An Implementation Strategy for the Adoption of an Evidence-Based Guideline for Pit-and-Fissure Sealants

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Summary of Changes from Previous Version:

Affected Section(s)	Summary of Revisions Made	Rationale
	Not applicable; this is the first version of the protocol	
Throughout	Responding to revisions requested by Dr. Rice.	Needed for approval by NIDCR
Throughout	Switching the DD sessions over to the online platform Adjusting the follow-up from 12 months to up to 9 months	Adapting the study to COVID-19 physical distancing requirements
Throughout	Switching the study design from RCT to step wedge, from 1 year to up to 9-month follow-up and adding in the primary outcome sealants that are treatment planned but not yet placed.	Adapting the study to fewer clinics, less time, and COVID-related restrictions on placing sealants.

CONFIDENTIALITY STATEMENT

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the Principal Investigator or other participating study leadership and as consistent with the NIH terms of award.

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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Principal Investigator or Clinical Site Investigator:

Signed:  Date: 11/17/2020

Name*: Deborah Polk

Title*: Assistant Professor

Investigator Contact Information

Affiliation*: University of Pittsburgh

Address:

Telephone:

Email: dpolk@pitt.edu

[For multi-site studies, the protocol should be signed by the clinical site investigator who is responsible for the day to day study implementation at his/her specific clinical site.]

Signed: Date:

Name:

Title:

Affiliation:

1 PROTOCOL SUMMARY

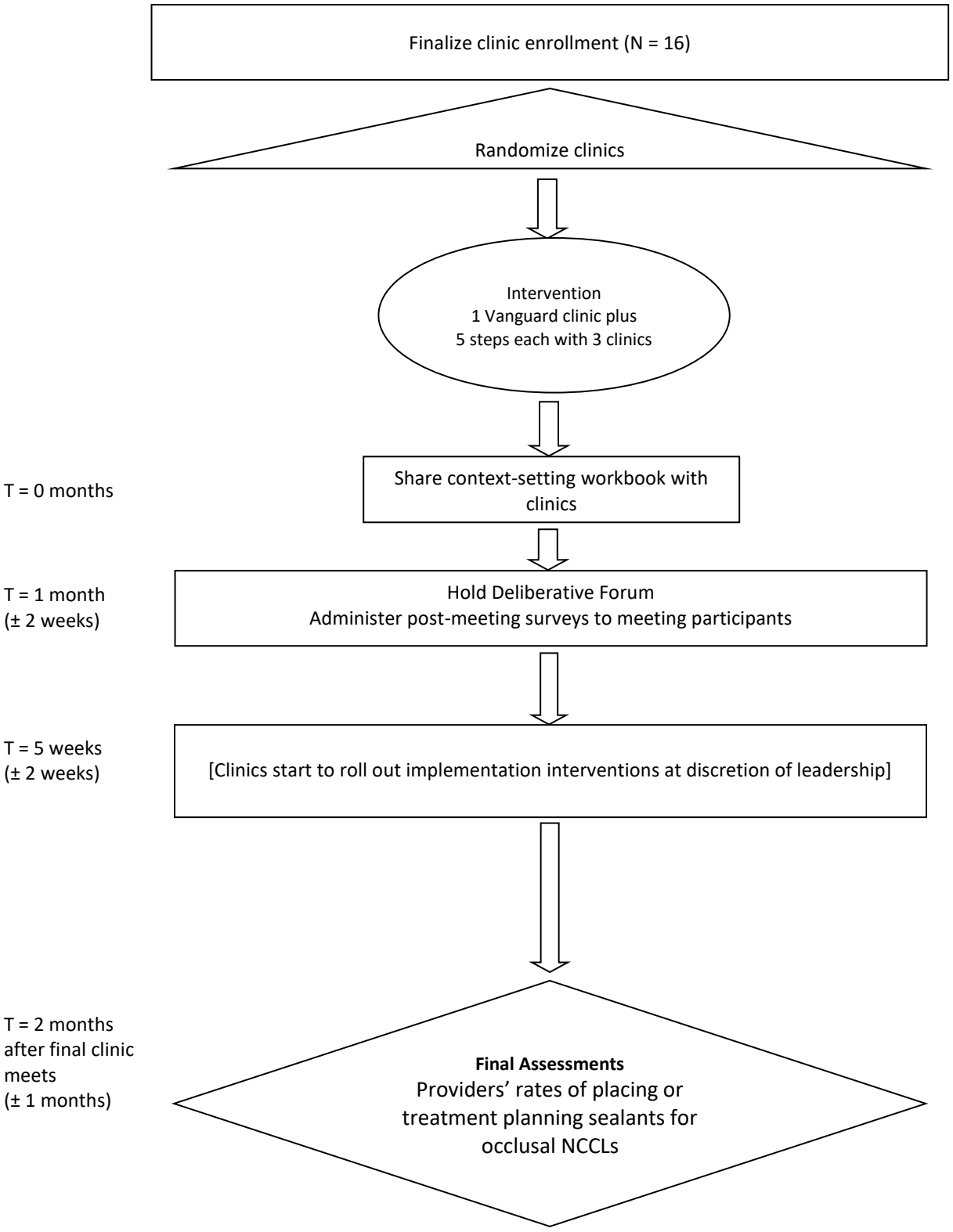
1.1 SYNOPSIS

Title:	An implementation strategy for the adoption of an evidence-based pit-and-fissure sealant guideline by salaried dental providers: Using a framework from organizational development
Grant Number:	U01DE027452
Study Description:	The purpose of this study is to determine whether Deliberative Loops are effective in increasing providers' adherence to the non-cavitated caries component of the American Dental Association's pit-and-fissure sealant evidence-based clinical practice guideline. We use a stepped wedge design to randomly assign dental clinics to the Deliberative Loop intervention. In a Deliberative Loop, stakeholders receive background information, participate in a facilitated discussion, and share their views with leadership. The Deliberative Loop intervention is designed to help stakeholders form informed opinions; in this study, stakeholders will be forming informed opinions about the implementation interventions they think will increase their clinic's adherence to the guideline. We hypothesize that compared with the pre-intervention period, following the intervention, providers will place or treatment plan sealants for significantly more occlusal non-cavitated carious lesions.
Objectives*:	Primary Objective: Determine whether the providers' rates of placing or treatment planning sealants for occlusal NCCL increase after clinic stakeholders are exposed to the Deliberative Loop intervention. Secondary Objectives: Quantify the proportion of occlusal NCCLs that are treatment planned for sealants that is sealed by the end of the post-intervention period. Estimate the total program cost, cost per clinic, and cost per member per month (PMPM) for the Deliberative Loop intervention. If effective, estimate the incremental cost-effectiveness of increasing sealant placements from the Deliberative Loop intervention compared to the pre-intervention period.
Endpoints*:	Primary Endpoint: The change in the providers' rates of placing or treatment planning sealants for occlusal NCCLs from before to after clinic stakeholders are exposed to the Deliberative Loop intervention. Secondary Endpoints: Sealant treatment plans – The proportion of occlusal NCCLs with a treatment plan for sealants that is sealed by the end of the post-intervention evaluation period; Program costs – a) total intervention costs, cost per clinic, and costs per member per month (PMPM) for the DD intervention, and annualized costs for guideline implementation interventions and NCCL treatment costs Cost-effectiveness: Estimated incremental cost-effectiveness ratios (ICERs) for clinics after exposure to the intervention. ICERs calculated for annualized total costs, costs per clinic, and costs PMPM.
Study Population:	All persons employed by Kaiser Permanente Northwest or Permanente Dental Associates and who work in a Kaiser Permanente Northwest dental clinic at any level [e.g., part time, full time] will be eligible to participate in the study. This includes both service providers and front-of-the-house staff, approximately 800 employees.

Phase* or Stage:	Stage III
Description of Sites/Facilities Enrolling Participants:	Participating sites include the 16 general dental clinics of Kaiser Permanente Northwest. All clinics are located within the United States.
Study Duration*:	The estimated time from when the study opens to enrollment until completion of data collection is 12 months.
Participant Duration:	It will take approximately one to two months for each individual participant to complete all study-related tasks, depending on how soon after the introductory session the Deliberative Forum can be scheduled.

1.2 SCHEMA

Study Design for the Stepped-Wedge Study



1.3 SCHEDULE OF ACTIVITIES

Not applicable

2 INTRODUCTION

2.1 STUDY RATIONALE

Despite the broad, evidence-based support for the use of dental sealants in permanent molars with both sound occlusal surfaces and noncavitated occlusal carious lesions (NCCLs) in children and adolescents, most general dentists are not implementing the ADA's pit and fissure sealant guideline. Compliance among general dentists ranges from less than 5% to 38.5% (O'Donnell et al., 2013; Tellez, Gray, Gray, Lim, & Ismail, 2011). In a descriptive study of the dental practice participating in the current study (Polk et al., 2018), almost 95% of the general and pediatric dentists reported using sealants to prevent caries, but only 51% reported using sealants to arrest decay. Furthermore, using sealants to arrest decay was the approach least frequently adopted. Dentists reported using less effective approaches such as providing office remineralization (67%), prescribing a behavioral intervention (66%), indicating a "watch" in the chart (58%), and placing a restoration (58%). Until dental providers start implementing the guideline, they will continue to use less successful approaches to prevent the progression of decay from non-cavitation to cavitation. Thus, patients may unnecessarily develop caries that requires restoration and experience associated negative consequences.

To date, the only implementation interventions targeting the pit and fissure sealant guideline that have been examined empirically involved financial incentives and education (Clarkson et al., 2008). In that study, the implementation strategy targeting incentives was effective in increasing implementation of the guideline, but the strategy targeting knowledge through education was not (Clarkson et al., 2008). Thus, our knowledge about how to increase adherence to this guideline is quite limited.

The reason for conducting the present study is to determine whether the Deliberative Democracy process encourages leadership to select implementation interventions that enable clinics to increase the proportion of occlusal NCCLs sealed. In this intervention, stakeholders including general and pediatric dentists, dental hygienists, dental assistants, and clinic administrative staff will share their experiences and learn from the experiences of their co-workers in facilitated small group discussions. This allows them to discuss important issues in a richer way than our everyday interactions often enable. At the end of the forum, stakeholders will complete a survey in which they identify the implementation interventions they believe will be effective in their clinic. The results of the survey will be shared with KPNW Dental and clinic leadership, who will decide whether to introduce any of the recommended implementation interventions. We anticipate that most interventions can be implemented at the clinic level so that decisions will be made by clinic leaders. Some interventions may need to be implemented at the practice level; in these cases, decisions will be made by KPNW Dental leadership.

There are different ways of achieving behavior change, including top down and bottom up. The Deliberative Democracy process enables leaders to make policy decisions (i.e., top down) informed by the opinions of those who will be affected by the policy decision (i.e., bottom up). These informed opinions constitute information leaders may not have access to otherwise. Thus, the process of participating in the Deliberative Loop will give stakeholders voice in the process. Voice has been defined as "expressing relevant ideas, information, and opinions about possible improvement" (Van Dyne, Ang, & Botero, 2003). The Deliberative Loop intervention itself is complete after the results of the survey are shared with leadership. The outcome of interest is the change in the providers' rates of placing or

treatment planning sealants for occlusal NCCLs from before to after clinic stakeholders are exposed to the Deliberative Loop intervention.

2.2 BACKGROUND

We are proposing to employ a Deliberative Loop (Cavalier, 2009), which is a general term for describing procedures to help stakeholders develop informed opinions on issues and policy options. There are three steps to a Deliberative Loop. In the first step, stakeholders receive background information that attempts to include the full range of perspectives on the issue. In the second step, the stakeholders participate in facilitated small group discussions in which they share their lived experience and hear the lived experience of their fellow stakeholders. Achieving consensus is not a goal of the process. In the third step, the stakeholders complete a survey sharing their now informed opinion about the policy issue being addressed.

Deliberative Loops seek to create conditions that allow a clinic to realize the principles of Deliberative Democracy. These principles are inclusion, reciprocity, and legitimacy. In a Deliberative Democracy, decision-makers solicit the informed opinion of those who will be affected by a policy (i.e., stakeholders). Involving those who will be affected by a policy addresses the principle of inclusion. Enabling those people to share their lived experiences with one another addresses the principle of reciprocity. And when decision-makers use these informed opinions as a basis for determining which policies to enact, this establishes legitimacy. As expressed by Gutmann and Thompson (Gutmann & Thompson, 2004), the principles of Deliberative Democracy are realized when "citizens and officials [can] justify any demands for collective action by giving reasons that can be accepted by those who are bound by the action." In service of the principles of Deliberative Democracy, Deliberative Loops provide stakeholders with the opportunity to compare values and experiences, consider a range of policy options, and engage relevant arguments and information (Nabatchi, Gastil, Weiksner, & Leighninger, 2012). By bringing together stakeholders with diverse points of view, these conversations provide stakeholders with an opportunity to understand and consider multiple perspectives on the issue about which they are developing an opinion.

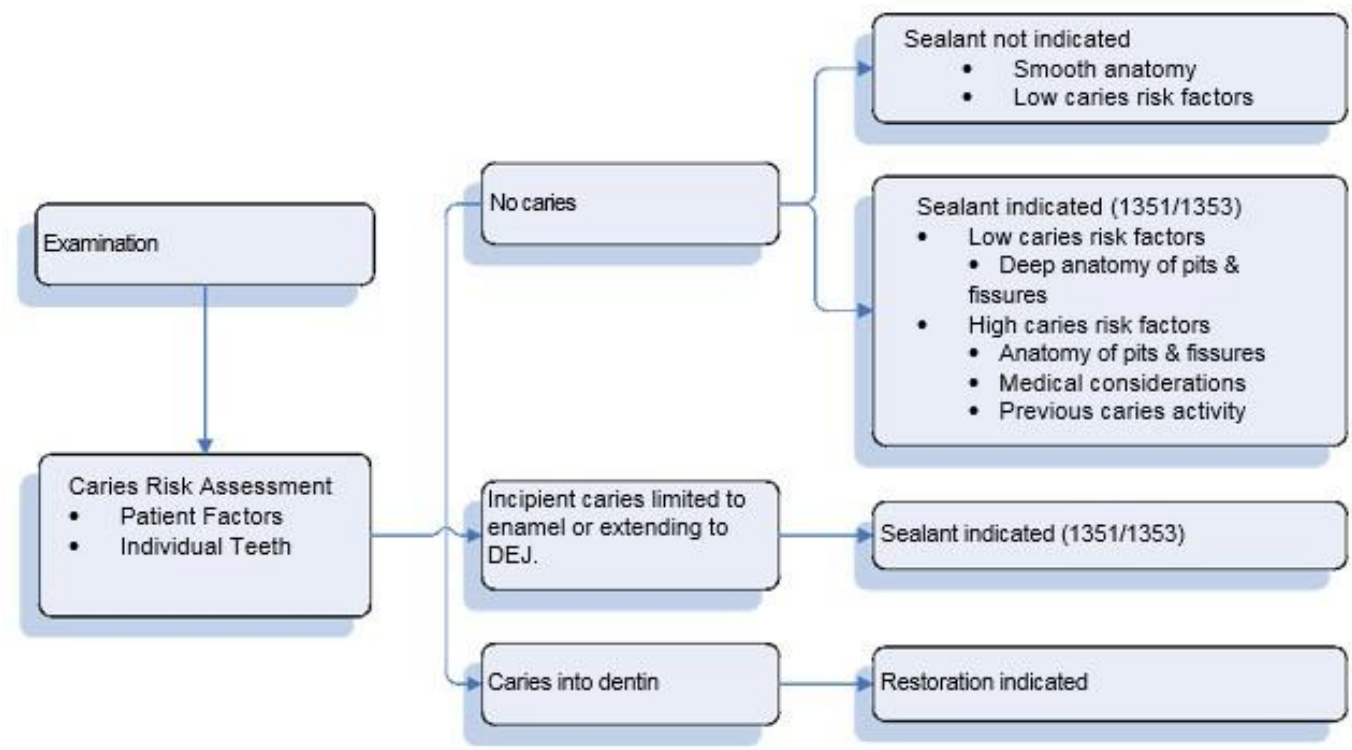
Two articles review the theory and provide a critical review of Deliberative Loops in multiple countries. Delli Carpini and colleagues (Delli Carpini, Lomax Cook, & Jacobs, 2004) reviewed the benefits posited by theories of Deliberative Democracy, research (case studies, surveys, laboratory experiments, and quasi-experimental designs) from social psychology on group deliberation, and research specifically designed to test the theories of Deliberative Democracy. Recently, Kuyper (Kuyper, 2018) offered a similar review informed by a larger body of research than was available in 2004. Both articles caution that the benefits of deliberation are highly context dependent. In these articles and others, researchers draw particular attention to how the quality of the participants' deliberations and the quality of facilitation affect attainment of these benefits. A series of articles reporting on research funded by the National Institutes of Health and published by researchers from the University of Michigan provides guidance for assessing both. These researchers detailed their particular deliberative methods for eliciting the public's views on research ethics controversies (Kim, Wall, Stanczyk, & De Vries, 2009) and provided frameworks for assessing the quality of deliberation and facilitation (De Vries, Stanczyk, Ryan, & Kim, 2011; De Vries et al., 2010) derived from research on public deliberation in multiple countries (Steenbergen, Bachtiger, Sporndli, & Steiner, 2003; Steiner, Bachtiger, Sporndli, & Steenbergen, 2004; Stromer-Galley, 2007).

Below is the Permanente Dental Associates guideline for dental sealants.

Introduction

Sealants are placed to cover pit and fissures of teeth at risk of developing caries. Current research supports sealants as an effective preventive service to offer patients.

Clinical decision making



This guideline is designed to support clinician and patient decisions about appropriate evaluation and treatment. It is not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by practitioners, considering each patient's needs on an individual basis. Guideline recommendations apply to populations of patients. Clinical judgment and shared decision-making are necessary to design treatment plans for individual patients.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

The only foreseeable risk to the study is informational risk (Committee on Revision to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences, 2014). Because the information to be obtained is neither private nor sensitive in nature, the study protocol also meets criteria for minimal risk per 45 CFR 46.102(i): "*[T] the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."*

2.3.2 KNOWN POTENTIAL BENEFITS

There are no known benefits of participating in the present study. If the intervention is indeed effective, "[D]eliberation is expected to lead to empathy with the other and a broadened sense of people's own interests through an egalitarian, open-minded and reciprocal process of reasoned argumentation. Following from this result could be other benefits: citizens may be more enlightened about their own and others' needs and experiences, may better resolve deep conflict, may be more engaged in politics, place their faith in the basic tenets of democracy, perceive their political system as legitimate, and lead a healthier civic life" (Delli Carpini et al., 2004).

Research reveals a "strong link" between deliberation and the following outcomes relevant to this proposal (Kuyper, 2018):

- Micro (impacts on individuals): knowledge gain, opinion and preference change.
- Meso (impacts on groups and collectives): social learning, or a deeper understanding of the views of others; reduced polarization; meta-consensus, or a shared understanding on the nature of an issue and an agreement on a limited range of preferred outcomes (Dryzek & Niemeyer, 2006).
- Macro (impacts on polity): Increased perception of legitimacy of decisions as a consequence of informed and inclusive deliberative decision-making processes.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Some degree of informational risk is present in all research studies and thus cannot be avoided. To minimize the risk of personal information disclosure, several measures will be taken to ensure the privacy and security of participant research information. Consistent with the Privacy Rule, no member of the research staff will disclose participant research data to any other person or entity except as required by law or for authorized oversight of the research project. The data will be used only for the specific purposes of this study. To protect the confidentiality of participant information, all data will be de-identified and labeled with a unique study ID code. Measures to ensure the security of participant data are detailed in section 10.1.3.

Although there are no known benefits of participation, if the intervention is effective, benefits consequent to dental providers' participation may include: (1) broadening their perspectives on the use of pit-and-fissure sealants and by providing them with an opportunity to become more engaged in the

establishment of guidelines for use of pit-and-fissure sealant; (2) changing professional behavior by encouraging more frequent use of pit-and-fissure sealants when appropriate. The knowledge to be gained in the present research clearly outweighs the minimal risk associated with the possible disclosure of information that is neither private nor sensitive.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
Determine whether the providers' rates of placing or treatment planning sealants for occlusal NCCL increase after clinic stakeholders are exposed to the Deliberative Loop intervention.	The change in the providers' rates of placing or treatment planning sealants for occlusal NCCLs from before to after clinic stakeholders are exposed to the Deliberative Loop intervention.	Proportion of occlusal NCCL with a sealant placed or treatment planned is an indicator of adherence to the clinical practice guideline.
Secondary		
Sealant treatment plan resolution: Quantify the proportion of occlusal NCCLs that are treatment planned for sealants that is sealed by the end of the post-intervention period ***Program cost and cost-effectiveness:*** Estimate the total program cost, cost per clinic, and cost per member per month (PMPM) for the Deliberative Loop intervention. If effective, estimate the incremental cost-effectiveness of increasing sealant placements from the Deliberative Loop intervention compared to the pre-intervention period.	***Sealant treatment plan resolution:*** The proportion of occlusal NCCLs with a treatment plan for sealants that is sealed by the end of the post-intervention evaluation period. ***Program costs****:* a) total intervention costs, cost per clinic, and costs per member per month (PMPM) for the DD intervention, and annualized costs for guideline implementation interventions and NCCL treatment costs. ***Cost-effectiveness***: Estimated incremental cost-effectiveness ratios (ICERs) for clinics after exposure to the intervention. ICERs calculated for annualized total costs, costs per clinic, and costs PMPM.	***Sealant treatment plan resolution:*** *we expect dentists will initiate treatment plans for sealants if there is limited time availability at the time of the diagnosis. A treatment plan for a sealant will also enable a dental hygienist to place a sealant at a follow-up visit without additional dentist consultation. Because of the limited post-intervention evaluation period, we included treatment planned sealants in the primary outcome. This secondary aim is used to quantify the proportion of surfaces that are sealed during the follow-up period.* An economic evaluation of a health system intervention is an important component for demonstrating the value of implementing practice change. This secondary aim will provide important data for the net

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
		financial costs for a health system and dental offices associated with the implementation of the DD intervention. Costs are assessed from a health system perspective, adjusting for patient-paid treatment costs.
Tertiary/Exploratory		
E1. Determine whether Promotive Voice, Prohibitive Voice, or the perception that the suggestions one shares will be taken into consideration by leadership mediate the relationship between type of discussion and change in the proportion of NCCLs sealed.	Promotive Voice scale (Liang, Farh, & Farh, 2012) (measured on the post-session survey immediately following the Deliberative forum) Prohibitive Voice scale (Liang et al., 2012) (measured on the post-session survey immediately following the Deliberative forum) Single item assessing self-reported perception that the suggestions one shares will be considered by leadership (measured on the post-session survey immediately following the Deliberative forum)	Voice is "intentionally expressing relevant ideas, information, and opinions" about work-related issues (Van Dyne, Ang, & Botero, 2003). We hypothesize that voice may be part of the pathway through which the experience of participating in the Deliberative Loop affects guideline adherence. That is, we hypothesize it may be part of the mediational pathway.
E2. Determine whether the intervention was acceptable to stakeholders.	Leadership ratings of acceptability and feasibility of resources required for the Deliberative Loop. (measured following the final Deliberative forum) Stakeholder ratings of acceptability of the Context-Setting Workbook, group discussion, and process. (measured on the post-session survey immediately following the Deliberative forum)	Even if an intervention is effective, it will not be adopted by the stakeholders if they do not find it acceptable or feasible. For that reason, we are assessing stakeholder perceptions of acceptability and feasibility.
E3. Describe how the DD process works.	Perceptions of leadership responsiveness in the past year and anticipated following the Deliberative forum (measured	We are obtaining additional information to be able to provide a rich description of the process.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
	on the post-session survey immediately following the Deliberative forum) Implementation interventions endorsed by stakeholders (measured on the post-session survey immediately following the Deliberative forum) Implementation interventions selected by leadership (measured in the 3 months following the Deliberative forum)	

4 STUDY DESIGN

4.1 OVERALL DESIGN

We hypothesize that compared with the pre-intervention period, following the intervention, providers will place or treatment plan sealants for significantly more occlusal non-cavitated carious lesions.

This is a stepped wedge randomized trial design.

Every clinic will eventually experience the intervention. Clinics will be randomized to one of five intervention periods. We will randomize three clinics at a time. There is a six-week window in which to run the three clinics that are in a given step and then a week gap before the next step's six-week window starts.

There will be an intervention period and a non-intervention period that will determine when the clinic experiences the Deliberative Loop (DL) process. The cumulative duration of the study intervention is 105 minutes. This includes a 15-minute overview in the month prior to the DL session and 90 minutes dedicated to the DD session and post session survey. In the Overview, participants will receive the Context-Setting Workbook. In the DL session, participants will engage in the Deliberative forum and complete the post-forum survey identifying implementation interventions they believe will or will not be effective in their own clinic. The final endpoint assessment for each clinic will occur 2 months after the final clinic's Deliberative forum.

The economic evaluation has two components: a program cost analysis and an incremental cost-effectiveness analysis (CEA). A program cost analysis (PCA) (Drummond, Sculpher, Claxton, Stoddart, & Torrance, 2015) will be conducted to quantify the total direct costs (labor time and non-labor resources) of developing and implementing the Deliberative Loop intervention, including the annualized costs of selected clinic implementation interventions. For this study, we will use PCA to value resources using an

opportunity cost method, i.e., that resources used for the intervention cannot be used for other purposes, from a health system perspective.

To characterize the DD process, the post-session survey will also include questions addressing the stakeholders' perceptions of leadership responsiveness to feedback in the past year, barriers they identify, perceptions of promotive and prohibitive voice, anticipated responsiveness to the feedback from the forum, perceptions of helpfulness of the Context-Setting Workbook, perceptions of helpfulness of the Deliberative forum, and perceptions of helpfulness to the stakeholder of the forum. We will also assess leadership's perceptions of the feasibility of the Deliberative Loop process. Finally, we will use surveys and conduct qualitative interviews with clinic managers to obtain information about which implementation interventions were actually implemented in their clinics.

This will be a single-site, multi-clinic (n = 16) trial.

We are proposing to employ a Deliberative Loop (Cavalier, 2009), which is a general term for describing procedures to help stakeholders develop an informed opinion on issues and policy options. Key elements of Deliberative Loops include providing stakeholders the following elements:

- background information on an issue
- a facilitated conversation as a member of a group of stakeholders that offers a range of perspectives on an issue as a result of its members' diverse lived experience
- the opportunity to record their views after having become informed with relevant facts, expert information, and an understanding of the effects issues and policy options can have on diverse members of a community (Cavalier, 2009).

Clinics in the non-intervention period will experience standard processes for decision-making and administrative support. Selection of the timing of the non-intervention period for clinics will be based on randomization.

Interim analyses will not be used to guide the current research study.

Given the limited number of clinics, we will not be stratifying.

We are not including any additional sub-studies in this protocol.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

Given the almost complete lack of prior research testing interventions to improve clinics' implementation of the ADA's pit-and-fissure sealant guideline for occlusal NCCLs, we selected a stepped wedge clinical trial. Every clinic will eventually receive the intervention, which we think will be beneficial. A stepped wedge design also likely provides more power and accounts for intraclass correlation in a more efficient way than clustered randomized trials. By having non-intervention and intervention periods, we will be able to establish a benchmark for provider behavior (i.e., sealing NCCLs), which could drift over the study period or change in response to factors other than the intervention.

4.3 JUSTIFICATION FOR INTERVENTION

The number and frequency of the intervention contacts is typical for a Deliberative Loop. The length of time of these intervention contacts is shorter than is typical due to the constraints of administering the intervention in a busy clinic setting. The minimum-acceptable participation in, or exposure to, the intervention to have evaluable data requires participation in two of the three elements of the intervention: reading the Context-Setting Workbook and completing a post-session survey.

4.4 END-OF-STUDY DEFINITION

The end of the study, defined as when we will stop pulling from the EHR the proportion of NCCLs sealed, will occur 2 months after the last clinic completes their Deliberative Forum.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

All persons employed by Kaiser Permanente Northwest or Permanent Dental Associates and who work in a Kaiser Permanente Northwest dental clinic at any level [e.g., part time, full time] will be eligible to participate in the study. This includes both service providers and front-of-the-house staff. We assume all participants are at least 18 years old.

Please note: To measure the provider behavior that is our primary outcome, we are using patient data from the Electronic Health Record. Patients are not our participants, however. We describe use of the EHR data in section 8.1. Per CHR policy, clinical data for patients will be excluded from the analysis for patients who have requested their data not be used for research purposes.

The study includes a pragmatic evaluation of clinical information collected in the routine conduct of patient dental care. Data collected electronically as part of care will be collected for all patients ages 6-80 with a dental office visit during the clinic evaluation period and who have a documented NCCL (or suspected NCCL) on an occlusal tooth surface. These patients will not be recruited directly or contacted by study or dental office staff to obtain patient-reported data.

Note: We obtained a waiver of signed consent to access and utilize these data. Patient data will be stored securely using established procedures at CHR, and data sharing among the study team will be governed by an appropriate data use and data transfer agreements.

5.2 EXCLUSION CRITERIA

There are no exclusions for KPNW and PDA staff who are otherwise eligible for the intervention.

5.3 LIFESTYLE CONSIDERATIONS

N/A

5.4 SCREEN FAILURES

N/A

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

Clinic managers and leadership will reach out to potential participants. We will leave the exact method to the discretion of the managers and leaders.

Participants will not receive compensation, nor will they be provided any incentives for study participation.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

Presentation of the Context-Setting Workbook
Background information will be given to the stakeholders before they engage in the Deliberative Forum. One goal of these Context-Setting Workbook is to present the diverse perspectives held by the stakeholders regarding barriers they face in adhering to the guideline. Stakeholders should see their own perspective or voice in the materials. To accomplish this goal, we surveyed the stakeholders about their views regarding barriers. We will also provide information about a range of possible implementation interventions together with their targets. All implementation interventions included in the Context-Setting Workbook will have been vetted by KPNW leadership to ensure that they are open for consideration.

Exposure to DD Session
Stakeholders from a given clinic will come together for a Deliberative Forum (i.e., facilitated conversation), enabling them to hear the full range of perspectives held by their fellow colleagues and stakeholders and to share their own perspective regarding how best to implement the guideline in small-group discussions.

Completion of Post-intervention Survey
Following the Deliberative Forum, each stakeholder will have the opportunity to record their opinions regarding possible implementation interventions. These opinions will be shared with the clinic's decision-makers to help guide their decision-making about which implementation interventions to deploy. If a stakeholder happens to be absent the day of their clinic's DD session, they will still have the opportunity to complete the survey.

The mechanistic targets of the intervention are employees' perceptions of promotive voice, prohibitive voice, and anticipation that KP leadership will take their recommendations under consideration.

The targeted endpoint is the change in the providers' rates of placing or treatment planning sealants for occlusal NCCLs from before to after clinic stakeholders are exposed to the Deliberative Loop intervention.

All clinics will have a non-intervention period and an intervention period.

6.1.2 ADMINISTRATION AND/OR DOSING

Introduction to the Study & Presentation of Context-Setting Workbook
At a clinic meeting one month before the clinic's Deliberative forum, one member of the study staff will give a 15-minute presentation providing background information about the DISGO study and the Deliberative forum. In addition, stakeholders (i.e., general and pediatric dentists, dental hygienists, Expanded Function Dental Assistants (EFDAs), dental assistants, and front-of-the-house staff) will watch a five minute video demonstrating the online platform and be given the Context-Setting Workbook. We will ask the stakeholders to review the Context-Setting Workbook before participating in their clinic's Deliberative forum.

Exposure to DD Session
Stakeholders working in intervention clinics will participate in clinic-specific Deliberative forums. Given KPNW Dental policy, we expect that all stakeholders who are present on the day of the forum will attend and participate in the forum. These forums will take place via an online platform. The forum will start with a quick review of the material in the Context-Setting Workbook. Then, depending on the number of stakeholders in the clinic, the stakeholders will be divided into small groups of 5 – 8 members with one facilitator per group. The membership within each group will be representative of the diversity among job categories (i.e., general and pediatric dentists, dental hygienists, EFDAs, dental assistants, and front-of-the-house staff). The facilitators will lead the small groups in focused discussions of barriers and implementation interventions to address those barriers. The facilitators will seek to elicit from the stakeholders their lived experience and the reasoning for their opinions but will discourage any pressure to arrive at consensus. The Deliberative forums will last for one hour.

Completion of Post-intervention Survey
Immediately following the Deliberative forum, stakeholders will complete a survey on which they will record their opinions about the implementation interventions they recommend their clinic adopt. If a stakeholder is absent on the day of their forum, we will still give them the post-session survey to complete. The results of the surveys will be shared with whatever level of leadership has the ability to enact the recommendations. Thus, for implementation interventions that require system-wide intervention, such as continuing education, those recommendations will be shared with the Clinical Effectiveness Council. For implementation interventions that require intervention at the clinic level, those recommendations will be shared with clinic leadership and administration.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

Facilitators will be drawn from persons working as facilitators who work with Common Ground for Action. The role of the facilitator is to make sure that every stakeholder has the opportunity to share their lived experience. In addition, the facilitators encourage stakeholders to support their views with specific reasons. They will receive training in the form of facilitation specific to Deliberative Loop forums from Tim Dawson, a study consultant. All Deliberative forums will be recorded. Following each Deliberative forum, we will code the recordings to assess how well the facilitator adhered to the protocol and share feedback with the facilitators. The following elements will be assessed:

1. Impartial/non-judgmental: Avoids sharing their own opinion or appraising the opinion of participants.
2. Task-oriented: keeps participants on track if discussion gets side-tracked. Reminds participants of goals and issues that are central to discussion.
3. Elicits viewpoints from every participant/ensures that no one dominates the discussion: Encourages equal participation of each participant, makes room for participants to share their opinions.
4. Conflict resolution: resolves confrontation and maintains focus on issues rather than personalities

Immediately following the Deliberative forum, we will administer a survey to the participating stakeholders. On that survey, we will include two items assessing fidelity (e.g., “Today’s discussion caused me to consider points of view that I had not previously considered”) scored on a five-point Likert-type scale ranging from “Strongly Disagree” to “Strongly Agree” together with a free response box for comments and suggestions. We will use descriptive statistics to analyze these data. If we determine from the fidelity assessment that the training for the facilitators could be improved, we will make that change to the training.

We will take several measures to quantify the degree to which the Deliberative forums occurred as planned. We will assess which stakeholders from each clinic attended. We will code the recordings to assess whether stakeholders participated in the facilitated discussions. We will record whether stakeholders returned a survey at the end of the forum.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

The study will not be blinded. One clinic will be designated as a vanguard clinic for the intervention. The vanguard clinic will be randomly selected as follows: the 16 clinics will be ranked by number of providers. The sample function in R will be used to randomly select one clinic from the 8 clinics in the middle 50% This will be our vanguard clinic. This is done to ensure the vanguard clinic is generally representative of most clinics in terms of number of providers.

The remaining fifteen clinics will be randomly assigned to one of five intervention periods. We will use a restricted randomization approach to ensure relative balance in providers randomized in each period. We will rank the fifteen clinics by provider size and divide them into five groups of three. We will randomly select one clinic from each group for each intervention period. We will use the sample() function in R to randomly assign clinics into intervention periods, with three clinics assigned during each intervention period. The sample() function will be used to randomize each group of three into a step.

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

There are three parts to the intervention: The Context-Setting Workbook; the Deliberative Loop; and the post-session survey.

To measure stakeholders' engagement with the Context-Setting Workbook, we will ask them on the post-session survey whether they read the Context-Setting Workbook.

To measure stakeholders' engagement in the Deliberative Loop, we will take attendance, to see whether they attended. We will also review the transcripts to determine whether they participated.

To measure stakeholders' exposure to the post-session survey, we will have them put their study ID on the survey.

6.5 CONCOMITANT THERAPY

N/A

6.5.1 RESCUE THERAPY

N/A

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

Not applicable.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

We will discontinue participants from the study if they cease to be employed by either PDA or KPNW. The reason for participant discontinuation or withdrawal from the study will be recorded on the enrollment tracker. Participants who undergo the consent process, receive the study intervention, and subsequently withdraw or are discontinued from the study will not be replaced.

Because the study intervention process is fundamentally a group process, we may discontinue participants from the study intervention if the participants disrupt the process for other participants. Disruption includes threatening physically. Disagreeing is not included in the definition of disruption. When we discontinue a participant from the study intervention but not the study, we will give the participant the opportunity to complete remaining study procedures. When we discontinue a participant from the study, we will collect the reason(s) we identified for discontinuing the participant

from the intervention and the methods we used to determine the need to discontinue the participant. Given the one-time-only nature of the Deliberative loop for each clinic, we are unable to anticipate a situation in which we would discontinue a participant from the study intervention temporarily.

Clinic staff from dental offices receiving the DD intervention may relocate to a clinic still in its non-intervention period during the evaluation period. To minimize contamination associated with staff movement between clinics, we will monitor provider staffing changes and NCCL treatment decisions (procedures, treatment plans, etc.) of providers who change clinic locations. We will assess the potential for staff change on study results and consider excluding data for these providers if warranted. We expect any provider cross-contamination would reduce the differences between non-intervention and intervention periods, thus making the results more conservative than if no provider movement had occurred.

For participants who have been discontinued from the study intervention but remain in the study for follow-up, we will continue contact to be able to capture adverse events (AE), serious adverse events (SAE), and unanticipated problems (UPs).

7.3 LOST TO FOLLOW-UP

Participants will be considered lost to follow-up if they cease to be employed by either PDA or KPNW. If they remain employed but don't attend the DL session or don't complete the post-session survey, they will be included in the analyses (see 9.3 Populations for Analyses).

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Primary Objective

The primary objective of this study is to determine whether following the initiation of the Deliberative Loop, sealant placement rates on occlusal tooth surfaces with a non-cavitated carious lesion (NCCL) increase significantly during the post-initiation period compared to sealant placement on NCCLs during the pre-intervention period. To fulfill the primary objective, we will assess at both the provider and clinic levels the change in the providers' rates of placing or treatment planning sealants for occlusal NCCLs from before to after clinic stakeholders are exposed to the Deliberative Loop intervention.

$$((\text{sealant+TPS})/\text{NCCL})_{OT1} - ((\text{sealant+TPS})/\text{NCCL})_{OT0}$$

where TPS is treatment planned sealant and OT0 and OT1 refer to all occlusal (O) surfaces for time periods T0 (before) and T1 (after) the intervention. Currently, similar to most practicing dentists, PDA dentists do not use diagnosis codes. Instead, dentists use clinical observations and radiographs to establish clinical finding of caries by tooth and surface, and estimate the pre-intervention depth (E1, E2, D1, etc.) of the affected surface. Practitioners then enter these data in the clinical findings tab of the

electronic records by tooth surface. Study staff will draw these data from the electronic health record (i.e., HealthConnect [EPIC CARE] WISDOM module) to define eligible tooth surfaces with an E1 or E2 caries finding and use procedure data to determine how the tooth surface was treated.

Definitions from the HealthConnect [EPIC CARE] WISDOM module:

> An NCCL is defined as an unrestored primary or permanent tooth surface of a molar or premolar with a documented clinical finding of caries at depths E1 or E2 (NCCL, non-cavitated, or incipient caries). Primary molars are included in the PDA guideline, which will support analyses for young children, adolescents and adults. Eligible teeth with multi-surface carious lesions will be excluded if the non-occlusal surface(s) are frank caries (depth: D1-D3), which would likely warrant surgical restoration.
>
> A sealant is defined as CTD procedure code D1351 (Sealant per tooth) or D1353 (Sealant repair per tooth).
>
> A treatment planned sealant is defined as the presence of a sealant placement, and date corresponding to the NCCL, documented visit in the Treatment Plan table in HealthConnect.
>
> Other non-surgical treatment procedures include D1352 (PRR), D1354 (interim caries arresting medicament, D1999 (unspecified preventive procedure, D1208 (topical fluoride), and D1206 (fluoride varnish).
>
> Occlusal surfaces are denoted (O) in HealthConnect for primary and permanent teeth.

Secondary Objectives

A secondary objective is to quantify the proportion of occlusal NCCLs that are treatment planned for sealants that are sealed during the study period. Details of the analysis plan are provided in section 9.4.3 below

Another secondary objective is to estimate the total program cost, cost per clinic, and cost per member per month (PMPM) for the Deliberative Loop intervention. The cost-effectiveness analysis will be focused on the cost of developing and conducting the DD intervention (using an implementation costing approach that excludes the research-related costs that would not accrue to health plans doing this on their own), the cost of selected implementation interventions following the DD session, and the clinical service delivery costs for eligible tooth surfaces during the evaluation period. Details of the analysis plan are provided in section 9.4.3 below.

Exploratory Objectives

<u>Acceptability & Feasibility</u>

Following the final deliberative forum, we will assess KPNW Dental and PDA management's perceptions of acceptability and feasibility of the Deliberative Loop process. We will measure the resources required to conduct the deliberative forums including the researchers' time preparing the Context-Setting Workbook and preparing for the deliberative forums. We will use descriptive statistics to quantify the resources. We will then share this information with the clinic, KPNW Dental, and PDA management

teams and have them rate the acceptability and feasibility of the deliberative loop on a 5-point Likert scale.

Immediately following the deliberative forum on the post-session survey, we will obtain measures of acceptability from the stakeholders.

Item
3-item scale assessing helpfulness of the Context-Setting Workbook to the discussion
3-item scale assessing helpfulness of the discussion to identifying implementation interventions
3 items assessing experience during the discussion

We will assess the acceptability of the Context-Setting Workbook via three items (e.g., "I found the written materials clear and easy to understand") scored on a five-point Likert-type scale ranging from "Strongly Disagree" to "Strongly Agree" together with a free response box for comments and suggestions.

We will assess the helpfulness of the group discussions via three items (e.g., "I found the group discussions informative") scored on a five-point Likert-type scale ranging from "Strongly Disagree" to "Strongly Agree" together with a free response box for comments and suggestions.

We will assess the acceptability of the process via three items (e.g., "Today's discussion made me more likely to become engaged in my clinic's efforts to resolve issues related to implementing the incipient caries guideline" and "In the future, I would be willing to participate in deliberative forums like the one today") scored on a five-point Likert-type scale ranging from "Strongly Disagree" to "Strongly Agree" together with a free response box for comments and suggestions.

<u>Examining the mediating role of Voice</u>

We will examine whether Voice mediates the relationship between type of discussion (i.e., preintervention Unit-based team discussion and Deliberative Loop discussion) and the primary outcome (i.e., the change in the providers' rates of placing or treatment planning sealants for occlusal NCCLs from before to after clinic stakeholders are exposed to the Deliberative Loop intervention.).

Item
5-item scale assessing Promotive Voice
5-item scale assessing Prohibitive Voice
1-item scale assessing perceptions of future leadership responsiveness
1 item assessing overall perception of Voice

Different aspects of Voice will be measured in different ways. Measures of voice distinguish between expressing new ideas or suggestions for improving the clinic, which is called promotive voice, and expressing concern about work practices that may be harmful to the clinic, which is called prohibitive voice (Liang, Farh, & Farh, 2012). Promotive voice focuses on realizing ideals or possibilities; whereas prohibitive voice focuses on stopping or preventing harm. The perception of having the opportunity to share one's views will be measured using the Promotive and Prohibitive Voice scales (Liang et al., 2012).

For both types of discussion (see above), both Promotive Voice and Prohibitive Voice will be assessed immediately following the DL forum, via a survey administered to all stakeholders attending the meeting (i.e., post-session survey). Each scale has five items and is scored on a five-point Likert-type scale ranging from "Strongly Disagree" to "Strongly Agree." Six-week test-retest reliability was shown to be 0.42 for Promotive Voice and 0.44 for Prohibitive Voice. In validation studies, these scales were shown to have convergent and discriminant validity. Confirmatory analysis that also included measures of psychological safety, felt obligation for constructive change, and organization-based self-esteem, demonstrated that a five-factor model in which each scale loaded on a separate factor fit best.

Another aspect of Voice is the perception that the suggestions that one shares will be taken into consideration by leadership. To measure this perception, we are administering a single item "I am confident KP leadership (Upper Management) will take our suggestions into consideration." This item will be assessed immediately following the DL forum, via a survey administered to all stakeholders attending the meeting (i.e., post-session survey). It is scored on the same scale as the Promotive and Prohibitive Voice scales. Finally, we will measure an overall assessment of voice using a single item "Today's discussion made me feel as though my voice has been heard." This item will be assessed immediately following the DL forum via a paper survey administered to all stakeholders attending the meeting (i.e., post-session survey). It is scored on the same scale as the Promotive and Prohibitive Voice scales.

Characterizing the DD Process

We will also conduct exploratory analyses to learn more about the DD process.

Item
For each barrier, items assessing endorsement of implementation interventions
2 items assessing perceptions of past leadership responsiveness
3 items assessing perceived barriers
2 items assessing fidelity

The usual product of the intervention is the stakeholders' informed opinions about what implementation interventions their clinic should adopt. Immediately following the deliberative forum, on the post-session survey, for each barrier, stakeholders will indicate the degree to which they agree using a five-point scale (strongly disagree to strongly agree) that their clinic should adopt a series of implementation interventions. In addition to the list of implementation interventions, stakeholders will be able to write in additional interventions not included in the list or indicate that no interventions are needed. They will also be able to select interventions for barriers not included in the Deliberative Forum agenda and Context-Setting Workbook.

Immediately following the Deliberative forum, we will assess stakeholders' perceptions of leadership responsiveness in the past year with two questions, which are scored on a five-point Likert-type scale ranging from "Strongly Disagree" to "Strongly Agree" together with free response boxes for comments and suggestions.

Immediately following the Deliberative forum, we will assess the barriers stakeholders perceive in their clinic (3 items; e.g., “In my clinic, the following are barriers: Concern that sealants make things worse”). These items will be scored on a five-point Likert-type scale ranging from “Strongly Disagree” to “Strongly Agree” together with free response boxes for comments and suggestions.

Immediately following the Deliberative Forum, we will measure stakeholders’ perceptions about the discussions using the following two items: “Today’s discussion gave me an understanding of important issues related to implementing the incipient caries guideline;” and “Today’s discussion caused me to consider points of view that I had not previously considered.” Both items are scored on a five-point Likert-type scale ranging from “Strongly Disagree” to “Strongly Agree” together with free response boxes for comments and suggestions. We are using these items to assess fidelity,.

To assess the implementation interventions adopted by the clinics, we will take several steps. First, we will provide a template to clinics that they can fill out to document progress of the implementation process for 3 months. We will collect copies of the progress sheet quarterly. After 3 months, select clinic staff will be invited for qualitative interviews and the progress sheets will serve as the basis for the interview to better understand the implementation process in the intervention clinics.

8.2 SAFETY ASSESSMENTS

N/A

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS

An adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

A serious adverse event (SAE) is one that meets one or more of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability or incapacity
- Results in a congenital anomaly or birth defect

An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize

the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events result in only mild, momentary psychological or physical discomfort that dissipates quickly and that can be resolved without outside intervention.
- **Moderate** – Events result in more prolonged and intense psychological or physical distress that may require informal outside intervention.
- **Severe** – Events result in significant psychological or physical distress that extends beyond the duration of a single focus group meeting and/or is associated with damage or destruction of physical property and/or necessitates the intervention of medical, local security, or police personnel.

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by appropriately trained study personnel. The degree of certainty about causality will be graded using the categories below.

- **Related** – The AE is known to occur with the study procedures, there is a reasonable possibility that the study procedures caused the AE, or there is a temporal relationship between the study procedures and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the AE.
- **Not Related** – There is not a reasonable possibility that the study procedures caused the event, there is no temporal relationship between the study procedures and event onset, or an alternate etiology has been established.

8.3.3.3 EXPECTEDNESS

There are no anticipated adverse effects associated with this protocol.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel (i.e., discussion group facilitator) during discussion group meetings. As no probing questions will be asked by the group facilitator, all AEs and SAEs will be treated as unsolicited events. Documentation and reporting of AEs and SAEs will occur throughout the duration of the study as

appropriate. If the AE or SAE is not resolved within the time period of the group meeting, subsequent meetings will be monitored for reoccurrence or escalation.

8.3.5 ADVERSE EVENT REPORTING

All AEs, not otherwise precluded per the protocol, will be documented by study personnel present at the time of occurrence. Documentation will include the time and date of the event, a brief description of the event, an assessment of severity, identification of the involved parties, and whether and how the issue was resolved. The event will be reported to the principal investigator within a reasonable timeframe, depending on the event's severity. Following report of the event, the principal investigator, site investigator, and the individual who recorded the event will evaluate safety events for relatedness and seriousness to the DD study intervention and discuss the necessity of taking corrective and/or preventive action.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

In consultation with the PI, a trained member of the study team will be responsible for conducting an evaluation of a serious adverse event and shall report the results of such evaluation to the reviewing Institutional Review Board (IRB) as soon as possible, but in no event later than 5 working days after the investigator first learns of the event.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

N/A

8.3.8 EVENTS OF SPECIAL INTEREST

N/A

8.3.9 REPORTING OF PREGNANCY

N/A

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or

others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 UNANTICIPATED PROBLEMS REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB) and the lead principal investigator (PI). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB, the lead PI, and to the study sponsor (University of Pittsburgh) within 5 days of the investigator becoming aware of the event
- Any other UP will be reported to the IRB, the lead PI, and to the study sponsor within one week of the investigator becoming aware of the problem
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within 30 days of the IRB's receipt of the report of the problem from the investigator]

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

N/A

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

- Primary Endpoint:

We hypothesize that compared with the pre-intervention period, following the intervention, providers will place or treatment plan sealants for significantly more of the occlusal non-cavitated carious lesions. Alternatively, our null hypothesis is that there will be no difference in the effects of Deliberative Democracy on guideline implementation.

- Secondary Endpoints:

We hypothesize that the Deliberative Loop will be cost effective at 6 months following participation in the Deliberative Loop forums.

9.2 SAMPLE SIZE DETERMINATION

The primary outcome is the change in the providers' rates of placing or treatment planning sealants for occlusal NCCLs from before to after clinic stakeholders are exposed to the Deliberative Loop intervention. Fifteen clinics will be randomized in a stepped wedge design. Three clinics will be randomized during each of five time periods. Our sample size will be the number of clinics participating in the trial, as well as the number of providers within those clinics.

Our null hypothesis is that the change in providers' rates of placing or treatment planning sealants for occlusal NCCLs is not different between the non-intervention and intervention periods. Our alternative hypothesis is that the change in providers' rates of placing or treatment planning sealants for occlusal NCCLs is different between the non-intervention and intervention periods. We will assume a Type I error of 0.05. Randomizing 15 clinics along with 1 vanguard clinic, using a stepped wedge approach, we will have at least 80% power, and close to 100% under several scenarios. This assumes the non-intervention period will see a 3% rate of placing or treatment planning sealants and the intervention period will see a 10% rate. Power was calculated using 50 as the average number of providers per clinic in a conservative scenario and 60 in a more realistic scenario using provider data from participating clinics. These increases are similar to those seen in similar interventions (Traeger, Lee, Hubscher, & al, 2019). The analysis assumes different level of intraclass correlation: 0.01, 0.1, and 0.25. The power calculation is was done using the "stepped wedge" package in Stata 16 (Hemming & Gerling 2014), based on the approach developed by Hussey and Hughes (2007).

9.3 POPULATIONS FOR ANALYSES

The population includes all providers who worked in a KPNW Dental clinic during the non-intervention and intervention periods. Providers in the study are dental care providers in KPNW dental clinics.

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

Categorical data will be presented as percentages, and continuous data will be presented as means with standard deviations. P-values will determine statistical significance with $p<0.05$ determining statistical significance. Shapiro-Wilk tests will be used to determine normality, and corresponding non-parametric tests will be used if necessary. A multi-level random effects regression model will be used with providers nested within clinics.

Randomization should eliminate the need to adjust for covariates in the analysis of the primary endpoint. We will not check for failures of randomization, as this practice has been determined to be unsound (de Boer, Waterlander, Kuijper, Steenhuis, & Twisk, 2015).

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

The primary end point will be calculated as the change in the providers' rates of placing or treatment planning sealants for occlusal NCCLs from before to after clinic stakeholders are exposed to the Deliberative Loop intervention. The PDA guideline includes children, adolescents, and adults. To enable comparison with studies following the ADA guideline, in addition to analyzing lesions occurring in children, adolescents, and adults, we will also conduct analyses for lesions occurring in just children and adolescents. Per the ADA, we will define "children and adolescents" as persons ranging in age from 6 through 17. The rates, and their difference, will be treated as continuous variables. We will compare the change in providers' rates of placing or treatment planning sealants between the intervention and non-intervention periods by using a multi-level modeling approach. . We will use a generalized linear model or generalized estimating equations to model the intervention effect while nesting sealant outcomes within provider and accounting for secular trends, if necessary. In this scenario, we will treat the change in the provider's rate of placing or treatment planning sealants as the outcome variable and examine the clinic-level effects of the intervention.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

Treatment planned sealants resolved. Health Connect data are used to identify occlusal surfaces with an NCCL with a treatment plan and plan date and to record subsequent resolution of the treatment plan for patients with a dental office visit during the evaluation period. The resolution of the treatment plan may include a sealant placement, other procedure, revision of the treatment plan, or no additional procedures.

Program costs for the DD intervention. We will quantify total program costs, total costs per clinic, and total costs per member per month (PMPM). Total costs to the health system and mean total costs per clinic will be assessed, including personnel time, facility space, and materials and supplies used in the development, delivery, and clinic implementation of the Deliberative Loop. Resources used beyond a 6-month study period will be adjusted (discounted) to a single dollar year using an appropriate medical services inflation rate. Given that the intervention is expected to change treatment patterns for NCCLs,

expenditures for treatment strategies (procedures) on eligible occlusal tooth surfaces will also be evaluated during the non-intervention and intervention periods. Intervention and NCCL treatment costs during a 6-month clinic evaluation period will be annualized as necessary given the staggered rollout of the intervention across participating dental offices.

Cost data for the Deliberative Loop will be obtained for staff time, facility space use, and supplies. We use a replication cost approach to estimate the costs of the tested intervention and usual care "as if" the health system/clinic was managing the process. We will work with KPNW and PDA staff time to develop realistic real-world estimates of the staff time and resources used to develop and print a context setting workbook, including staff time that would be needed to conduct an appropriate literature review, collect and assess health records data, develop clinic monitoring processes, and prepare, print and distribute a completed context setting workbook. This is necessary because study staff has been responsible for developing the context setting workbook. Staff time for meetings, context setting workbook review, the Deliberative Loop intervention, and relevant clinic follow-up meetings will be documented, and average labor costs, by profession type, will be assigned. Facility space for DD session meetings and subsequent clinic follow-up meetings will be obtained and valued using local rental costs per square foot. Costs for selected implementation interventions (equipment, trainings, CE, staff time) will be obtained from clinic managers and other KPNW and PDA staff during the implementation period. Treatment costs (procedure costs based on local market paid claims) for eligible tooth surfaces and patient-paid costs will be obtained from the electronic health records.

Cost-effectiveness analysis. The incremental CEA will be conducted to quantify the additional intervention costs associated with increasing the sealant placement rates during the intervention period compared with the non-intervention period. An incremental cost-effectiveness ratio (ICER) will be estimated using the following formula: (mTCi – mTCni) / (mSPRi – mSPRni), where mTCi and mTCni represent the mean total intervention costs for intervention and non-intervention periods, including NCCL treatment costs, and mSPRi and mSPRni represent the mean cumulative sealant placement rates for eligible teeth among patients with a routine care visit during intervention and non-intervention periods. We include treatment planned sealants in the numerators. We also estimate ICERs that exclude treatment planned NCCLs from the numerator if they remain unsealed at the end of the evaluation period. This provides a more conservative estimate of cost-effectiveness.

Treatment costs and CEA results for the health system or clinic may vary based on differences in implementation interventions, treatment practices for eligible teeth, and the proportion of treatment costs paid by patients. The availability of these data will allow us to conduct exploratory analyses to assess the impact of variations in these factors on program costs and CEA results.

We will calculate ICERs and confidence intervals using appropriate statistical methods based on the data (Gold, Siegel, Russell, & WEinstein, 1996). We expect differences in both costs and sealant placement rates to be unequivocally positive. If, however, the results are equivocal we will conduct simulation modeling using bootstrapping and incremental net benefit approaches to assess the effects of model input variability on outcomes (Fenwick, O'Brian, & Briggs, 2004; Hunink et al., 2014; Nixon, Wonderling, & Grieve, 2010). Incremental net benefit analysis allows adjustment for known statistical issues associated with confidence intervals (CIs) for equivocal ICERs by estimating CIs around the organizations (payer's) willingness to pay for the intervention.

The cost and cost-effectiveness analyses do not expect to include downstream sequalae associated with the potential arrest of sealed NCCLs or retreatment, due to the limited evaluation period for this study.

However, we will examine tooth-level data to determine the frequency of repeat procedures on included occlusal tooth surfaces and include these data if appropriate.

9.4.4 SAFETY ANALYSES

N/A

9.4.5 BASELINE DESCRIPTIVE STATISTICS

Baseline sealant application rates will be calculated for each clinic as stated above.

9.4.6 PLANNED INTERIM ANALYSES

After each session, we will calculate descriptive statistics for the two survey items assessing fidelity to determine the facilitators are maintaining fidelity to the intervention.

9.4.7 SUB-GROUP ANALYSES

N/A

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

Individual participant data will not be listed by measure and time point.

9.4.9 EXPLORATORY ANALYSES

Target of the Intervention

We will use descriptive statistics to characterize the target of the intervention.

Feasibility and Acceptability

We will use descriptive statistics to quantify the perceptions of the KPNW and PDA management teams' ratings of the acceptability and feasibility of the deliberative loop.

We will use descriptive statistics to summarize the results of the stakeholders' ratings of acceptability.

Mediator: Voice

We will use mediation analysis to examine the effect of voice as a mediator in the relationship between deliberative democracy and guideline adherence. We will use causal inference methods (VanderWeele & Vansteelandt, 2014) that have been extended to allow for multiple mediators, as well as exposure-mediator and mediator-mediator interactions. Their framework includes both regression-based approaches and approaches based on inverse probability weighting. We will default to the regression-

based approach. If model fitting issues are present, we will use the inverse probability weighting approach.

Characterizing the DD Process

To determine whether there are differences in the change in perception of leadership responsiveness as a result of the intervention, we will use t-tests. We will use descriptive statistics to summarize the results of the measures of barriers identified.

We will conduct an exploratory qualitative analysis to track, document and analyze the progress of implementation interventions that clinics select for implementation. These data will enable us to understand and contextualize quantitative data collected. If for example there is no clear effect of our intervention, qualitative data can help identify differences in the implementation process among clinics.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

We were granted a waiver of signed informed consent for deliberative loop session participants by the KPNW IRB. A fact sheet describing in detail the study intervention, study procedures, and risk of harms / benefits will outline all elements of consent and will be given to the participant.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

We were granted a waiver of signed informed consent for the following:

1. Stakeholders who participate in the vanguard study deliberative loop forums.

2. Stakeholders who participate in the stepped wedge deliberative loop forums.

We were granted a waiver of consent for:

1. To enable collection and use of patient data from the electronic health records and administrative data for study purposes. The randomized trial uses a data-only process for evaluating study outcomes. We do not expect to consent patients to be part of the evaluation. Consenting patients is not feasible.

Note: Requesting written consent would disrupt clinic operations and deter staff from participating in the forum. We will give participants a fact sheet, which provides an overview of the study, study procedures, and risks / benefits, and outlines all elements of consent. The fact sheet states: "There is no penalty if a study participant decides not to participate, and participation may stop at any time." We will allow time for participants to ask questions. This process will be documented. Any unforeseen need to modify the consent process will be reviewed by the KPNW IRB prior to implementation.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor/funding agency and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Determination that the primary endpoint has been met

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, or other relevant regulatory or oversight bodies.

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the sponsor(s) and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

Certificate of Confidentiality

To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical, or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (https://humansubjects.nih.gov/coc/index). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and

maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

N/A

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator	**KPNW Investigator**	**Medical Monitor**
Deborah Polk, PhD Assistant Professor	Jeffrey L. Fellows, PhD Senior Investigator	Kevin McBryde, MD Medical Monitor
University of Pittsburgh	Kaiser Permanente Center for Health Research	NIDCR
381 Salk Hall - 3501 Terrace Street Pittsburgh, PA 15261	3800 N. Interstate Ave. Portland, OR 97227	6701 Democracy Blvd Bethesda, MD 20817
412-648-8656	503-335-6784	301-594-0170
Dpolk@pitt.edu	Jeffrey.Fellows@kpchr.org	kevin.mcbryde@nih.gov

In addition, a Core Committee provides regular oversight and decision-making for the study.

10.1.6 SAFETY OVERSIGHT

In addition to the PI's responsibility for oversight, study oversight will be standard oversight. Reporting will occur via the annual Research Performance Progress Report and enrollment reports. There will be six enrollment reports total. The first will be due two weeks after the Deliberative Loop session is completed for the vanguard clinic; and subsequent enrollment reports will be due two weeks after the completion of the last Deliberative Loop session in each step of the stepped wedge design.

A data and safety monitoring plan will be implemented by the Principal Investigator to ensure that there are no changes in the risk/benefit ratio during the course of the study and that confidentiality of research data is maintained. Investigators will meet annually at minimum to discuss the study (e.g. study goals and modifications of those goals; progress in data coding and analysis; documentation, identification of adverse events or research subject complaints; violations of confidentiality) and address any issues or concerns at that time. Any instances of adverse events will be reported to the KPNW IRB using standard forms and/or procedures that have been established by the IRB.

10.1.7 CLINICAL MONITORING

No outside clinical site monitoring will be employed for this study. The Principal Investigator(s) and staff will closely monitor the subjects as they progress through the study. They will monitor and evaluate study processes and documentation based on the International Council for Harmonisation (ICH), E6: Good Clinical Practice guidelines (GCP), and internal quality management plans. The NIDCR reserves the right to conduct independent clinical site monitoring as necessary.

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

Quality Assurance (QA) procedures will include the creation of standard operating procedures that address the following activities:

- **Data Review***:*
    - Recordings of Deliberative forums will be reviewed for fidelity within one week of recording by a qualitative research associate.
    - EHR data: CHR implements a quality control process when extracting the data from the EHR.
- **QA and QC Issues**. The principal investigator will discuss QA and QC issues with relevant study personnel and determine appropriate corrective/preventive actions.
- **Study Staff Training.** All study personnel will be trained on the study protocol and will participate in human research subjects training. Personnel also will be trained on standard operating procedures relevant to their roles and responsibilities. All training will be documented.
- For a description of the plans for tracking compliance with the treatment fidelity evaluations, please see section 6.2.1.

Each clinical site will perform internal quality management of study conduct, data collection, documentation and completion. All sites will follow a common quality management plan.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection from individuals: Practitioner / staff data will be collected from recordings of the DD sessions and surveys.

Data measuring provider adherence to the guideline will be collected from the KPNW data systems. No patients will be contacted to collect data. To reduce the risk of breaching confidentiality, records will be identified only with a unique ID# on a secure server. We will use the Participant ID number established by KP CHR instead of MRNs. The analyst will have sole access to and maintain a link file for patient ID and MRN number. Other study team members with access to individual-level data will not have access to MRNs.

Data storage plan and access: All individual-level study data obtained from the electronic records systems and DD session will be stored on a password-protected file service at Kaiser Permanente Center for Health Research (CHR), consistent with established CHR protocols. Access to individual patient data will be stored in a study (top) file service that is restricted to CHR analysts, Principal Investigator, and project manager. Non-CHR study staff will not have access to the individual-level data stored on the file service. At the University of Pittsburgh, all data will be stored on password-protected Box account in the cloud. Only the study biostatistician will have access to the raw data.

All study staff will be HSP and FCOI trained and follow CHR protocols for data sharing.

Data sharing: A limited data set will be shared with external (outside of KP) study team members. Data use and transfer agreements will be established as necessary before data are shared with external study partners. All study data will be sent via secure file transfer (SFT) or encrypted email. No information will be released in any publication or presentation that will enable identification of participants. No one outside the research process will have access to results about any individual.

Clinical data will be aggregated monthly and de-identified data (sealant placement rates) will be shared with DISGO study staff. Periodically during the intervention period and at its completion, a limited data set will be compiled and shared with the study statistician for ongoing monitoring and to support reporting and manuscript development

10.1.9.2 STUDY RECORDS RETENTION

Once the study is completed and manuscript preparation has ended, all study data will be archived and/or destroyed (electronic files deleted; paper files securely disposed) following CHR protocols and NIH requirements.

10.1.10 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the protocol, noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

It will be the responsibility of the site investigator and project manager to use continuous vigilance to identify and report deviations as part of the Medical Monitor Oversight Report. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements.

10.1.11 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers up to five years after the completion of the primary endpoint by contacting Jeffrey L. Fellows, Kaiser Permanente Center for Health Research. Considerations for ensuring confidentiality of these shared data are described in Section 10.1.3.

10.1.12 CONFLICT OF INTEREST POLICY

Any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

10.2 ADDITIONAL CONSIDERATIONS

N/A

10.3 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
CEA	Cost-Effectiveness Analysis
CFR	Code of Federal Regulations
CRF	Case Report Form
CHR	Center for Health Research
CRA	Caries Risk Assessment
DCC	Data Coordinating Center
DD	Deliberative Democracy
DL	Deliberative Loop
DSMB	Data Safety Monitoring Board
E1/E2	Enamel Lesions
EFDA	Expanded-Function Dental Assistant

EHR	Electronic Health Record
FCOI	Financial Conflict of Interest
HSP	Human Subjects Protections
ID	Identification
IRB	Institutional Review Board
IS	Implementation Strategies
ISM	Independent Safety Monitor
ITT	Intention-To-Treat
KPNW	Kaiser Permanente Northwest
MOP	Manual of Procedures
MRN	Medical Record Number
NCCL	Noncavitated carious lesion
NIDCR	National Institute of Dental and Craniofacial Research
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHP	Oregon Health Plan
PCA	Program Cost Analysis
PDA	Permanente Dental Associates
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
SFT	Secure File Transfer
UP	Unanticipated Problem
US	United States

10.4 PROTOCOL AMENDMENT HISTORY

Version	Date	Description of Change	Brief Rationale

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