

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (if previously endorsed): 0655

Measure Title: Otitis Media with Effusion: Antihistamines or Decongestants—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 Antihistamines or Decongestants 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*

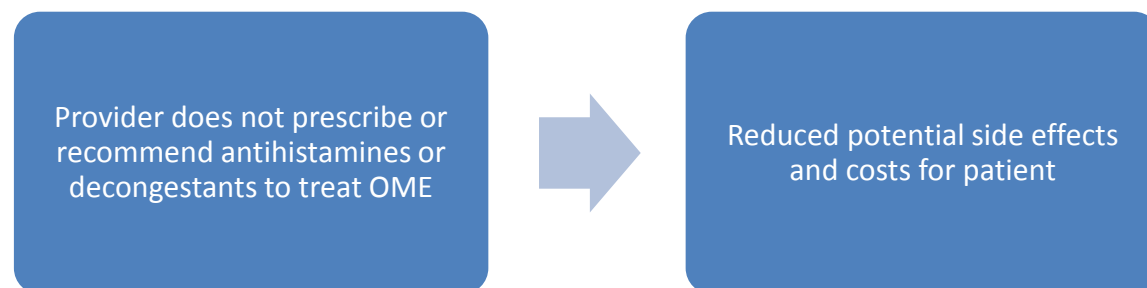
1a.2. Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.

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:

“Antihistamines and decongestants are ineffective for OME and are not recommended for treatment.”

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):

Griffin G, Flynn CA. Antihistamines and/or decongestants for otitis media with effusion (OME) in children (review). *Cochrane Database Syst Rev*. 2011;9:CD003423.
doi:10.1002/14651858.CD003423.pub3.

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

Electronic search methodology:

Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Assessment of risk of bias in included studies methodology:

Mohar D, Jadad AR, Nichol G. Assessing the quality of randomized controlled trials: an annotated bibliography of scales and checklists. *Controlled Clinical Trials* 1995;16:62-73.

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: Antihistamines and/or decongestants for otitis media with effusion (OME) 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 was assigned to the quality of evidence. However, quality scores were assigned to individual included studies. The quality score is a scale of 0-5, with a study receiving one point for each of the following: mentioning randomization, describing the method of randomization, describing all loss to follow-up, mentioning blinding, and describing the process of blinding. Out of 16 studies included in the systematic review, 8 studies had a quality score of 3 or more and 8 studies had a quality score of 2 or less. Adequacy of allocation concealment was determined separately and only 2 of 16 studies demonstrated appropriate concealment of allocation to intervention or control groups.

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: 1994-2011

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 antihistamines and decongestants cites a meta-analysis of 4 randomized trials.

Cochrane Review: 16 randomized controlled trials using antihistamines, decongestants, or antihistamine/decongestant combinations as treatment for OME in children were included.

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 rated the evidence as Grade A quality, meaning the evidence comes from well-designed, randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population

Cochrane Review:

The Cochrane Review does not provide an estimate of the overall quality of the evidence across studies.

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:

A meta-analysis of 4 randomized trials showed no significant benefit for antihistamines or decongestants versus placebo.

Cochrane Review:

Pooled data from six trials with a dichotomous outcome of cure or no cure of OME at one month or less resulted in a risk ratio (RR) of 0.99 with a 95% confidence interval of 0.92 to 1.05 for any combination of antihistamines and/or decongestants. Results for individual interventions were similar: decongestants alone had a RR of 1.06 (0.92-1.22) and antihistamine/decongestant combinations had a RR of 0.97 (0.89-1.04), both of which are statistically and clinically non-significant. Risk ratios for delayed persistence of OME (OME at one to three months) were similar: any medication combination RR 1.06 (0.92-1.22), decongestant alone RR 1.05 (0.85-1.30), antihistamine alone RR 1.05 (0.8-1.38), and antihistamine/decongestant combination RR 1.09 (0.85-1.40).

Other outcomes reviewed are as follows:

Complications

--Recurrent OME (antihistamine/decongestant versus control): RR 1.30 (0.80-2.11)

--Acute Otitis Media (AOM): antihistamine alone RR 0.89 (0.46-1.73), decongestant alone RR 0.55 (0.23-1.31), antihistamine/decongestant combination RR 0.76 (0.46-1.26)

Hearing loss

--at one month follow-up: RR 1.08 (0.93-1.27)

--at late follow-up: RR 1.50 (0.63-3.56)

Surgery

--any medication: RR 1.07 (0.81 to 1.41)

--antihistamine alone: RR 2.08 (0.77 to 5.58)

--decongestant alone: RR 1.07 (0.71-1.62)

Medication side effects

--Any medication treatment vs placebo: RR 2.70 (1.87-3.88)

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

AAFP Guideline:

Adverse effects of antihistamines and decongestants include insomnia, hyperactivity, drowsiness, behavioral change, and blood-pressure variability. The risk of these side effects coupled with the lack of significant benefit associated with these drugs indicates that the potential harms outweigh the benefits.

Cochrane Review:

As summarized in the data above, this review primarily evaluated the potential for harm associated with side effects of antihistamine and/or decongestant use. This review found significantly increased risk for medication side effects in the group treated with antihistamines and/or decongestants when compared with a placebo group. This potential harm combined with the evidence of no net benefit of treatment with these medications led the authors to recommend against their use for treatment of OME in children.

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.

No updates to the body of evidence were found for this topic.

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.