TENNESSEE DEPARTMENT OF HEALTH

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COMMUNICABLE AND ENVIRONMENTAL DISEASE SERVICES

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2004-2005 INFLUENZA SEASON VACCINE SHORTAGE

On October 5, 2004, the British equivalent of the Food and Drug Administration (FDA) suspended the license of the Liverpool influenza vaccine manufacturing plant owned by the Chiron Corporation, resulting in the loss of 48 million doses of influenza vaccine bound for the U.S. market. Instead of the expected 100 million doses, ultimately, there will be at least 61million doses of influenza vaccine available for Americans, including 58 million doses of trivalent inactivated vaccine from Aventis Pasteur and 3 million doses of FluMist, MedImmune's live-attenuated nasal-spray vaccine. The FDA has approved the importation of 1.2 million doses of vaccine from Europe under an Investigational New Drug (IND) protocol.

In response to the shortage, the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) issued emergency changes in the groups recommended for influenza vaccination this season; these focused on protecting those at highest risk of morbidity and mortality. Although there remains tremendous unmet need for influenza vaccination among the highest priority groups, for a number of reasons, the demand for vaccine among these groups has declined. In order to ensure that no available vaccine is wasted, on December 21, the Department of Health expanded these original high priority groups to include all persons aged 50-64 and close contacts of high priority patients. The expanded indications also apply to children through the age of 18 eligible for the Vaccines for Children program. Where vaccine is available, it may be used for anyone in these expanded priority groups. We do not expect any further expansion of eligibility for influenza vaccine this season. The availability of vaccine varies widely across the state, with many county health departments out of vaccine; expanded eligibility does not

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ADULT PNEUMOCOCCAL VACCINATION

Invasive pneumococcal disease is a leading cause of serious illness in older adults and can complicate the course of influenza infection. Pneumococcal vaccination is recommended for all adults aged 65 years and over, those with serious long-term health problems, a weakened immune system, and for members of Alaskan Native or certain Native American populations which have high rates of invasive disease.

Despite this recommendation, , only 54% of people aged 65 years and over had been vaccinated for invasive pneumococcal disease as of 2002(see reference). Rates are even lower among younger adults with chronic illnesses who should be vaccinated. People over 65 years of age require only one injection for lifetime protection. If a person is vaccinated at less than 65 years of age, they should get one booster 5 years later for lifetime protection.

Because some chronically ill patients and those 65 or over will be unable to obtain influenza vaccinations this season, this is an excellent opportunity to educate them about the value of pneumococcal vaccination.

While pneumococcal vaccination cannot prevent influenza, overall it is 60-70% effective at preventing invasive pneumococcal disease – a common bacterial complication of influenza. There is no shortage of pneumococcal vaccine this year.

Reference:

Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson A, Hamborsky J, Wolfe S, eds. 8th ed. Washington DC: Public Health Foundation, 2004;233-245.

2004-2005 INFLUENZA FLU VACCINE SHORTAGE (CONTINUED)

(Continued from page 1)

mean that these persons will necessarily find vaccine available to them this season.

In order to make vaccine available to those in the high priority groups, the CDC and Aventis Pasteur began redistributing the 24 million doses of influenza vaccine remaining in warehouses to high priority customers, such as the federal Vaccines for Children (VFC) program, the VA hospital system, health departments, hospitals, long-term care facilities, and pediatricians that ordered vaccine from Aventis. In order to reach private sector facilities that ordered from Chiron, the CDC apportioned 7.2 million doses of vaccine to state health departments to direct distribution within their states through January 2005.

Tennessee's apportionment was 98,000 adult doses; of these, 35,600 will be available in January 2005. In November, the Tennessee Department of Health identified three priority groups for distribution of the state-controlled vaccine. The first priority group included residents and staff of long-term care facilities. The second was patient care staff of hospitals, while the remaining vaccine was to be made available to other high priority groups through county health department clinics.

Private physicians were offered the opportunity to purchase the 35,600 doses of vaccine available for shipment in January. As of Tuesday, December 28, the Department of Health had filled as many orders as possible and had ceased taking new orders for January vaccine. Pre-filled syringes for children between the ages of 6 and 35 months remain available through January 15, 2005.

Interest in stretching the vaccine supply through intradermal injection was stimulated because of the shortage and has been reinforced by preliminary research showing good response to this technique in healthy adults. Despite these initial promising findings, this strategy is not recommended at this time. Additional studies will be needed to confirm these results, particularly in high-risk populations.

Vaccination is worthwhile for high priority patients at any point in the influenza season; however, public demand typically drops off sharply after Thanksgiving. The influenza season usually does not peak until late January or February in Tennessee, and there had been just two culture-confirmed influenza A and one influenza B isolate reported as of December 22, 2004. Because vaccine will continue to arrive in the state through January, health care providers should continue to encourage high priority patients to be vaccinated whenever vaccine is available.

References:
Treanor, J. Weathering the influenza crisis. N Engl J Med 2004; 351: 2037-2040

Belshe RB, Newman FK, Cannon J, et al. Serum antibody responses after intradermal vaccination against influenza. N Engl J Med 2004;351(22)2286-94.

Kenney RT, Frech SA, Muenz LR, et al. Dose sparing with intradermal injection of influenza vaccine. N Engl J Med 2004;351 (22):2295-301.

RESPIRATORY ETIQUETTE: COVER YOUR COUGH!

The influenza vaccine shortage offers a new opportunity to educate the public about alternative measures to prevent the spread of respiratory viruses this winter. Alternative protective measures can be divided into those appropriate for the general public and those for health care facilities.

Five measures are recommended to the public for protecting oneself and others from respiratory viruses:

- Practice proper hand hygiene, by washing hands often. Alcohol-based hand sanitizers also are effective.
- Avoid touching your face and eyes with your hands.
- Avoid close contact with people who are sick – caregivers of the sick should wash their hands often. When possible, those at high risk of complications from influenza should not be the primary caregivers for the sick.
- Cover coughs and sneezes with a tissue or sleeve, and wash hands afterwards.
- If ill, stay home from work or school until you are well.

Respiratory etiquette strategies in health care facilities focus on keeping vulnerable patients away from those with respiratory infections. Effective steps include:

- Make tissues and hand hygiene products readily accessible to visitors. Influenza is primarily spread by large respiratory droplets expelled when sneezing, coughing or through contact with these secretions deposited on surfaces.
- Patients coming to hospitals and doctors' offices with coughs and other respiratory symptoms should be offered masks or seated more than three feet from others. Masks should be worn by these patients until: (1) it is determined that they do not have an infectious disease requiring droplet or airborne isolation; or (2) they have been isolated in a private room or cohorted with other patients with the same illness.
- Once admitted, standard and droplet precautions should be observed for patients with symptoms of respiratory infection until a communicable cause has been ruled out. Standard precautions include proper hand hygiene and wearing a gown and gloves if in contact with body fluids. Droplet precautions also require health care personnel to wear a surgical mask if they are working within three feet of the patient to prevent the deposition of respiratory droplets onto mucous membranes. Such patients should wear a surgical mask, if tolerated, when transported outside their rooms.
- Patients with respiratory infections should be cohorted together or placed in a private room.

Educational posters suitable for offices and hospitals are available from the CDC at www.cdc.gov/flu/professionals/patiented.htm and from the Tennessee Department of Health at www2.state.tn.us/health/FactSheets/etiquette.htm.

VACCINE STORAGE

In recent weeks, several clinics in Tennessee have recognized that vaccines in their clinics were stored at incorrect temperatures for months or years, resulting in the destruction of vaccine and the need to identify and recall patients that received spoiled vaccine for revaccination. Only consistent, proper vaccine storage and monitoring practices can ensure that problems requiring revaccination do not occur. The proper freezer storage temperature for varicella and FluMist is ≤5˚F (minus 15˚C); other vaccines should be stored at refrigerator temperatures maintained between 35-46˚F (2-8˚C).

If you store and use any type of vaccine in your facility, please take a moment to review your storage and handling policies, as well as recent temperature logs. To help identify potential problems, the Immunization Action Coalition (www.immunize.org) has put together a list of common errors in vaccine storage and handling (Table 1).

Corrective action should always be taken at the time that the temperature is noted to be out of the normal range. The thermostat should be adjusted and re-checked to ensure that the temperature returns to the proper range. Vaccine may be removed to another refrigerator or freezer at the proper temperature while the problem refrigerator or freezer is adjusted or repaired.

If your review of the vaccine temperature logs reveals more than one measurement out of range without documented corrective action, the manufacturers of each type of vaccine stored in the unit at that time should be contacted for recommendations about the viability of their vaccine.

Following manufacturers' recommendations about vaccine viability, any spoiled vaccine should be removed from the refrigerator immediately to prevent its use. Patients who received spoiled vaccine should be identified and contacted about the need for revaccination. Antibody titers are not recommended as a substitute for, or prerequisite of, revaccination because they are difficult to interpret, costly, and certain assays are not available outside research settings.

If additional information or assistance is needed concerning vaccine storage problems, please contact the Tennessee Immunization Program at 615-741-7247.

Reference:
Immunization Action Coalition. Don't Be Guilty of These Errors in Vaccine Storage and Handling. http://www.immunize.org/catg.d/p3036.htm. Last accessed December 12, 2004.

Table 1. Common Errors in Vaccine Storage and Handling

Common Errors:

- Training only one person in the office to be responsible for vaccine storage and handling instead of at least two, so that a knowledgeable person is always there.
- Recording storage temperatures only once per day instead of at the beginning and end of the day. Invest in a high quality, accurate thermometer.
- Recording temperatures for only the refrigerator or freezer, instead of both.
- Documenting out of range temperatures on vaccine temperature logs and not taking action. Immediately correct out of range temperatures; move vaccine to another refrigerator if necessary, while problems are assessed and corrected. You may need to contact vaccine manufacturers to determine if vaccine is still viable.
- Throwing away temperature logs at the end of the month. Keep these logs on file for at least three years.
- Storing vaccine in the refrigerator in a way that can inappropriately affect its temperature. Do not over pack a refrigerator, or store vaccine in the door, vegetable bins, or near the cold air outlet from the freezer.
- Storing frozen vaccine in a dormitory-style freezer compartment. Frozen varicella and live-attenuated influenza vaccine must be kept at ≤5˚F – a temperature that only can be maintained in a separate freezer compartment with its own door.
- Inadvertently leaving the freezer or refrigerator door open or poorly sealed.
- Discarding multi-dose vials 30 days after they are opened. While multi-dose vials of reconstituted vaccine must be used or discarded within a specified time period after reconstitution, most multi-dose vials are good until the expiration date.
- Not having an emergency plan for a power outage. Every clinic should have a back-up plan for storing vaccine in a refrigerator with a generator or in another facility in case of power outage or natural disaster.
- Storing food and drinks in the vaccine refrigerator. Frequent opening and closing of the refrigerator door can adversely affect the refrigerator temperature.

ANTI-VIRAL MEDICATIONS

The influenza vaccine shortage has forced clinicians to plan for alternative protective measures for high-risk patients who could not obtain influenza vaccine this season. In addition to respiratory etiquette and avoiding exposure to the virus, antiviral medications are available for treatment and prophylaxis of influenza illness, and are particularly important among those at high risk of complications of influenza. Three antivirals, amantadine, rimantadine, and oseltamivir have been approved for chemoprophylaxis; these antivirals plus zanamivir (administered by nebulizer and in limited supply; not discussed here) are approved for treatment of influenza. Any of these medications, when begun in the first two days of illness, can reduce the duration of illness by one to two days.

The adamantanes (amantadine, rimantadine), and oseltamivir have different advantages in terms of cost, efficacy, and side effect profile. The adamantanes are the least expensive and most plentiful antivirals. The Centers for Disease Control and Prevention (CDC) is building a stockpile of rimantadine to respond to institutional outbreaks of influenza this season, if commercial supplies run low. There are three drawbacks to this class of antiviral: 1) they are only active against influenza A, 2)central nervous system and gastrointestinal side effects are common (more so with amantadine), and 3) resistant strains of influenza develop in up to one-third of patients taking an adamantane to treat influenza. Unlike the adamantanes, oseltamivir is active against both influenza A and B, and resistance is uncommon. Oseltamivir is much more expensive and supply is limited because it takes months to manufacture each batch in a factory in Switzerland. In addition, it is the only antiviral proven to be effective against the H5N1 "avian" influenza strain with pandemic potential. For this reason, the CDC does not plan to release the national stockpile for annual influenza needs.

The CDC has put forth guidelines for the use of antivirals this season. The use of amantadine or rimantadine is encouraged for chemoprophylaxis and the use of oseltamivir or zanamivir for treatment. Local supplies of these medications will vary; people at high risk of serious complications from influenza should be given priority for treatment. Treatment should be offered to anyone with potentially life-threatening influenza illness and to those within two days of illness and at high risk for complications. Rather than waiting for illness, individuals at high risk for complications may be given chemoprophylaxis for seven days following close exposure to someone with influenza, such as a household contact.

In the event of an institutional outbreak taking place in a nursing home or hospital, vaccination and chemoprophylaxis are important components of infection control. Any unvaccinated patient care staff should be vaccinated, where possible, and given 2 weeks of chemoprophylaxis until the vaccine takes effect if they are caring for influenza patients. If vaccine is not available, those working with high risk patients should receive chemoprophylaxis during the outbreak. Both vaccinated and unvaccinated residents of the institution should receive chemoprophylaxis for the duration of the outbreak. Cohorting of patients with confirmed or suspected influenza, respiratory etiquette practices, as well as appropriate standard and droplet precautions should be implemented immediately. Contact your local health department or the Communicable and Environmental Disease Services section at the Tennessee Department of Health at 615-741-7247 for assistance or further questions about institutional outbreak management.

For additional updated information on antivirals, visit the CDC influenza website for health care professionals: www.cdc.gov/flu/professionals/treatment/index.htm. Information on antivirals also is available in Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP) (MMWR 28 May 2004;53[RR06]:1-40).

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RETURN SERVICE REQUESTED