

Management of Acute Otitis Media After Publication of the 2004 AAP and AAFP Clinical Practice Guideline



WHAT'S KNOWN ON THIS SUBJECT: The 2004 AAP and AAFP clinical practice guideline on AOM allowed for observation of the patient without initial antibiotic therapy, recommended amoxicillin as the first-line antibiotic treatment, and recommended treatment to reduce pain if it was present.



WHAT THIS STUDY ADDS: The management of AOM without antibiotics has not increased after publication of the 2004 guideline. Children who did not receive antibiotics were more likely to have mild infections. The prescribing of amoxicillin and analgesic agents has increased after publication of the guideline.

abstract

OBJECTIVES: Observation without initial antibiotic therapy was accepted as an option for acute otitis media (AOM) management in the 2004 American Academy of Pediatrics and American Academy of Family Physicians clinical practice guideline. The guideline also recommended amoxicillin as the first-line treatment for most children, and analgesic treatment to reduce pain if it was present. Our objective was to compare the management of AOM after publication of the 2004 guideline.

PATIENTS AND METHODS: We analyzed the National Ambulatory Medical Care Survey, 2002–2006 ($N = 1114$), which occurred in US physicians' offices. The patients were children aged 6 months to 12 years who were diagnosed with AOM. The time comparisons were the 30-month periods before and after the guideline. The main outcome was the encounter rate at which no antibiotic-prescribing was reported. Secondary outcomes were the identification of factors associated with encounters at which no antibiotic-prescribing was reported and antibiotic- and analgesic-prescribing rates.

RESULTS: The rate of AOM encounters at which no antibiotic-prescribing was reported did not change after guideline publication (11%–16%; $P = .103$). Independent predictors of an encounter at which no antibiotic-prescribing was reported were the absence of ear pain, absence of reported fever, and receipt of an analgesic prescription. After guideline publication, the rate of amoxicillin-prescribing increased (40%–49%; $P = .039$), the rate of amoxicillin/clavulanate-prescribing decreased (23%–16%; $P = .043$), the rate of cefdinir-prescribing increased (7%–14%; $P = .004$), and the rate of analgesic-prescribing increased (14%–24%; $P = .038$).

CONCLUSIONS: Although management of AOM without antibiotics has not increased after the publication of the 2004 American Academy of Pediatrics and American Academy of Family Physicians clinical practice guideline, children who did not receive antibiotics were more likely to have mild infections. In accordance with the guideline, the prescribing of amoxicillin and analgesics has increased. Contrary to the guideline, the prescribing of amoxicillin/clavulanate has decreased, whereas the prescribing of cefdinir has increased. *Pediatrics* 2010; 125:214–220

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KEY WORDS

acute otitis media, antibiotics, practice guidelines

ABBREVIATIONS

AOM—acute otitis media

AAP—American Academy of Pediatrics

AAFP—American Academy of Family Physicians

NAMCS—National Ambulatory Medical Care Survey

NCHS—National Center for Health Statistics

PCV—pneumococcal conjugate vaccine

CDC—Centers for Disease Control and Prevention

ICD-9-CM—*International Classification of Diseases, 9th Revision, Clinical Modification*

CI—confidence interval

OR—odds ratio

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Acute otitis media (AOM) is one of the most common diseases of childhood, affecting more than 80% of children by the age of 5 years. Essentially all diagnosed episodes of AOM in the United States have been historically treated with antibiotics, making it by far the most common condition for which antibacterial agents are prescribed for US children.¹ However, in other developed countries, most notably the Netherlands, antibiotics are not routinely prescribed for uncomplicated AOM, and this approach has also been gaining interest in the United States.²⁻⁴ Furthermore, antibiotic choices are not always straightforward, because clinicians need to be concerned about increased resistance among many of the pathogens that cause AOM.⁵⁻⁷

In May 2004, the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP) jointly issued a well-publicized clinical practice guideline on the management of AOM in children aged 6 months through 12 years.⁸ The guideline endorsed an observation option in selected children with AOM on the basis of their age, severity of symptoms, and certainty of diagnosis and made specific antibiotic recommendations on the basis of illness severity and treatment response. In addition, the guideline also made a strong recommendation that the management of AOM should include an assessment of pain and the appropriate analgesic treatment if pain is present.

A recent survey of physicians in a national pediatric practice-based research network compared AOM management before and after publication of the 2004 guideline.⁹ The responses indicated that most primary care physicians agreed with the concept of an observation option, although they infrequently chose it, and the acceptance rate decreased slightly 2 years after the guideline was published. The

survey authors also concluded that antibiotic choices for AOM differed markedly from the guideline's recommendations, and the difference has increased since 2004. There are no data from actual comparisons of the rate of initial observation and antibiotic-prescribing choices after guideline implementation. Data on comparative analgesic-prescribing rates are also lacking.

To measure changes in the rate of encounters managed without antibiotics and changes in patterns of antibiotics and analgesic agents prescribed for AOM after publication of the 2004 AAP/AAFP clinical practice guideline, "Diagnosis and Management of Acute Otitis Media," we analyzed data from the National Ambulatory Medical Care Survey (NAMCS) from 2002 to 2006.

METHODS

Study Design and Administration

The NAMCS is administered by the National Center for Health Statistics (NCHS) for the Centers for Disease Control and Prevention (CDC). The survey was designed to meet the need for objective, reliable information about ambulatory medical care services in the United States. The NAMCS collects information on patient visits to nonfederally employed, office-based physicians in the United States. The survey sample includes physicians who are considered to be within the survey scope and who work in federally qualified health centers and other government clinics. The NAMCS has a 3-tiered design that includes geographic location, physician specialty, and individual patient visits within the practice. The NCHS weights each visit by taking into account the location and specialty. Physicians are randomly selected from national databases compiled by the American Medical Association and the American Osteopathic Association.

Each selected physician is randomly assigned to a 1-week reporting period. During this period, the physicians or the office staff record data for a systematic random sample of visits on a standardized encounter form, which is provided for that purpose and checked for completeness by the field staff. The goal is for physicians included in the sample to complete 30 records per sampling week.

Study Sample: Episodes of Care for AOM

Up to 3 diagnoses were recorded for each visit as free text. The survey staff then coded the diagnoses by using the *International Classification of Diseases, 9th Revision, Clinical Modification* (ICD-9-CM).¹⁰ Our analysis included patient visits with ICD-9-CM diagnoses of acute suppurative otitis media (ICD-9-CM 382.0), unspecified suppurative otitis media (ICD-9-CM 382.4), and unspecified otitis media (ICD-9-CM 382.9). Patient visits with a diagnosis of nonsuppurative otitis media (ICD-9-CM 381-381.4) were not included, because the AOM clinical practice guideline did not address this condition. Patient visits with an alternative diagnosis that may have justified an antibiotic prescription were excluded, which included visits with a diagnosis of acute sinusitis (ICD-9-CM 461), chronic sinusitis (ICD-9-CM 473), acute pharyngitis (ICD-9-CM 462), acute tonsillitis (ICD-9-CM 463), streptococcal sore throat (ICD-9-CM 034.0), or pneumonia (ICD-9-CM 481-486). In addition, only patient visits that were recorded as being for an acute or new problem were included. After the inclusion and exclusion criteria were applied, 1114 records comprised the study sample.

Covariates

The patients' age from 6 months to 12 years (collapsed to <2 and ≥2 years), gender, race (categories condensed to white or nonwhite), and insurance sta-

tus (categories condensed to private, Medicare/Medicaid, or other) were recorded for each visit. The providers' self-selected specialty was coded as general pediatrician, family practitioner, or other. The geographic region was also recorded. Up to 3 complaints, symptoms, or other reason(s) for the visit were abstracted as free text and then coded centrally by using a standard reason-for-visit classification (RVC) system. Patient visits that were coded as presenting with symptoms of ear pain (RVC code 13551) and fever (RVC code 10100) were identified.

Preclinical and Postclinical Guideline Periods

Two 30-month periods were developed on the basis of the clinical guideline publication date of May 2004. The preguideline period ranged from January 2002 through June 2004 and included 584 patient visits. The post-guideline period ranged from July 2004 through December 2006 and included 530 patient visits.

Outcome of Prescribed Antibiotics

Up to 6 medications were recorded for each visit in 2002, and up to 8 medications were recorded for each visit from 2003 to 2006. All recorded medications were used in the analysis. From 2002 to 2005, the NAMCS used a 5-digit code that had been assigned to each official generic name given to every drug entity by the US Pharmacopeia.¹¹ Beginning with the 2006 data release, the generic components and therapeutic classifications of NAMCS drugs were coded by using Lexicon Plus, a proprietary database of Cerner Multum, Inc (Denver, CO).¹² Amebicides, anthelmintic, antifungal, antimalarial, antituberculosis, and antiviral agents, and aminoglycosides were excluded. Topical agents were also excluded.

Amoxicillin was defined to include ampicillin. If more than 1 antibiotic was

used in a single visit (3.1% of sample records), we counted each antibiotic prescribed in its respective class, but the visit only counted once as an episode of care in which an antibiotic was prescribed.

Outcome of Prescribed Analgesic Agents

Analgesic agents were identified by using a unique classification scheme that was developed at the NCHS.¹¹ The following drug entries were included: acetaminophen, Tylenol, Children's Tylenol, Tylenol Elixir, Advil, ibuprofen, Motrin, children's ibuprofen, Children's Advil, and Auralgan. Only those visits as defined above in "Episodes of Care for AOM" were included in the analysis for analgesic-prescribing.

Data Analysis

We used the weights, strata, and primary sampling-unit design variables that were provided by the NCHS for all of the analyses. The main outcomes, percentage comparison of visits with and without antibiotic prescriptions after publication of the 2004 guideline, were evaluated by using the χ^2 test. To control for potential confounding variables, a multivariate logistic regression model was developed to determine the associations with visits in which no antibiotic prescription was reported, while controlling for age, gender, race, preguideline or post-guideline period, insurance status, physician specialty, symptoms of ear pain or fever, and receipt of an analgesic prescription. To further explore temporal changes in the rate of encounters during which no antibiotic was prescribed, the 5-year study period was divided into ten 6-month periods and analyzed by using the linear-trend test. For all analyses we used survey weights and took into account the complex survey design by using the `svy` command provided in Stata 10 (Stata Corp, College Station, Texas). All

P values were 2-tailed, and *P* < .05 was considered significant.

RESULTS

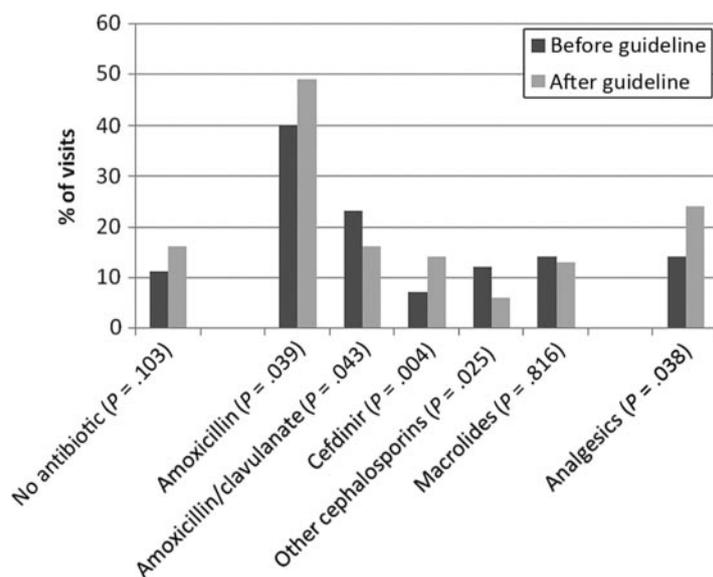
The average annual number of visits of children with AOM was 10.3 million (95% confidence interval [CI]: 9.0–11.7 million). Among children with AOM, 53% were male patients and 86% were white (Table 1). Forty-eight percent of the patients were <2 years old. Eighty-two percent of the visits were with pediatricians, 14% with family physicians, and 4% with other physicians. Fifty-one percent (95% CI: 45%–58%) of the visits occurred in the preguideline period. Visits in the preguideline and postguideline periods were similar in terms of demographic, insurance, and symptom variables (Table 1).

Overall, antibiotics were not prescribed in 13% (95% CI: 10%–17%) of the visits. The percentage of AOM diagnoses that were managed without an antibiotic did not change significantly, ranging from 11% before to 16% after (*P* = .103) (Fig 1) publication of the 2004 guideline. The proportion of visits at which amoxicillin was prescribed increased (40%–49%; *P* = .039), whereas the prescribing of amoxicillin/clavulanate decreased (23%–16%; *P* = .043) after guideline publication (Fig 1). Cefdinir-prescribing increased (7%–14%; *P* < .004), whereas the prescribing of cephalosporins other than cefdinir decreased (12%–6%; *P* = .025) after publication. Macrolide-prescribing did not change (14%–13%; *P* = .82) after the clinical guideline was issued. The number of visits with other antibiotic prescriptions was too small to analyze. The rate of analgesic-prescribing increased from 14% to 24% (*P* = .038) after the guideline was published (Fig 1).

Because the AAP/AAFP guideline has different criteria for the observation option according to age greater than or less than 2 years, we also examined

TABLE 1 Visit Characteristics of Children Diagnosed With AOM From 2002 to 2006 in US Physicians' Offices Before and After Publication of the 2004 AAP/AAFP Clinical Practice Guideline (N = 1114)

Characteristic	Overall Proportion of Visits, %	Proportion of Visits Before Clinical Guideline, Jan 2002 to Jun 2004 (n = 584), %	Proportion of Visits After Clinical Guideline, Jul 2004 to Dec 2006 (n = 530), %	P
Gender				
Male	53	54	51	.58
Female	47	46	49	
Age				
<2 y	48	47	49	.58
≥2 y	52	53	51	
Race				
White	86	87	85	.41
Nonwhite	14	13	15	
Health insurance				
Private	64	68	58	.06
Medicaid/Medicare	30	27	32	
Self-pay and other	7	4	10	
Physician specialty				
Pediatrics	82	83	81	.69
Family practice	14	14	14	
Other	4	3	5	
Geographic region				
Northeast	21	19	24	.38
Midwest	23	26	19	
South	33	34	33	
West	23	21	24	
Symptoms				
Fever	22	24	19	.26
Ear pain	36	34	38	.35

**FIGURE 1**

Comparison of prescribing choices in visits for children with a diagnosis of AOM to US physicians' offices before and after publication of the AAP/AAFP 2004 clinical practice guideline (N = 1114).

whether age was a modifier of the effect of the proportion of cases in which an antibiotic was prescribed (Fig 2). In

logistic regression modeling, age (<2 vs ≥2 years) was not an independent predictor of a visit at which no

antibiotic-prescribing was reported (odds ratio [OR]: 1.42 [95% CI: 0.86–2.35]).

Over the 5-year study period, there was a gradual upward trend in the rate of encounters in which no antibiotic-prescribing was reported, increasing from 6% in the first half of 2002 to 24% in the last half of 2004 and to 14% in the last half of 2006 ($P = .01$ for the trend) (Fig 3). The trend was not characterized, however, by a sustained positive inflection after the period of the guideline publication in the second half of 2004.

In multivariable logistic regression modeling, independent predictors of a patient visit at which antibiotic-prescribing was not reported were the absence of ear pain (OR: 3.08 [95% CI: 1.92–4.96]), absence of fever (OR: 2.70 [95% CI: 1.22–6.00]), and receipt of an analgesic prescription (OR: 2.40 [95% CI: 1.06–5.46]).

DISCUSSION

In this analysis of data on the ambulatory management of AOM in the United States, our results revealed that the percentage of pediatric AOM visits during which an antibiotic was not prescribed did not increase significantly in the 30 months after the dissemination of a well-publicized clinical guideline by the AAP/AAFP in 2004, shifting only from 11% to 16%. Indeed, although the results of our analysis demonstrate a slightly increased trend in the management of AOM without antibiotics over the study period, the absence of an inflection point around the time of the guideline publication argues against the guideline being a large factor in what more likely represents a general secular trend. It seems that, despite the guideline's endorsement, physicians have been reluctant to frequently use the observation option, perhaps because of percep-

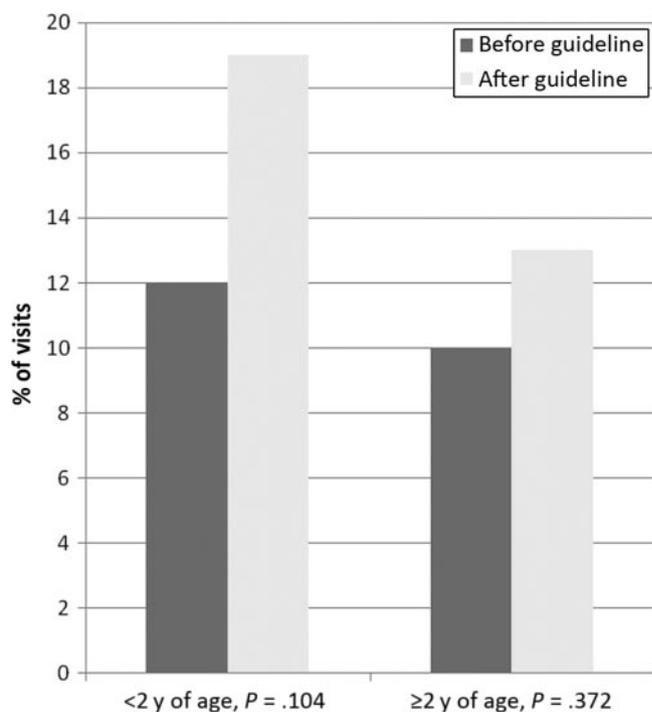


FIGURE 2

Effect of age on proportion of visits at which no antibiotic-prescribing was reported for children with a diagnosis of AOM to US physicians' offices before and after publication of the AAP/AAPF 2004 clinical practice guideline ($N = 1114$).

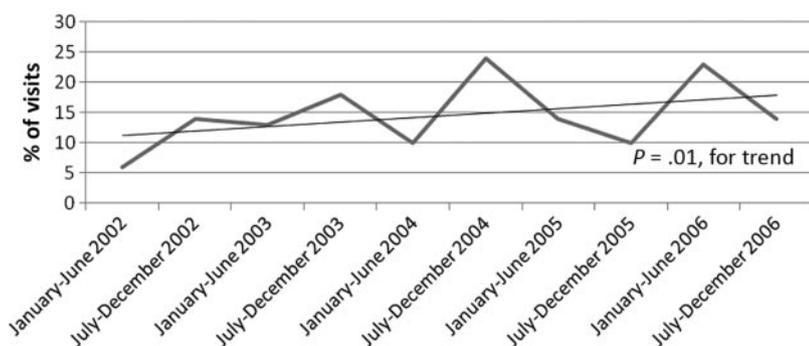


FIGURE 3

Trend in the rate of visits at which no antibiotic-prescribing was reported for children with a diagnosis of AOM to US physicians' offices before and after publication of the AAP/AAPF 2004 clinical practice guideline ($N = 1114$).

tions of parental reluctance to accept this approach and barriers to follow-up as noted previously.¹³ Although our results were derived from a nationally representative sample of physicians in multiple ambulatory settings, the percentage of visits (16%) without an antibiotic prescription after guideline availability is similar to the percentage of physicians who stated that they used

the observation option in a pair of sequential surveys that were conducted in 2004 and 2006. The sequential surveys included 500 physicians from 42 states who participated in a pediatric research network.^{9,13} This consistency in findings between 2 studies with different methods lends credibility to our results. It is encouraging that children who did not receive antibiotics were also less likely

to present with symptoms of severe infection such as fever or ear pain. Thus, consistent with the guideline, it seems that the initial observation option was more likely to be chosen in children with mild infections.

In terms of the choice of antibiotics for AOM treatment, it was somewhat unexpected that amoxicillin/clavulanate-prescribing, the recommended guideline treatment for children with severe infection (up to 22% of children with AOM¹⁴) and those with treatment failure, has decreased after publication of the guideline. However, our findings are consistent with the lack of enthusiasm that physicians have previously shown for prescribing amoxicillin/clavulanate for severe infections.⁹ It seems that physicians, in the 2006 survey⁹ and in our study, were choosing cefdinir (doubling from 7% to 14% of all antibiotics after publication of the 2004 guideline) as a second-line agent instead, perhaps because of a more convenient dosing schedule, a lower incidence of diarrhea, or more aggressive marketing.¹⁵

A secondary, but important, result of our analysis was the 71% increase in analgesic-prescribing in the period after the guideline was issued. It seems that pediatric providers have accepted this strong recommendation to treat the pain that is often associated with AOM,¹⁶ which is a reversal of previous findings showing that treating otalgia is not prioritized by clinicians.¹⁷ It would seem that physicians were more willing to adopt a recommendation from the guideline to add a treatment (analgesic agents) rather than to withhold one (antibiotics). In addition, our results demonstrate that children managed with observation are more likely to receive a prescription for an analgesic agent, perhaps as a means of demonstrating provider willingness to take parental concerns of

ear pain seriously despite not deeming an antibiotic prescription necessary. These findings are limited by a lack of data on visits in which an analgesic agent was recommended but not prescribed.

In some ways, these results are not entirely surprising, given the limited impact of previous clinical guidelines. Other research results have demonstrated that mere familiarity with a clinical practice guideline is unlikely to result in the adoption of its specific recommendations.¹⁸ It is possible that the initial intense publicity that the AOM guideline received, through conferences and news reports, waned over the 30-month study period or that some practitioners were unaware of the recommendations. Our results may also reflect clinician overload with the large number of pediatric guidelines that have been published in recent years,^{19,20} or our findings may simply indicate a lack of agreement

with the guideline recommendations themselves.

There were some aspects of the data that may limit the conclusions that can be drawn from our results. First, and most important, because of the retrospective nature of the data, we were unable to identify use of the observation option with a safety-net antibiotic prescription. This approach, endorsed in the clinical guideline, has the physician provide a prescription for antibiotics, but with instructions to delay having it filled unless symptoms persist after 2 to 3 days. The NAMCS data did not allow us to determine if an antibiotic prescription was meant to be filled immediately or to be used as a safety net. In this regard, our analysis may have underestimated the number of children who were initially treated with observation. Second, inclusion of data immediately after the release of the guideline may not have allowed sufficient time for adaptation to the

guideline recommendations. Third, telephone and e-mail contact information was not included. Last, the data did not allow us to distinguish between the prescribing of high-dose amoxicillin (recommended in the guidelines) versus standard-dose amoxicillin.

CONCLUSIONS

We found no compelling evidence that the 2004 AAP/AAFP guideline for AOM treatment substantially increased the proportion of the pediatric AOM cases being managed without antibiotics, despite a gradual secular trend in this direction. However, our data suggest that children with AOM who are not prescribed antibiotics are more likely to have mild infections, consistent with the guideline's recommendations. It is encouraging that after the publication of the guideline, amoxicillin-prescribing has increased and the pain associated with AOM is more frequently being treated.

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Announcement: The National Institute of Allergy and Infectious Diseases to Seek Public Comment on Food Allergy Clinical Practice Guidelines: *The National Institute of Allergy and Infectious Diseases (NIAID) will seek public comment on draft "Guidelines for the Diagnosis and Management of Food Allergy." The period for public comment will open in early 2010 and will last for sixty days. At that time, you are encouraged to examine the guidelines and participate in the open comment period by visiting the NIAID Food Allergy Clinical Guidelines public comment site: <http://www3.niaid.nih.gov/topics/foodAllergy/clinical/comments.htm>.*

As part of the process of developing the guidelines, NIAID convened a Coordinating Committee (CC) that includes representatives from 33 professional organizations, advocacy groups, and federal agencies. The role of the CC is to advise NIAID, review draft(s), approve the final guidelines, and develop a plan for the dissemination of the final guidelines.

The guidelines will be based on an independent, systematic review of the scientific and clinical literature. The Rand Corporation was awarded the contract to perform this comprehensive literature review and has prepared an evidence-based report.

An Expert Panel (EP) has been convened, composed of 25 members with expertise from a variety of relevant clinical and scientific areas and chaired by Dr Joshua A. Boyce of Harvard Medical School. The EP will use both the evidence-based report and consensus expert opinion as the foundation for developing the draft clinical guidelines. The final guidelines are expected to be completed and ready for dissemination by the summer of 2010.

More information and updates on this project are available at the NIAID Web site: www3.niaid.nih.gov/topics/foodAllergy/clinical/.

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