

Diagnosis and Treatment of Otitis Media in Children

Executive Summary

May 2004

Scope and Target Population:

Children from birth to age 18.

Clinical Highlights and Recommendations:

1. Schedule an appointment for the child within 24 hours of the call to the clinic.
2. A clinical examination is necessary to diagnose acute otitis media. Diagnosis made over the phone is generally discouraged.
3. Educate parents on measures to prevent the occurrence of otitis media.
4. Prescribe first-line antibiotics (amoxicillin) when the diagnosis of otitis media is made.
5. Prescribe second line antibiotics when the patient fails to respond to first-line drugs, has a history of lack of response to first-line drugs, is hypersensitive to first-line medications, has a resistant organism as defined by culture, or has a coexisting illness requiring a second line medication.
6. Recheck in 3-4 weeks or at next well child visit (if within 4-6 weeks) for:
 - all children < 5 years of age, and
 - those 5 years of age or older if risk factors are identified, there is a history of previous ventilation tubes or ear surgery, or if there is a history of speech or development delay.
7. Refer the patient to an ENT physician when the criteria are met.

Priority Aims and Suggested Measures:

1. Increase appropriate antibiotic usage for otitis media infections.
2. Increase the timely and appropriate clinical follow-up for patients with a diagnosis of otitis media.
3. Improve parents' (caretakers') knowledge of symptoms suggestive of otitis media, appropriate indicators for a provider visit, risk factors, and outcomes of otitis media.

Additional Background:

Otitis media is the most frequent diagnosis made at visits to U.S. office-based physicians by children under the age of 15. Moreover, these office visits have shown a dramatic increase in recent years. It is estimated that 24.5 million visits to office-based physicians were made in 1990, a 150% increase over the number of visits in 1975 (AHCPR Publication #94-0620).

Eighth Edition
May 2004

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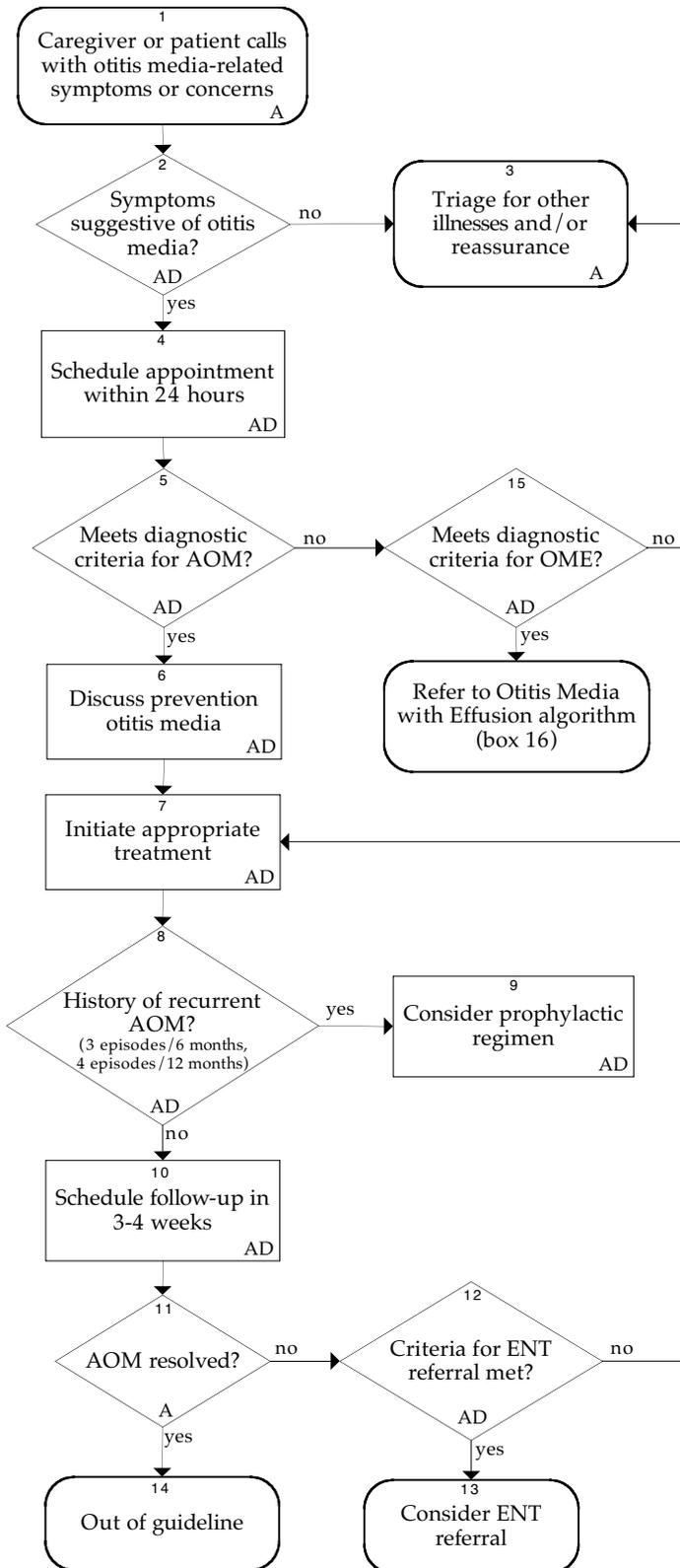
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These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.



A = Annotation
D = Discussion

2 Symptoms Suggestive of Otitis Media

Children < 3 Years

- irritability
- fever
- night waking
- poor feeding
- coryza
- conjunctivitis
- balance problems
- hearing loss
- otalgia

Children 3 Years and Older

- otalgia
- otorrhea
- hearing loss
- ear popping
- ear fullness
- dizziness

5 Diagnostic Criteria for Acute Otitis Media (AOM)

- Middle ear effusion (seen on exam and/or confirmed by pneumatic otoscopy) with either:
 - local signs of inflammation; or
 - otalgia, otorrhea, irritability, restlessness, or poor feeding.

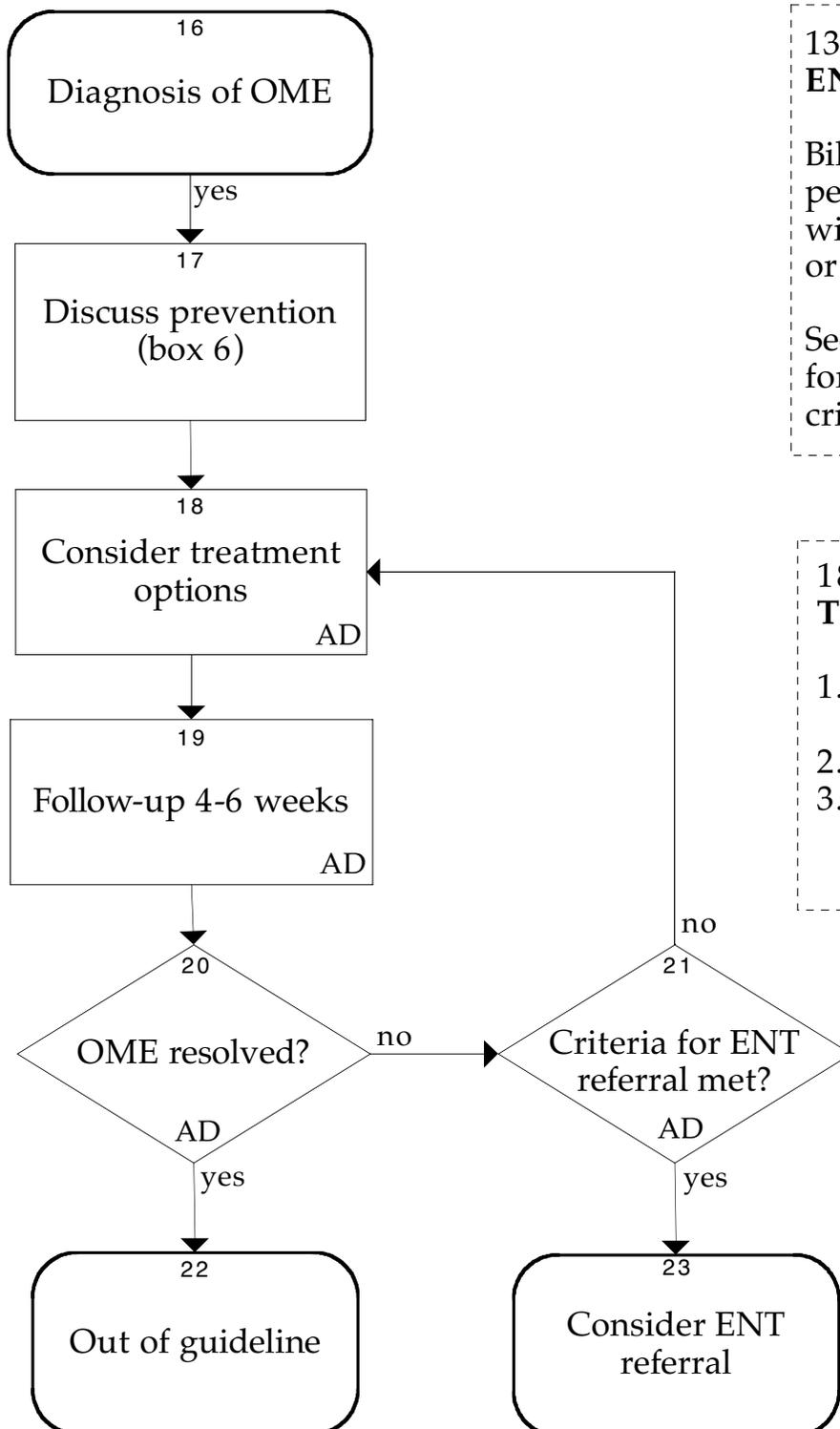
Diagnostic Criteria for Otitis Media with Effusion (OME)

- Middle ear effusion (seen on exam and/or confirmed by pneumatic otoscopy) or abnormal tympanometry without signs or symptoms of AOM.

7 Appropriate Treatment

- Antibiotic regimen using criteria for first vs. second line antibiotics or
- Observation for mildly symptomatic children

Otitis Media with Effusion Algorithm



13/23 ENT Referral Criteria for OME

Bilateral or unilateral OME persisting for at least 3 months with hearing threshold of 20 dB or worse.

See the Algorithm Annotations for a complete list of ENT referral criteria.

18 Treatment Options

1. Observe - recheck in 4-6 weeks
2. Course of antibiotics
3. Referral for ventilating tubes if patient meets ENT referral criteria

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Foreword

Scope and Target Population

Children from birth to age 18.

Related ICSI Scientific Documents

Other ICSI guidelines whose scope and/or recommendations are closely related to the content of this guideline are:

1. Viral Upper Respiratory Infection in Adults and Children
2. Rhinitis
3. Acute Pharyngitis

Clinical Highlights and Recommendations

1. Schedule an appointment for the child within 24 hours of the call to the clinic. (*Annotation #4*)
2. A clinical examination is necessary to diagnose acute otitis media. Diagnosis made over the phone is generally discouraged. (*Annotation #4*)
3. Educate parents on measures to prevent the occurrence of otitis media. (*Annotation #6*)
4. Prescribe first-line antibiotics (amoxicillin) when the diagnosis of otitis media is made. (*Annotation #7*)
5. Prescribe second-line antibiotics when the patient fails to respond to first-line drugs, has a history of lack of response to first-line drugs, is hypersensitive to first-line medications, has a resistant organism as defined by culture, or has a coexisting illness requiring a second-line medication. (*Annotation #7*)
6. Recheck in 3-4 weeks or at next well child visit (if within 4-6 weeks) for:
 - all children < 5 years of age, and
 - those 5 years of age or older if risk factors are identified, there is a history of previous ventilation tubes or ear surgery, or if there is a history of speech or development delay. (*Annotation #10*)
7. Refer the patient to an ENT physician when the criteria are met. (*Annotation #12*)

Priority Aims and Suggested Measures

1. Increase appropriate antibiotic usage for otitis media infections.
Possible measures of accomplishing this aim:
 - a. Percentage of children with a diagnosis of acute otitis media who were prescribed first-line antibiotics.
 - b. Percentage of children with a diagnosis of acute otitis media who were prescribed second-line antibiotics who met the indications for second-line antibiotics.

2. Increase the timely and appropriate clinical follow-up for patients with a diagnosis of otitis media.
Possible measures of accomplishing this aim:
 - a. Percentage of children with a diagnosis of acute otitis media referred to ENT meeting the criteria for referral.
 - b. Percentage of children less than 5 years old with a diagnosis of acute otitis media who had an appropriate routine follow-up visit within the recommended time interval.
3. Improve parents' (caretakers') knowledge of symptoms suggestive of otitis media, appropriate indicators for a provider visit, risk factors, and outcomes of otitis media.
Possible measure of accomplishing this aim:
 - a. Percentage of parents' (caretakers') receiving education on the symptoms suggestive of otitis media, appropriate indicators for a provider visit, risk factors, and outcomes of otitis media.

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 Discussion and References section of the guideline.

Disclosure of Potential Conflict of Interest

In the interest of full disclosure, ICSI has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

No 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.

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 calls regarding an ill child whose symptoms are suggestive of otitis media, or when a provider discovers findings of otitis media on exam.

2. Symptoms Suggestive of Otitis Media?

Children less than 3 years old more often present with non-specific symptoms (irritability, fever, night waking, poor feeding, coryza, conjunctivitis, and occasionally balance problems). 90% of infants and toddlers with otitis media have associated rhinitis symptoms.

For more information on symptoms of AOM please refer to Annotation Appendix A, "Recommended Patient Education Content."

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

Supporting evidence if of classes: C, 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.

For more information on triage and reassurance, please refer to Annotation Appendix A, "Recommended Patient Education Content."

4. Schedule Appointment Within 24 Hours

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. (Refer to Annotation Appendix A, "Recommended Patient Education Content" and Support for Implementation section of the guideline.)

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).

5. Meets Diagnostic Criteria for AOM?

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

- a. local signs of inflammation (redness, bulging)
- b. symptoms associated with AOM
 - otalgia

Algorithm Annotations

- otorrhea
- irritability
- restlessness
- poor feeding
- fever

AOM 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 AOM.

6. Discuss Prevention 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
- feeding child upright if bottle fed
- avoiding exposure to passive smoke
- 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
- ensure immunizations are up-to-date; including influenza and Prevnar®

For more information on prevention of OM, please refer to Annotation Appendix A, "Recommended Patient Education Content."

Supporting evidence if of classes: B, C, D

7. Initiate Appropriate Treatment

Treatment options for AOM

- Antibiotic regimen using criteria for first- vs. second-line antibiotics.
 - Observation of mildly symptomatic children is encouraged in the absence of risk factors. Risk factors may include: severity of symptoms, age < 2 years, and parental acceptance.
- I. Options for treatment include:
- A. Therapeutic (10 day) course of antibiotics. Consideration may be given to a shortened course of antibiotics (5 days) for children who are at low risk, i.e., age > 2 years, no history of chronic or recurrent OM and intact tympanic membranes.

Algorithm Annotations

1. First-line medications
 - a. amoxicillin (40 mg/kg/day) if low risk (> 2 years, no day care, and no antibiotics for the past three months).
 - b. 80 mg/kg/day if not low risk or for resistant AOM if the lower dose was used initially.
 2. Recommended second-line medications include: (Check the health plan formulary listing for currently available medications.)
 - a. amoxicillin/clavulanate potassium (Augmentin®)
 - b. cefuroxime axetil (Ceftin®)
 - c. ceftriaxone sodium (Rocephin®): prescribe one dose for new onset otitis media and a three-day course for a truly resistant pattern of OM or if oral treatment cannot be given.
 - d. cefprozil (Cefzil®)
 - e. loracarbef (Lorabid®)
 - f. cefdinir (Omnicef®)
 - g. cefixime (Suprax®)
 - h. cefpodoxime proxetil (Vantin®)
 3. Indications for second-line medications include:
 - a. failure to respond to first-line drugs (resistant or persistent AOM)
 - b. history of lack of response to first-line drug (failure of medication on at least two occasions in the current respiratory season)
 - c. hypersensitivity to first-line medications
 - d. presence of resistant organism determined by culture
 - e. coexisting illness requiring a second-line medication.
 4. Second-line 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.
 - a. trimethoprim sulfa (Bactrim®, Septra®)
 - b. clarithromycin (Biaxin®)
 - c. erythromycin ethylsuccinate and sulfisoxazole acetyl (Pediazole®)
 - d. azithromycin (Zithromax®)
- II. Observation with or without provisional prescription if symptoms of AOM should worsen. This option is not recommended in the acutely ill child but may be considered in an asymptomatic or only mildly symptomatic child with mild findings on exam. Parents should be instructed to call back if symptoms persist, if the child is inconsolable, or if the child is becoming more ill.

For the child with a draining middle ear, whether from ventilation tubes or perforation, a nonototoxic drop (such as ciprofloxin or ofloxacin) may be added to oral antibiotic treatment.

The use of nasal decongestants and corticosteroids is not supported in the literature.

Treatment of resistant AOM

Resistant AOM is defined as persistence of moderately severe symptoms (pain and fever) after 3 to 5 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 ENT specialist may be indicated if significant pain and fever continue for 4-5 days on the second medication or if complications of otitis media occur.)

Treatment of persistent AOM

Persistent AOM is defined as continued findings of AOM present within 6 days of finishing a course of antibiotics. A second course of therapy with a different antibiotic is indicated for persistent AOM.

Supporting evidence if of classes:

First-line medications: A, M, R

Second-line medications: A, D

Treatment of resistant OM: A, M, R

Treatment of persistent AOM: R

8. History of Recurrent AOM?

History should be reviewed or elicited at the time of diagnosis of AOM. If criteria of recurrent AOM 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 AOM

- a minimum of three or more episodes of AOM in a 6-month period or during a respiratory season or 4 or more in a year.

Children at increased risk of recurrent AOM

- cleft palate, craniofacial abnormalities and Down's syndrome (very high risk category)
- first episode early (under 6 months)
- family history of recurrent AOM in a sibling or parent
- day care attendance
- exposure to tobacco smoke
- not breast-fed
- ethnic origin: Native American or Inuit (Eskimo)

Supporting evidence if of classes: B, C, D, R

9. Consider Prophylactic Regimen

Prophylactic treatment options

- amoxicillin (20 mg/kg QD)

The usual duration of antibiotic prophylaxis is 2-6 months. Parents should be advised that prophylaxis has been shown to reduce the frequency of AOM by 40-50% but will not eliminate its occurrence.

Supporting evidence if of class: A

10. Schedule Follow-Up in 3-4 Weeks

Follow-up considerations

- Recheck all children < 5 years old
- Recheck ≥ 5 years old if:
 - risk factors identified
 - history of previous ventilating tubes or ear surgery
 - history of speech or developmental delay

Timing of rechecks

- Recheck in 3-4 weeks or at next well child visit if within the next 4-6 weeks.
- Reassess for symptoms of unresponsive otitis: pain, fever, or irritability continuing after 3-5 days of treatment. (Refer to Annotation #7, "Initiate Appropriate Treatment.")

Supporting evidence if of class: D

11. AOM 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.

12. Criteria for ENT Referral Met?

A child should meet one of the following nine criteria for ENT referral for consideration of ventilating tubes:

1. Patients in high-risk categories should be referred immediately to ENT; patients with craniofacial anomalies, Down's syndrome, cleft palate, and patients with speech and language delay.
2. Recurrent AOM which fails medical management (≥ 3 episodes in 6 months or ≥ 4 episodes in one year) with failure of prophylaxis defined as recurrence x2 on prophylaxis in a 2-6 month time period. (Prophylactic regimen described in Annotation #9, "Consider Prophylactic Regimen.")
3. Refractory acute otitis media with moderate to severe symptoms unresponsive to at least 2 antibiotics. (Refer to Annotation #7, "Initiate Appropriate Treatment.")
4. Bilateral or unilateral OME persisting for at least 3 months with hearing threshold of 20 dB or worse.
5. Development of advanced middle ear disease involving tympanic membrane atrophy, retraction pockets, ossicular erosion or cholesteatoma.

Algorithm Annotations

6. Medical treatment failure secondary to multiple drug allergy or intolerance.
7. At least 2 recurrences of otitis media within 2-3 months following ventilating tube extrusion with failed medical management.
8. Impending or actual complication of otitis media including:
 - a. Mastoiditis
 - b. Facial nerve paralysis
 - c. Lateral (sigmoid) sinus thrombosis
 - d. Meningitis
 - e. Brain abscess
 - f. Labyrinthitis
9. 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 6 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 Otitis Media.") Discussions with parents should take place regarding medical versus surgical treatment.

Supporting evidence if of classes: R, X

15. Meets Diagnostic Criteria for OME?

Middle ear effusion (seen on examination and/or confirmed by pneumatic otoscopy) or abnormal tympanometry or acoustic reflectometry without signs or symptoms of AOM.

The diagnosis of OME is distinguished from AOM 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.

Supporting evidence if of classes: C, R, X

Otitis Media with Effusion Algorithm Annotations

18. Consider Treatment Options

Treatment options to be considered include:

1. Observe - rechecking in 4-6 weeks.

Course of antibiotics should be given as a trial prior to referral for ventilating tubes. Ten-day course of antibiotics using first- and second-line criteria. (Refer to Annotation #7, "Initiate Appropriate Treatment.")

Algorithm Annotations

2. Referral for ventilating tubes if patient meets ENT referral criteria.

Course of antibiotics should be given as a trial prior to referral for ventilating tubes. Ten-day course of antibiotics using first- and second-line criteria. (Refer to Annotation #7, "Initiate Appropriate Treatment.")

Supporting evidence if of class: R

19. Follow-Up 4-6 Weeks

More frequent rechecking than every 4-6 weeks of OME is unnecessary and inappropriate. 90-95% of OME will resolve in 3-4 months. Continued observation to assure complete resolution is appropriate since hearing loss accompanies OME.

Supporting evidence if of classes: A, D

20. OME Resolved?

Mobility of the eardrum should be normal or results of tympanogram or pneumatic otoscopy should confirm resolution.

Supporting evidence if of classes: C, X

21. Criteria for ENT Referral Met?

Refer to Annotation #12, "Criteria for ENT Referral Met?"

Annotation Appendix A – Recommended Patient Education Content

Messages With Which Health Care Providers Can Teach And Reassure Parents

Symptoms Suggestive of Otitis Media

Generally:

Restlessness, irritability, wakefulness, and poor feeding usually associated with cold symptoms and/or conjunctivitis.

For Children Ages 3 and Older:

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

For Children Less Than 3 Years of Age:

Symptoms include irritability, fever, night waking, poor feeding, cold symptoms, conjunctivitis, and occasionally balance problems.

Children without above symptoms who tug on their ears rarely have otitis media.

Triage

Although the symptoms of otitis are often dramatic, the illness is rarely an emergency. Most children can be treated at home through the night unless symptoms of a more serious illness are present. Diagnosis of otitis is made by exam. Although the child having symptoms suggestive of otitis media should be seen within 24 hours, it is important to stress the benign nature of routine ear infections.

If the child does not have symptoms suggestive of otitis media, anticipatory education of the symptoms of otitis should be provided if appropriate.

Parents should be instructed to call back if symptoms persist, if the child is inconsolable, or the child is becoming more ill. Special consideration needs to be given to the febrile neonate.

Comfort Measures for the Child with Otitis Media

- Hold or rock child.
- Acetaminophen as appropriate for age and size of child.
- Apply warm compresses to ear.
- A hooded sweatshirt may be worn by an afebrile child to act like a heating pad.
- 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.

Prevention of Otitis Media

- Encourage breast feeding.
- If child is bottle fed, feed child upright – do not allow child to fall asleep with bottle.
- Avoid exposure to passive smoke.
- Limit exposure to numbers of children to the extent possible (i.e. daycare).
- Teach children careful hand washing technique.
- Limit exposure to viral upper respiratory infections.

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

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 May 2004 for Eighth Edition.

The next scheduled revision will occur within 12 months.

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Evidence Grading System

I. 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

Discussion and References

Otitis Media Algorithm

2. Symptoms Suggestive of Otitis Media?

Symptoms originating in the middle ear include earache, otorrhea, hearing loss, ear fullness or popping, dizziness or vertigo.

Baker RB. "Is ear pulling associated with ear infection?" *Pediatrics* 90:1006-07, 1992. (Class C)

Kemphorne J, Giebink GS. "Pediatric approach to the diagnosis and management of otitis media." *Otolaryngol Clin North Am* 24:905-29, 1991. (Class R)

Ruuskanen O, Heikkinen T. "Otitis media: etiology and diagnosis." *Pediatr Infect Disease J* 13: S23-6, 1994. (Class R)

4. Schedule Appointment Within 24 Hours

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)

Shelov SP, Hannemann RE, eds. *In Caring for Your Baby and Young Child Birth to Age Five*. New York: Bantam Books, 1991. (Class R)

5. Meets Diagnostic Criteria for AOM?

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 Otitis Media

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* 13:183-88, 1994. (Class B)

Duncan B, Ey J, Holberg CJ, et al. "Exclusive breast-feeding for at least 4 months protects against otitis media." *Pediatrics* 91:867-72, 1993. (Class B)

Hinton AE, Buckley G. "Parental smoking and middle ear effusions in children." *J Laryngol Otol* 102: 992-96, 1988. (Class C)

Niemelä M, Uhari M, Möttönen M. "A pacifier increases the risk of recurrent acute otitis media in children in day care centers." *Pediatrics* 96:884-88, 1995. (Class B)

Strachan DP, Jarvis MJ, Feyerabend C. "Passive smoking, salivary cotinine concentrations, and middle ear effusion in 7 year old children." *BMJ* 298:1549-52, 1989. (Class D)

Strangert K. "Otitis media in young children in different types of day-care." *Scand J Infect Dis* 9:119-23, 1977. (Class C)

7. Initiate Appropriate Treatment

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 which will self-resolve.

Bollag U, Bollag-Albrecht E. "Recommendations derived from practice audit for the treatment of acute otitis media." *Lancet* 338:96-99, 1991. (Class R)

Browning GG. "Childhood otalgia: acute otitis media." *BMJ* 300:1005-07, 1990. (Class X)

Burke P, Bain J, Robinson D, et al. "Acute red ear in children: controlled trial of non-antibiotic treatment in general practice." *BMJ* 303:558-62, 1991. (Class A)

Van Buchem FL, Peeters MF, Van 't Hof MA. "Acute otitis media: a new treatment strategy." *BMJ* 290:1033-37, 1985. (Class 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.

Cunningham AS. "Antibiotics for otitis media: restraint, not routine." *Contemp Ped* 11:17-30, 1994. (Class X)

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* 7:23-26, 1988. (Class M)

First-line medications

Antibiotic susceptibilities continue to change. The choice of antibiotic therapy needs to be based on the most current information available. It is the provider's responsibility to be aware of these changes.

Amoxicillin is the first-line drug of choice.

Claessen JQPJ, Appelman CLM, Touw-Otten FWMM, et al. "A review of clinical trials regarding treatment of acute otitis media." *Clin Otolaryngol* 17:251-57, 1992. (Class R)

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* 18:1-9, 1999. (Class R)

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* 57:594-96, 1982. (Class A)

Kaleida PH, Casselbrant ML, Rockette HE, et al. "Amoxicillin or myringotomy or both for acute otitis media: results of a randomized clinical trial." *Pediatrics* 87:466-74, 1991. (Class A)

Pichichero ME. "Assessing the treatment alternatives for acute otitis media." *Pediatr Infect Dis J* 13:S27-34, 1994. (Class R)

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* 7:23-26, 1988. (Class M)

Amoxicillin or trimethoprim/sulfa (Bactrim®/Septra®) are appropriate first-line choices in spite of some evidence of increasing resistance of pneumococcus to penicillin in various parts of the United States. At present, the rate does not exceed 25 to 30%, which is the usual level at which an antibiotic must be aban-

Discussion and References

done, in our community. If a patient has failed with a medication in the previous respiratory season, trying the medication again in subsequent seasons is warranted.

Kemphorne J, Giebink GS. "Pediatric approach to the diagnosis and management of otitis media." *Otolaryngol Clin North Am* 24:905-29, 1991. (Class R)

Pichichero ME. "Assessing the treatment alternatives for acute otitis media." *Pediatr Infect Dis J* 13:S27-34, 1994. (Class R)

Second-line medications

Second-line medications include amoxicillin/clavulanate potassium, trimethoprim/sulfa, clarithromycin, cefaclor, cefuroxime axetil, cefprozil, loracarbef, erythromycin ethylsuccinate and sulfisoxazole acetyl, ceftriaxone sodium, cefixime, cefpodoxime proxetil, zithromycin.

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 AOM. 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 AOM, a daily dose of ceftriaxone for 3-5 days is also an option and does not need additional oral antibiotics. This would be an option prior to referral to ENT for persistent AOM if the patient failed on several second-line antibiotics.

Barnett ED, Teele DW, Klein JO, et al. "Comparison of ceftriaxone and trimethoprim-sulfamethoxazole for acute otitis media." *Pediatrics* 99:23-28, 1997. (Class A)

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* 14:751-59, 1995. (Class D)

Treatment of resistant OM

The Drug-Resistant-*Streptococcus pneumoniae* Therapeutic Working Group, convened by the CDC, has stated the following: "Agents selected for alternative therapy for true clinical treatment failures should meet two criteria: (1) they should be effective against beta-lactamase-producing *H. influenzae* and *M. catarrhalis*; and (2) they should be effective against *S. pneumoniae* including most DRSP."

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)

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* 18:1-9, 1999. (Class R)

Odio CM, Kusmiesz H, Shelton S, et al. "Comparative treatment trial of augmentin versus cefaclor for acute otitis media with effusion." *Pediatrics* 75:819-26, 1985. (Class A)

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* 7:23-26, 1988. (Class M)

Persistent acute otitis media

Persistent AOM is defined as continued findings of AOM present within 6 days of finishing a course of antibiotics.

Kemphorne J, Giebink GS. "Pediatric approach to the diagnosis and management of otitis media." *Otolaryngol Clin North Am* 24:905-29, 1991. (Class R)

8. History of Recurrent AOM?

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* 13:183-88, 1994. (Class B)

Berman S, Roark R. "Factors influencing outcome in children treated with antibiotics for acute otitis media." *Pediatr Infect Dis J* 12:20-24, 1993. (Class C)

Duncan B, Ey J, Holberg CJ, et al. "Exclusive breast-feeding for at least 4 months protects against otitis media." *Pediatrics* 91:867-72, 1993. (Class B)

Henderson FW, Giebink GS. "Otitis media among children in day care: epidemiology and pathogenesis." *Rev Infect Dis* 8:533-37, 1986. (Class R)

Hinton AE, Buckley G. "Parental smoking and middle ear effusions in children." *J Laryngol Otol* 102:992-96, 1988. (Class C)

Kempthorne J, Giebink GS. "Pediatric approach to the diagnosis and management of otitis media." *Otolaryngol Clin North Am* 24:905-29, 1991. (Class R)

Klein JO. "Current issues in upper respiratory tract infections in infants and children: rationale for antibiotic therapy." *Pediatr Infect Dis J* 13:S5-8, 1994. (Class R)

Pichichero ME. "Assessing the treatment alternatives for acute otitis media." *Pediatr Infect Dis J* 13:S27-34, 1994. (Class R)

Strachan DP, Jarvis MJ, Feyerabend C. "Passive smoking, salivary cotinine concentrations, and middle ear effusion in 7 year old children." *BMJ* 298:1549-52, 1989. (Class D)

Strangert K. "Otitis media in young children in different types of day-care." *Scand J Infect Dis* 9:119-23, 1977. (Class C)

9. Consider Prophylactic Regimen

Amoxicillin (20 mg/kg QD) is an appropriate antibiotic for prevention.

Gonzalez CG, Arnold JE, Erhardt JB, et al. "Prevention of recurrent acute otitis media: chemoprophylaxis versus tympanostomy tubes." *Laryngoscope* 96:1330-34, 1986. (Class A)

There is no data to support use of second-line medications for prevention.

10. Schedule Follow-Up in 3-4 Weeks

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.

A recheck at 3 to 4 weeks from onset of treatment is recommended in order to assess whether there is evidence of a middle ear effusion. The work group feels that because children over age five are reasonably reliable reporters of hearing problems, they do not need to be rechecked unless there are symptoms to suggest an effusion or a new infection. Children under age five are not reliable to report a decrease in hearing, and thus should be rechecked for the possibility of an effusion.

Hathaway et al. addresses elimination of early rechecks. The article does not address the appropriate timing of follow-up for middle ear effusion after AOM.

Hathaway TJ, Katz HP, Dershewitz RA, et al. "Acute otitis media: who needs posttreatment follow-up?" *Pediatrics* 94:143-47, 1994. (Class D)

12. Criteria for ENT Referral Met?

Generally, ENT 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. "Tympanostomy with tube insertion." Based on criteria developed by the American Academy of Otolaryngology/Head and Neck Surgery, 1990. (Class R)

Paradise JL. "Managing otitis media: a time for change." *Pediatrics* 96:712-15, 1995. (Class X)

ENT referral is appropriate for bilateral or unilateral OME persisting for at least 3 months with a hearing threshold of 20 dB or worse.

Bluestone CD, Klein JO. "Chapter 23: Otitis media, atelectosis, and eustachian tube dysfunction." In *Pediatric Otolaryngology*, 3rd ed. Bluestone CD, Stool SE, Kenna MA, eds. Philadelphia: WB Saunders. 388-89, 521, 540-45. (Class R)

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)

15. Meets Diagnostic Criteria for OME?

Serous otitis is characterized by a translucent membrane with thin watery or yellow fluid seen. Mucoid effusions may appear more opaque, or the eardrum may appear somewhat thickened. Tympanometry will confirm the diagnosis.

Babonis TR, Weir MR, Kelly PC. "Impedance tympanometry and acoustic reflectometry at myringotomy." *Pediatrics* 87:475-80, 1991. (Class C)

Grundfast KM. "Otitis media in children." *Current Ther Otolaryngol Head and Neck Surg* 4:15-20, 1990. (Class R)

Kemphorne J, Giebink GS. "Pediatric approach to the diagnosis and management of otitis media." *Otolaryngol Clin North Am* 24:905-29, 1991. (Class R)

Paradise JL. "On classifying otitis media as suppurative or nonsuppurative, with a suggested clinical schema." *J Pediatr* 111:948-51, 1987. (Class R)

Discussion and References**Acoustic reflectometry**

Acoustic reflectometry is a new procedure not routinely used in most offices.

An acoustic otoscope is used in acoustic reflectometry to measure sound waves. The nullification of sound, also known as reflectivity, is measured. The higher the reflectivity, the more sound is bouncing back from the tympanic membrane and the more likely it is that a middle ear effusion is present. Acoustic reflectometry is extremely sensitive to user technique.

Combs JT. "Two useful tools for exploring the middle ear." *Contemp Pediatr* 10:60-75, 1993. (Class X)

Otitis Media with Effusion Algorithm Discussion and References**18. Consider Treatment Options**

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.

Patients with effusion may benefit from a course of antibiotics. Prolonged therapy (> 10-14 days) seems to provide no benefit. Several studies have examined the use of prednisone to hasten resolution of OME. Studies to date do not support the routine use of prednisone for OME.

Burke P. "Otitis media with effusion: is medical management an option?" *J R Coll Gen Pract* 39:377-82, 1989. (Class R)

19. Follow-Up 4-6 Weeks

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* 11:270-77, 1992. (Class A)

Teele DW, Klein JO, Rosner B and 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* 160:83-94, 1989. (Class D)

20. OME Resolved?

Combs JT. "Two useful tools for exploring the middle ear." *Contemp Pediatr* 10:60-75, 1993. (Class X)

Paradise JL, Smith CG, Bluestone CD. "Tympanometric detection of middle ear effusion in infants and young children." *Pediatrics* 58:198-210, 1976. (Class C)

21. Criteria for ENT Referral Met?

Refer to Discussion #12, "Criteria for ENT Referral Met?"

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
- Recommended Website Resources
- Key Implementation Recommendations
- Knowledge Products
- Recommended Patient Education Resources

Priority Aims and Suggested Measures

1. Increase appropriate antibiotic usage for otitis media infections.

Possible measures of accomplishing this aim:

- a. Percentage of children with a diagnosis of acute otitis media who were prescribed first-line antibiotics.
- b. Percentage of children with a diagnosis of acute otitis media who were prescribed second-line antibiotics who met the indications for second-line antibiotics.

2. Increase the timely and appropriate clinical follow-up for patients with a diagnosis of otitis media.

Possible measures of accomplishing this aim:

- a. Percentage of children with a diagnosis of acute otitis media referred to ENT meeting the criteria for referral.
- b. Percentage of children less than 5 years old with a diagnosis of acute otitis media who had an appropriate routine follow-up visit within the recommended time interval.

3. Improve parents' (caretakers') knowledge of symptoms suggestive of otitis media, appropriate indicators for a provider visit, risk factors, and outcomes of otitis media.

Possible measure of accomplishing this aim:

- a. Percentage of parents' (caretakers') receiving education on the symptoms suggestive of otitis media, appropriate indicators for a provider visit, risk factors, and outcomes of otitis media.

Priority Aims and Suggested Measures

Measurement Specifications**Possible Success Measure #1a**

Percentage of children with a diagnosis of acute otitis media who were prescribed first-line antibiotics.

Population Definition

All children less than 5 years old

Data of Interest

$$\frac{\text{\# of records where first-line antibiotic was prescribed}}{\text{Total \# of children less than 5 years old with acute otitis media whose records are reviewed}}$$

Total # of children less than 5 years old with acute otitis media whose records are reviewed

Numerator/Denominator Definitions

Numerator: Number of records where patients with acute otitis media is prescribed a first-line antibiotic and have not been treated for otitis media 60 days prior to current visit.

First-line antibiotics are defined as:

amoxicillin	trimethoprim/sulfa (TMX)	Trimox	Bactrim
Wynox	Septra	Amoxil	Sulfatrim

Denominator: All children less than 5 years old 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.

Steps:

1. Identify children less than 5 years old with a diagnosis of acute otitis media.
2. Determine which children had first-line antibiotics prescribed. Count these cases as "yes". Count as "no" those cases where another type of antibiotic was prescribed or no antibiotic was prescribed.

Time Frame Pertaining to Data Collection

Suggested data collection time frame is monthly.

Notes

Antibiotic recommendations are an important part of this guideline. This measure was felt to address an area in which most variation exists and in which the most improvement might be made. An upward trend would be the goal of this measure. A medical group should not expect the measure to reach 100%.

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Priority Aims and Suggested Measures**Possible Success Measure #2b**

Percentage of children less than 5 years old with a diagnosis of acute otitis media who had an appropriate routine follow-up visit within the recommended time interval.

Population Definition

All children less than 5 years old.

Data of Interest

$$\frac{\begin{array}{l} \# \text{ of records with documentation in the medical record} \\ \text{of a follow-up visit at 3-4 weeks OR well child visit within 4-6 weeks} \end{array}}{\begin{array}{l} \text{total \# of acute otitis media patients less than 5 years old} \\ \text{whose medical records are reviewed} \end{array}}$$

Numerator/Denominator Definitions

Numerator: Number of records where patient with acute otitis media has documented evidence in the medical record that a follow-up visit occurred at 3-4 weeks OR at next well child visit within 4-6 weeks. A follow-up visit for otitis media includes documentation of assessment for symptoms of: pain, fever or irritability continuing after 3-5 days of treatment.

Denominator: All children less than 5 years old 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 documentation of a follow-up visit in 3-4 weeks or well child visit at 4-6 weeks.

Steps:

1. Identify children less than 5 years old with a diagnosis of acute otitis media.
2. Determine which children had a follow-up visit at 3-4 weeks or a well child visit at 4-6 weeks. Count these cases as "yes". Count as "no" those cases where there is no documented evidence in the medical record that a follow-up visit occurred.

Time Frame Pertaining to Data Collection

Suggested data collection time frame is monthly.

Notes

A recheck at 3 to 4 weeks from the onset of treatment is recommended in order to assess whether there is evidence of a middle ear infection. This measure was felt to address the issue of eliminating unnecessary rechecks to reduce unnecessary visits and possible overtreatment. Rechecks at 10-14 days are not recommended unless symptoms recur or are persistent. An upward trend would be the goal of this measure. A medical group should not expect the measure to reach 100%.

Priority Aims and Suggested Measures**Possible Success Measure #3a**

Percentage of parents' (caretakers') 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 children less than 5 years old.

Data of Interest

$$\frac{\text{\# of records with documentation of education provided to the parent/caregiver about otitis media}}{\text{total \# of children less than 5 years old with otitis media whose medical records are reviewed}}$$
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 less than 5 years old 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. The eligible children are those less than 5 years old and who have been continuously enrolled in the clinic for the past 6 months. Records will be pulled and reviewed for any evidence that a clinician provided education to the parent or caregiver related to otitis media.

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.

Knowledge Products

Resources and knowledge products may be developed by the guideline work group, member and non-member organizations, or identified by ICSI staff as useful implementation tools.

ICSI has a wide variety of other knowledge products including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Products, go to www.icsi.org/knowledge or email requests to knowledgeproducts@icsi.org

Recommended Patient Education Resources

Description	Title	Author	Order Information
Brochure	Easing Earaches	Park Nicollet Health Services	PNHS; Call
Brochure	Earache & Otitis Media	American Academy of Otolaryngology – Head and Neck Surgery, Inc.	MIC203992 (703) 836-4444; \$20/100
Booklet	Middle Ear Fluid in Young Children	Agency for Health Care Policy and Research	MIC213986 (800) 358-9295; Free

Mayo Clinic does not wish to be a source of distribution at this time, but is willing to share content. To review items developed by Mayo, call Mary Ann Djonne at (507) 284-8780.

Park Nicollet does not wish to be a source of distribution at this time, but is willing to share content. To review items developed by Park Nicollet, call Lisa Harvey at (952) 993-1170.

Diagnosis and Treatment of Otitis Media in Children

SUMMARY OF CHANGES

May 2004

Algorithm, Annotations, Discussion/References

- 6 Additional prevention measure added: Ensure immunizations are up-to-date, including influenza and pneumococcal.
- 7 For a child with a draining middle ear, whether from ventilation tubes or perforation, a nonototoxic drop such as ciprofloxin or ofloxacin may be added to oral antibiotic treatment.
- 12 A child *should* meet one of the following nine criteria for ENT referral for consideration of ventilating tubes: ...

Aims and Measures, Measurement Specifications

No changes were made to the aims, measures or measurement specifications.

Support for Implementation

Patient Health Education tables were updated.