NATIONAL QUALITY FORUM

Memo

TO: Consensus Standards Approval Committee (CSAC)

FR: Karen Johnson, Senior Director, and Shaconna Gorham, Senior Project Manager

RE: Eye Care and Ear, Nose and Throat (EENT) Conditions: Off-Cycle: Measure Review 2017

DA: July 11 -12, 2017

The CSAC will review recommendations from the EENT project at its July 11 – 12, 2017 in-person meeting and vote whether to uphold the recommendations from the Committee. This memo includes a summary of the project and the measures under evaluation. NQF received only pre-evaluation comments. No additional comments were submitted during the post-evaluation commenting period.

NQF Member voting on these recommended measures will end on July 7. A voting addendum will be submitted to the CSAC with voting results on July 8.

Accompanying this memo are the following documents:

1. **Eye Care and Ear, Nose and Throat (EENT) Conditions: Off-Cycle: Measure Review 2017 Draft Report.** The draft report has been updated to reflect the changes made following the June 13 post comment call. The complete draft report and supplemental materials are available on the project page.
2. **Comment table**. This table lists two pre-evaluation comments.

DRAFT REPORT

The EENT: Off-Cycle Measure Review 2017 Draft Report presents the results of the evaluation of two measures considered under the CDP. One was recommended for endorsement and one was not recommended.

The measures were evaluated against NQF's standard evaluation criteria.

	Maintenance	New	Total
Measures under consideration	0	2	2
Measures recommended for endorsement	0	1	1
Measures not recommended for endorsement	0	1	1
Reasons for not recommending	Importance – N/A Scientific Acceptability – N/A Overall – N/A Competing Measure – N/A	Importance – 0 Scientific Acceptability – 1 Overall – 0 Competing Measure – 0	

CSAC ACTION REQUIRED

Pursuant to the CDP, the CSAC may consider approval of one candidate consensus standard.

EENT Measures Recommended for Endorsement:

- 2811: Acute Otitis Media – Appropriate First-Line Antibiotics

Overall Suitability for Endorsement: Y-10; N-0

EENT Measures Not Recommended (See Appendix A for the Committee's votes)

- 2640: Otitis Media with Effusion - Antibiotics Avoidance

COMMENTS AND THEIR DISPOSITION

NQF did not receive any comments pertaining to the general draft report or to the measures under consideration. NQF received only pre-evaluation comments. A table of comments submitted pre-evaluation is posted to the CDP Standing Committee Off-Cycle Activities project page.

COMMITTEE RE-CONSIDERATION AND RE-VOTE ON MEASURE #2640

During the March 14, 2017 evaluation of this measure, the Standing Committee voted against endorsement, primarily due to concerns with the difficulty of diagnosing otitis media with effusion (OME) and the potential for providers to miscode OME as acute otitis media (AOM). After a lengthy discussion, the Committee agreed that the measure did not pass the reliability subcriterion.

In considering the voting results, NQF staff determined that the committee's discussion regarding the ability to diagnosis OME and potential for miscoding the diagnosis is more appropriate within the context of validity rather than reliability. During the June 13, 2017 post comment call, NQF asked the Committee to re-vote on reliability, basing its rating on clarity of specifications and results of reliability testing, and to consider the question of diagnosis accuracy and the data provided by the developer in a discussion on validity. The Committee voted to pass the measure on the Reliability sub-criterion. However, the Committee failed the measure on the Validity sub-criterion, again citing concerns about accuracy of diagnosis and potential for providers to miscode OME as AOM.

NQF MEMBER VOTING RESULTS

Member voting on the recommended measure will end on July 7. A voting addendum will be submitted to the CSAC with voting results on July 8.

Appendix A – Measure Not Recommended for Endorsement

The table below lists the Committee's vote and rationale for the measure not recommended for endorsement.

LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

Measure	Voting Results	Standing Committee Rationale
2640: Otitis Media with Effusion - Antibiotics Avoidance	**Evidence** H-10; M-0; L-0; I-0 **Gap** H-0; M-6; L-4; I-0 **Reliability** H-0; M-2; L-8; I-0 **Validity** H-X; M-X; L-X; I-X **Feasibility** H-X; M-X; L-X; I-X **Usability and Use** H-X; M-X; L-X; I-X **Post Comment Call Vote:** **Reliability** H-7; M-4; L-0; I-0 **Validity** H-1; M-5; L-5; I-X	The Committee did not pass the measure on the validity subcriterion, expressing concerns with the difficulty of diagnosing OME and "concerns that providers might miscode OME as AOM". Thus, the Committee did not recommend the measure for endorsement.

Appendix B – Measure Evaluation Summary Tables

Measure Recommended

2811: Acute Otitis Media – Appropriate First-Line Antibiotics
Submission | Specifications
Description: The proportion of encounters at which antibiotics prescribed to patients aged 2 months to 12 years for Acute Otitis Media (AOM) conform to the AAP/AAFP recommendation for first-line use of amoxicillin. Numerator Statement: Eligible encounters at which patients were prescribed amoxicillin, in conformance with the AAP/AAFP recommendation that this drug be the first-line antibiotic choice for AOM. Note that this measure is structured for feasibility and scalability over large populations, and does n ot by design account for individual patient characteristics such as detailed history of drug hypersensitivity, prior response of AOM to antibiotics, or comorbidities, such as immunodeficiency, requiring changes in antibiotic selection. As a result, performance should not be assessed with the expectation of a "perfect" outcome of 100% amoxicillin usage. Nonetheless, results over 90% should be readily achieved in most care contexts. The prevalence of penicillin allergy has been previously reported at =5% (Borch, JE et al. Basic Clin Pharmacol Toxicol. 2006 , PMID 16623858; Meng et al., Ann Allergy Asthma Immunol 2016, PMID 27613461), and our examination of electronic health records for a large pediatric health system yielded a similar figure (4.5%). The prevalence of the most common indications for antibiotic prophylaxis are ca.1% (e.g. sickle cell disease ~0.25% in the African American population, pediatric cancer 0.3%, and urinary tract infection with vesicoureteral reflux 0.5-2%). The utility of the measure for benchmarking across similar entities, or for detection of trends over time, is not affected by these factors, which are expected to remain relatively constant. Denominator Statement: All patients aged 2 months through 12 years with a diagnosis of Acute Otitis Media (AOM), an antibiotic prescribed at the current visit, and no antibiotic prescription in the prior 30 days. Exclusions: Diagnosis of alternate, co-occurring infection for which antibiotics are typically indicated will be excluded (as specified in S.11. Denominator Exclusion Details). Adjustment/Stratification: No risk adjustment or risk stratification Measure validity is not dependent on stratification, but an organization may consider stratifying by socio demographic factors in order to assess disparities in care provided for Acute Otitis Media. Level of Analysis: Facility, Clinician : Group/Practice, Clinician : Individual Setting of Care: Clinician Office/Clinic, Other, Urgent Care - Ambulatory Type of Measure: Process Data Source: Other Measure Steward: The Children's Hospital of Philadelphia Pediatric Quality Measures Program Center of Excellence
STANDING COMMITTEE MEETING [03/14/2017] 1. Importance to Measure and Report: **The measure meets the Importance criteria** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: H-7; M-3; L-0; I-0 1b. Performance Gap: H-7; M-3; L-0; I-0; Rationale: • To support the measure, the developer provided a 2013 American Academy of Pediatrics recommendation based on grade B evidence for use of amoxicillin for acute otitis media (AOM) when a decision to treat with antibiotics has been made and the child has not received

amoxicillin in the past 30 days or the child does not have concurrent purulent conjunctivitis or the child is not allergic to penicillin.

- Based on data from 106,728 visits documented in the Children´s Hospital of Philadelphia's electronic health records from 2009-2014, the provider-level "mean failure rate" reported by the developer was 34.80%, meaning that, on average, providers prescribed an appropriate antibiotic for AOM less than two-thirds of the time.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-5; M-5; L-0; I-0 2b. Validity: H-0; M-10; L-0; I-0

Rationale:

- The developer clarified that the use of amoxicillin, penicillin, or ampicillin would be appropriate and thus "meet" the measure, and that there is no penalty in the measure in the event that the clinician decides not to prescribe an antibiotic at all. The Committee requested the developer update the numerator statement to be consistent throughout the submission (i.e., include penicillin and ampicillin in addition to amoxicillin).
- The Committee asked if patients with an allergy to penicillin are excluded from the measure. The developer clarified that they are not excluded because EHR data allow for that level of specificity. The developer also noted that, per the literature, the true rate of allergy to amoxicillin and penicillin is approximately 5%. The Committee noted that this means that achieving a 100% performance rate for the measure will not be possible.
- The Committee questioned whether or not a provider must have at least five encounters to be eligible for the measure. The developer confirmed this specification, noting that limiting the measure to providers with more than five eligible encounters in the measurement time period will not exclude many providers because of the disease prevalence.
- The Committee requested clarification on the timeframe of the measure, which was not specified in the submission. The developer responded that the timeframe was not specified because it is context dependent (e.g., if measure is used for provider benchmarking, a longer timeframe will allow greater discriminate ability; in contrast, if used for quality improvement, then a shorter timeframe might be appropriate.) The Committee accepted this rationale.
- The developer conducted score-level reliability testing for the three levels of analysis specified for the measure. Results indicate an average reliability of >0.94 for all three levels of analysis. These results are based on data for January 2009-June 2016 from 6 academic pediatric health systems, 2,940 clinicians and 186 practices, and 3 EHR systems.
- The Committee questioned whether children with bacterial conjunctivitis would be excluded from the measure. The developer said that they would, but noted that it is not a highly-prevalent diagnosis.
- The Committee questioned the generalizability of the testing results, given that testing was conducted on data from academic centers. The developer noted that the literature suggests that appropriate prescribing of antibiotics for AOM is higher in academic centers and therefore expects that the results presented reflect better performance than would be expected in non-academic settings.
- Although the developer provided some data element validity testing results, these were based on data from only one EHR system and thus do not meet NQF requirements for eMeasures. To demonstrate score-level validation (based on data from multiple EHRs), the developer hypothesized, and were able to show, that measure results within individual providers/departments would vary less across time than measure results between

2811: Acute Otitis Media – Appropriate First-Line Antibiotics
providers/departments, given the lack of external influences that would affect results across time. • The Committee asked for clarification regarding the standard code for medication, where 10% of values were missing in the testing data. The developer explained that medications can be recorded in different ways in EHRs and that the standardized coding system (RxNorm) had missing values for 10% of the encounters in their testing data. For testing, the developer used other information in the EHR to determine prescribed medications for those encounters where RxNorm was missing; if using RxNorm exclusively, those encounters would be ineligible and not included in the measure.
3. Feasibility: H-2; M-8; L-0; I-0 (3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale: • The Committee agreed the measure is feasible for implementation, as all data elements used for the measure are in defined fields in EHRs.
4. Usability and Use: H-4; M-6; L-0-; I-0 (Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences) Rationale: • This measure is currently not in use. The planned use is to include the measure in a public reporting program for children enrolled in Medicaid and Children's Health Insurance Program (CHIP). • Committee members noted that making a diagnosis for AOM is less problematic than for OME.
Steering Committee Recommendation for Endorsement: Y-10; N-0
6. Public and Member Comment: April 27-May 30, 2017 • No post-meeting comments received.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Appeals

Measure Not Recommended

2640: Otitis Media with Effusion - Antibiotics Avoidance
Submission
Description: The proportion of encounters with a diagnosis of Otitis Media with Effusion (OME) made at age 2 months to 12 years, where patients were not prescribed systemic antimicrobials. Numerator Statement: Eligible encounters at which a systemic antibiotic was not prescribed. Denominator Statement: Outpatient encounters at which Otitis Media with Effusion is diagnosed, but at which common conditions for which antibiotics are indicated are not diagnosed. It is expected that a small fraction of patients with rare non-OME indications for antibiotic usage will not be identified by the specified exclusion criteria, but these will be rare cases, and will not alter the measure score significantly in most practice contexts. Of note, however, applicability may be limited in specific practice environments in which a large proportion of patients seen have immune deficiencies requiring chronic antibiotic use (e.g. immunology or hematology/oncology clinics). Exclusions: Diagnosis at the visit of common childhood infection for which antibiotics are frequently indicated.

2640: Otitis Media with Effusion - Antibiotics Avoidance

Adjustment/Stratification: No risk adjustment or risk stratification Measure validity is not dependent on stratification, but an organization may consider stratifying by sociodemographic factors in order to assess disparities in care provide in Otitis Media with Effusion.

Level of Analysis: Facility, Clinician : Group/Practice, Clinician : Individual, Integrated Delivery System

Setting of Care: Clinician Office/Clinic, Urgent Care - Ambulatory

Type of Measure: Process

Data Source: Other

Measure Steward: The Children's Hospital of Philadelphia Pediatric Quality Measures Program Center of Excellence

STANDING COMMITTEE MEETING [03/14/2017]

1. Importance to Measure and Report: **Consensus Not Reached on the Importance criterion.**

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: H-10; M-0; L-0; I-0; 1b. Performance Gap: H-0; M-6; L-4; I-0;

Rationale:

- The developer provided a clinical practice guideline recommendation against using systemic antibiotics for treating Otitis Media with Effusion (OME). The recommendation, graded as "strong" and supported by grade A evidence, is published in two peer-reviewed publications: The Pediatrics Journal (2004) and Otolaryngology Head and Neck Surgery (2016).
- Based on data from 36,060 visits documented in the Children´s Hospital of Philadelphia's electronic health records from 2009-2014, the provider-level "mean failure rate" reported by the developer was 15.05% and the facility-level rate was 11.42%.
    - Committee members questioned the meaning of the 15% mean failure rate. The developer clarified that for providers the average provider-level performance rate for the measure is approximately 85%, meaning that, on average, providers prescribed an antibiotic 15% of the time when the patient had a diagnosis of OME but no other conditions that might require antibiotics.
- The Committee noted that the performance rate (85%) was relatively high, and questioned the ability to improve performance. The developer noted that approximately 25% of providers included in their testing data are achieving 100%, suggesting it is possible for other providers to do so.
- Members questioned whether there were any differences in performance for particular population subgroups (e.g., ethnicity, race, sex, and socioeconomic status). The developers reported finding relatively small, but statistically significant, differences in provider-level performance between racial/ethnic groups and those with varying insurance status/type. However, they did not provide the data from these analyses.
- Several Committee members questioned the need for this measure, noting the decrease in the incidence of OME over the past several years. However, the developer noted that otitis media is "the primary driver of antibiotic prescriptions" in their dataset.

2. Scientific Acceptability of Measure Properties: **The measure does not meet the Scientific Acceptability criteria**

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: Initial vote: H-0; M-2; L-8; I-0;

Re-vote on post-comment call: H-7; M-4; L-0; I-0 2b. Validity: Vote on post-comment call: H-1; M-5; L-5; I-X

Rationale:

- The developer conducted score-level reliability testing for the three levels of analysis specified for the measure. Results indicate an average reliability of >0.96 for all three levels

of analysis. These results are based on data for January 2009-June 2016 from 6 academic pediatric health systems, 704 clinicians and 207 practices, and 3 EHR systems.

- Committee members had a lengthy discussion regarding the difficulty in accurately diagnosing Otitis Media with Effusion. Several members expressed concern that providers may miscode OME as Acute Otitis Media (AOM) if they have decided to prescribe antibiotics. The developer agreed that accurate diagnosis is a problem, but pointed out that the measure is designed to assess prescription of antibiotics when the clinician has diagnosed as OME.
- After much discussion, the Committee agreed that the measure did not pass the reliability subcriterion and did not recommend the measure for endorsement.

During the March 2017 call, the Committee failed to pass the measure on the Reliability criterion, although its primary concerns centered on diagnostic accuracy and potential gaming of the measure. However, these concerns more appropriately apply under the Validity subcriterion than the Reliability subcriterion. Therefore, NQF staff directed the Committee to re-vote on the Reliability criterion during the June 2017 post-comment call, this time basing its rating on clarity of specifications and results of reliability testing. During the post-comment call:

- The Committee agreed that the measure specifications were complete and unambiguous. Members also agreed that the average reliability estimates provided by the developer (>0.96 for all three levels of analysis) indicated sufficient ability to differentiate between providers.
- The developer described data element validity testing for the measure, noting that for the 225 records from one EHR system that were examined, testing results indicated a sensitivity of 90 percent and specificity of 92 percent.
- The Committee had a robust discussion regarding the potential of miscoding OME as AOM if they have decided to prescribe antibiotics. The developer agreed that such gaming was possible, but reminded the Committee of the AOM measure (#2811) that promotes use of narrow-spectrum antibiotics when diagnosing as AOM. The developer reiterated that the OME measure is meant to discourage use of antibiotics when the diagnosis is coded as OME, not to discern whether the diagnosis was accurate or not. Ultimately, however, the Committee agreed that the difficulty in accurately diagnosing OME, along with the potential for mis-coding the diagnosis, invalidates the measure and did not pass the measure on the validity subcriterion
- The Committee suggested the developer work with American Academy of Otolaryngology – Head and Neck Surgery, the developer of NQF #0657 – Otis Media with Effusion: Systemic Anitmicrobials – Avoidance of Inappropriate Use (paper measure) for future development.

3. Feasibility: H-X; M-X; L-X; I-X

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

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4. Usability and Use: H-X; M-X; L-X; I-X

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

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5. Related and Competing Measures

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Steering Committee Recommendation for Endorsement: **Not Recommended**

Rationale:

2640: Otitis Media with Effusion - Antibiotics Avoidance
•
6. Public and Member Comment: April 27-May 30, 2017 • No post-meeting comments received
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Appeals

Eye Care, Ear, Nose and Throat (EENT): Off-Cycle Measure Review 2017

Consensus Standards Approval Committee Review and Recommendations

July 11 - 12, 2017

Co-Chairs:
Daniel Merenstein, MD
Kathleen Yaremchuk, MD, MSA

NQF Staff:
Shaconna Gorham, Senior Project Manager
Karen Johnson, Senior Director

NATIONAL QUALITY FORUM

Eye Care, Ear, Nose and Throat (EENT): Off-Cycle Measure Review 2017

- For this project, the 15 member Standing Committee evaluated two newly developed measures against NQF's standard evaluation criteria:
  - Measure topics included Otitis Media with Effusion and Acute Otitis Media
  - The Committee recommended one measure for endorsement and did not recommend one measure.

Eye Care, Ear, Nose and Throat (EENT): Off-Cycle Measure Review 2017

- The Committee recommended one measure for endorsement:
  - 2811: Acute Otitis Media – Appropriate First-Line Antibiotics

- The Committee did not recommend the following measure:
  - 2640: Otitis Media with Effusion - Antibiotics Avoidance

EENT: Off-Cycle Measure Review 2017

On March 14, 2017, the EENT Standing Committee evaluated two new eMeasures.

	Maintenance	New	Total
Measures under consideration	0	2	2
Measures recommended for endorsement	0	1	1
Measures not recommended for endorsement	0	1	1
Reasons for not recommending	Importance – N/A Scientific Acceptability – N/A Overall – N/A Competing Measure – N/A	Importance – 0 Scientific Acceptability – 1 Overall – 0 Competing Measure – 0	

Comments Received

EENT: Off-Cycle Measure Review 2017 Comments Received

- Two pre-evaluation comments were received.
- No additional comments were received during the post-evaluation commenting period.

Committee Re-Consideration and Re-Vote on Measure #2640

- Committee reviewed new information provided by the developer, and then re-voted on Reliability and voted on Validity during the post-comment call.

- For Reliability: the Committee based its rating on clarity of specifications and results of reliability testing, and passed the measure on this subcriterion.

- For Validity: the Committee considered the questions of diagnosis accuracy and coding accuracy during validity discussion, and did not pass the measure on this subcriterion.

EENT Off-Cycle Measure Review 2017
Project Timeline and Next Steps

Appeals*	July 14 – August 13
Final Report	September 26

*Measure endorsement decisions that are eligible for appeal:
- CSAC endorses a measure that a standing committee recommends for endorsement.
- The CSAC declines to endorse a measure that a standing committee recommends for endorsement

Questions?

NATIONAL QUALITY FORUM

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Memo

TO: Consensus Standards Approval Committee (CSAC)

FR: Karen Johnson, Senior Director and Shaconna Gorham, Senior Project Manager

RE: Eye Care and Ear, Nose and Throat (EENT) Conditions Off-Cycle: Measure Review 2017-Addendum-Member Voting Results

DA: July 11 -12, 2017

The CSAC will review recommendations from the EENT project at its July 11-12, 2017 in-person meeting. This serves as an addendum to the previous memo and contains the updated voting results; the NQF Member voting period closed on July 7, 2017.

NQF MEMBER VOTING RESULTS

The one recommended measure was approved with 100% approval. Representatives of two member organizations voted; no votes were received from Consumer, Health Plan, Health Professional, Public/Community Health Agency, QMRI and Supplier/Industry Councils.

NQF Member Council	Voting Organizations	Eligible to Vote	Rate
Consumer	0	37	0%
Health Plan	0	21	0%
Health Professional	0	104	0%
Provider Organizations	1	110	1%
Public/Community Health Agency	0	15	0%
Purchaser	1	22	5%
QMRI	0	74	0%
Supplier/Industry	0	35	0%
All Councils	2	418	1%

Measure #2811 Acute Otitis Media – Appropriate First-Line Antibiotics

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer				0	
Health Plan				0	
Health Professional				0	
Provider Organizations	1			1	100%
Public/Community Health Agency				0	
Purchaser	1			1	100%
QMRI				0	
Supplier/Industry				0	
All Councils	2	0	0	2	100%
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

Voting Comments:

- University of Texas - MD Anderson Cancer Center: I approve this measure for NQF endorsement.
- Maine Health Management Coalition: I approve this measure for NQF endorsement.