**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Title**: Prevention: Topical Fluoride for Children at Elevated Caries Risk, Dental Services

**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**: 2/11/2014

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| **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 (*incudes 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](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **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.**  **Subcriterion 1a.** **Evidence to Support the Measure Focus**  The measure focus is a health outcome or is evidence-based, demonstrated as follows:   * Health outcome:**[3](#Note3)** a rationale supports the relationship of the health outcome to processes or structures of care. * Intermediate clinical outcome, Process,**[4](#Note4)** or Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence[**5**](#Note5)that the measure focus leads to a desired health outcome. * Patient experience with care: evidence that the measured aspects of care are those valued by patients and for which the patient is the best and/or only source of information OR that patient experience with care is correlated with desired outcomes. * Efficiency:**[6](#Note6)** evidence for the quality component as noted above.   **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.** 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.  **5.** The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **6.** Measures of efficiency combine the concepts of resource use and quality (NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**:

Outcome

☐ Health outcome: Click here to name the health outcome

*Health outcome includes patient-reported outcomes (PRO, i.e., HRQoL/functional status, symptom/burden, experience with care, health-related behaviors)*

☐ Intermediate clinical outcome: Click here to name the intermediate outcome

**X**☐ Process: Receipt of evidence-based preventive service - topical fluoride application - during the reporting period

☐ Structure: Click here to name the structure

☐ Other: Click here to name what is being measured

**HEALTH OUTCOME PERFORMANCE MEASURE**  *If not a health outcome, skip to* [*1a.3*](#Section1a3)

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

Not applicable.

**1a.2.1.** **State the rationale supporting the relationship between the health outcome (or PRO) and at least one healthcare structure, process, intervention, or service**.

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

Not applicable.

**intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measure**

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

Topical Fluoride for Children at Elevated Caries Risk indicates the percentage of children at moderate to high risk for caries who received at least two topical fluoride applications as dental services during the reporting year. Evidence suggests that topical fluoride applied to children starting as early as six months of age is beneficial in preventing dental caries (Weyant et al. 2013). Evidence-based clinical recommendations also suggest that topical fluoride should be applied at least every three to six months in children at elevated risk for caries (Weyant et al. 2013). This measure directly reflects evidence-based guidelines regarding an effective caries prevention measure (professionally applied topical fluoride), including the frequency required for clinical effectiveness (at least every three-six months). As described in 1b1 (Importance), dental caries is the most common chronic disease in children in the U.S. and a significant percentage of children have untreated dental caries. Dental decay causes significant short- and long-term adverse consequences for children’s health and functioning. As detailed below, professionally applied topical fluoride has demonstrated effectiveness in reducing caries among children at elevated caries risk, thereby improving oral health, overall health, and overall well-being.

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

**☐X** Clinical Practice Guideline recommendation – ***complete sections*** [***1a.4***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

☐ US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

**☐** Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

☐ Other – ***complete section*** [***1a.8***](#Section1a8)

*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*):

Full Report: Weyant RJ, Tracy SL, Anselmo TT, Beltrán-Aguilar ED, et al; American Dental Association Council on Scientific Affairs Expert Panel on Topical Fluoride Caries Preventive Agents. Topical fluoride for caries prevention: full report of the updated clinical recommendations and supporting systematic review. Available at: <http://ebd.ada.org/contentdocs/Topical_fluoride_for_caries_prevention_2013_update_-_full_manuscript.pdf>.

Condensed version: Weyant RJ, Tracy SL, Anselmo TT, Beltrán-Aguilar ED, et al; American Dental Association Council on Scientific Affairs Expert Panel on Topical Fluoride Caries Preventive Agents. J Am Dent Assoc. 2013 Nov;144(11):1279-91. Topical fluoride for caries prevention: executive summary of the updated clinical recommendations and supporting systematic review. Available at: <http://ebd.ada.org/contentdocs/JADA_updated_executive_summary_Nov_2013.pdf>.

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

**Summary of Clinical Recommendations:** “For people who are at an elevated risk of developing dental caries, the panel makes clinical recommendations for the use of specific topical fluoride agents; these recommendations are based on the evidence statements and the balance of benefits with potential harm. The panel recommends topical fluoride agents only for people who are at elevated risk of developing dental caries.” (Weyant et al. 2013, full report, 0. 10)

**Age –Specific Recommendations:** “The panel recommends the following for people at risk of developing dental caries: 2.26% fluoride varnish or 1.23% fluoride (APF) gel, or a prescription-strength, home-use 0.5% fluoride gel or paste or 0.09% fluoride mouthrinse for 6 years or older. Only 2.26% fluoride varnish is recommended for children younger than 6 years. The strengths of the recommendations for the recommended products varied from “in favor” to “expert opinion for.” As part of the evidence-based approach to care, these clinical recommendations should be integrated with the practitioner’s professional judgment and the patient’s needs and preferences.” (Weyant et al. 2013, full report, p. 10)

For children at elevated risk of developing caries specifically, the recommendations are “in favor” for:

* “2.26 percent fluoride varnish at least every three to six months” for children younger than 6 years
* “2.26 percent fluoride varnish at least every three to six months OR 1.23 percent fluoride (APF) gel for four minutes at least every three to six months” for children 6-18 years

(Weyant et al., 2013, p. 11, Table 1)

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

**Grade:** The grade for both bulleted items is **“in favor”** which is defined as: “Evidence favors providing this intervention.” This is the second highest recommendation out of a six-point scale. The grading system was adapted from that used by the U.S. Preventive Services Task Force. (Weyant et al. 2013, full report, p. 11, Table 1; p. 20, Table 6)

**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:** Evidence strongly supports providing this intervention.

**In Favor:** Evidence favors providing this intervention.

**Weak:** Evidence suggests implementing this intervention after alternatives have been considered.

**Expert Opinion For:**† Evidence is lacking; the level of certainty is low. Expert opinion guides this recommendation

**Expert Opinion Against:**† Evidence is lacking; the level of certainty is low. Expert opinion suggests not implementing this intervention.

**Against**: Evidence suggests not implementing this intervention or discontinuing ineffective procedures.

† The USPSTF system defines this category of evidence as “insufficient”; “grade I indicates that the evidence is insufficient to determine the relationship between benefits and harms (i.e., net benefit).” The corresponding recommendation grade “I” is defined as follows: “The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.”

Grades definitions can be found at Weyant et al. 2013, full report, p. 20, Table 6. The grading system was adapted from that used by the U.S. Preventive Services Task Force. (U.S. Preventive Services Task Force. Methods and processes. Available at: www.uspreventiveservicestaskforce.org/methods.htm.)

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

Same as that provided for the guidelines provided in 1a.4.1.

**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)?**

☐ **X**Yes **→ *complete section*** [***1a.7***](#Section1a7)

☐No **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

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

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

Not applicable.

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

Not applicable.

**1a.5.3.** **Grade assigned to the quoted recommendation with definition of the grade**: Not applicable.

**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.*)

Not applicable.

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

Not applicable.

***Complete section*** [***1a.7***](#Section1a7)

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

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

Not applicable.

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

Not applicable.

***Complete section*** [***1a.7***](#Section1a7)

**1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE supporting the measure**

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

The following three clinical questions were addressed:

* “In primary and permanent teeth, does the use of a topical fluoride compared to no topical fluoride reduce the incidence of new lesions, or arrest or reverse existing coronal and/or root caries?”
* “For primary and permanent teeth, is one topical fluoride agent more effective than another in reducing the incidence of, or arresting or reversing coronal and/or root caries?”
* “Does the use of prophylaxis before application of topical fluoride reduce the incidence of caries to a greater extent than the application of topical fluoride without prophylaxis?”

(Weyant et al., 2013, full report, pp. 7-8)

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

For children at elevated risk of developing caries specifically, the recommendations are “in favor” for:

* “2.26 percent fluoride varnish at least every three to six months” for children younger than 6 years
* “2.26 percent fluoride varnish at least every three to six months OR 1.23 percent fluoride (APF) gel for four minutes at least every three to six months” for children 6-18 years

(Weyant et al., 2013, p. 11, Table 1)

**Grade:** The evidence grade for both bulleted items is **“moderate”** which is defined as: “This statement is based on preliminary determination from the current best available evidence, but confidence in the estimate is constrained by one or more factors, such as: the number, size, or risk of bias of individual studies; inconsistency of findings across individual studies; limited applicability due to the populations of interest; or lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change could be large enough to alter the conclusion.” (Weyant et al., 2013, full report, pp. 18-19, Table 4)

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

**High**: This statement is strongly established by the best available evidence; the conclusion is unlikely to be affected strongly by the results of future studies. The body of evidence usually includes consistent results from well-designed, well-conducted studies in representative populations. This conclusion is unlikely to be strongly affected by the results of future studies.

**Moderate:** This statement is based on preliminary determination from the current best available

evidence, but confidence in the estimate is constrained by one or more factors, such as: the number, size, or risk of bias of individual studies; inconsistency of findings across individual studies; limited applicability due to the populations of interest; or lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change could be large enough to alter the conclusion.”

**Low**: The available evidence is insuffi cient to support the statement, or the statement is based on

extrapolation from the best available evidence. Evidence is insufficient or the reliability of estimated effects is limited by factors such as: the limited number or size of studies; important flaws in study design or methods leading to high risk of bias; inconsistency of findings across individual studies; gaps in the chain of evidence; findings not applicable to the populations of interest; or a lack of information on important health outcomes. More information could allow a reliable estimation of effects on health outcomes.

(Weyant 2013, full report, pp. 18-19)

The grading system was adapted from that used by the U.S. Preventive Services Task Force (U.S. Preventive Services Task Force. Available at: www.uspreventiveservicestaskforce.org/methods.htm.)

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**: 1965-2012

**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*)

71 studies included in evidence reviews, representing 82 citations. All studies included were controlled clinical trials.

**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*)

The quality of the evidence was rated by the expert panel as “moderate” - i.e., the evidence statements “are based on preliminary determination from the current best available evidence, but confidence in the estimate is constrained by one or more factors, such as: the number, size, or risk of bias of individual studies; inconsistency of findings across individual studies; limited applicability due to the populations of interest; or lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change could be large enough to alter the conclusion.”

However, the clinical recommendations for fluoride among children and adolescents received an evidence grade of “in favor”, which is the second highest out of six grading categories. The expert panel not only made recommendations based on the study designs, but also on an evaluation on the *net benefit* of the interventions, explicitly balancing benefits to potential harms in conjunction with the level of the certainty of the evidence. The full methodology is provided in Weyant et al., full report, 2013.

The evidence directly pertains to both the measure focus and the measure target population.

**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*)

**Recommendations:**

* “2.26 percent fluoride varnish at least every three to six months” for children younger than 6 years
* “2.26 percent fluoride varnish at least every three to six months OR 1.23 percent fluoride (APF) gel for four minutes at least every three to six months” for children 6-18 years

**Estimates of Benefit in Support of Recommendations:**

**(1) 2.26% Fluoride Varnish**

“The results of meta-analyses for primary teeth indicate tha the application of 2.26% fluoride varnish has a statistically significant effect (SMD -0.19 [95% CI: -0.31, -0.08)on caries prevention as measured by increment or incidence using surface-level data.” Weyant et al., full report, 2013, p. 25

“The results of meta-analyses for permanent teeth indicate that 2.26% fluoride varnish has a statistically significant effect (SMD= -0.38 [95% CI: -0.53, -0.24])on caries prevention as measured by increment or incidence using surface-level data.” Weyant et al., full report, 2013, p. 25

Evidence Profile (Weyant et al., full report, 2013, pp. 26-27):

(a) Primary teeth (children under age 6):

* Level of certainty: Moderate
* Benefit: Yes (smaller caries increment or incidence with topical fluoride use).
  + Standardized mean difference=-0.19 [-0.31, -0.08]
  + Prevented fraction=0.27
  + Number needed to treat for control rate of 1 DMFS per year = 4
* Adverse events or harms: Little potential for harms if swallowed
* Benefit-harm assessment (Net benefit rating): Benefits outweigh potential harms
* Strength of clinical recommendation: In favor

(b) Permanent teeth (children):

* Level of certainty: Moderate
* Benefit: Yes (smaller caries increment or incidence with topical fluoride use).
  + Standardized mean difference=-0.38 [-0.53, -0.24]
  + Prevented fraction=0.36
  + Number needed to treat for control rate of 1 DMFS per year = 3
* Adverse events or harms: None if used as manufacturers recommend
* Benefit-harm assessment (Net benefit rating): Benefits outweigh potential harms
* Strength of clinical recommendation: In favor

The table below (Table 8 from the report) summarizes the findings.



**(2) 1.23% fluoride (APF) gel**

“The panel concluded with moderate certainty that there is a benefit of APF gel (1.23% fluoride) application up to every three months for 4G minutes for caries prevention in the permanent teeth of 6-14 year olds. This statement is based on meta-analysis of 12 studies with moderate to high bias scores and including over 4,000 participants; although there was some inconsistency, there was low statistical heterogeneity (I2=43) between the studies.” (Weyant, full report, 2013, p. 33)

**Evidence Profile (Weyant et al., full report, 2013, p. 34):**

Permanent teeth (children):

* Level of certainty: Moderate
* Benefit: Yes (smaller caries increment or incidence with topical fluoride use).
  + Standardized mean difference=-0.25 [-0.33, -0.16]
  + Prevented fraction=0.27
  + Number needed to treat for control rate of 1 DMFS per year = 4
* Adverse events or harms: None if used as manufacturers recommend
* Benefit-harm assessment (Net benefit rating): Benefits outweigh potential harms
* Strength of clinical recommendation: In favor

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

Potential harms evaluated included: (1) nausea and vomiting associated with the ingestion of topical fluorides and (2) dental fluorosis while tooth enamel is developing until approximately age 6, due to daily ingestion of topical fluoride, such as from toothpaste or from prescription home gels.

“There is less of a concern with professionally-applied topical fluorides that have much longer intervals between applications [citing Wong et al. 2010]. Additionally, fluoride varnish has less potential for harms than other forms of high concentration topical fluoride because the amount of fluoride that is placed in the mouth with fluoride varnish is approximately one-tenth that of other professionally-applied products [citing Beltran-Aguilar et al. 2000]. The panel judged that the benefits outweighed the potential for harms for all professionally-applied or prescription-strength topical fluorides and age groups except for children under age 6, where the risk of swallowing and associated events (particularly nausea and vomiting) outweighed the potential benefits for all professionally-applied or prescription-strength topical fluorides except 2.26% fluoride varnish.” (Weyant et al., 20130, p. 10)

Citations

Beltran-Aguilar ED, Goldstein JW, Lockwood SA. Fluoride varnishes - A review of their clinical use, cariostatic mechanism, efficacy and safety. JADA 2000;131(May):589-96.

Weyant RJ, Tracy SL, Anselmo TT, Beltrán-Aguilar ED, et al; American Dental Association Council on Scientific Affairs Expert Panel on Topical Fluoride Caries Preventive Agents. Topical fluoride for caries prevention: full report of the updated clinical recommendations and supporting systematic review. Available at: <http://ebd.ada.org/contentdocs/Topical_fluoride_for_caries_prevention_2013_update_-_full_manuscript.pdf>

Wong MC, Glenny AM, Tsang BW, et al. Topical fluoride as a cause of dental fluorosis in children. Cochrane Database of Systematic Reviews 2010;Jan 20(1).

**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**.

This review was published on November 2013 and reflects the latest evidence.

**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?**

Not applicable.

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

Not applicable.