



Risk of Bacterial Meningitis in Children with Cochlear Implants

July, 2003

Many people have received cochlear implants to help them hear and communicate. The Centers for Disease Control and Prevention (CDC) has been looking at a possible link between cochlear implants and meningitis. This study is now complete and has been published in the *New England Journal of Medicine*. The study had two purposes: (1) to find out how many children who had cochlear implants got bacterial meningitis afterwards, and (2) to find out if there are factors that might make it more likely that someone would get meningitis after getting a cochlear implant.

The purpose of this packet is to give you some basic information about the study results, as well as sources where you can find out more about cochlear implants, meningitis, and related subjects. This packet has the following three sections:

“About the Study”, a summary of the results.

“Questions and Answers”, frequently asked questions and the answers.

“Resources About Hearing Loss, Cochlear Implants, and Meningitis”, an information resource list that has the telephone numbers and websites of organizations that can give you more information about cochlear implants and meningitis.

Because CDC is a public health agency, CDC personnel cannot give individual medical advice. If after reading through the information in this packet you still have questions about cochlear implants or meningitis as they apply to you or to someone you know, you should contact your doctor. A personal doctor can get a complete medical history and prescribe treatment, and is your best source for medical advice.

If you have any other questions about this study you can call CDC’s Immunization Hotline, which will be answering all cochlear implant related questions.

Telephone English: 800-232-2522 Spanish: 800-232-0233
Hours of Operation: Monday – Friday 8 a.m. – 11 p.m. EST

TTY: 800-243-7889

You can also check CDC’s website for the full text article at:
<http://www.cdc.gov/ncbddd/ehdi>

We at CDC realize that this study could not have been done without the help of the parents of children with cochlear implants, state and local health departments, other federal health agencies, and cochlear implant manufacturers. Their cooperation is greatly appreciated.



Risk of Bacterial Meningitis in Children with Cochlear Implants

Background

In summer 2002, the U.S. Food and Drug Administration (FDA) began receiving reports of bacterial meningitis occurring among people who had cochlear implants. In response, the Centers for Disease Control and Prevention (CDC), with the FDA and the health departments of 36 states, the District of Columbia, Chicago, and New York City, began an investigation.

Conducting the Study

The purposes of the study were (1) to find out how many children who had cochlear implants got bacterial meningitis afterwards and (2) to find out what factors might make it more likely that someone would get meningitis after getting a cochlear implant. The study was limited to children who were 6 years of age or younger when they got their implant because the majority of cases reported were in children in this age group, and because children in this age group will receive most implants in the future. Children who had received their implant during the period from January 1, 1997, through August 6, 2002 were included. Potential cases of bacterial meningitis were identified from reports to implant manufacturers, the FDA Adverse Events Reporting System, and CDC and state and local health department tracking systems. In addition, study researchers contacted the parents of all the children in this group to ask them if their child had been seriously ill since getting the implant.

Some Basic Facts About the Study

- A total of 4,262 children 6 years of age or younger received a cochlear implant during the period from January 1, 1997, through August 6, 2002. This large study group was used to estimate how many of the children with cochlear implants got bacterial meningitis. This number was then compared with the number of children of this age in the general population who got bacterial meningitis.
- A smaller study group was used to find what factors made it more likely for someone with an implant to get meningitis. This smaller study was made up of all 26 children with confirmed bacterial meningitis and a random sample of 200 children with implants who did not get bacterial meningitis after receiving the implant.
- Detailed interviews of parents were done only for the small study group. A review of medical records was also done.
- The study was limited to children who received their cochlear implants in the United States.

Study Findings and Conclusions

The study found that:

- Bacterial meningitis occurred more often in children with all types of cochlear implants than in children of the same age group in the general population.
- The majority of cases of meningitis were caused by *S. pneumoniae*, a type of bacteria.
- Children with an implant with a positioner were much more likely to get bacterial meningitis than children with other types of cochlear implants. (The implant with a positioner was voluntarily taken off the market by the manufacturer in July 2002.)
- Because the study was not able to find out how the positioner increased the risk for bacterial meningitis, it was not clear whether removing the implant would lower the risk and we cannot make recommendations about that. The removal procedure could place the child at risk for meningitis or other related complications following surgery.
- Children with a cochlear implant who had inner ear malformations and cerebrospinal fluid leaks were at increased risk for bacterial meningitis.

Recommendations

- Children should be up to date on vaccines at least 2 weeks before having a cochlear implant if they are not already up-to-date on these vaccinations. (Specific vaccine recommendations for children with cochlear implants are included in the attached Questions and Answers.)
- Parents of children who have already received an implant should check with their child's doctor to ensure that their child is up to date on all vaccinations.
- Doctors and other health care providers should review vaccination records of their patients who are cochlear implant recipients or candidates to ensure that they have received pneumococcal vaccinations based on the age-appropriate schedules for high risk people and that they have received age-appropriate Hib vaccinations.
- Parents of children with cochlear implants should be watchful for possible signs and symptoms of meningitis (which are listed in the Questions and Answers section of this packet) and seek prompt attention for any bacterial infection their child might have. Any questions parents have about their child's health should be discussed with the child's doctor.
- Parents of children with cochlear implants should also be watchful for signs and symptoms of an ear infection, which can include ear pain, fever, and decreased appetite. Parents should seek prompt medical attention for any possible ear infections.
- Parents should talk about the risks and benefits of cochlear implants with their child's doctor and should discuss whether their child has certain medical conditions that might make him or her more likely to get meningitis.

Frequently Asked Questions

Cochlear Implant, Immunization, and Meningitis



What is meningitis and what are its signs and symptoms?

Meningitis is an infection in the fluid that is around the brain and spinal cord. There are two types of meningitis—viral and bacterial. Bacterial is the more serious of the two and is the type that has been reported in people with cochlear implants.

Signs and symptoms of meningitis are high fever, headache, stiff neck, nausea or vomiting, discomfort looking into bright lights, and sleepiness or confusion. A young child or infant with meningitis might be sleepy, cranky, or eat less.

What should be done if someone has signs or symptoms of meningitis?

Any person who is showing signs or symptoms of meningitis should seek immediate medical care by contacting their doctor or going to a clinic or emergency room. If that person has a cochlear implant, the doctor or other health care provider should be told. The doctor can look at and examine the person and do other tests as needed.

Why wasn't the risk of meningitis for children with an implant compared with the risk for children with severe to profound hearing loss but with no implant?

Children with cochlear implants were not compared with children without implants because the information that would have allowed such a comparison was not available during this study. However, scientists in Denmark, sponsored by CDC, do have access to the needed data and are now working on a joint project that could make such a comparison possible.

Can vaccinations protect children with cochlear implants from getting meningitis?

Some vaccines are very good at preventing meningitis. However, as good as they are, vaccines can't prevent all types of meningitis. Current vaccines protect against the most common strains of bacteria causing meningitis, but they do not protect against all strains.

Are any changes being made to meningitis immunization recommendations for people with cochlear implants?

Before the cochlear implant and meningitis study began, there were no special immunization recommendations for people with cochlear implants. However, in October 2002 (before study results were available), researchers saw that people with cochlear implants might be more likely to get bacterial meningitis, especially pneumococcal meningitis. Because there are two vaccines that can prevent pneumococcal meningitis, CDC recommended that people with cochlear implants get the vaccine using the schedule for people who are at high risk. The findings made in this study agree with that decision and led the Advisory Committee for Immunization Practices to adopt these recommendations on June 19, 2003. Recommendations for the timing and type of pneumococcal vaccination vary with age and each person's vaccination history. The following immunization schedule provides age-specific information. However, any immunization decisions should be talked over with a health care provider.

Use of Pneumococcal Vaccinations for People With Cochlear Implants

Children younger than 2 years of age who have cochlear implants should get pneumococcal conjugate vaccine (Pneumovax®) according to the routine pneumococcal conjugate vaccination schedule for this age group. Children and adolescents with cochlear implants should receive vaccines according to the recommended schedule. <http://www.cdc.gov/nip/recs/child-schedule.htm#Printable>

Frequently Asked Questions *(cont'd)*

Recommendations for people who have cochlear implants and who are 2 years of age or older:

- Children who have cochlear implants, who are 2 years of age or older, and who have completed the pneumococcal conjugate vaccine (Prevnar®) series should have one dose of the pneumococcal polysaccharide vaccine (Pneumovax® 23). If they have just gotten the pneumococcal conjugate vaccine, they should wait at least 2 months following the last dose before getting the pneumococcal polysaccharide vaccine.
- Children who have cochlear implants, who are 24 through 59 months of age, and who have never had either the pneumococcal conjugate vaccine or the pneumococcal polysaccharide vaccine should get a total of two doses of the pneumococcal conjugate vaccine 2 or more months apart and then, at least 2 months later, should get one dose of the pneumococcal polysaccharide vaccine.
- People who have cochlear implants and who are 5 years of age or older should get one dose of pneumococcal polysaccharide vaccine.

What can parents of children with cochlear implants do to reduce their child's risk of getting meningitis?

First of all, parents need to watch their child for any of the possible signs and symptoms of meningitis, and to get prompt medical attention if the child develops these symptoms. Parents should also seek prompt medical attention if they think their child might have an ear infection or any other bacterial infection. Second, parents should be sure that all of the child's immunizations are up to date. In addition, like all children, children with cochlear implants should not be near tobacco smoke because it has been shown to increase the risk for bacterial infections.

Can someone who has lost his or her hearing as a result of having meningitis still get meningitis again?

Yes, anyone who has had bacterial meningitis can get it again. This is true whether or not the first meningitis caused a loss of hearing. A person who gets some kinds of bacterial meningitis might be more likely to get it again.

Have more cases of bacterial meningitis occurred in children with cochlear implants in recent months?

Yes. The study included only the 26 children with confirmed bacterial meningitis that occurred before September 15, 2002. In the months since that date, six additional cases of meningitis have occurred in the group of children who received their implant when they were 6 years of age or younger. Any additional cases of bacterial meningitis in cochlear implant recipients should be reported to CDC's Early Hearing Detection and Intervention Program by calling 1-877-232-4327 (voice), 1-877-232-7672 (TTY).

Where can parents find out more about this study and about their child's health and risks?

Parents who have additional questions about the study can call CDC's Immunization Hotline.

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For questions that apply specifically to a child's health, parents should contact their child's primary health care provider.

