Los Angeles County Department of Health Services
Acute Communicable Disease Control Unit

Public Health Alert:

Bacterial Meningitis Associated With Cochlear Implants

September 4, 2002

Please Share this Alert with All ENT, Pediatric, Internal Medicine, Family Medicine, Emergency Medicine, and Infectious Disease Staff in Your Hospital

The Problem

The Federal Drug Administration (FDA) has become aware of a possible association between cochlear implants and the occurrence of bacterial meningitis. Over a period of 14 years, 52 cases of meningitis have been reported worldwide to Advanced Bionics Corporation and Cochlear Corporation. These have occurred in children and adults ranging in age from 21 months to 72 years who have undergone cochlear implantation for severe to profound deafness. Most of the patients have been children, predominantly under the age of 5, but some adults with cochlear implants have also developed meningitis. The onset of meningitis symptoms ranged from less than 24 hours to greater than 5 years from time of implant. A total of 12 known deaths have resulted from these cases.

Cerebrospinal fluid culture results in 14 cases showed that most cases have been caused by *Streptococcus pneumoniae* (pneumococcus), however, other organisms -- including *Haemopohilus influenza*, enterococcus, *E. coli*, and *S. viridans* -- have been cultured. The vaccination history was available in 6 cases and showed that none had been vaccinated against Pneumococcus.

Suspect Cause

The cochlear implant, because it is a foreign body, may act as a nidus for infection when patients have bacterial illnesses. The Advanced Bionics CLARION device differs from other currently marketed cochlear implants because it uses an additional piece (i.e., a positioner), which is introduced next to the electrode into the cochlea (inner ear) to facilitate transmission of sound information to the auditory nerve. During an ad hoc meeting in Amsterdam on July 5, 2002, a group of European physicians concluded that there were more cases of meningitis with the CLARION device than with other cochlear implants and that this difference may be attributable to the use of the positioner. The organizers of this meeting recommended that use of the positioner be discontinued, and the regulatory authorities of several European countries (e.g., France, Germany, and Spain) have accepted these recommendations. Consequently, Advanced Bionics has agreed to discontinue use of the positioner in these countries and will be marketing one of their current electrode systems (HiFocus) without the positioner. The company has also initiated a voluntary recall of any unimplanted CLARION devices in the United States and has announced that it will be seeking FDA approval for the HiFocus electrode without the positioner.

Risk Factors

Some deaf patients may have congenital abnormalities of the cochlea, which predispose them

to meningitis even prior to implantation. Patients who become deaf as a result of meningitis are also at increased risk of subsequent episodes of meningitis compared to the general population. Other predisposing factors may include young age (< 5 years), otitis media, immunodeficiency, or surgical technique.

What can you do?……VACCINATE

Cochlear implant candidates, as well as those already implanted, may benefit from vaccinations against organisms that commonly cause bacterial meningitis, particularly *Streptococcus pneumoniae* and *Haemophilus influenzae*. For additional information regarding immunizations contact the Immunization Program at the Los Angeles County Department of Health Services (LAC DHS). They may be reached at 213-351-7800 or http://lapublichealth.org/ip/index.htm.

- Ascertain immunization status of all candidates for cochlear implants prior to surgery as well as for those with an existing implant. At least one cochlear implant manufacturer provides reimbursement for vaccination.
- *Haemophilus influenzae* conjugate vaccines are recommended by the Advisory Committee on Immunization Practices (ACIP) for all children up to age 5 years.
- Heptavalent pneumococcal conjugate vaccine (Prevnar®) is indicated for use in infants and toddlers, and is recommended by the ACIP for all children less than age 2 years, and for children up to age 5 years who are at high risk of invasive pneumococcal infections.
- The 23-valent pneumococcal polysaccharide vaccines (Pnu-Imune®23 and Pneumovax®23) are recommended for children over age 2 years, adolescents, and adults who are at high risk of invasive pneumococcal disease.
- For children age 2 to 5 years who are at high risk of invasive pneumococcal infections, ACIP recommends use of pneumococcal conjugate vaccine followed at least 2 months later by 23-valent pneumococcal polysaccharide vaccine, in order to provide protection against a broader range of serotypes, although supporting data are limited. See individual product labeling for information on dosage and scheduling of the vaccines.

Reporting cases

- All healthcare professionals are required by State law to report bacterial meningitis (Section 2500 California Code of Regulation) to the health department. Use the Confidential Morbidity Report (CMR) form to report cases of bacterial meningitis. CMR forms may be obtained from the LAC DHS website at http://lapublichealth.org/acd/reports/acdcmr.pdf. You may also call 1-888-397-3993 for CMR forms.

  Send completed forms to the Communicable Disease Reporting System (CDRS) via toll-free faxline (1-888-397-3778) or hotline (1-888-397-3993), or the forms may be mailed to the Morbidity Central Reporting Unit, 313 N. Figueroa St., Room #117, Los Angeles, CA, 90012

- If you have knowledge of cases associated with cochlear implants, we can facilitate the reporting of these cases to the CDC, FDA, and the California Dept. of Health Services.

Please contact the LAC-DHS Acute Communicable Disease Control Unit at (213) 240-7941.

Adapted from the FDA Public Health Web Notification: Cochlear Implant Recipients may be at Greater Risk for Meningitis dated 7/24/02.