Policy Statement—Cochlear Implants in Children: Surgical Site Infections and Prevention and Treatment of Acute Otitis Media and Meningitis

Lorry G. Rubin, MD, Blake Papsin, MD and the COMMITTEE ON INFECTIOUS DISEASES AND SECTION ON OTOLARYNGOLOGY—HEAD AND NECK SURGERY

KEY WORDS
cochlear implant, deafness, meningitis, acute otitis media, vaccination

ABBREVIATIONS
FDA—Food and Drug Administration
CSF—cerebrospinal fluid
CI—confidence interval
PCV7—heptavalent pneumococcal conjugate vaccine
PPSV23—23-valent pneumococcal polysaccharide vaccine
PCV13—13-valent pneumococcal conjugate vaccine
Hib—Haemophilus influenzae type b conjugate vaccine

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The use of cochlear implants is increasingly common, particularly in children younger than 3 years. Bacterial meningitis, often with associated acute otitis media, is more common in children with cochlear implants than in groups of control children. Children with profound deafness who are candidates for cochlear implants should receive all age-appropriate doses of pneumococcal conjugate and Haemophilus influenzae type b conjugate vaccines and appropriate annual immunization against influenza. In addition, starting at 24 months of age, a single dose of 23-valent pneumococcal polysaccharide vaccine should be administered. Before implant surgery, primary care providers and cochlear implant teams should ensure that immunizations are up-to-date, preferably with completion of indicated vaccines at least 2 weeks before implant surgery. Imaging of the temporal bone/inner ear should be performed before cochlear implantation in all children with congenital deafness and all patients with profound hearing impairment and a history of bacterial meningitis to identify those with inner-ear malformations/cerebrospinal fluid fistulas or ossification of the cochlea. During the initial months after cochlear implantation, the risk of complications of acute otitis media may be higher than during subsequent time periods. Therefore, it is recommended that acute otitis media diagnosed during the first 2 months after implantation be initially treated with a parenteral antibiotic (eg, ceftriaxone or cefotaxime). Episodes occurring 2 months or longer after implantation can be treated with a trial of an oral antimicrobial agent (eg, amoxicillin or amoxicillin/clavulanate at a dose of approximately 90 mg/kg per day of amoxicillin component), provided the child does not appear toxic and the implant does not have a spacer/positioner, a wedge that rests in the cochlea next to the electrodes present in certain implant models available between 1999 and 2002. “Watchful waiting” without antimicrobial therapy is inappropriate for children with implants with acute otitis media. If feasible, tympanocentesis should be performed for acute otitis media, and the material should be sent for culture, but performance of this procedure should not result in an undue delay in initiating antimicrobial therapy. For patients with suspected meningitis, cerebrospinal fluid as well as middle-ear fluid, if present, should be sent for culture. Empiric antimicrobial therapy for meningitis occurring within 2 months of implantation should include an agent with broad activity against Gram-negative bacilli (eg, meropenem) plus vancomycin. For meningitis occurring 2 months or longer after implantation, standard empiric antimicrobial therapy for meningitis (eg, ceftriaxone plus vancomycin) is indicated. For patients with meningitis, urgent evaluation by an otolaryngologist is indicated for consideration of imaging and surgical exploration. Pediatrics 2010; 126:381–391
BACKGROUND

A cochlear implant is an implanted electronic hearing device designed to produce useful hearing sensations to a person who is profoundly deaf or severely hard of hearing by electrically stimulating nerves inside the inner ear. The implant consists of an external portion that sits behind the ear and internal components that are surgically placed under the skin and inserted in the cochlea (Fig 1). Cochlear implants are increasingly being used as a treatment for hearing loss.

By the end of 2005, nearly 15,000 children and 22,000 adults in the United States and nearly 100,000 people worldwide had received cochlear implants for treatment of hearing loss. In another important trend, some adults and children are now receiving bilateral cochlear implants. Approximately 1 million people in the United States are potential candidates for cochlear implants. The current minimum age for placement of cochlear implants approved by the US Food and Drug Administration (FDA) is 1 year, although implants have been placed successfully in infants younger than 1 year with profound hearing loss. It is increasingly likely that a primary care pediatrician will have 1 or more children with a cochlear implant in his or her practice. Potential infectious complications of cochlear implants include postoperative wound and device-related infections and bacterial meningitis. In children with cochlear implants, an episode of acute otitis media may lead to inner-ear infection, device infection, device extrusion, device

FIGURE 1
Diagram of the implanted cochlear device. External devices pick up, process, and transmit the sound across the skin to a receiver-stimulator implanted in bone. The receiver sends the code down a bundle of wires that passes through the middle ear and continues as the electrode array that is threaded into the cochlea. (Reprinted with permission from Papsin BC, Gordon KA. *N Engl J Med.* 2007;357[23]:2380–2387. Copyright © 2007 Massachusetts Medical Society. All rights reserved.)
failure, and/or meningitis. Thus, there is a need for guidelines for prevention, recognition, and management of cochlear implant–related infections, acute otitis media, and bacterial meningitis in children with cochlear implants.

Postoperative Wound Infections

Postoperative surgical site infection has been reported in 1% to 12% of patients who have undergone cochlear implantation.6,7 Major infections may have serious consequences, including loss of the implant, and may occur more frequently in pediatric patients.6 In 1 case series, 8 of 9 patients with device exposure (ie, an opening in the skin overlaying the device as a result of wound infection and resultant wound dehiscence) ultimately required device removal, compared with 3 of 17 patients with a wound infection without device exposure.7 Although the use of prophylactic perioperative antimicrobial agents has varied among centers and surgeons, the FDA recommended in 2003 that “[h]ealth care providers should consider prophylactic antibiotic treatment perioperatively in children receiving cochlear implants.”8 This recommendation was made to reduce the risk of meningitis that occurs in the immediate postoperative period, but it is possible that the use of prophylactic antimicrobial agents may also reduce the rate of occurrence of postoperative wound infection, acute otitis media, and implant infection. Patients with suspected postoperative wound infections should be referred urgently to the surgeon who performed the implant.

Acute Otitis Media in Cochlear Implant Recipients

With an increasing number of children younger than 3 years receiving cochlear implants, primary care providers are likely to be confronted with children with cochlear implants who present with acute otitis media. Rates of morbidity associated with acute otitis media may be higher in children with cochlear implants than in other children, because the surgically placed electrode traverses the middle ear to the inner ear through the cochlear wall (cochleostomy) or the round window membrane (Fig 1). Although the opening created between the middle and inner ear is generally sealed with fascia or other material, it remains a potential route for acute otitis media—causing bacteria in the middle ear to spread to the inner ear. Inner-ear infection can result in severe symptoms including hearing loss attributable to damage to auditory primary afferent neurons, vestibular dysfunction, and meningitis. In addition, inner-ear infection can result in loss of the implant because of implant contamination or implant malfunction related to ossification of the cochlea.

Published data concerning the incidence and prognosis of acute otitis media in children with implants are limited (Table 1).9–13 Theoretically, in the initial months after placement of a cochlear implant, the risk of complications associated with an episode of acute otitis media may be higher if the cochleostomy, the communication between the middle and inner ear created during implantation, has not healed. An animal model has demonstrated that acute otitis media induced within 2 weeks after cochlear implantation may result in severe cochlear damage.14 However, postmortem study of the temporal bone of implant recipients 2 to 10 years after implantation demonstrated that the opening in the round window around the electrode was sealed with fibrous tissue.15 In the only prospective study of acute otitis media in implant recipients, Luntz et al8,16 studied 60 children whom

TABLE 1

<table>
<thead>
<tr>
<th>Reference (Year)</th>
<th>Study Design</th>
<th>No. of Patients Evaluated</th>
<th>No. of Patients With ≥1 Episode of Acute Otitis Media in Implanted Ear (Total No. of Episodes That Occurred in Either or Both Ears)</th>
<th>Age at Implantation (Mean Age at Implantation, y)</th>
<th>Length of Follow-up Time After Implantation (Mean, y)</th>
<th>Time Interval From Implantation to Acute Otitis Media, Range (Mean), mo</th>
<th>Time From Acute Otitis Media to Meningitis, Range (Mean), mo</th>
<th>Management</th>
<th>No. of Episodes of Meningitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luntz et al9 (2004)</td>
<td>Prospective</td>
<td>60</td>
<td>17 (22)</td>
<td>(3.4)</td>
<td>0.25–2.5 (1.7)</td>
<td>&lt;1, 6 cases &gt;1, 11 cases</td>
<td>Myringotomy and tube placed All received oral antimicrobial agents; 46% also received parenteral antimicrobial agents</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>House et al10 (1983)</td>
<td>Retrospective</td>
<td>43</td>
<td>NR (4)</td>
<td>2.7–17.5 (8.3)</td>
<td>Up to 2 1/4</td>
<td>NR</td>
<td>Oral antimicrobial therapy</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>House et al11 (1985)</td>
<td>Retrospective</td>
<td>20</td>
<td>8 (15)</td>
<td>2.9–8.7</td>
<td>1–4 (1.3)</td>
<td>1–17 (6.4)</td>
<td>Oral antimicrobial therapy</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Kempf et al12 (2000)</td>
<td>Retrospective</td>
<td>366</td>
<td>11 (20)</td>
<td>1–14</td>
<td>≤8</td>
<td>NR</td>
<td>Route or choice of antimicrobial agent not specified; myringotomy performed in 7 of 20 episodes Intravenous ceftriaxone for 3–5 d; no myringotomy</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Migirov et al13 (2006)</td>
<td>Retrospective</td>
<td>234</td>
<td>47</td>
<td>0.9–16 (4.8)</td>
<td>≥2</td>
<td>NR</td>
<td>Intravenous ceftriaxone for 3–5 d; no myringotomy</td>
<td>NR</td>
<td></td>
</tr>
</tbody>
</table>

NR indicates not reported.
they categorized as otitis media prone (on the basis of previous history of frequent otitis media; \( n = 34 \); mean age at cochlear implant: 48 months) and non–otitis media prone (\( n = 26 \); mean age at cochlear implant: 35 months). Preoperatively, the otitis media–prone group underwent ventilation-tube placement with or without adenoidectomy and, in some cases, additional measures. Patients were required to have a normal tympanic membrane and no drainage via the ventilation tube for at least 2 weeks before implantation. With a mean follow-up period of 20 months after implantation, at least 1 episode of acute otitis media had occurred in 15 (44%) of the 34 otitis media–prone children and 2 (8%) of the non–otitis media–prone children. Six (10%) children with implants, 5 of whom were in the otitis media–prone group, had an episode of acute otitis media within 1 month of implantation, a finding that supports the assertion that children are at highest risk of acute otitis media during the immediate postoperative period. All these episodes of acute otitis media were treated successfully with oral antimicrobial agents, typically amoxicillin/clavulanate. Thirteen patients developed acute otitis media later than 1 month after implantation; all of them had installation of a new ventilation tube to establish middle-ear drainage, unless the patient had a preexisting ventilation tube, and were treated initially with oral antimicrobial therapy. Six children required hospitalization and administration of intravenous antimicrobial therapy because of failure of oral antimicrobial agents and, in 2 of these 6 children, acute mastoiditis.

Four retrospective studies of acute otitis media in children with implants have been reported. In 3 studies, the severity or outcome of acute otitis media was found to be satisfactory when using standard treatments (Table 1).\(^1,^{10,11,13}\) In contrast, the fourth study\(^12\) revealed that patients with implants were more likely to require intravenous antimicrobial therapy and a myringotomy.\(^12\) Furthermore, of the 11 episodes of acute otitis media reported in this study, 7 patients underwent surgical treatment for mastoiditis. No child in any of the 4 series was reported to have developed bacterial meningitis. Although these reports provide useful insight, they contain significant limitations, including the retrospective design, possibly leading to identification and inclusion of only the more severe acute otitis media episodes. Another limitation is the lack of report of pathogens causing acute otitis media episodes.

That no cases of bacterial meningitis were reported in these case series of children with acute otitis media is not surprising, given the small number of cases in these series and a reported incidence of \textit{Streptococcus pneumoniae} meningitis in children with cochlear implants of 138 cases per 100 000 person-years.\(^17\) However, in a study of bacterial meningitis in children with implants, for the subgroup of children with bacterial meningitis that occurred at least 30 days after implant surgery (and for whom clinical information was available concerning the presence of acute otitis media), acute otitis media was present in 13 (50%) of 26 patients at the time of presentation with meningitis (although whether acute otitis media was in the same ear as the implant was not reported).\(^17,18\) These findings indicate that, at least in some cases, there may be a causal relationship between acute otitis media and bacterial meningitis. Signs of acute otitis media were not reported in any of 9 episodes of bacterial meningitis that presented within 30 days of implantation of a cochlear device. To prevent episodes of acute otitis media after cochlear implantation, surgeons may place tympanostomy tubes before or at the time of implantation in children with a history of recurrent acute otitis media or persistent middle-ear effusion.\(^16,18\) A consensus report prepared by 8 cochlear implant surgeons recommended, on the basis of theoretical considerations and a series of otitis media–related meningitis episodes in adults,\(^20\) avoidance of implantation if middle-ear fluid is present.\(^21\) The surgeons stated that if middle-ear fluid is encountered at the time of implantation, they recommended high-volume irrigation of the middle ear, administration of topical antimicrobial agents into the middle-ear space, and systemic therapy with ceftriaxone.\(^21\)

**Bacterial Meningitis in Cochlear Implant Recipients**

Factors independent of cochlear implantation may place children with hearing loss at increased risk of bacterial meningitis.\(^17\) Some children have an inner-ear malformation (eg, common cavity malformation) that predisposes them to bacterial meningitis as a complication of middle- and inner-ear infection. For example, a 6-year-old child with Mondini-type malformation and a cochlear implant in the left ear placed 2 years earlier developed rapidly fatal meningitis.\(^22\) Examination of the temporal bones at autopsy showed that acute meningitis was related to right middle-ear infection and supplicative labyrinthitis. The left middle ear on the side of the implant was unaffected. Thus, in this case and in a second case,\(^23\) just having an inner-ear malformation, rather than a cochlear implant, was the risk factor for acute otitis media–related meningitis. Bacterial meningitis in infants is an important cause of acquired deafness, which may lead to cochlear implantation, and preimplant meningitis has been identified as a risk factor for postimplant meningitis.\(^24\)
In most cases of meningitis in patients with an implant, the initial event in the pathogenesis of meningitis is acute otitis media that occurs in the ipsilateral ear, especially when meningitis occurs more than 30 days after surgery. After acute otitis media develops, bacteria can enter the inner ear through an incompletely sealed cochleostomy. Pathways of bacterial access to the cerebrospinal fluid (CSF) from the inner ear include entry into the labyrinth, infiltration of the cochlear turns along the electrode entering the Schuknecht bony channels, and following perineural and/or perivascular pathways into the internal auditory canal to the meninges. In patients with a malformed cochlea in which there is a connection to the subarachnoid space, meningitis also can occur via the cochlear aqueduct. In the absence of a surgical procedure to reduce such risks, these children remain at increased risk of meningitis after cochlear implantation. In addition, as postulated by Arnold et al and studied experimentally by Wei et al, cases of bacterial meningitis in implant recipients may originate via pneumococcal bacteremia with hematogenous seeding of the cochlea, such as at a site of tissue necrosis related to the electrode or positioner (locus minoris resistentiae) with contiguous spread to the CSF and meninges.

In addition, cochlear implants themselves increase the risk of bacterial meningitis, especially during the first 2 months after implantation. In a nested case-control investigation of US children younger than 6 years with cochlear implants and meningitis between 1997 and 2002, 26 children with bacterial meningitis were identified among 4264 children with cochlear implants. During an additional 2 years of follow-up of this cohort, 12 additional episodes of bacterial meningitis were identified. The rate of bacterial meningitis was 189 cases per 100 000 person-years, a more than 30-fold increased risk compared with that in the overall population. In a study in Denmark, the rate of bacterial meningitis was 43 cases per 100 000 person-years in young children with hearing loss (10.4% of the cohort had cochlear implants). In the same study, young children with hearing loss and without a cochlear implant were at a 4.1-fold increased relative risk (95% confidence interval [CI]: 1.5–11.0) for development of bacterial meningitis compared with a group of children without hearing loss. Within the group of children with implants in the US study, the risk of meningitis was significantly higher for patients with a particular implant model (AB-5100H or AB-5100H-11 [Advanced Bionics, Sylmar, CA]) that included a positioner (or a so-called spacer, a wedge that rests in the cochlea next to the electrodes). During the period from 1997 to 2004, only 19% of the cohort of children had a model with a positioner, yet these children accounted for 71% of the children with meningitis. The models with positioners were available beginning in 1999 and were voluntarily recalled in the United States in July 2002. In a multivariate analysis of a case-control study, the odds ratio for meningitis in patients with an implant with a positioner was 4.5 (95% CI: 1.3–17.9). Although the increased risk of meningitis in patients with an implant with a positioner continues beyond 24 months after implantation, to date, elective removal of these implants or their positioners is not recommended, and these implants remain in place in many patients. In the same analysis, an additional risk factor for development of meningitis was inner-ear malformation with a CSF leak (odds ratio: 9.3 [95% CI: 1.2–94.5]).

Episodes of meningitis in patients with a cochlear implant may have a fatal outcome. Of 198 cases of postimplant bacterial meningitis in children and adults reported to the FDA, the mortality rate in the 184 cases for which the outcome of infection was known was 16% (Eric Mann, FDA, personal communication, February 7, 2008). Of 38 children who experienced 41 episodes of meningitis reported by Reefhuis et al and Biernath et al, 3 children died. *Streptococcus pneumoniae* is the most common pathogen that causes meningitis in children with cochlear implants and in patients with an inner-ear malformation that predisposed them to bacterial meningitis. Pathogens associated with bacterial meningitis that occurred within 30 days of implant surgery were *S pneumoniae* in 4 of 9 cases and *Acinetobacter baumannii* (2 cases), *Escherichia coli*, *Haemophilus influenzae* type b, and *Enterococcus spp* in the remainder. Of 25 cases that occurred more than 30 days after implant surgery with an identified pathogen, the etiology was *S pneumoniae* in 80%, nontypeable *H influenzae* in 12%, *H influenzae* type b in 4%, and *Streptococcus pyogenes* in 4%. *Neisseria meningitidis* (meningococcus) has not been reported as an etiology of meningitis in children with cochlear implants (although meningococcal meningitis has been reported in 2 children with congenital malformation of the middle ear), and available data do not support cochlear implants as a risk factor for meningitis attributable to *N meningitidis*. As noted earlier, acute otitis media was not noted to be present at the time of diagnosis in any of the cases that occurred during the first 30 days after implantation but was noted in 52% of cases that occurred more than 30 days after implantation.
Use of Pneumococcal and H influenzae Type b Vaccines for Prevention of Acute Otitis Media and Meningitis

Immunization of the general population of infants with the primary series of heptavalent pneumococcal conjugate vaccine (PCV7) has resulted in a marked decrease in invasive pneumococcal disease, including meningitis. In addition, immunization of infants has resulted in an approximately 7% reduction in episodes of acute otitis media from all etiologies and a 34% reduction in pneumococcal otitis media. However, 2 randomized double-blind studies of prevention of acute otitis media in children 1 to 6 years of age identified as otitis prone in which the treatment group received 1 or 2 doses of PCV7 followed 6 months later by a dose of 23-valent pneumococcal polysaccharide vaccine (PPSV23) revealed no effect on the rate or severity of episodes of acute otitis media. Although PCV7 results in a reduction in nasopharyngeal colonization with vaccine serotypes, overall carriage of pneumococci is unchanged as a result of colonization with nonvaccine serotypes. PCV23, licensed for children 2 years of age and older, reduces the incidence of invasive pneumococcal disease but does not prevent pneumococcal colonization or acute otitis media. Therefore, it is uncertain, theoretically, whether PPSV23 in children with implants would prevent meningitis attributable to pneumococcal infections that originate in the middle ear and cause meningitis by contiguous spread of bacteria. There are no data on the efficacy of PCV7 or PPSV23 in prevention of pneumococcal meningitis in children with cochlear implants, but there are immunogenicity data. A single dose of PCV7 in children 14 months through 5 years of age with cochlear implants induced a substantial immune response with mean 12-fold and 7.8-fold increases in anticapsular antibody concentration to the 7 serotypes in the vaccine in children 14 months to 2 years of age and children 2 through 5 years of age, respectively. Among children 2 through 5 years of age, a single dose of PCV7 was more immunogenic than a single dose of PPSV23 for the 7 serotypes in PCV7. PPSV23 was immunogenic in children older than 5 years, adolescents, and young adults; there was a mean 4.2-fold increase in anticapsular antibody concentration to the 7 PCV7 serotypes. The distribution of serotypes of S pneumoniae causing meningitis in implant recipients is unknown but is assumed to be the same as in children without cochlear implants. On February 24, 2010, a 13-valent pneumococcal conjugate vaccine (PCV13) was licensed by the FDA on the basis of safety and immunogenicity. This vaccine contains polysaccharides of the 7 serotypes in PCV7 and polysaccharides from 6 additional serotypes. It has not been studied in children with cochlear implants or in children older than 71 months. This vaccine replaces PCV7 for all scheduled doses of PCV7 in infants. In addition, a supplemental dose of PCV13 is recommended for children 14 months through 18 years of age with a cochlear implant. H influenzae type b conjugate vaccine (Hib) is highly effective for prevention of invasive disease and colonization with this pathogen and, presumably, is effective for prevention of acute otitis media attributable to H influenzae type b. Cochlear implant recipients have anticapsular antibody concentrations to H influenzae type b after immunization that are likely to be protective. Hib vaccine does not prevent colonization or infection with non-serotype b strains; most H influenzae strains that cause acute otitis media are nontypeable strains, as were the isolates from most cases of H influenzae meningitis in implant recipients.

RECOMMENDATIONS

US Preventive Services Task Force Ratings criteria were used to assess the strength of evidence for recommendations. All of the recommendations were classified as “I” indicating insufficient evidence except where a different rating (ie, ratings A, B, C, or D) is noted after the statement (see Appendix).

1. Evaluations and Management Before or During Insertion of Cochlear Implant

● Imaging of the temporal bone/inner ear should be performed before cochlear implantation in all children with congenital deafness and all patients with profound hearing impairment and a history of bacterial meningitis (if not known to have normal hearing before meningitis) to identify those with inner-ear malformations/CSF fistulas or ossification of the cochlea. In patients with inner-ear malformations that are associated with a higher likelihood of CSF fistulas after cochlear implantation (eg, wide vestibular aqueduct syndrome or Mondini malformation), particular attention must be paid to sealing the cochleostomy during the cochlear implant surgery to further lower the risk of developing bacterial meningitis.

● For otitis-prone children or children with persistent middle-ear effusion, tympanostomy tube placement should be considered before cochlear implantation.

2. Primary and Secondary Prevention of Meningitis and Acute Otitis Media

● All children, including those with severe hearing impairment or infants with profound deafness, should receive all doses of PCV13 (or PCV7 if PCV13 is not yet available) and Hib, according to the routine recom
A single supplemental dose of PCV13 should be administered to children 14 months through 71 months who have been fully immunized with PCV7. A supplemental dose is unnecessary if the fourth dose of pneumococcal conjugate vaccine given at 12 months of age or older was PCV13.

- A single dose or supplemental dose of PCV13 may be administered to pediatric patients 6 through 18 years of age who have a cochlear implant or are scheduled to receive a cochlear implant regardless of previous doses of PCV7 and PPSV23.

- When assessing a history of previous immunization with pneumococcal vaccines, care should be exercised to avoid confusing past immunization with other vaccines that could be considered “meningitis vaccines” (ie, Hib and quadrivalent meningococcal polysaccharide or conjugate vaccines) with doses of PCV7 and PPSV23.

- Meningococcal conjugate vaccine should be administered in accordance with routine recommendations, but given current data, cochlear implant recipients should not be considered a group at high risk of invasive meningococcal disease. Therefore, children younger than 11 years should not be immunized routinely.

- In most studies, administration of influenza vaccine to healthy children reduced the incidence of episodes of acute otitis media during influenza season. To reduce the number of episodes of acute otitis media, annual administration of influenza vaccine with trivalent inactivated vaccine or live attenuated nasal vaccine (if the child has no condition that constitutes a medical contraindication) to patients with a cochlear implant is recommended, and influenza immunization of their household contacts should be strongly considered.

- Tymanostomy tube placement also should be considered if recurrent episodes of acute otitis media occur after cochlear implantation.

3. Management of Postoperative Wound Infection or Suspected Cochlear Implant Infection

- Patients with suspected postoperative wound infection or suspected implant infection should be referred urgently to the surgeon who performed the implant procedure. Broad-spectrum antimicrobial therapy that includes an agent or agents with activity against methicillin-susceptible and methicillin-resistant Staphylococcus aureus should be initiated.

4. Early Diagnosis of Acute Otitis Media and Meningitis

- Patients and parents should be educated as to symptoms of acute otitis media and meningitis and to seek immediate medical evaluation for acute illness with symptoms possibly attributable to either acute otitis media (eg, fever or earache) or meningitis (eg, fever, headache, vomiting, stiff neck, or change in level of consciousness).

- Clinicians should consider bacterial meningitis in the differential diagnosis of all patients with cochlear implants who present with fever with or without acute otitis media on physical examination, particularly during the first 2 years after implantation in patients with cochlear implants without positioners and indefinitely in patients with cochlear implants placed between 1999 and August 2002 with positioners (Advanced Bionics model AB-5100H or AB-5100H-11).

5. Management of Acute Otitis Media in Children With Cochlear Implants

- Patients with cochlear implants who are diagnosed with acute otitis media should be started urgently on systemic antimicrobial therapy; watchful waiting is inappropriate for these children. Initial empiric treatment...
with an oral antimicrobial agent (eg, amoxicillin or amoxicillin/clavulanate, at a dose of 80–90 mg/kg per day) is reasonable if all of the following criteria are fulfilled: (1) the episode occurs 2 or more months after cochlear implantation; (2) the patient does not have an uncorrected Mondini or similar inner-ear malformation or CSF/middle-ear fistula; (3) the patient does not appear severely ill and there is no clinical evidence of mastoiditis or meningitis; and (4) the cochlear implant does not have a spacer/positioner (Advanced Bionics model AB-5100H or AB-5100H-11). Patients with acute otitis media who fulfill these criteria are likely to be at a lower risk of developing inner-ear infection or meningitis complicating acute otitis media. If feasible, middle-ear fluid should be obtained through the tympanostomy tube or a tympanocentesis or myringotomy for culture just before initiation of antimicrobial therapy, but this should not be allowed to cause an undue delay in initiation of antimicrobial therapy. For patients with a cochlear implant who do not meet these criteria (including patients with implants of an unknown type implanted between 1999 and August 2002), initial therapy with a parenteral antimicrobial agent for treatment of acute otitis media (eg, ceftriaxone or cefotaxime plus vancomycin) is similar to that for children without implants. An exception is for children with the onset of meningitis during the first 2 weeks after cochlear implantation; in such circumstances, causal bacteria may include a broader range of pathogens, including Gram-negative bacilli such as A baumannii and Gram-positive bacteria such as Enterococcus spp. Selection of a combination of agents that provide broader-spectrum activity against Gram-negative bacilli (eg, meropenem and vancomycin) should be considered. Patients with a cochlear implant and bacterial meningitis should be evaluated urgently by an otolaryngologist for consideration of imaging and surgical exploration.

6. Management of Bacterial Meningitis in Patients With a Cochlear Implant

- CSF should be submitted for culture. If present, middle-ear fluid should be obtained and sent for culture. The choice of empiric antimicrobial therapy for meningitis (eg, ceftriaxone or cefotaxime plus vancomycin) is similar to that for children without implants. An exception is for children with the onset of meningitis during the first 2 weeks after cochlear implantation; in such circumstances, causal bacteria may include a broader range of pathogens, including Gram-negative bacilli such as A baumannii and Gram-positive bacteria such as Enterococcus spp. Selection of a combination of agents that provide broader-spectrum activity against Gram-negative bacilli (eg, meropenem and vancomycin) should be considered. Patients with a cochlear implant and bacterial meningitis should be evaluated urgently by an otolaryngologist for consideration of imaging and surgical exploration.

REFERENCES

5. Miyamoto RT, Houston DM, Bergeson T Co-


## APPENDIX  Grading of Recommendations

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Recommended: there is high certainty that the net benefit is substantial.</td>
</tr>
<tr>
<td>B</td>
<td>Recommended: there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.</td>
</tr>
<tr>
<td>C</td>
<td>Recommendation against routinely providing; there may be considerations that support providing the service in an individual patient, and there is at least moderate certainty that the net benefit is small.</td>
</tr>
<tr>
<td>D</td>
<td>Recommends against the service: there is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.</td>
</tr>
<tr>
<td>I</td>
<td>The current evidence is insufficient to assess the balance of benefits and harms of the recommendation. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.</td>
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