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Evidence Based Practice

Critically Appraised Topic (CAT):
Acute Otitis Media (AOM) Low-Dose versus High-Dose Amoxicillin

Specific Care Question

For pediatric patients with acute otitis media, is low-dose amoxicillin equivalent to or better than high-dose amoxicillin in terms of clinical cure, failure rate, and adverse events?

Recommendations from the AOM Committee

*A **conditional** recommendation **against** the intervention of low-dose versus high-dose amoxicillin based on the findings in the literature and clinical expertise; see the Summary of Findings Table. Although one cohort study (Chu et al., 2014) and one randomized controlled trial (Bielicki et al., 2021) found no difference between low- and high-dose amoxicillin, the overall certainty of the evidence is very low. One RCT (Bielicki et al., 2021) found that a lower dose was equivalent to a high dose, but only in patients with community-acquired pneumonia rather than AOM. Based on the inclusion criteria, patients with viral rather than bacterial illness were likely included in all study groups, potentially underestimating the effect of antibiotic therapy. Additionally, clinicians were unlikely to prescribe an antibiotic without documenting a diagnosis of AOM, introducing further bias. Therefore, the clinical pathway committee recommends high-dose amoxicillin for the treatment of AOM.*

Literature Summary

Background

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). The American Academy of Pediatrics Clinical Practice Guideline (Lieberthal et al., 2013) recommends providing a safety-net antibiotic prescription (SNAP) to parents of children > 6 months of age with mild-to-moderate unilateral AOM, utilizing a dose of 80-90 mg/kg/day of amoxicillin as first-line therapy for most children for 10 days in patients ≤ 23 months of age and 7 days in patients 2-5 years of age (Lieberthal et al., 2013). Alternatively, in a systematic review (Suzuki et al., 2020) of European Clinical Practice Guidelines (CPGs), only 7 of 14 CPGs recommended high-dose amoxicillin (80-90mg/kg/day) as a first-line option.

Summary by Outcome

Retreatment by Day 28

One RCT (Bielicki et al., 2021) measured retreatment by day 28 (*N* = 814). For the outcome of re-treatment by day 28, the *OR* indicated that for patients with CAP, the intervention of low-dose amoxicillin (35-50 mg/kg/d) was not different from the comparator of high-dose amoxicillin (70-90 mg/kg/d), *OR* = 1.03, 95% CI [0.68, 1.56] (see Table 2)

> **Certainty Of The Evidence For Retreatment by Day 28.** The certainty of the body of evidence was low. The body of evidence was assessed as having no serious risk of bias; however, it was noted to have serious indirectness and serious imprecision. Indirectness was serious as the study population investigated was patients with CAP. Imprecision was serious due to the low number of events (*n* = 100). As only one study (Bielicki et al., 2021) was identified to answer this question, consistency could not be assessed.

Adverse Events

One RCT (Bielicki et al., 2021) measured adverse events (*N* = 814). For the outcome of adverse events, the *OR* indicated that for patients with CAP, the intervention of low-dose amoxicillin (35-50 mg/kg/d) was not different from the comparator of high-dose amoxicillin (70-90 mg/kg/d), *OR* = 1.14, 95% CI [0.62, 2.11] (see Table 2).

> **Certainty Of The Evidence For Adverse Events.** The certainty of the body of evidence was low. The body of evidence was assessed as having no serious risk of bias; however, it was noted to have serious indirectness and serious imprecision. Indirectness was serious as the study population investigated was patients with CAP. Imprecision was serious due to the low number of events (*n* = 100). As only one study (Bielicki et al., 2021) was identified to answer this question, consistency could not be assessed.

Successful Control (see Chu et al., 2014, for the definition of this outcome on page 13 of this synopsis)
One cohort study (Chu et al., 2014) measured successful control (*N* = 165). For the outcome of successful control, the *OR* indicated that for patients with AOM, the intervention of low-dose amoxicillin (40-50 mg/kg/d) was not different from the comparator of high-dose amoxicillin (80-90 mg/kg/d), *OR* = 0.52, 95% CI [0.14, 1.88] (see Table 2)

> **Certainty Of The Evidence For Successful Control.** The certainty of the body of evidence was very low. The body of evidence was assessed as not having serious indirectness but as having a serious risk of bias and serious imprecision. Risk of bias was serious due to the study being a retrospective cohort that was unable to verify compliance with antibiotics. Imprecision was a serious concern due to the small sample size (N = 165) and the limited number of events (*n* = 121). As only one study (Chu et al., 2014) was identified to answer this question, consistency could not be assessed.

Failed Control (see Chu et al., 2014, for the definition of this outcome on page 13 of this synopsis)
One cohort study (Chu et al., 2014) measured failed control (*N* = 165). For the outcome of failed control, the *OR* indicated that for patients with AOM, the intervention of low-dose amoxicillin (40-50 mg/kg/d) was not different from the comparator of high-dose amoxicillin (80-90 mg/kg/d), *OR* = 1.93, 95% CI [0.53, 7.03] (see Table 2).

> **Certainty Of The Evidence For Failed Control.** The certainty of the body of evidence was very low. The body of evidence was assessed as not having serious indirectness but as having a serious risk of bias and serious imprecision. Risk of bias was serious due to the study being a retrospective cohort that was unable to verify compliance with antibiotics. Imprecision was a serious concern due to the small sample size (*N* = 165) and the limited number of events (*n* = 44). As only one study (Chu et al., 2014) was identified to answer this question, consistency could not be assessed.

Study characteristics
Version 1 (July 2022):
The initial literature search for suitable studies was completed on July 11, 2022, in PubMed. R. El Feghaly, MD, MSCI and D. Wyly, MSN, RN, APRN, CPNP-AC, PPCNP-BC, ONC, reviewed the 127 titles and/or abstracts found in the search and identified[b] 12 single studies believed to answer the question. After an in-depth review of the single studies, two single studies (Bielicki et al., 2021; Chu et al., 2014) answered the question.
This review excludes older articles published before the pneumococcal vaccine was widely administered, as its impact on AOM infection rates and causative organisms (Eskola et al., 2001) is not considered. Studies examining community-acquired pneumonia (CAP) were included in this review, as this disease is caused by the same 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 and PubMed. K. Berg, MD, reviewed the 54 titles and/or abstracts found in the search and did not identify any new studies that answered the question.

Identification of Studies
Search Strategy and Results (see Figure 1)
(**2022**:py OR **2023**:py OR **2024**:py OR **2022**:py) AND ([child]/lim OR [infant]/lim OR [preschool]/lim OR [school]/lim) AND (**'article'**/it OR **'article in press'**/it) **'acute otitis media'**/exp OR **'acute otitis media' amoxicillin**:ti,ab,kw **'drug dose'** OR **dosing**:ti,ab,kw OR **'low drug dose'** OR **'drug megadose'** OR **'low dose'**:ti,ab OR **'high dose'**:ti,ab OR **dosage**:ti,ab,kw `**amoxicillin'**/exp/dd_do

Records identified through database searching, *n* = 54
Additional records identified through other sources *n* = 0

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Studies Included in this Review

Citation	Study Type
Chu et al. (2014)	Cohort
Bielicki et al. (2021).	RCT

Studies Not Included in this Review with Exclusion Rationale

Citation	Reason for exclusion
Baig et al. (2017)	Outcome of interest not reported
Garrison et al. (2004)	Older studies prior to the pneumococcal vaccine
Heinrichs & Frère (2018)	Non-English
Jung et al. (2019)	Outcome of interest not reported
Kondratieva et al. (2019)	Outcome of interest not reported
Lyttle et al. (2019)	Study Protocol
Peters et al. (2016)	Study on dosing instructions
Pichichero et al. (2013)	No comparison of low versus high dose
Vilas-Boas et al. (2014)	No comparison of low versus high dose
Wu et al. (2021)	Outcome of interest not reported

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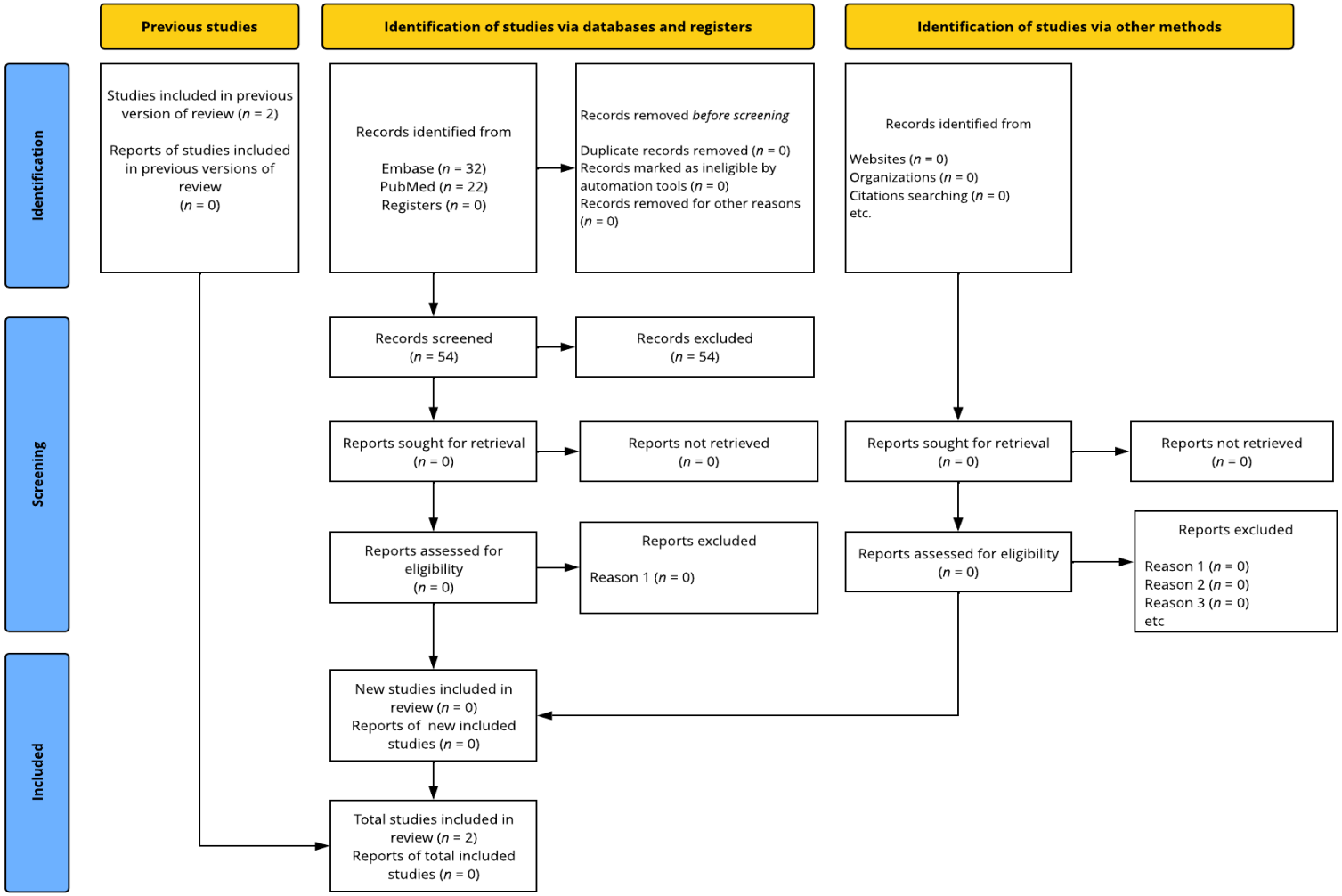
Figure 1

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



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 1
Summary of Findings Table

Certainty assessment							№ of patients		Effect		Certainty
№ of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**High dose**	**Low dose**	**Relative (95% CI)**	**Absolute (95% CI)**	
Re-treatment by day 28											
1	randomized trials	not serious	not serious	serious[d]	serious[e]	none	51/410 (12.4%)	49/404 (12.1%)	**OR 1.03** (0.68 to 1.56)	**3 more per 1,000** (from 35 fewer to 56 more)	⊕⊕◯◯ Low
Serious adverse event											
1	randomized trials	not serious	not serious	serious[d]	serious[f]	none	23/410 (5.6%)	20/404 (5.0%)	**OR 1.14** (0.62 to 2.11)	**7 more per 1,000** (from 18 fewer to 50 more)	⊕⊕◯◯ Low
Successful Control											
1	observational studies	serious[a]	not serious	not serious	serious[b]	none	106/147 (72.1%)	15/18 (83.3%)	**OR 0.52** (0.14 to 1.88)	**111 fewer per 1,000** (from 422 fewer to 71 more)	⊕◯◯◯ Very low
Failed Control											
1	observational studies	serious[a]	not serious	not serious	serious[c]	none	41/147 (27.9%)	3/18 (16.7%)	**OR 1.93** (0.53 to 7.03)	**112 more per 1,000** (from 71 fewer to 418 more)	⊕◯◯◯ Very low

Explanations

a. A retrospective cohort that was unable to verify compliance for antibiotics
b. Low number of subjects (*N* = 165) and low number of events (*n* = 121)
c. Low number of subjects (*N* = 165) and low number of events (*n* = 44)
d. Study of patients with Community-Acquired Pneumonia
e. Low number of events (*n* = 100)
f. Low number of events (*n* = 43)

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Characteristics of Intervention Studies
Bielicki et al. (2021)

Methods	**Randomized Control Trial**
Participants	**Participants:** Children with clinically diagnosed CAP and planned treatment with amoxicillin upon discharge **Setting:** Children discharged from emergency and inpatient wards of 28 hospitals in the UK and 1 in Ireland between February 2017 and April 2019 **Randomized into study:** *N* = 824 • **Group 1, low-dose amoxicillin for 3 days:** *n* = 209 • **Group 2, low-dose amoxicillin for 7 days:** *n* = 203 • **Group 3, high-dose amoxicillin for 3 days:** *n* = 207 • **Group 4, high-dose amoxicillin for 7 days:** *n* = 205 **Completed Study:** *N* = 814 • **Group 1:** *n* = 208 • **Group 2:** *n* = 202 • **Group 3:** *n* = 205 • **Group 4:** *n* = 199 **Gender, males (as defined by researchers):** • **Group 1:** *n* = 110 (53%) • **Group 2:** *n* = 100 (50%) • **Group 3:** *n* = 107 (52%) • **Group 4:** *n* = 104 (52%) **Race/ethnicity or nationality (as defined by researchers):**

Race and Ethnicity	Group 1 (*n* = 208)	Group 2 (*n* = 202)	Group 3 (*n* = 205)	Group 1 (*n* = 199)
Asian or British Asian	32 (15%)	23 (11%)	21 (10%)	30 (15%)
Black or British Black	20 (10%)	20 (10%)	20 (10%)	16 (8%)
Multiracial	15 (7%)	17 (8%)	14 (7%)	14 (7%)
White	139 (67%)	136 (67%)	144 (70%)	135 (68%)
Other	2 (1%)	6 (3%)	6 (3%)	4 (2%)

Age, median in years, (IQR)
- **Group 1:** 2.5 (1.7-3.7)
- **Group 2:** 2.6 (1.6-3.9)
- **Group 3:** 2.5 (1.7-3.8)
- **Group 4:** 2.3 (1.4-3.6)

Inclusion Criteria:
- Age 6 months and older
- Weight 6 to 24 kilograms
- Diagnosis of CAP consistent with British Thoracic Society guidelines:
  - Parent- or guardian-reported cough within the previous 96 hours
  - Measured temperature of 38°C or parent- or guardian-reported fever within the previous 48 hours
  - Signs of labored or difficult breathing or focal chest sign

Exclusion Criteria:
- Uninterrupted prior β-lactam antibiotic treatment for more than 48 hours or any prior non-β-lactam treatment
- Severe underlying chronic disease
- Any contraindications to amoxicillin, including allergy
- Complicated pneumonia (defined as signs of sepsis or local parenchymal or pleural complications)

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	• Bilateral wheezing without focal chest signs **Power Analysis:** The trial was designed to demonstrate the noninferiority of lower-dose amoxicillin compared with higher-dose amoxicillin, and a shorter duration (3 days) compared with a longer duration (7 days). The sample size of 800 participants was estimated to achieve 90% power.
Interventions	• **Group 1:** Randomized to receive amoxicillin, 35-50 mg/kg/d for 3 days • **Group 2:** Randomized to receive amoxicillin, 35-50 mg/kg/d for 7 days • **Group 3:** Randomized to receive amoxicillin, 70-90 mg/kg/d for 3 days • **Group 4:** Randomized to receive amoxicillin, 70-90 mg/kg/d for 7 days

Outcomes	**Primary outcome(s):**
	• The primary end point was clinically indicated treatment with systemic antibiotics (other than trial medication) for a respiratory tract infection, including CAP, within 28 days of randomization
	  ○ The noninferiority margin was 8%
	  ○ All primary endpoints were reviewed by an endpoint review committee, blinded to treatment allocation, to adjudicate whether treatment was clinically indicated and prescribed for respiratory tract infection
	Secondary outcome(s):
	• Severity (graded as not present, slight/little, moderate, bad, severe/very bad) and duration (with the first day the symptom is reported not present defined as resolved) of 9 parent-reported CAP symptoms (fever, cough, phlegm, fast breathing, wheezing, disturbed sleep, eating/drinking less, interference with normal activity, vomiting)
	• Potential amoxicillin-related clinical adverse events (diarrhea, thrush, skin rash)
	• Adherence to trial medication
	• Phenotypic penicillin nonsusceptibility or resistance at 28 days in nasopharyngeal S. pneumoniae isolates
	Safety outcome(s):
	• Serious adverse events

Notes	• Among children with CAP discharged from an ED or hospital ward (within 48 hours), low-dose outpatient oral amoxicillin was noninferior to high dose, and 3-day duration was noninferior to 7 days, with regard to need for further antibiotic retreatment
	• See comparison tables for serious adverse events
	  ○ No participant had more than one serious adverse event; all serious adverse events were hospitalizations (most for respiratory distress), and there were no deaths. The data stratified by randomization groups are presented in Table 10 of Supplement 2.
	  ○ One serious adverse event (hospital admission for intravenous treatment because of vomiting on day 2 in a patient randomized to the higher-dose, shorter-duration group) was classified as related to trial medication.
	• Findings should not be generalized to patients with very severe disease or underlying comorbidities

Risk of bias table

Bias	**EBP Scholars' judgement**	**Support for judgment**
Random sequence generation (selection bias)	Low risk	A computer-generated randomization list was produced by the trial statistician based on blocks of 8 and containing an equal number of the 4 possible combinations of dose and duration in random order.
Allocation concealment (selection bias)	Low risk	Trial kits were assigned sequential numbers based on the randomization list and delivered ready to dispense to site pharmacies.

Blinding of participants and personnel (performance bias)	Low risk	Blinding was achieved by independent rebottling, packaging, and labeling of 2 amoxicillin brands. To ensure blinding for the duration comparison, a single amoxicillin brand was used for the first 3 days, followed by a different amoxicillin containing suspension (of the same concentration) or a matching placebo suspension for days 4 to 7.
Blinding of outcome assessment (detection bias)	Unclear risk	Primary endpoint was subjectively adjudicated by an endpoint review committee
Incomplete outcome data (attrition bias)	Low risk	Data analyzed per protocol, however very few subjects were excluded from analysis and would be unlikely to impact results
Selective reporting (reporting bias)	Low risk	Data reported as expected
Other bias	Low risk	No concerns: conflicts of interest reported appropriately and unlikely to impact study results

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Chu et al. (2014)

Methods	**Retrospective Cohort**
Participants	**Participants:** Children with acute otitis media (AOM) **Setting:** Taiwan, General Hospital, January 2005 to December 2008 **Number of medical records with correct diagnosis code:** *N* = 400 **Number who meet inclusion criteria:** *N* = 165 • **Group 1,** Antibiotic with recommended amoxicillin component: *n* = 18 • **Group 2,** Antibiotic with an underdosed amoxicillin component *n* = 14 **Gender, males** • 57% (Not specified by group) **Race/ethnicity or nationality (as defined by researchers):** • Not reported **Age, mean +/- SD in years:** • 4.91 +/- 2.52 (Not specified by group) **Inclusion Criteria:** • Children 2 months to 12 years • Diagnosis of AOM ICD-9-CM (diagnosis code 382.00) • Patients treated with amoxicillin-clavulanate **Exclusion Criteria:** • Any anatomic or genetic abnormalities, such as craniofacial anomalies or Down syndrome • Immune deficiencies • History of recurrent AOM (three or more previous episodes of AOM within 12 months) • Patients with any history of middle ear or inner ear procedure • Patients with only one visit • Patients with missing records • Patients treated with amoxicillin alone or with another antibiotic **Covariates Identified:** • Illness season • Single vs bilateral disease

Interventions	**Both:** Reassessment performed within 14 days after antibiotic prescription expiry (sic) date
	Amoxicillin doses based on the AOM Clinical Practice Guidelines: Diagnosis and Management of AOM, published in May 2004 (AAP, 2004)
	• **Group 1:** Amoxicillin clavulanate antibiotic dose of amoxicillin 80-90 mg/kg/day, 1500 mg/day max (referred to as "High-dose" in tables)
	• **Group 2:** Amoxicillin clavulanate antibiotic dose < 10% of the recommended amoxicillin dose (referred to as "Underdose" in tables)
	  ○ Average dose of amoxicillin component 45.5 mg/kg/day
	  ○ 52.1% of the prescriptions were in the amoxicillin range of 40-50 mg/kg/day

Outcomes	**Primary outcome(s):** • Successful control (defined as a medical record of an eardrum that was either normal or showed otitis media with effusion (OME)) • Failed control, defined as improvement in only one of two affected ears or a change in antibiotics before the end of the treatment period due to failure to control illness rather than side effects
Notes	**Results:** • Control was achieved in 121 patients • Patients given high-dose amoxicillin had generally, but not statistically significantly, better AOM prognosis • Bilateral AOM was borderline significantly correlated with failed control

	• There was no significant correlation between high-dose amoxicillin and better disease control in most groups. • Illness in autumn and winter was strongly associated with a poor prognosis • In this study, the ratio of boys who failed AOM control was not significant; this is different than other studies referenced • The correlation between underdosage and failed control was significant in children below 20 kg with bilateral AOM (*OR* = 1.63; 95% CI [1.02, 2.59], *p* = .04) **Limitations:** • No study of amoxicillin as a standalone medication for AOM • The duration of treatment for both the high dose and the underdose was never specified in this study. The reassessment was performed within 14 days of the prescription, but the exact number of days between diagnosis and reassessment was not specified.

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Appendix

Evidence to Decision Assessment

Problem Is the problem a priority?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	Acute Otitis Media is the most common infection in early childhood (Venekamp et al., 2015). Although AOM usually resolves without treatment, it is the most common condition for which antibiotics are prescribed in the United States (Lieberthal et al., 2013).	
Desirable Effects How substantial are the desirable anticipated effects?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Trivial ● Small ○ Moderate ○ Large ○ Varies ○ Don't know	**Successful Control** (see Chu et al., 2014, for the definition of this outcome on page 13 of this synopsis) One cohort study (Chu et al., 2014) measured successful control (*N* = 165). For the outcome of successful control, the *OR* indicated that for patients with AOM, the intervention of low-dose amoxicillin (40-50 mg/kg/d) was not different from the comparator of high-dose amoxicillin (80-90 mg/kg/d), *OR* = 0.52, 95% CI [0.14, 1.88].	The desirable effects of a lower dose are fewer adverse drug reactions, medication side effects, and antimicrobial resistance.
Undesirable Effects How substantial are the undesirable anticipated effects?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Large ○ Moderate ● Small ○ Trivial ○ Varies ○ Don't know	***Retreatment by Day 28*** One RCT (Bielicki et al., 2021) measured retreatment by day 28 (*N* = 814). For the outcome of re-treatment by day 28, the *OR* indicated that for patients with CAP, the intervention of low-dose amoxicillin (35-50 mg/kg/d) was not different from the comparator of high-dose amoxicillin (70-90 mg/kg/d), *OR* = 1.03, 95% CI [0.68, 1.56]. ***Adverse Events*** One RCT (Bielicki et al., 2021) measured adverse events (*N* = 814). For the outcome of adverse events, the *OR* indicated that for patients with CAP, the intervention of low-dose amoxicillin (35-50 mg/kg/d) was not different from the comparator of high-dose amoxicillin (70-90 mg/kg/d), *OR* = 1.14, 95% CI [0.62, 2.11]. **Failed Control** (see Chu et al., 2014, for the definition of this outcome on page 13 of this synopsis) One cohort study (Chu et al., 2014) measured failed control (*N* = 165). For the outcome of failed control, the *OR* indicated that for patients with AOM, the intervention of low-dose amoxicillin (40-50 mg/kg/d) was not different from the comparator of high-dose amoxicillin (80-90 mg/kg/d), *OR* = 1.93, 95% CI [0.53, 7.03].	

Certainty of evidence
What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies	**Certainty Of The Evidence For Retreatment by Day 28.** The certainty of the body of evidence was low. The body of evidence was assessed as not having a serious risk of bias but as having serious indirectness and serious imprecision. Indirectness was serious as the study population investigated was patients with CAP. Imprecision was serious due to the low number of events (*n* = 100). As only one study (Bielicki et al., 2021) was identified to answer this question, consistency could not be assessed. **Certainty Of The Evidence For Adverse Events.** The certainty of the body of evidence was low. The body of evidence was assessed as not having a serious risk of bias but as having serious indirectness and serious imprecision. Indirectness was serious as the study population investigated was patients with CAP. Imprecision was serious due to the low number of events (*n* = 100). As only one study (Bielicki et al., 2021) was identified to answer this question, consistency could not be assessed. **Certainty Of The Evidence For Successful Control.** The certainty of the body of evidence was very low. The body of evidence was assessed as not having serious indirectness but having a serious risk of bias and serious imprecision. Risk of bias was serious due to the study being a retrospective cohort that was unable to verify compliance with antibiotics. Imprecision was serious due to the low number of subjects (*N* = 165) and the low number of events (*n* = 121). As only one study (Chu et al., 2014) was identified to answer this question, consistency could not be assessed. **Certainty Of The Evidence For Failed Control.** The certainty of the body of evidence was very low. The body of evidence was assessed as not having serious indirectness but having a serious risk of bias and serious imprecision. Risk of bias was serious due to the study being a retrospective cohort that was unable to verify	Minimal evidence exists on outcomes of lower doses versus higher doses. Only one cohort study on patients with AOM and one RCT on patients with CAP were included.

	compliance with antibiotics. Imprecision was serious due to the low number of subjects (*N* = 165) and the low number of events (*n* = 44). As only one study (Chu et al., 2014) was identified to answer this question, consistency could not be assessed	
Values Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Important uncertainty or variability ● Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty or variability		Some providers (e.g., Antimicrobial Stewardship) may place greater emphasis on the risks of adverse drug events, side effects, and antimicrobial resistance. Some parents/families of patients may weigh more heavily the risk of treatment failure.
Balance of effects Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Favors the comparison ○ Probably favors the comparison ● Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Minimal evidence exists on outcomes of lower doses versus higher doses. Only one cohort study on patients with AOM and one RCT on patients with CAP were included.	
Resources required How large are the resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Large costs ○ Moderate costs ● Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	The mean cost of treatment for the amoxicillin group is $189.20 (Gaboury et al., 2010) The indirect costs of AOM, accrued primarily by parental time lost, are $1330.58, 95% CI [$1008.75, $1652.43] (Alsarraf et al., 1999).	
Certainty of evidence of required resources What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Very low ○ Low ○ Moderate ○ High ● No included studies	No studies have compared the required resources of low versus high doses.	

Cost effectiveness
Does the cost-effectiveness of the intervention favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ● No included studies	Likely lower costs for lower dose. No included studies.	Families would have to travel to pharmacies, obtain prescriptions, and follow written prescription instructions regardless of the dose. However, the cost would be greater for the higher dose.

Equity
What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ● Probably no impact ○ Probably increased ○ Increased ○ Varies ○ Don't know		

Acceptability
Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ● Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know		This would be a large change in practice. Would need stronger evidence.

Feasibility
Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

Critically Appraised Topic (CAT): Acute Otitis Media (AOM) Low-Dose versus High-Dose Amoxicillin

○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	No issues with feasibility in prescribing a lower dose	

SUMMARY OF JUDGEMENTS

JUDGEMENT							
PROBLEM	No	Probably no	Probably yes	**Yes**		Varies	Don't know
DESIRABLE EFFECTS	Trivial	**Small**	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	**Small**	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	**Possibly important uncertainty or variability**	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	**Does not favor either the intervention or the comparison**	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	**Negligible costs and savings**	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the	Probably favors the intervention	Favors the intervention	Varies	**No included studies**

Critically Appraised Topic (CAT): Acute Otitis Media (AOM) Low-Dose versus High-Dose Amoxicillin

JUDGEMENT							
			intervention or the comparison				
EQUITY	Reduced	Probably reduced	**Probably no impact**	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	**Probably no**	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	**Yes**		Varies	Don't know

CONCLUSIONS

Recommendation

Conditional recommendation against the intervention

If you have questions regarding this CAT – please contact evidencebasedpractice@cmh.edu