Complete Summary

GUIDELINE TITLE

Otitis media.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System (UMHS). Otitis media. Ann Arbor (MI): University of Michigan Health System (UMHS); 2007 July. 12 p. [13 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Otitis media. Ann Arbor (MI): University of Michigan Health System; 2002 May. 12 p. [7 references]

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning 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.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Otitis media, including:

- Acute otitis media (AOM)
- Otitis media with effusion (OME)

GUIDELINE CATEGORY

Diagnosis
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Otolaryngology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To limit acute symptoms and suppurative complications caused by acute otitis media
- To maximize language development and minimize long term damage to middle ear structure associated with otitis media with effusion
- To limit complications of antibiotic therapy including the development of antibiotic-resistant bacteria

TARGET POPULATION

Pediatric patients greater than two months old and adults with suspected or confirmed otitis media (acute otitis media or otitis media with effusion)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Pneumatic otoscopy
2. Adjunctive techniques: tympanometry, acoustic reflectometry

3. Evaluation for symptoms (otalgia, irritability, fever) and signs of inflammation

Management of Acute Otitis Media

1. Analgesics (ibuprofen, acetaminophen, topical analgesics)
2. Observation versus initiating antibiotic therapy (deferred therapy with access to antibiotics if condition worsens)
3. Antibiotics
    - First-line: high dose amoxicillin
    - High dose azithromycin or cefdinir for patients allergic to amoxicillin
    - High dose amoxicillin/clavulanate or azithromycin for children with persistent symptoms despite initial amoxicillin
    - Ceftriaxone for episodes of clinical failure or suspected serious bacterial infection
4. Follow-up after at least 3 months
5. Management of recurrent acute otitis media, including preventive measures (immunizations, reduction in exposure to passive smoke, treatment of gastroesophageal reflux, consideration of placement of tympanostomy tubes)

Management of Otitis Media with Effusion (OME)

1. Clinical reevaluation at 3 month intervals
2. Referral to otolaryngology for persistent abnormal findings or complications
3. Parental education regarding approaches to maximizing language

Management of Special Circumstances

1. Management of special populations (infants 0-8 weeks old, otitis media in adults)
2. Tympanostomy tube management
3. Cerumen removal
4. Acute otitis externa (AOE)

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Degree of symptomatic improvement
- Bacteriologic and clinical response rates to treatment
- Rates of antibiotic resistance
- Complication rates (e.g., hearing loss, speech language delays)
- Medication and treatment side effects

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

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

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline team had accesses to the literature searches performed for the initial version of this guideline (1997) and its update (2002). For this update the literature search began with a review of the national guidelines published in 2004 on acute otitis media (AOM) and on otitis media with effusion (OME) (see "annotated references" in the original guideline document). The systematic literature searches for those guidelines included literature into early 2003. To supplement these searches with more recent findings, the team then conducted a prospective search of literature published on Medline since 1/1/03 using the major keywords of: human, English language, clinical trials, and guidelines. Seven specific searches were performed using the following terms. Detailed search terms and strategy available upon request.

1. Otitis media with effusion or serous effusion: audiogiogram or oto acustic emissions, diagnosis, treatment
2. Recurrent otitis media, recurrent acute otitis media, or chronic or persistent otitis media: diagnosis, treatment
3. Acute otitis media since 1/1/98 (not recurrent, persistent, or chronic [addressed in #2]): etiology and natural history, diagnosis (signs and symptoms, hearing loss, delayed language development, otoscopy, pneumatic otoscopy, tympanometry, tympanocentesis, other diagnosis). treatment since 1/1/98 (antibiotic therapy (amoxicillin, cephlaosporins, other antibiotics), adjunctive therapy since 1/1/98 (corticosteroid, antihistamines, decongestants, other), myringotomy or tympanostomy tubes since 1/1/98, laser tympanostomy or laser miringotomy, other treatment
4. Otitis media and mastoiditis
5. Otitis Media not in #1–#4: diagnosis, treatment
6. Cerumen impaction: treatment
7. Otorrhea: treatment

The search was conducted in components each keyed to a specific causal link in a formal problem structure (available upon request). The search was supplemented with recent clinical trials known to expert members of the panel. Negative trials were specifically sought. The search was a single cycle.

NUMBER OF SOURCE DOCUMENTS

Not stated

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

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

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

Drug tables were reviewed by UMHHC Pharmacy Services. The guideline was reviewed at clinical conferences or grand round meetings of divisions and departments to which the content is most relevant. This guideline was reviewed at meetings of, Family Medicine, General Medicine, General Pediatrics, Pediatric Infectious Disease, and Pediatric Otolaryngology. The revised document is reviewed by the Guidelines Steering Committee, composed of representatives from all primary care specialties. The UMHS Executive Committee on Clinical Affairs performs a final review prior to institutionally endorsing the guideline.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text of the original guideline document for additional information, including detailed information on dosing, possible side effects, and cost of medications; risk factors; subspecialty referrals; and considerations for special circumstances. Definitions for the levels of evidence (A, B, C, D) are provided at the end of the "Major Recommendations" field.

Diagnosis

- Distinguish between acute otitis media (AOM) and otitis media with effusion (OME) in making therapeutic decisions. Symptoms of pain or fever, together with an inflammatory middle ear effusion, are required to make a diagnosis of AOM. (Refer to Table 1 in original guideline document for details.) *[D]*
- The presence of middle ear effusion should be determined by the combined use of otoscopy, pneumatic otoscopy, and tympanometry when necessary *[D]*.

Therapy of Acute Otitis Media

- Recommend adequate analgesia for all children with AOM *[D]*.
- Consider deferring antibiotic therapy for lower risk children with AOM *[A].*
- When antibiotic therapy is deferred, facilitate patient access to antibiotics if symptoms worsen (e.g., a "back-up" prescription given at visit or a convenient system for subsequent call-in) *[D]*.
- Amoxicillin is the first choice of antibiotic therapy for all cases of AOM. For children under 4 years of age, amoxicillin should be dosed at 80 mg/kg/day divided twice a day (BID) for 5 to 10 days. Children 4 years of age or older can probably be treated at 40-60 mg/kg/day *[C]*. In the event of allergy to amoxicillin, azithromycin dosed at 30 mg/kg for one dose is the appropriate first line therapy.
- Treat AOM that is clinically unresponsive to amoxicillin after 72 hours of therapy with amoxicillin/clavulanate (amoxicillin component 80 mg/kg/day divided twice a day) for 10 days or with azithromycin 20 mg/kg daily for 3 days *[C]*.
- Patients with significant, persistent symptoms on high-dose amoxicillin/clavulanate or azithromycin should receive 1-3 doses of intramuscular (IM) ceftriaxone *[C]*. The decision to use ceftriaxone should take into account the possible impact of this antibiotic on patterns of antibiotic resistance.

Therapy of Otitis Media with Effusion

- Children with middle ear effusions should be examined at 3 month intervals for clearance of the effusion *[D]*.
- Children with evidence of mucoid effusions or anatomic damage to the middle ear should be referred to otolaryngology if effusion or abnormal physical findings persist for 3 months *[D]*.
- Children with apparent serous effusions should be referred to otolaryngology if effusion persists for 6 months and there is evidence of hearing loss or language delay *[D]*.

- Children with an asymptomatic middle ear effusion (no apparent developmental or behavioral problems) can be followed without referral *[D]*.
- Parents of all children with otitis media with effusion should be informed about approaches to maximize language development in a child with a possible hearing loss *[C]*.

Definitions:

Levels of Evidence:

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for the most significant recommendations (see "Major Recommendations").

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size. Expert consensus was used to formulate recommendations based on the available evidence.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Accurate diagnosis and effective treatment and management of otitis media

POTENTIAL HARMS

- Common side effects of antibiotics are diarrhea, rash, and candidal infections. Occasionally, children on antibiotics acquire more aggressive and antibiotic resistant bacteria leading to invasive bacterial infections requiring hospital admission and intravenous antibiotics.
- Excessive use of azithromycin is associated with increasing rates of erythromycin resistance, particularly involving group A beta-hemolytic streptococci, and therefore its routine use should be discouraged.
- Cefdinir carries with it an excessive risk of selection of resistant bacteria.

- The overuse of ceftriaxone is likely to significantly increase high level penicillin resistance in this population
- Placement of ventilation tubes is also associated with an increased risk of long-term tympanic membrane abnormalities and reduced hearing compared to medical therapy

QUALIFYING STATEMENTS

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These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources
Staff Training/Competency Material

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

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

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

DATE RELEASED

1997 Nov (revised 2007 Jul)

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

University of Michigan Health System

GUIDELINE COMMITTEE

Otitis Media Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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Guidelines Oversight Team: Connie Standiford, MD; William E. Chavey, MD; R. Van Harrison, PhD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

Team Member; Company; Relationship

Alexander Blackwood, MD, PhD (None)

James Cooke, MD (None)

R. Van Harrison, PhD (None)

Richard Linsk, MD, PhD (None)

Peter P. Passamani, MD (None)

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GUIDELINE AVAILABILITY

Electronic copies: Available for download (in Portable Document Format [PDF]) from the University of Michigan Health System Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Continuing Medical Education (CME) information is available from the University of Michigan Health System Web site.

PATIENT RESOURCES

The following is available:

- Ear infection and middle ear fluid (otitis media). University of Michigan Health System; 2007 Mar. Various p.

Available from the University of Michigan Health System Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on January 7, 2003. The information was verified by the guideline developer on February 4, 2003. 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). This NGC summary updated by ECRI Institute on January 22, 2008. The updated information was verified by the guideline developer on February 11, 2008.

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