agency of Canada (May 2009). *Canadian Pandemic Influenza Plan for the Health Sector: Annex E – The Use of Antiviral Drugs During a Pandemic*. Retrieved from

<http://www.phac-aspc.gc.ca/cpip-pclcpi/ann-e-eng.php>

^{vi} Public Health Agency of Canada (PHAC). (2009, October). *Clinical recommendations for patients presenting with respiratory symptoms during the 2009-2010 influenza season*. Retrieved from http://www.phac-aspc.gc.ca/alert-alerte/h1n1/pdf/H1N1_DecisionTree_oct23_e.pdf

^{vii} Health Canada (2009, July 20). *Interim Order Respecting the Sale of Oseltamivir Phosphate – Expanded use for Children under 1 year of age*. Retrieved from <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/interimorders-arretesurgence/tamiflu-eng.php>

^{viii} Public Health Agency of Canada (PHAC). (2009, October). *Clinical recommendations for patients presenting with respiratory symptoms during the 2009-2010 influenza season*. Retrieved from http://www.phac-aspc.gc.ca/alert-alerte/h1n1/pdf/H1N1_DecisionTree_oct23_e.pdf

^{ix} Public Health Agency of Canada (PHAC) (October 4-October 10, 2009). *FluWatch*. Retrieved from http://www.phac-aspc.gc.ca/fluwatch/09-10/w40_09/index-eng.php

^x Health Canada (2009). *Canada Vigilance Reporting Form*. Retrieved from http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/medeff/ar-ei_form-eng.pdf

^{xi} Roche Canada (2009, July). *Tamiflu product monograph*. Retrieved from www.rochecanada.com

^{xii} Public Health Agency of Canada (May 2009). *Canadian Pandemic Influenza Plan for the Health Sector: Annex E – The Use of Antiviral Drugs During a Pandemic*. Retrieved from <http://www.phac-aspc.gc.ca/cpip-pclcpi/ann-e-eng.php>

^{xiii} Society of Obstetricians and Gynaecologists of Canada (SOGC), (September 4th 2009) *H1N1: Recommendations in Pregnancy*. Retrieved from <http://www.sogc.org/h1n1/lisH1N1ExecMotion090904B.pdf>

^{xiv} Roche Canada (2009, July). *Tamiflu product monograph*. Retrieved from www.rochecanada.com

^{xv} Roche Canada, addition approved as per email communication on October 23, 2009

¹ Note, epidemiological data (from April-August 2009) showed that in laboratory confirmed patients: 100% of children under 2 presented *with* fever; 90% of pregnant women presented *with* fever; and 50% of people >65 presented *without* fever. Atypical presentations were most common in infants, the elderly and the immunocompromised.

² This number is derived from the assumptions present in the National Antiviral Strategy as outlined in Annex E of the *Canadian Pandemic Influenza Plan for the Health Sector*. It represents the proportion of the population that is anticipated to present to a clinician and receive antivirals during a pandemic of moderate severity.

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