Children's Mercy KANSAS CITY — Evidence Based Practice

Critically Appraised Topic (CAT):
Acute Otitis Media (AOM) Short Course Antibiotics

Specific Care Question

For children >2 years of age with uncomplicated acute otitis media (AOM), are short-course antibiotics (5 days) versus longer-course antibiotics (7-10 days) equivalent for the outcomes of cure rate and adverse events?

Recommendations from the AOM Clinical Pathway Committee

*A **conditional** recommendation is made **against** the use of short-course antibiotics for children < 2 years old and those with severe AOM based on the findings in the literature and clinical expertise; see the Summary of Findings Table. Even though the three cohort studies (El-Shabrawi et al., 2016; Frost et al., 2024; Katz et al., 2024) found that shorter-course antibiotics were equivalent to longer-course antibiotics for patients with AOM, the overall certainty is very low. In these studies, AOM was defined solely by physical exam; therefore, patients with viral disease were likely included in all study groups, potentially underestimating the effect of antibiotic therapy. Additionally, clinicians are unlikely to prescribe an antibiotic without documenting a diagnosis of AOM, introducing further bias. The largest study (Katz et al, 2024) did not include patients < 2 years of age. Therefore, across all studies, the findings should be interpreted with caution. Balancing the risk of antibiotic exposure with the risk of treatment failure, the clinical pathway committee recommends the following:*
< 2 years of age or severe AOM: 10 days of treatment
2-5 years of age (non-severe): 7 days of treatment
> 5 years of age (non-severe): 5-7 days of treatment

Rationale for Question Asked

Acute otitis media (AOM) is the most common bacterial infection in early childhood and thus, the most common indication for antibiotics, affecting over 5 million children with more than 10 million antibiotic prescriptions annually in the United States (Ahmed et al., 2014; Hersh et al., 2011; Katz et al., 2024). Uncomplicated AOM, defined as AOM without otorrhea (Lieberthal et al., 2013), has been studied to better understand the effects of antibiotic treatment. Although longer antibiotic durations have contributed to the emergence of antimicrobial-resistant bacteria, the minimal effective duration of antibiotic therapy remains uncertain (Kim et al., 2024). Studies comparing shorter durations of antibiotic use have shown no difference in risk of treatment failure and similar rates for clinical cure (Kozyrskyj et al., 2010; Frost et al., 2022; Kim et al., 2024; Pichichero et al., 2001).

The American Academy of Pediatrics clinical practice guideline (Lieberthal et al., 2013) recommends an antibiotic duration of 10 days for patients 23 months or younger and 7 days for patients 2–5 years old with mild to moderate infection (Lieberthal et al., 2013). For patients aged 6 months or older with mild-to-moderate unilateral AOM, safety-net antibiotic prescriptions (SNAPs) may be an option. In contrast, the National Institute for Clinical Excellence (NICE, 2018) guideline emphasizes symptomatic care and recommends not giving antibiotics or using SNAP. If an antibiotic is prescribed, the recommended duration is 5 to 7 days.

Overview and Certainty of Evidence

Cure rate *(Defined as the absence of fever, otalgia, irritability, and otoscopic signs of AOM)*.

One cohort study (El-Shabrawi et al., 2016) measured the cure rate (*N* = 1371) of 5 days of antibiotic versus >5 days of antibiotic for the treatment of AOM. For the outcome of cure rate, the *OR* = 1.40, 95% CI [1.06, 1.85], *p* = 0.02, indicating that 5 days of antibiotic (cefpodoxime proxetil) was favorable compared to greater than 5 days of antibiotic (cefpodoxime proxetil) [*see Table 2*].

> **Certainty of Evidence for Cure Rate.** The certainty of the evidence was very low. The body of evidence was assessed to have a serious risk of bias and serious imprecision. The risk of bias was significant due to potential selection bias in the cohort study, and the imprecision was serious because the outcome measure, cure rate, was informed by a single observational study. As only one study was identified to answer this question, consistency could not be assessed.

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Treatment Failure (*defined as the need for additional antibiotics for AOM 2–14 days after the index encounter*)**.**
   Treatment failure: 5 days of antibiotic versus 10 days of antibiotic. Two cohort studies (Frost et al., 2024; Katz et al., 2024) measured treatment failure after 5 days of antibiotic therapy compared with 10 days (n = 49,015). For the outcome of treatment failure, the OR = 1.45, 95% CI [0.95, 2.19], p = .06, indicating 5 days of antibiotic therapy was no different than 10 days of antibiotic therapy (*see Figure 2 and Table 2*).

   Treatment failure: 5 days of antibiotic versus 7 days of antibiotic. Two cohort studies (Frost et al., 2024; Katz et al., 2024) measured treatment failure after 5 days of antibiotic therapy compared with 7 days (n = 15,244). For the outcome of treatment failure, the OR = 0.92, 95% CI [0.58, 1.45], p = .30, indicating that 5 days of antibiotic therapy was no different than 7 days of antibiotic therapy (*see Figure 3 and Table 2*).

   Certainty of Evidence for Treatment Failure.
   For the two cohort studies (Frost et al., 2024; Katz et al., 2024), the certainty of the evidence was very low. The body of evidence was assessed as having serious imprecision. Imprecision was serious due to the low number of events, and results were largely based on a single study (Katz et al., 2024), thereby increasing uncertainty in the findings.

AOM Recurrence (*defined as the need for a new antibiotic prescription for AOM 15-30 days after the index encounter*).
   AOM Recurrence: 5 days of antibiotic versus 10 days of antibiotic. One cohort study (Katz et al., 2024) measured AOM recurrence with 5 days of antibiotic therapy versus 10 days (n = 48,833). For the outcome of AOM recurrence, the OR = 0.61 (95% CI [0.36, 1.05], p = .08, suggesting that 5 days of antibiotic therapy was no different from 10 days of antibiotic therapy (*see Table 2*).

   AOM Recurrence: 5 days of antibiotic versus 7 days of antibiotic. One cohort study (Katz et al., 2024) studied children aged 2 to 17 years diagnosed with uncomplicated otitis media (n = 15,204). For the outcome of AOM recurrence, the OR = 0.46, 95% CI [0.27, 0.81], p = .007, indicating 5 days of antibiotic therapy was associated with a lower risk for AOM recurrence (*see Table 2*).

   Certainty of Evidence for AOM Recurrence.
   For the Katz et al. (2024) cohort study, the certainty of the evidence was very low. The body of evidence was assessed as having serious risk of bias and serious imprecision. The risk of bias was downgraded due to reliance on observational data and probable confounding by indication (clinical reasoning-driven treatment). Imprecision was downgraded due to duration-specific recurrence estimates being informed by a single cohort study.

Study characteristics
Version 1 (April 2022):
The initial search for suitable studies was completed in PubMed on April 13, 2022. T. Stewart, MSN, RN, FNP-BC, CPN, and D. Wyly, MSN, RN, APRN, CPNP-AC, PPCNP-BC, ONC reviewed the 117 titles and/or abstracts found in the search and identified two guidelines and 10 single studies believed to answer the question (Ouzzani et al., 2016). After an in-depth review of the guidelines and single studies, two single studies (El-Shabrawi et al., 2016; Frost et al., 2022) addressed the question. This review excludes older articles published before the widespread administration of the pneumococcal vaccine, as vaccination has affected infection rates and the causative organisms (Eskola et al., 2001).

Version 2 (November 2025):
An updated literature search (April 2022 – November 2025) using the same search strategy was conducted on November 6, 2025, in Embase. K. Berg, MD, reviewed the 143 titles and/or abstracts found in the search and identified four single studies believed to address the question. After an in-depth review of

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the single studies, two answered the question. Two observational studies (Frost et al., 2024; Katz et al., 2024) were identified in the search and are included in the updated review.

Table 1
Characteristics of Included Studies

Author (year)	Study Type	Population	N	Intervention	Control	Results
El Shabrawi et al., 2016	Cohort, prospective	Children aged 1-13 years diagnosed with AOM	*N* = 1380	Prescribed 5 days of cefpodoxime proxetil 8 mg/kg/day	Prescribed 7 to 10 days of cefpodoxime proxetil 8 mg/kg/day	*Cure rate* 5 days: 659/779 (84.6%) >5 days: 472/592 (79.7%) Patients taking a 5-day course had a significantly higher cure rate compared to those taking >5 days (*p* = .019)
Frost et al., 2024	Cohort, prospective	Children aged 6-35 months diagnosed with AOM and prescribed an antibiotic (ABX)	*N* = 205	Amoxicillin for 5 days	Amoxicillin for 7 or 10 days	*Treatment failure* 5 days: 4/24 (16.7%) 7 days: 1/16 (6.2%) 10 days: 6/158 (3.8%)
Katz et al., 2024	Cohort, retrospective	Children 2 – 17 years with uncomplicated acute otitis media and prescribed an ABX	*N* = 61,076 encounters with a duration value on the antibiotic	Antibiotic prescribed for 5 days	Antibiotic prescribed for 7, 10, 14, or other duration	*Treatment failure* 5 days: 21/3144 (0.7%) 7 days: 93/12,060 (0.8%) 10 days: 237/45,689 (0.5%) *AOM recurrence* 5 days: 14/3144 (0.4%) 7 days: 115/12,060 (1.0%) 10 days: 330/45,689 (0.7%)

Identification of Studies
Search Strategy and Results (see Figure 1)

(**2022**:py OR **2023**:py OR **2024**:py OR **2025**:py) AND ([adolescent]/lim OR [child]/lim OR [infant]/lim OR [newborn]/lim OR [preschool]/lim OR [school]/lim) AND (**'article'**/it OR **'article in press'**/it) **'amoxicillin'**/exp OR **amoxicillin** OR **'amoxicillin plus clavulanic acid'**/exp OR **'amoxicillin plus clavulanic acid'** OR **'cephalosporin'**/exp OR **cephalosporin** OR **'cefdinir'**/exp OR **cefdinir** OR **'cefpodoxime'**/exp OR **cefpodoxime** OR **'cefaclor'**/exp OR **cefaclor** OR **'cefixime'**/exp OR **cefixime 'time'**/exp OR **time** OR **'time factor'**/exp OR **'time factor'** OR **'treatment duration'**/exp OR **'treatment duration'** OR **'duration'**/exp OR **duration** OR **course** OR **days** OR **short** OR **long**
     Records identified through database searching, *n* = 143

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Additional records identified through other sources *n* = 0

Question Originator
   R. El-Feghaly, MD, MSCI
Medical Librarian Responsible for the Search Strategy
   K. Swaggart, MLIS, AHIP
EBP Team Members Responsible for Analyzing Literature
   K. Hess, PharmD
   K. Ott, OTD, OTR/L
   M. Gripka, MPH, MLS (ASCP) SM
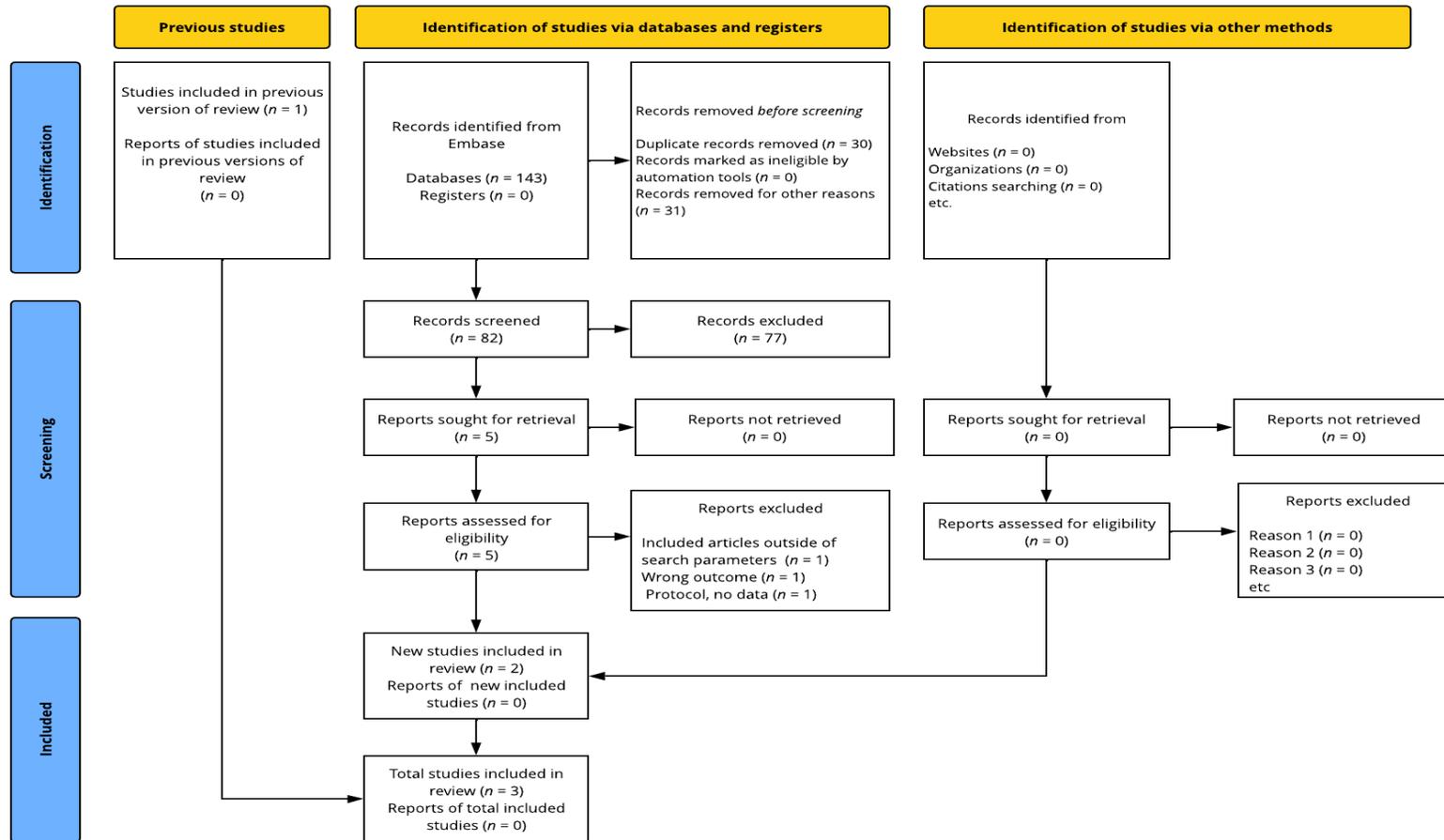**EBP Medical Director Responsible for Reviewing the Literature**
   K. Berg, MD, FAAP
EBP Team Member Responsible for Reviewing, Synthesizing, and Developing this Document
   A. Melanson, OTD, OTR/L

Figure 1
Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRIMSA) [Page et al., 2021]

Identification

Previous studies	Identification of studies via databases and registers		Identification of studies via other methods
Studies included in previous version of review (*n* = 1)	Records identified from Embase	Records removed *before screening*	Records identified from
Reports of studies included in previous versions of review (*n* = 0)	Databases (*n* = 143) Registers (*n* = 0)	Duplicate records removed (*n* = 30) Records marked as ineligible by automation tools (*n* = 0) Records removed for other reasons (*n* = 31)	Websites (*n* = 0) Organizations (*n* = 0) Citations searching (*n* = 0) etc.

Screening

- Records screened (*n* = 82) → Records excluded (*n* = 77)
- Reports sought for retrieval (*n* = 5) → Reports not retrieved (*n* = 0)
- Reports assessed for eligibility (*n* = 5) → Reports excluded: Included articles outside of search parameters (*n* = 1); Wrong outcome (*n* = 1); Protocol, no data (*n* = 1)
- Reports sought for retrieval (*n* = 0) → Reports not retrieved (*n* = 0)
- Reports assessed for eligibility (*n* = 0) → Reports excluded: Reason 1 (*n* = 0); Reason 2 (*n* = 0); Reason 3 (*n* = 0); etc

Included

- New studies included in review (*n* = 2) Reports of new included studies (*n* = 0)
- Total studies included in review (*n* = 3) Reports of total included studies (*n* = 0)

From: Page, M.J., McKenzie, J.E., Bossuyt, P.M., Boutron, I., Hoffmann, T.C., Mulrow, C.D., et al., (2021). The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. British Medical Journal, 372 (n71). https://doi.org/10.1136/bmj.n71

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Summary of Findings Table (GRADEpro GDT, 2022)
Table 2
Summary of Findings Table: Antibiotic duration

Certainty assessment							№ of patients		Effect		
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Short duration of antibiotic	Long duration of antibiotic	Relative (95% CI)	Absolute (95% CI)	Certainty
1	non-randomized studies	serious[a]	not serious	not serious	not serious	none	659/779 (84.6%)	472/592 (79.7%)	OR 1.40 (1.06 to 1.85)	49 more per 1,000 (from 9 more to 82 more)	⊕◯◯◯ Very low[a]
2	non-randomized studies	not serious	not serious	not serious	not serious	none	25/3168 (0.8%)	243/45847 (0.5%)	OR 1.45 (0.95 to 2.19)	2 more per 1,000 (from 0 fewer to 6 more)	⊕⊕◯◯ Low
2	non-randomized studies	not serious	not serious	not serious	not serious	none	25/3168 (0.8%)	94/12076 (0.8%)	OR 0.92 (0.58 to 1.45)	1 fewer per 1,000 (from 3 fewer to 3 more)	⊕⊕◯◯ Low
1	non-randomized studies	serious[a]	not serious	not serious	serious[b]	none	14/3144 (0.4%)	330/45689 (0.7%)	OR 0.61 (0.36 to 1.05)	3 fewer per 1,000 (from 5 fewer to 0 fewer)	⊕◯◯◯ Very low[a,b]
1	non-randomized studies	serious[a]	not serious	not serious	serious[b]	none	14/3144 (0.4%)	115/12060 (1.0%)	OR 0.46 (0.27 to 0.81)	5 fewer per 1,000 (from 7 fewer to 2 fewer)	⊕◯◯◯ Very low[a,b]

CI: confidence interval; OR: odds ratio

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Explanations
a. reliance on observational data and likely confounding by indication
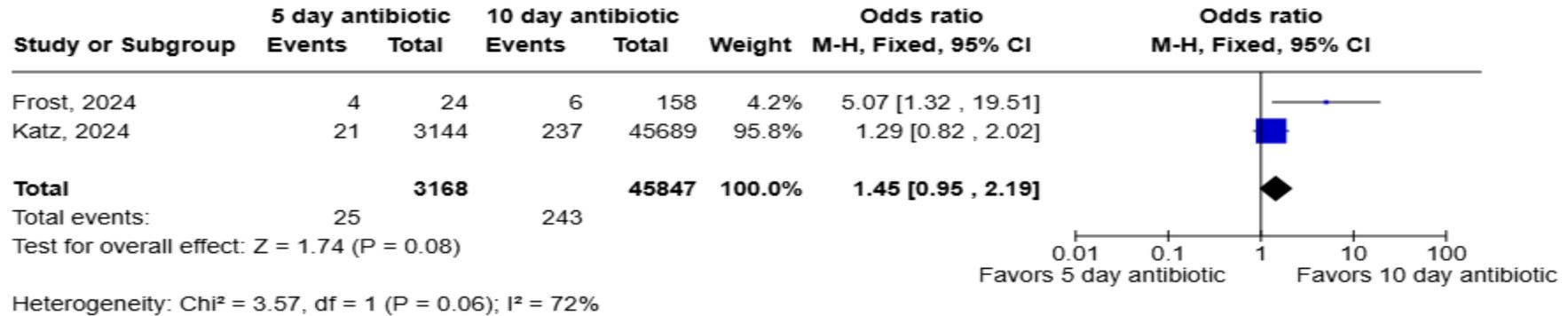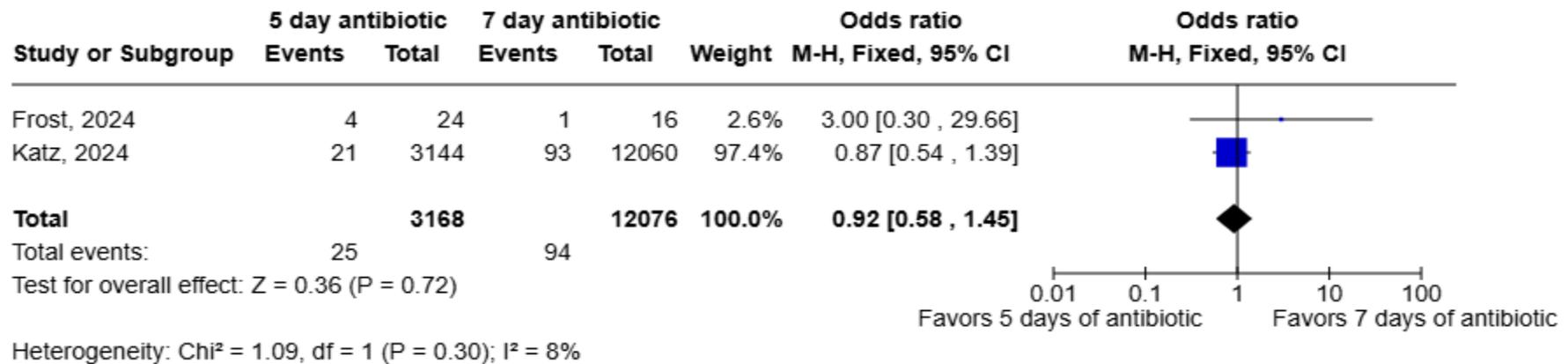b. Duration-specific recurrence estimates informed by a single cohort study

Meta-analyses

Figure 2
Comparison: 5-day antibiotic versus 10-day antibiotic, Outcome: Treatment failure

Study or Subgroup	5 day antibiotic		10 day antibiotic		Weight	Odds ratio M-H, Fixed, 95% CI
	Events	Total	Events	Total		
Frost, 2024	4	24	6	158	4.2%	5.07 [1.32 , 19.51]
Katz, 2024	21	3144	237	45689	95.8%	1.29 [0.82 , 2.02]
Total		**3168**		**45847**	**100.0%**	**1.45 [0.95 , 2.19]**
Total events:	25		243			

Test for overall effect: Z = 1.74 (P = 0.08)

Heterogeneity: Chi² = 3.57, df = 1 (P = 0.06); I² = 72%

Odds ratio M-H, Fixed, 95% CI — Favors 5 day antibiotic / Favors 10 day antibiotic

Figure 3
Comparison: 5-day antibiotic versus 7-day antibiotic, Outcome: Treatment failure

Study or Subgroup	5 day antibiotic		7 day antibiotic		Weight	Odds ratio M-H, Fixed, 95% CI
	Events	Total	Events	Total		
Frost, 2024	4	24	1	16	2.6%	3.00 [0.30 , 29.66]
Katz, 2024	21	3144	93	12060	97.4%	0.87 [0.54 , 1.39]
Total		**3168**		**12076**	**100.0%**	**0.92 [0.58 , 1.45]**
Total events:	25		94			

Test for overall effect: Z = 0.36 (P = 0.72)

Heterogeneity: Chi² = 1.09, df = 1 (P = 0.30); I² = 8%

Odds ratio M-H, Fixed, 95% CI — Favors 5 days of antibiotic / Favors 7 days of antibiotic

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Characteristics of Intervention Studies

El-Shabrawi et al. (2016)

Methods	Cohort
Participants	**Participants:** Children ages 1-13 years diagnosed with AOM **Setting:** 26 Egyptian medical centers **Number enrolled in the study:** *N* = 1380 • **Group,** cefpodoxime proxetil 8 mg/kg/day**:** *N* = 1380 **Gender, males (as defined by researchers):** • **Group:** *n* = 788 (57.2%) **Race/ethnicity or nationality (as defined by researchers):** • Not reported **Age, mean in years,** • **Group 1:** 3.8 **±** 2.5 years **Inclusion Criteria:** • Diagnosis of purulent AOM is based on the triad of clinical symptoms: otalgia, fever, and irritability, tympanic membrane (TM) signs of AOM such as middle ear effusion characterized by bulging, limited or absent mobility of the TM or air-fluid level behind the membrane; and evidence of TM inflammation indicated by erythema, perforation of otorrhea in at least one ear. **Exclusion Criteria:** • Patients with hypersensitivity to cephalosporin antibiotics **Covariates Identified:** • Not reported
Interventions	The study was conducted in two visits: a baseline visit at clinical evaluation and treatment initiation, and a follow-up visit (days 7–14) • **Group:** cefpodoxime proxetil 8mg/kg/day for 5-10 days
Outcomes	**Primary outcome(s):** • *Cure rate • *Failure rate **Secondary outcome(s):** • Length of therapy **Safety outcome(s):** • *Adverse events *Outcomes of interest to the Children's Mercy clinical pathway development team

Results	**Results:**
	• The most frequently reported prescription durations
	  ○ Five days in 783 (56.8%)
	  ○ Seven days in 326 (23.7%)
	  ○ Ten days in 269 (19.5%)
	• Patients with a 5-day course of therapy had a significantly higher cure rate compared to those receiving 7 to 10 days of antibiotics: (*p* = .019)
	  ○ Five days: 84.6% (659/779)
	  ○ > Five days 79.7% (472/592)
	• 1371 completed the study (2 did not show, and 7 were non-compliant)
	  ○ 1131 patients (82.5%) were cured, the cure or improvement rate was 100% in all signs and symptoms except:
	    ▪ spontaneous otorrhea (98%),

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	- purulent discharge (98.5%), - nasal discharge (93.5%) 15 patients (1.1 %) failed to respond to therapy - Adverse events were reported by 16 patients (1.2%), which included diarrhea (n = 9) and skin rash (n = 7), both mild to moderate in nature, and did not require dose reduction or discontinuation. **Limitations:** - Not reported

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Frost et al. (2024)

	Cohort, prospective
Methods	**Participants:** Children aged 6 – 35 months diagnosed with AOM and prescribed amoxicillin. **Setting:** Single health system (emergency department/urgent care, pediatric primary care, family medicine primary care) **Number enrolled in the study:** *N* = 205 Patients who took antibiotics and the duration prescribed: • 5-day amoxicillin**:** *n* = 24 • 7-day amoxicillin: n = 16 • 10-day amoxicillin: *n* = 158 **Gender, males (as defined by researchers):** • **Total for study:** *n* = 87 (42.4%) **Race/ethnicity (as defined by researchers):** *Race* • White: *n* = 117 (57.1%) • Unknown or not reported: *n* = 65 (31.7%) • African American/Black: *n* = 14 (6.8%) • Other or multiracial: *n* = 9 (4.4%) *Ethnicity* • Hispanic/Latinx: *n* = 155 (75.6%) • Not Hispanic/Latinx: *n* = 48 (23.4%) • Unknown or not reported: *n* = 2 (1.0%) **Age, mean in months, (SD)** • 6 – 11 months: *n* = 64 (31.2) • 2 – 23 months: *n* = 90 (43.9) • 24 – 35 months: *n* = 51 (24.88) **Inclusion Criteria:** • Children 6–35 months old • Diagnosed with AOM by a clinician • Prescribed amoxicillin at the index visit **Exclusion Criteria:** • Prior antibiotic use immediately before enrollment (though 149 of 205 had no prior amoxicillin exposure; others were included but analyzed separately) • Incomplete data or inability to collect nasopharyngeal swab (implied, not explicitly detailed) **Covariates Identified:** • Age (within 6–35 months range) • Pathogen type (e.g., *Moraxella catarrhalis*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Staphylococcus aureus*) • Beta-lactamase production status • Prior antibiotic exposure • Symptom severity and treatment adherence (from parent surveys)
Interventions	**Both:** • No experimental intervention: all children received amoxicillin as per standard care. • Parents completed symptom and adherence surveys; nasopharyngeal swabs were analyzed for pathogens and resistance markers
Outcomes	**Primary outcome(s):**

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	• *Treatment failure (need for additional antibiotics for AOM 2 – 14 days after the index encounter) **Secondary outcome(s):** • Improvement in Acute Otitis Media Severity of Symptoms (AOM-SOS) scale version 5.0 scores by at least 20% from baseline or a score ≤ 2 at days 5 and 14 • Improvement in AOM-SOS scores by at least 50% from baseline or a score ≤2 at days 5 and 14 • Parent-reported time to symptom improvement and resolution • Parent-reported adverse drug event • *Recurrence, defined as the need for a new antibiotic prescription for AOM 15-30 days after the index encounter **Safety outcome(s):** • *ADEs *Outcomes of interest to the Children's Mercy Clinical Pathway development team

Results	**Results:**
	• ***Treatment failure***: 8 children (5.4%)
	In patients who took their antibiotics, there was a similar finding (Day 5, OR = 1.11, 95% CI (.999, 1.23), p = 0.052, and Day 14 OR = 1.12, 95% CI (1.01, 1.25), p = 0.025
	  ◦ 5-day amoxicillin: n = 4/24 (16.7%)
	  ◦ 7-day amoxicillin: n = 1/16 (6.2%)
	  ◦ 10-day amoxicillin: n = 6/158 (3.8%)
	• ***Clinical recurrence***: 14 children (6.8%).
	Among patients enrolled, male sex, attending daycare, being seen in a primary care setting rather than an emergent setting, meeting AAP diagnostic criteria, and a high Day 14 AOM-SOS score were all associated with increased odds of infection recurrence, with the following adjusted OR:
	  ◦ Male (relative to female): aOR = 25.27, 95% CI (2.14, 295.6), p = .010
	  ◦ Daycare (relative to no daycare): aOR = 5.97, 95%CI (.898, 39.7), p = .066
	  ◦ Pediatric Primary Care (relative to emergent care): aOR = 13.7, 95%CI (1.5, 120.6), p = .018
	  ◦ Family Medicine Primary Care (relative to emergency care): aOR = 28.8, 95%CI (2.8, 292.4), p = .005
	  ◦ Met AAP criteria (relative to not meeting criteria): aOR = 24.8, 95%CI (1.4, 438.4), p = .028
	  ◦ Day 14 AOM-SOS Score (continuous): aOR = 1.39, 95%CI (1.1, 1.7), p = .005
	• ***ADEs***: 56 children (27.3%), mostly mild (GI upset, rash)
	Enrolled patients (ITT), meeting AAP diagnostic criteria, OR = 3.84, 95%CI (1.72, 8.57), p = .001) and a high Day 5 [OR = 1.01, 95%CI (1.01, 1.18), p = .023] or Day 14 [OR = 1.12, 95%CI (1.02, 1.22), p = .012] AOM-SOS score was associated with increased odds of having at least one ADE.
	  ◦ 5-day amoxicillin: n = 8/24 (33.3%)
	  ◦ 7-day amoxicillin: n = 5/16 (31.2%)
	  ◦ 10-day amoxicillin: n = 59/162 (37.3%)
	Limitations:
	• Single-center study limiting generalizability

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	• Small sample size (205 children) with limited power for subgroup analyses • Parent-reported outcomes create potential recall and reporting bias • Short follow-up may miss late recurrences or complications • No randomization or blinding, causing a risk of confounding by indication • Microbiologic data from nasopharyngeal swabs may not perfectly represent middle ear pathogens

Katz et al. (2024)

	Cohort, retrospective
Methods	**Participants:** Children 2 – 17 years with uncomplicated AOM **Setting: 135 different sites, including emergency departments, urgent care centers, primary care clinics, or retail clinics, from two major academic centers—Vanderbilt University Medical Center and Washington University—between January 1, 2019, and December 31, 2022.** **Number enrolled in the study:** Outpatient encounters for children aged 2 -17 years: *N* = 73,198 Encounters with an antibiotic prescription: *n* = 61,612 Encounters with a duration value on the antibiotic: *n* = 61,076 • 5 days of antibiotic: *n* = 3144 • 7 days of antibiotic: *n* = 12,060 • 10 days of antibiotic: *n* = 45,689 • 14 days of antibiotic: *n* = 72 • Other duration of antibiotic: *n* = 111 **Gender, males (as defined by researchers):** • Total number of unique visits that were male children**:** *n* = 37,803 (52%) **Race/ethnicity or nationality** (total number per unique visit – some children had more than one visit)**:** *Race* • White: *n* = 54,548 • Black: *n* = 10,378 • Asian: *n* = 1,111 • American Indian or Alaskan Native: *n* = 163 • Middle Eastern or North African: *n* = 225 • Native Hawaiian/other Pacific Islander: *n* = 134 *Ethnicity* • Hispanic/Latino: *n* = 5,230 • Non-Hispanic/Latino: *n* = 53,750 • Unknown/declined: *n* = 14,218 **Age, median in months, (range)** • Of the total number of children enrolled: n = 55 months (24 – 215) **Inclusion Criteria:** • Outpatient encounters (in-person or telehealth) at emergency departments, urgent care, primary care clinics, or retail clinics. • Children aged 2 – 17 years • Encounters between January 1, 2019, and December 31, 2022 • Diagnosis of uncomplicated AOM **Exclusion Criteria:** • Patients with alternate or competing bacterial diagnoses (CDC Tier 1 and Tier 2 diagnoses where antibiotics are always or sometimes indicated). • Encounters for patients who had received an antibiotic within 30 days prior to the index visit. • Patients with a history of tympanostomy tubes prior to the encounter date. **Covariates Identified:** • Year of visit (2019–2022) • Antibiotic prescribed (first-line vs. non-first-line) • Prescription duration category (5, 7, or 10 days)

Interventions	5 days of antibiotic: *n* = 3,144 (~5%) 7 days of antibiotic: *n* = 12,060 (~20%) 10 days of antibiotic: *n* = 45,689 (~75%) 14 days of antibiotic: *n* = 72 - Other duration of antibiotic: *n* = 111
Outcomes	**Primary outcome(s):** - Percent of prescriptions for a 5-day duration **Secondary outcome(s):** - Proportion of prescriptions for a 7-day duration - Proportion of prescriptions for a 10-day duration - Proportion of prescriptions for non-first-line antibiotics (other than amoxicillin) **Safety outcome(s):** *Treatment failure: new antibiotic associated with an AOM encounter within 3 -14 days of the initial encounter. *AOM recurrence: new antibiotic associated with an AOM encounter within 15-30 days of initial encounter. *ADE: medically attended visits within 14 days of the index visit with an ICD-10 diagnosis code for nausea, vomiting, diarrhea, candidiasis, non-candidal skin rash, or allergic reaction. *Hospitalizations and follow-up visits: any hospitalization and office/urgent care/ED visits for AOM within 30 days after the index visit. *Outcomes of interest to the Children's Mercy Clinical Pathway development team
Results	**Results:** Complications were rare (< 1 – 1.2%) for all adverse events and complications - Treatment failure: 5-day duration: 21 (0.7%) 7-day duration: 93 (0.8%) 10-day duration: 237 (0.5%) 14-day duration: 0 (0%) - AOM recurrence: 5-day duration: 14 (0.4%) 7-day duration: 115 (1.0%) 10-day duration: 330 (0.7%) 14-day duration: 0 (0%) - ADE: - ADEs were rare occurrences across the cohort, but exact ADE counts were not stratified by 5-, 7-, or 10-day durations. - Hospitalizations and follow-ups: - Rare across the cohort, but exact counts were not stratified by 5-, 7-, or 10-day durations **Limitations:** - The study relied on electronic health record (EHR) data, which limits the ability to confirm clinical details such as symptom severity, adherence to therapy, or reasons for prescribing longer durations - Because this was an observational study, there is potential for confounding (e.g., clinicians may have prescribed longer courses for

	children perceived as higher risk, but those clinical judgments were not fully captured in the dataset). • Safety outcomes (treatment failure, recurrence, adverse drug events) were identified through coded diagnoses and encounters, which may underestimate true event rates if families sought care outside the health systems or if events were not documented accurately • The study was conducted in two large academic health systems with established stewardship programs, so prescribing patterns may differ in community or rural settings • The analysis did not evaluate whether antibiotics were clinically indicated for each encounter, nor did it assess guideline adherence beyond duration (e.g., choice of antibiotic) • The study could not confirm whether patients completed the prescribed course, which affects the interpretation of duration-related outcomes

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