



*British Columbia Perinatal Health Program*  
*Optimizing Neonatal, Maternal and Fetal Health*

- *British Columbia Reproductive Care Program (BCRCP)*
- *Provincial Specialized Perinatal Services (PSPS)*



**ALERT**

**ATTENTION: Perinatal Care Providers**

**H1N1 Management Guidelines for  
Pregnancy, Postpartum and Newborns with  
suspected or confirmed  
H1N1 influenza virus (novel H1N1)**

**Interim Guidelines  
developed by a multidisciplinary team  
coordinated by the  
BC Perinatal Health Program**

**Updated: November 25, 2009**

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## Introduction

The purpose of this document is to pull together information on novel H1N1 (swine-origin influenza A/H1N1) influenza virus and provide advice in the context of the care of an obstetrical patient. It draws upon multiple documents to provide a single simple source of preliminary information for the prenatal care provider.

The Public Health Agency of Canada has developed an information sheet for pregnant women – *Pregnancy and the H1N1 Flu Virus* ([www.phac-aspc.gc.ca/alert-alerte/swine-porcine/pregnancy-grossesse-eng.php](http://www.phac-aspc.gc.ca/alert-alerte/swine-porcine/pregnancy-grossesse-eng.php)).<sup>1</sup>

The management of an obstetrical patient in the context of the current novel H1N1 pandemic must follow the most current public health and infection control recommendations. At the time of writing of this document the following general recommendations are in effect.

### Recommendations for health care providers seeing patients in clinics or hospital facilities: screening triage for fever and respiratory symptoms

All patients, including pregnant women, who present to a health care setting (whether an office, ambulatory care clinic etc.) should be screened for fever and respiratory symptoms. This should include:

- If possible, screen for respiratory symptoms by phone when the person makes or confirms their appointment; if a person coming in for routine perinatal care has respiratory symptoms assess the need for the visit and whether they can come at a time when contact with other pregnant women and young children is minimized.
- Passive screening: signs posted at the entrances to all health care settings (clinics, Emergency Departments) asking patients to report whether they have fever and any new or worsening respiratory symptoms, and
- Active screening: At first contact, staff asks about fever and respiratory symptoms.
- Respiratory symptoms include cough, sore throat, coryza (runny nose), and myalgias (general body aches).

### Infection prevention and control precautions for patients

Patients who report fever and respiratory symptoms should be instructed to:

- Clean their hands with 60-90% alcohol-based hand rub (or soap and water if immediately available).
- Put on a surgical mask, and
- Be seated at least 2 metres (6 feet) away from others.
- If this is not possible in the waiting room setting, she should be placed immediately in an examining room.

### Routine practices and contact precautions for clinicians

Individual facility specific infection control guidelines should be reviewed on a regular basis as recommendations are changing over time. However, the general infection control practices are indicated when assessing patients with fever and respiratory symptoms:

**Before** a clinical assessment:

- Ensure patient is still wearing a surgical mask.
- Perform hand hygiene (alcohol based hand rub or soap and water) before and after patient assessment.
- Put on gloves.
- A gown is needed only when there is a risk of clothing or skin contamination (such as when examining young children who may have difficulty controlling their secretions).
- Consider most appropriate respiratory protection.

**Respiratory protection**

Along with gloves and a gown (if needed), clinicians should wear respiratory protection when providing care within 2 meters of a suspect influenza-like-illness (ILI) case. For most care a surgical mask and eye protection is required; an N95 respirator with eye protection is only required if you are performing an aerosol-generating medical procedure

**After** a clinical assessment:

- Eye or face protection should be removed after leaving the presumed infected woman's room and disposed of in either a hands-free waste receptacle (if disposable) or in a separate receptacle to go for reprocessing (if reusable).
- The mask should be removed by the straps, being careful not to touch the mask or respirator itself, after leaving the woman's room and disposed of in a hands-free waste receptacle.
- Health care workers should perform hand hygiene after removing the respiratory protection and after leaving the case's room.
- Affected surfaces that may have been contaminated with droplets need to be cleaned. Routine office cleaning products are effective for respiratory viruses including influenza; no special cleaning products are needed.<sup>2</sup>

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## Overview of novel H1N1 Influenza (Swine Origin A/H1N1 Influenza)

Novel H1N1 (swine origin A/H1N1) influenza is a novel influenza virus that has established person-to-person transmission and spread globally. On June 11, 2009 the World Health Organization declared the first pandemic of the 21<sup>st</sup> century due to this novel virus – the first pandemic in more than 40 years. Novel H1N1 causes illness that may be clinically indistinguishable from human influenza viruses. In the early reports, there was apparent worse severity in Mexico but as the outbreak has spread to many countries and the cases in Mexico have been reviewed, the level of severity has been comparable across regions. Like seasonal influenza, symptoms include fever, cough, sore throat, fatigue, and lack of appetite. Some people, particularly younger individuals have reported vomiting and diarrhea.<sup>3, 4</sup> Elderly persons appear relatively spared from novel H1N1 illness. Unlike seasonal human influenza, novel H1N1 is associated with more serious outcomes such as hospitalization and death in children and young adults, rather than the elderly. The risk factors associated with serious outcomes and the contribution of other pathogens have not yet been fully elucidated. Early reports suggest pregnant women, especially those in third trimester or peri-partum, are at increased risk of serious outcomes due to novel H1N1. Reports from the Public Health Agency of Canada up to August 22, 2009, show that pregnant woman made up 5% of cases of all reproductive aged women with H1N1 infection but were 30% of hospitalized patients and 30% of women of childbearing age who died were pregnant.

Because novel H1N1 is antigenically quite distinct from recent human influenza viruses, the seasonal influenza vaccine administered in 2008-2009 is not anticipated to provide protection against novel H1N1. Early immunogenicity studies show little effect of seasonal vaccine on novel H1N1 antibody levels pre- and post-immunization among young adults.<sup>5</sup> A specific pandemic H1N1 vaccine is now available for pregnant women in BC (see later section for details). Antiviral therapy with oseltamivir is recommended for early treatment of ILI in pregnant women (see later section on antivirals in pregnancy).

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## Review of Epidemiology to date

The epidemiology of this infection is changing rapidly and up to date reporting is being posted on Public Health Agency of Canada ([http://www.phac-aspc.gc.ca/alert-alerte/swine\\_200904-eng.php](http://www.phac-aspc.gc.ca/alert-alerte/swine_200904-eng.php)), the BC Centre for Disease Control websites as well as on the PHSA website. ([www.bccdc.org](http://www.bccdc.org), [www.phsa.ca](http://www.phsa.ca)) International information is available on the World Health Organization (WHO) website as well as the Centre for Disease Control (Atlanta, Georgia).<sup>6,7,8,9,10</sup>

Because the novel H1N1 virus has already established easy person-to-person transmission and has spread globally, neither the WHO nor Canada are advising restriction of regular travel or closure of borders. People who are ill with ILI are advised to delay international travel and for people who develop symptoms following international travel are advised to seek medical attention, in line with guidance from national authorities.

There is no risk of infection from this virus from consumption of pork and pork products. Individuals are advised to wash hands thoroughly with soap and water on a regular basis and stay home if they develop any symptoms of influenza-like illness. If they think they may need medical attention and are in B.C., they can call HealthLink BC at 8-1-1 for advice.<sup>11</sup>

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## **Clinical guideline on specimen collection and testing for novel H1N1**

In British Columbia, routine testing of individuals in the community with influenza like illness is not recommended. However, for individuals in a hospital setting who are unwell, testing is advised. Clinicians can test individuals if decision making will be altered by the results of the test and at present, it is suggested that this is helpful in the management of pregnant women with influenza like illness. However, testing should not delay initiation of therapy

Clinicians should test suspected cases of novel H1N1 among those hospitalized with influenza-like illness or otherwise with severe manifestations by obtaining an upper respiratory specimen, preferably with a nasopharyngeal swab. Where appropriate, bronchoalveolar lavage (BAL) may also be submitted from severe cases. A confirmed case of novel H1N1 is defined as detection by PCR, culture or four-fold rise in specific antibody titre based on acute compared to convalescent sera.

It is unknown how long viral shedding continues with novel H1N1 but current guidelines suggest that communicability is from 1 day prior to onset of symptoms until 7 days from illness onset OR until symptoms including fever have resolved, whichever happens sooner.

Some facilities in BC have the ability to do rapid testing for respiratory pathogens to rule influenza A in or out, but confirmatory testing for novel H1N1 is only available at the BCCDC laboratories and requires mandatory information be completed on the lab requisitions.

## Lab Requisitions:

Please complete the requisition as thoroughly as possible. Medical mandatory requirements are outlined below and must be used on the regular BCCDC Virology-Culture (HLTH 1811) requisitions (including use with ILI outbreak form):

- Please provide **medical mandatory information** including the following if present:
  - Fever
  - Lower Respiratory Tract Infection / Pneumonia / Severe Respiratory Infection (SRI) / Hospitalized
  - Upper Respiratory Tract Infection
  - Degree of severity – i.e., hypoxia, requiring mechanical ventilation
  
- In the "Other (Please Specify)" area, please use the code **SWFLU09** as a unique Outbreak/Alert Identifier and highlight SRI or hospitalized as applicable.

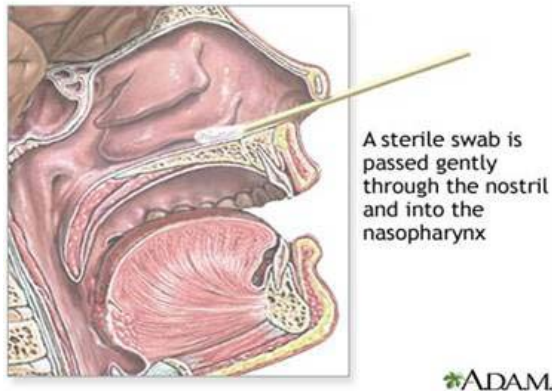
| BCCDC LABORATORY SERVICES<br>B.C. CENTRE FOR DISEASE CONTROL            |             | VIRUS — CULTURE<br>Phone: (604) 660-6080   |                      | LABORATORY USE ONLY     |             |
|---|-------------|--|----------------------|-------------------------|-------------|
| PATIENT'S SURNAME (PRINT)   |             | GIVEN NAME(S)  |                      | DATE RECEIVED           | LAB No.     |
| ADDRESS   |             | PERSONAL HEALTH No.  |                      | ASSIGNMENT              |             |
| DATE OF BIRTH   | YR. MO. DAY | SEX<br><input type="checkbox"/> M. <input type="checkbox"/> F  | SUBMITTER'S REF. No. | DATE SPECIMEN COLLECTED | YR. MO. DAY |
| DOCTOR'S MSC No.  |             | DOCTOR OR HOSPITAL   |                      |                         |             |
| STAMP, PRINT OR TYPE FULL POSTAL ADDRESS IN BOX FOR CONFIDENTIAL REPORT |             |  |                      |                         |             |
| COPY OF REPORT TO DOCTOR'S MSC No. 1. _____ 2. _____ 3. _____           |             |  |                      |                         |             |
| TYPE OF SPECIMEN:   |             | CLINICAL DIAGNOSIS   |                      |                         |             |
|   |             | <b>Travel or Contact History</b>   |                      |                         |             |
| SYMPTOMS:   |             | Respiratory:   |                      |                         |             |
| <input type="checkbox"/> Fever  |             | <input type="checkbox"/> Upper <input type="checkbox"/> Lower <input type="checkbox"/> Vomiting <input type="checkbox"/> Other |                      |                         |             |
| <input type="checkbox"/> Headache                                       |             | <input type="checkbox"/> Rash:   |                      |                         |             |
| <input type="checkbox"/> Neck Rigidity                                  |             | <input type="checkbox"/> Maculopapular <input type="checkbox"/> Vesicular  |                      |                         |             |
| <input type="checkbox"/> Diarrhoea                                      |             | EXAMINATION DESIRED  |                      | DATE OF ONSET           |             |
|   |             | <input type="checkbox"/> HERPES SIMPLEX VIRUS  |                      |                         |             |
| <input type="checkbox"/> Others (Please Specify)                        |             | <b>SWFLU09</b>   |                      |                         |             |
| HLTH 1811 Rev00/06 - 00055685 - 94055                                   |             |  |                      |                         |             |

- SPECIMEN COLLECTION INSTRUCTIONS**
- Use VI Outfit for all swabs.
  - Obtain specimens **early** in the course of the illness. Swab affected area **firmly** to obtain superficial cells.
  - For fluid specimens (urine, etc.) use leakproof containers with lids tightly secured. Vacutainer tubes are satisfactory for this purpose.
  - Biopsy and autopsy tissues — send 1 to 2 cu. cm. of tissue moistened with sterile saline. Transport on ice — DO NOT freeze.
  - Rectal swabs **must** contain some faecal material. Stool specimens are preferred for investigation of gastroenteritis. Submit stools in sterile, leakproof container — DO NOT ADD FLUID OR PRESERVATIVE.
  - For detailed instructions, refer to the Provincial Laboratories Manual of Services.

## Specimens:

Optimal specimens continue to be **Nasopharyngeal Swabs (COPAN flocked swabs)** BUT Starplex® non-flocked swabs are also acceptable for nasopharyngeal and nasal samples. **For those offices and clinics that do not have ready access to these swabs, the swabs and transport media used for genital herpes culture/PCR are acceptable.** DO NOT use the wire shaft pertussis swab as it interferes with the test and may give false negative results.

## Specimen Collection:



Allow the swab to sit in place for 5 – 10 seconds.

- Rotate the swab several times to dislodge the columnar epithelial cells. Note: Insertion of the swab can induce a cough.
- Withdraw the swab and place it in the collection tube.
- Refrigerate immediately.
- Remove gloves
- Perform hand hygiene.
- Label collection tube with the patient's **full name** and **date of birth**. Attach completed Virology Services requisition.  
<http://www.phsa.ca/NR/rdonlyres/FBDA7450-2866-4772-9A7A-3CE43547628A/0/VIRReq.pdf>.
- Transport to the laboratory.

## Transport/Alerts

Standard transportations procedures used to transport to BCCDC can be utilized.

## BCCDC Tests/Results

Testing for Influenza using RT-PCR will take place in the BCCDC Virology Lab regularly depending on the volume and stage of the outbreak/epidemic. Please ensure that correct, reachable phone numbers are included on the requisition,

As noted the Medical Microbiologists on-call is available at 604-661-7033 for other issues.<sup>12</sup>

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## **Clinical guideline for management of pregnant women**

Current information from the experience from April to August of 2009 would suggest that pregnant women are not more likely to become infected but if infected are at increased risk of severe illness and complications from the novel H1N1 influenza A infection.

Pregnant women have been noted to be at higher risk of dying during the pandemics of 1918 and 1957. Adverse pregnancy outcomes were also highlighted during the 1918 pandemic, with increased rates of spontaneous abortion and preterm birth reported, especially among women with pneumonia. Pregnant women, especially those in third trimester, are also known to be at higher risk of complications requiring hospitalization due to seasonal influenza.<sup>13,14,15</sup>

Early reports suggest that pregnant women are at higher risk of complications due to novel H1N1.<sup>16,17</sup> Specific reports regarding the pattern of novel H1N1 illness in pregnancy are only just being made available. Prior to this outbreak, there was a report from 1988 of a previously healthy 32-year-old pregnant woman who was hospitalized for pneumonia and died 8 days later after infection with another variant of swine influenza. A recent report from MMWR (May 12, 2009),<sup>18</sup> stated that to date in the U.S. there have been 20 cases of novel H1N1 in pregnancy. Subsequent to this there has been a publication from a series of pregnancies in the US that have reviewed 34 cases of pregnant women with confirmed or probably H1N1 influenza virus infection. The cases spanned all trimesters of pregnancy, resulted in 11 being hospitalized, 3 in ICU and one death. In addition, a review of 6 deaths in pregnant women reported to the CDC revealed that all women developed a pneumonia and a subsequent illness resembling adult respiratory distress syndrome (ARDS).<sup>19</sup>

### **Clinical Presentation**

Pregnant women with novel H1N1 may present with typical acute respiratory illness (e.g., fever/feverishness, cough, sore throat, fatigue). Many pregnant women will go on to have a typical course of uncomplicated influenza. However, for some pregnant women, illness might progress rapidly. Fetal distress associated with severe maternal illness can occur.

### **General Management**

- Prophylaxis with antiviral medication (oseltamivir) for pregnant women is not recommended even if exposed to a household or work contact.
- Vaccination with novel H1N1 unadjuvanted vaccine is recommended for all pregnant women once the vaccine is available in November-December and vaccination with the seasonal influenza vaccination is recommended for all pregnant women and will also be available in early November-December.
- Vaccination with novel H1N1 adjuvanted vaccine has been administered prior to the availability of unadjuvanted vaccine and there should be no concern with the use of this vaccine in pregnancy.
- Pregnant women with mild influenza like illness should be managed at home but should self isolate and call their prenatal care provider.
- The prenatal care provider should decide if they need to be seen in person for an assessment but if highly suspicious of influenza like illness in the context of widespread novel H1N1 disease in their community it is recommended that the pregnant women be treated with oseltamivir (see below).
- Any pregnant woman with serious respiratory symptoms, very high fever or any evidence of medical or obstetrical complications should be seen in person.
- If assessment in office or clinic is required they should be advised to call ahead and on arrival should put on a mask and sanitize or wash their hands, mask and be seen in a separate room from other patients, ideally at the end of a clinic.
- If assessment or admission to hospital is required, again women and or their

care providers should alert infection control and primary staff that they are coming and ideally should be shown into a separate room for assessment following hospital infection control procedures for respiratory infections.

- These guidelines may change as the epidemic evolves so consultation with local infection control staff is important.
- Pregnant women should be instructed that if household contacts become ill, attention to good handwashing and cleaning of household surfaces with normal cleaning products will decrease the chances of illness. If possible pregnant women should not be the primary caregiver to household members who are ill with ILI.

## **Vaccine Information**

### **Unadjuvanted Vaccine**

Unadjuvanted vaccine is considered the preferred option for pregnant women, given that there is extensive experience regarding the safety of unadjuvanted seasonal influenza vaccines in pregnant women and there are currently no data on the safety of the adjuvanted pH1N1 vaccine in this group. This recommendation is made as a precaution for this population, given the potential concern of pregnant women about receiving a newly developed adjuvanted vaccine during their pregnancy.

Unadjuvanted vaccine may be administered at any stage of pregnancy.

### **Adjuvanted Vaccine**

Clinical data on the use of the adjuvanted pH1N1 vaccine in pregnant women are not currently available. However, for women at higher risk of complications of pH1N1 infection, this formulation should be considered if unadjuvanted vaccine is not available.

## **Antiviral Information**

Oseltamivir and zanamivir are neuraminidase inhibitors active against novel H1N1 but the current seasonal influenza is resistant in many cases to these antivirals. Their mechanism of action involves a crucial step in the life cycle of influenza A and B. A viral surface glycoprotein (hemagglutinin) binds to sialic acid residues on respiratory epithelial surface glycoproteins, which is necessary for the initiation of infection. After the virus replicates, it is also attached to the host cell the same way until neuraminidase cleaves this link and frees the new virions.<sup>20,21</sup>

Zanamivir is inhaled as a dry powder (10 mg bid for five days for treatment) and oseltamivir is an oral drug (75mg po bid for five days for treatment). The major side effects are nausea and vomiting, but there has been some concern with respiratory distress associated with zanamivir, particularly in asthmatic persons.<sup>22,23</sup>

### **Antiviral Treatment for novel H1N1 in Pregnancy**

The currently circulating novel H1N1 is sensitive to the neuraminidase inhibitor antiviral medications zanamivir (Relenza<sup>®</sup>) and oseltamivir (Tamiflu<sup>®</sup>), but is resistant to the adamantane antiviral medication, amantadine. Current access to zanamivir is very limited so the only available antiviral, at present, is oseltamivir (Tamiflu<sup>®</sup>). **Pregnant women with influenza like illness with symptoms that may include cough, fever, myalgias, respiratory distress (with or without nausea and vomiting), should be offered empiric**

**antiviral therapy. Early treatment, within 24 – 48 hours appears to be most effective, so treatment should not be withheld awaiting test results.** SOGC recommends that pregnant women be provided with a prescription for oseltamivir at routine prenatal visits to be used after consultation if the pregnant woman develops symptoms. This provides the opportunity to discuss prevention and symptoms with all pregnant women. However, the patient should be encouraged to contact their physician if they develop an influenza like illness and the physician should triage to stay home and start medication or be seen if seriously ill. Benefit declines when therapy is started more than 48 hours after illness onset. However, some data from studies on seasonal influenza suggest there may be benefit for hospitalized patients even if treatment is started more than 48 hours after onset.<sup>24</sup>

### **Antiviral Treatment for novel H1N1 in Pregnancy – Benefit/Risk Considerations**

Choice of antiviral regimen needs to be consistent with current public health recommendations and based on availability of antivirals. Early evidence suggests pregnant women may be at higher risk for severe complications (including stillbirth) from novel H1N1, and the benefits of treatment appears to outweigh the theoretical risks of antiviral use.

Although, both oseltamivir and zanamivir are FDA Category C drugs (see below for details) indicating there is no human data,<sup>25, 26</sup> there are no proven human pregnancy risks or complications so they can be used at the clinicians' discretion in pregnancy.<sup>27, 28, 29</sup> There is limited pregnancy data with animal studies with doses 100 times that of treatment doses, demonstrating minor skeletal alterations in rats when pregnant rats are given zanamivir and there are similar findings in pregnant rabbits given oseltamivir.

A recent review of the safety of influenza antivirals in pregnancy published in the Canadian Medical Association Journal emphasizes that limited data suggest oseltamivir is not a major human teratogen and, because of more data about its safety in pregnancy, the use of oseltamivir may be preferred over zanamivir during pregnancy.<sup>30</sup>

Several studies have shown that fever during pregnancy is associated with an increased risk of birth defects and other adverse outcomes. For this reason, fever in pregnant women should be treated. Acetaminophen appears to be the best option for treatment of fever during pregnancy.

### **Antiviral Dosing Regimens**

Recommendations for use of antivirals for pregnant women might change as additional data on the benefits and risks of antiviral therapy in pregnant women become available. Current dosing recommendations for **treatment** are per usual as:

Oseltamivir – 75mg po bid x 5 days

Zanamivir – 10mg (2 inhalations) inhaled, twice daily x 5 days.<sup>31</sup>

### **Peripartum, Postpartum and Breastfeeding Considerations**

Recommendations for infection control management of the infant delivered to an infected mother vary amongst jurisdictions, but there does not appear to be evidence that separation of infant from the mother immediately after birth will lessen the risk of the neonate developing novel H1N1 influenza infection. In addition, successful onset of breastfeeding may prove to be protective. As such, breastfeeding is encouraged (early initiation and frequent feedings) as there may be a theoretical advantage to the neonate of passive transmission of antibodies to influenza virus from an exposed or infected mother. Prior to handling of her infant and breast-

feeding a mother should wash her hands, put on a mask and clean gown to minimize exposure. Women can continue breastfeeding while receiving antivirals.

Although the risk for novel H1N1 influenza transmission through breast milk is unknown, reports of transmission of seasonal influenza infection are rare.

A handout from the CDC that might be useful:<sup>32</sup> <http://www.cdc.gov/h1n1flu/infantfeeding.htm>

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## **Clinical guideline for management of the neonate and infants less than 1 year of age**

It is recommended that neonates of mothers with an influenza-like illness be observed closely for signs of respiratory illness. Isolation of these infants from others by rooming in with the mother is generally the appropriate approach. Neonates requiring admission to a nursery should be isolated as per standard respiratory precautions. If neonates become ill with possible influenza like illness, consultation with a pediatrician and/or infectious diseases is recommended.

Oseltamivir use for children less than 1 year old was recently approved in the US by the FDA under an Emergency Use Authorization (EUA), and dosing for these children is age-based. As well Health Canada has developed an *Interim Order Respecting the Sale of Oseltamivir Phosphate – Expanded use for Children under One Year of Age* ([http://www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/interim\\_order\\_arrete\\_urgence\\_H1N1-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/interim_order_arrete_urgence_H1N1-eng.php)) allowing its use in Canada. Recommended doses of oseltamivir antiviral medication for infants <3 months is 12 mg twice daily, however dose adjustments in this age group may need to be modified based on weight. Consultation with an expert is recommended.<sup>33</sup> The Canadian Pediatric Society Guideline provides a helpful reference to general management of children and youth.<sup>34</sup> *Interim Guidance for emergency use of oseltamivir (Tamiflu®) In Children under one year of age in context with 2009 (H1N1) pandemic* is also available at the PHAC website (<http://www.phac-aspc.gc.ca/alert-alerte/h1n1/guidance-orientation-07-20-eng.php>)

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## REFERENCES

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