

**PROTOCOL FOR
MANAGEMENT OF THE PATIENT WITH H1N1 INFLUENZA VIRUS (as of 8/09)**

PURPOSE: To provide a standardized approach for the management of patients with Pandemic (H1N1) influenza and to prevent the spread of H1N1 to health care personnel and other patients.

LEVEL: Interdependent

SUPPORTIVE DATA

H1N1 influenza is a strain of the Influenza A virus that causes illness in people. The World Health Organization declared this disease a pandemic in July, 2009. Sacramento County is experiencing widespread disease as is much of California.

Infection with H1N1 is similar to infection with seasonal flu. Symptoms include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills, and fatigue. A significant number of people infected with this virus also report diarrhea and vomiting. Like seasonal flu, severe illness and death have been reported. There are certain people at higher risk of flu-related complications. These include:

- Children less than 5 years old;
- Persons aged 65 years or older;
- Children and adolescents (less than 18 years) who are receiving long-term aspirin therapy and who might be at risk for experiencing Reye syndrome after influenza virus infection;
- Pregnant women;
- Adults and children who have chronic pulmonary, cardiovascular, hepatic, hematological, neurologic, neuromuscular, or metabolic disorders;
- Adults and children who have immunosuppression (including immunosuppression caused by medications or by HIV);
- Residents of nursing homes and other chronic-care facilities.
- Obesity (BMI \geq 35)

Flu viruses are spread mainly from person to person through coughing or sneezing. Spread of H1N1 is thought to be the same as seasonal flu – droplets or contact with items that may come in contact with droplets. People may be contagious from one day before symptoms develop to 7 days after onset of symptoms. When doing procedures that contribute to potential aerosolization of secretions, airborne particles may be released. These procedures include:

- nasopharyngeal sampling (specimen collection)
- administration of nebulized medications
- bronchoscopy
- suctioning of airway secretions
- CPR
- endotracheal intubation
- post-mortem examinations

DIAGNOSIS, TESTING AND TREATMENT

Protocol For
Management Of The Patient With H1N1 Influenza Virus

1. Diagnosis

- a. Due to the widespread occurrence of cases of H1N1 infection in Sacramento County, patients presenting with the constellation of symptoms described above should be assumed to be H1N1 positive.

2. Testing (See Attachment A for Ordering and Collection Procedure)

- a. Testing is recommended for patients who are moderately to severely ill.
- b. A preliminary rapid (EIA) screening test for Influenza A is available on-site in the SMCS lab. The sensitivity of this test is variable, depending on where the patient is in their disease process. False negatives have been reported in the 10-50% range. A positive rapid EIA Influenza A test can be considered as *most likely* positive for H1N1. However, a negative rapid EIA result should not be interpreted as a definitive answer.
- c. A H1N1 PCR test is available. H1N1 PCR tests for presence of viral DNA. Order this test in SHIPER. This test methodology has been endorsed by the CDC due to its specificity and sensitivity
- d. *Do not withhold treatment for moderate or seriously ill patients pending test results.* Test results may take as long as 4 days.

3. Treatment/Prophylaxis

- a. All hospitalized patients with suspected, probable, or confirmed influenza A (H1N1) virus infection should be empirically treated with oseltamivir or as early after illness onset as possible.
- b. Chemoprophylaxis can be considered for close contacts who are at high risk for complications of influenza.
- c. Pre-exposure antiviral chemoprophylaxis is not recommended

Table 1. Antiviral medication dosing recommendations for treatment or chemoprophylaxis of influenza A (H1N1) infection. (Table extracted from IDSA guidelines for seasonal influenza.)			
Agent, group		Treatment	Chemoprophylaxis
Oseltamivir			
Adults		75-mg capsule twice per day for 5 days	75-mg capsule once per day X 10 days
Children ≥ 12 months	15 kg or less	60 mg per day divided into 2 doses for 5 days	30 mg once per day X 10 days
	16-23 kg	90 mg per day divided into 2 doses for 5 days	45 mg once per day X 10 days
	24-40 kg	120 mg per day divided into 2 doses for 5 days	60 mg once per day X 10 days
	>40 kg	150 mg per day divided into 2 doses for 5 days	75 mg once per day X 10 days
Zanamivir			
Adults		Two 5-mg inhalations (10 mg total) twice per day for 5 days	Two 5-mg inhalations (10 mg total) once per day X 10 days

Table 1. Antiviral medication dosing recommendations for treatment or chemoprophylaxis of influenza A (H1N1) infection. (Table extracted from IDSA guidelines for seasonal influenza.)		
Agent, group	Treatment	Chemoprophylaxis
Children	Two 5-mg inhalations (10 mg total) twice per day (age, 7 years or older) for 5 days	Two 5-mg inhalations (10 mg total) once per day (age, 5 years or older) X 10 days

Children Under 1 Year of Age

Children under one year of age are at high risk for complications from seasonal human influenza virus infection. The characteristics of human infection (H1N1) influenza virus are still being studied, and it is not known whether infants are at higher risk for complications associated with (H1N1) influenza virus infection compared to older children and adults. Oseltamivir is not licensed for use in children less than 1 year of age. However, limited safety data on oseltamivir treatment for seasonal influenza in children less than one year of age suggest that severe adverse events are rare.

Because infants experience high rates of morbidity and mortality from influenza, infants with novel (H1N1) influenza virus infections may benefit from treatment using oseltamivir. (Tables 2 and 3, Emergency Use Authorization of Tamiflu (oseltamivir)).

Table 2. Dosing recommendations for antiviral treatment of children younger than 1 year using oseltamivir.	
Age	Recommended treatment dose for 5 days
<3 months	12 mg twice daily
3-5 months	20 mg twice daily
6-11 months	25 mg twice daily

Table 3. Dosing recommendations for antiviral chemoprophylaxis of children younger than 1 year using oseltamivir.	
Age	Recommended prophylaxis dose for 10 days
<3 months	Not recommended unless situation judged critical due to limited data on use in this age group
3-5 months	20 mg once daily
6-11 months	25 mg once daily

Healthcare providers should be aware of the lack of data on safety and dosing when considering oseltamivir use in a seriously ill young infant with confirmed (H1N1) influenza virus infection or who has been exposed to a confirmed (H1N1) influenza case, and carefully monitor infants for adverse events when oseltamivir is used. Additional information on oseltamivir for this age group can be found at: Swine Flu: Emergency Use Authorization (EUA) of Medical Products and Devices.

CONTROL MEASURES

1. Patient placement

- a. Any patient presenting with signs and symptoms of H1N1 should be asked to wear a surgical mask. Once they have been placed in a room and appropriate precautions implemented, it will be the staff who wear appropriate protective equipment.
- b. The patient should be placed in an airborne infection isolation room (AIIR) – also known as negative pressure room - if available. If an airborne infection isolation room there is not available, place the patient in a private room with the door closed. In the event there is no private room available, patients with H1N1 can be housed in the same room. This is a last resort. Consult with Infection Control.
- c. For procedures that may generate an aerosol (see above), the ideal patient placement is in an airborne infection isolation room.
- d. For mother-baby couplets, see Addendum B

2. Personal Protection.

- a. For contact with suspect/confirmed H1N1 patients, careful hand hygiene is vital before and after patient contact (remember your 5 Moments of Hand Hygiene). As always, if hands are visibly soiled, use soap and water. Alcohol-based products can also be used if hands are not visibly soiled.
- b. Use Airborne and Contact Precautions for suspected/confirmed cases of H1N1.
Contact Precautions - Use gowns and gloves for all contact with patient and their environment. Perform hand hygiene after removing gloves (soap and water OR alcohol-based product)
Airborne Precautions – Use an N-95 mask when entering the room. Discard the mask on leaving the room and decontaminate hands by washing or using an alcohol based handrub.
- c. In addition to the personal protective equipment defined above, enhanced respiratory protection (N-95 mask) and eye protection (goggles or face shield) is required for any aerosol generating procedures on patients. Aerosol producing procedures include
 - i. *collecting NP swabs*
 - ii. administration of nebulized medications (e.g. albuterol)
 - iii. diagnostic sputum induction
 - iv. bronchoscopy
 - v. airway suctioning
 - vi. endotracheal intubations
 - vii. post mortem examinations
 - viii. cardiopulmonary resuscitation
- d. Advise patients to cover their mouth and nose with tissue when coughing and to use hand hygiene after touching tissues/sneezing

3. Patient transportation

- a. Place a surgical mask on the patient when transporting. Discard the mask and replace if it becomes moist or soiled.

4. Eating utensils

- a. Disposable dishes and utensils are not necessary. Dishes and utensils should be washed in a routine manner with soap and hot water. Don gloves, remove the tray from the room, and place it on the tray cart. DO NOT place the trays in the soiled utility rooms.

5. Linen

- a. Use gowns and gloves to handle soiled linen from isolation rooms. No special precautions required when washing linen.

6. **Environmental/Equipment cleaning**
 - a. Environmental surfaces and patient care areas should be cleaned with the routine hospital disinfectant. The quaternary spray and bleach wipes are available for surface cleaning as well.
 - b. Use dedicated equipment when possible. Disinfect equipment following usual hospital protocols.
7. **Visitors**
 - a. Visitors who are ill should not visit any patient.
 - b. For maternal-newborn couplets, see Addendum B
 - c. Instruct visitors on hand hygiene. The visitor is to wear gloves, gown and surgical mask while in the patient's room. Children or siblings of an infected patient may be allowed to visit if they are able to understand and comply with instructions to prevent transmission.
8. **Discontinuation of Contact and Airborne precautions**
 - a. Patients should remain in precautions for 7 days or until symptoms subside, whichever is longest.
 - b. If a patient will be discharged prior to the 7th day after symptom onset, advise the patient to stay home and avoid going into the public for at least 24 hours after they are free of fever or signs of fever without the use of fever-reducing medications.

EMPLOYEE EXPOSURE or ILLNESS

1. Because of the widespread occurrence of H1N1 infection cases in the community, isolated cases of confirmed H1N1 will not be worked up as an exposure.
2. Staff are encouraged to self-monitor for illness (see Attachment C)
3. Should staff become ill with H1N1, they should be off work for 7 days or until symptoms subside, whatever is longest.
4. If possible, do not assign pregnant women to patients with known or suspect H1N1 disease.

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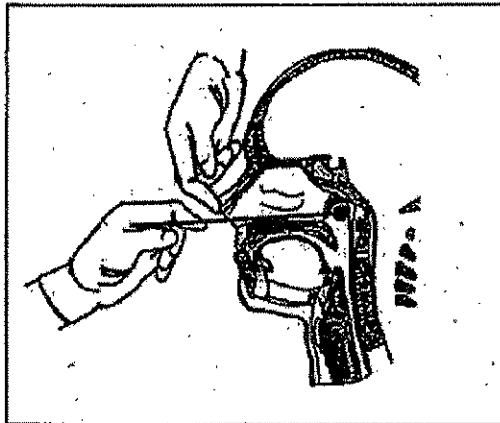
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References:

1. Sacramento County, Department of Health and Human Services, "Influenza-A H1N1 – Healthcare Provider Information." July 1, 2009
2. Centers for Disease Control and Prevention. "Novel H1N1 Flu (Swine Flu) and You." June 30, 2009
3. Centers for Disease Control and Prevention. "Interim Guidance on Antiviral Recommendations for Patients with Novel Influenza A (H1N1) Virus Infection and their Close Contacts." May 6, 2009
4. Center for Disease Control and Prevention, Considerations regarding novel H1N1 flu virus in Obstetric setting. July 6, 2009
5. <http://www.cdc.gov/h1n1flu/recommendations.htm>
6. http://www.cdc.gov/h1n1flu/clinician_pregnant.htm

ADDENDUM A: SPECIMEN ORDERING AND COLLECTION

1. Obtain MD order. The physician may order an Influenza A/B Virus, Rapid EIA and/or a H1N1 PCR. *Note: If the physician writes "Swab for H1N1," order the H1N1 PCR.*
2. Order the appropriate test in SHIPER.
 - a. SHIPER Manual entry Lab order is "Rapid Influenza A/B, EIA", or "Influenza A/B Virus, Rapid"
 - b. SHIPER Manual entry Lab order is "H1N1 (PCR) Influenza A, Nasopharygeal or "H1N1 (PCR) Influenza A, Throat".
3. If the order is for the **Influenza A/B Virus, Rapid EIA**, use 1 green top Naso Pharyngeal swab.
4. If the order is for **H1N1 PCR**, use either a green cap VCM (viral culture media) or a red cap UTM (universal culture media) to collect the specimen. 1 swab is sufficient.
5. Don N-95 equivalent mask, face shield and gloves.
6. Have the patient stand straight with their back to the wall, or lying in bed with their head flat.
7. Inform them that this may be uncomfortable.
8. Insert the swab into the nostril until you feel resistance: to the back of the pharynx. Swab for 10 seconds. If collecting for Influenza A/B virus, insert the swab into the green tube. If collecting for H1N1 PCR, insert the swab into the tube with culture media.
9. Transport immediately to the lab.



ADDENDUM B: Maternal Newborn

Pregnant women are a High-Risk group for complications related to the H1N1 flu.

Hyperthermia is a common adverse effect of influenza. Hyperthermia in the first trimester can double the risk for neural tube defects, other defects and adverse outcomes. Hyperthermia during labor has a risk factor for adverse neonatal outcomes, including neonatal seizures, encephalopathy, cerebral palsy, and neonatal death.

Screening for possible H1N1

Moderate to severe illness

- All patients should be screened for upper respiratory illness, cough, sore throat, rhinorrhea and/or fever.
- If a patient displays these symptoms:
 - Immediately place a surgical mask on the patient
 - Do not send them to the waiting room. (For patients in ATU, the ATU RN will call the L&D charge nurse to arrange for the patient to be placed in a L&D room for monitoring, or if not available, any private room).
 - Place the patient and their visitors in a patient room.
 - If the patient displays moderate to severe illness, inform them that it is recommended that they be screened for H1N1 virus.
 - If any of their visitors display any of the symptoms, request that they leave the facility immediately.
 - If the family member “must stay with the patient”, and they display these symptoms, inform them that they must wear a mask and remain in the patient’s room.

Treatment

Osetamivir (Tamiflu) is the preferred antiviral medication. The medication can be started within 48 hours of symptom onset. 5 days of Tamiflu is recommended for a case of positive H1N1. The medication should be started before the lab results are obtained. If results are negative, the medication can be stopped, if the physician feels it is not H1N1 influenza

Isolation

- The newborn should be considered to be potentially infected if delivery occurs during the 2 days before through 7 days after illness onset in the mother.
- Immediately after delivery, the newborn will be moved to either newborn nursery or SCN depending on the infant’s condition.
- Place the potentially infected newborn in contact isolation. The newborn should be closely observed for signs and symptoms of illness (lethargy, poor feeding, temperature instability, respiratory distress)
- Place ill mother in an airborne infection isolation room (negative pressure). If an airborne infection isolation room is not available, use a single room with the door closed. Use contact and airborne precautions.
- Mother can resume contact with the infant when she has completed 48 hours of antiviral medications, her fever is fully resolved and she can control cough and secretions.
- Significant other/visitors are not considered infected until they display symptoms of influenza. They should wear a surgical mask to protect themselves from possible infection from mother/newborn.
- If mother refuses to be separated from her infant, contact the pediatrician to discuss the potential outcomes. Document this conversation in the medical record. Inform the

mother that the newborn will remain with her and will not be able to go to the nursery. Encourage early discharge.

Breastfeeding

Treatment with antiviral medications is not a contraindication for breastfeeding.

- While mother is separated from the newborn, she should pump her breasts and the breast milk should be fed to the newborn.
- For at least 7 days after the onset of influenza symptoms, the mother should wear a surgical mask, change to a clean gown/clothing and maintain strict hand hygiene before she breastfeeds.

Mothers Visiting the SCN

- Mothers may visit their babies in the SCN after they have completed 48 hours of antiviral medications, their fever is fully resolved and they can control cough and secretions. The mother must wear a mask while in the SCN for 7 days from the onset of flu like symptoms.

References

1. Center for Disease Control and Prevention, Considerations regarding novel H1N1 flu virus in Obstetric setting. July 6, 2009
2. <http://www.cdc.gov/h1n1flu/recommendations.htm>
3. http://www.cdc.gov/h1n1flu/clinician_pregnant.htm

ADDENDUM C: Self monitoring for Illness

Monitor yourself daily for influenza type symptoms

Symptoms of an Influenza like Illness:

- Fever >100.5 along with any of the following:
 - Cough
 - acute onset of respiratory illness
 - sore throat
 - arthralgia
 - myalgia
 - GI symptoms (i.e. diarrhea, vomiting nausea)

Stay Home if you develop flu symptoms

- Stay home until you have been free of fever for 24 hours, except to seek medical care or for other necessities.
- Over-the-counter cold and flu medications used according to the package instructions may help lessen some symptoms such as cough and congestion. Importantly, these medications will not lessen how infectious a person is.
- Get plenty of rest
- Drink clear fluids (such as water, broth, sports drinks, electrolyte beverages for infants) to keep from being dehydrated
- Cover coughs and sneezes. Clean hands with soap and water or an alcohol-based hand rub often and especially after using tissues and after coughing or sneezing into hands

Consult your Doctor if your flu symptoms become severe, if you are Pregnant or have any of the following medical conditions which could put you at risk of developing complications from the Flu (High Risk conditions include: Pregnancy, Asthma, Diabetes Mellitus, Chronic cardiopulmonary disease, Immuno-suppression, Liver/kidney problems, Hematologic/Neuromuscular conditions, Body mass index > 30).

Return to work: You may return to work 7 days or after symptoms subside, whatever is longest.

For further information: See CDC website: Interim Guidance for Novel H1N1 Flu (Swine Flu): Taking Care of a Sick Person in Your Home