

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (if previously endorsed): 0657

Measure Title: Otitis Media with Effusion: Systemic Antimicrobials—Avoidance of Inappropriate Use

IF the measure is a component in a composite performance measure, provide the title of the

Composite Measure here: [Click here to enter composite measure #/ title](#)

Date of Submission: [3/27/2015](#)

Instructions

- For composite performance measures:
 - A separate evidence form is required for each component measure unless several components were studied together.
 - If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.
- Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of supplemental materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Maximum of 10 pages (includes questions/instructions; minimum font size 11 pt; do not change margins).
Contact NQF staff if more pages are needed.
- Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](#).

Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF's evaluation criteria.

1a. Evidence to Support the Measure Focus

The measure focus is evidence-based, demonstrated as follows:

- **Health outcome:** ³ a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior.
- **Intermediate clinical outcome:** a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured intermediate clinical outcome leads to a desired health outcome.
- **Process:** ⁵ a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured process leads to a desired health outcome.
- **Structure:** a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured structure leads to a desired health outcome.
- **Efficiency:** ⁶ evidence not required for the resource use component.

Notes

3. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
4. The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](#) and [methods](#), or Grading of Recommendations, Assessment, Development and Evaluation ([GRADE](#)) [guidelines](#).
5. Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.
6. Measures of efficiency combine the concepts of resource use and quality (see NQF's [Measurement Framework: Evaluating Efficiency Across Episodes of Care](#); [AQA Principles of Efficiency Measures](#)).

1a.1. This is a measure of: (should be consistent with type of measure entered in De.1)

Outcome

- ☐ Health outcome: Click here to name the health outcome
- ☐ Patient-reported outcome (PRO): Click here to name the PRO
PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors
- ☐ Intermediate clinical outcome (e.g., lab value): Click here to name the intermediate outcome
- ☒ Process: [Avoidance of Inappropriate Use of Systemic Antimicrobials for Otitis Media with Effusion](#)
- ☐ Structure: Click here to name the structure
- ☐ Other: Click here to name what is being measured

HEALTH OUTCOME/PRO PERFORMANCE MEASURE *If not a health outcome or PRO, skip to 1a.3*

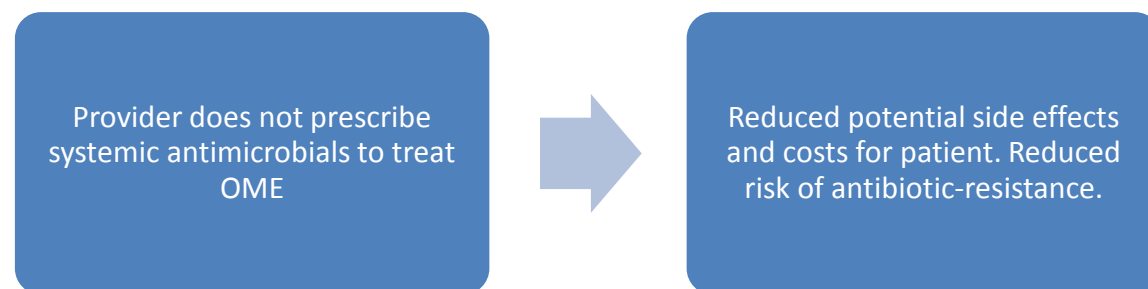
1a.2. Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.

1a.2.1. State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).

Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.

INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURE

1a.3. Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes. Include all the steps between the measure focus and the health outcome.



1a.3.1. What is the source of the systematic review of the body of evidence that supports the performance measure?

- ☒ Clinical Practice Guideline recommendation – **complete sections [1a.4](#), and [1a.7](#)**
- ☐ US Preventive Services Task Force Recommendation – **complete sections [1a.5](#) and [1a.7](#)**
- ☒ Other systematic review and grading of the body of evidence (e.g., *Cochrane Collaboration*, *AHRQ Evidence Practice Center*) – **complete sections [1a.6](#) and [1a.7](#)**
- ☐ Other – **complete section [1a.8](#)**

Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (including date) and URL for guideline (if available online):

American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Pediatrics Subcommittee on Otitis Media with Effusion. Otitis media with effusion. *Pediatrics*. 2004;113(5):1412-1429.

1a.4.2. Identify guideline recommendation number and/or page number and quote verbatim, the specific guideline recommendation.

Recommendation Number 5, page 1418:

“Antimicrobials and corticosteroids do not have long-term efficacy and are not recommended for routine management”

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:

“Recommendation Against”: A recommendation means that the subcommittee believes that the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C).^{*} In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.

1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system. (Note: If separate grades for the strength of the evidence, report them in section 1a.7.)

“Strong Recommendation”: A strong recommendation means that the subcommittee believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B).^{*} In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.

“Option”: An option means that either the quality of evidence that exists is suspect (grade D)^{*} or that well-done studies (grade A, B, or C)^{*} show little clear advantage to one approach versus another.

“No Recommendation”: No recommendation means that there is both a lack of pertinent evidence (grade D)^{*} and an unclear balance between benefits and harms.

1a.4.5. Citation and URL for methodology for grading recommendations (if different from 1a.4.1):

American Academy of Pediatrics, Steering Committee on Quality Improvement and Management. A taxonomy of recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874-877.

1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?

☒ Yes → complete section [1a.7](#)

☐ No → report on another systematic review of the evidence in sections [1a.6](#) and [1a.7](#); if another review does not exist, provide what is known from the guideline review of evidence in [1a.7](#)

1a.5. UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

1a.5.1. Recommendation citation (including date) and URL for recommendation (if available online):

1a.5.2. Identify recommendation number and/or page number and quote verbatim, the specific recommendation.

1a.5.3. Grade assigned to the quoted recommendation with definition of the grade:

1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system. (Note: the grading system for the evidence should be reported in section 1a.7.)

1a.5.5. Citation and URL for methodology for grading recommendations (if different from 1a.5.1):

Complete section [1a.7](#)

1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE

1a.6.1. Citation (including date) and URL (if available online):

vanZon A, van der Heijden GJ, van Dongen TMA, Burton MJ, Schilder AGM. Antibiotics for otitis media with effusion in children. *Cochrane Database Syst Rev*. 2012 Sep 12;9:CD009163.
doi:10.1002/14651858.CD009163.pub2.

1a.6.2. Citation and URL for methodology for evidence review and grading (if different from 1a.6.1):

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). 5.1. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011.

Complete section [1a.7](#)

1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE

If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.

1a.7.1. What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?

AAFP Guideline:

Medication: Potential benefits of antihistamines, decongestants, antimicrobials, and corticosteroids for treatment/management of OME.

Cochrane Review: Antibiotics for otitis media with effusion in children

1a.7.2. Grade assigned for the quality of the quoted evidence with definition of the grade:

AAFP Guideline:

Assigned Quality: A

Definitions:

Grade A Evidence: Well-designed, randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population

Cochrane Review: No overall grade of quality of the evidence was presented in the review

1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.

AAFP Guideline:

Grade B Evidence: Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies

Grade C Evidence: Observational studies (case-control and cohort design)

Grade D Evidence: Expert opinion, case reports, or reasoning from first principles (bench research or animal studies)

Cochrane Review: No grades assigned for quality of evidence

1a.7.4. What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range: [1980-2012](#)

QUANTITY AND QUALITY OF BODY OF EVIDENCE

1a.7.5. How many and what type of study designs are included in the body of evidence? (*e.g., 3 randomized controlled trials and 1 observational study*)

AAFP Guideline:

The AAFP guideline recommendation against antimicrobials cites 1 clinical practice guideline, 2 meta-analyses (including 10 studies each), 1 large randomized controlled trial, and 1 observational study.

Cochrane Review: 23 randomized controlled trials involving the assessment of antimicrobials were included in the review.

1a.7.6. What is the overall quality of evidence across studies in the body of evidence? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as*

design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)

AAFP Guideline:

The AAFP Guideline does not provide a description of the overall quality of the evidence across studies.

Cochrane Review:

The Cochrane review describes the overall quality of the evidence as having a “fairly low” risk of bias. In addition, the following table was included that illustrates the risk of various types of bias for each study included in the review. Green circles indicate low risk of bias, yellow circles indicate unclear risk of bias, and a red circle indicates high risk of bias.

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Ardrehan 2008	+	+	+	+	+	?	?
Choung 2008	?	?	?	+	+	?	?
Comin 1986	+	?	+	+	+	?	?
Daly 1991	+	+	+	+	+	?	?
de Castro 1982	?	?	?	+	+	?	?
Emmison 1985	?	?	?	+	+	?	?
Gieblink 1990	?	?	?	+	+	?	?
Healy 1984	+	+	+	+	+	?	?
Hemlin 1997	?	?	+	+	+	?	?
Leach 2008	+	+	+	+	+	?	?
Mandel 1987	+	+	+	+	+	?	?
Mandel 1991	+	+	+	+	+	?	?
Marchisio 1998	+	?	+	+	+	?	?
Marks 1981	+	+	+	+	+	?	?
Moller 1990	?	?	+	+	+	?	?
Olsen 1990	?	?	+	+	+	?	?
Ozmen 2010	+	+	+	+	+	?	?
Podoshin 1990	?	?	+	+	+	?	?
Principi 1989	?	?	?	+	+	?	?
Sarik 2001	?	?	+	+	+	?	?
Schwartz 1982	+	+	+	+	+	?	?
Thomsen 1989	?	?	+	+	+	?	?
van Balen 1996	+	+	+	+	+	?	?

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1a.7.7. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance)

AAFP Guideline:

Some RCTs show a modest short-term benefit for 2-8 weeks, but that benefit becomes nonsignificant within 2 weeks of stopping medication. The guideline estimates that approximately 7 children would need to be treated with antimicrobials to achieve one short-term response.

Cochrane Review:

Due to heterogeneity among the included studies, the review was unable to provide an estimate of benefit across studies. However, the risk ratios for complete resolution of OME at 2 to 3 months for antibiotics versus placebo for the included studies are as follows: 4.00 (95% CI 1.25-12.75), 1.85 (95% CI 0.96-3.54), 4.00 (95% CI 1.63-9.82), 2.13 (95% CI 1.35-3.34), 1.09 (95% CI 0.16-7.31).

1a.7.8. What harms were studied and how do they affect the net benefit (benefits over harms)?

AAFP Guideline:

Adverse effects of systemic antimicrobials can include rash, vomiting, diarrhea, allergic reactions, alteration of the child’s nasopharyngeal flora, development of bacterial resistance and cost. Societal consequences include direct transmission and spread of resistant bacterial pathogens. The risk of these

side effects coupled with the lack of long-term benefit associated with these drugs indicates that the potential harms outweigh the benefits.

Cochrane Review:

Adverse effects described in the review include haematological complications (eg, leukopenia, neutropenia, anaemia, and thrombocytopenia), rash, diarrhea, and vomiting. However, the actual severity of the adverse events was not reported. The risk of these side effects coupled with the lack of long-term benefit associated with these drugs indicates that the potential harms outweigh the benefits.

UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1a.7.9. If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

There have been no updates to the body of evidence evaluating the effectiveness of antimicrobials in the management of OME. Recent research has instead focused on the use and effectiveness of ventilation tubes for otitis as well as the use of antimicrobials for Acute Otitis Media (AOM).

1a.8 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.8.1 What process was used to identify the evidence?

1a.8.2. Provide the citation and summary for each piece of evidence.