Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Use of silver diamine fluoride for dental caries management in children and adolescents, including those with special health care needs.

Bibliographic Source(s)

Crystal YO, Marghalani AA, Ureles SD, Wright JT, Sulyanto R, Divaris K, Fontana M, Graham L. Use of silver diamine fluoride for dental caries management in children and adolescents, including those with special health care needs. Pediatr Dent. 2017 Sep-Oct;39(5):E135-E145. [42 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition
YES	Multidisciplinary Group
YES	Methodologist Involvement

	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
	Search Strategy
	Study Selection
	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
	Grading the Quality or Strength of Evidence
	Benefits and Harms of Recommendations
	Evidence Summary Supporting Recommendations
	Rating the Strength of Recommendations
	Specific and Unambiguous Articulation of Recommendations
	External Review
	Updating

Recommendations

Major Recommendations

Definitions for the quality of the evidence (High, Moderate, Low, Very Low) and the strength of recommendations (Strong, Conditional) are provided at the end of the "Major Recommendations" field.

Recommendations

The silver diamine fluoride (SDF) panel supports the use of 38 percent SDF for the arrest of cavitated caries lesions in primary teeth as part of a comprehensive caries management program. (Conditional recommendation, low-quality evidence)

Definitions

Quality of Evidence Grades

Grade	Definition
High	The panel is very confident that the true effect lies close to that of the estimate of the effect.
Moderate	The panel is moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	The panel's confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Grade	Definition
Very Low	The panel has very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

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Implications of Strong and Conditional Recommendations for Different Users of Guidelines

Implications	Strong Recommendation	Conditional Recommendation
For Patients	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
For Clinicians	Most individuals should receive the recommended course of action. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Recognize that different choices will be appropriate for patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may well be useful helping individuals making decisions consistent with their values and preferences. Clinicians should expect to spend more time with patients when working towards a decision.
For Policy Makers	The recommendation can be adapted as policy in most situations including for the use as performance indicators.	Policymaking will require substantial debates and involvement of many stakeholders. Policies are also more likely to vary between regions. Performance indicators would have to focus on the fact that adequate deliberation about the management options has taken place.

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Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Dental caries

Guideline Category

Management

Treatment

Clinical Specialty

Dentistry

Family Practice

Pediatrics

Intended Users

Dentists

Physicians

Guideline Objective(s)

- To inform the clinical practices involving the application of silver diamine fluoride (SDF) to enhance dental caries management outcomes in children and adolescents, including those with special health care needs
- To provide the best available information for practitioners and patients or their representatives to determine the risks, benefits, and alternatives of SDF application as part of a caries management program

Target Population

Children and adolescents, including those with special health care needs

Interventions and Practices Considered

Silver diamine fluoride (SDF)

Note: SDF in this guideline's recommendation refers to 38 percent SDF, the only formula available in the United States.

Major Outcomes Considered

- Incidence of dental caries in the primary dentition
- Adverse effects

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Search Strategy

Literature searches were used to identify systematic reviews that would serve as the basis of the guideline. Secondly, the results of the searches served as sources of evidence or information on issues related to, but outside the context of, the Population, Intervention, Control, and Outcome (PICO), such as cost, adverse effects, and patient preferences.

Literature searches were conducted in PubMed®/MEDLINE, EMBASE®, Cochrane Central Register of Controlled Trials, gray literature, and trial databases to identify systematic reviews and randomized controlled trials of silver diamine fluoride (SDF). Search results were reviewed in duplicate at both the title and abstract and the full-text level when warranted. Disagreements were resolved by consensus; if agreement could not be reached, the American Academy of Pediatric Dentistry (AAPD) Evidence-Based

Dentistry Committee (EBDC) overseeing the workgroup was consulted to settle the question. A detailed description of the search strategies is presented in Appendix I in the original guideline document.

Inclusion and Exclusion Criteria

The criteria used to identify publications for use in the guideline were determined by the clinical PICO question. See Appendix I in the original guideline document for search strategies. Publications which addressed the use of SDF to arrest caries lesions in primary teeth, regardless of language, merited full-text review; in vitro studies and studies of the use of SDF outside of the guideline's stated outcomes were excluded. No new randomized controlled trials were identified that warranted updating the meta-analysis found in the systematic review selected as the basis for this guideline.

Refer to the systematic review for additional information about the search strategy and selection of clinical studies (see the "Availability of Companion Documents" field).

Number of Source Documents

8 publications were included for meta-analysis.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence Grades

Grade	Definition
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Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Assessment of the Evidence

The main strength of this guideline is that it is based on a systematic review of prospective randomized and controlled trials of silver diamine fluoride (SDF). Evidence was assessed via the Grading of

Recommendations Assessment, Development and Evaluation (GRADE) approach, a widely adopted and peer reviewed system of evaluating study quality (see the "Rating Scheme for the Strength of the Evidence" field). The guideline recommendation is based on the meta-analysis of four controlled trials (three randomized), extracted in duplicate, from a systematic review of SDF. Randomized (RCTs) and controlled clinical trials (CCTs) offer the highest level of clinical evidence; therefore, a recommendation based on a systematic review and meta-analysis of graded RCTs/CCTs provides more reliable and accurate conclusions that can be applied towards patient care.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Workgroup

In December 2016, the American Academy of Pediatric Dentistry's (AAPD's) Board of Trustees approved a panel nominated by the Evidence-Based Dentistry Committee (EBDC) to develop a new evidence-based clinical practice guideline on silver diamine fluoride (SDF). The panel consisted of general and pediatric dentists in public and private practice involved in research and education; the stakeholders consisted of representatives from general dentistry, dental hygiene, governmental and non-governmental agencies, and international and specialty dental organizations.

Clinical Questions Addressed

The panel members used the Population, Intervention, Control, and Outcome (PICO) formulation to develop the clinical questions that will aid practitioners in the use of SDF in primary teeth with caries lesions. *Does the application of SDF arrest cavitated caries lesions as effectively as other treatment modalities in primary teeth?*

Formulation of the Recommendations

The panel formulated this guideline collectively via surveys, teleconferences, and electronic communications from January 2017–August 2017. The panel used the evidence-to-decision framework in an iterative manner to formulate the recommendations. Specifically, the main methods used were discussion, debate, and consensus seeking. To reach consensus, the panel voted anonymously on all contentious issues and on the final recommendation. Grading of Recommendations Assessment, Development, and Evaluation (GRADE) was used to determine the strength of the evidence.

Understanding the Recommendations

Grading of Recommendations Assessment, Development, and Evaluation (GRADE) rates the strength of a recommendation as either strong or conditional (refer to the "Rating Scheme for the Strength of the Recommendations" field). A strong recommendation "is one for which guideline panel is confident that the desirable effects of an intervention outweigh its undesirable effects (strong recommendation for an intervention) or that the undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention)." A strong recommendation implies most patients would benefit from the suggested course of action (i.e., either for or against the intervention). A conditional recommendation "is one for which the desirable effects probably outweigh the undesirable effects (conditional recommendation for an intervention) or undesirable effects probably outweigh the desirable effects (conditional recommendation against an intervention), but appreciable uncertainty exists." A conditional recommendation implies that not all patients would benefit from the intervention. The individual patient's circumstances, preferences, and values need to be assessed more than usual. Practitioners need to allocate more time for consultation along with explanation of the potential benefits and harms to the patients and their caregivers when recommendations are rated as conditional. Practitioners' expertise and judgment as well as patients' and their caregivers' needs and preferences

establish the suitability of the recommendation to individual patients. The strength of a recommendation presents different implications for patients, clinicians, and policy makers.

Rating Scheme for the Strength of the Recommendations

Implications of Strong and Conditional Recommendations for Different Users of Guidelines

Implications	Strong Recommendation	Conditional Recommendation
For Patients	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
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Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Stakeholders and External Review

This guideline was reviewed by external and internal stakeholders continuously from the beginning of the process until the formulation of the guideline. Stakeholders were invited to take part in anonymous surveys to determine the scope and outcomes of the guideline, bringing in points of view from different geographical regions, dental specialties, and patient advocates. Comments also were sought on the draft of the guideline. All stakeholder comments were taken into consideration, addressed, and acted upon as appropriate per group deliberation. Additional feedback from stakeholders is expected after publication and dissemination of the guideline.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The guideline is based on analysis of data included in a recent systematic review and meta-analysis.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

With caries lesion arrest rates upwards of 70 percent (i.e., higher than other comparable interventions), silver diamine fluoride (SDF) presents as an advantageous modality. Besides its efficacy, SDF is favored by its less invasive (clinically and in terms of behavior guidance requirements) nature and its inexpensiveness.

Potential Harms

Adverse Reactions

No severe pulpal damage or reaction to SDF has been reported. However, SDF should not be placed on exposed pulps. Teeth with deep caries lesions should be closely monitored clinically and radiographically. Serum concentration of fluoride following SDF application per manufacturer recommendations posed little toxicity risk and was below EPA oral reference dose in adults.

The following adverse effects have been noted in the literature:

Metallic/bitter taste.
Temporary staining to skin which resolves in 2 to 14 days.
Mucosal irritation/lesions resulting from inadvertent contact with SDF, resolved within 48 hours.

Refer to "Potential Adverse Effects" in the original guideline document for additional information.

Contraindications

Contraindications

Silver diamine fluoride should not be used in patients with an allergy to silver compounds.

Qualifying Statements

Qualifying Statements

- These recommended practices are based upon the best available evidence to-date. However, the ultimate decisions regarding disease management and specific treatment modalities are to be made by the dental professional and the patient or his/her representative, acknowledging individuals' differences in disease propensity, lifestyle, and environment.
- This guideline is limited by the small number of randomized controlled trials (RCTs) evaluating silver diamine fluoride (SDF), the heterogeneity of the included trials, and selection bias that may have been introduced by possibly poor sequence generation and selective reporting by one study. Weaknesses of this guideline are inherent to the limitations found in the systematic review upon

which this guideline is based. Major limitations of the supporting literature include lack of calibration and/or evidence of agreement for examiners assessing clinical outcomes and unclear definitions or inconsistent criteria for caries lesion activity. Arguably, without a valid and reliable method to determine lesion activity at baseline and follow-up, misclassification bias is possible, especially because clinicians cannot be blinded with regard to SDF application (due to the dark staining). The absence of rigorous caries detection and activity measurement criteria in the reviewed literature can decrease the validity of the reported results. Other reviewers of the systematic review noted similar and additional limitations.

Implementation of the Guideline

Description of Implementation Strategy

This guideline will be published in the American Academy of Pediatric Dentistry's (AAPD's) Reference Manual and the journal *Pediatric Dentistry*. Social media, news items, and presentations will be used to notify AAPD members about the new guideline.

This guideline will be available as an open access publication on the AAPD's Web site. Patient education materials are being developed and will be offered in the AAPD's online bookstore. See Appendix II in the original guideline document for practical silver diamine fluoride (SDF) guidance and the Resource Section of the AAPD Reference Manual for a SDF chairside guide (see the "Availability of Companion Documents" field).

Implementation Tools

Patient Resources

Pocket Guide/Reference Cards

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Crystal YO, Marghalani AA, Ureles SD, Wright JT, Sulyanto R, Divaris K, Fontana M, Graham L. Use of silver diamine fluoride for dental caries management in children and adolescents, including those with special health care needs. Pediatr Dent. 2017 Sep-Oct;39(5):E135-E145. [42 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Sep-Oct

Guideline Developer(s)

American Academy of Pediatric Dentistry - Professional Association

Source(s) of Funding

The preparation of this guideline was funded by the American Academy of Pediatric Dentistry, a dental specialty organization with over 10,000 members.

Guideline Committee

Silver Diamine Fluoride (SDF) Workgroup

Composition of Group That Authored the Guideline

Workgroup Members: Yasmi O. Crystal, DMD, MSc, FAAPD (*Workgroup Chair*), clinical associate professor of pediatric dentistry, NYU College of Dentistry, New York, N.Y., USA, and pediatric dentist in private practice, New Jersey and New York City, N.Y., USA; Abdullah A. Marghalani, BDS, MSD, DrPH, pediatric dental fellow, Division of Pediatric Dentistry, University of Maryland Dental School, Baltimore, Md., USA; Steven D. Ureles, DMD, MS, instructor in developmental biology, Harvard School of Dental Medicine/Boston Children's Hospital, Boston, Mass., USA, pediatric dentist in private practice, New London County, Conn., clinical assistant professor, Department of Pediatric Dentistry, University of Connecticut School of Dental Medicine, Farmington, Conn., and MSc graduate student, Postgraduate Programme in Evidenced-Based Health Care Studies, Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK; John Timothy Wright, DMD, MS, Bawden Distinguished Professor, Department of Pediatric Dentistry School of Dentistry, University of North Carolina-Chapel Hill, Chapel Hill, N.C.; Rosalyn Sulyanto, DMD, MS, instructor, Developmental Biology, Harvard School of Dental Medicine and Boston Children's Hospital, Boston, Mass., USA; Kimon Divaris, DDS, PhD, associate professor, Departments of Pediatric Dentistry, UNC School of Dentistry and Epidemiology, Gillings School of Global Public Health, University of North Carolina-Chapel Hill, Chapel Hill, N.C., USA; Margherita Fontana, DDS, PhD, professor, Department of Cardiology, Restorative Sciences, and Endodontics, University of Michigan School of Dentistry, Ann Arbor, Mich., USA; Laurel Graham, MLS, senior evidence-based dentistry manager, American Academy of Pediatric Dentistry, Chicago, Ill., USA

Financial Disclosures/Conflicts of Interest

Declaration of Interest

Dr. Crystal is a member of the American Academy of Pediatric Dentistry (AAPD) Editorial Board. Dr. Divaris is a member of the AAPD Editorial Board. Dr. Marghalani is an ad hoc reviewer for *Pediatric Dentistry*. Dr. Sulyanto is an ad hoc reviewer for *Pediatric Dentistry*. Dr. Wright is a member of the AAPD Editorial Board. No other conflicts of interested were reported.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the American Academy of Pediatric Dentistry (AAPD) Web site .

Availability of Companion Documents

The following are available:

Gao SS, Zhao IS, Hiraishi N, Duangthip D, Mei ML, Lo ECM, Chu CH. Clinical trials of silver diamine fluoride in arresting caries among children: a systematic review. International JDR Clin Translat Res. 2016:1(3):201-10. Available from the JDR Clinical and Translational Research Web site .

Chairside guide: silver diamine fluoride in the management of dental caries lesions. Chicago (IL): American Dental Association; 2017. 2 p. Available from the American Academy of Pediatric Dentistry (AAPD) Web site .

See Appendix II in the original guideline document for practical silver diamine fluoride guidance.

Patient Resources

Pamphlets for patients are available from the American Academy of Pediatric Dentistry (AAPD) store .

NGC Status

This NGC summary was completed by ECRI Institute on March 6, 2018. The information was verified by the guideline developer on April 16, 2018.

This NEATS assessment was completed by ECRI Institute on January 10, 2018. The information was verified by the guideline developer on April 16, 2018.

Copyright Statement

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