Clinical Guidelines And Primary Care

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Otitis Media With Effusion In Young Children: Treatment In Search Of A Problem?

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Family physicians and pediatricians see patients who have otitis media with effusion (OME), also known as serous otitis or "glue ear," on a daily basis. OME is a common sequela of acute otitis media, but the timing and appropriate types of intervention are subject to debate. Current practice includes observation only, treatment with antibiotics and decongestants, referral for ear tubes, and even adenoidectomy with or without tonsillectomy. Both the utility of these interventions for resolving OME and the value of resolving OME to prevent long-term complications, particularly compromised development of language skills, are uncertain.

Otitis Media with Effusion in Young Children. Clinical Practice Guideline[1] addresses these and related issues. A consortium of the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Academy of Otolaryngology-Head and Neck Surgery under contract with the Agency for Health Care and Policy Research (AHCPR) convened an expert panel to produce the guideline. On the basis of limited evidence and expert opinion, the panel recommended that antibiotics or insertion of ear tubes (if a hearing deficit exists) be offered to children whose OME has not resolved by 3 months and that children with hearing deficits of 20 dB or more receive ear tubes by 4 to 6 months. We advise physicians to question both recommendations. Figure 1 displays the practice algorithm published as part of the *Clinical Practice Guideline* and incorporates its recommendations.

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We based our review on the published *Clinical Practice Guideline*, research reports used to derive the panel recommendations, research reports not considered by the panel, one author's (LC) personal participation on the panel, and clinical practice experience. Presentation and discussion (by LC) of the guideline at a Hastings Center for Ethics meeting further enriched this review. In the following sections we present a summary of the content of the report and conclude with our critique of the guideline.

Importance of the Problem

Otitis media with effusion is one of the most common reasons for prescribing antibiotics to children and the most common reason for a surgical procedure. The number of visits to physicians for otitis media, including both acute otitis media and OME, increased from 9.9 million in 1975 to 24.5 million in 1990.[2] The AHCPR panel estimated that 25 to 35 percent of these cases represented OME. Visits to pediatricians accounted for 56.4 percent of otitis media visits; those to family physicians and general practitioners 30.4 percent. Only 7.2 percent of otitis media visits were to otolaryngologists (percentage obtained from a special analysis at our request by the National Center for Health Statistics using National Ambulatory Medical Care Survey data).

The US Food and Drug Administration found that about 14 percent of all courses of antibiotics prescribed in the United States were for otitis media. In 1986, 44.5 million courses were prescribed for children 10 years old or younger for otitis media, constituting 42 percent of all antibiotic prescriptions they received.[3] Using federal data, one recent estimate is that approximately 800,000 children received 1.3 million tympanostomy tubes in 1988. Of these, 30 percent were replacements.[4] In 1986, 31 million visits to physicians were due to otitis media, and

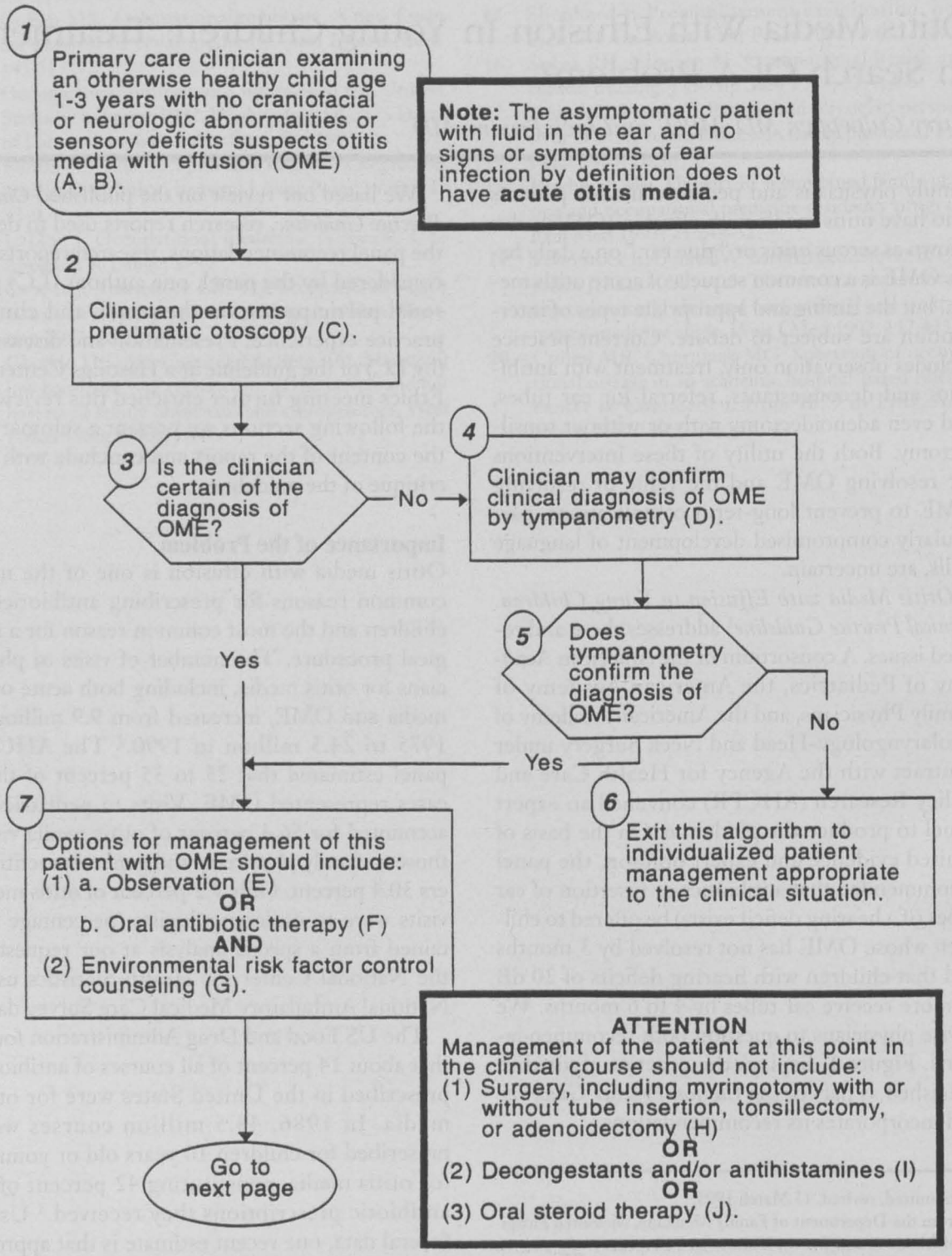


Figure 1. Algorithm for managing otitis media with effusion in an otherwise healthy child aged 1 through 3 years.[1]

Figure 1 (continued)

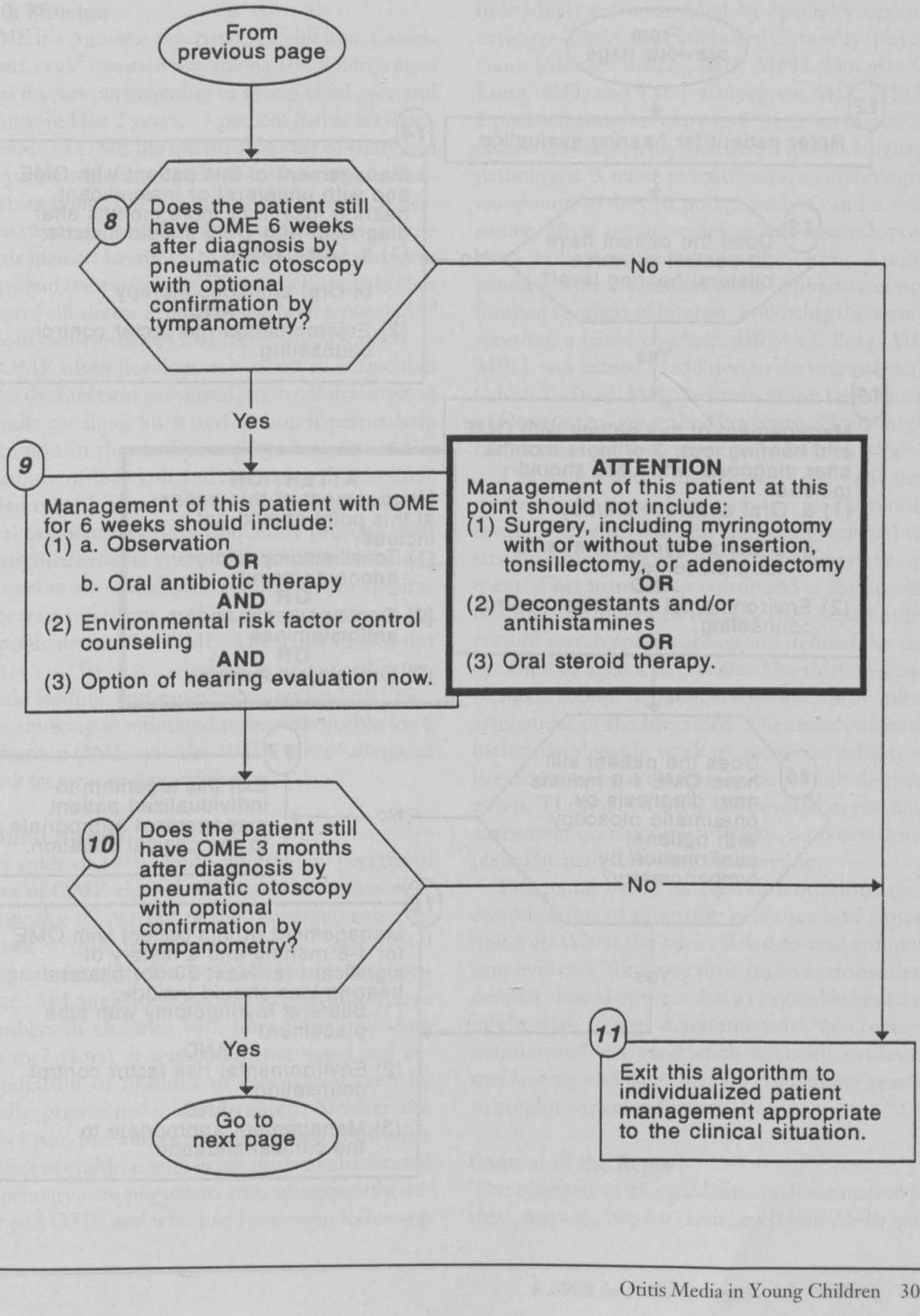
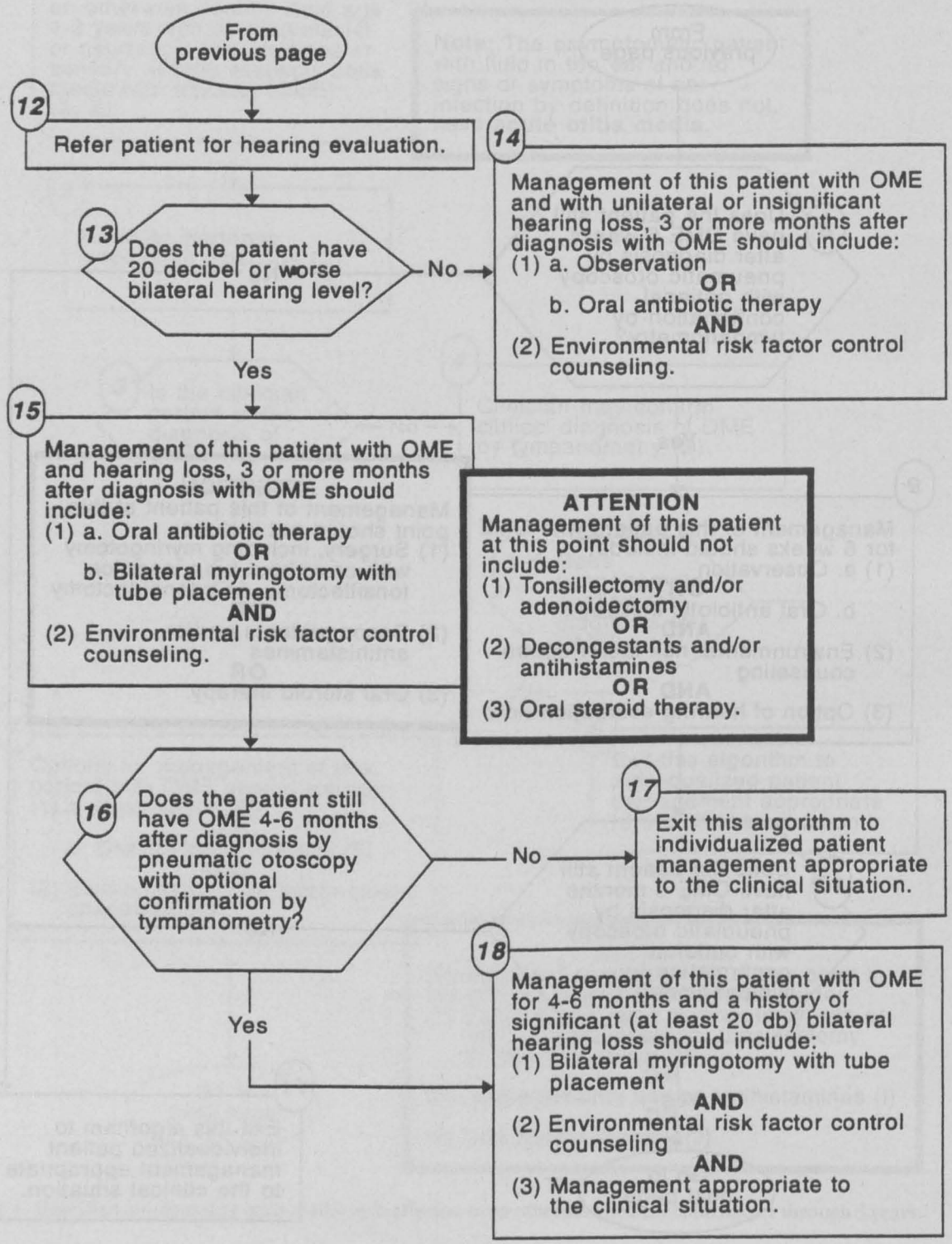


Figure 1 (continued)



the total direct and indirect costs for that year have been estimated at $3.5 billion.[5] Surgical costs for procedures for otitis media exceed $1.2 billion annually.[6]

Prevalence and Epidemiology of Otitis Media with Effusion

OME is a common experience for children. Casselbrant, et al.[7] reported that among 103 children aged 2 to 6 years participating in group child care and monitored for 2 years, 53 percent had at least one episode of OME during the first year of study and 61 percent in the second year; 30 percent had recurrent bouts. OME is present in at least 20 percent of cases 2 months following an attack of acute otitis media.[1] In studies that used pneumatic otoscopy and tympanometry to detect effusion, higher rates of effusion at 2 months have been reported.[1,8,9] About two-thirds of OME occurs bilaterally.[10]

OME often develops as a result of eustachian tube dysfunction preventing normal drainage of middle ear fluid. Such dysfunction is particularly common in those of young age because of the anatomy of the skull and diameter of the eustachian tube. Upper respiratory tract infections of viral or bacterial origin frequently precede both acute otitis media and OME. Children in environments associated with frequent upper respiratory tract infections, such as day-care settings, are at particular risk for OME. The panel singled out other risk factors including male sex, siblings, bottle feeding, and supine position feeding.[1] Passive smoking is estimated to be responsible for 8 percent of OME episodes.[11] The role of allergy as a risk factor is undetermined.

Natural History

In a study of 1439 Dutch children, 60 percent of cases of OME cleared without intervention after 3 months; 60 percent of the remaining cases resolved within another 3 months.[7] The panel adopted this duration of OME as the best estimate. Although the Dutch study involved large numbers of children with long-term follow-up (up to 7 years), it was population based and extrapolation of findings to individuals seen by family physicians is unwarranted. Neither the panel nor the authors were able to find large studies of children with acute otitis media treated by primary care physicians who subsequently developed OME and who had long-term follow-up without treatment. The natural history of this group of children, therefore, is unknown.

The Guideline Development Process

With AHCPR approval, the consortium convened an interdisciplinary panel selected from individuals recommended by specialty organizations. The panel included 3 family physicians (Alfred O. Berg, MD, MPH, Douglas G. Long, MD, and Larry Culpepper, MD, MPH), 2 pediatricians, 5 otolaryngologists, an infectious disease specialist, a psychologist, a speech-language pathologist, 3 nurse practitioners, an audiologist, an economist-health policy analyst, and a consumer. Most are in academic and research positions. Following the first panel meeting, 2 initial panelists were replaced because of pharmaceutical funding conflicts of interest. Following the second meeting, a panel co-chair, Alfred O. Berg, MD, MPH, was named in addition to the original chair, Sylvan E. Stool, MD, chairman of the Department of Otolaryngology at the University of Pittsburgh, the location of the controversial Cantekin Affair.[12]

The panel held 5 meetings. At the first, they narrowed the general topic of otitis media to otitis media with effusion, and the panel received instructions in evidence-based guideline development. This instruction continued at the second meeting, during which the panel developed its literature search specifications and defined the target child as aged 1 to 3 years. The third meeting included receipt of public testimony and an initial assessment of the literature. The fourth meeting included subgroup work to assess the validity of literature to be included in the panel's deliberations. The final meeting was devoted to reaching agreement on recommendations, a process completed by mail following the meeting.

The panel based its recommendations on a combination of scientific evidence and expert opinion. When the panel failed to find compelling evidence for or against interventions, they defined clinical options that a reasonable clinician might wish to use. A statement of "No recommendation" was used when scientific evidence was lacking and there was no compelling reason to employ expert judgment.

Content of the Report

The contents of the guideline is disseminated in three formats, two for clinicians (*Otitis Media with*

Effusion in Young Children. Clinical Practice Guideline[1] and *Managing Otitis Media with Effusion in Young Children. Quick Reference Guide for Clinicians*[13]) and the third for parents (*Middle Ear Fluid in Children. Parent Guide*).[14] The panel divided the *Clinical Practice Guideline* into chapters that address major issues involved in the diagnosis and treatment of OME. Additional chapters summarize recommendations and discuss costs and research issues.

The interventions considered by the panel include treatment with antibiotics, antibiotics plus steroids, steroids alone, antihistamines with or without decongestants, and the surgical procedures of myringotomy with tympanostomy tubes insertion, adenoidectomy, and tonsillectomy. The guideline also addresses other therapies and includes recommendations to parents regarding environmental modifications.

Target Child Defined

The target child is "age 1–3 years with no craniofacial or neurologic abnormalities or sensory deficits, otherwise healthy except for otitis media with effusion." It is this age group for which there is concern that impaired hearing as a result of bilateral otitis media with effusion might compromise speech and language development. Physicians and parents must use their own judgment in assessing the applicability of the guideline to younger or older children.

Clinical Outcomes

The panel defined short- and long-term outcomes associated with either therapy or observation of OME. Short-term outcomes include either clearance or persistence of middle ear effusion with its impact on hearing; common and rare side effects of antibiotics, steroids, and antihistamine-decongestants; and risks of the surgical procedures including anesthetic risks, costs, and complications. Symptoms and associated quality-of-life issues were not considered.

The long-term outcomes of interest are those related to impaired hearing and the potential for abnormal speech and language development. The panel found only weak scientific evidence, which did not include any randomized control trials, for a connection between hearing loss due to OME and abnormal speech and language development. The panel based its assessment on the 14 studies it considered adequate. Meta-analysis of these 14 studies was not possible because of the diversity of measurement instruments used and lack of uniformity in data. The definitions of OME varied, and often hearing status assessment was lacking; instead investigators often used presence of effusion as a proxy for hearing loss. In addition, investigators used a variety of tests to assess language and speech status at outcome. Of the 14 studies, only four had a "no treatment" control group, the largest of which contained only 26 subjects.

Given the pervasive weakness of the literature, it is not surprising that, "In summary, the panel found that rigorous, methodologically sound research does not adequately support or refute the theory that untreated OME results in speech/language delays or deficit." It further found that (1) the OME-related level of hearing loss (if one exists) required to produce language and speech deficits is unknown; (2) the duration required for hearing loss to produce such deficits is unknown; and (3) whether these deficits are transient or are long-lasting is unknown.

Because of the weakness of the literature and disparate panel opinion, by majority vote the panel concluded that "the published data support the following trends: (1) a weak association between otitis media with effusion in early life and abnormal speech and language development of children younger than age 4 years; and (2) a weak association between early otitis media with effusion and delay in expressive language development and behavior (attention) in children over 4 years. The effects of OME on other hearing related domains are less clear." The *Clinical Practice Guideline* notes that available data "do not show a consistent effect of OME on language and/or learning once the disease process and its associated hearing loss have resolved," and, "there seems to be little long-term effect of OME that appears for the first time after age 3."

Diagnosis and Hearing Evaluation

A strong recommendation of the panel, based on limited scientific evidence and strong consensus, was that the diagnostic evaluation of suspected otitis media with effusion should include pneumatic otoscopy. "Otoscopy alone (without the use of pneumatic otoscopy to test tympanic membrane mobility) is not recommended."

In patients visiting otolaryngologists for whom myringotomy is planned, pneumatic otoscopy has a sensitivity of 85 to 90 percent and a specificity of 70 to 79 percent.[15] Although the sensitivity and specificity are the same in primary care populations, the prevalence of OME is lower, so the positive predictive value of pneumatic otoscopy is less.

The panel suggested that use of tympanometry as a confirmatory test for OME is a clinical option. The positive predictive value of a flat (type B) tympanogram is estimated at between 49 and 99 percent. This value is the likelihood that effusion is present, using myringotomy as the criterion standard. Given a positive predictive value of only 49 percent, less than one-half the children with an abnormal tympanogram have a hearing loss.[16,17] Thus, using a combination of pneumatic otoscopy and tympanometry to detect children with OME and associated hearing loss will yield a high rate of false positives, because many children with abnormal findings have no hearing deficiency. For this reason the panel recommended, based on limited scientific evidence and expert opinion, that hearing evaluation be performed for any child who has had bilateral OME for a total of 3 months and that such testing be an option among children who have OME for a shorter duration.

The panel noted also that, especially for young children, there are several methods of evaluating hearing and that such evaluation can be technically difficult. In addition, hearing testing might not be available in many primary care settings, especially in rural areas. Nevertheless, the panel recommended hearing testing because of the "firm belief that placement of tympanostomy tubes is not indicated when OME is unaccompanied by bilateral hearing impairment." Of note, the panel found no evidence on which to base its determination of the level of hearing impairment requiring intervention. It arbitrarily chose 20 dB or worse in both ears as the threshold.

Control of Environmental Factors

The panel found that several factors amenable to change increase the chance that a child will develop OME including (1) bottle feeding, particularly in a supine position; (2) passive smoking; and (3) enrollment in group child care. The panel found no evidence that intervening to decrease these exposures makes a clinically important difference. Consequently, it proposed as a clinical option, based on limited scientific evidence and strong panel consensus, that "parents should be encouraged to control environmental risk factors."

Pharmaceutical Therapies

The panel concluded that antibiotics confer a 14 percent improvement within the first month, based on several meta-analyses that combined data from blinded randomized control trials of antibiotics. Their recommendation, based on limited and inconsistent scientific evidence and panel consensus, was "use of antibiotic agents is one option for the treatment of a child with otitis media with effusion." They noted that the small improvement in resolution of OME must be weighed against the side effects and costs of antibiotic therapy.

The panel found contradictory evidence between studies of steroid therapy alone, antibiotic plus steroid therapy, antibiotics alone, and placebos. Consequently, based on limited scientific evidence and majority opinion, the panel concluded that "steroid medications are not recommended for treatment of otitis media with effusion in a child of any age." The use of steroids in children recently exposed to varicella can lead to disseminated varicella with severe consequences.

The panel also made a strong recommendation, based on evidence that can be generalized to a child of any age, that "antihistamine and/or decongestant agents are not recommended for treatment of otitis media with effusion."

Surgical Therapies

The panel made three recommendations on insertion of tympanostomy tubes. First, they made a strong recommendation, based on evidence that OME resolves spontaneously in most cases, that "myringotomy with or without insertion of tympanostomy tubes should NOT be performed for initial management of otitis media with effusion in an otherwise healthy child."

Second, based on limited scientific evidence and panel consensus, they recommended that as a clinical option "antibiotic therapy OR bilateral myringotomy with insertion of tympanostomy tubes may be chosen to manage bilateral otitis media with effusion that has lasted a total of three

months in an otherwise healthy child age 1–3 years who has a bilateral hearing deficit (defined as 20 decibels hearing threshold level or less in the better-hearing ear)." In this matter, the *Clinical Practice Guideline* and the published algorithm conflict with the discussion in the *Quick Reference Guide for Clinicians*. While the *Clinical Practice Guideline* and the algorithm indicate that at 3 months the clinician must either use antibiotics or insert tubes, the *Quick Reference Guide* states, "Observation OR antibiotic therapy are treatment options for children with effusion that has been present less than 4 to 6 months and at any time in children without a 20-decibel hearing threshold level or worse in the better-hearing ear."

Third, it made a moderate recommendation, based on limited evidence and strong consensus, that "bilateral myringotomy with insertion of tympanostomy tubes is recommended to manage bilateral otitis media with effusion that has lasted a total of 4 to 6 months in an otherwise healthy child age 1 through 3 years who has a bilateral hearing deficit."

Tympanosclerosis occurs in 51 percent of patients following the initial insertion of tubes.[18,19] Additional complications include persistent otorrhea (in 13 percent) and more rarely, granuloma formation, cholesteotoma, and permanent tympanic membrane perforation. The panel noted that up to 30 percent of children receiving one set of tubes will receive a second set within 5 years and that structural changes, such as flaccidity, retraction, and tympanosclerosis, occur at increased rates with repeat surgery. The panel did not investigate the long-term effects, if any, on hearing later in childhood of having ear tubes as a young child.

The panel reviewed additional forms of surgery and, based on limited scientific evidence and strong panel consensus, recommended that adenoidectomy not be performed for OME in the absence of specific adenoid disease. The panel also recommended that "tonsillectomy should not be performed, either alone or with adenoidectomy, for the treatment of otitis media with effusion in a child of any age."

Allergy and Hyposensitization

Because of insufficient evidence clarifying the relation between allergy and OME, the panel concluded, "No recommendation is made regarding allergy management as a treatment for otitis media with effusion." Literature on the role of allergy hyposensitization as a treatment for OME is limited and flawed by weak research designs.

Other Therapies

Similarly, because of lack of scientific evidence, the panel concluded "No recommendation is made regarding other therapies (chiropractic, holistic, naturopathic, traditional or indigenous, homeopathic) for the treatment of otitis media with effusion in the otherwise healthy child age 1 to 3 years."

Cost Impacts

Through a series of extrapolations based on several large data sets, a contractor employed by the panel estimated the 1991 costs of treating OME, if the guideline had been implemented for all 2-year-old children. For this cohort, total costs would have been $246.6 million, of which $118.8 million was for medical care during the first 3 months of OME, $80.3 million for surgical treatments, $16.8 million for pharmaceutical costs, and $77.1 million for indirect costs.

Research Issues

The panel named priority issues for research. These issues include the natural history of OME; approaches to hearing evaluation; control of environmental risk factors; the role of antibiotics, steroids, allergy treatment and other therapies; and the impact of surgery, including on symptoms and quality of life.

Critique

The *Clinical Practice Guideline* can help physicians become aware of critical issues and approaches that might be useful for the care of their patients. There are areas, however, in which physicians should carefully examine the information presented and consult additional sources, because they could come to conclusions different from those reached by the panel.

Critical Issues

Perhaps most important is the controversy surrounding the hypothesized relation between effusion-related hearing deficit and compromised speech and language development. As the guideline notes, such an association has yet to be

proved or expressed in quantitative terms. If it exists, it is also necessary to determine the duration and magnitude of the required hearing loss and whether it needs to be intermittent or constant. Similarly the age during which effusion-related hearing loss is associated with impaired development of speech and language has not been ascertained. Finally, whether hypothesized deficits are transient, last through childhood, or are permanent is unknown. Although not explored by the panel, this controversy can be viewed as part of the larger debate about whether there are limited temporal windows of developmental opportunity for children that, if not used, permanently compromise human potential.

The absence of compelling published studies that document an association between OME and abnormal speech and language development does not prove that a causal association does not exist or that such a relation is unimportant. Several studies use the presence of effusion as a surrogate marker for hearing loss, which might result in the inclusion of a large number of children whose hearing is either normal or only mildly impaired. Consequently, analyses that fail to show an association might be flawed because only a minority of children in the sample have a serious OME-related hearing deficit with impaired speech and language development.

Another critical issue involves the narrow definition of the patient and the relevant outcomes. The target child as defined by the panel is a young child with a persistent middle ear effusion and no intervening recurrent episodes of acute otitis media. This case is not the otitis-prone child who seeks care for frequent repeat episodes of acute otitis for whom OME might be an important risk factor for recurrent infection. Instead, the target child is an "otherwise healthy," often asymptomatic child with effusion, which is usually detected either at follow-up for an episode of acute otitis media at a preventive health maintenance visit or as an incidental finding upon examination for other illness. The target child of the guideline also is not the older child with asymptomatic effusion detected serendipitously or following referral from school for hearing loss found on a screening examination. The major concern for the targeted child is the possibility that hearing loss during the first 2 to 3 years of life might affect speech and language development. For other groups of children there might be additional clinical concerns and outcomes of interest to the physician and family that influence treatment.

A third issue highlighted by the panel is the distinction between OME and hearing loss. The panel provides a valuable service by distinguishing these two conditions. Persistent effusion often occurs with little or no hearing deficit. Consequently, placement of tympanostomy tubes based on effusion alone will subject great numbers of children to needless surgery. The amount of effusion and consequent hearing deficit can wax and wane; therefore, a single test result below threshold for intervention could be false reassurance. The converse is also true; a single abnormal hearing test is insufficient evidence that the child has a persistent hearing deficit and is possibly at risk for abnormal speech and language development.

The Clinical Approach

The clinical approach outlined by the panel is of some value to physicians, even if the specific steps are questionable. The panel took into account the natural history of OME; even with no intervention 60 percent of children clear their effusion during every 3-month period of continued observation.[7] The panel recommended against tympanostomy tube insertion at the time OME is diagnosed. Instead, it recommended at least 3 months of observation before consideration of ear tubes and suggested that observation for a total of 4 to 6 months is appropriate. Second, the panel recommended a hearing evaluation before insertion of tympanostomy tubes. Because a great number of children with OME will have normal or only mildly impaired hearing, such testing frequently will prevent needless surgery. This recommendation is particularly important in light of the recent finding that 59 percent of surgeries for tube placement are for equivocal or inappropriate indications.[20] The panel's recommended timing for a hearing test is flawed. They recommended hearing assessment if bilateral effusion has persisted for 3 months. Because the purpose of a hearing test is to decide whether insertion of ear tubes is warranted, testing should be done immediately before a decision to insert tubes. A test done at 3 months is of no value if referral for ear tube insertion is delayed until 4 to 6 months.

Areas of Controversy

Perhaps one of the important insights gained from the *Clinical Practice Guideline* is that there is limited scientific evidence on which to base clinical care of children with OME. The panel based virtually all recommendations on expert opinion with limited or no scientific evidence. Such is the case not only for recommendations related to antibiotics and tympanostomy tubes placement, but even for whether hearing deficits secondary to OME are related to impaired speech and language development. In many instances the recommendations represented an action by majority vote of a panel with divergent opinions, rather than a consensus reached through discussion. The panel had only one meeting at which it arrived at most of its conclusions and was not subsequently assembled to discuss the draft of the final report. (Most panelists did not see the final version of the guideline publications before its public release.)

In several areas, the guideline is a product of the dichotomy between an interventionist approach to prevent a possible unproved problem and a prudent approach, which shuns interventions of unproved benefit, especially when those entail considerable cost and possible adverse effects. These conflicting views and the lack of true consensus are reflected in the language of the *Clinical Practice Guideline*. For instance, given the limited evidence of the efficacy of antibiotics, in the chapter on drug treatments the panel presented antibiotics as an option rather than a recommendation; however, in the chapter on surgical treatments and in the algorithm, it recommended that antibiotics be given to all children not receiving ear tubes by 3 months.

The *Parent Guide* provides a major disservice in one area. It recommends environmental modifications with little regard for whether parents can implement the recommendations. There is no evidence that such modifications will work; yet they might produce anxiety and guilt among parents who did not breast feed, who smoke, or who must work and place their child in day care. The *Parent Guide* contains two recommendations that conflict with both the panel discussions and available data. First, the *Parent Guide* advises parents to "Try to keep your child away from playmates who are sick" to prevent OME. There is no evidence that such isolation is useful; yet it can cause considerable difficulty for families. Second, for children who have had OME for at least 3 months, the *Parent Guide* recommends "Taking steps to prevent middle ear fluid (especially keeping your child away from cigarette smoke)." This advice suggests a basis of scientific evidence. While secondhand smoke has been implicated as a risk factor for OME, there has been no investigation of its role in persistence of OME and no evidence that removing this exposure will alter outcomes. The two presentations of this advice in the section on treatment could lead to family conflict or feelings of guilt, especially if the child subsequently receives tympanostomy tubes.

Areas of Clinical Uncertainty

There are at least two areas for which the *Clinical Practice Guideline* does not fully discuss information critical to a clinician's treatment decisions.

Evidence Regarding Outcomes Following Antibiotic Treatment of OME

Although the panel did discuss it, the *Clinical Practice Guideline* does not highlight consistent evidence that there is no difference between children who receive antibiotics and those who receive placebo as measured by persistent effusion or hearing deficit 2 to 4 months later. This equivalence was shown not only by meta-analyses conducted for the panel, but has been reported by others conducting similar analyses.[21] Thus the limited (14 percent, or 1 out of 6 children treated) benefit obtained for the 1 month highlighted in the *Clinical Practice Guideline* is transient. Given the cost and real potential for side effects, this additional evidence that any effect of antibiotics lasts for only 1 month should be included in a physician's decision of whether to use them.

Hearing Level Threshold for Intervention

A second area of clinical uncertainty, not explored by the panel, is the need to determine the magnitude of hearing impairment that presumably requires intervention. Without discussion of the issues involved, the panel adopted a 20-dB level of hearing loss in the better ear as the threshold for intervention. All children with OME for 4 to 6 months whose hearing loss is above this threshold are to receive tympanostomy tubes.

Yet this threshold is arbitrary and based on no evidence. Its adoption encourages a very aggres-

sive approach to placing ear tubes. To put this level in perspective, 25 to 30 dB is the level of the whispered voice and 50 to 60 dB is the level of average speech. Vowel sounds are louder, consonants are softer. Twenty-five to 40 dB is classified as mild hearing loss; 41 to 55 dB as moderate loss. For young children with permanent hearing loss, otolaryngologists might not recommend use of a hearing aid unless the level of loss in the better ear exceeds 30 to 35 dB. The panel's arbitrary choice of a level 10 dB less as the criterion upon which to recommend surgery is unwarranted.

Determination of the appropriate threshold for action is of substantial practical importance. Few studies have reported the distribution of hearing acuity in children with OME. Available studies, however, all have reported hearing acuity for most children to be in the range of no or mild loss (25 to 40 dB). For example, a study by Fria, et al.[10] used speech awareness threshold for infants 24 months or younger and speech reception threshold and pure tone audiology for children older than 24 months. They found that hearing acuity among children with OME did not change significantly with duration of OME. Using the distribution reported by Fria, et al., the panel's threshold will result in at least 56 percent of infants and 50 percent of children with OME persisting for 4 to 6 months being referred for surgery. If, instead, they used a 25-dB referral rate threshold, 41 percent of infants and 36 percent of children would be referred; for a 30-dB threshold this drops to 26 percent and 23 percent, respectively. For a 35-dB threshold, referral for surgery decreases to 18 percent and 14 percent, and for a 40-dB level (the upper limit of "mild loss"), it decreases to 11 percent and 4 percent, respectively. Thus, a shift upward of only 10 dB would decrease the number of children receiving ear tubes by more than 50 percent. An increase of 15 dB reduces by more than two-thirds the number of children receiving ear tubes.

Fria, et al.[10] studied children examined at an ear, nose, and throat clinic and found that the average hearing level in the better ear was 27.5 dB. In comparison, a large Dutch community study of children with OME, aged 2 to 4 years, reported an average hearing level of 20 dB (range 5 to 45 dB). Of note, this latter study assessed hearing on follow-up at age $7\frac{1}{2}$ to 8 years. For those whose ears had been free of OME at original assessment, the air conduction threshold was 5 dB; for those with OME treated without surgery, 7.8 dB; and for those that received ear tubes, 12.6 dB. Thus ear tubes themselves might result in an average long-term 5-dB loss, possibly caused by tympanosclerosis or other tympanic membrane changes.[22]

Summary

Ultimately, the physician making decisions regarding the care of a child with OME must realize that evidence required for rational care of children with OME is not yet available. We do not know the level or duration of OME-related hearing deficit, if any, that leads to clinically important speech and language development impairment, nor do we know the age and other characteristics of children vulnerable to such problems. If such developmental problems do occur, we do not know whether they are transient or permanent. The panel included a disproportionate number of otolaryngologist members, whose recommendations might have been driven by an interventionist mind-set. Were the panel to have been composed predominately of generalists and those with expertise in research methods, rather than representatives of disciplines that gain from an interventionist approach, it is likely that the limited scientific information available on OME would have resulted in a different set of recommendations. A careful reading of the *Clinical Practice Guideline*, supplemented by additional sources, indicates that a less aggressive approach is reasonable. The physician caring for a child with OME might find that symptoms, associated quality-of-life issues, and family preferences (issues not considered by the panel) all appropriately play an important role in determining treatment and that for the asymptomatic child with OME, no treatment might be the most appropriate decision.

References

1. Stool SE, Berg AO, Berman S, Carney CJ, Cooley JR, Culpepper L, et al. Otitis media with effusion in young children. Clinical practice guideline. Number 12. AHCPR Publication No. 94-0622. Rockville, MD: Agency for Health Care Policy and Research, Public Health Services, US Department of Health and Human Services, July 1994.
2. Schappert SM. National Ambulatory Medical Care Survey: 1991, summary. Advance data. Vital and Health Statistics. Hyattsville, MD: US Dept. of Health and Human Services, Public Health Service, 1992.

3. Teele DW, Klein JO, Rosner B. Epidemiology of otitis media during the first seven years of life in children in greater Boston: a prospective cohort study. J Infect Dis 1989; 160:83-94.
4. Bright RA, Moore RM, Jeng LL, Sharkness CM, Hamburger SE, Hamilton PM. The prevalence of tympanostomy tubes in children in the United States, 1988. Am J Public Health 1993; 83(7):1026-8.
5. Stool SE, Field MJ. The impact of otitis media. Pediatric Infec Dis J 1989; 8(1 Suppl):S11-4.
6. Grundfast K, Carney CJ. Otitis media in our society today. In: Grundfast K, Carney CJ. Ear infections in your child. Hollywood, FL: Compact Books, 1987:6-19.
7. Casselbrant ML, Brostoff LM, Cantekin EI, Flaherty MR, Doyle WJ, Bluestone CD, et al. Otitis media with effusion in preschool children. Laryngoscope 1985; 95:428-36.
8. Kaleida PH, Casselbrant ML, Rockette HE, Paradise JL, Bluestone CD, Blatter MM, et al. Amoxicillin or myringotomy or both for acute otitis media: results of a randomized clinical trial. Pediatrics 1991; 87:466-74.
9. Hendrickse WA, Kusmiesz H, Shelton S, Nelson JD. Five vs. ten days of therapy for acute otitis media. Pediatr Infect Dis J 1988; 7:17-23.
10. Fria TJ, Cantekin EI, Eichler JA. Hearing acuity of children with otitis media with effusion. Arch Otolaryngol 1985; 111:10-6.
11. Etzel RA, Pattishall EN, Haley NJ, Fletcher RH, Henderson FW. Passive smoking and middle ear effusion among children in day care. Pediatrics 1992; 90:228-32.
12. Rennie D. The Cantekin affair. JAMA 1991; 266:3333-7.
13. Stool SE, Berg AO, Berman S, Carney CJ, Cooley JR, Culpepper L, et al. Managing otitis media with effusion in young children. Quick reference guide for clinicians. AHCPR Publication No. 94-0623. Rockville, MD: Agency for Health Care Policy and Research, Public Health Services, US Department of Health and Human Services, July 1994.
14. Stool SE, Berg AO, Berman S, Carney CJ, Cooley JR, Culpepper L, et al. Middle ear fluid in young children. Parent guide. AHCPR Publication No. 94-0624. Rockville, MD: Agency for Health Care Policy and Research, Public Health Services, US Department of Health and Human Services, July 1994.
15. Kaleida PH, Stool SE. Assessment of otoscopists' accuracy regarding middle-ear effusion. Am J Dis Child 1992; 146:433-5.
16. Maw AR. Using tympanometry to detect glue ear in general practice: overreliance will lead to overtreatment. BMJ 1992; 304:67-8.
17. van Balen FAM, de Melker RA. Validation of a portable tympanometer for use in primary care. Int J Pediatr Otorhinolaryngol 1994; 29:219-25.
18. Lindholdt T. Ventilation tubes in secretory otitis media. A randomized, controlled study of the course, the complications, and the sequelae of ventilation tubes. Acta Otolaryngol (Stockh) 1983; 398(Suppl):1-28.
19. Maw AR. Development of tympanosclerosis in children with otitis media with effusion and ventilation tubes. J Laryngol Otol 1991; 105:614-7.
20. Kleinman LC, Kosecoff J, Dubois RW, Brook RH. The medical appropriateness of tympanostomy tubes proposed for children younger than 16 years in the United States. JAMA 1994; 271:1250-5.
21. Williams RL, Chalmers TC, Strange KC, Chalmers FT, Bowlin SJ. Use of antibiotics in preventing recurrent acute otitis media and in treating otitis media with effusion. A meta-analytic attempt to resolve the brouhaha. JAMA 1993; 270:1344-51.
22. Zielhuis GA, Rach GH, van den Broek P. The natural course of otitis media with effusion in preschool children. Eur Arch Otolaryngol 1990; 247:215-21.