disease prevention news

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Cochlear Implants and Meningitis

The Food and Drug Administration (FDA) has received reports of cases of people who have cochlear implants contracting bacterial meningitis. In response to this public health concern, the FDA is working with the Centers for Disease Control and Prevention (CDC) and state health departments to investigate the association between cochlear implants and meningitis. This report describes the results of anFDA survey of cochlear implant vendors, the risk factors for meningitis associated with these implants, and the recommendations for reducing this risk.

According to an FDA survey of cochlear implant vendors, as of November 2001, an estimated 70,000 people worldwide have received implants; approximately 21,000 are people in the US. Over a 14-year period, 52 cases of meningitis in cochlear implant recipients have been identified worldwide; 24 cases have been in North America. The 52 cases have occurred in children and adults ranging in age from 21 months to 72 years; 12 died from sequelae. The time period for developing symptoms and signs of meningitis ranged from within 24 hours of implantation to 5 years post-implantation. Cerebrospinal fluid results are available from 14 cases: *Streptococcus pneumoniae* was the most common pathogen, but *Hemophilus influenza, Escherichia coli, Streptococcus viridans* and *enterococcus* species have also been cultured.

To determine risk factors for meningitis associated with cochlear implants, CDC is planning a case-control study in collaboration with the FDA and state health departments. The target population is children younger than 6 years of age who have received cochlear implants. Information regarding the type of implant, medical and surgical history, age, gender, race, and ethnicity will be collected from study participants and analyzed for risk factors.

Potential risk factors are many. Congenital deafness may increase baseline risk even prior to implantation, and deafness secondary to meningitis may increase recurrence risk. Prior otitis media or immunodeficiency may also be predisposing factors. Additionally, each of the three US manufacturers of cochlear implants have different implant designs, and it is possible that certain design features increase risk for meningitis. Two implant surgeons, Drs. Noel Cohen and Thomas Balkany, surveyed the North American cases: 9 cases were in patients with the Advanced Bionics Corporation CLARION device, 15 were in patients with the Cochlear Nucleus Corporation device, and none were among patients with the MED-EL Corporation device.

Removal of cochlear implants is not recommended at this time. Vaccination against *Streptococcus pneumoniae* and *Hemophilus influenza* may offer protective benefit for cochlear implant candidates and recipients. However, 3 of the meningitis cases developed despite vaccination. At least one of the cochlear implant manufacturers is offering to reimburse for vaccination.

The Advisory Committee on Immunization Practices (ACIP) recommends the following schedule for vaccines against *Streptococcus pneumoniae* and *H. influenza*:

Vaccination against *H. influenza*

- **All children < 5 years old:** *H. influenzae* conjugate vaccine series is recommended

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Vaccination against *S. pneumoniae*

- **All children < 2 years old:** Heptavalent pneumococcal conjugate vaccine (Prevnar®) series is recommended
- **Children 2 to 4 years old at high risk for invasive disease:** Both vaccines are recommended—the heptavalent pneumococcal conjugate vaccine (Prevnar®) series followed by a 23-valent pneumococcal polysaccharide vaccine 6-8 weeks later.*
- **Children 5 years old through adults at high risk for invasive disease:** A 23-valent pneumococcal polysaccharide vaccine is recommended.

Prepared by Swati Avashia, MD, TDH Infectious Disease Epidemiology and Surveillance division.

Please report ALL Texas cases of meningitis in cochlear implant recipients to Dr. Swati Avashia at Texas Department of Health: phone (512) 458-7676 or e-mail swati.avashia@tdh.state.tx.us

** For a detailed immunization schedule refer to the American Academy of Pediatrics (AAP) policy statement on recommendations for the prevention of pneumococcal infections in Pediatrics (106) 2:362-366, August 2000 or on the AAP website* www.aap.org/policy/re9960.html.

Visit the following FDA website for updated information about meningitis infections associted with cochlear implants: www.fda.gov/cdrh/safety/cochlear.html.

Lupus, a Leading Cause of Morbidity in Women

The Lupus Foundation of America (LFA) estimates that at least 1.4 million Americans have a form of lupus, a potentially life-threatening disease that causes the immune system to attack the body's own cells. The Health Resources and Services Administration (HRSA) of the Department of Health and Human Services issued a report, "Women's Health USA 2002," that lists lupus as a leading cause of morbidity among women. Nine of ten cases of lupus are among women, with the highest prevalence among women of color. A recent Centers for Disease Control and Prevention (CDC) study showed a 60% increase in deaths over a 20-year period resulting from systemic lupus erythematosus (SLE). Women were found to be 5 times more likely to die from complications of lupus than were men.

The most common symptoms of lupus are joint swelling, joint and muscle pains, extreme fatigue, fevers, and skin rashes on the face, neck, and scalp. Other symptoms can include sensitivity to sunlight, hair loss, fingers turning white or blue in the cold, and mouth or nose ulcers. Symptoms and signs that can indicate that vital organs are affected include pleurisy, excessive protein in the urine, and seizures.

Most people with lupus will experience only a few of these symptoms, which can range from mild to severe. Lupus also can go into periods when symptoms are absent or less noticeable, making lupus difficult to detect.

Early diagnosis and treatment of lupus is the key to preventing or minimizing damage to vital organs. However, this is not easily accomplished because public recognition and understanding of lupus remains low, the symptoms are non-specifice, and there is no single diagnostic test. Survey participants reported having had symptoms for 4 or more years and having visited 3 or more physicians before being diagnosed with lupus.

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TDH to Pilot Test the Pharmacy Inventory Control System

Starting in November 2002, the Texas Department of Health (TDH) Public Health Region (PHR) 6/5S headquarters (Houston) will conduct a pilot test of the Pharmacy Inventory Control System (PICS), a newly developed Internet-based system that replaces one which has been in operation for 20 years.

Whereas the current inventory system has been accessible only by TDH employees, PICS will be available to any health care provider in Texas who receives drugs or vaccines from or managed by TDH. Users will thus include health professionals in local, regional, and state health departments; hospitals; and private practice.

Compared with the current inventory system, PICS provides many user benefits: workload reduction , job quality improvements, management tool improvements, and potential cost savings. Specifically, PICS will offer automatic preparation of vaccine inventory (C-33) and shots administered reports (C-5), data sharing between systems, near-real-time visibility of all inventories, and availability of drug usage data.

To maximize potential benefits, the TDH Central Office and PHR headquarters, local health departments, and private providers will need to update information on drug and vaccine usage. TDH and local health departments will support PICS with training assistance, control access, and help spread PICS usage within their areas. The higher the usage of PICS, the lower the need for paper reports, faxes, and telephone calls. Duplicate data keyed into into automated systems also will be minimized.

PICS design is based on information gathered from 200 public and private health care providers and staff (from all 11 PHRs) during a 2000 feasibility study and 2001 requirements analysis effort.

The PICS joint development team, composed of staff from the TDH Pharmacy and from Northrop Grumman Information Technology, visited the Houston PHR 6/5S office in August 2002 to coordinate the PICS pilot test. Training of staff who will participate in the pilot test will occur in early November.

During the pilot test, health care providers in the field will test PICS core functionality and its training materials, which are based on the concept of the train-the-trainers approach. Staff in PHR 6/5S and 2 local health departments (Galveston County and the City of Beaumont) will learn to be PICS trainers during pilot test training by the PICS team. The staff in training will include program managers and subject matter experts (SMEs) who are specialists in public health programs that focus on immunization, tuberculosis elimination, sexually transmitted disease prevention, and women's health. The PICS Team will also train TDH managers in the Refugee Screening, Hansen's Disease, and Neural Tube Defects Recurrence Prevention programs. These trainers will then teach others how to provide instruction in the fundamentals of PICS and how to train new instructors.

Once the pilot test is completed, appropriate revisions will be made. January 2003 is the starting date for general implementation of PICS throughout Texas. The ultimate goal for PICS is to provide near real time visibility of all drugs and vaccines in the system. In terms of readiness for potential acts of bioterrorism, this capability is essential.

For further information about PICS, contact Gene Trautmann, MS/CS, TDH PICS Project Manager, by phone at 512/536-7860 or 512/458-7677, *or by e-mail at* gene.traumann@tdh.state.tx.us.

Disease Prevention News (DPN)
Texas Department of Health
1100 West 49th Street
Austin, TX 78756-3199
Phone: (512) 458-7677
Fax: (512) 458-7340
E-mail: dpn@tdh.state.tx.us

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Diagnosis of lupus is made after a careful review of a person's entire medical history, coupled with an analysis of the results of routine laboratory tests and specialized tests related to immune status. Although there is no cure for lupus at this time, medications are available to treat most patients symptoms if the disease is diagnosed early.

For further information, including the complete reports excerpted in this article, visit the LFA Web site: www.lupus.org.

October is National Lupus Awareness Month

Reminder: Print subscriptions for *Disease Prevention News* (DPN) will be discontinued at the end of this renewal period, December 31, 2002. The last printed issue will be the one dated December 9, 2002 (Vol 62, No. 26). See *DPN* Vol. 62, No. 20 for further details. Print subscribers are advised to sign up for one of the *DPN* electronic subscription services, available online at www.tdh.state.tx.us/phpep, as soon as possible to ensure continuation of subscriptions without a lapse. Please send any questions or comments to *DPN* staff at dpn@tdh.state.tx.us or

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