Complete Summary

GUIDELINE TITLE

Otitis media with effusion.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Pediatrics Subcommittee on Otitis Media with Effusion. Otitis media with effusion. Pediatrics 2004 May;113(5):1412-29. [172 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

American Academy of Pediatrics (AAP) Policies are reviewed every 3 years by the authoring body, at which time a recommendation is made that the policy be retired, revised, or reaffirmed without change. Until the Board of Directors approves a revision or reaffirmation, or retires a statement, the current policy remains in effect.

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SCOPE

DISEASE/CONDITION(S)

Otitis media with effusion

GUIDELINE CATEGORY

Diagnosis
Evaluation

Management
Risk Assessment

CLINICAL SPECIALTY

Family Practice
Otolaryngology
Pediatrics
Speech-Language Pathology
Surgery

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians
Speech-Language Pathologists

GUIDELINE OBJECTIVE(S)

To inform clinicians of evidence-based methods to identify, monitor, and manage otitis media with effusion (OME) in children aged 2 months through 12 years

TARGET POPULATION

Children aged 2 months through 12 years with or without developmental disabilities or underlying conditions that predispose to otitis media with effusion (OME) and its sequelae

Note: The guideline may not apply to children more than 12 years old, because OME is uncommon and the natural history is likely to differ from younger children who experience rapid developmental change.

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Pneumatic otoscopy
2. Tympanometry
3. Population-based screening (considered but not recommended)
4. Documenting the laterality, duration of effusion, and presence and severity of associating symptoms at each assessment of children with otitis media with effusion (OME)
5. Distinguishing the child with OME at risk for speech, language, or learning problems from other children with OME and evaluating hearing, speech, language, and need for intervention more promptly

Management

1. Watchful waiting in children with OME who are not at risk

2. Antihistamines, decongestants, antimicrobials, and corticosteroids (considered but not recommended)
3. Hearing and language testing as needed
4. Re-examination of children who are not at risk at 3- to 6-month intervals
5. Referral to a specialist
6. Surgery as appropriate, including tympanostomy tube insertion; adenoidectomy, repeat surgery with adenoidectomy plus myringotomy, tonsillectomy alone or myringotomy alone

MAJOR OUTCOMES CONSIDERED

- Sensitivity, specificity, and predictive values of diagnostic tests
- Hearing loss
- Effects of otitis media with effusion (OME) on speech, language, and learning
- Physiologic sequelae of OME
- Health care utilization (medical, surgical)
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): In developing an evidence-based clinical practice guideline on managing otitis media with effusion (OME), the American Academy of Pediatrics (AAP), American Academy of Family Physicians, and American Academy of Otolaryngology-Head and Neck Surgery worked with the Agency for Healthcare Research and Quality (AHRQ) and other organizations. The most current literature on managing children with OME was reviewed, and research questions were developed to guide the evidence-review process. The AHRQ report on OME was prepared by the Southern California Evidence- Based Practice Center (EPC) and focused on key questions of natural history, diagnostic methods, and long-term speech, language, and hearing outcomes.

Searches were conducted through January 2000 in Medline, Embase, and the Cochrane Library. Additional articles were identified by review of reference listings in proceedings, reports, and other guidelines. EPC staff accepted 970 articles for full review after screening 3,200 abstracts. The EPC reviewed articles by using established quality criteria and included randomized trials, prospective cohorts, and validations of diagnostic tests (validating cohort studies).

The American Academy of Pediatrics (AAP) subcommittee on otitis media with effusion (OME) updated the Agency for Healthcare Research and Quality (AHRQ) review with articles identified by an electronic Medline search through April 2003 and with additional material identified manually by subcommittee members.

Copies of relevant articles were distributed to the subcommittee for consideration. A specific search for articles relevant to complementary and alternative medicine (CAM) was performed by using Medline and the Allied and Complementary Medicine Database through April 2003. Articles relevant to allergy and OME were identified by using Medline through April 2003.

NUMBER OF SOURCE DOCUMENTS

Total number of articles retrieved: 3,200 abstracts

Total number of articles accepted for full review after screening: 970

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Evidence Quality for Grades of Evidence

Grade A: Well-designed, randomized, controlled trials or diagnostic studies performed on a population similar to the guideline´s target population

Grade B: Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies

Grade C: Observational studies (case-control and cohort design)

Grade D: Expert opinion, case reports, or reasoning from first principles (bench research or animal studies)

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The AHRQ report on otitis media with effusion (OME) was prepared by the Southern California Evidence- Based Practice Center (EPC) and focused on key questions of natural history, diagnostic methods, and long-term speech, language, and hearing outcomes.

The EPC reviewed articles by using established quality criteria and included randomized trials, prospective cohorts, and validations of diagnostic tests (validating cohort studies).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus
Other

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The subcommittee met 3 times over a 1-year period, ending in May 2003, with interval electronic review and feedback on each guideline draft to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines. In May 2003, the Guidelines Review Group of the Yale Center for Medical Informatics used the Guideline Elements Model to categorize content of the present draft guideline. Policy statements were parsed into component decision variables and actions and then assessed for decidability and executability. Quality appraisal using established criteria was performed with Guideline Elements Model-Q Online. Implementation issues were predicted by using the Implementability Rating Profile, an instrument under development by the Yale Guidelines Review Group. Otitis media with effusion (OME) subcommittee members received summary results and modified an advanced draft of the guideline.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Guideline Definitions for Evidence-Based Statements

Strong Recommendation: A strong recommendation means that the subcommittee believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B)*. In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. *Implication*: Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

Recommendation: A recommendation means that the subcommittee believes that the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C)*. In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms. *Implication*: Clinicians also should generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.

Option: An option means that either the quality of evidence that exists is suspect (grade D)* or that well-done studies (grade A, B, or C)* show little clear advantage to one approach versus another. *Implication*: Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set boundaries on alternatives; patient preference should have a substantial influencing role.

No Recommendation: No recommendation means that there is both a lack of pertinent evidence (grade D)* and an unclear balance between benefits and

harms. *Implication*: Clinicians should feel little constraint in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

* Refer to "Rating Scheme for the Strength of the Evidence" field above for the definitions of evidence grades.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The final draft practice guideline underwent extensive peer review by numerous entities identified by the subcommittee. Comments were compiled and reviewed by the subcommittee cochairpersons.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The evidence grades (A-D) and evidence-based statements (Strong Recommendation, Recommendation, Option, and No Recommendation) are repeated at the end of the "Major Recommendations" field.

1A. Pneumatic Otoscopy: Clinicians should use pneumatic otoscopy as the primary diagnostic method for otitis media with effusion (OME), and OME should be distinguished from acute otitis media (AOM).
(This is a strong recommendation based on systematic review of cohort studies and the preponderance of benefit over harm).

*Aggregate evidence quality: **A**, diagnostic studies in relevant populations*
*Policy level: **strong recommendation***

1B. Tympanometry: Tympanometry can be used to confirm the diagnosis of OME.
(This option is based on cohort studies and a balance of benefit and harm.)

*Aggregate evidence quality: **B**, diagnostic studies with minor limitations*
*Policy level: **option***

1C. Screening: Population-based screening programs for OME are not recommended in healthy, asymptomatic children.
(This recommendation is based on randomized, controlled trials and cohort studies, with a preponderance of harm over benefit.)

*Aggregate evidence quality: **B**, randomized, controlled trials with minor limitations and consistent evidence from observational studies*
*Policy level: **recommendation against***

2. **Documentation**: Clinicians should document the laterality, duration of effusion, and presence and severity of associated symptoms at each assessment of the child with OME.
   (This recommendation is based on observational studies and strong preponderance of benefit over harm.)

   *Aggregate evidence quality: **C**, observational studies*
   *Policy level: **recommendation***

3. **Child at Risk**: Clinicians should distinguish the child with OME who is at risk for speech, language, or learning problems from other children with OME and should evaluate hearing, speech, language, and need for intervention more promptly.
   (This recommendation is based on case series, the preponderance of benefit over harm, and ethical limitations in studying children with OME who are at risk.)

   *Aggregate evidence quality: **C**, observational studies of children at risk; **D**, expert opinion on the ability of prompt assessment and management to alter outcomes*
   *Policy level: **recommendation***

4. **Watchful Waiting**: Clinicians should manage the child with OME who is not at risk with watchful waiting for 3 months from the date of effusion onset (if known) or diagnosis (if onset is unknown).
   (This recommendation is based on systematic review of cohort studies and the preponderance of benefit over harm.)

   *Aggregate evidence quality: **B**, systematic review of cohort studies*
   *Policy level: **recommendation***

5. **Medication**: Antihistamines and decongestants are ineffective for OME and are not recommended for treatment; antimicrobials and corticosteroids do not have long-term efficacy and are not recommended for routine management.
   (This recommendation is based on systematic review of randomized, controlled trials and the preponderance of harm over benefit.)

   *Aggregate evidence quality: **A**, systematic review of well-designed, randomized, controlled trials*
   *Policy level: **recommendation against***

6. **Hearing and Language**: Hearing testing is recommended when OME persists for 3 months or longer or at any time that language delay, learning problems, or a significant hearing loss is suspected in a child with OME; language testing should be conducted for children with hearing loss.
   (This recommendation is based on cohort studies and the preponderance of benefit over risk.)

*Aggregate evidence quality: **B**, diagnostic studies with minor limitations; **C**, observational studies*
*Policy level: **recommendation***

7. **Surveillance**: Children with persistent OME who are not at risk should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.
(This recommendation is based on randomized, controlled trials and observational studies with a preponderance of benefit over harm.)

*Aggregate evidence quality: **C**, observational studies and some randomized trials*
*Policy level: **recommendation***

8. **Referral**: When children with OME are referred by the primary care clinician for evaluation by an otolaryngologist, audiologist, or speech-language pathologist, the referring clinician should document the effusion duration and specific reason for referral (evaluation, surgery) and provide additional relevant information such as history of acute otitis media (AOM) and developmental status of the child.
(This option is based on panel consensus and a preponderance of benefit over harm.)

*Aggregate evidence quality: **C**, observational studies*
*Policy level: **option***

9. **Surgery**: When a child becomes a surgical candidate, tympanostomy tube insertion is the preferred initial procedure; adenoidectomy should not be performed unless a distinct indication exists (nasal obstruction, chronic adenoiditis). Repeat surgery consists of adenoidectomy plus myringotomy, with or without tube insertion. Tonsillectomy alone or myringotomy alone should not be used to treat OME.
(This recommendation is based on randomized, controlled trials with a preponderance of benefit over harm.)

*Aggregate evidence quality: **B**, randomized, controlled trials with minor limitations*
*Policy level: **recommendation***

10. **Complementary and Alternative Medicine (CAM)**: No recommendation is made regarding complementary and alternative medicine (CAM) as a treatment for OME.
(There is no recommendation based on lack of scientific evidence documenting efficacy and an uncertain balance of harm and benefit.)

*Aggregate evidence quality: **D**, case series without controls*
*Policy level: **no recommendation***

11. **Allergy Management**: No recommendation is made regarding allergy management as a treatment for OME.

(There is no recommendation based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME.)

*Aggregate evidence quality: **D**, case series without controls*
*Policy level: **no recommendation***

Definitions:

Evidence-Based Statements

Strong Recommendation: A strong recommendation means that the subcommittee believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B)*. In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. *Implication*: Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

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Grade C: Observational studies (case-control and cohort design)

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations contained in the practice guideline are based on the best available published data through April 2003. Where data are lacking, a combination of clinical experience and expert consensus was used. The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Pneumatic Otoscopy: improved diagnostic accuracy; inexpensive equipment
- Tympanometry: increased diagnostic accuracy beyond pneumatic otoscopy; documentation
- Screening: potentially improved developmental outcomes, which have not been demonstrated in the best current evidence
- Documentation: defines severity, duration has prognostic value, facilitates future communication with other clinicians, supports appropriate timing of intervention, and, if consistently unilateral, may identify a problem with specific ear other than otitis media with effusion (OME) (e.g., retraction pocket or cholesteatoma).
- Child at Risk: optimizing conditions for hearing, speech, and language; enabling children with special needs to reach their potential; avoiding limitations on the benefits of educational interventions because of hearing problems from OME.
- Watchful Waiting: avoid unnecessary interventions, take advantage of favorable natural history, and avoid unnecessary referrals and evaluations
- Medication: avoid side effects and reduce cost by not administering medications; avoid delays in definitive therapy caused by short-term improvement then relapse
- Hearing and Language: to detect hearing loss and language delay and identify strategies or interventions to improve developmental outcomes
- Surveillance: avoiding interventions that do not improve outcomes.
- Referrals: better communication and improved decision-making
- Surgery: improved hearing, reduced prevalence of OME, reduced incidence of acute otitis media, and less need for additional tube insertion (after adenoidectomy)
- Complementary and Alternative Medicine (CAM): not established
- Allergy Management: not established

POTENTIAL HARMS

- Pneumatic Otoscopy: cost of training clinicians in pneumatic otoscopy
- Tympanometry: acquisition cost, administrative burden, and recalibration
- Screening: inaccurate diagnosis (false-positive or false-negative), overtreating self-limited disease, parental anxiety, cost of screening, and/or unnecessary treatment
- Documentation: administrative burden
- Child at Risk: cost, time, and specific risks of medications or surgery
- Watchful Waiting: delays in therapy for otitis media with effusion (OME) that will not resolve with observation; prolongation of hearing loss
- Medication: adverse effects of specific medications: side effects of antihistamines and decongestants include insomnia, hyperactivity, drowsiness, behavioral change, and blood-pressure variability; side effects of antimicrobials may include rashes, vomiting, diarrhea, allergic reactions, alteration of the child's nasopharyngeal flora, societal impact of antimicrobial therapy on bacterial resistance and transmission of resistant pathogens, and cost; oral steroids can produce behavioral changes, increased appetite, weight gain, adrenal suppression, fatal varicella infection, and avascular necrosis of the femoral head
- Hearing and Language: parental anxiety, direct and indirect costs of assessment, and/or false-positive results
- Surveillance: allowing structural abnormalities to develop in the tympanic membrane, underestimating the impact of hearing loss on a child, and/or failing to detect significant signs or symptoms that require intervention
- Referrals: confidentiality concerns, administrative burden, and/or increased parent or caregiver anxiety
- Surgery: risks of anesthesia and specific surgical procedures; sequelae of tympanostomy tubes
- Complementary and Alternative Medicine (CAM): potentially significant depending on the intervention
- Allergy Management: adverse effects and cost of medication, physician evaluation, elimination diets, and desensitization.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guideline is not intended as a sole source of guidance in evaluating children with otitis media with effusion. Rather, it is designed to assist primary care and other clinicians by providing an evidence-based framework for decision-making strategies. It is not intended to replace clinical judgment or establish a protocol for all children with this condition and may not provide the only appropriate approach to diagnosing and managing this problem.
- Guidelines are never intended to overrule professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a strong recommendation than might be expected with a recommendation. Options offer the most opportunity for practice variability. All clinicians should always act and decide in a way that they believe will best serve their patients´ interests and needs regardless of guideline recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 May

GUIDELINE DEVELOPER(S)

American Academy of Family Physicians - Medical Specialty Society
American Academy of Otolaryngology - Head and Neck Surgery Foundation - Medical Specialty Society
American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics
American Academy of Family Physicians
American Academy of Otolaryngology-Head and Neck Surgery

GUIDELINE COMMITTEE

Subcommittee on Otitis Media with Effusion

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Dr Marcy serves as a consultant to Abbott Laboratories GlaxoSmithKline (vaccines).

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GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Pediatrics (AAP) Web site.

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 2, 2004. The information was verified by the guideline developer on August 4, 2004.

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