15. OTITIS MEDIA
Lee Hilborne, M.D., and Cheryl Damberg, Ph.D.

OTITIS MEDIA WITH EFFUSION (SEROUS OTITIS MEDIA)

Quality indicators for otitis media were derived based on a review of the following sources: (1) a MEDLINE search of the English language medical literature from 1990 to 1995; (2) The AHCPR Clinical Practice Guideline on Otitis Media with Effusion in Young Children (Stool et al., 1994); (3) relevant references in articles identified by the medical literature search; and (4) a general pediatrics textbook (Williams, in Hoekelman et al., 1992). The review pertains to children 1 to 3 years of age.

IMPORTANCE

Second to respiratory tract infections, otitis media is the most common childhood disease. Williams (in Hoekelman et al., 1992) reports that approximately 75 percent of children will develop at least one episode of otitis media before the age of 10. The term otitis media refers to a broad range of clinical conditions, including acute middle ear infections (acute otitis media, purulent otitis media, suppurative otitis media), the accumulation of fluid in the middle ear (otitis media with effusion, serous otitis media), or both (Kemp, 1990). Table 15.1 defines the different otitis conditions.

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1This search yielded 70 references specifically addressing management of otitis media and the effectiveness of that management.
### Table 15.1

#### Classification of Otitis Media

<table>
<thead>
<tr>
<th>Clinical Terms</th>
<th>Synonyms and Definitions</th>
</tr>
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</table>
| Otitis media without effusion | Synonym: myringitis  
Presence of erythema and opacification of the tympanic membrane without the presence of an effusion. May be seen in the early states of acute otitis media or as otitis media resolves. |
| Acute otitis media (AOM) | Synonyms: Acute suppurative, purulent or bacterial otitis media  
Clinically identifiable infection of the middle ear. Recent, rapid onset of signs and symptoms associated with middle ear inflammation. |
| Otitis media with effusion (OME) | Synonyms: Secretory, nonsuppurative, serous or mucoid otitis media  
Otitis media without signs or symptoms of acute disease, but with the presence of a middle ear effusion. May be subdivided into acute, subacute, and chronic based on duration of effusion. |
| Chronic otitis media (COM) | Synonym: Chronic suppurative, purulent, or intractable otitis media  
Presence of pronounced intractable middle ear pathology with or without suppurative otorrhea. Suppurative refers to an active infection while otorrhea refers to a discharge through a perforated tympanic membrane. |


This review focuses on otitis media with effusion, a process that frequently follows acute otitis media. Stool et al. (1994) estimate otitis media with effusion represents 25 to 35 percent of all otitis media cases.

In 1990, there were 24.5 million physician visits with the diagnosis of otitis media. Of the total number of visits, children under age 15 accounted for 19.7 million visits (Schappert, 1992). For children younger than age 15, otitis media represented the most frequent diagnosis for physician visits (Schappert, 1992). According to Williams (in Hoekelman et al., 1992), young children are more prone to otitis media, especially those between 6 and 24 months of age. Although specific incidence rates vary, the Greater Boston Study found that more
than 60 percent of children had at least one episode of acute otitis media by age one; 80 percent had one episode by three years of age, and more than 40 percent had at least three episodes (Teele et al., 1989). The prevalence of otitis media by age group is shown in Table 15.2.

Table 15.2  
Prevalence of Otitis Media by Age

<table>
<thead>
<tr>
<th>Age</th>
<th>Prevalence</th>
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<tbody>
<tr>
<td>Neonate</td>
<td>0-12%</td>
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<tr>
<td>1 year</td>
<td>12%</td>
</tr>
<tr>
<td>2 years</td>
<td>7-12%</td>
</tr>
<tr>
<td>3-4 years</td>
<td>12-18%</td>
</tr>
<tr>
<td>5 years</td>
<td>4-17%</td>
</tr>
<tr>
<td>6-8 years</td>
<td>3-9%</td>
</tr>
<tr>
<td>9 years</td>
<td>0-6%</td>
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</tbody>
</table>


With respect to pediatric visits, otitis media was second only to well-child care as a reason for a physician visit (Schappert, 1992). Children under age two have the highest rate of visits to physician offices for otitis media (Stool et al., 1994; Schappert, 1992). Visits for otitis media are roughly the same for males and females. Approximately 25 percent of all prescriptions for children under age 10 are for oral antibiotics to treat otitis media (Bluestone, 1986). Berman (1995) notes that inappropriate antibiotic treatment of otitis media facilitates multidrug-resistant strains of bacterial pathogens. The estimated annual costs of medical and surgical treatment of otitis media range between $3 and $4 billion (Stool et al., 1994; Schappert, 1992).

Hearing loss is the most prevalent functional impairment resulting from otitis media. If hearing loss persists, evidence, although not entirely conclusive, suggests that patients may have impaired speech, hearing, and language development (Lous et al., 1988; Callahan and Lazoritz, 1988). These problems are most common when otitis media affects younger children.
EFFICACY AND/OR EFFECTIVENESS OF INTERVENTIONS

Screening

Although an ear examination is part of the recommended general pediatric history and physical examination, controversy remains regarding explicit screening for otitis media. Gates et al. (1989) recommend a screening battery when children enter school to guard against learning problems secondary to hearing loss. An abnormal screen exists when the middle ear pressure is more negative than -200 mm H\textsubscript{2}O and there is low compliance on tympanometry. Screen failure also exists when audiometric testing reveals inability to detect a 25 dB tone at 4,000 Hz. However, when otitis media with effusion is suspected, certain diagnostic tests are warranted. Furthermore, because otitis media with effusion frequently follows an episode of acute otitis media, diagnostic tests are recommended for these patients.

Diagnosis

Otitis media with effusion may be asymptomatic or patients may experience ear discomfort, hearing loss, tinnitus, possibly vertigo, or a feeling of ear fullness. Diagnostic tests include otoscopy (viewing the tympanic membrane with illumination) and pneumatic otoscopy (otoscopy viewing the tympanic membrane with small amounts of positive and negative air pressure). The AHCPR Guideline panel strongly recommended the use of pneumatic otoscopy as the diagnostic evaluation tool for suspected otitis media with effusion, because pneumatic otoscopy can suggest the presence of effusion, even when visual inspection of the eardrum (i.e., otoscopy alone) gives no indication of middle ear pathology (Stool et al., 1994). Based on limited scientific evidence and expert opinion, tympanometry may be useful to confirm the diagnosis of otitis media with effusion, with the inference that this technique is more reliable than audiometry alone (Gates et al., 1989; Kemp, 1990).

Hearing loss evaluation may be beneficial early in the disease process (i.e., in the first 3 months of disease) and, based on expert opinion and limited scientific evidence, is recommended for a child who has bilateral otitis media with effusion for a total of three months.
Tympanometry is neither an appropriate nor reliable predictor of hearing impairment (Stool et al., 1994), given that its positive predictive value for hearing loss can be as low as 49 percent.

**Treatment**

The antibiotic treatment of otitis media with effusion remains controversial because most cases of otitis media resolve without any intervention within 3 months (Zielhuis et al., 1990; Stool et al., 1994). Furthermore, there is a lack of consensus in the literature with respect to the efficacy of antibiotics for otitis media with effusion. (Mandel et al., 1987; Cantekin et al., 1991). Most studies conclude that antibiotics have a small but significantly positive effect on the resolution of otitis media with effusion.

Williams et al. (1993) completed a meta-analysis of the literature and demonstrated that antibiotics provided benefit in the short-term treatment of otitis media with effusion (relative difference = 0.16; 95 percent confidence interval = 0.03 to 0.29). However, long-term benefit was not found when comparing the use of antibiotics to placebo (relative difference = 0.06; confidence interval = -0.03 to 0.14). Rosenfeld and Post (1992), also by meta-analysis, found that antibiotics favor more rapid resolution of serous otitis media and recommend their use in otitis media with effusion patients. AHCPR’s meta-analysis showed a 14 percent increase in the probability that otitis would resolve when antibiotic therapy was given versus no treatment (Stool et al., 1994).

During the initial management period (up to 12 weeks), observation of the otherwise healthy child with a unilateral effusion is the treatment of choice (Berman et al., 1994). Myringotomy, with or without insertion of tympanostomy tubes, is not recommended for initial management of otitis media with effusion in an otherwise healthy child (Stool et al., 1994). Early antibiotic therapy is also an option and should be more strongly considered in the following situations:

- bilateral serous otitis media, particularly when accompanied by a hearing loss;
- very young infants unable to verbalize complaints;
• in association with a purulent upper respiratory infection;
• when the tympanic membrane or middle ear appear possibly damaged;
• when episodes frequently recur (i.e., three or more times); or
• in the presence of associated vertigo.

The choice of antibiotics is the same as those recommended for acute otitis media given that similar organisms are isolated from both disease processes. Recommended antibiotics include, among others:

1) Amoxicillin (Pukander et al., 1993; Mandel et al., 1991)
2) Amoxicillin-clavulanate (McCarty et al., 1993);
3) Cefaclor (Mandel et al., 1991);
4) Cefuroxime axetil (McLinn et al., 1994);
5) Cefixime (Asmar et al., 1994);
6) Erythromycin-sulfisoxazole (Mandel et al., 1991);
7) Trimethoprim-sulfamethoxazole (Daly et al., 1991); and
8) Clarithromycin (Pukander et al., 1993; Mandel et al., 1991).

Evidence from cohort studies suggests that second hand smoke (i.e., passive smoke) may increase the likelihood of otitis media with effusion, although, at present, the data are not conclusive (Maw and Bawden, 1994; Maw et al., 1992). Nevertheless, given the overall health benefits to smoking cessation for both parents and children, parents who smoke should be advised to stop and referred to a smoking cessation program.

When considering treatment options for patients with uncomplicated otitis media with effusion, antihistamines, decongestants, and steroid therapy are contraindicated because they have not been shown to offer benefit, particularly given their associated risks such as central nervous system depression and steroid dependence (Estelle and Simons, 1994). The AHCPR clinical guideline also recommends against adenoidectomy and/or tonsillectomy for the treatment of otitis media with effusion (Stool et al., 1994).
Patients identified as having otitis media with effusion, whether treated or not, should be evaluated every 4-6 weeks to determine whether there is persistence or resolution of the process (Stool et al., 1994). Patients who have persistent bilateral otitis media with effusion (≥ 3 months in duration) should be evaluated for hearing loss. If hearing loss is not severe (less than 20 db in the best ear) and the disease is unilateral, continued observation or continuation/introduction of antibiotics is appropriate (Mandel et al., 1991). In the presence of a bilateral hearing deficit (defined as 20 decibels hearing threshold level or worse in the better-hearing ear), antibiotics or myringotomy with tympanostomy tube placement is recommended (Bluestone et al., 1986). However, 10 percent of children with otitis media with effusion will have persistent disease at three months and many of these cases will resolve without intervention (Stool et al., 1994). Some argue that tympanostomy tube placement is never appropriate treatment for otitis media with effusion in the absence of a significant hearing loss (Kleinman et al., 1994). In any case, placement of tympanostomy tubes as a first line of treatment is considered inappropriate (Kleinman et al., 1994).

At subsequent follow-up (about 4-6 months), if antibiotics have failed to resolve the effusion in patients with significant bilateral hearing loss (as defined above), placement of tympanostomy tubes is recommended (Stool et al., 1994). Patients with persistent otitis media with effusion should be evaluated for possible hearing loss (Stool et al., 1994).
**RECOMMENDED QUALITY INDICATORS FOR OTITIS MEDIA WITH EFFUSION**

These indicators apply to children ages 1-3 years.

### Diagnosis

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Quality of evidence</th>
<th>Literature</th>
<th>Benefits</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. All patients with the diagnosis of suspected otitis media with effusion should be evaluated with pneumatic otoscopy.</td>
<td>III</td>
<td>Stool et al., 1994</td>
<td>Prevent allergic reactions from antibiotics. Avoid unnecessary placement of tubes. Prevent antibacterial drug resistance.</td>
<td>Achieves better precision in making diagnosis. Reduces false positives and false negatives. Otoscopy alone is not recommended since visual inspection of the eardrum may give no indication of middle ear pathology. Inappropriate antibiotic treatment can lead to drug resistance.</td>
</tr>
<tr>
<td>2. Patients with persistent (≥3 months duration) bilateral otitis media with effusion should have a hearing evaluation.</td>
<td>II/III</td>
<td>Lous, 1988; Stool et al., 1994; Daly, 1982; Callahan &amp; Lazaritz, 1988</td>
<td>Prevent delayed language development and hearing loss.</td>
<td>Recommendation based on limited scientific evidence and expert opinion.</td>
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</tbody>
</table>

### Treatment

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>3. All patients with the diagnosis of otitis media with effusion should receive either: – antibiotics, or – trial of observation.</td>
<td>I, II/III</td>
<td>Stool et al., 1994; Mandel, 1987; Cantenkin, 1991; Williams, 1992; Behrman, 1992</td>
<td>Prevent hearing and language development problems. Minimize discomfort and behavior changes.</td>
<td>Most effusions spontaneously resolve by 3 months. Antibiotics are considered for treatment because studies show that in 27 to 50 percent of cases, aspirates contain bacteria or provide a medium for bacteria to grow. Meta-analysis showed a 14-percent increase in the probability that otitis would resolve when antibiotic therapy was given versus no treatment. Use of antibiotics must be weighed against the side effects and costs of treatment.</td>
</tr>
<tr>
<td>4. For all patients with a diagnosis of otitis media with effusion, during the initial management period (up to 12 weeks), myringotomy with or without insertion of tympanostomy tubes should not be performed in an otherwise healthy child (no other complications).</td>
<td>II</td>
<td>Stool et al., 1994</td>
<td>Prevent complications of surgery.* Prevent complications of anesthesia.** Prevent tympanosclerosis and persistent perforation.</td>
<td>Myringotomy at this stage has not been shown to be of benefit and may cause morbidity, such as external auditory canal wall laceration, persistent otorrhea, granuloma formation of the myringotomy site, cholesteatoma, and permanent membrane perforation.</td>
</tr>
</tbody>
</table>
5. All patients with the diagnosis of otitis media with effusion who have tympanostomy tubes should have a bilateral hearing loss (defined as 20 decibels hearing threshold level or worse in both ears) documented in the record. Because of risks associated with insertion of tympanostomy tubes and the lack of controlled studies documenting benefits, this procedure should be limited to children with more severe symptoms.

6. Patients with persistent otitis media with effusion (≥ 3 months duration) and hearing loss (bilateral hearing deficits of 20 decibels hearing threshold or worse) should receive:
   - oral antibiotic therapy if child has not been on antibiotics, or
   - a change in antibiotics, or
   - bilateral myringotomy with tube placement; and
   - environmental risk factor control counseling.

   Scientific evidence is limited to support recommendation of tube replacement; however, strong panel consensus exists. Exposure to cigarette smoke has been shown to increase risk of otitis media with effusion. The panel also noted that parents may wish to remove children from a child care facility.

7. Management of patients with otitis media with effusion for 4-6 months and a history of significant bilateral hearing loss (at least 20 decibels) and a failure of adequate antibiotic therapy should include:
   - bilateral myringotomy with tube placement, and
   - environmental risk factor counseling.

   Severity and duration of disease suggest intervention is warranted. Assumes failure of antibiotic therapy.

Follow-up

<table>
<thead>
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<tr>
<td>8. All patients identified as having otitis media with effusion must either have a recommendation for follow-up visit or have been seen for reevaluation within 8 weeks of diagnosis.</td>
<td>II/III</td>
<td>Lous, 1988; Stool et al., 1994; Daly, 1982</td>
<td>Prevent hearing loss and problems with language development.</td>
<td>The AHCPR Guideline recommends a six-week follow-up period. Eight weeks allows plans addition time to have accomplished follow-up.</td>
</tr>
</tbody>
</table>

*Complications of surgery include: external auditory canal wall laceration, persistent otorrhea, granuloma formation at the myringotomy site, cholesteatoma, and permanent tympanic membrane perforation. Structural changes in the tympanic membrane are also possible, especially with repeated tube insertions. The risk of repeated tube insertions has been estimated to be as high as 30 percent within 5 years of initial surgery.

**Complications of anesthesia include mortality, cardiac arrest, and allergic reactions.

Quality of Evidence Codes:

I: RCT
II-1: Nonrandomized controlled trials
II-2: Cohort or case analysis
II-3: Multiple time series
III: Opinions or descriptive studies
ACUTE OTITIS MEDIA

IMPORTANCE

This review focuses on acute otitis media (AOM), a process that frequently precedes otitis media with effusion (Fliss, et al., 1994). Recurrent acute otitis media is defined as repeated episodes of acute otitis, conventionally defined as three episodes of acute otitis media (Teele et al., 1989). The propensity for recurrent acute otitis media is associated with onset of disease before one year of age (Fliss et al., 1994). Persistent acute otitis media is defined as symptoms beyond six days of initiating therapy or recurrence within a few days of completing at least a 10 day course of antibiotics (Fliss et al., 1994). These children should be watched closely.

EFFICACY AND/OR EFFECTIVENESS OF INTERVENTIONS

Screening

Because acute otitis media is an acute episodic illness, screening for this process is not appropriate.

Diagnosis

Patients with acute otitis media usually experience some or all of the following symptoms often following an acute upper respiratory illness: ear pain (otalgia), fever (23 percent of patients) (Schwartz et al., 1981), and hearing loss. A suggestion of these symptoms by history or nondescript findings (Baker, 1991) provided by the parents or patient, such as irritability, lethargy, decreased appetite, vomiting, or diarrhea should result in an otoscopic examination to observe for redness and opacity, possibly with bulging of the tympanic membrane. In acute disease, the membrane will usually be less compliant and therefore less mobile on pneumatic otoscopy. The presence of a mucopurulent drainage (otorrhea) may occur should the tympanic membrane be ruptured or compromised by tympanostomy tubes.
Treatment

Initial treatment of acute otitis media is with antibiotics, although studies do suggest that there is a spontaneous cure rate, in some studies up to 80 percent (Haddad, 1994; Pichichero, 1994). The choice of antibiotics is the same as those recommended for otitis media with effusion because similar organisms are isolated from both disease processes. Recommended antibiotics include, among others:

1) Amoxicillin (Pukander et al., 1993; Mandel et al., 1991; Berman, 1995);
2) Amoxicillin-clavulanate potassium (McCarty et al., 1993);
3) Cefaclor (Mandel et al., 1991);
4) Cefuroxime axetil (McLinn et al., 1994);
5) Cefixime (Asmar et al., 1994);
6) Erythromycin-sulfisoxazole (Mandel et al., 1991);
7) Trimethoprim-sulfamethoxazole (Daly et al., 1991; Berman, 1995);
8) Clarithromycin (Pukander et al., 1993; Mandel et al., 1991);
9) Erythromycin (Berman, 1995) and;
10) Sulfisoxazole.

Most general discussions of the antimicrobial treatment of acute otitis media favor the use of amoxicillin in the child without allergy to penicillin drugs (Pichichero, 1994).

For patients who do not respond within the first two days of treatment (i.e., 48 hours), aspiration, both for diagnosis and therapy, should be considered; at the very least, the patient’s antibiotic coverage should be expanded to achieve broader coverage. The pediatrician should inform the parents to watch the child closely for either lack of resolution or progressive clinical signs (e.g., increasing lethargy) that may suggest extension of the disease. However, Berman (1995) notes that the effectiveness of antibiotics for acute otitis media is controversial, since in two-thirds of treated children the clinical signs and symptoms resolve without eradication of the middle-ear pathogen.
Follow-up Care

Once resolved, the child should be seen again to ensure that serous otitis media is not present. This evaluation should occur after the course of antibiotics is completed.
**RECOMMENDED QUALITY INDICATORS FOR ACUTE OTITIS MEDIA**

These indicators apply to children ages 1-3 years.

### Diagnosis

<table>
<thead>
<tr>
<th>Indicator</th>
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<th>Literature</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1. All children presenting to the clinician with fever, nonspecific behavioral changes (e.g., irritability, lethargy, decreased appetite, vomiting, diarrhea), or ear pain should receive an ear examination using a pneumatic otoscope.</td>
<td>III</td>
<td>Fliss et al., 1994; Howie et al., 1993</td>
<td>Prevent hearing loss and problems with language development from untreated infections.</td>
<td>In young children, fever and/or nonspecific complaints may be the only symptoms of ear infection. Pneumatic otoscopy is more informative than otoscopy alone as a diagnostic tool.</td>
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### Treatment

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>2. For all patients with the diagnosis of acute otitis media, at least 10 days of antibiotics should be prescribed.</td>
<td>III</td>
<td>Pichichero, 1994</td>
<td>Prevent hearing loss and problems with language development.</td>
<td>Treatment failure may be greater if the course of antibiotic therapy is less than 10 days.</td>
</tr>
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</table>

### Follow-up

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>3. Once a diagnosis of acute otitis media is made, follow-up chart review should document a return visit after the course of antibiotics within 8 weeks of diagnosis.</td>
<td>III</td>
<td>Berman, 1995</td>
<td>Prevent hearing loss and problems with language development.</td>
<td>Follow-up visit is necessary to determine whether inflammation of the tympanic membrane has resolved; persistent infection may not be symptomatic.</td>
</tr>
</tbody>
</table>

Quality of Evidence Codes:

I: RCT
II-1: Nonrandomized controlled trials
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