



Complete Summary

GUIDELINE TITLE

Diagnosis and management of acute otitis media.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. Pediatrics 2004 May;113(5):1451-65. [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.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

- [September 11, 2007, Rocephin \(ceftriaxone sodium\)](#): Roche informed healthcare professionals about revisions made to the prescribing information for Rocephin to clarify the potential risk associated with concomitant use of Rocephin with calcium or calcium-containing solutions or products.

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** REGULATORY ALERT **

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

SCOPE

DISEASE/CONDITION(S)

Acute otitis media

GUIDELINE CATEGORY

Diagnosis
Prevention
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Emergency Medicine
Family Practice
Infectious Diseases
Otolaryngology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations to primary care clinicians for the management of children from 2 months through 12 years of age with uncomplicated acute otitis media

TARGET POPULATION

Children from 2 months through 12 years of age with uncomplicated acute otitis media seen in primary care settings

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Assessment of patient history
2. Assessment of pain associated with acute otitis media

Prevention

1. Patient/parent education regarding reduction of risk factors including:
 - Altering child care center attendance patterns
 - Breastfeeding implementation
 - Avoidance of supine bottle feeding
 - Reduction or elimination of pacifier use

Treatment

1. Pain relief (see table 3 in the original guideline document for context):
 - Acetaminophen, ibuprofen
 - Home remedies
 - Topical agents including:
 - Benzocaine (Auralgan®, Americaine Otic®)
 - Naturopathic agents (Otikon Otic Solution®)
 - Homeopathic agents
 - Narcotic analgesia with codeine or analogs
 - Tympanostomy/myringotomy
2. Observation without treatment
3. Antibacterial agents (Amoxicillin, amoxicillin-clavulanate, cefdinir, cefuroxime, cefpodoxime, azithromycin, clarithromycin, ceftriaxone, clindamycin)
4. Complementary and alternative medicine treatments are considered but not recommended.

MAJOR OUTCOMES CONSIDERED

Outcomes included the presence or absence of signs and symptoms within 48 hours, at 3 to 7 days, 8 to 14 days, 15 days to 3 months, and more than 3 months, and the presence of adverse effects from antibacterial treatment.

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): The American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP) partnered with the Agency for Healthcare Research and Quality (AHRQ) and the Southern California Evidence-Based Practice Center (EPC) to develop the evidence report, which served as a major source of data for these practice guideline recommendations (see the "Companion Documents" field).

Literature Search

EPC project staff searched MEDLINE (1966–March 1999), the Cochrane Library (through March 1999), HealthSTAR (1975–March 1999), International Pharmaceutical Abstracts (1970–March 1999), CINAHL (1982–March 1999), BIOSIS (1970–March 1999), and EMBASE (1980–March 1999). Additional articles were identified by review of reference lists in proceedings, published articles, reports, and guidelines. Members of the Subcommittee on Management of Acute Otitis Media reviewed additional articles published through September 2003.

Inclusion Criteria

Studies relevant to treatment questions were limited to randomized, controlled trials. For natural history, prospective and retrospective comparative cohort studies were also included.

Results of the literature review were presented in evidence tables and published in the final evidence report (see the "Companion Documents" field).

NUMBER OF SOURCE DOCUMENTS

74

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review
Review of Published Meta-Analyses

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Articles were nonsystematically evaluated for quality of methodology and importance of results. Articles used in the Agency of Healthcare Research and Quality (AHRQ) review were also reevaluated for their quality.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Conclusions were based on the consensus of the subcommittee after the review of newer literature and reevaluation of the Agency for Healthcare Research and Quality evidence.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strong Recommendation

A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

Recommendation

A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms, but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms. Clinicians would be prudent to follow a recommendation, but should remain alert to new information and sensitive to patient preferences.

Option

Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to one approach over another. Clinicians should consider the option in their decision making, and patient preference may have a substantial role.

No Recommendation

No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear. Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A draft version of this practice guideline underwent extensive peer review by committees and sections within the American Academy of Pediatrics, reviewers appointed by the American Academy of Family Physicians, outside organizations, and other individuals identified by the subcommittee as experts in the field. Members of the subcommittee were invited to distribute the draft to other representatives and committees within their specialty organizations. The resulting comments were reviewed by the subcommittee and, when appropriate, incorporated into the guideline.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

A definition of the recommendations rating scheme is provided at the end of the "Major Recommendations" field.

Recommendation 1: To diagnose acute otitis media (AOM), the clinician should confirm a history of acute onset, identify signs of middle-ear effusion, and evaluate for the presence of signs and symptoms of middle-ear inflammation. **(Recommendation)** (See Table 2 in the original guideline document.)

Recommendation 2: The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain. **(Strong Recommendation)**

Recommendation 3A: Observation without use of antibacterial agents in a child with uncomplicated AOM is an option for selected children based on diagnostic certainty, age, illness severity, and assurance of follow-up. **(Option)**

Recommendation 3B: If a decision is made to treat with an antibacterial agent, the clinician should prescribe amoxicillin for most children. **(Recommendation)** When amoxicillin is used, the dose should be 80 to 90 mg/kg/day. **(Option)**

Recommendation 4: If the patient fails to respond to the initial management option within 48 to 72 hours, the clinician must reassess the patient to confirm AOM and exclude other causes of illness. If AOM is confirmed in the patient initially managed with observation, the clinician should begin antibacterial therapy. If the patient was initially managed with an antibacterial agent(s), the clinician should change the antibacterial agent(s). **(Recommendation)**

Recommendation 5: Clinicians should encourage the prevention of AOM through reduction of risk factors. **(Recommendation)**

Recommendation 6: There is insufficient evidence to make a recommendation regarding the use of complementary and alternative medicine (CAM) for AOM. **(No Recommendation)**

Definitions:

Strong Recommendation

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Recommendation

A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms, but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms. Clinicians would be prudent to follow a recommendation, but should remain alert to new information and sensitive to patient preferences.

Option

Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to one approach over another. Clinicians should consider the option in their decision making, and patient preference may have a substantial role.

No Recommendation

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CLINICAL ALGORITHM(S)

A clinical algorithm is provided in the original guideline document for the management of acute otitis media.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Recommendation 1: Based on observational studies and a preponderance of benefit over risk

Recommendation 2: Based on randomized, clinical trials with limitations and a preponderance of benefit over risk

Recommendation 3A: Based on randomized controlled trials with limitations and a relative balance of benefit and risk

Recommendation 3B:

- Amoxicillin use: Based on randomized controlled trials with limitations and a preponderance of benefit over risk
- Dosage: Based on extrapolation from microbiologic studies and expert opinion, with a preponderance of benefit over risk

Recommendation 4: Based on observational studies and a preponderance of benefit over risk

Recommendation 5: Based on strong observational studies and a preponderance of benefits over risks

Recommendation 6: Based on limited and controversial data

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate diagnosis and initial treatment of a child presenting with acute otitis media
- Improved adherence to a consistent definition of acute otitis media
- Appropriate use of antibacterial agent(s) including improved decision making when an alternative to amoxicillin is indicated

POTENTIAL HARMS

- Antibacterial agent treatment might mask mastoiditis signs and symptoms, producing a subtle presentation that can delay diagnosis.
- Antibiotics may lead to diarrhea, rash, anaphylaxis, and symptoms of hematologic, cardiovascular, central nervous, renal, hepatic and respiratory systems.
- Antimicrobial drug resistance may increase with increased use of antibiotics.
- Narcotic analgesia with codeine or analogs has a risk of respiratory depression, altered mental status, gastrointestinal upset, and constipation.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The recommendations in this guideline do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.
- This clinical practice guideline is not intended as a sole source of guidance in the management of children with acute otitis media. Rather, it is intended to assist primary care clinicians by providing a framework for clinical decision making. It is not intended to replace clinical judgment or establish a protocol

for all children with this condition. These recommendations may not provide the only appropriate approach to the management of this problem.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. Pediatrics 2004 May;113(5):1451-65. [PubMed](#)

ADAPTATION

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

DATE RELEASED

2004

GUIDELINE DEVELOPER(S)

American Academy of Family Physicians - Medical Specialty Society
American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics

GUIDELINE COMMITTEE

Subcommittee on Management of Acute Otitis Media

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Allan S. Lieberthal, MD, Co-chairperson, AAP; Theodore G. Ganiats, MD, Co-chairperson, AAFP; Edward O. Cox, MD, AAP; Larry Culpepper, MD, MPH, AAFP; Martin Mahoney, MD, PhD, AAFP; Donald Miller, MD, MPH, AAP; Desmond K. Runyan, MD, DrPH, AAP; Nina Lisbeth Shapiro, MD, AAP; Ellen Wald, MD, AAP

Liaisons: Richard Besser, MD, Centers for Disease Control and Prevention; Ellen Friedman, MD, American Academy of Otolaryngology-Head and Neck Surgery; Norman Wendell Todd, MD, American Academy of Otolaryngology-Head and Neck Surgery

Consultants: S. Michael Marcy, MD; Richard M. Rosenfeld, MD, MPH; Richard Shiffman, MD

Staff: Maureen Hannley, PhD, AAO-HNS; Carla Herrerias, MPH, AAP; Bellinda Schoof, MHA, CPHQ, AAFP

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Academy of Pediatrics \(AAP\) Policy 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

The following is available:

- Marcy M, Takata G, Shekelle P, et al. Management of Acute Otitis Media. Evidence Report/Technology Assessment No. 15 (Prepared by the Southern California Evidence-based Practice Center under Contract No. 290-97-0001). AHRQ Publication No. 01-E010. Rockville, MD: Agency for Healthcare Research and Quality. May 2001.

Electronic copies: Available from the [National Library of Medicine \(NLM\) Health Services/Technology Assessment Text \(HSTAT\) Web site](#).

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on June 8, 2004. The information was verified by the guideline developer on July 6, 2004. This summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on October 3, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Rocephin (ceftriaxone sodium).

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Date Modified: 9/22/2008

