Indiana State Department of Health

LONG TERM CARE NEWSLETTER

ISDH Long Term Care
Newsletter Issue # 09-32
November 2, 2009

In Today's Issue:

ISDH Staff Appointments

ISDH Long Term Care Survey Manager

The Indiana State Department of Health (ISDH) is pleased to announce the appointment of Brenda Buroker as Survey Manager for the Division of Long Term Care. Most recently, Brenda served as ISDH Long Term Care Survey Supervisor for Area 3 in northeast central Indiana. Brenda assumes her new responsibilities on November 2, 2009.

The Survey Manager oversees the survey process for nursing home and residential care facility surveys. As Survey Manager, Brenda will supervise the seven area supervisors and continue to strive toward consistency and integrity in the survey process. Brenda brings to the Survey Manager position over 15 years of experience as a surveyor and supervisor. Brenda's knowledge and understanding of the Long Term Care survey process and regulations made her an outstanding supervisor and an ideal candidate for Survey Manager.

Brenda graduated from Parkview School of Nursing and began her career as a Registered Nurse in 1979. Brenda went on to complete a Bachelors of Science in Nursing from Indiana Wesleyan in 1995. Prior to becoming a surveyor with the Indiana State Department of Health, in February 1994, Brenda worked in hospitals and home health agencies.

Brenda may be reached via email at bburoker@isdh.in.gov. She has not been assigned a new telephone number yet, but can still be reached at her former number - 317-233-7772.

Influenza Update

CDC Communication to Clinicians Regarding IV Peramivir

Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

October 25, 2009

Dear Colleague,

On Friday, October 23, 2009, the US Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the use of the investigational antiviral drug Peramivir intravenous (IV) in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection who are admitted to a hospital.

Specifically, Peramivir IV is authorized only for hospitalized adult and pediatric patients for whom therapy with an IV drug is clinically appropriate, based on one or more of the following reasons:

1. The patient is not responding to either oral or inhaled antiviral therapy, or

2. When drug delivery by a route other than an intravenous route -- e.g., enteral (absorbed by the intestines) or inhaled -- is not expected to be dependable or feasible;

3. For adults only, when the clinician judges IV therapy is appropriate due to other circumstances.

There are no FDA-approved intravenously administered antiviral drugs for the treatment of influenza. Peramivir is the only intravenously administered influenza treatment currently authorized for use under EUA for 2009 H1N1 infections.

Clinicians considering use of Peramivir IV under EUA must read and understand the content of the FDA-issued Emergency Use Authorization of Peramivir IV: Fact Sheet For Health Care Providers (www.cdc.gov/h1n1flu/eua)) prior to initiating a request and must agree to comply with terms and conditions of authorized use of Peramivir per the FDA-issued EUA. Clinicians who, after reading the Fact Sheet for Health Care Providers, wish to obtain Peramivir IV for a patient can download the request form (or access an electronic request portal) at http://www.cdc.gov/H1N1flu/EUA/peramivir_recommendations.htm.

Additionally, clinical studies of Peramivir IV in hospitalized patients are currently underway. Clinicians who wish to consider whether their patients would be appropriate for inclusion in those studies should refer to http://www.ClinicalTrials.gov for more information on these trials.

Clinicians and public health officials are reminded that two other neuraminidase inhibitor drugs i.e., oseltamivir (Tamiflu®) and Zanamivir (Relanza®) are available, and their use may be appropriate in some patients with 2009 H1N1 influenza infections. Conditions for use of these agents and additional guidance are available at http://www.cdc.gov/H1N1flu/recommendations.htm and http://www.cdc.gov/h1n1flu/eua/.

Additional information on 2009 Influenza H1N1 diagnosis and patient management is available at http://emergency.cdc.gov/h1n1antivirals or by calling 1-800-CDC-INFO (1-800-232-4636), 24 hours a day, 7 days a week. Updates are placed on the website and made available to callers whenever new information becomes available. We encourage you to access the website regularly. In addition, state and local health department officials may call 770-488-7100 (CDC Emergency Operations Center) and request assistance at any hour if the need is urgent.

Thank you in advance for your efforts to make clinicians in your state aware that Peramivir IV is available, and that it may be requested for use in their seriously ill patients under the conditions of the EUA. Please let us know if you have questions or require additional information.

Sincerely,

David M. Bell, MD
Captain, US Public Health Service
Task Force Lead, H1N1 Med Care and Countermeasures
CDC Emergency Operations Center

Recommendations for Early Empiric Antiviral Treatment in Persons with Suspected Influenza who are at Increased Risk of Developing Severe Disease

CDC Health Advisory
October 19, 2009

Summary Recommendations: When treatment of influenza is indicated in a patient with suspected

influenza, health care providers should initiate empiric antiviral treatment as soon as possible. Waiting for laboratory confirmation of influenza to begin treatment with antiviral drugs is not necessary. Patients with a negative rapid influenza diagnostic test should be considered for treatment if clinically indicated because a negative rapid influenza test result does not rule out influenza virus infection. The sensitivity of rapid influenza diagnostic tests for 2009 H1N1 virus can range from 10% to 70%, indicating that false negative results occur frequently.

Situation

The 2009 pandemic H1N1 influenza virus continues to be the dominant influenza virus in circulation in the U.S. The benefit of antiviral treatment is greatest when it is initiated as early as possible in the clinical course. Several recent reports have indicated two problems related to antiviral treatment: (1) some patients with suspected influenza who are at higher risk of developing severe complications, including hospitalized patients, were not treated at all with antiviral medications because of a negative rapid influenza diagnostic test result and (2) initiation of treatment was delayed for some patients with suspected influenza who are at higher risk of developing severe complications, including hospitalized patients, because clinicians were waiting for results of real-time reverse transcriptase-polymerase chain reaction (rRT-PCR) assay.

Who is prioritized for treatment with influenza antiviral drugs?

Most healthy persons (i.e., those without a condition which puts them at higher risk for complications) who develop an illness consistent with uncomplicated influenza do not need to be treated with antiviral medications and will recover without complications. However, clinical judgment should be the ultimate guide in making antiviral treatment decisions for ill persons who are not at higher risk for complications from influenza.

Early empiric treatment with oseltamivir or zanamivir is recommended for all persons with suspected or confirmed influenza requiring hospitalization. Prompt empiric outpatient antiviral therapy is also recommended for persons with suspected influenza who have symptoms of lower respiratory tract illness or clinical deterioration regardless of previous health or age.

Early empiric treatment should be considered for persons with suspected or confirmed influenza who are at higher risk for complications, even if not hospitalized, including:

- Children younger than 2 years old

- Adults 65 years and older

- Pregnant women

- Persons with the following conditions:

- Chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological (including sickle cell disease), or metabolic disorders (including diabetes mellitus);

- Disorders that that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders)

- Immunosuppression, including that caused by medications or by HIV;

- Persons younger than 19 years of age who are receiving long-term aspirin therapy, because of an increased risk for Reye syndrome.

When should health care providers start treatment with antiviral drugs?

Once the decision to administer antiviral treatment is made, oseltamivir or zanamivir should be initiated as soon as possible. Evidence for benefit from antiviral treatment in studies of seasonal influenza is strongest when treatment is started within 48 hours of illness onset. However, some studies of oseltamivir treatment of hospitalized patients with seasonal influenza have indicated benefit, including reductions in mortality or duration of hospitalization, even for patients whose treatment was started more than 48 hours after illness onset.

When treatment is indicated, health care providers should not wait for laboratory confirmation of influenza to begin oseltamivir or zanamivir treatment of patients with suspected 2009 pandemic H1N1 influenza virus infection. Patients with a negative rapid influenza diagnostic test should be considered for treatment if clinically indicated because a negative result does not rule out influenza virus infection. The sensitivity of rapid influenza diagnostic tests to detect 2009 H1N1 virus in respiratory specimens ranges from 10% to 70%, and therefore false negative results occur frequently. Similarly, false negative results can also occur with immunoflorescence assays.

What actions should health care providers take when waiting for influenza test results?

Health care providers should empirically treat persons with suspected influenza illness who are at increased risk for complications if clinically indicated while influenza test results are pending. Antiviral treatment is most effective when administered as early as possible in the course of illness. The rRT-PCR tests are the most sensitive and specific influenza diagnostic tests, but they may not be readily available, obtaining test results may take one to several days, and test performance depends on the individual rRT-PCR assay. Antiviral treatment should not be delayed until rRT-PCR test results are available.

For More Information

Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season: http://www.cdc.gov/H1N1flu/recommendations.htm

Interim Recommendations for Clinical Use of Influenza Diagnostic Tests During the 2009-10 Influenza Season: http://www.cdc.gov/h1n1flu/guidance/diagnostic_tests.htm

Questions & Answers:

Antiviral Drugs, 2009-2010 Flu Season: http://www.cdc.gov/h1n1flu/antiviral.htm

Influenza Diagnostic Testing: http://www.cdc.gov/h1n1flu/diagnostic_testing_clinicians_qa.htm

Updated Interim Recommendations for Obstetric Health Care Providers Related to Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season: http://www.cdc.gov/H1N1flu/pregnancy/antiviral_messages.htm

Antiviral Drugs: Summary of Side Effects: http://www.cdc.gov/flu/protect/antiviral/sideeffects.htm

General information for the public on antiviral drugs is available in '2009 H1N1 and Seasonal Flu: What You Should Know About Flu Antiviral Drugs' at http://www.cdc.gov/H1N1flu/antivirals/geninfo.htm .

Downloadable brochures and informational flyers, including one on antiviral drugs, are available at http://www.cdc.gov/h1n1flu/flyers.htm .

For the FDA page on antiviral influenza drugs:

http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm

For additional information, you can also call CDC's toll-free hotline, 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, which is available 24 hours a day, every day.

Recalls

Accusure Insulin Syringes (Qualitest Pharmaceuticals) - Recall

Audience: Diabetes healthcare professionals and patients

[Posted 10/27/2009] Qualitest Pharmaceuticals and FDA notified healthcare professionals of a nationwide recall of Accusure Insulin Syringes. All syringes, regardless of lot number, are subject to this recall. These syringes were distributed between January 2002 and October 2009 to wholesale and retail pharmacies nationwide (including Puerto Rico). The syringes in these lots may have needles which detach from the syringe. If the needle becomes detached from the syringe during use, it can become

stuck in the insulin vial, push back into to the syringe, or remain in the skin after injection. Consumers who have any Accusure insulin syringes should stop using them and contact Qualitest at 1-800-444-4011 for reimbursement.

Relenza (zanamivir) Inhalation Powder

Audience: Infectious disease healthcare professionals, risk managers

[Posted 10/09/2009] GlaxoSmithKline (GSK) and FDA notified healthcare professionals of a report of the death of a patient with influenza who received Relenza (zanamivir) Inhalation Powder which was solubilized and administered by mechanical ventilation. Relenza (zanamivir) Inhalation Powder is not intended to be reconstituted in any liquid formulation and is not recommended for use in any nebulizer or mechanical ventilator.

GSK is aware that Relenza Inhalation Powder is being removed from its FDA-approved packaging and dissolved in various solutions for the purpose of nebulizing zanamivir for inhalation by patients with influenza who are unable to take oral medications or unable to inhale Relenza Inhalation Powder using the Diskhaler. Relenza or zanamivir for nebulization have not been approved by the FDA. The safety, effectiveness, and stability of zanamivir use by nebulization have not been established.

Relenza Inhalation Powder should only be used as directed in the prescribing information by using the Diskhaler device provided with the drug product. Relenza Inhalation Powder is a mixture of zanamivir active drug substance and lactose drug carrier. This formulation is not designed or intended to be administered by nebulization. There is a risk that the lactose sugar in this formulation can obstruct proper functioning of mechanical ventilator equipment.

Medical Device Power Cords Safety Investigation: Initial Communication

Audience: Healthcare professionals, patients/caregivers

[Posted 10/19/2009] FDA is investigating whether certain types of power cords used with medical devices may be defective. Two medical device manufacturers (Hospira, Inc. and Abbott Nutrition) have sent FDA 122 reports of sparking, charring, and fires from the power cords used with their devices. The companies' investigations of these reports determined that the power cord's prongs may crack and fail at/or inside the plug. The potential risks from this power cord failure include electrical shock, delay in setup and therapy, interruption of therapy, device failure, and fires. Depending on the device and therapy, these failures may potentially lead to serious adverse health consequences, including death.

All the reports received so far from Hospira and Abbott have involved AC power cords with a black plastic bridge manufactured by the Electri-cord Manufacturing Company. FDA is aware that Electri-cord has supplied the affected power cords to other medical device manufacturers.The agency is now attempting to determine which devices may be equipped with these cords.

FDA recommends that all users of medical devices, either in healthcare facilities or in the home, closely monitor the wear and tear on the electric cords used to power these devices. T his vigilance is especially important in oxygen rich environments, in which electrical sparking and arcing may trigger a fire.

National Alzheimer's Disease Awareness Month

According to the Alzheimer's Association *2009 Alzheimer's Disease Facts and Figures* report, there are more than 5 million Americans living with Alzheimer's and as many as 10 million family caregivers. This November, during National Alzheimer's Disease Awareness Month and National Family Caregivers Month, the Alzheimer's Association is providing insight and support to those caring for someone with Alzheimer's with two new resources: *Alzheimer's Association Caregiver Notebook* and Alzheimer's Association Comfort Zone™.

The Indiana Coalition of Alzheimer's Association Chapters have developed a database of individuals who help give a voice to those suffering from the devastation of Alzheimer's disease. This group, called *The ALERT Network*, helps focus on the needs of families living with Alzheimer's disease.

Have a good week.

Terry Whitson
Assistant Commissioner
Indiana State Department of Health

Indiana State Department of Health

Visit the ISDH home page at http://www.in.gov/isdh/ for the latest public health information.

Visit the ISDH Division of Long Term Care home page at http://www.in.gov/isdh/23260.htm for information on long term care.