



INSTITUTE FOR CLINICAL
SYSTEMS IMPROVEMENT

Health Care Guideline:

Diagnosis and Treatment of Otitis Media in Children

Ninth Edition
January 2008

The information contained in this ICSI Health Care Guideline is intended primarily for health professionals and the following expert audiences:

- physicians, nurses, and other health care professional and provider organizations;
- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- health care teaching institutions;
- health care information technology departments;
- medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
- employee benefit managers.

This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. If you are not one of the expert audiences listed above you are urged to consult a health care professional regarding your own situation and any specific medical questions you may have. In addition, you should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in your individual case.

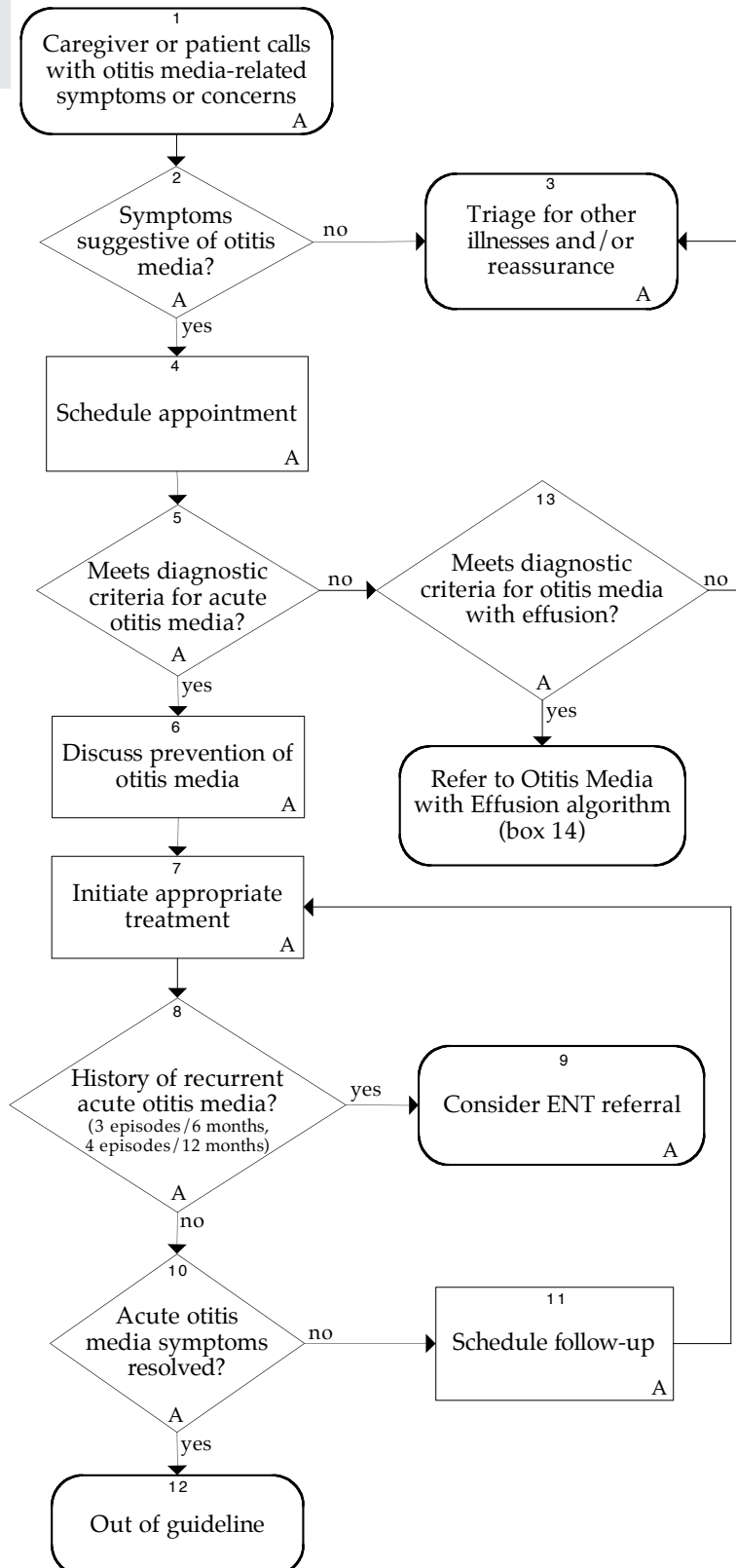
This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. An ICSI Health Care Guideline rarely will establish the only approach to a problem.

Copies of this ICSI Health Care Guideline may be distributed by any organization to the organization's employees but, except as provided below, may not be distributed outside of the organization without the prior written consent of the Institute for Clinical Systems Improvement, Inc. If the organization is a legally constituted medical group, the ICSI Health Care Guideline may be used by the medical group in any of the following ways:

- copies may be provided to anyone involved in the medical group's process for developing and implementing clinical guidelines;
- the ICSI Health Care Guideline may be adopted or adapted for use within the medical group only, provided that ICSI receives appropriate attribution on all written or electronic documents; and
- copies may be provided to patients and the clinicians who manage their care, if the ICSI Health Care Guideline is incorporated into the medical group's clinical guideline program.

All other copyright rights in this ICSI Health Care Guideline are reserved by the Institute for Clinical Systems Improvement. The Institute for Clinical Systems Improvement assumes no liability for any adaptations or revisions or modifications made to this ICSI Health Care Guideline.

Acute Otitis Media



- 2**
Symptoms Suggestive of Otitis Media
- Children Less Than Three Years**
- irritability
 - fever
 - night waking
 - poor feeding
 - running nose
 - conjunctivitis
 - balance problems
 - hearing loss
 - ear pain
- Children Three Years and Older**
- ear pain
 - ear drainage
 - hearing loss
 - ear popping
 - ear fullness
 - dizziness

- 5**
Diagnostic Criteria for Acute Otitis Media
- Middle ear effusion (seen on exam and/or confirmed by pneumatic otoscopy) with either:
 - local signs of inflammation; or
 - ear pain, ear drainage, irritability, restlessness, or poor feeding
- Diagnostic Criteria for Otitis Media with Effusion**
- Middle ear effusion (seen on exam and/or confirmed by pneumatic otoscopy) or abnormal tympanometry without signs or symptoms of acute otitis media

A = Annotation

Otitis Media with Effusion Algorithm

A = Annotation

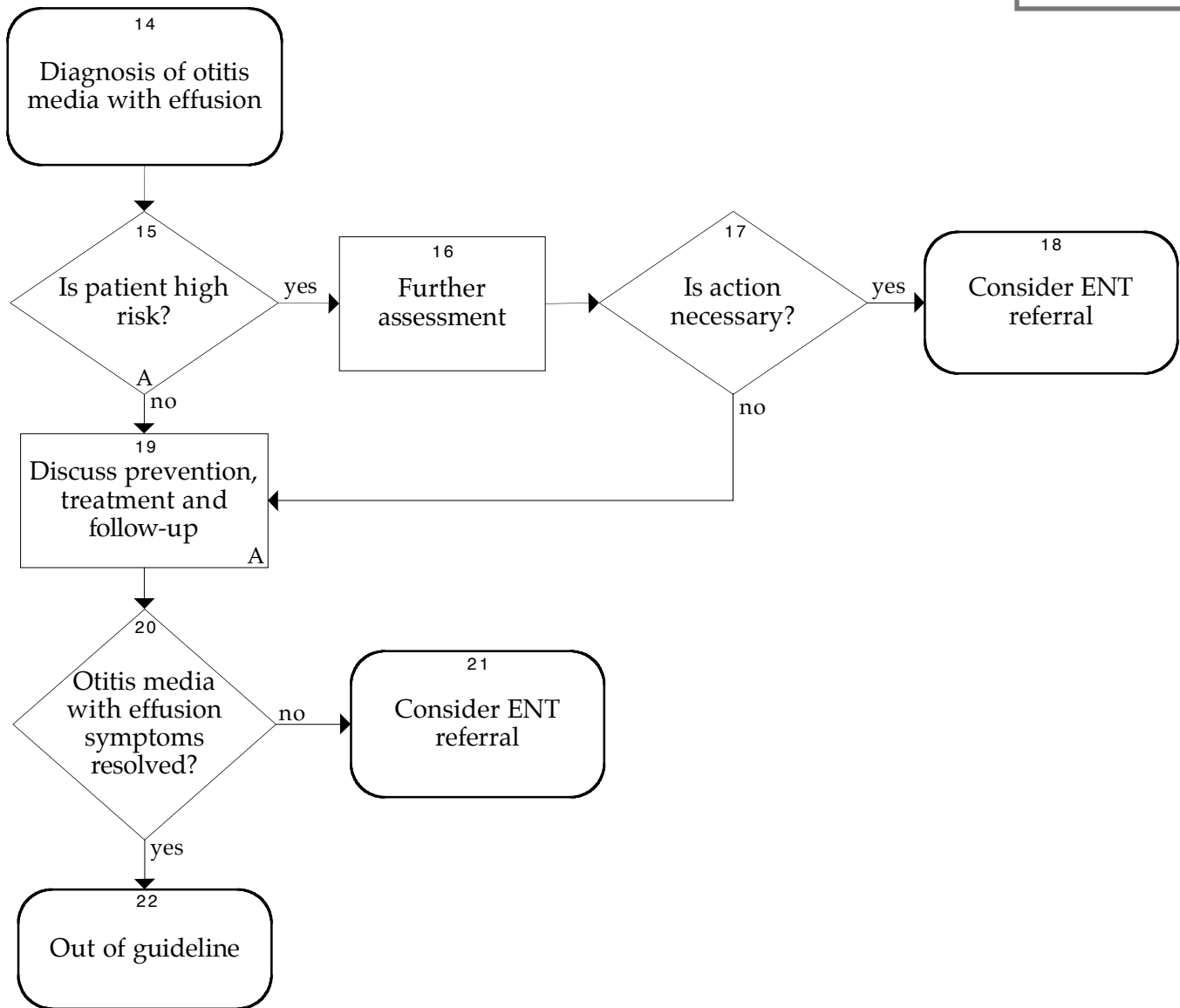


Table of Contents

Work Group Leader

Leonard Snellman, MD
*Pediatrics, HealthPartners
 Medical Group*

Work Group Members

Allergy

David Graft, MD
*Park Nicollet Health
 Services*

ENT

William Avery, DO
Sanford Health
 Barbara Malone, MD
Midwest ENT

Family Practice

Jeffrey Jenkins, MD
Sanford Health
 Heather Krueger, MD
Quello Clinic, Ltd.
 Carolyn Sparks, MD
University of MN Physicians

Pharmacy

Peter Marshall, PharmD
HealthPartners

Measurement/ Implementation Advisor

Teresa Huntman, RRT,
 CPHQ
ICSI

Facilitator

Melissa Marshall, MBA
ICSI

Algorithms and Annotations	1-14
Algorithm (Acute Otitis Media)	1
Algorithm (Otitis Media with Effusion).....	2
Foreword	
Scope and Target Population.....	4
Clinical Highlights and Recommendations	4
Priority Aims	4
Key Implementation Recommendations.....	4
Related ICSI Scientific Documents	4
Disclosure of Potential Conflict of Interest.....	5
Introduction to ICSI Document Development.....	5
Description of Evidence Grading.....	6
Annotations	7-14
Annotations (Acute Otitis Media).....	7-14
Annotations (Otitis Media with Effusion)	14
Supporting Evidence.....	15-19
Brief Description of Evidence Grading	16
References	17-19
Support for Implementation	20-25
Priority Aims and Suggested Measures.....	21
Measurement Specifications	22-23
Key Implementation Recommendations	24
Knowledge Resources	24
Resources Available	25

Foreword

Scope and Target Population

Children greater than 3 months to age 18.

Clinical Highlights and Recommendations

- A clinical examination is necessary to diagnose acute otitis media. Diagnosis should be made with pneumatic otoscopy. (*Annotations #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 specialist when the criteria are met. (*Annotation #9*)

Priority Aims

1. Increase the percentage of patients with a diagnosis of acute otitis media who were advised to "wait and see."
2. Improve appropriate antibiotic usage for otitis media infections.
3. Improve caregivers' knowledge of symptoms suggestive of otitis media, appropriate indicators for a provider visit, risk factors, and outcomes of otitis media.
4. Improve the percentage of patients with otitis media who receive an appropriate referral to an ear, nose and throat specialist.

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.

Related ICSI Scientific Documents

Related Guidelines

- Diagnosis and Treatment of Respiratory Illness in Children and Adults

Disclosure of Potential Conflict of Interest

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.

Introduction to ICSI Document Development

This document was developed and/or revised by a multidisciplinary work group utilizing a defined process for literature search and review, document development and revision, as well as obtaining and responding to ICSI members.

For a description of ICSI's development and revision process, please see the Development and Revision Process for Guidelines, Order Sets and Protocols at <http://www.icsi.org>.

Evidence Grading 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

Citations are listed in the guideline utilizing the format of (*Author, YYYY [report class]*). A full explanation of ICSI's Evidence Grading System can be found at <http://www.icsi.org>.

Algorithm Annotations

Acute Otitis Media Algorithm

1. Caregiver or Patient Calls with Otitis Media-Related Symptoms or Concerns

Entrance into the guideline occurs when a caregiver or patient calls regarding an ill child /themselves whose symptoms are suggestive of otitis media, or when a provider discovers findings of otitis media on exam.

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 (*Ruuskanenen, 1994 [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 (*Ruuskanenen, 1994 [R]*). Symptoms include irritability, fever, night waking, poor feeding, cold symptoms, conjunctivitis and occasional balance problems (*Kemphrone, 1991 [R]*).

Ear pulling without associated symptoms is usually not a symptom of otitis media (*Baker, 1992 [C]*).

For Children Ages Three and Older

Symptoms include earache, drainage from ears, hearing loss, ear popping, ear fullness or dizziness (*Kemphrone, 1991 [R]*).

3. Triage for Other Illnesses and/or Reassurance

For symptoms not suggestive of otitis, reassurance and anticipatory education of the symptoms of otitis should be provided. If symptoms suggestive of another illness are described, refer to the appropriate guideline.

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.

Algorithm Annotations

- 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) (*Pantell, 1990 [R]; Shelov, 1991 [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
 - 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 (*Aniansson, 1994 [B]; Duncan, 1993 [B]*)
- Feeding child upright if bottle fed
- Avoiding exposure to passive smoke (*Hinton, 1988 [C]; Strachan, 1989 [D]*)

Algorithm Annotations

- 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 (*Niemelä, 1995 [B]*)
- Ensure immunizations are up-to-date; including influenza and 7 valent conjugated polysaccharide vaccine (PCV7)

7. Initiate Appropriate Treatment

Key Point:

- 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 48-72 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 (*Spiro, 2006 [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 (*Merenstein, 2005 [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°C 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 (*Subcommittee on Management of Acute Otitis Media, 2004 [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 (*Weiss, 1987 [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 (*Subcommittee on Management of Otitis Media, 2004 [R]*).

Indications for using another medication include:

- failure to respond to initial treatment drug (resistant or persistent acute otitis media),

Algorithm Annotations

- 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, and
- 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, and
- 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 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 (*Barnett, 1997 [A]; Block, 1995 [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 *H. influenzae* and *M. catarrhalis* and they should be effective against *S. pneumoniae* including most Drug-Resistant-*Streptococcus pneumoniae* (Appelman, 1991 [A]; Odio, 1985 [A]; Weiss, 1988 [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 (Kempthorne, 1991 [R]).

Research has shown that only 20%-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 (Bollag, 1991 [R]); Burke, 1991 [R]; Van Buchem, 1985 [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 (Weiss, 1988 [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 six-month period or during a respiratory season or four or more in a year (Berman, 1993 [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 six months) (Klein, 1994 [R])
- Family history of recurrent acute otitis media in a sibling or parent (Klein, 1994 [R])
- Day care attendance (Strangert, 1977 [C]; Henderson, 1986 [R])
- Exposure to tobacco smoke (Hinton, 1988 [C]; Strachan, 1989 [D])
- Not breast-fed (Anransson, 1994 [B]; Duncan, 1993 [B])
- Ethnic origin: Native American or Inuit (Eskimo)

9. Consider ENT Referral

A child should meet one of the following 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 to an ear, nose and throat specialist; patients with craniofacial anomalies, Down's 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 two 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.

Generally, ear, nose and throat specialist consultation should be sought for otitis media non-responsive to medical treatment or complicated by hearing loss, medical treatment intolerance or failure, or deterioration of middle ear structures.

Research has indicated that for poorly understood reasons, children of Native American or Inuit descent are at high risk for developing otitis media.

Placement of middle-ear ventilating tubes has been shown to reverse otitis media-related hearing loss and reduce the frequency of otitis media for 6-12 months following placement.

Adenoidectomy has recently been demonstrated to reduce the risk of otitis media in children 4-8 years of age and may be indicated outside this age range. This benefit is irrespective of adenoid size and independent of obstructive symptoms. Adenoidectomy is usually reserved for children at high risk with a record of prior middle ear ventilating tube placement (*Minnesota Academy of Otolaryngology-Preferred Practice Patterns, 1990 [R]; Paradise, 1995 [X]*).

Ear, nose and throat specialist referral is appropriate for bilateral or unilateral otitis media with effusion persisting for at least three months with a hearing threshold of 20 dB or worse (*Bluestone [R]; Stool, 1994 [R]*).

10. Acute Otitis Media Symptoms 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 10-14 days are not recommended unless symptoms recur or are persistent. Often rechecks may be timed with the next routine health maintenance visit.

Hathaway et al. address elimination of early rechecks. The article does not address the appropriate timing of follow-up for middle-ear effusion after acute otitis media (*Hathaway, 1994 [D]*).

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%-50% of cases of otitis media with effusion, neither affected children nor their caregivers describe significant complaints (*American Academy of Pediatrics, 2004 [R]*).

Kempthorne and Glebink define otitis media with effusion as mild middle-ear inflammation with effusion but without symptoms of fever, pain and infection (*Kempthorne, 1991 [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 (*American Academy of Pediatrics, 2004 [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 (*Griffin, 2007 [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 10-14 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 (*Burke, 1989 [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 (*American Academy of Pediatrics, 2004 [R]*). Otitis media with effusion will most likely resolve in three to four months (*Rosenfeld, 2003 [R]*). Follow-up is not needed unless symptoms do not resolve.

Document Drafted
Mar – Jun 1994

First Edition
May 1995

Second Edition
Dec 1996

Third Edition
Oct 1997

Fourth Edition
Nov 1998

Fifth Edition
Jan 2000

Sixth Edition
Jul 2001

Seventh Edition
Jan 2003

Eighth Edition
Begins Jun 2004

Ninth Edition
Begins Feb 2008

Availability of references

References cited are available to ICSI participating member groups on request from the ICSI office. Please fill out the reference request sheet included with your guideline and send it to ICSI.

Released in January 2008 for Ninth Edition.

The next scheduled revision will occur within 36 months.

Original Work Group Members

William Barbaresi, MD
Pediatrics
Mayo Clinic

Paul Berry, MD
Pediatrics, Work Group Leader
Group Health, Inc.

Brian Ebeling, MD
Family Practice
Family Physicians, PA

Stacie Emberley, RN
Facilitator
ICSI

Mark Hagberg, MD
Family Practice
Park Nicollet Medical Center

Carl Hasbargen, MD
Family Practice
Group Health, Inc.

Robert Karasov, MD
Pediatrics
Park Nicollet Medical Center

Kate Libra, RN
Pediatric Nursing
Group Health, Inc.

Michelle Regan, MPH
Health Education
HealthPartners

Ann Robinow
BHCAG Representative
Business Health Care Action Group

Cheri Rolnick, PhD
Measurement
Group Health Foundation

Jane Spencer, PNP
Pediatric Nurse Practitioner
Park Nicollet Medical Center

Kent Wilson, MD
ENT
Otolaryngology & Head and Neck Surgery, PA

Contact ICSI at:

8009 34th Avenue South, Suite 1200; Bloomington, MN 55425; (952) 814-7060; (952) 858-9675 (fax)
Online at <http://www.ICSI.org>

Brief Description of Evidence Grading

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

A full explanation of these designators is found in the Foreword of the guideline.

References

- American Academy of Pediatrics. Diagnosis and management of acute otitis media. *Pediatrics* 2004;113:1451-65. (Class R)
- American Academy of Pediatrics. Otitis media with effusion. *Pediatrics* 2004;113:1412-29. (Class R)
- Aniansson G, Alm B, Andersson B, et al. A prospective cohort study on breast-feeding and otitis media in Swedish infants. *Pediatr Infect Dis J* 1994;13:183-88. (Class B)
- Appelman CLM, Claessen JQPJ, Touw-Otten FWMM, et al. Co-amoxiclav in recurrent otitis media: placebo controlled study. *BMJ* 303:1450-52, 1991. (Class A)
- Babonis TR, Weir MR, Kelly PC. Impedance tympanometry and acoustic reflectometry at myringotomy. *Pediatrics* 1991;87:475-80. (Class C)
- Baker RB. Is ear pulling associated with ear infection? *Pediatrics* 1992;90:1006-07. (Class C)
- Barnett ED, Teele DW, Klein JO, et al. Comparison of ceftriaxone and trimethoprim-sulfamethoxazole for acute otitis media. *Pediatrics* 1997;99:23-28. (Class A)
- Berman S, Roark R. Factors influencing outcome in children treated with antibiotics for acute otitis media. *Pediatr Infect Dis J* 1993;12:20-24. (Class C)
- Block SL, Harrison CJ, Hedrick JA, et al. Penicillin-resistant streptococcus pneumoniae in acute otitis media: risk factors, susceptibility patterns and antimicrobial management. *Pediatr Infect Dis J* 1995;14:751-59. (Class D)
- Bluestone CD, Klein JO. Chapter 23: Otitis media, atelectosis, and eustacian tube dysfunction. *In Pediatric Otolaryngology, 3rd ed.* Bluestone CD, Stool SE, Kenna MA, eds. Philadelphia: WB Saunders. 388-89, 521, 540-45. (Class R)
- Bollag U, Bollag-Albrecht E. Recommendations derived from practice audit for the treatment of acute otitis media. *Lancet* 1991;338:96-99. (Class R)
- Browning GG. Childhood otalgia: acute otitis media. *BMJ* 1990;300:1005-07. (Class X)
- Burke P. Otitis media with effusion: is medical management an option? *J R Coll Gen Pract* 1989;39:377-82. (Class R)
- Burke P, Bain J, Robinson D, et al. Acute red ear in children: controlled trial of non-antibiotic treatment in general practice. *BMJ* 1991;303:558-62. (Class A)
- Claessen JQPJ, Appelman CLM, Touw-Otten FWMM, et al. A review of clinical trials regarding treatment of acute otitis media. *Clin Otolaryngol* 1992;17:251-57. (Class R)
- Combs JT. Two useful tools for exploring the middle ear. *Contemp Pediatr* 1993;10:60-75. (Class X)
- Cunningham AS. Antibiotics for otitis media: restraint, not routine. *Contemp Ped* 1994;11:17-30. (Class X)
- Dowell SF, Butler JC, Giebink GS, et al. Acute otitis media: management and surveillance in an era of pneumococcal resistance – a report from the Drug-resistant Streptococcus pneumoniae Therapeutic Working Group. *Pediatr Infect Dis J* 1999;18:1-9. (Class B)
- Duncan B, Ey J, Holberg CJ, et al. Exclusive breast-feeding for at least 4 months protects against otitis media. *Pediatrics* 1993;91:867-72. (Class B)

References

- Feldman W, Richardson H, Rennie B, et al. A trial comparing cefaclor with co-trimoxazole in the treatment of acute otitis media. *Arch Dis Child* 1982;57:594-96. (Class A)
- Gonzalez CG, Arnold JE, Erhardt JB, et al. Prevention of recurrent acute otitis media: chemoprophylaxis versus tympanostomy tubes. *Laryngoscope* 1986;96:1330-34. (Class A)
- Griffin GH, Flynn C, Bailey RE, Schultz JK. Antihistamines and/or decongestants for otitis media with effusion (OME) in children. *Cochrane Database Syst Rev* 2006;CD003423. (Class M)
- Grundfast KM. Otitis media in children. *Current Ther Otolaryngol Head and Neck Surg* 1990;4:15-20. (Class R)
- Hathaway TJ, Katz HP, Dershewitz RA, et al. Acute otitis media: who needs posttreatment follow-up? *Pediatrics* 1994;94:143-47. (Class D)
- Henderson FW, Giebink GS. Otitis media among children in day care: epidemiology and pathogenesis. *Rev Infect Dis* 1986;8:533-37. (Class R)
- Hinton AE, Buckley G. Parental smoking and middle ear effusions in children. *J Laryngol Otol* 1988;102:992-96. (Class C)
- Kaleida PH, Casselbrant ML, Rockette HE, et al. Amoxicillin or myringotomy or both for acute otitis media: results of a randomized clinical trial. *Pediatrics* 1991;87:466-74. (Class A)
- Kemphorne J, Giebink GS. Pediatric approach to the diagnosis and management of otitis media. *Otolaryngol Clin North Am* 1991;24:905-29. (Class R)
- Klein JO. Current issues in upper respiratory tract infections in infants and children: rationale for antibiotic therapy. *Pediatr Infect Dis J* 1994;13:S5-8. (Class R)
- Mandel EM, Rockette HE, Bluestone CD, et al. Efficacy of myringotomy with and without tympanostomy tubes for chronic otitis media with effusion. *Pediatr Infect Dis J* 1992;11:270-77. (Class A)
- Merenstein D, Diener-West M, Krist A, et al. An assessment of the shared-decision model in parents of children with acute otitis media. *Pediatrics* 2005;116:1267-75. (Class M)
- Minnesota Academy of Otolaryngology-Preferred Practice Patterns. Tympanostomy with tube insertion. Based on criteria developed by the American Academy of Otolaryngology/Head and Neck Surgery, 1990. (Class R)
- Niemelä M, Uhari M, Möttönen M. A pacifier increases the risk of recurrent acute otitis media in children in day care centers. *Pediatrics* 1995;96:884-88. (Class B)
- Odio CM, Kusmiesz H, Shelton S, et al. Comparative treatment trial of augmentin versus cefaclor for acute otitis media with effusion. *Pediatrics* 1985;75:819-26. (Class A)
- Pantell R, Fries J, and Vickery D. In *Taking Care of Your Child: a Parent's Guide to Medical Care*, 3rd ed. New York: Addison-Wesley, 1990. (Class R)
- Paradise JL. Managing otitis media: a time for change. *Pediatrics* 1995;96:712-15. (Class X)
- Paradise JL. On classifying otitis media as suppurative or nonsuppurative, with a suggested clinical schema. *J Pediatr* 1987;111:948-51. (Class R)
- Paradise JL, Smith CG, Bluestone CD. Tympanometric detection of middle ear effusion in infants and young children. *Pediatrics* 1976;58:198-210. (Class C)
- Pichichero ME. Assessing the treatment alternatives for acute otitis media. *Pediatr Infect Dis J* 1994;13:S27-34. (Class R)
- Rosenfeld RM, Kay D. Natural history of untreated otitis media. *Laryngoscope* 2003;113:1645-57. (Class M)

References

- Ruuskanen O, Heikkinen T. Otitis media: etiology and diagnosis. *Pediatr Infect Disease J* 1994;13:23-26. (Class R)
- Shelov SP, Hannemann RE, eds. *In Caring for Your Baby and Young Child Birth to Age Five*. New York: Bantam Books, 1991. (Class R)
- Spiro DM, Tay KY, Arnold DH, et al. Wait-and-see prescription for the treatment of acute otitis media: a randomized controlled trial. *JAMA* 2006;296:1235-41. (Class A)
- Stool SE, Berg AO, Berman S, et al. Managing otitis media with effusion in young children. In Quick Reference Guide for Clinicians. AHCPR Publication No. 94-0623. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, July 1994. (Class R)
- Strachan DP, Jarvis MJ, Feyerabend C. Passive smoking, salivary cotinine concentrations, and middle ear effusion in 7 year old children. *BMJ* 1989;298:1549-52. (Class D)
- Strangert K. Otitis media in young children in different types of day-care. *Scand J Infect Dis* 1977;9:119-23. (Class C)
- Teele DW, Klein JO, Rosner B, the greater Boston Otitis Media Study Group. Epidemiology of otitis media during the first seven years of life in children in greater Boston: a prospective, cohort study. *J Infect Dis* 1989;160:83-94. (Class D)
- Van Buchem FL, Peeters MF, Van't Hof MA. Acute otitis media: a new treatment strategy. *BMJ* 1985;290:1033-37. (Class C)
- Weiss JC, Melman ST. Cost effectiveness in the choice of antibiotics for the initial treatment of otitis media in children: a decision analysis approach. *Pediatr Infect Dis J* 1988;7:23-26. (Class M)

This section provides resources, strategies and measurement specifications for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Priority Aims and Suggested Measures
 - Measurement Specifications
- Key Implementation Recommendations
- Knowledge Resources
- Resources Available

Priority Aims and Suggested Measures

1. Increase the percentage of patients with a diagnosis of acute otitis media who were advised to "wait and see."

Possible measures for accomplishing this aim:

- a. Percentage of patients with a diagnosis of acute otitis media who were advised to "wait and see."
- b. Percentage of patients with a diagnosis of acute otitis media who filled the perscription after 24 hours.

2. Improve appropriate antibiotic usage for otitis media infections.

Possible measure for accomplishing this aim:

- a. Percentage of patients with a diagnosis of acute otitis media who were prescribed amoxicillin.

3. Improve caregivers knowledge of symptoms suggestive of otitis media, appropriate indicators for a provider visit, risk factors, and outcomes of otitis media.

Possible measure for accomplishing this aim:

- a. 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.

4. Improve the percentage of patients with otitis media who receive an appropriate referral to an ear, nose and throat specialist.

Possible measure for accomplishing this aim:

- a. Percentage of patients with otitis media who meet the appropriate criteria for an ear, nose and throat specialist referral.

Measurement Specifications

Possible Success Measure #2a

Percentage of patients with a diagnosis of acute otitis media who were prescribed amoxicillin.

Population Definition

All patients diagnosed with acute otitis media.

Data of Interest

$$\frac{\text{\# of records where amoxicillin was prescribed}}{\text{Total \# of patients with acute otitis media whose records are reviewed}}$$

Numerator/Denominator Definitions

Numerator: Number of records where patients with acute otitis media have amoxicillin prescribed and have not been treated for otitis media 60 days prior to current visit.

Denominator: All patients with a diagnosis of acute otitis media and who have not been treated for otitis media 60 days prior to current visit.

Diagnosis of acute otitis media is defined by the suggested ICD-9 codes: 381.0, 381.00, 381.01, 381.4, 382.00, 382.01, 382.4, 382.9.

Method/Source of Data Collection

Data will be collected through medical record review. A minimum of 10 charts will be randomly sampled from all cases seen in the target month. Records will be pulled and reviewed for antibiotic prescription use.

Time Frame Pertaining to Data Collection

Suggested data collection time frame is monthly.

Priority Aims and Suggested Measures

Possible Success Measure #3a

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.

Population Definition

All patients seen in the clinic for otitis media.

Data of Interest

$$\frac{\text{\# of records with documentation of education provided to the parent/caregiver about otitis media}}{\text{total \# of children with otitis media whose medical records are reviewed}}$$

Numerator/Denominator Definitions

Numerator: Documented is defined as any evidence in the medical record that a clinician provided patient education to the parent or caregiver related to:

- Symptoms suggestive of otitis media
- Indications for a clinic visit
- Risk factors for otitis media/recurrent otitis media
- Outcomes of otitis media

Denominator: All children with a diagnosis of acute otitis media as defined by the suggested ICD-9 codes: 381.0, 381.00, 381.01, 381.4, 382.00, 382.01, 382.4, 382.9.

Method/Source of Data Collection

Data will be collected through medical record review. A minimum of 10 charts will be randomly sampled from all cases of otitis media seen in the target month.

Time Frame Pertaining to Data Collection

Suggested data collection time frame is monthly.

Notes

Providing education to parents or caregivers of children with otitis media is important for successful management. It should begin at the time of diagnosis and be ongoing.

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.

Knowledge Resources

Criteria for Selecting Resources

The following resources were selected by the Diagnosis and Treatment of Otitis Media in Children guideline work group as additional resources for providers and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the guideline.
- The content is supported by evidence-based research.
- The content includes the source/author and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

Resources Available to ICSI Members Only

ICSI has a wide variety of knowledge resources that are *only* available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources Available table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Resources, go to <http://www.icsi.org/knowledge>. To access these materials on the Web site, you must be logged in as an ICSI member.

The resources in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge.

Resources Available

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
	American Academy of Family Practice	Clinical practice guidelines, clinical care, research and quality improvement resources. Includes information for parents and caregivers.	Patients and Families; Health Care Providers	http://www.aafp.org
	American Academy of Pediatrics	Education on symptoms and treatment for caregivers. General information, questions and answers, and clinical practice guidelines for health care providers.	Patients and Families; Health Care Providers	http://www.aap.org/healthtopics/earinfections.cfm
	Mayo Clinic	Health information on various diseases and conditions.	Patients and Families; Health Care Providers	http://www.mayoclinic.com
	Minnesota Antibiotic Resistance Collaborative	Information and educational materials on antibiotic facts, preventing antibiotic-resistant infections and appropriate use of antibiotics.	Patients and Families; Health Care Professionals	http://www.minnesotaarc.org
	New York State Department of Health and the New York Region Otitis Project Committee	"Observation Option Toolkit for Acute Otitis Media" – caregiver information sheet; focuses on appropriate antibiotic use.	Patients and Families	http://www.health.state.ny.us/nysdoh/antibiotic/toolkt

* Available to ICSI members only.