

FDA Public Health Web Notification: Cochlear Implant Recipients may be at Greater Risk for Meningitis

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The FDA has become aware of a possible association between cochlear implants and the occurrence of bacterial meningitis. The cause of meningitis in these cochlear implant recipients has not been established. The design of the electrode is being considered as a possible factor.

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. A total of 12 known deaths have resulted from these cases. Two implant surgeons, Drs. Noel Cohen and Thomas Balkany, have recently surveyed cochlear implant centers and manufacturers in North America. They identified 24 cases (of the 52 worldwide cases) of meningitis. Nine cases were identified in patients with the Advanced Bionics CLARION device, 15 cases with the Cochlear Nucleus device, and no cases with the MED-EL Corporation device.

Cerebrospinal fluid culture results are available in 14 cases. Although most cases have been caused by *Streptococcus pneumoniae* (pneumococcus), other organisms -- including *Hemophilus influenza*, enterococcus, E. coli, and S. viridans -- have been cultured. Although vaccination is usually protective against both pneumococcus and H. influenza, 2 cases of pneumococcal meningitis and 1 case of H. influenza meningitis have developed after the patient had received the appropriate vaccine. The onset of meningitis symptoms ranged from less than 24 hours to greater than 5 years from time of implant. Most of the patients have been children, predominantly under the age of 5, but some adults with cochlear implants have also developed meningitis.

The cause of meningitis in these cochlear implant recipients has not been established. Some deaf patients may have congenital abnormalities of the cochlea (inner ear) 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. The cochlear implant, because it is a foreign body, may act as a nidus for infection when patients have bacterial illnesses.

Design of the electrode is also being considered as a possible predisposing factor. 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 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 the 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.

Cochlear Corporation, in reviewing all data from North American patients implanted with the Nucleus device, claims to have an overall incidence of reported meningitis that is comparable to the incidence of meningitis in the general population. Cochlear Corporation noted that the majority of the reported cases of meningitis in these implanted patients had predisposing factors for meningitis (e.g., Mondini deformity, prior history of meningitis).

Meningitis

Meningitis is an infection of the lining of the surface of the brain. Early symptoms of meningitis include fever, irritability, lethargy and loss of appetite in infants and young children. Older children and adults may also manifest headache, stiff neck, nausea and vomiting, and confusion or alteration in consciousness. Physicians are encouraged to consider a diagnosis of meningitis in cochlear implant patients when such symptoms exist and to begin appropriate diagnosis and treatment as soon as possible.

The younger patient population (< 5 yr) and the elderly are most vulnerable to meningitis.

Cochlear Implants and Otitis Media

In some of the reported cases of meningitis in cochlear implant recipients, patients may have had overt or sub-clinical otitis media prior to surgery or before the meningitis developed. Physicians are encouraged to consider appropriate prophylactic perioperative antibiotic treatment, and to diagnose and treat otitis media promptly in patients with cochlear implants.

Cochlear Implants and Vaccination

Cochlear implant candidates, as well as those already implanted, may benefit from vaccinations against organisms that commonly cause bacterial meningitis, particularly *Streptococcus pneumoniae* and *Hemophilus influenzae*. The immunization status should be ascertained for all candidates for cochlear implants prior to surgery as well as for those with an existing implant. Cochlear implant patients should consult their physicians about receiving immunizations. At least one cochlear implant manufacturer provides reimbursement for vaccination.

- *Hemophilus 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 years to 5 years of age 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 limited¹. See individual product labeling for information on dosing and scheduling of the vaccines.

For additional information regarding immunizations refer to the National Vaccine Program Office of the Centers for Disease Control and Prevention (<http://www.cdc.gov/od/nvpo/>).

Reporting Cases of Meningitis in Cochlear Implant Recipients

We encourage you to report cases of meningitis in cochlear implant recipients. You can report these directly to the device manufacturer or you can report them to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch one of four ways: online at <http://www.accessdata.fda.gov/scripts/medwatch/> by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

FDA Contact

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Additionally, a voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible.

¹Preventing Pneumococcal Disease Among Infants and Young Children Recommendations of the Advisory Committee on Immunization Practices (ACIP) October 06, 2000 / 49(RR09);1-38.