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 outcome of cure rate and adverse events?

Recommendations from the AOM CPM Committee

*A **conditional** recommendation is made **against** the use of short-course antibiotics, based on the GRADE Evidence to Decision instrument[a] the Summary of Findings Table[a]. Even though the evidence is promising for the reduction of antibiotic length, the overall certainty in the evidence is very low[a].* Only one *cohort study* (El-Shabrawi et al. 2016) *and a quality improvement study (*Frost et al., 2022) found shorter-course antibiotics to be equivalent or better to longer-course antibiotics for patients with AOM. *When there is a lack of scientific evidence, standard work should be developed, implemented, and monitored.*

Literature Summary

Background 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 prescribed antibiotics in the United States (Lieberthal et al., 2013). The American Academy of Pediatrics clinical practice guideline (Lieberthal et al., 2013) recommends using delayed antibiotics for children >6 months of age with mild to moderate unilateral AOM by implementing the safety-net antibiotic prescriptions (SNAP). Amoxicillin is recommended as first-line therapy for most children with AOM with a duration of 10 days for patients ≤23 months of age and 7 days for patients 2-5 years of age with mild to moderate infection (Lieberthal et al., 2013). The National Institute of Health and Care Excellence (NICE) guideline (2018) recommends antibiotics for those <2 years of age with bilateral AOM or for those at any age with otorrhea. For most other children, the guideline focuses on symptomatic care and recommends not providing antibiotics or providing SNAP. If an antibiotic is prescribed, amoxicillin with a duration of 5 to 7 days is recommended. Even though NICE (2018) is a more recent guideline, its recommendations are based on the same evidence as the 2013 AAP guideline. This review aims to explore the current literature on the topic. This review excludes older articles before the pneumococcal vaccine was widely administered due to its effect on the rate and causative organisms of AOM (Eskola et al., 2001). This review will summarize identified literature to answer the specific care question.

Study characteristics. The search for suitable studies was completed 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[b] two guidelines and 10 single studies believed to answer the question. After an in-depth review of the guidelines[c] and single studies, two single studies (El-Shabrawi et al., 2016; Frost et al., 2022) answered the question.

Summary by Outcome

Data Summary by Outcome (rationale for evidence certainty rating[a] provided for each outcome)

Cure rate *One cohort* study (El-Shabrawi et al. 2016) measured cure rate, (*N* = 1380). For the outcome of cure rate, the *p*-value indicated the observation of 5 days of antibiotic (cefpodoxime proxetil) was favorable to >5 days of antibiotics (cefpodoxime proxetil), 5 days: 659/779 versus > 5 days: 472/592, *p*-value = .019.

> **Certainty Of The Evidence For Cure Rate.** The certainty of the body of evidence was very low. The body of evidence was assessed to have serious risk of bias and serious imprecision. The risk of bias was serious due to the potential selection bias of the cohort study and imprecision was serious due to the low number of participants. As only one study was identified to answer this question consistency could not be assessed.

Data Summary by Outcome (rationale for evidence certainty rating[a] provided for each outcome)

Treatment Failure and AOM Recurrence *One quality improvement (QI)* study (Frost et al., 2022) measured AOM recurrence and treatment failure rate, (*N* = 1017). The study measured these outcomes after the implementation of measures to decrease antibiotic length to 5 days from 10 days for AOM. After the implementation of these measures, there was no significant change in the negative outcomes of recurrence or treatment failure, *p*-value > 0.05.

Certainty Of The Evidence For Cure Rate. The certainty of the body of evidence was very low. The body of evidence was assessed to have serious risk of bias and serious indirectness, and serious imprecision. The risk of bias was serious due to the potential selection bias of a QI study. Indirectness was serious due to the generalizability of QI studies. As only one study was identified to answer this question, consistency could not be assessed.

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

(**2002**:py OR **2003**:py OR **2004**:py OR **2005**:py OR **2006**:py OR **2007**:py OR **2008**:py OR **2009**:py OR **2010**:py OR **2011**:py OR **2012**:py OR **2013**:py OR **2014**:py OR **2015**:py OR **2016**:py OR **2017**:py OR **2018**:py OR **2019**:py OR **2020**:py OR **2021**:py OR **2022**: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* = 111
Additional records identified through other sources *n* = 6

Studies Included in this Review

Citation	Study Type
El-Shabrawi et al. (2016)	Cohort
Frost et al. (2022)	QI

Studies Not Included in this Review with Exclusion Rationale

Citation	Reason for exclusion
Dagan et al. (2008)	Patients less than 3 years of age
Di Mario et al. (2016)	No comparison to 5 days of antibiotics
Frost et al. (2020)	No outcome of interest
Frost et al. (2021)	Survey
Hoberman et al. (2016)	Patients less than 2 years of age
Kozyrskyj et al. (2010)	Inappropriate antibiotics and older studies prior to pneumococcal vaccine
Neumark et al. (2007)	5 days versus no antibiotics
Venekamp et al. (2015)	Antibiotics vs placebo

Methods Used for Appraisal and Synthesis

[a]The GRADEpro Guideline Development Tool (GDT) is the tool used to create the Summary of Findings (SOF) table(s) for this analysis. Using the GDT, the author of this CAT rates the certainty of the evidence based on four factors: *within-study risk of bias*, *consistency among studies, directness of evidence*, and *precision of effect estimates*. Each factor is subjectively judged against the author's confidence of the estimated treatment effect. Confidence is assessed as not serious, serious or very serious. If the attribute of serious or very serious is assessed, the author will provide an explanation.

[b]Rayyan is a web-based software used for the initial screening of titles and / or abstracts for this analysis (Ouzzani, Hammady, Fedorowicz & Elmagarmid, 2017).

[c]The Appraisal of Guidelines Research and Evaluation II (AGREE II) is an international instrument used to assess the quality and reporting of clinical practice guidelines for this analysis (Brouwers et al. 2010).

[d]Review Manager (Higgins & Green, 2011) is a Cochrane Collaborative computer program used to assess the study characteristics as well as the risk of bias and create the forest plots found in this analysis.

[e]The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram depicts the process in which literature is searched, screened, and eligibility criteria is applied (Moher, Liberati, Tetzlaff, & Altman, 2009).

References to Appraisal and Synthesis Methods

[a]GRADEpro GDT: GRADEpro Guideline Development Tool (2015). McMaster University, (developed by Evidence Prime, Inc.). [Software]. Available from gradepro.org.

[b]Ouzzani, M., Hammady, H., Fedorowicz, Z., & Elmagarmid, A. (2016). Rayyan-a web and mobile app for systematic reviews. *Systematic Reviews, 5*(1), 210. doi:10.1186/s13643-016-0384-4

[c]Brouwers, M.C. et al. for the AGREE Next Steps Consortium. (2010) AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Canadian Medical Association Journal, 182*, E839-842. Retrieved from https://www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf

[d]Higgins, J. P. T., & Green, S. e. (2011). *Cochrane Handbook for Systematic Reviews of Interventions [updated March 2011]* (Version 5.1.0 ed.): The Cochrane Collaboration, 2011.

[e]Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097 **For more information, visit www.prisma-statement.org.**

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Acronyms Used in this Document

Acronym	Explanation
AGREE II	Appraisal of Guidelines Research and Evaluation II
AOM	Acute Otitis Media
CAT	Critically Appraised Topic
EBP	Evidence Based Practice

NICE	National Institute of Health and Care Excellence
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SNAP	Safety-net antibiotic prescriptions

Statistical Acronyms Used in this Document

Statistical Acronym	Explanation
M or $\bar{X}$	Mean
Mdn	Median
n	Number of cases in a subsample
N	Total number in sample
OR	Odds Ratio
P or p	Probability of success in a binary trial
SD	Standard deviation
SR	Systematic Review

Figure 1
Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRIMSA)[e]

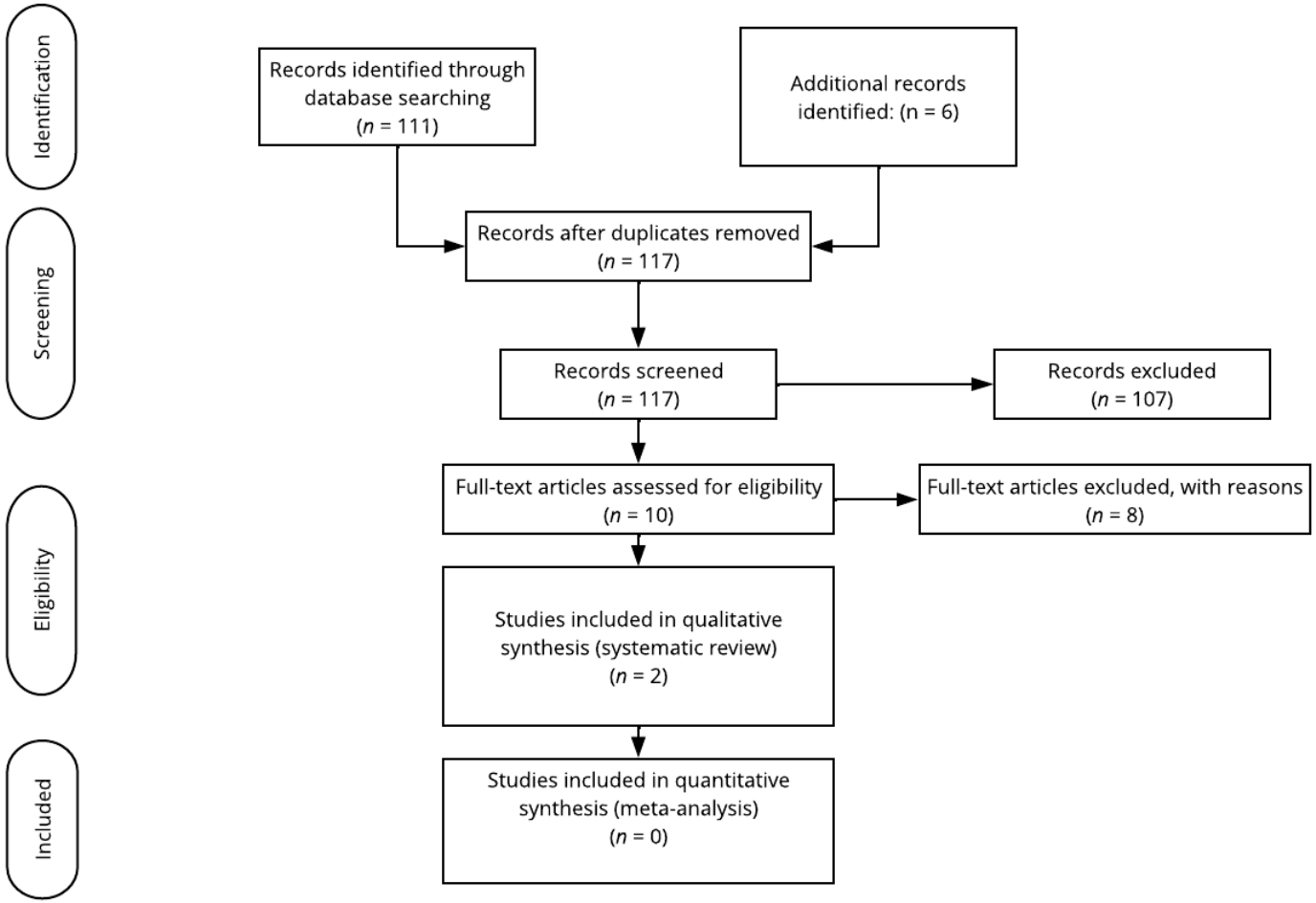

Table 1

AGREE II[b] Summary for the AAP Guideline (Lieberthal et al., 2013)

Domain	Percent Agreement
Scope and purpose	100%
Stakeholder involvement	85%
Rigor of development	93%
Clarity and presentation	93%
Applicability	83%
Editorial independence	83%
Overall guideline assessment	90%
Team's recommendation for guideline use	Yes with modifications

Note: Four EBP Team members or Scholars completed the AGREE II on this guideline.

AGREE I[Xb] Summary for the NICE Guideline (NICE et al., 2018)

Domain	Percent Agreement
Scope and purpose	100%
Stakeholder involvement	88%
Rigor of development	90%
Clarity and presentation	99%
Applicability	76%
Editorial independence	85%
Overall guideline assessment	90%
Team's recommendation for guideline use	Yes with modifications

Note: Four EBP Team members or Scholars completed the AGREE II on this guideline.

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

Characteristics of Intervention Studies

El-Shabrai et al. (2016)

Methods	Cohort
Participants	**Participants:** Children ages 1-13 diagnosed with AOM **Setting:** 26 Egyptian medical centers **Number enrolled into 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 based on 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 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 Children's Mercy CPM 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 therapy had a significantly higher cure compared to those receiving 7 to 10 day of antitibics: (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, cure or improvement rate was 100% in all signs and symptoms except:
	  ▪ spontaneous otorrhea (98%),
	  ▪ 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

Frost et al. (2022)

Methods	**Quality Improvement**
Participants	**Participants:** Children ≥ 2 years of age with Acute Otitis Media **Setting:** Denver Health System; Family Medicine Clinics **Number enrolled into study:** *N* = 1017 • **Pre-intervention, Bundled ASP interventions:** *n* = 388 • **Post-intervention, Bundled ASP interventions:** *n* = 115 • **Pre-intervention, Electronic Health Record (HER)-only interventions:** *n* = 409 • **Post-intervention, EHR-only interventions:** *n* = 105 **Gender, males (as defined by researchers):** • **Pre-intervention:** *n* = 50.0 (%) • **Post-intervention:** *n* = 44.4 (%) • **Pre-intervention:** *n* = 48.9 (%) • **Post-intervention EHR:** *n* = 45.7 (%) **Race (as defined by researchers):** (%) Preintervention Postintervention Black 11.3 8.7 White 76.3 79.1 Other 12.4 12.2 **Ethnicity:** (%) Preintervention Postintervention Non-Hispanic 27.8 27.8 Hispanic 72.2 72.2 **Age, mean in years:** • **Pre-intervention Bundled:** 5.8 • **Post-intervention Bundled**: 6.0 • **Pre-intervention EHR:** 5.5 • **Post-intervention EHR**: 6.2 **Inclusion Criteria:** • Children ≥ 2 years of age • Uncomplicated Acute Otitis Media **Exclusion Criteria:** • Antibiotic use within 30 days prior to visit • History of tympanostomy or tubes • Competing bacterial diagnosis • Patients receiving intramuscular antibiotics • Patients receiving azithromycin
Interventions	**Bundled ASP intervention:** • **Pre-intervention:** No monthly individualized provider audit and feedback, education or electronic decision support in EHR • **Post-intervention:** Monthly individualized provider audit and feedback, education or electronic decision support in EHR **EHR-only intervention:** • **Pre-intervention:** No hyperlink to guidelines for common pediatric infections, help text for antibiotic selection/duration of therapy, quick buttons to select appropriate dosing/duration of therapy • **Post-intervention**: Hyperlink to guidelines for common pediatric infections, help text for antibiotic selection/duration of therapy, quick buttons to select appropriate dosing/duration of therapy
Outcomes	**Primary outcome(s):** • Guideline-concordant prescribing rates **Secondary outcome(s):**

	• Treatment failure* • Recurrence* **Safety outcome(s):** • Not reported *Outcomes of interest to the CMH CPG /CAT development team
Results	**Results:** • Guideline-concordant prescribing rates increased from 10.6% to 85.2% with bundled intervention from 14.4% to 63.8% with EHR-only intervention • *Treatment failure was not significant for the bundled intervention and the EHR intervention, *p*-value = .62 and *p*-value =0.64, respectively • *Recurrence in the bundled intervention and EHR-only intervention were not significant, *p*-value = .18, *p*-value = 1.0, respectively **Limitations:** • Interventions took place in a single healthcare system and may not be generalizable to other organizations • Bundled interventions took place in only pediatric clinics, EHR-only interventions only in family medicine clinics so unable to evaluate effectiveness in each specialty • Unclear whether observed improvement in prescribing due to actual intervention or how each intervention was received from providers • Unable to account for antibiotics prescribed outside of Denver Health System • Effect of COVID-19 pandemic and number of patients presenting with AOM • Unable to evaluate long-term sustainability of program due to short study duration

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

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 prescribed antibiotics 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	***Cure rate*** *One cohort* study (El-Shabrawi et al. 2016) measured cure rate, (*N* = 1380). For the outcome of cure rate, the *p*-value indicated the observation of 5 days of antibiotic (cefpodoxime proxetil) was favorable to >5 days of antibiotics (cefpodoxime proxetil), 5 days: 659/779 versus > 5 days: 472/592, *p*-value = .019. 85% versus 80% cure rate	The desirable effects of a shorter course 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	***Treatment Failure and AOM Recurrence*** *One quality improvement (QI)* study (Frost et al., 2022) measured AOM recurrence and treatment failure rate, (*N* = 1017). The study measured these outcomes after the implementation of measures to decrease antibiotic length to 5 days from 10 days for AOM. After the implementation of these measures, there was no significant change in the negative outcomes of recurrence or treatment failure, *p*-value > 0.05. No difference in treatment failure	Undesirable effects of shorter-course are treatment failure of AOM Return to care

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 Cure Rate.** The certainty of the body of evidence was very low. The body of evidence was assessed to have serious risk of bias and serious imprecision. The risk of bias was serious due to the potential selection bias of the cohort study and imprecision was serious due to the low number of participants. As only one study was identified to answer this question consistency could not be assessed. **Certainty Of The Evidence For Treatment Failure and Recurrence.** The certainty of the body of evidence was very low. The body of evidence was assessed to have serious risk of bias and serious indirectness, and serious imprecision. The risk of bias was serious due to the potential selection bias of a QI study. Indirectness was serious due to the generalizability of QI studies. As only one study was identified to answer this question, consistency could not be assessed.	Minimal evidence exists on outcomes of longer vs shorter therapy. Only one quality improvement study and one cohort study (see above) make this comparison.

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 weigh more heavily on the risk 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 longer vs shorter therapy. Only one quality improvement study and one cohort study (see above) make this comparison.	

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 versus $198.68 for the SNAP group. (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 compared 5 versus 10 days of antibiotics.	

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 cost 5 versus 10 days. No included studies.	

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		Families would have to travel to pharmacies, obtain prescriptions, and follow written prescription instructions regardless of the duration. However, the cost would be greater for the longer antibiotic course.

Acceptability Is the intervention acceptable to key stakeholders?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ○ Yes • Varies ○ Don't know		If evidence is stronger, stakeholders would likely be accepting of the intervention of a shorter duration.

Feasibility Is the intervention feasible to implement?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes • Yes ○ Varies ○ Don't know	No issues with feasibility in prescribing short versus long course.	

CONCLUSIONS

Recommendation

*A **conditional** recommendation is made **against** the use of short-course antibiotics based on the GRADE Evidence to Decision instrument.*