

Advice for Patients with Cochlear Implants: New Information on Meningitis Risk

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New Information on Meningitis Risk



- Two cochlear implant patients [recently died](#) from infections. Neither one was fully vaccinated. One of these two likely died because of the lack of vaccination.
- A [survey of parents](#) of cochlear implanted children showed nearly half of them did not know whether their child had been fully vaccinated.

This **Advice for Patients** is to remind you of the increased and life-threatening risk of bacterial meningitis in cochlear implant patients and the importance of their being fully vaccinated.

Cochlear implant patients appear to be at some increased risk of bacterial meningitis caused by *Streptococcus pneumoniae*. However, **those children implanted with cochlear implants with a positioner component** are at greatest risk. This particular model of cochlear implant is no longer being manufactured and was withdrawn from the market in July, 2002.

Recommendations

- Review your child's immunization records with your doctor to assure that all the proper vaccinations have been given.
 - Check the patient's record of vaccinations against Center for Disease Control and Prevention's (CDC) recommendations that show what vaccines cochlear implant patients should receive and when the vaccines should be given.
 - Go to CDC's website for vaccination recommendations: (<http://www.cdc.gov/vaccines/vpd-vac/mening/cochlear/dis-cochlear-gen.htm>)
- Continue close monitoring for meningitis and middle ear infections for all children with a cochlear implant.
 - There is an increased risk if your child's implant has a positioner.
 - Consult your implanting doctor if you are not certain if your child's cochlear implant has a positioner.

- Contact your doctor immediately if the patient has any symptoms of meningitis or middle ear infection. These may include:

• high fever	• discomfort looking into bright lights
• headache	• sleepiness or tiredness
• stiff neck	• confusion
• nausea	• ear pain
• vomiting	• hearing loss
• irritability	• appetite loss

- Remind your doctor that your child has a cochlear implant.
- Follow your doctor's prescription for antibiotics very carefully. It is very important that the patient takes the antibiotic as often and for as long as prescribed, so it can work properly.
- Contact the CDC Immunization Center for any questions or information you may need. That telephone number is 800-232-4636. The TTY number is 888-232-6348.

New Information

FDA has become aware of two deaths from meningitis within the past year in children implanted with the Advanced Bionics cochlear implant with positioner.

- Neither of these children was fully vaccinated, according to the CDC recommended vaccination schedule.
- These children, ages 9 and 11, had completed only part of the recommended two-stage vaccinations for pneumococcal disease for their age group (Under two years for the first stage and over two years of age for the second stage.)
- At least one of these children had meningitis caused by a serotype of *Streptococcus pneumoniae* that may have been prevented by full vaccination.

Dr. John Niparko of the Johns Hopkins University recently conducted a survey on the University's cochlear implant patient population.

- The survey showed that 29% of the parents/guardians of patients under 2 years of age were uncertain if their child had both levels of vaccination to prevent meningitis.
- In patients greater than 2 years of age, vaccination status was unknown for 43% of the patients while 12% of the patients were shown not to be properly vaccinated.
- This is in spite of repeated information bulletins about the importance of vaccination to reduce the risk of this life-threatening infection.

FDA is working with the CDC and professional societies to alert parents to the importance of vaccinations in the cochlear implant population.

Previous Information

- A study published in the New England Journal in 2003 by FDA and CDC* followed children with cochlear implants for two years after the device was implanted.
 - The study showed that children whose implants have a positioner get bacterial meningitis more often than children with implants that don't have positioners or children without implants.
 - A positioner is a small rubber wedge that helps the physician position the implant during surgery.
 - Only Advanced Bionics Corporation sold an implant that had a positioner. None were implanted after July 2002.
 - Bacterial meningitis, a serious infection in the cerebrospinal fluid (CSF) around the brain and spinal cord, can be fatal.
 - The source of this study is (NewEngJMed, 349.5: 435-445) or <http://content.nejm.org/cgi/content/full/349/5/435>
- In a February 2006 FDA and CDC published a study report in Pediatrics, titled "Bacterial Meningitis Among Children With Cochlear Implants Beyond 24 Months After Implantation" that
 - followed the children for two more years
 - found that the increased risk for meningitis continued beyond two years after implantation
 - highlighted the importance of continuing to monitor children with cochlear implants for signs of middle ear infection and meningitis.
 - **emphasized that children need to be monitored for as long as the implant is in place**
 - The Pediatrics study is located at: <http://pediatrics.aappublications.org/cgi/content/abstract/117/2/284>

Additional Background Information

*The original CDC/FDA study (2003)

- reviewed the medical records of 4,264 children under the age of six at the time of they received their implants
- was conducted because of increased concern about the risk of meningitis associated with cochlear implants
- focused on young children because they
 - account for most known meningitis cases
 - represent the population that now receives a large proportion of cochlear implants

In the original study, 26 of the 4,264 children developed meningitis during the first 24 months after receiving their implants. Children who had cochlear implants with positioners developed meningitis more often than children who had implants without positioners. The study was unable to determine how the positioner increased the risk for developing meningitis.

Because the number of meningitis cases in the original study was small, it is hard to predict the risk of developing meningitis with various cochlear implant models. **The study also concluded there is not enough information now to recommend surgical removal of devices with a positioner.**

Information for caregivers/patients with cochlear implants appears on the web at <http://www.fda.gov/cdrh/medicaldevicesafety/atp/020606-cochlear.html>.

Information for health care providers appears on the web at <http://www.fda.gov/cdrh/safety/101007-cochlear.html>.

For general information on cochlear implants visit: <http://www.fda.gov/cdrh/cochlear/> .