

# OBSERVATION<sup>2002</sup> OPTION TOOLKIT for Acute Otitis Media

*Prepared by*  
The New York State Department of Health  
and The New York Region Otitis Project Committee

The observation option for acute otitis media (AOM) refers to deferring antibiotic treatment of selected children for up to 72 hours, and limiting management to symptomatic relief.

With appropriate follow-up, complications are not increased and clinical outcomes compare favorably with routine initial antibiotic therapy. This approach is used commonly in The Netherlands and certain Scandinavian countries, and is gaining acceptance in Europe and the United States.

This toolkit presents evidence-based materials developed by the New York Region Otitis Project (NYROP) for judicious use of the observation option. The Department of Health and the Project committee would

like to acknowledge the leadership of Richard Rosenfeld, M.D., M.P.H., in this endeavor. The toolkit is not intended to endorse the observation option as a preferred method of management, nor is it intended as a rigid practice guideline to supplant clinician judgment. Rather, it gives busy clinicians the tools needed to implement the observation option in everyday patient care should they so desire.

The following documents comprise the toolkit:

**Overview of AOM Treatment**

**Health Care Provider Information Sheet**

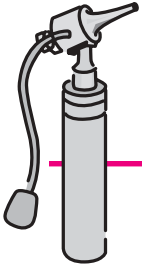
**Parent or Caregiver Information Sheet**

**Annotated Bibliography**

For information about the New York Region Otitis Project or the observation option call the New York State Department of Health at (518) 474-9219, or e-mail at [abxuse@health.state.ny.us](mailto:abxuse@health.state.ny.us)

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# Overview of AOM Treatment

Acute otitis media (AOM) is the presence of middle-ear effusion in conjunction with the rapid onset of one or more signs and symptoms of inflammation of the middle ear. AOM is the most common illness for which children receive antibiotics, but such use is associated with an alarming increase in resistant bacteria. This document offers evidence-based strategies for judicious use of antibiotics, including the observation option and short-course antibiotic therapy.

## What is the observation option?

The observation option refers to *deferring antibiotic treatment* of selected children with AOM for up to 72 hours, during which time management is limited to analgesics and symptomatic relief. This practice is based on data from randomized trials that suggest that most children will improve naturally, and that antibiotics provide only a marginal benefit. Antibiotic therapy is begun, however, if symptoms persist or worsen during this initial period of observation. The observation option for AOM is an official government policy in The Netherlands, and an unofficial policy in Denmark, Norway and Sweden. Complication rates from AOM (mastoiditis) are no greater with the observation option than with initial antibiotic therapy, *provided that* antibiotics are given when symptoms persist or worsen.

## To observe or to treat?

The following table is based on the principle that children benefit most from antibiotics if 1) they are less than two years of age, and 2) the diagnosis of AOM is very certain. Some degree of uncertainty always exists in diagnosing AOM, because of the difficulties in detecting middle-ear effusion (MEE). Children *without* MEE do not have true AOM, and do not benefit from antibiotic therapy.

## The importance of individualized treatment decisions

While the above guidelines are based on published evidence, individual decisions must also reflect provider experience and patient preference. This is particularly relevant to antibiotic *choice*, since no comparative studies show definitive clinical benefits for any single drug or drug class. A *short course* of antibiotics (five days) can be used instead of the traditional seven- to ten-day duration, but is not recommended for children under two years of age.

Last, please note that some groups of children benefit from initial antibiotics and are not candidates for observation. These include children with immune deficiency, complicated AOM, AOM relapse within 30 days, craniofacial syndromes, or co-existing sinusitis or streptococcal pharyngitis.

## Overview of Acute Otitis Media Treatment Options

Child Age	Certain Diagnosis	Uncertain Diagnosis
Under 6 months	Antibiotics	Antibiotics
6 months to 2 years	Antibiotics	Antibiotics if severe illness Observe* if non-severe illness
2 years or older	Antibiotics if severe illness Observe* if non-severe illness	Observe*

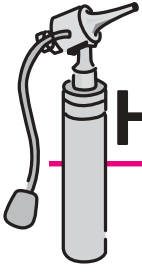
\* Observation is appropriate *only when* follow-up can be assured and antibiotics started if symptoms persist or worsen.

*Non-severe illness* implies mild otalgia and fever <39°C orally (about 102°F) or 39.5°C rectally in the past 24 hours.

*Severe illness* is moderate to severe otalgia or higher fever.

*Certain diagnosis* is a clinical picture suggesting acute otitis media with a high probability of middle-ear effusion.

*Uncertain diagnosis* is a clinical picture suggesting acute otitis media with anything less than a high probability of middle ear effusion.



# Healthcare Provider Information Sheet

The *target child* is two months to 18 years of age, and has acute otitis media (AOM) defined as middle-ear effusion (MEE) *plus* onset within 48 hours of otalgia, ear pulling, otorrhea, fever, or irritability. The strategies presented below are *not appropriate* for children with immune deficiency, craniofacial anomalies, AOM treatment failures or relapse (within 30 days), AOM with co-existing acute sinusitis or streptococcal pharyngitis, or AOM with signs of mastoiditis or other complications.

## General Principles of Antibiotic Therapy for AOM

1. Most AOM resolves without antibiotics, but initial therapy speeds recovery slightly.
2. Children with a low probability of MEE benefit least from initial antibiotic therapy.
3. MEE *without* acute symptoms (otitis media with effusion) benefits minimally from antibiotics.
4. Initial antibiotics are best for children less than two years of age *or* when illness is severe.
5. Initial observation is best for children aged two years or older with non-severe illness.
6. Short-course antibiotics for five days are an option for children aged two years or older.

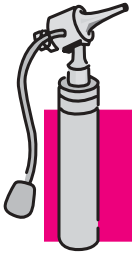
Considering the difficulties involved in detecting MEE, the level of diagnostic certainty is used to guide decision-making in the following strategies. The severity of illness is also used, with *severe illness* defined as moderate to severe otalgia, high fever, or both within the past 24 hours. Conversely, *non-severe illness* implies mild otalgia and fever less than 39°C orally (about 102°F) or 39.5°C rectally (about 103°F).

## Specific Guidelines for Judicious Antibiotic Therapy of AOM

1. **Certain Diagnosis of AOM:** clinical picture suggesting AOM with a high probability of MEE (fluid in the middle ear) diagnosed by pneumatic otoscopy, tympanometry, or acoustic reflectometry
  - a) *Infants and children up to age 23 months* receive antibiotics for ten days.
  - b) *Children aged 24 months and older with severe illness* receive antibiotics for five to ten days.
  - c) *Children aged 24 months and older with non-severe illness* are managed with either initial antibiotics for five to ten days *or* observation for two to three days *provided that* telephone or office visit follow-up can be assured and antibiotics started if symptoms persist or worsen.
2. **Uncertain Diagnosis of AOM:** clinical picture suggesting AOM with anything less than a high probability of MEE as a result of obstructing cerumen, child apprehension, or other factors that impair visibility of the tympanic membrane or the performance of pneumatic otoscopy
  - a) *Infants less than six months of age* receive antibiotics for ten days.
  - b) *Infants and children aged six to 23 months with severe illness* receive antibiotics for ten days
  - c) *Infants and children aged six to 23 months with non-severe illness* are managed with either initial antibiotics for five to ten days *or* observation for one to two days *provided that* telephone or office visit follow-up can be assured and antibiotics can be started if symptoms persist or worsen.
  - d) *Children aged 24 months and older* are observed for up to 72 hours *provided that* telephone or office visit follow-up can be assured and antibiotics started if symptoms persist or worsen.

## Expected Outcomes Based on Cumulative Published Evidence

1. Symptom relief at 24 hours will occur for about two-thirds of children aged two years or older and for about one-third of younger children.
2. About 25 percent of children managed with initial observation may require antibiotics for persistent or worsening symptoms.
3. Symptom relief at 2-7 days will occur in about 85-95 percent of children; roughly 5-15 percent of this results from antibiotic use, but the effect may be greater in children less than two years of age.
4. Asymptomatic fluid (MEE) will persist in about 35-45 percent of children after one month, decreasing to 10-25 percent by three months; additional antibiotics will not improve MEE resolution rates.
5. Antibiotics given for seven-ten days increase resolution at 10-14 days by about eight percent over shorter courses, but the effect is larger (about 12-20 percent) in children less than two years of age.



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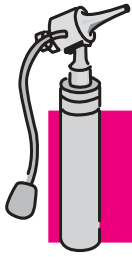
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# OBSERVATION OPTION

## TOOLKIT for Acute Otitis Media

Prepared by

The New York State Department of Health and The New York Region Otitis Project Committee

### Parent or Caregiver Information Sheet

Parents worry when their children's ears hurt. But, not every child with an earache needs an antibiotic. In fact, many children who have earaches get better without an antibiotic. The New York State Health Department wants antibiotics to be taken only by children who would benefit the most from them. Ask your child's doctor if your child really would benefit from an antibiotic.

#### What happens when children are given antibiotics that are not really needed?

Doctors use antibiotics to kill germs. But, sometimes, the germs are strong enough to resist the antibiotic. Then, each time your child takes an antibiotic, more germs may live. Eventually, the antibiotic stops working for your child. When this happens, the germs may spread to other family members, neighbors and playmates. Also, when a child is given antibiotics too often, he or she may get a rash, diarrhea, upset stomach, yeast infections, or other problems. If given antibiotics when they are not needed, the child may not respond to them when needed for a more serious infection, such as pneumonia or meningitis.

#### Do antibiotics help all children who have ear infections?

Doctors often give antibiotics to treat infections in the middle ear. About eight out of ten children with ear infections get better with no antibiotics at all. If your child has an earache, remember that antibiotics do not relieve pain during the first 24 hours and do not reduce fever any quicker or better than pain medicines. They also do not protect children from getting more ear infections. Your doctor will prescribe an antibiotic for your child if it is needed.

#### If antibiotics only help a few children, why use them?

Antibiotics work best for children who are under the age of two, or for older children who have really bad ear infections. Before antibiotics were discovered, children with really bad ear infections often became even sicker.

#### Which children should be given antibiotics?

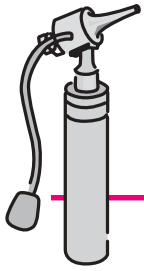
#### Which should not?

Your doctor will talk to you about your child. Antibiotics may be right for infants and very young children who have infections, not just fluid in their ears. They may also be right if a child is very sick or has a high fever. If the child is older and not very sick, or if the doctor is not sure if it is a real ear infection, it may be better to use a non-aspirin pain reliever (ACETAMINOPHEN or IBUPROFEN) for pain, and to wait and watch for up to 72 hours. If the child is still sick after 72 hours, the doctor will recheck the child and probably give an antibiotic. Never give your child an antibiotic that was not prescribed for him or her. Never share antibiotics with others. Make sure your child is given an antibiotic only for a true ear infection, not just fluid alone.

#### How long should a child take an antibiotic?

Antibiotic treatment of five, seven and ten days is effective. Antibiotic resistance occurs less often with a five-day treatment. Ask your doctor what is best for your child. Be sure to give your child all the full dosage of the antibiotic even if your child appears to feel better.

You can learn more about the proper use of antibiotics from the American Academy of Pediatrics. Visit their website at [www.aap.org](http://www.aap.org).



# Annotated Bibliography

## Randomized controlled trials of non-antibiotic therapy for AOM

- 1 Appelman CLM, Claessen JQJP, Touw-Otten FWMM, et al. Coamoxiclav in recurrent acute otitis media: placebo-controlled study. *BMJ* 1991; 303:1450-1452. *Netherlands; minimum age 6 months.*
- 2 Burke P, Bain J, Robinson D, Dunleavy J. Acute red ear in children: controlled trial of nonantibiotic treatment in general practice. *BMJ* 1991; 303:558-562. *England; minimum age 3 years.*
- 3 Damoiseaux RA, van Balen FA, Hoes AW, et al. Primary care based randomised, double blind trial of amoxicillin vs. placebo for acute otitis media in children aged under 2 years. *BMJ* 2000; 320: 350-4. *Netherlands; only study limited to age less than 2 years; 60-70% still symptomatic at 24 hours with 13% absolute antibiotic benefit.*
- 4 Halsted C, Lepow ML, Balassanian N, et al. Otitis media: clinical observations, microbiology, and evaluation of therapy. *AJDC* 1968; 115:542-551. *United States; minimum age 2 months.*
- 5 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: 466-474. *United States; minimum age 7 months.*
- 6 Laxdal OE, Merida J, Trefor Jones RH. Treatment of acute otitis media: a controlled study of 142 children. *Can Med Assoc J* 1970; 102:263-268. *Canada; minimum age not specified; no drug instead of placebo.*
- 7 Little P, Gould C, Williamson I, et al. Pragmatic randomised controlled trial of two prescribing strategies for childhood acute otitis media. *BMJ* 2001; 322:336-42. *England; minimum age 6 months; only 24% of children initially observed required antibiotics.*
- 8 Mygind N, Meistrup-Larsen KI, Thomsen J, et al. Penicillin in acute otitis media: a double-blind, placebo-controlled trial. *Clin Otolaryngol* 1981; 6:5-13. *Denmark; minimum age 1 year.*
- 9 Thalín A, Densert O, Larsson A, et al. Is penicillin necessary in the treatment of acute otitis media? In: Proceedings of the International Conference on Acute and Secretory Otitis Media, Part 1, Jerusalem, Israel 17-22 November 1985. Amsterdam: Kugler Publications, 1985:441-446. *Sweden; minimum age 2 years.*
- 10 van Buchem FL, Dunk JHM, van't Hof MA. Therapy of acute otitis media: myringotomy, antibiotics, or neither: a double-blind study in children. *Lancet* 1981; 2:883-887. *Netherlands; minimum age 2 years.*

## Systematic reviews of antibiotic therapy for AOM

- 1 Rosenfeld RM, Vertrees JE, Carr J, et al. Clinical efficacy of antimicrobial drugs for acute otitis media: meta-analysis of 5400 children from thirty-three randomized trials. *J Pediatr* 1994;124:355-367. *Spontaneous resolution of AOM (excluding middle-ear effusion) in 81% of children within 7 days (95% CI, 69-94%), with an absolute increase of 14% with antibiotic therapy (95% CI, 9-18%); drug choice did not affect outcome.*
- 2 Del Mar C, Glasziou P, Hayem M. Are antibiotics indicated as initial treatment for children with acute otitis media? A meta-analysis. *BMJ* 1997; 314:1526-1529. *Absolute increase in pain relief of 5% from antibiotic therapy at 2-7 days (95% CI, 1-8%); spontaneous clinical relief of 60% at 24 hours with no additional antibiotic benefit.*
- 3 Marcy M, Takata G, Shekelle P, et al. Management of Acute Otitis Media. Evidence Report/Technology Assessment No. 15 (Prepared by the Southern California Evidence-based Practice Center under Contract No. 290-97-0001). AHRQ Publication No. 01-E010. Rockville, MD: Agency for Healthcare Research and Quality. May 2001. *Spontaneous clinical relief of AOM in 81% of children at 1-7 days (95% CI, 72-90%), with an absolute increase of 12% at 2-7 days with antibiotic therapy (95% CI, 3-22%); no increase in complications from observation option with good follow-up.*

## Evidence concerning illness severity and child age

- 1 Appelman CLM, Claessen JQJP, Touw-Otten FWMM, et al. Coamoxiclav in recurrent acute otitis media: placebo-controlled study. *BMJ* 1991; 303:1450-1452. *Children under 2 years benefited more from antibiotics (32% increase in clinical relief) but the impact was not statistically significant (95% CI, -4-67%).*
- 2 Carlin SA, Marchant CD, Shurin PA, et al. Host factors and early therapeutic response in acute otitis media. *J Pediatr* 1991; 118:178-83. *Failure to eliminate bacteria from the middle ear after antibiotic therapy occurred almost exclusively in children less than 18 months of age, but only 37% had clinical failure.*
- 3 Harsten G, Prellner K, Heldrup J, et al. Treatment failure in acute otitis media: a clinical study of children during their first three years of life. *Acta Otolaryngol* 1989; 108:253-8. *Clinical treatment failure was most common in the first year of life (19%) and decreased in the second and third years (5% and 4%).*
- 4 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: 466-474. *Compared*

*to children with non-severe AOM, children with severe AOM (all aged 2 years or older) had lower rates of spontaneous clinical relief (76% vs. 92%) and greater absolute benefit from initial antibiotic therapy (17% vs. 4%).*

- 5 Schutzman SA, Petrycki S, Fleisher GR. Bacteremia with otitis media. *Pediatric* 1991; 87:48-53. *Prevalence of bacteremia was only 3% but higher rates were observed in infants and with temperatures above 40C.*

## Impact of short-course antibiotic therapy on AOM outcomes

- 1 Cohen R, Levy C, Boucherat M, et al. A multicenter, randomized, double-blind trial of 5 versus 10 days of antibiotic therapy for acute otitis media in young children. *J Pediatr* 1998; 133:634-9. *Compared with a 5-day course of amoxicillin-clavulanate, treatment for 10 days in 395 children younger than 2.5 years resulted in an absolute increase of 11% in clinical resolution rates at 12-14 days. In daycare the benefit was 16%.*
- 2 Cohen R, Levy C, Boucherat M, et al. Five vs. ten days of antibiotic therapy for acute otitis media in young children. *Pediatr Infect Dis J* 2000; 19:458-63. *Compared with a 5-day course of cefpodoxime-proxetil, treatment for 10 days in 450 children aged 2 years or younger resulted in an absolute increase of 8% in clinical resolution rates at 12-14 days. In daycare the benefit was 11%.*
- 3 Guillemot D, Carbon C, Balkau B, et al. Low dosage and long treatment duration of beta-lactams: risk factors for carriage of penicillin-resistant *Streptococcus pneumoniae*. *JAMA* 1998; 279:365-70. *Long treatment results in selective pressure on nasopharyngeal flora and penicillin-resistant pneumococci.*
- 4 Hoberman A, Paradise JL, Burch DJ, et al. Equivalent efficacy and reduced occurrence of diarrhea from a new formulation of amoxicillin/clavulanate potassium (Augmentin) for treatment of acute otitis media in children. *Pediatr Infect Dis J* 1997; 16:463-70. *Compared with a 5-day course of therapy, treatment for 10 days in children younger than 2 years resulted in an absolute increase of 15% in clinical resolution rates at 12-14 days, and 23% at 32-38 days.*
- 5 Korzyskiy AL, Hildes-Ripstein GE, Longstaffe SEA, et al. Treatment of acute otitis media with shortened course of antibiotics: a meta-analysis. *JAMA* 1998; 279:1736-42. *Treatment for 7 days or longer resulted in an absolute increase of 8% in clinical resolution rates (95% CI, 4-12%) over short course therapy, but was no longer significant at 20-30 days. Rates of relapse and recurrence were unrelated to duration of therapy.*
- 6 Paradise JL. Short-course antimicrobial treatment for acute otitis media: not best for infants and young children. *JAMA* 1997; 278:1640-42. *Good commentary on issue of short-course therapy.*

## Other commentaries and articles

- 1 Berman S, Byrns PJ, Bondy J, et al. Otitis media-related antibiotic prescribing patterns, outcomes, and expenditures in a pediatric Medicaid population. *Pediatrics* 1997; 100:585-592. *Found that 88% of over 12,000 AOM episodes were successfully treated with a single antibiotic, regardless of the cost or antibacterial spectrum of the initial drug.*
- 2 Cates C. An evidence based approach to reducing antibiotic use in children with acute otitis media: controlled before and after study. *BMJ* 1999; 318:715-6. *A restrictive antibiotic policy for AOM decreased antibiotic prescriptions by 32% (95% CI, 25-39%) versus the prior year. For comparison, antibiotic prescriptions decreased by 12% (95% CI, 4-20%) in a local control practice during the same period.*
- 3 Culpepper L, Froom J. Routine antimicrobial therapy of acute otitis media. Is it necessary? *JAMA* 1997; 278:1643-1645. *Good commentary on observation option as an alternative to initial antibiotic therapy.*
- 4 Dowell SF, Marcy SM, Phillips WR, et al. Otitis media: principles of judicious use of antimicrobial agents. *Pediatrics* 1998; 101(Suppl Pt 2):165-71. *Good review, but doesn't consider the observation option.*
- 5 Rosenfeld RM. Natural history of untreated otitis media. In: Rosenfeld RM, Bluestone CD (eds). *Evidence-Based Otitis Media*. Hamilton, Ontario: BC Decker Inc; 1999:156-77. *Systematic review of natural history.*
- 6 Management of Acute Otitis Media. Evidence Report/Technology Assessment: Number 15, June 2000. Agency for Healthcare Quality and Research. Rockville, MD. <http://www.ahrq.gov/clinic/otitisum.htm>. *A brief, but useful, summary of the official government-sponsored evidence summary on acute otitis media.*
- 7 Rosenfeld RM. Observation option toolkit for acute otitis media. *Intl J Pediatr Otorhinolaryngol* 2001; 58:1-8. *Overview of methodology and recommendations from the New York Region Otitis Project.*

Suggested citation: New York Regional Otitis Project.  
Observation Option Toolkit for Acute Otitis Media.  
State of New York, Department of Health, Publication #4894, March 2002  
4894

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