

Patient Safety Advisory

Veterans Health Administration Warning System Published by VA Central Office

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- Item:** COCHLEAR IMPLANT RECIPIENTS MAY BE AT INCREASED RISK FOR BACTERIAL MENINGITIS.
- General Information:** See the attached FDA Public Health Web Notification or click on the following URL (<http://www.fda.gov/cdrh/safety/cochlear.html>).
- Specific Incident:** FDA has determined that, over the past 14 years, 52 cases of meningitis have been reported worldwide, out of which 12 known deaths have resulted from these cases. It was identified that 24 cases (of the 52 worldwide cases) were in North America.
- Suggestions:**
1. The FDA advised that cochlear implant candidates, as well as those already implanted, may benefit from vaccinations against organisms commonly associated with bacterial meningitis, particularly *S. pneumoniae* and *H. influenzae* (ACIP recommends 23valent pneumococcal vaccines [Pnu-Imune^R 23 and Pneumovax^R] for adults with increased risk of invasive pneumococcal disease). Therefore, all veterans who are candidates for cochlear implant (s) should be ascertained of their immunization status prior to surgery as well as all patients with existing implants received from VA and non-VA facilities. Previously unvaccinated adults with a high-risk condition (functional or anatomic asplenia, immunodeficiency, [particularly, persons with IgG2 subclass deficiency], immunosuppression from cancer chemotherapy, and infection with human immunodeficiency virus) should be given at least one dose of any licensed Hib conjugate vaccine. As neither FDA nor CDC specifically notes the use of Hib vaccine in adults related to cochlear implants, the use of Hib vaccine in this scenario would be based on theoretical risk. For additional info on immunizations refer to the following websites.
<http://www.cdc.gov/nip/publications/pink/>
<http://www.cdc.gov/mmwr/preview/mmwrhtml/00025228>
<http://www.cdc.gov/mmwr/PDF/rr/rr4608.pdf>
 2. In some of the reported cases, patients may have had overt or sub-clinical otitis media prior to surgery or before 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.
 3. Patient Safety Managers, please make sure that Primary Care Physicians, EENT specialists (on Surgery service) and Audiologists are aware of this. Follow FDA MedWatch reporting instructions to report cases of meningitis in cochlear implant recipients.
- Source:** FDA Public Health Web Notification issued 7/24/2002 and updated 8/29/2002
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