H1N1 Update

from the Fort Wayne-Allen County Department of Health

Date: October 15, 2009
Topic: Antivirals and Vaccine

Epidemiology

- We are seeing an increase in transmission among young people and are hearing that many of you are inundated with calls from patients.

Antivirals

I have been authorized to release a portion of the Strategic National Stockpile (SNS) antiviral supply. This can be used for providing antivirals to the indigent. You obviously cannot charge the patient for the antiviral medication. Please contact Corrie at 449-7105 for more information. Supplies of pediatric doses are limited.

Dosing

- Treatment is recommended for all hospitalized patients with confirmed, probable or suspected 2009 H1N1 or seasonal influenza.
- Early empiric treatment should be considered for outpatients who are at higher risk for influenza-related complications (see above). Clinical judgment should be used in deciding whether outpatients with risk factors for influenza-related complications require treatment.
- Treatment with oseltamivir or zanamivir is recommended for persons with suspected or confirmed influenza who are severely ill or who are showing evidence of rapid clinical deterioration. Signs and symptoms of severe illness due to suspected influenza are in indication for immediate treatment, regardless of previous health or age.
- Treatment should be initiated empirically when the decision is made to treat patients who have illnesses that are clinically compatible with influenza. Treatment should not await laboratory confirmation because laboratory-based testing could delay treatment and because a negative rapid test does not rule out influenza

Table 1.Antiviral medication dosing recommendations for treatment or chemoprophylaxis of 2009 H1N1 infection.
(Table extracted from product information for Tamiflu® and Relenza®)

Medication		Treatment (5 days)	Chemoprophylaxis (10 days)
Oseltamivir			
Adults			
		75-mg capsule twice per day	75-mg capsule once per day
Children ≥ 12 months			
Body Weight (kg)	Body Weight (lbs)		
≤15 kg	≤33lbs	30 mg twice daily	30 mg once per day
> 15 kg to 23 kg	>33 lbs to 51 lbs	45 mg twice daily	45 mg once per day
>23 kg to 40 kg	>51 lbs to 88 lbs	60 mg twice daily	60 mg once per day
>40 kg	>88 lbs	75 mg twice daily	75 mg once per day
Zanamivir			
Adults			

	10 mg (two 5-mg inhalations) twice daily	10 mg (two 5-mg inhalations) once daily
Children (≥7 years or older for treatment, ≥5 years for chemoprophylaxis)		
	10 mg (two 5-mg inhalations) twice daily	10 mg (two 5-mg inhalations) once daily

Because infants experience high rates of morbidity and mortality from influenza, infants with 2009 H1N1 influenza virus infections may benefit from treatment using oseltamivir.

Table 2. Dosing recommendations for antiviral treatment or chemoprophylaxis of children younger than 1 year using oseltamivir.

Age	Recommended treatment dose for 5 days	Recommended prophylaxis dose for 10 days
Younger than 3 months	12 mg twice daily	Not recommended unless situation judged critical due to limited data on use in this age group
3-5 months	20 mg twice daily	20 mg once daily
6-11 months	25 mg twice daily	25 mg once daily

H1N1 Vaccine

We have received about 3,400 doses of H1N1 flumist in the last few days and have been providing this to healthy children ages 2 to 24 years of age and caregivers of infants. We have also received about 2,000 doses of injectable H1N1 vaccine, which we distributed to pediatricians, asthma centers, pediatric specialists and ob docs and hospitals for staff. Obviously, this is a small amount of vaccine to distribute, so please be patient and we will continue to distribute vaccine to those providers who have signed an MOU with us as soon as we get the vaccine. Our goal is to distribute within 24 hours of receipt.

Below you will find some information that you might find useful in making your decisions about the vaccine.

Vaccine Pearls

1. The number of children who have died from swine flu has jumped sharply as the virus continues to spread widely around the United States, striking youngsters, teenagers, young adults and pregnant women unusually often, federal officials said Friday. The deaths of another 19 children and teenagers from the new H1N1 virus were reported in the past week around the country pushing to 76 the number of fatalities this year among those under 18. It was the largest number of pediatric deaths reported in a single week since the pandemic began in the spring.
2. ADJUVANTS . According to the CDC, **Neither** live, attenuated or inactivated influenza A (H1N1) 2009 monovalent vaccine formulations will contain adjuvants.
   http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm
3. Priority Groups:
   Below are the priority groups we will follow until vaccine availability increases (order of target groups does not indicate priority):
   - Pregnant women,
   - Persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers)
   - Health-care and emergency medical services personnel who have direct contact with patients or infectious material
   - Children aged 6 months--4 years
   - Children and adolescents aged 5--18 years who have medical conditions that put them at higher risk for influenza-related complications.

   As the vaccine supply increases we will move to the expanded priority groups
   - Pregnant women,
   - Persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers)

- Health-care and emergency medical services personnel
- Persons aged 6 months--24 years
- Persons aged 25--64 years who have medical conditions that put them at higher risk for influenza-related complications.

4. People born before 1957 may have some residual immunity, so they are at a reduced risk of acquiring the infection so you may want to target staff in this age group to receive it a bit later if you don't have enough vaccine to start with.
5. Providers cannot charge or bill for the 2009 H1N1 vaccine because the vaccine and ancillary supplies have been purchased by the federal government. However, providers can charge or bill for administration of the 2009 H1N1 vaccine to patients. The fee may not exceed the regional Medicare payment rate for seasonal influenza vaccine administration.
6. The currently established CPT code for 2009 H1N1 vaccine is 90663 (influenza virus vaccine, pandemic formulation, H1N1). This code may be reported in conjunction with the unique CPT code for H1N1 vaccine administration: 90470, H1N1 immunization administration (intramuscular, intranasal), including counseling when performed. Providers should follow instructions provided by the health plans with whom they contract related to billing for 2009 H1N1 vaccine administration.
7. The 2009 H1N1 vaccine and its administration are covered under the Part B preventive services benefit for all Medicare beneficiaries with Part B coverage. Medicare FFS will reimburse the administration of 2009 H1N1 influenza vaccine at the same rate that is paid for administration of seasonal influenza vaccine, for each dose administered. For Medicare FFS beneficiaries, co-insurance and deductible requirements are not applied to influenza vaccine administration, including 2009 H1N1.
8. CMS has established two new Healthcare Common Procedure Coding System (HCPCS) codes for 2009 H1N1 vaccine and vaccine administration: G9141- Influenza A (H1N1) immunization administration (includes the physician counseling the patient/family), and G9142- Influenza A (H1N1) vaccine, any route of administration. Providers may elect to submit the HCPCS code for the 2009 H1N1 vaccine along with the vaccine administration code. However, since Medicare FFS will not provide payment for the 2009 H1N1 vaccine itself, only the vaccine administration code is required for payment.
9. CMS recently issued guidance to States outlining existing Medicaid and CHIP authorities available to States for the administration of 2009 H1N1 vaccine. States should consult the guidance at the following link to address concerns that may arise regarding Medicaid and 2009 H1N1 vaccine administration: http://www.cms.hhs.gov/SMDL/SHO/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS1228935&intNumPerPage=10
10. For more information about vaccine financing visit: http://www.cdc.gov/H1N1flu/vaccination/statelocal/vaccine_financing.htm

Vaccine Manufacturers, Ages and Dosages:

CSL
Age group: 18 years and older

Dosage and Administration:
•A single 0.5 mL intramuscular injection

GSK
Age Group: 18 years and older

Dosage and Administration:
•A single 0.5-mL intramuscular injection

Novartis
Age group: 4 years and older

Dosage and Administration:
•Children 4 through 9 years of age: Two 0.5-mL intramuscular injections approximately 1 month apart
•Children 10 through 17 years of age: A single 0.5-mL intramuscular injection
•Adults 18 years of age and older: A single 0.5-mL intramuscular injection

Sanofi
Age group: age 6 months and older

Dosage and Administration:
Children
•6 through 35 months of age (0.25 mL dose, intramuscular injection):

- Previously unvaccinated children – should receive two 0.25 mL doses, one on day 1 followed by another 0.25 mL dose at least one month later.
- Previously vaccinated children should receive only one 0.25 mL dose.

•36 months through 8 years of age (0.5 mL dose, intramuscular injection):
- Previously unvaccinated children – should receive two 0.5 mL doses, one on day 1 followed by another 0.5 mL dose at least one month later.
- Previously vaccinated children should receive only one 0.5 mL dose.

•9 years of age and older
- A single 0.5 mL dose, intramuscular injection.

Adults
- A single 0.5 mL dose, intramuscular injection.

Model Declination for Staff:

Model H1N1 Influenza Vaccination Declination Form

I UNDERSTAND that due to my occupational exposure to blood or other potentially infectious materials I be at risk of acquiring the influenza virus. I have read the information about the H1N1 vaccine. I have had an opportunity to ask questions of a qualified medical professional and understand the benefits and risks of vaccination. I have been given the opportunity to be vaccinated, at no charge to myself. I, however, decline vaccination at this time. I understand that if I change my mind in the future and wish to be vaccinated, and if the vaccine is still available from my employee, I may receive it free of charge. I understand that by declining this vaccine, I continue to be at risk of acquiring a serious disease. I further understand that my duties during the current pandemic may be different than my normal duties due to extenuating public health circumstances. I understand that I may be working in situations where potential exposure to the virus may be unavoidable. I realize that I may still be reassigned as needed within the department regardless of my vaccination status. I understand my employer is simply offering the vaccine to me as a protective measure, but I respectfully decline.

_____ _____ _____

Printed Name Signature Date

Below you will find a triage chart that you might want to share with your patients to help them self-triage and we will also share with the public and place on our www.fightheflu.org website

Below you will also find “model” standing orders for H1N1

Deb McMahan, MD 403-3435

Protecting Yourself, Protecting Others

If you have flu symptoms, use the guidelines in this table to help make the best decision for you and your loved ones.

Box A: SITUATION FOR AN ADULT OR CHILD
The person does not have a fever (temperature less than 38°C or 100.4°F), but does have these symptoms:
> Sore throat > Stuffy nose
> Runny nose > Cough

DECISION
Probably a cold.
Rest is indicated.
Call your doctor or go to an urgent care center if you develop any of the symptoms in Box D

Box B: SITUATION FOR AN ADULT OR CHILD
The person has a fever over 38°C (100.4°F). The fever came on suddenly and is accompanied by these symptoms:
> Cough
> Sore throat > Significant fatigue
> Headache > Muscle aches

DECISION
Probably the flu.
Rest at home is indicated. Do not go to work or school until fever is gone for 24 hours off all medications or your own company's policy if more restrictive (Healthcare workers need to stay home 7 days after symptoms began, or 24 hours after resolution of acute symptoms, whichever is longer).
Monitor for worsening of symptoms listed in

Box C: SITUATION FOR AN ADULT OR CHILD AT RISK FOR COMPLICATIONS
The person has a fever over 38°C (100.4°F) and belongs to a group at risk of developing complications:

- Children under 5 years of age
- Adults 65 years and older
- Pregnant women
- Individuals with chronic diseases including:
  - Cancer
  - Blood disorders (including sickle cell disease)
  - Chronic lung disease [including asthma or COPD
  - Diabetes
  - Heart disease
  - Kidney disorders
  - Liver disorders
  - Neurological disorders (including nervous system, brain or spinal cord)
  - Neuromuscular disorders (including muscular dystrophy and multiple sclerosis)
  - Weakened immune systems (including people with AIDS)

DECISION
Call your doctor today or go to an Urgent Care Center

Box D: SITUATION FOR AN ADULT OR CHILD
The person has a fever and one of these symptoms:

- Shortness of breath
- Difficulty breathing
- Painful breathing
- Vomiting for more than four hours
- Fever in a child who is too quiet and less active than normally or who refuses to play or is agitated despite aggressive fever management
- Severe neck stiffness
- Drowsiness, confusion, disorientation, or difficulty being roused
- Convulsions
- No urination for 12 hours
- Fever in an infant under 3 months old (100.2F or greater)

DECISION
Go to the emergency room immediately.
Call 9-1-1, if necessary

Keep yourself informed: www.fightheflu.org and http://www.cdc.gov/h1n1flu/

MODEL
STANDING ORDER FOR ADMINISTERING H1N1 TIV VACCINE
October 2009

Priority Groups
Below are the priority groups we will follow until vaccine availability increases (order of target groups does not indicate priority):

- Pregnant women,
- Persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers)
- Health-care and emergency medical services personnel who have direct contact with patients or infectious material
- Children aged 6 months--4 years
- Children and adolescents aged 5--18 years who have medical conditions that put them at higher risk for influenza-related complications.

As the vaccine supply increases we will move to the expanded priority groups

- Pregnant women,
- Persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers)
- Health-care and emergency medical services personnel
- Persons aged 6 months--24 years
- Persons aged 25--64 years who have medical conditions that put them at higher risk for influenza-related complications.

Vaccine Manufacturers, Ages and Dosages:

CSL
Age group: 18 years and older

Dosage and Administration:
•A single 0.5 mL intramuscular injection

GSK

Age Group: 18 years and older

Dosage and Administration:
•A single 0.5-mL intramuscular injection

Novartis

Age group: 4 years and older

Dosage and Administration:
•Children 4 through 9 years of age: Two 0.5-mL intramuscular injections approximately 1 month apart
•Children 10 through 17 years of age: A single 0.5-mL intramuscular injection
•Adults 18 years of age and older: A single 0.5-mL intramuscular injection

Sanofi

Age group: age 6 months and older

Dosage and Administration:
Children
•6 through 35 months of age (0.25 mL dose, intramuscular injection):
- Previously unvaccinated children – should receive two 0.25 mL doses, one on day 1 followed by another 0.25 mL dose at least one month later.
- Previously vaccinated children should receive only one 0.25 mL dose.

•36 months through 8 years of age (0.5 mL dose, intramuscular injection):
- Previously unvaccinated children – should receive two 0.5 mL doses, one on day 1 followed by another 0.5 mL dose at least one month later.
- Previously vaccinated children should receive only one 0.5 mL dose.

•9 years of age and older

- A single 0.5 mL dose, intramuscular injection.

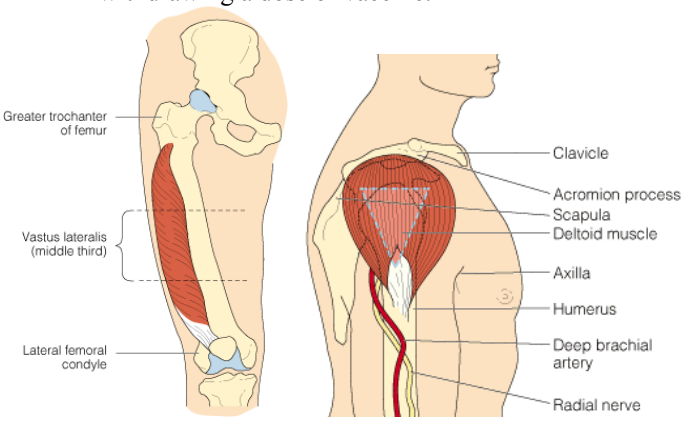
Adults
- A single 0.5 mL dose, intramuscular injection.

CONTRAINDICATIONS
Severe hypersensitivity to egg proteins or any component of the vaccine or life-threatening reactions after previous administration of any influenza vaccine.

WARNINGS
1. If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of previous influenza vaccination, the decision to give Fluzone should be based on careful consideration of the potential benefits and risks.
2. Immunocompromised persons may have a reduced immune response to Fluzone.

DRUG INTERACTIONS
- Do not mix with other vaccines in the same syringe or vial.
- Immunosuppressive therapies may reduce the immune response to Fluzone.

ORDER:
1. Determine if patient meets criteria listed above.
2. Screen all patients for contraindications and precautions to influenza vaccine including:
    a. Contraindications:
        - Hypersensitivity to eggs, egg proteins, gentamicin, gelatin or arginine or life threatening reactions to previous influenza vaccination.
    b. Precautions: moderate or severe acute illness with or without a fever
3. Provide patient, parent or legal representative with a copy of the most current Vaccine Information Statement (VIS)
4. Have patient complete the health history form and review responses. The inactivated vaccine should not be administered under the following conditions:
    a. History of an anaphylactic response to prior flu vaccine
    b. History of an anaphylactic response after ingesting eggs
5. If no contraindications exist, administer appropriate dose of injectable TIV IM (22-25g, 1-1 ½" needle) in the vastus lateralis for infants (or toddlers lacking adequate deltoid mass) or in the deltoid muscle for toddlers ad older children.. Shake the syringe and single-dose vials well before administering the vaccine and shake the multi-dose vial each time before withdrawing a dose of vaccine.



6. Document dose and lot number on Patient Consent Form
7. Counsel the patient and family regarding the following:
    a. Remind parents (and give reminder card) that all children ages 6 months to less than 9 years of age who receive influenza vaccine for the first time should be given 2 doses. The interval between doses is 4 weeks. Children who received only one dose in the first year of vaccination should receive two doses, rather than one, in their second year of vaccination.
8. Refer patients to Observation Area for 10 minutes to observe for an allergic reaction
9. Implement Epi-Pen standing orders for anaphylactic response.
10. All adverse reactions should be reported to the patient's primary care doctor and to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or www.vaers.org.

_____ _____
Date

Medical Director