

SDF and Beyond: Patient-Centered Brush-On Therapies for Caries Management

CareQuest Institute Continuing Education Webinar

December 8, 2022

Housekeeping

- We will keep all lines muted to avoid background noise.
- We will send a copy of the slides and a link to the recording via email after the live program.
- We'll also make the slides and recording available on carequest.org.

To receive CE Credits:

- Look for the evaluation form, which we'll send via email within 24 hours.
- Complete the evaluation by **Friday, December 16**.
- Eligible participants will receive a certificate soon after via email.

We appreciate your feedback to help us improve future programs!



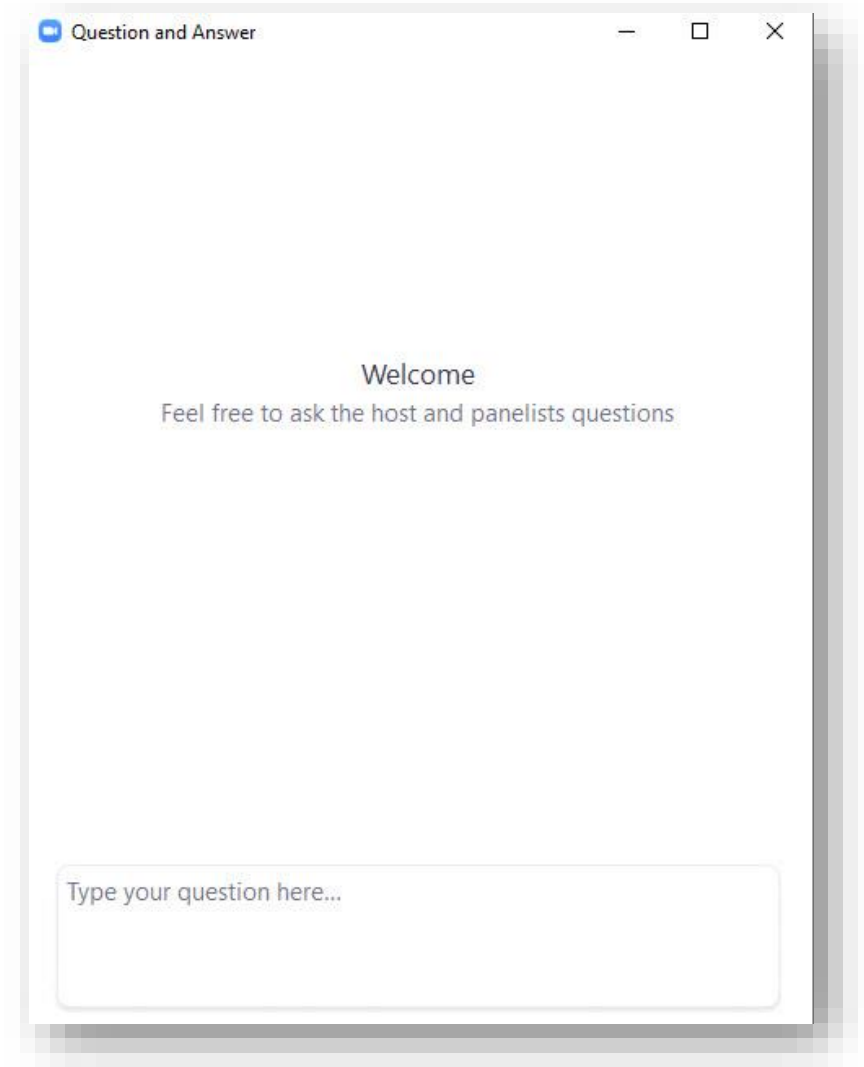
The CareQuest Institute for Oral Health is an ADA CER-P Recognized Provider. This presentation has been planned and implemented in accordance with the standards of the ADA CER-P.

*Full disclosures available upon request



Question & Answer Logistics

- Feel free to enter your questions into the **Question & Answer box** throughout the presentations.
- We will turn to your questions and comments toward the end of the hour.



Learning Objectives

At the end of this webinar, you'll be able to:

- Explain how silver diamine fluoride, povidone iodine, and peptide-guided enamel regeneration are effective for caries management.
- Select appropriate brush-on caries management therapies, including silver diamine fluoride, povidone iodine, and peptide-guided enamel regeneration based on patient characteristics.
- Review the clinical evidence supporting minimally invasive techniques for caries management.
- Demonstrate application techniques for minimally invasive dentistry interventions.

Our Strategy

Vision

A future where every person can reach their full potential through optimal health

Mission

To improve the oral health of all

Purpose

To catalyze the future of health through oral health



SDF and Beyond: Patient-Centered Brush-On Therapies for Caries Management



WEBINAR | Thursday, December 8, 2022 | 7–8 p.m. ET | ADA CERP Credits: 1

MODERATOR & PRESENTER



Laura Skaret, BS, RDH
Manager, Clinical Innovation,
CareQuest Innovation Partners

PRESENTER



Jeremy Horst Keeper, DDS, PhD
Director, Clinical Innovation,
CareQuest Innovation Partners

PRESENTER



Peter Milgrom, DDS
Emeritus Professor of Oral Health
Sciences, University of Washington

Disclosures

- CareQuest Innovation Partners has financial and/or investment relationships with companies that market a noninvasive caries therapy, a brush-on caries diagnostic, an intraoral camera, a teledentistry platform, portable geriatric dentistry, and possibly other relevant products by the time of this talk, in support of its mission to improve oral health for all.
- This material is presented for dental professionals or health care professionals with oral health training and is not intended to educate or train professionals on how to diagnose conditions or disease states.
- Dr. Milgrom is a principal in Dental Silver Arrest LLC, a small business firm created to develop, research, and gain FDA approval for new preventive agents.
- This presentation will include discussion of the off-label use of FDA cleared medical devices or approved drugs.

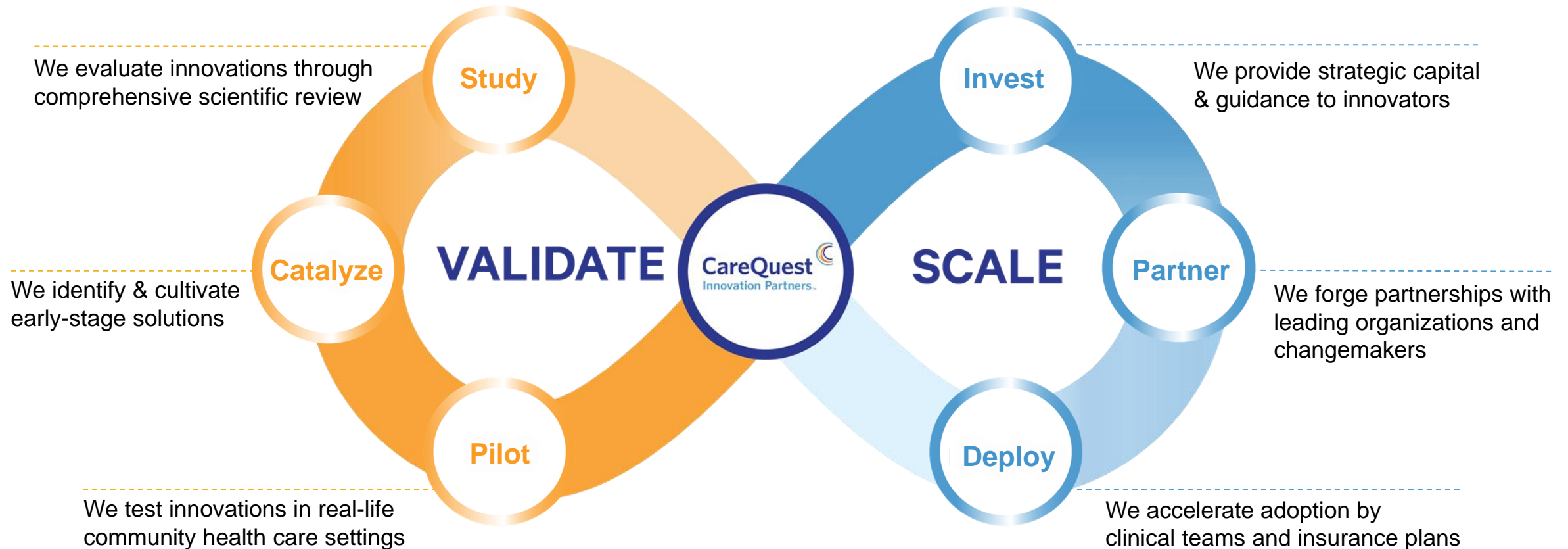
Joined by a Shared Mission



Improve
the oral
health
of all



We **Validate** and **Scale** Innovations to Improve Oral Health for All



Non-Invasive Caries Therapies Empower Improved Health Outcomes

Access

- Can be done in mobile/portable settings
- Can be performed by non-dentist providers

Costs

- Convert 1/2 of 1-3 surface fillings to MIC
- Prevents expensive procedures
- Saves >\$3,000 in the lifetime of a tooth

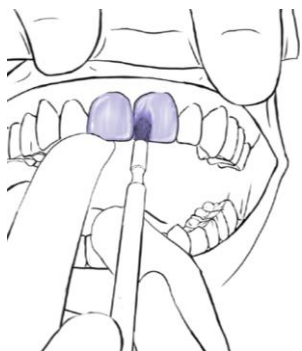
Experience

- No needles, no drills
- Brush on liquids
- Simple & quick, during re-care visits

Disease Management

- Addresses & reverses disease
- Better overall health from better oral health

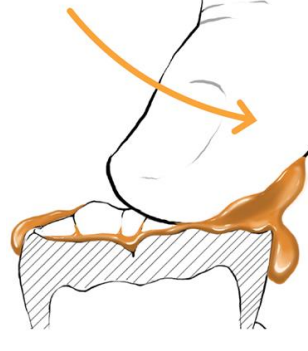
Varnish



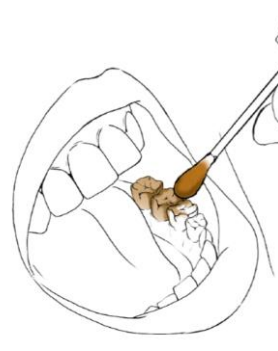
SDF



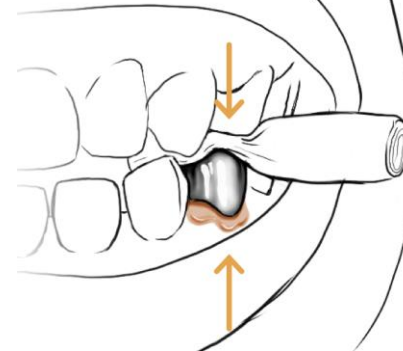
GIC



Iodine



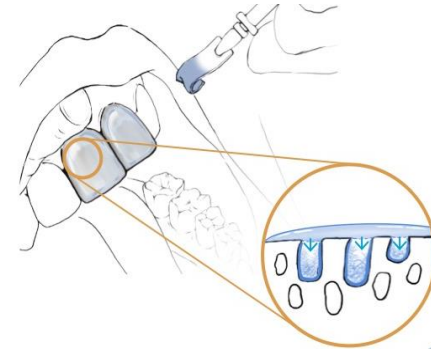
Hall



SMART



P₁₁-4



Healing Tooth Decay with Brush-On Therapies

Silver Diamine Fluoride

Peter Milgrom, DDS

University of Washington

How Do You Use It? — Patient Protection



Application process for caries arrest, CDT code D1354, per tooth/repeat every 6 months to maximize benefit



Remove debris with microbrush



Brush on a coat of SDF with a microbrush



Wait or use curing light



Arrested lesion

SDF: What Is It? And What Does it Do?

25% Silver: Antimicrobial

5% Fluoride: Remin

8% Ammonia: Stabilization

Remainder: Medical Grade
Water

Cover with fluoride varnish
to improve the taste.

- ✓ Universal acceptance by Schools of Dentistry
- ✓ Used by most pediatric dentists



SDF Gel Now Available in the US

- More viscous
- Easier to protect adjacent teeth
- Easier with moving targets
- Root surfaces, near sulcus



Accepted CPT Code Allows Billing by Medical Clinics — 2023

X115T Application of silver diamine fluoride, 38%, by a physician or other qualified health care professional



Safety

Millions of doses without a single report of adverse events

No adverse events related to SDF in U Michigan Phase 3 trial conducted under FDA supervision including 24-48 h recall

Michigan study used one or two ampules/visit

Pharmacokinetics studies under FDA supervision show that after treatment fluoride levels remain at baseline, silver levels rise for up to 2 weeks but then return to normal

Levels of safety are greater than 500X

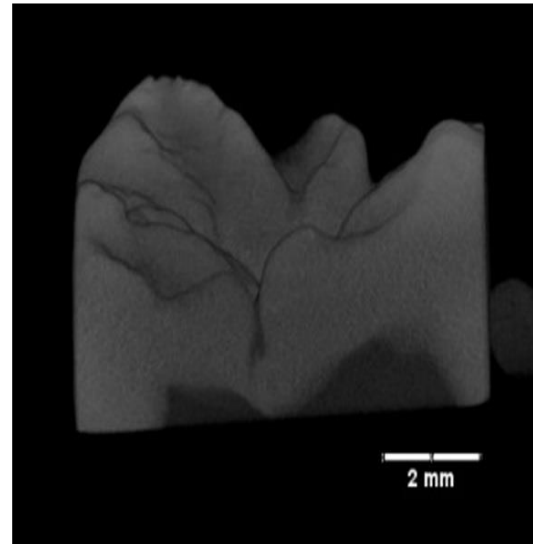


Prevention CDT D1355

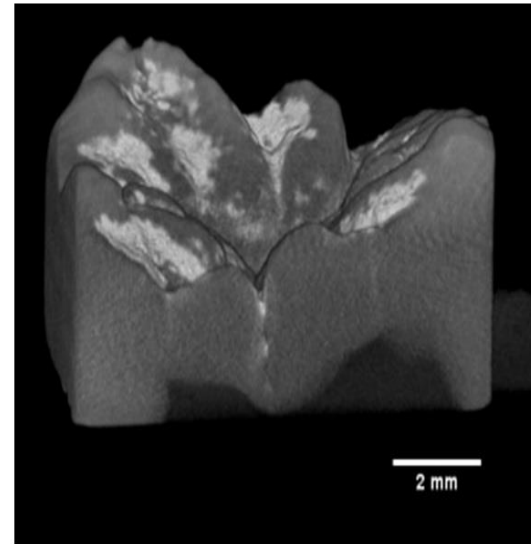
Occlusal surface treated with 38% SDF as an alternative to sealants (no stain). Cost effective.

Especially Effective in Erupting Teeth

3-D CT-Scan Shows Silver Sealing the Fissures



Before SDF application (cross section)



After SDF application (cross section)

Clarification on D1355 Billing

No Evidence of Abuse of these Codes

D1355 is site-specific preventive treatment

Not intended to replace fluoride varnish whole mouth treatment—D1206 – appropriate after site specific SDF treatment

D1355 can be billed in conjunction with D1354

The Big Picture

Application of SDF Is Standard of Care

- ADA Chairside Guidance
- AAPD Clinical Guideline
- WHO Essential Medicine

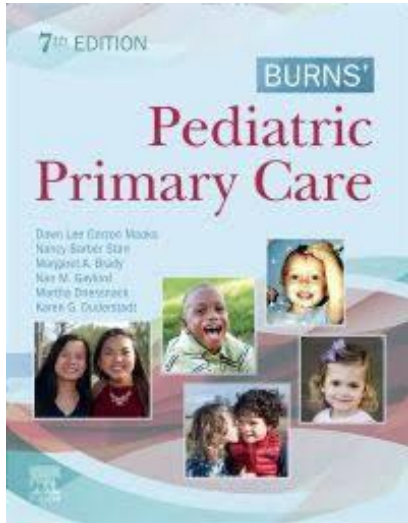
Impact

- Relieves pain and hypersensitivity
- Eliminates toothaches in children waiting for restorative treatment
- Increases time to when restorative treatment is needed

The Road Ahead with FDA

- Completion of required studies Spring 2023
- Conference with FDA
- New Drug Application Summer 2023
- Approval late 2023

The Big Picture



Implications of FDA Approval

Proper labeling

Focus on professional ads and education

Direct-to-consumer ads

Physician prescription

World-wide acceptance

- ✓ Grow acceptance in general practice
- ✓ Train physicians, NPs, PAs, RNs
- ✓ Grow adoption in medical practice





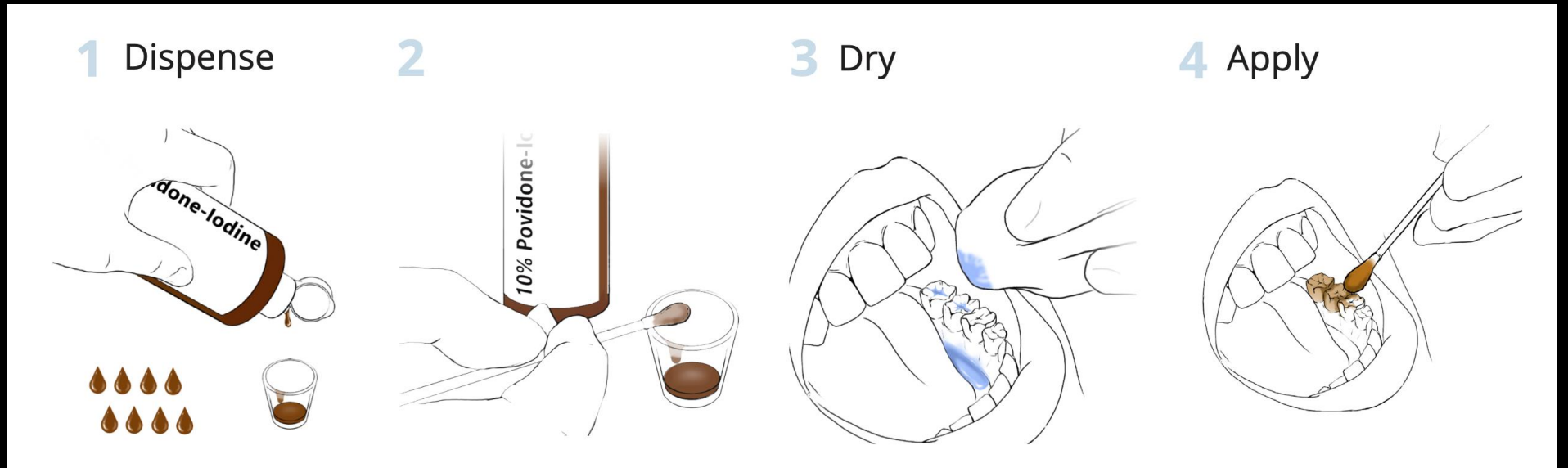
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Emeritus Professor of Oral Health Sciences,
University of Washington
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10% Povidone-Iodine for Caries Prevention

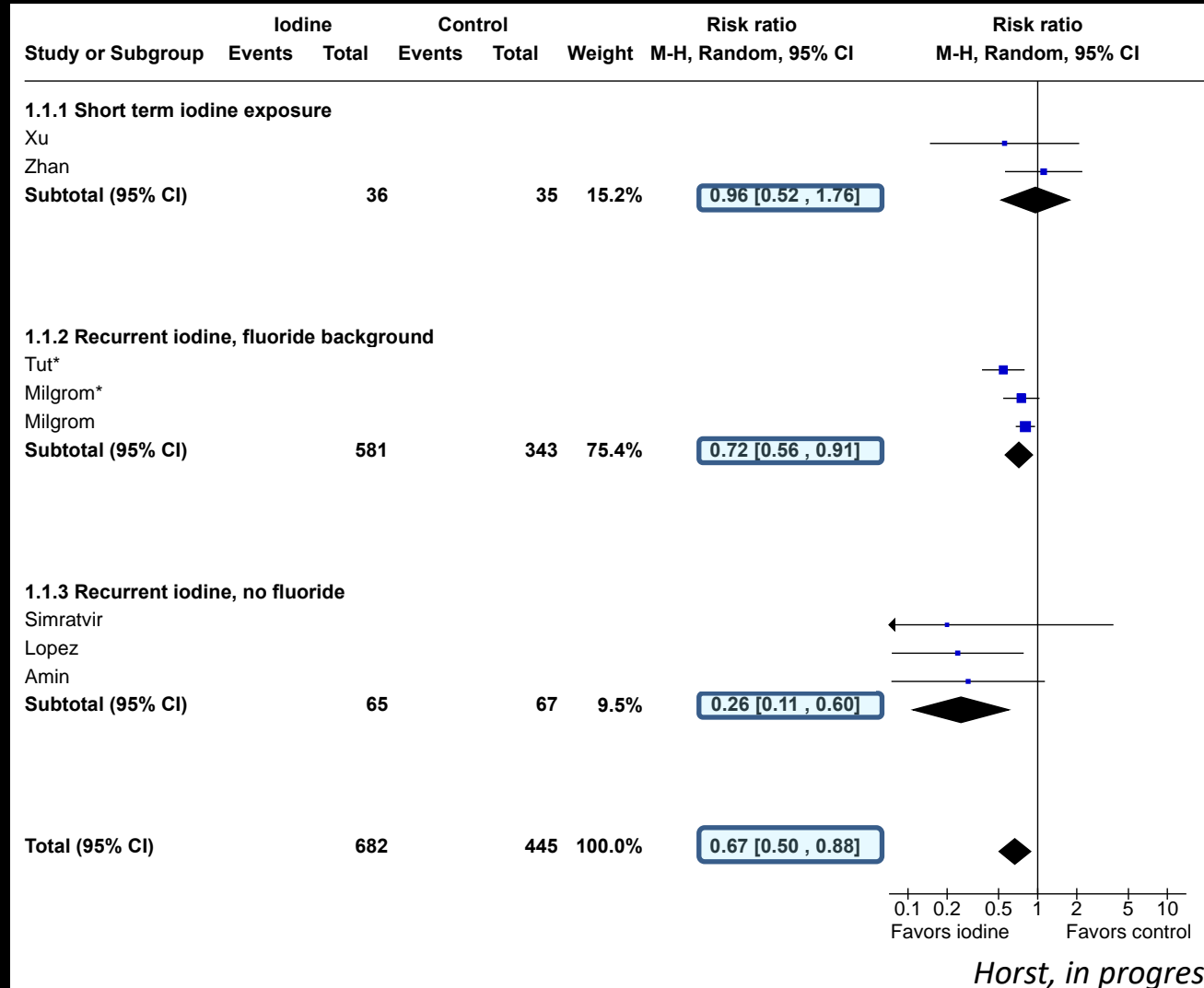
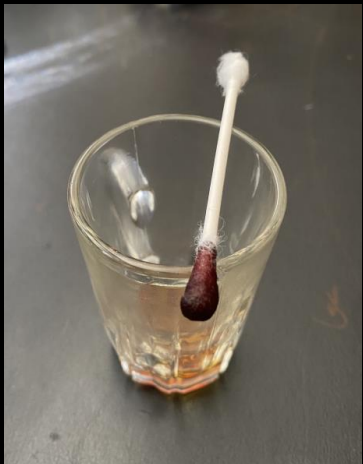
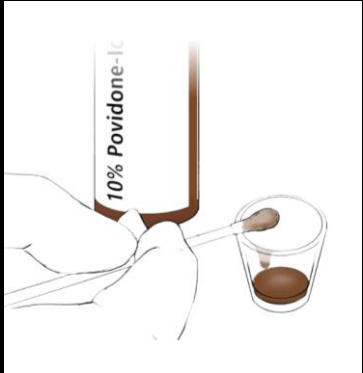
Jeremy Horst Keeper, DDS, PhD
Director, Clinical Innovation,
CareQuest Innovation Partners

10% Povidone Iodine

an *antiseptic* that prevents the bacterial manifestation of the most common disease of childhood



Iodine works, application needs to continue ~quarterly, and is not dependent on fluoride.



Application needs to persist.

Works with Fluoride.

Stronger effect in younger children, - without F ??

HOW TO

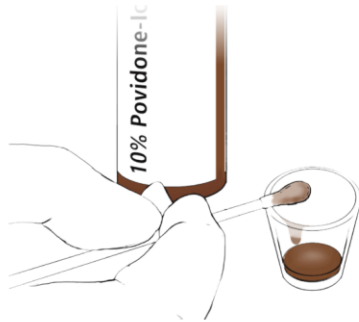
apply Povidone Iodine for caries prevention.

1 Dispense



Dispense 8 drops of 10% povidone-iodine.

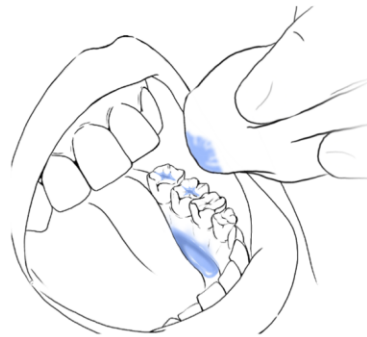
2



Saturate one end of a cotton swab.

Note: To avoid too much iodine, do not re-dip after applying to teeth.

3 Dry



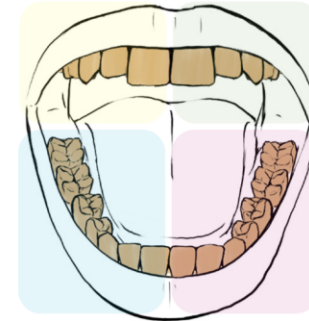
Ask the patient to swallow. Use cotton or suction to remove excess saliva.

4 Apply



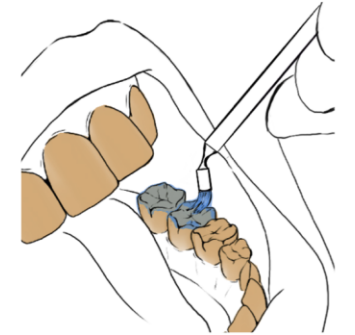
Roll the swab and push to release more iodine into high risk areas, like contact points and exposed roots.

5



Continue across all teeth. Keep mouth open for 10 seconds.

6 Optional fluoride varnish



Fluoride varnish may be applied.

Wait 30 minutes to eat or drink.

Which CDT Code Should I Use?

D1355 – Caries preventive medicament application - per tooth.

D9630 – Drugs or medicaments dispensed in the office for home use.

D1999 – Unspecified preventive procedure – by report.

D4381 - Localized delivery of antimicrobial agents via a controlled release vehicle into diseased crevicular tissue, per tooth.

D1355 ADA Guide – Version 1a – October 15, 2020 – Page 1 of 3
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D1355 – ADA Guide to Reporting Caries Preventive Medicament Application

2. Is there a specific medicament applicable to this procedure?

No –D1355's CDT Code entry describes a discrete procedure for application of a "caries preventive medicament" excluding only topical fluorides. Examples of topical fluorides are foams, gels, rinses and varnish. Medicaments that would be applied during the delivery of the D1355 procedure include Silver Diamine Fluoride (SDF), Silver Nitrate (SN), thymol-CHX varnish, and topical povidone iodine (PVP-I). The

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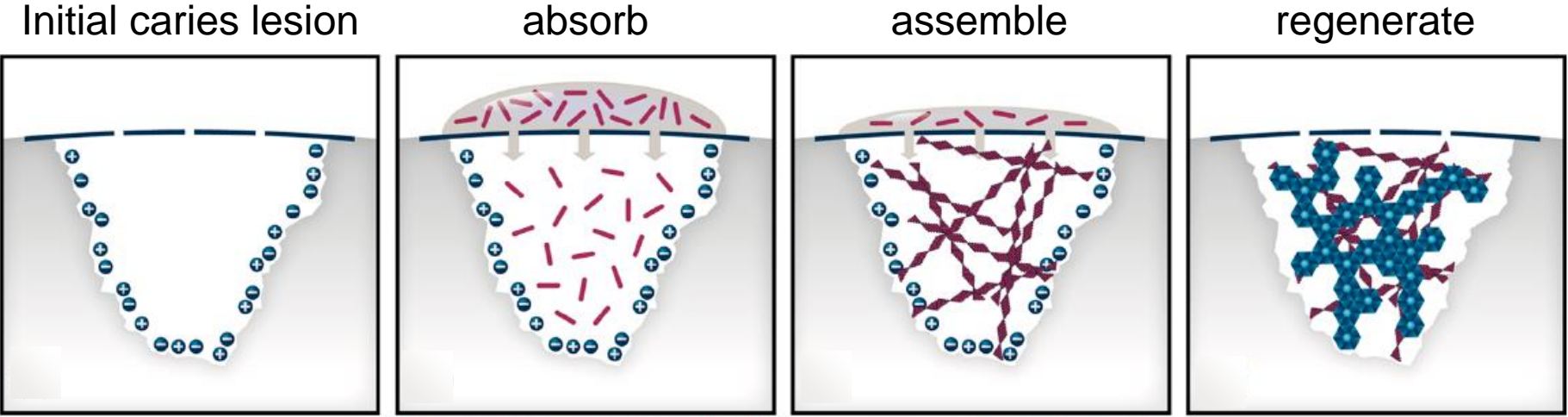
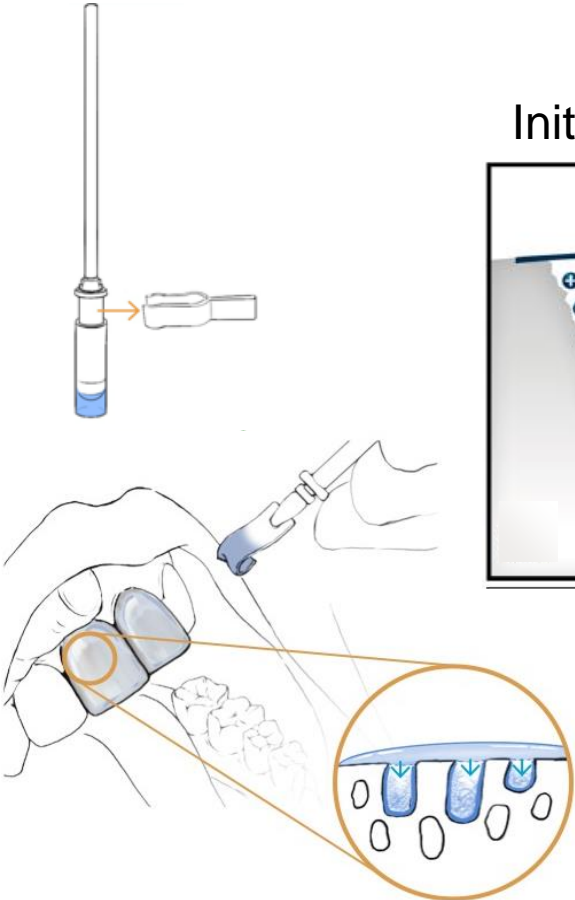
Jeremy Horst Keeper, DDS, PhD
Director, Clinical Innovation
CareQuest Innovation Partners

To connect with Dr. Keeper, visit
<http://carequestinnovation.com/connect>

Self-Assembling Peptide P₁₁-4 with Fluoride

Laura Skaret, BS, RDH
Manager, Clinical Innovation,
CareQuest Innovation Partners

SAP P₁₁-4 Guided Enamel Regeneration

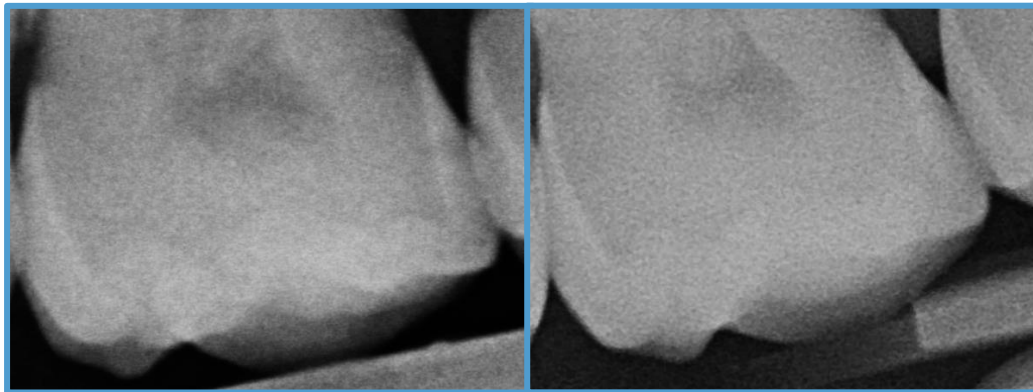


Alkilzy et al., *A Dent Res* 2018

Successful SAP P₁₁-4 Cases

Before

After

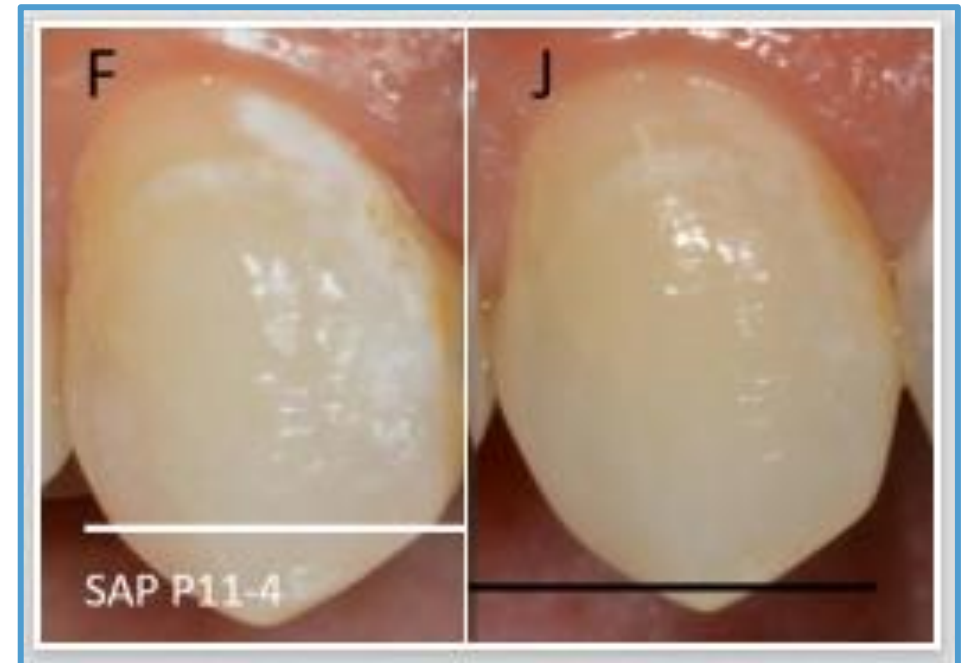


7.5 years after SAP P₁₁-4 treatment,
the lesion is smaller (c/o C. Bommer)

No stain
No taste
Single application

Before

After



9 months after SAP P₁₁-4 treatment, the
lesion is arrested (Sedlakova Kondelova et al., 2020)

Safety and Regulation

FDA National Drug Code (NDC) Directory

Added to the January 2019

GRASE: Generally Regarded As Safe and Effective

Approved under 21CFR355

Anticaries Drug Products for OTC Human Use
a.k.a. “the fluoride monograph.”

ISO 10993. Biological evaluation of medical devices

- 1: Evaluation and testing within a risk management process
- 3: Tests for genotoxicity, carcinogenicity and (reproductive) toxicity
- 4: Selection of tests for interactions with blood
- 5: Tests for in vitro cytotoxicity.
- 6: Tests for local effects after implantation
- 9: Framework for identification and quantification of potential degradation products
- 10: Tests for irritation and skin sensitization
- 11: Tests for systemic toxicity
- 18: Chemical characterization of medical device materials within a risk management process
- 19: Physico-chemical, morphological and topographical characterization of materials
- 20: Principles and methods for immunotoxicology testing of medical devices
- 23: Tests for irritation



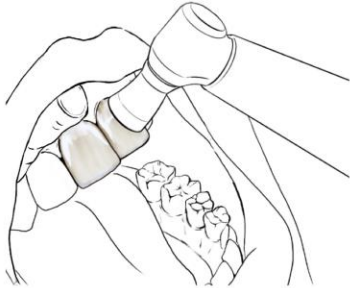
HOW TO

apply P₁₁₋₄
to initial caries lesions (non-cavitated).

This protocol is different than
manufacturer's instructions

Clean

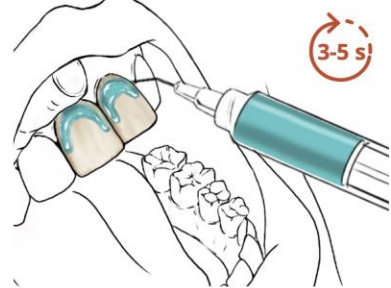
1



Clean the teeth with pumice. Rinse or wipe clean. Isolate with cotton.

Ensure lesion porosity

2

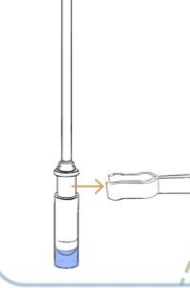


If the lesion is not already porous, etch the white spot lesion(s) for 3-5 seconds. Rinse thoroughly.

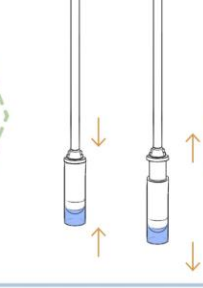
No decay is removed.

Activate

3



4



Plunge together and pull apart

5



IMPORTANT: Mix the active ingredient on the sponge applicator together with the liquid at the bottom.

Dry

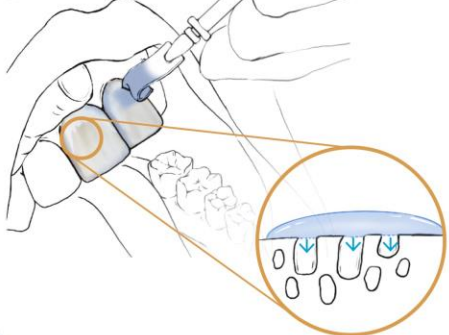
6



Thoroughly dry the affected areas (desiccate).

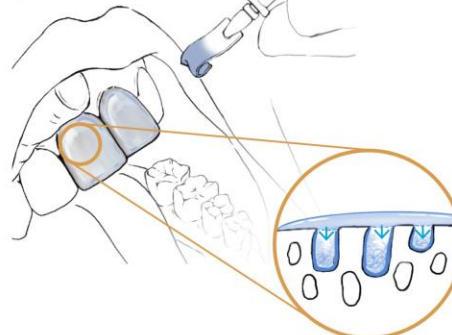
Apply

7



Reapply until saturated

9

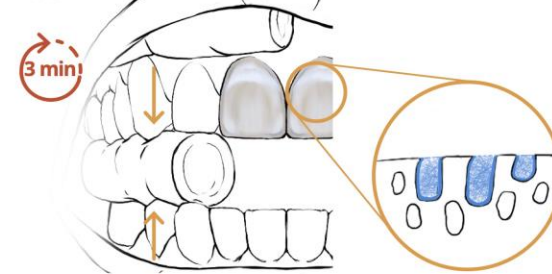


Apply SAP P₁₁₋₄ to dried white spots. Allow to soak in. Re-apply every 10 seconds, until the area is saturated.

IMPORTANT: The sponge applicator must be used.

Wait

10



Leave saturated for 3 minutes while isolated with cotton.

After, fluoride varnish may be applied. Help the patient promote a healthy oral environment to optimize enamel regeneration.



Tooth-Specific Non-Invasive Therapies for Initial Caries Lesions

Attribute Comparison	SDF	Glass Sealant	P ₁₁ -4
Use on initial lesions	Yes	Yes	Yes
Use on cavitated lesions	Yes	No	No
Use on all surfaces	Yes	No	Yes
Protects neighboring teeth	Yes	Yes	No
Aversive taste	Yes	No	No
Stains caries lesions	Yes	No	No

SAP P₁₁-4 Meta-Analysis

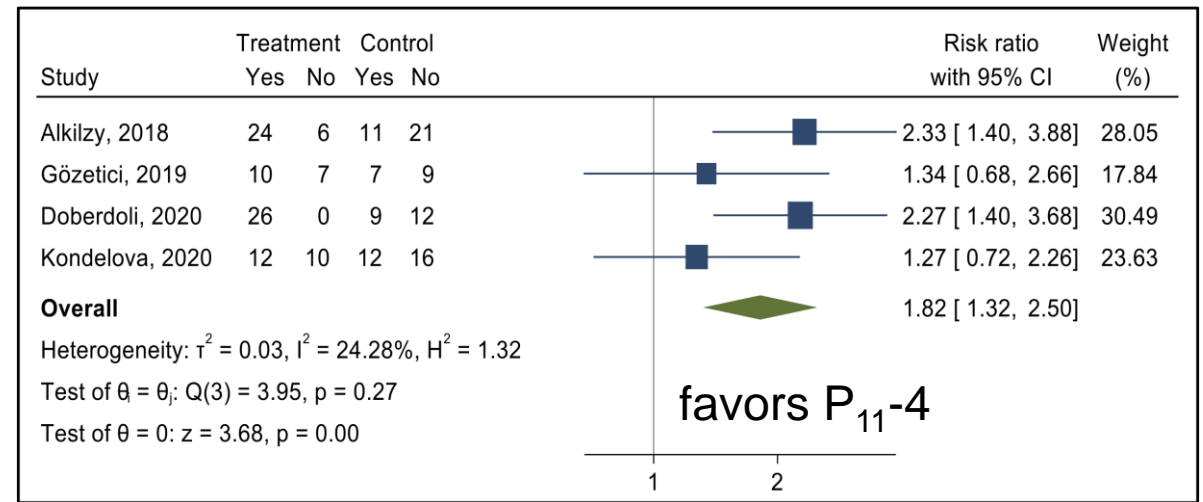


Authors

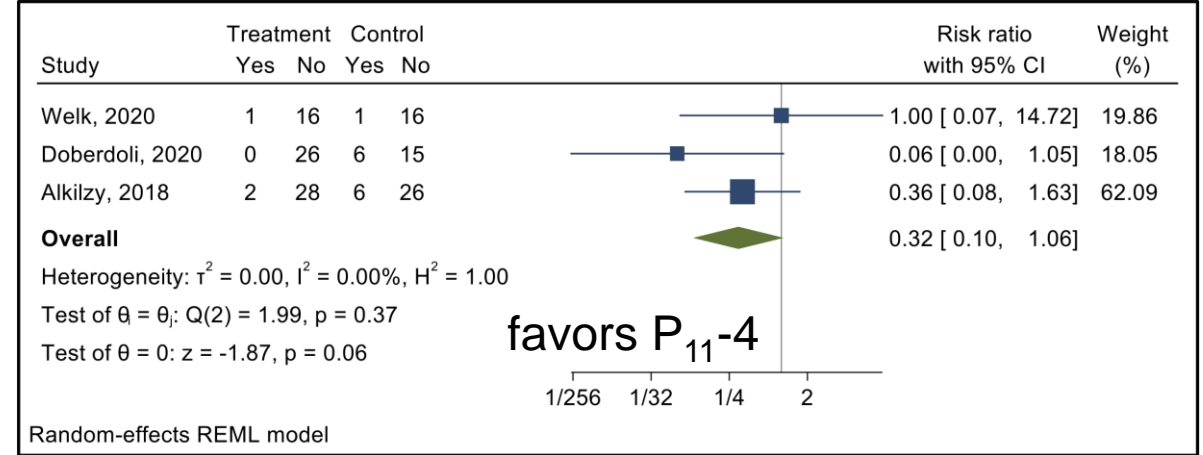
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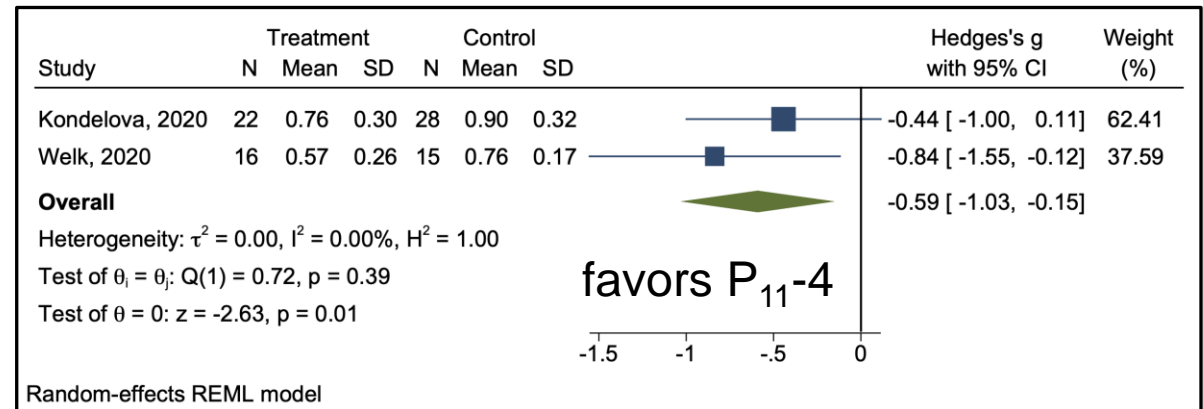
Arrests caries lesions



Prevents restorations



Shrinks caries lesions



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CSH Cold Spring Harbor Laboratory BMJ Yale

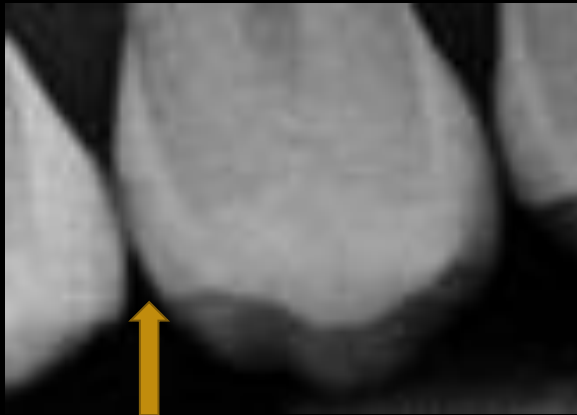
Systematic Review and Meta-Analysis on the Effect of Self-Assembling Peptide P₁₁-4 on Initial Caries Lesions

Show by month	Abstract	Full-text HTML	PDF
Total	2,436	79	436

SAP P₁₁-4 + Fluoride >> SAP P₁₁-4-Only



Overall
 Heterogeneity: $\tau^2 = 0.03$, $I^2 = 24.28\%$, $H^2 = 1.32$
 Test of $\theta_i = \theta_j$: $Q(3) = 3.95$, $p = 0.27$
 Test of group differences: $Q_b(1) = 3.93$, $p = 0.05$



1 year

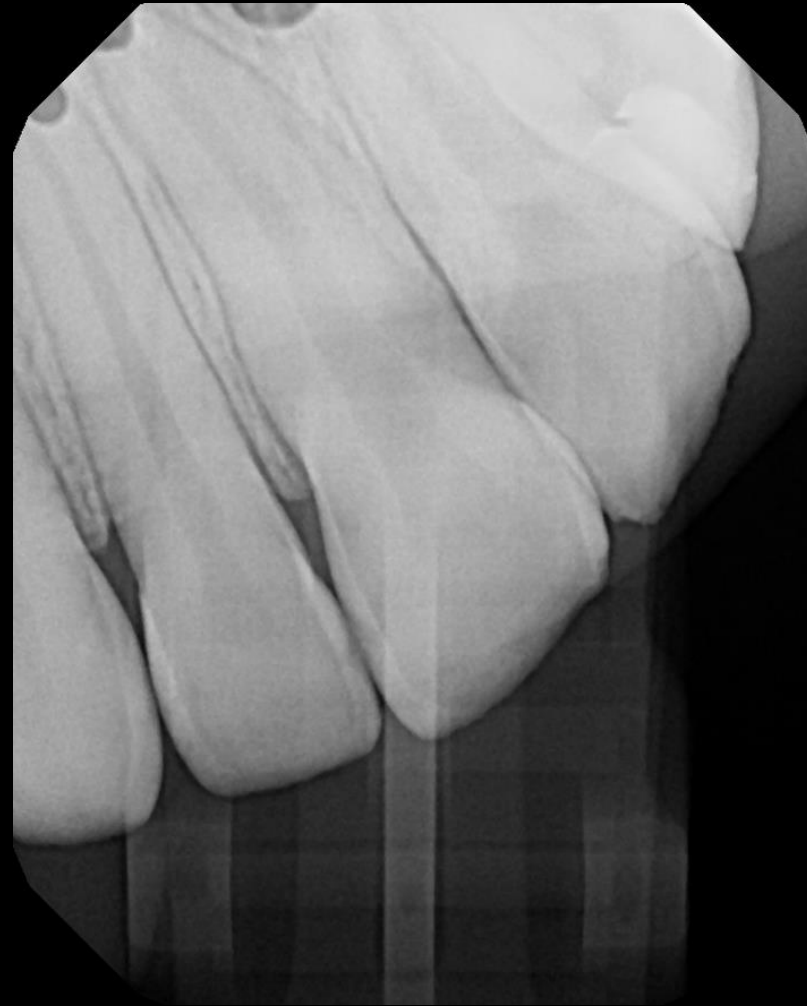
2 years



1 year

School-Based SAP P₁₁-4 Outcomes from 225 Swiss Kids

Successful SAP P₁₁-4 Case



19 month after SAP P₁₁-4 treatment,
all lesions are smaller (c/o S. Key)



Laura Skaret, BS, RDH
Manager, Clinical Innovation,
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Question and Answer

Feedback and Connecting

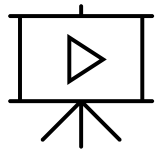
To provide feedback, ask questions, and connect to manufacturers, please take our survey (not connected to CE credit)



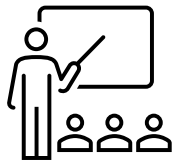
Continue Your Education on Non-Invasive Caries Therapies



Connect with us by visiting: <http://carequestinnovation.com/connect>



Scan the code to watch a CareQuest Innovation Partners' 6-minute training video on SAP P11-4



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Why We (Still) Need to Add Dental to Medicare	Adult Dental Benefit, Expanding Access, Health Equity	Report
A Cross-Sectional Analysis of Oral Health Care Spending over the Life Span in Commercial- and Medicaid-Insured Populations	Expanding Access, Health Equity	Article
Time Is on the Side of Change in Dentistry	COVID-19 and Oral Health, Health	Article

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Missed Connections
Providers and Consumers Want More Medical-Dental Integration

Oral health and overall health are inextricably linked. There is mounting evidence to suggest that poor oral health is related to a variety of chronic health conditions, such as high blood pressure, dementia, diabetes, and obesity. Despite this known connection, dental care is still largely siloed from medical care. The Centers for Disease Control and Prevention (CDC) estimates that integrating basic health screenings into a dental setting could save the health care system up to \$100 million every year.¹

CareQuest Institute for Oral Health conducted a nationally representative survey in January and February 2021 to assess consumers' perspectives on oral and overall health (n=5,320). CareQuest Institute also conducted a nationwide survey of oral health providers to assess perspectives and current behaviors related to interprofessional practice (n=377). Consumers and oral health providers described a lack of integration between medical and oral health care, and a desire for increased interprofessional collaboration.

Key Findings:
Medical-dental collaboration is currently uncommon.

- 63% of consumers report that their primary medical doctor "rarely" or "never" asks about their oral health.
- 33% of consumers report that their oral health provider "rarely" or "never" asks about their overall health.
- Less than a third of consumers report receiving general health screenings from their oral health provider.
- A majority (89%) of adults report never receiving a referral from their oral health provider to a non-oral health professional.
- Almost a fourth (24%) of participating oral health providers report currently implementing interprofessional practice.
- 45% of responding oral health providers report "rarely" integrating their care with clinicians outside of dentistry, with only 14% reporting it is part of their "daily" practice.

Webinar Evaluation

Complete the **evaluation by Friday, December 16** to receive CE credit. You will receive a link to the survey within 24 hours.

Next Webinars:

January 12: Antibiotic and Opioid Stewardship in Dentistry

January 26: Trauma-Informed Care in Dentistry

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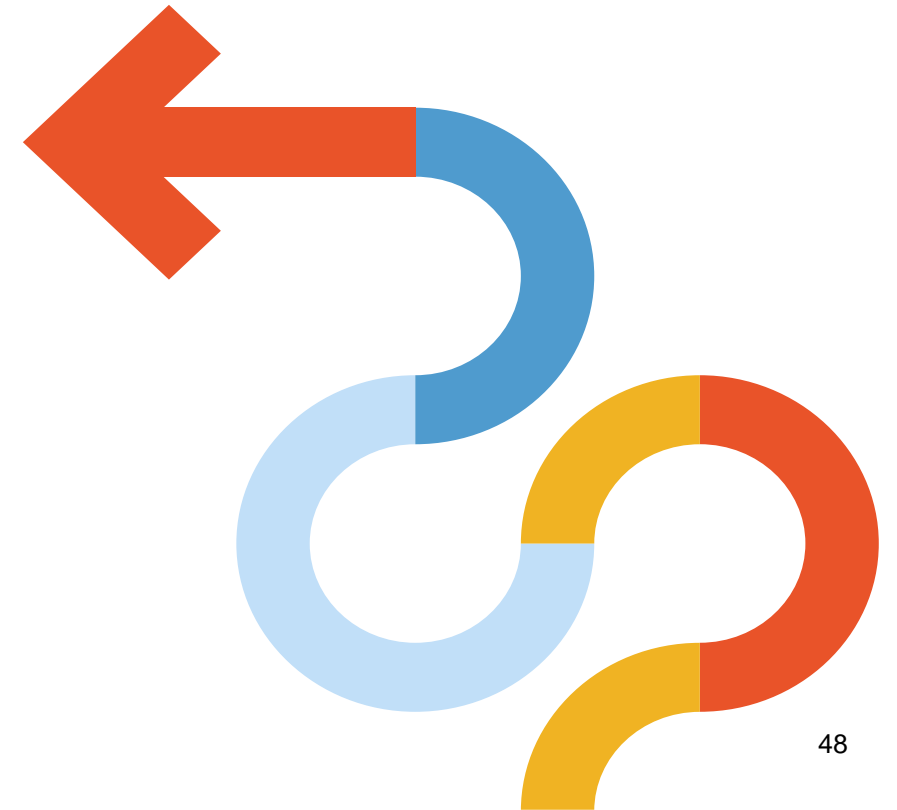
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