



## Complete Summary

---

### GUIDELINE TITLE

Diagnosis and treatment of otitis media in children.

### BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of otitis media in children. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Jan. 25 p. [49 references]

### GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously released version: Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of otitis media in children. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 May. 27 p. [58 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

\*\* REGULATORY ALERT \*\*

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

## SCOPE

### **DISEASE/CONDITION(S)**

- Acute otitis media
- Otitis media with effusion

### **GUIDELINE CATEGORY**

Diagnosis  
Management  
Prevention  
Risk Assessment  
Treatment

### **CLINICAL SPECIALTY**

Family Practice  
Nursing  
Otolaryngology  
Pediatrics  
Pharmacology

### **INTENDED USERS**

Advanced Practice Nurses  
Allied Health Personnel  
Health Care Providers  
Health Plans  
Hospitals  
Managed Care Organizations  
Nurses  
Physician Assistants  
Physicians

### **GUIDELINE OBJECTIVE(S)**

- To increase the percentage of patients with a diagnosis of acute otitis media who were advised to "wait and see"
- To improve appropriate antibiotic usage for otitis media infections
- To improve caregivers' knowledge of symptoms suggestive of otitis media, appropriate indicators for a provider visit, risk factors, and outcomes of otitis media
- To improve the percentage of patients with otitis media who receive an appropriate referral to an ear, nose and throat specialist

### **TARGET POPULATION**

Children greater than 3 months to age 18

## **INTERVENTIONS AND PRACTICES CONSIDERED**

### **Diagnosis**

1. Assessment of symptoms
2. Examination of ear using pneumatic otoscopy for suspected acute otitis media and otoscopy and/or tympanometry for suspected otitis media with effusion
3. Consideration of risk factors for recurrent otitis media

### **Treatment/Management**

1. Observation (watchful waiting) of low-risk, mildly symptomatic children and children with otitis media with effusion
2. Comfort measures including acetaminophen or ibuprofen, warm compress to the ear, head elevation, and analgesic ear drops
3. Therapeutic antibiotic regimens (first-line: amoxicillin; second-line: amoxicillin/clavulanate potassium, cefuroxime axetil, ceftriaxone sodium, cefprozil, loracarbef, cefdinir, cefixime, cefpodoxime proxetil; other second-line [not recommended after failed course of amoxicillin]: trimethoprim sulfa, clarithromycin, erythromycin ethylsuccinate and sulfisoxazole acetyl, azithromycin)
4. Prophylactic antibiotic regimens (amoxicillin)
5. Otitis media education for caretakers, including discussion of prevention measures
6. Referral to an ear, nose, and throat (ENT) specialist for consideration of ventilating tubes
7. Follow-up if symptoms have not resolved

## **MAJOR OUTCOMES CONSIDERED**

- Symptom relief
- Antibiotic resistance
- Otitis media recurrence rate
- Clinical resolution of acute otitis media and otitis media with effusion
- Hearing loss

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

A literature search of clinical trials, meta-analysis, and systematic reviews is performed.

### **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**

**Quality of individual research reports is assessed using a hierarchical rating system.**

#### A. Primary Reports of New Data Collection

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

#### B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

## **METHODS USED TO ANALYZE THE EVIDENCE**

Systematic Review

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

### **New Guideline Development Process**

A new guideline, order set, and protocol is developed by a 6- to 12-member work group that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, along with an Institute for Clinical Systems Improvement (ICSI) staff facilitator. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 members may be recruited from medical groups or hospitals outside of ICSI.

The work group will meet for seven to eight three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and footnotes and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

## **COST ANALYSIS**

The guideline developers reviewed published cost analyses.

## **METHOD OF GUIDELINE VALIDATION**

Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

## **Critical Review Process**

Every newly developed guideline or a guideline with significant change is sent to Institute for Clinical Systems Improvement (ICSI) members for Critical Review. The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within the ICSI.

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

## **Approval**

Each guideline, order set, and protocol is approved by the appropriate steering committee. There is one steering committee each for Respiratory, Cardiovascular, OB/GYN, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each guideline based on the following:

- Member comments have been addressed reasonably.
- There is consensus among all ICSI member organizations on the content of the document.
- Within the knowledge of the reviewer, the scientific recommendations within the document are current.
- Either a critical review has been carried out, or to the extent of the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of critical review is not needed.

Once the guideline, order set, or protocol has been approved, it is posted on the ICSI Web site and released to members for use. Guidelines, order sets, and protocols are reviewed regularly and revised, if warranted.

## **Revision Process of Existing Guidelines**

ICSI scientific documents are revised every 12 to 36 months as indicated by changes in clinical practice and literature. Every 6 months, ICSI checks with the work group to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Prior to the work group convening to revise the document, ICSI members are asked to review the document and submit comments. During revision, a literature search of clinical trials, meta-analysis, and systematic reviews is performed and

reviewed by the work group. The work group will meet for 1 to 2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

If there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations, it is sent to members to review prior to going to the appropriate steering committee for approval.

### **Review and Comment Process**

ICSI members are asked to review and submit comments for every guideline, order set, and protocol prior to the work group convening to revise the document.

The purpose of the Review and Comment process is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the order set and protocol. Review and Comment also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the guideline.

All member organizations are encouraged to provide feedback on order sets and protocol, however responding to Review and Comment is not a criterion for continued membership within ICSI.

After the Review and Comment period, the work group reconvenes to review the comments and make changes as appropriate. The work group prepares a written response to all comments.

## **RECOMMENDATIONS**

### **MAJOR RECOMMENDATIONS**

**Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI):** For a description of what has changed since the previous version of this guidance, refer to [Summary of Changes Report -- January 2008](#).

The recommendations for the diagnosis and treatment of otitis media in children are presented in the form of two algorithms with 22 components, accompanied by detailed annotations. Algorithms are provided for: [Acute Otitis Media](#) and [Otitis Media with Effusion](#). Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) ratings are defined at the end of the Major Recommendations field.

#### **Clinical Highlights**

- A clinical examination is necessary to diagnose acute otitis media. Diagnosis should be made with pneumatic otoscopy. (*Annotation #4,5*)

- Educate parents on measures to prevent the occurrence of otitis media. (*Annotation #6*)
- Children with low risk should use a wait-and-see approach to treatment. (*Annotation #7*)
- Refer the patient to an ear, nose, and throat physician when the criteria are met. (*Annotation #9*)

## **Acute Otitis Media Algorithm Annotations**

### **2. Symptoms Suggestive of Otitis Media?**

#### **Generally**

Restlessness, irritability, wakefulness and poor feeding usually associated with cold symptoms and/or conjunctivitis (inflammation of the eye) are all general symptoms of acute otitis media [R].

#### **For Children Less Than Three Years of Age**

Children less than three years old more often present with non-specific symptoms. Frequently, infants and toddlers with otitis media have associated upper respiratory infection symptoms [R]. Symptoms include irritability, fever, night waking, poor feeding, cold symptoms, conjunctivitis, and occasional balance problems [R].

Ear pulling without associated symptoms is usually not a symptom of otitis media [C].

#### **For Children Ages Three and Older**

Symptoms include earache, drainage from ears, hearing loss, ear popping, ear fullness or dizziness [R].

### **4. Schedule Appointment**

#### **Key Points:**

- It is recommended that an appointment be made to accurately diagnose acute otitis media.

While symptoms of acute otitis media are often dramatic, the illness is rarely an emergency. Most children can be treated symptomatically through the night unless symptoms of a more serious illness are present. Comfort measures can be discussed with parent/caretaker.

#### **Comfort Measures for the Child with Otitis Media**

- Hold or rock child.
- Acetaminophen or ibuprofen as appropriate for age and size of child.
- Apply warm compresses to ear.

- Elevate the head by raising the head of the crib or use pillows for an older child.
- Wipe away drainage as it appears.
- For pain or irritability, analgesic ear drops can be used (Auralgan, mineral oil drops, or vegetable oil drops such as olive oil). Analgesic ear drops are not to be given to a child with ventilating tubes or if drainage in the ear canal is present.

Diagnosis of otitis media is made by exam. Diagnosis by phone should be avoided except in special circumstances (children with a history of multiple sets of ventilating tubes or children in high-risk categories such as cleft palate or Down's syndrome who present with bloody or purulent drainage and who are well known to the provider, and in whom follow-up is assured) [R].

## 5. Meets Diagnostic Criteria for Acute Otitis Media?

### Key Points:

- Diagnosis for acute otitis media should be made with pneumatic otoscopy.

Middle ear effusion (seen on examination and/or confirmed by pneumatic otoscopy) with:

- Local signs of inflammation (redness, bulging)
- Symptoms associated with acute otitis media (AOM):
  - Otalgia (ear pain)
  - Otorrhea (ear drainage)
  - Irritability
  - Restlessness
  - Poor feeding
  - Fever

Acute otitis media is characterized by middle ear effusion with acute inflammation. (The tympanic membrane is usually full or bulging [decreased mobility by pneumatic otoscopy]. Color is usually red, yellow or cloudy.) Symptoms may include otalgia, otorrhea, irritability, restlessness, poor feeding, or fever. Tympanometry is usually not necessary to establish the diagnosis of acute otitis media.

Tympanocentesis, while it is the gold standard of diagnosis, is not usually indicated in the treatment of acute otitis media except for the relief of severe symptoms or when a culture is needed due to an associated, more serious infection.

## 6. Discuss Prevention of Otitis Media

Parents/caretakers should be counseled about otitis media prevention. Elimination of controllable risk factors should be encouraged whenever possible.

Otitis media prevention measures to discuss include:

- Encouraging breast feeding [B]
- Feeding child upright if bottle fed
- Avoiding exposure to passive smoke [C, D]
- Tobacco cessation counseling
- Limiting exposure to numbers of children to the extent possible
- Teaching adults and children careful hand washing technique
- Limiting exposure to viral upper respiratory infections
- Avoid pacifier use beyond 10 months of age [B]
- Ensure immunizations are up-to-date; including influenza and 7 valent conjugated polysaccharide vaccine (PCV7)

## 7. Initiate Appropriate Treatment

### Key Points:

- It is recommended that children with low risk be treated with a wait-and-see approach.
- If antibiotic treatment is necessary, it is recommended that amoxicillin be the initial treatment.

### Treatment Options for Acute Otitis Media

#### *Watch and Wait*

Low-risk children six months to two years without severe disease and an uncertain diagnosis should be treated with oral and topical analgesics and may be observed for 48 to 72 hours. If symptoms do not resolve or are worse, child should be rechecked and/or antibiotics prescribed. Parents may be provided with a prescription at the initial visit and advised to wait 48 hours, filling the prescription only if symptoms worsen or do not improve [A]. Clinicians must be available to communicate with parents regarding child's symptoms during the observation time. The opportunity to share decision-making for treatment can lead to higher parental satisfaction [A].

Low-risk children are defined as otherwise healthy, do not attend day care, and have had no prior ear infections within the last month.

Severe disease is defined as fever greater than or equal to 39 degrees Celsius in the past 24 hours and moderate to severe otalgia. A diagnosis of acute otitis media meets any of the following criteria: sudden onset of symptoms, signs of middle-ear effusion, and signs and symptoms of middle-ear inflammation [R].

#### *Antibiotic Treatment*

When antibiotics are necessary, the drug used for initial treatment is amoxicillin. Reasons for using amoxicillin include safety, effectiveness, well tolerated and reasonably priced [M].

Low-dose amoxicillin (40 mg/kg/day) may be used if low risk (greater than two years, no day care, and no antibiotics for the past three months) and high dose (80 mg/kg/day) may be used if not low risk or for resistant acute otitis media if the lower dose was used initially [R]./p>

Indications for using another medication include:

- Failure to respond to initial treatment drug (resistant or persistent acute otitis media)
- History of lack of response to initial treatment drug (failure of medication on at least two occasions in the current respiratory season)
- Hypersensitivity to initial treatment medications
- Presence of resistant organism determined by culture
- Coexisting illness requiring a different medication

Other recommended treatment medications include (check the health plan formulary listing for currently available medications):

- Amoxicillin/clavulanate potassium
- Cefuroxime axetil
- Ceftriaxone sodium: prescribe one dose for new onset otitis media and a three-day course for a truly resistant pattern of otitis media or if oral treatment cannot be given
- Cefprozil
- Loracarbef
- Cefdinir
- Cefixime
- Cefpodoxime proxetil

Other treatment medications that are currently used but are not as strongly supported in the literature are listed below. These medications are not recommended when the patient has failed a course of amoxicillin.

- Trimethoprim sulfa
- Clarithromycin
- Erythromycin ethylsuccinate and sulfisoxazole acetyl
- Azithromycin

Several studies have shown that a single dose of ceftriaxone 50 mg/kg is equivalent to a 10-day course of oral antibiotics for new cases of acute otitis media. No further doses of oral antibiotic are needed following ceftriaxone. This should be reserved for special cases to prevent the more widespread emergence of resistant organisms. This treatment is indicated primarily for patients with compliance problems similar to intramuscular (IM) penicillin in streptococcal pharyngitis.

For persistent acute otitis media, a daily dose of ceftriaxone for three to five days is also an option and does not need additional oral antibiotics. This would be an option prior to referral to an ear, nose and throat physician for persistent acute otitis media if the patient failed on several second-line antibiotics [A, D].

## **Treatment of Resistant Acute Otitis Media**

Resistant acute otitis media is defined as persistence of moderately severe symptoms (pain and fever) after three to five days of antibiotic therapy with findings of continued pressure and inflammation (bulging) behind the tympanic membrane. A second antibiotic should be chosen; the alternative first-line medication may be an appropriate choice. (Referral to ear, nose and throat specialist may be indicated if significant pain and fever continue for four to five days on the second medication or if complications of otitis media occur.)

The Drug-Resistant-*Streptococcus pneumoniae* (DRSP) Therapeutic Working Group, convened by the Centers for Disease Control and Prevention, has stated the following. Agents selected for alternative therapy for true clinical treatment failures should meet two criteria: they should be effective against beta-lactamase-producing *Haemophilus influenzae* and *Moraxella catarrhalis* and they should be effective against *S. pneumoniae* including most drug-resistant-*Streptococcus pneumoniae* [A, M].

## **Treatment of Persistent Acute Otitis Media**

Persistent acute otitis media is defined as continued findings of acute otitis media present within six days of finishing a course of antibiotics. A second course of therapy with a different antibiotic is indicated for persistent acute otitis media [R].

Research has shown that only 20% to 30% of ear infections require treatment with antibiotics. In Britain and the Netherlands, antibiotics are currently used much less frequently for acute otitis media, and patients are often treated symptomatically. The traditional approach in the United States is to treat acute ear infections since there is currently no predictor of those infections that will self-resolve [R, C].

Observation may be considered if there are mild symptoms and findings on exam. Parents should be carefully instructed to watch for escalating symptoms. These options should be discussed fully with the parent and/or patient; observation requires that they be comfortable with the plan and capable of the required observation and follow-up [M].

## **8. History of Recurrent Acute Otitis Media?**

History should be reviewed or elicited at the time of diagnosis of acute otitis media. If criteria of recurrent acute otitis media are present, a prophylactic antibiotic regimen follows the therapeutic course of antibiotics. Children in high-risk categories may be considered for more aggressive or earlier intervention with prophylactic antibiotics. The decision for prophylaxis should be based on both the diagnostic criteria and the child's risk factors.

*Diagnostic Criteria for Recurrent Acute Otitis Media*

- A minimum of three or more episodes of acute otitis media in a 6-month period or during a respiratory season or 4 or more in a year [C]

*Children at Increased Risk of Recurrent Acute Otitis Media*

- Cleft palate, craniofacial abnormalities and Down's syndrome (very high risk category)
- First episode early (under 6 months) [R]
- Family history of recurrent acute otitis media in a sibling or parent [R]
- Day care attendance [C, R]
- Exposure to tobacco smoke [C,[D]
- Not breast-fed [B]
- Ethnic origin: Native American or Inuit (Eskimo)

**9. Consider Ear, Nose, and Throat (ENT) Referral**

A child needs to meet one of the following nine criteria for ear, nose, and throat specialist referral for consideration of ventilating tubes:

- Impending or actual complication of otitis media including:
  - Mastoiditis
  - Facial nerve paralysis
  - Lateral (sigmoid) sinus thrombosis
  - Meningitis
  - Brain abscess
  - Labyrinthitis
- Patients in high-risk categories should be referred immediately to ear, nose, and throat specialist; patients with craniofacial anomalies, Downs' syndrome, cleft palate, and patients with speech and language delay.
- Recurrent acute otitis media that fails medical management (greater than three episodes in six months or greater than four episodes in one year) with failure of prophylaxis defined as recurrence times two on prophylaxis in a two- to six-month time period.
- Refractory acute otitis media with moderate to severe symptoms unresponsive to at least 2 antibiotics. (Refer to Annotation #7, "Initiate Appropriate Treatment.")
- Bilateral or unilateral otitis media with effusion persisting for at least three months with hearing threshold of 20 dB or worse.
- Development of advanced middle ear disease involving tympanic membrane atrophy, retraction pockets, ossicular erosion or cholesteatoma.
- Medical treatment failure secondary to multiple drug allergy or intolerance.
- At least two recurrences of otitis media within two to three months following ventilating tube extrusion with failed medical management.
- History of six or more months of effusions out of the previous twelve months.

Children at increased risk for otitis media include those under two years of age, those who have an episode of otitis media at less than six months of

age, children in day care, and children who have a positive family history of otitis media.

### *Counseling Messages*

When counseling parents/caregivers about otitis media prevention, encourage measures to diminish risk factors when possible. (Refer to Annotation #6, "Discuss Prevention of Otitis Media.") Discussions with parents should take place regarding medical versus surgical treatment.

Refer to the original guideline document for more information on counseling messages.

## **10. Acute Otitis Media Resolved?**

Resolution is defined as a return to normal on exam with no evidence of effusion or inflammation and/or normal mobility. Tympanometry is not routinely needed to document resolution.

## **11. Schedule Follow-Up**

### **Key Points:**

- The work group recommends that follow-up is only needed when symptoms have not resolved.

A well-child visit may present an opportunity to evaluate the status.

Eliminating unnecessary rechecks reduces unnecessary visits and possible overtreatment. Rechecks at 10 to 14 days are not recommended unless symptoms recur or are persistent. Often rechecks may be timed with the next routine health maintenance visit.

## **13. Meets Diagnostic Criteria for Otitis Media with Effusion?**

Symptoms suggestive of otitis media with effusion include:

- Ear rubbing, irritability or sleep disturbances in infants
- Failure of infants to respond appropriately to voice or environmental sounds
- Balance problems, unexplained clumsiness, or delayed gross motor development
- Delayed speech or language development
- Hearing loss that may be manifested by lack of attention, behavioral changes, or listening to television or audio devices at excessively high sound levels
- Mild intermittent ear pain, fullness or "popping"
- Problems with school performance

However, in approximately 40% to 50% of cases of otitis media with effusion, neither affected children nor their caregivers describe significant complaints [R].

Otitis media with effusion is defined as mild middle-ear inflammation with effusion but without symptoms of fever, pain, and infection [R].

The diagnosis of otitis media with effusion is distinguished from acute otitis media by the presence of an effusion with a lack of signs or symptoms of inflammation or pressure behind the eardrum. Tympanic membrane findings: opaque or yellow, position neutral or retracted, decreased mobility or air fluid level. Tympanometry or pneumatic otoscopy may be useful in establishing the diagnosis.

## **Otitis Media with Effusion Algorithm Annotations**

### **15. Is Patient High-Risk?**

Children considered high risk are at increased risk for developmental difficulties. As defined by the American Academy of Pediatrics in the Otitis Media with Effusion guideline, risk factors include permanent hearing loss independent of otitis media with effusion, speech and language delay or disorder, autism-spectrum disorder, children with craniofacial anomalies, blindness or uncorrectable visual impairment, cleft palate, and developmental delay [R].

### **19. Discuss Prevention, Treatment, and Follow-Up**

#### **Key Points:**

- Otitis media with effusion will typically resolve on its own, and patients should be educated on watchful waiting.

#### **Prevention**

See Annotation #6, "Discuss Prevention of Otitis Media" for additional information.

#### **Treatment**

Antihistamines and/or decongestants have not been beneficial in the treatment of otitis media with effusion [M].

Course of antibiotics should be given as a trial prior to referral for ventilating tubes. (Refer to Annotation #7, "Initiate Appropriate Treatment.")

Patients with effusion may benefit from a course of antibiotics. Prolonged therapy (greater than 10 to 14 days) seems to provide no benefit. Several studies have examined the use of prednisone to hasten resolution of otitis media with effusion. Studies to date do not support the routine use of prednisone for otitis media with effusion [R].

Referral for ventilating tubes if patient meets ear, nose, and throat referral criteria.

Effusions without signs or symptoms of inflammation occasionally harbor bacteria. If the patient has recently finished a course of antibiotics the fluid should be considered sterile.

### **Follow-Up**

The American Academy of Pediatrics recommends documenting the onset, duration and laterality of otitis media with effusion in the medical record [R]. Otitis media with effusion will most likely resolve in three to four months [R]. Follow-up is not needed unless symptoms do not resolve.

### **Definitions:**

#### **Classes of Research Reports**

##### A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

##### B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

## **CLINICAL ALGORITHM(S)**

Detailed and annotated clinical algorithms are provided for:

- [Acute Otitis Media](#)
- [Otitis Media with Effusion](#)

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

- Increased percentage of patients with acute otitis media who were advised to "wait and see"
- Symptom relief
- Reduction of recurrence of otitis media
- Appropriate antibiotic usage for otitis media infections in children
- Education of parent (caretakers) on the symptoms suggestive of otitis media, appropriate indicators for a provider visit, risk factors and outcomes of otitis media

### **POTENTIAL HARMS**

Not stated

## **QUALIFYING STATEMENTS**

### **QUALIFYING STATEMENTS**

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for

all patients with a particular condition. A guideline will rarely establish the only approach to a problem.

- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for release, a member group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

### Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Educate caregivers regarding the risks and benefits of antibiotic treatment, management of acute otitis media symptoms and follow-up care.
2. When clinically appropriate, involve caregivers in the decision-making process by incorporating a "watchful waiting" or "wait-and-see" approach to antibiotic use.

### IMPLEMENTATION TOOLS

Clinical Algorithm  
Pocket Guide/Reference Cards  
Quality Measures

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

## RELATED NQMC MEASURES

- [Diagnosis and treatment of otitis media in children: percentage of patients with a diagnosis of acute otitis media who were prescribed amoxicillin.](#)
- [Diagnosis and treatment of otitis media in children: percentage of caregivers receiving education on the symptoms suggestive of otitis media, appropriate indicators for a provider visit, risk factors, and outcomes of otitis media.](#)

## 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)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of otitis media in children. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Jan. 25 p. [49 references]

### ADAPTATION

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

### DATE RELEASED

1995 May (revised 2008 Jan)

### GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

### GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT SpecialtyCare, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty

Healthcare, Grand Itasca Clinic and Hospital, Hamm Clinic, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hennepin Faculty Associates, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Health Care, North Suburban Family Physicians, NorthPoint Health & Wellness Center, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, St. Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Winona Health

ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; e-mail: [icsi.info@icsi.org](mailto:icsi.info@icsi.org); Web site: [www.icsi.org](http://www.icsi.org).

## **SOURCE(S) OF FUNDING**

The following Minnesota health plans provide direct financial support: Blue Cross and Blue Shield of Minnesota, HealthPartners, Medica, Metropolitan Health Plan, PreferredOne, and UCare Minnesota. In-kind support is provided by the Institute for Clinical Systems Improvement's (ICSI) members.

## **GUIDELINE COMMITTEE**

Respiratory Steering Committee

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

*Work Group Members:* Leonard Snellman, MD (Work Group Leader) (HealthPartners Medical Group) (Pediatrics); David Graft, MD (Park Nicollet Health Services) (Allergy); William Avery, DO (Sanford Health) (Ear, Nose, and Throat); Barbara Malone, MD (Midwest ENT) (Ear, Nose, and Throat); Jeffrey Jenkins, MD (Sanford Health) (Family Practice); Heather Krueger, MD (Quello Clinic, Ltd) (Family Practice); Carolyn Sparks, MD (University of MN Physicians) (Family Practice); Peter Marshall, PharmD (HealthPartners) (Pharmacy); Teresa Huntman, RRT, CPHQ (Institute For Clinical Systems Improvement) (Measurement/Implementation Advisor); Melissa Marshall, MBA (Institute For Clinical Systems Improvement) (Facilitator)

## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Institute for Clinical Systems Improvement (ICSI) has adopted a policy of transparency, disclosing potential conflict and competing interests of all individuals who participate in the development, revision and approval of ICSI documents (guidelines, order sets and protocols). This applies to all work groups (guidelines, order sets and protocols) and committees (Committee on Evidence-Based Practice, Cardiovascular Steering Committee, Women's Health Steering Committee, Preventive & Health Maintenance Steering Committee, Respiratory Steering Committee and the Patient Safety & Reliability Steering Committee).

Participants must disclose any potential conflict and competing interests they or their dependents (spouse, dependent children, or others claimed as dependents) may have with any organization with commercial, proprietary, or political interests relevant to the topics covered by ICSI documents. Such disclosures will be shared with all individuals who prepare, review and approve ICSI documents.

David Graft receives consulting/speaker fees and conference and travel support for asthma-related projects.

No other work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at [www.icsi.org](http://www.icsi.org).

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previously released version: Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of otitis media in children. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 May. 27 p. [58 references]

## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](http://www.icsi.org).

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: [www.icsi.org](http://www.icsi.org); e-mail: [icsi.info@icsi.org](mailto:icsi.info@icsi.org).

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- Diagnosis and treatment of otitis media in children. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2008 Jan. 1 p. Electronic copies: Available from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](http://www.icsi.org).
- ICSI pocket guidelines. May 2007 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2007.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: [www.icsi.org](http://www.icsi.org); e-mail: [icsi.info@icsi.org](mailto:icsi.info@icsi.org).

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This summary was completed by ECRI on March 22, 1999. The information was verified by the guideline developer on April 19, 1999. This summary was updated by ECRI on October 13, 2000, December 20, 2001, and most recently on April 18, 2003. The updated information was verified by the guideline developer on May 22, 2003. This summary was updated by ECRI on August 23, 2004. 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 was updated by ECRI Institute on April 3, 2008.

## **COPYRIGHT STATEMENT**

This NGC summary (abstracted Institute for Clinical Systems Improvement [ICSI] Guideline) is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

The abstracted ICSI Guidelines contained in this Web site may be downloaded by any individual or organization. If the abstracted ICSI Guidelines are downloaded by an individual, the individual may not distribute copies to third parties.

If the abstracted ICSI Guidelines are downloaded by an organization, copies may be distributed to the organization's employees but may not be distributed outside of the organization without the prior written consent of the Institute for Clinical Systems Improvement, Inc.

All other copyright rights in the abstracted ICSI Guidelines are reserved by the Institute for Clinical Systems Improvement, Inc. The Institute for Clinical Systems Improvement, Inc. assumes no liability for any adaptations or revisions or modifications made to the abstracts of the ICSI Guidelines.

## **DISCLAIMER**

### **NGC DISCLAIMER**

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at <http://www.guideline.gov/about/inclusion.aspx>.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of

developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 9/29/2008

