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

**Measure Title**: Prevention: Dental Sealants for 6-9 Year-Old Children at Elevated Caries Risk

**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**: 2/10/2014

|  |
| --- |
| **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). |

|  |
| --- |
| **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 dental service – sealants on permanent molars - 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.

Sealants for 6-9 Year-Old Children at Elevated Caries Risk indicates the percentage of children at moderate to high risk for caries who received a sealant on a first permanent molar. Evidence-based clinical recommendations recommend that sealants be placed on pits and fissures of children’s primary and permanent teeth when it is determined that the tooth, or the patient, is at risk of experiencing caries, with greater evidence of effectiveness in permanent molars compared to primary molars (Beauchamp et al. 2008). Sealants benefit children across a wide age range; however, for greatest effectiveness in caries prevention, it is recommended that sealants be placed on teeth soon after they erupt (US DHHS 2010; CDC 2013). This measure directly reflects evidence-based guidelines regarding an effective caries prevention measure (sealants) as well as the specific tooth type for which the evidence is the strongest (permanent molar) and the timing of sealant placement to maximize effectiveness (shortly after eruption – 6-9 years of age for permanent first molars). 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, timely placement of sealants on permanent first molars have demonstrated effectiveness in reducing caries among children, 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)

**☐X** 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*):

Beauchamp J, Caufield PW, Crall JJ, Donly K, Feigal R, Gooch B, et al. Evidence-based clinical recommendations for the use of pit-and-fissure sealants: a report of the American Dental Association Council on Scientific Affairs. J Am Dent Assoc 2008;139(3):257-268. Available at: <http://jada.ada.org/content/139/3/257.full>.

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

“Caries Prevention: Sealants should be placed on pits and fissures of **children’s** and **adolescents’** permanent teeth when it is determined that the tooth, or the patient, is at risk of developing caries.” (Beauchamp et al. 2008, p. 263, Table 3)

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

**Grade/Strength of Recommendation: B** which is defined as: “Directly based on category II evidence or extrapolated recommendation for category I evidence.” (Beauchamp 2008, pp. 261, 263, Tables 1, 2, 3)

[See grades for strength of evidence in section 1a7.]

Grading system adapted from: Shekelle PG, Woolf SH, Eccles M, Grimshaw J. Clinical guidelines: developing guidelines. BMJ 1999;318(7183):593-596.

**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.*)

**A**: Directly based on category I evidence

**B**: Directly based on category II evidence or extrapolated recommendation from category I evidence

**C**: Directly based on category III evidence or extrapolated recommendation from category I or II evidence

**D**: Directly based on category IV evidence or extrapolated recommendation from category I, II or III evidence

Grading system adapted from: Shekelle PG, Woolf SH, Eccles M, Grimshaw J. Clinical guidelines: developing guidelines. BMJ 1999;318(7183):593-596.

**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*):

Beauchamp J, Caufield PW, Crall JJ, Donly K, Feigal R, Gooch B, et al. Evidence-based clinical recommendations for the use of pit-and-fissure sealants: a report of the American Dental Association Council on Scientific Affairs. J Am Dent Assoc 2008;139(3):257-268. Available at: <http://jada.ada.org/content/139/3/257.full>.

Ahovuo-Saloranta A, Forss H, Walsh T, Hiiri A, Nordblad A, Mäkelä M, Worthington HV. Sealants for preventing dental decay in the permanent teeth. Cochrane Database Syst Rev. 2013 Mar 28;3:CD001830. doi: 10.1002/14651858.CD001830.pub4.

**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 four clinical questions were addressed:

* “Under what circumstances should sealants be placed to prevent caries?”
* “Does placing sealants over early (noncavitated) lesions prevent progression of the lesions?”
* “Are there conditions that favor the placement of resin-based versus glass ionomer cement sealants in terms of retention or caries prevention?”
* “Are there any techniques that could improve sealants’ retention and effectiveness in caries prevention?”

(Beauchamp et al. 2008, pp. 259-260)

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

“Caries Prevention: Sealants should be placed on pits and fissures of **children’s** and **adolescents’** permanent teeth when it is determined that the tooth, or the patient, is at risk of developing caries.” (Beauchamp et al. 2008, p. 263, Table 3)

**Grade:** The evidence grade is **IA** which is defined as: “Evidence from systematic reviews of randomized controlled trials” (Beauchamp 2008, pp. 261, 263, Tables 1, 3). Grading system adapted from: Shekelle et al. (1999) cited in 1a.4.

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

**Ia:** Evidence from systematic reviews of randomized controlled trials

**Ib:** Evidence from at least one randomized controlled trial

**IIa:** Evidence from at least one controlled study without randomization

**IIb:** Evidence from at least one other type of quasiexperimental study, such as time series analysis or studies in which the unit of analysis is not the individual

**III:** Evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, cohort studies and case-control studies

**IV:** Evidence from expert committee reports or opinions or clinical experience of respected authorities

(Beauchamp et al. 2008, p. 261) Grading system adapted from: Shekelle et al. (1999).

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**: Literature studies for sealants were conducted to identify all systematic reviews through Oct. 4, 2006. To ensure new clinical studies published since the search within each review were included within the guideline development effort, additional searches were conducted for clinical trials until September 2006.

**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*)

7 systematic reviews and 14 individual clinical studies were reviewed with respect to the clinical questions identified. The evidence guidelines do not provide summary data regarding the number of studies by type of study. (Beauchamp 2008, p. 260)

However, the guidelines provide the following details regarding the strength and quality of the evidence related to sealants for caries prevention:

**Evidence Grade Ia (systematic reviews of randomized controlled trials)**

Supports the following evidence statements based on the evidence review by the expert panel:

* “Placement of resin-based sealants on the permanent molars of children and adolescents is effective for caries reduction.” (Beauchamp 2008, p. 260)
* “Reduction of caries incidence in children and adolescents after placement of resin-based sealants ranges from 86 percent at one year to 78.6 percent at two years and 58.6 percent at four years.” (Beauchamp 2008, p. 260)

Studies with evidence grade of Ia cited:

Ahovuo-Saloranta A, Hiiri A, Nordblad A, Worthington H, Mäkelä M. Pit and fissure sealants for preventing dental decay in the permanent teeth of children and adolescents. Cochrane Database Syst Rev 2004(3):CD001830.

Llodra JC, Bravo M, Delgado-Rodriguez M, Baca P, Galvez R. Factors influencing the effectiveness of sealants: a meta-analysis. Community Dent Oral Epidemiol 1993;21(5):261-268.

**Evidence Grade Ib (evidence from at least one randomized controlled trial)**

Supports the following evidence statements based on the evidence review by the expert panel:

* “Sealants are effective in reducing occlusal caries incidence in permanent first molars of children, with caries reductions of 76.3 percent at four years, when sealants were reapplied as needed. Caries reduction was 65 percent at nine years from initial treatment, with no reapplication during the last five years.” (Beauchamp 2008, p. 261)

Studies with evidence grade of Ib cited:

Bravo M, Montero J, Bravo JJ, Baca P, Llodra JC. Sealant and fluoride varnish in caries: a randomized trial. J Dent Res 2005;84(12):1138-1143.

**Evidence Grade III (evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, cohort studies and case control studies)**

Supports the following evidence statements based on the evidence review by the expert panel:

* “There is consistent evidence from private dental insurance and Medicaid databases that placement of sealants on first and second permanent molars in children and adolescents is associated with reductions in the subsequent provision of restorative service.” (Beauchamp 2008, p. 261)
* “Evidence from Medicaid claims data for children who were continuously enrolled for four years indicates that sealed permanent molars are less likely to receive restorative treatment, that the time between receiving sealants and receiving restorative treatment is greater, and that the restorations were less extensive than those in permanent molars that were unsealed.” (Beauchamp 2008, p. 261)

Studies with evidence grade of III cited:

Bhuridej P, Damiano PC, Kuthy RA, et al. Natural history of treatment outcomes of permanent first molars: a study of sealant effectiveness. JADA 2005;136(9):1265-1272.

Dennison JB, Straffon LH, Smith RC. Effectiveness of sealant treatment over five years in an insured population. JADA 2000;131(5):597-605.

Hotuman E, Rølling I, Poulsen S. Fissure sealants in a group of 3-4-year-old children. Int J Paediatr Dent 1998;8(2):159-160.

Weintraub JA, Stearns SC, Rozier RG, Huang CC. Treatment outcomes and costs of dental sealants among children enrolled in Medicaid. Am J Public Health 2001;91(11):1877-1881.

**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 is high, grades of Ia (systematic reviews of randomized controlled trials), for sealants placed on permanent molars of children and adolescents.

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*)

Meta-analyses were not conducted as part of the evidence review. Please see the response in 1a.7.5. regarding the identified benefits and associated strength of evidence. However, a more recent Cochrane Review published in 2013 by Ahovuo-Saloranta et al. brings together all the evidence in a quantitative manner. More information from this review is provided below in Section 1.a.7.9

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

Harms were not evaluated as part of this systematic review. However this question was addressed in a recent Cochrane Review on the effectiveness of sealants (Ahovuo-Saloranta et al. 2013), and it was noted: “Only two studies (Bravo 2005; Liu 2012) assessed side effects of the sealants. No adverse effects were detected or reported by patients included in the studies.”

Citations:

Ahovuo-Saloranta A, Forss H, Walsh T, Hiiri A, Nordblad A, Mäkelä M, Worthington HV. Sealants for preventing dental decay in the permanent teeth. Cochrane Database Syst Rev. 2013 Mar 28;3:CD001830. doi: 10.1002/14651858.CD001830.pub4.

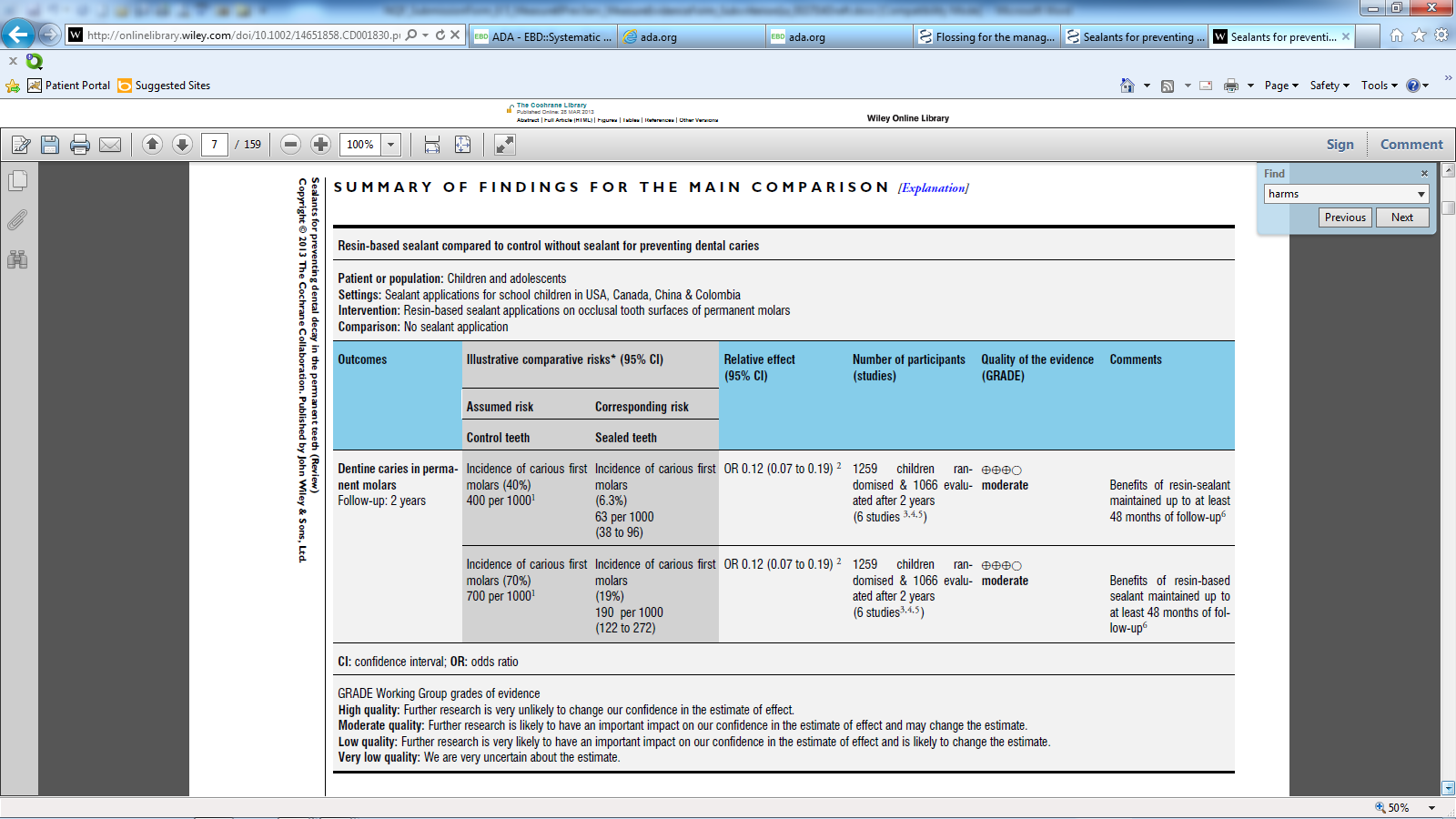
Bravo M, Montero J, Bravo JJ, Baca P, Llodra JC. Sealant and fluoride varnish in caries: a randomized trial. Journal of Dental Research 2005;84(12):1138-43.

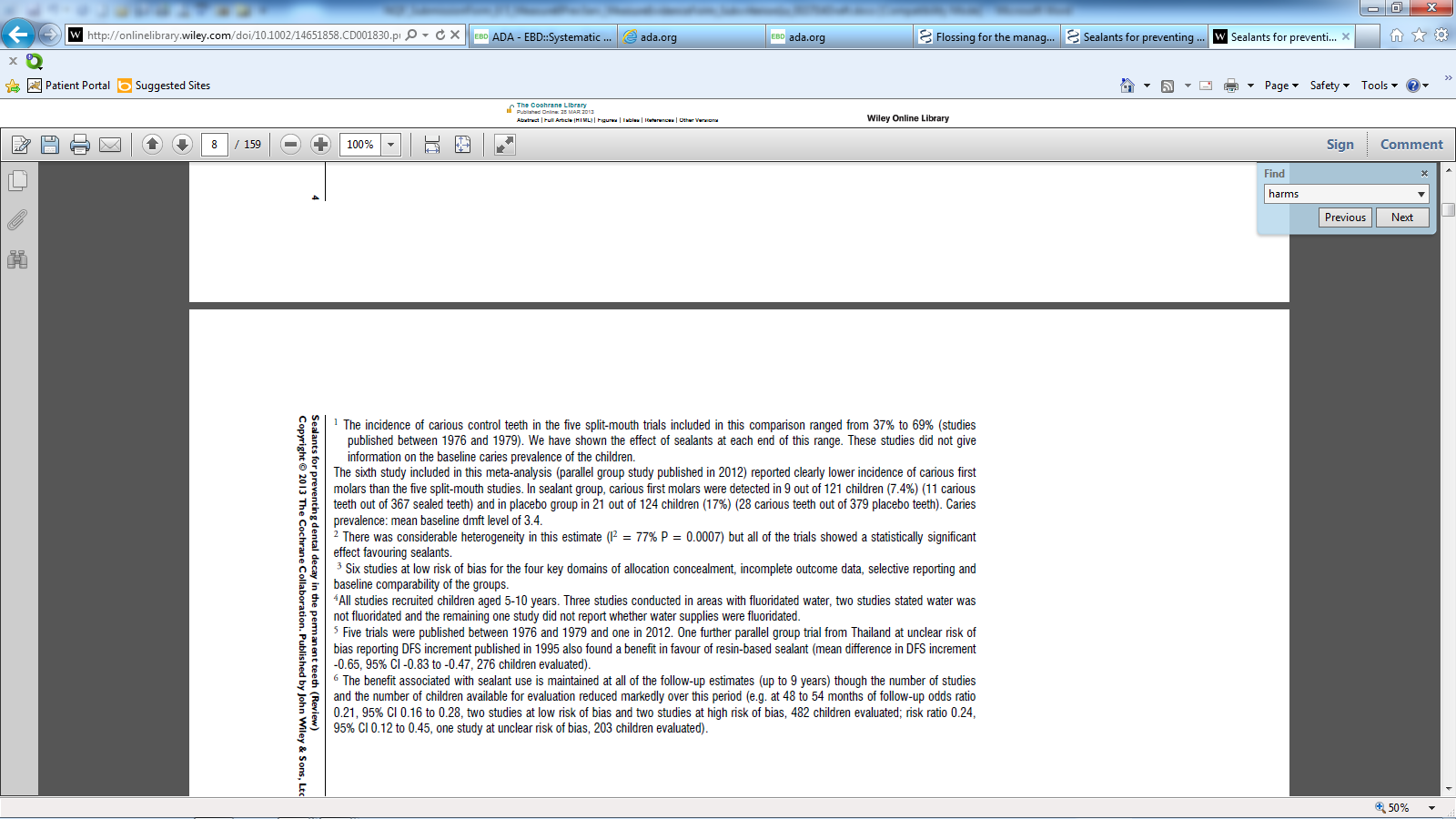
Liu BY, Lo ECM, Chu CH, Lin HC. Randomized trial on fluorides and sealants for fissure caries prevention. Journal of Dental Research 2012;91(8):753-8.

**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**.

A recent Cochrane Review on the effectiveness of sealants brings together all the evidence on this topic. The conclusions of this new review continue to support the recommendations of the ADA Sealant Guideline (Note: the ADA is currently updating this guideline). The summary of findings from the Cochrane review appears below:





Citations

Ahovuo-Saloranta A, Forss H, Walsh T, Hiiri A, Nordblad A, Mäkelä M, Worthington HV. Sealants for preventing dental decay in the permanent teeth. Cochrane Database Syst Rev. 2013 Mar 28;3:CD001830. doi: 10.1002/14651858.CD001830.pub4.

**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.