

The Tampa Bay Hearing and Balance Center  
Harbourside Medical Tower 4 Columbia Drive Suite 610 Tampa, FL 33606  
813 844 HEAR 813 844 4900 Fax 813 844 4905  
Loren J Bartels MD FACS

Re: Low meningitis risk in cochlear implant patients advises getting a vaccine

This certified letter is being sent to you to be sure you are aware of a recent discovery that cochlear implant patients appear to have a small, but significant risk of developing bacterial meningitis. Data collection in the United States indicate that cochlear implant children in particular have a risk of about 1 chance in a thousand of getting meningitis. The adult risk may be lower. In Europe, the risk appears more likely to involve adults than in the US for reasons not yet known. As a result of this information, the United States Food and Drug Administration has recommended the following in a bulletin published on the FDA web site <http://www.fda.gov/cdrh/safety/cochlear.html>:

The immunization status should be ascertained for all candidates for cochlear implants prior to surgery as well as for those with an existing implant.

*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 OR 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 limited. See individual product labeling for information on dosing and scheduling of the vaccines.

**What is meningitis?** There are several broad types of meningitis: bacterial, viral, chemical, autoimmune, and tumor related. The current concern is with bacterial meningitis. Bacterial meningitis is usually acquired from a throat infection in susceptible individuals. It turns out that virtually all persons for a few days at least once or twice a year have bacteria in their throats that can cause meningitis. Most persons have only a minor illness and recover without treatment because the throat based infection doesn't seem to spread. For reasons unclear and in relatively rare circumstances, the infection from the throat gets into the blood and eventually reaches the spinal fluid. Persons with less mature or weaker immune systems like young children, older persons, and persons with certain illnesses are at higher risk. The most common bacteria to do this are the same ones that commonly cause sinusitis, middle ear infection, and pneumonia: the *Streptococcus pneumoniae* organism. The second most common is *Haemophilus influenzae*. Neither of these is highly contagious. The type of bacterial meningitis that is highly contagious is *Neisseria meningitidis*, but it is a relatively rare form of meningitis. Bacterial meningitis, if not treated aggressively with antibiotics, may result in very serious life threatening illness. One can also get viral meningitis which is not caused by bacteria. Viral meningitis is relatively common, more so than bacterial, and gets better in almost all cases without treatment. There is no suggestion at this time that viral meningitis is more likely in cochlear implant patients. The only way to tell the difference among the various types of meningitis is with a spinal tap and cultures. Sometimes, blood, throat, sinus, and other cultures will help as well. In other words, without a careful diagnostic effort, the cause of the meningitis would be uncertain. If a person comes down with meningitis which is discovered early, and if aggressive treatment with antibiotics is initiated, recovery is quite likely.

The Tampa Bay Hearing and Balance Center  
Harbourside Medical Tower 4 Columbia Drive Suite 610 Tampa, FL 33606  
813 844 HEAR 813 844 4900 Fax 813 844 4905  
Loren J Bartels MD FACS

Why would cochlear implant patients potentially be at a higher risk for meningitis? The inner ear fluid has a direct though slow connection with spinal fluid through a bony channel called the cochlear aqueduct. Remember, the cochlear implant enters the inner ear from the middle ear/mastoid. If a middle ear infection were to allow bacteria to track along the cochlear implant cable, potentially, such could reach the cochlear aqueduct and travel along it to the spinal fluid spaces causing meningitis.

What could one do to reduce the risk of developing bacterial meningitis? We think that one can reduce bacterial meningitis risk by doing the things that reduce the risk of developing serious pneumonia: **get a vaccine**. The specific vaccine information is on the first page. Most internists and pediatricians should be able to provide such. I would suggest that you take this to him/her and ask for the appropriate vaccine. Please consider that older persons and persons with many types of chronic illness are supposed to get this vaccine anyway. As well, current medical literature recommends these vaccines for some children as well.

What cochlear implant systems have a reported meningitis problem and why? In the US, both companies with long experience, the Nucleus and Clarion systems, have reported meningitis cases. The company with only a limited time and fewer than a thousand cases, the MedEl device, has no reported cases, yet. It is thought that the pathway of the cochlear implant cable may allow bacteria that enter the middle ear during a respiratory illness to track into the inner ear and from there into the spinal fluid. For the Clarion device, the worry seems to be that the positioner increases the risk a bit, although such remains highly speculative. The Clarion positioner device has been withdrawn from the market hoping to re-release the Clarion HiFocus system within a couple of months as a device without the positioner. I am told that the newer software for the Clarion HiFocus II, Bionic Ear will work just as well without the positioner.

What does Dr. Bartels recommend?

1. Get the vaccine. Older persons are advised to do so, anyway, whether or not they plan to get a cochlear implant. The reason the vaccine is recommended for older persons is to reduce the risk of developing pneumonia.
2. Otherwise, we see no reason to panic. If you are considering a cochlear implant, go ahead and get the vaccine and, then, have the cochlear implant surgery with a device of your choice in a time frame you choose.

Please feel free to ask further questions by calling or by email (preferred wherever possible [lbartels@tampabayhearing.com](mailto:lbartels@tampabayhearing.com)). Please find attached a modified consent form that addresses this risk.

Sincerely,



Loren J Bartels MD  
Director, the Tampa Bay Hearing and Balance Center  
Clinical Professor of Otolaryngology, USF College of Medicine