



Spanning Miles in Linking Everyone to Services

SMILES DENTAL PROJECT®: PROJECT MODEL, CLINICAL GUIDANCE, AND ADDITIONAL PROGRAMMATIC CONSIDERATIONS

SMILES DENTAL PROJECT® MODEL: Philosophy and Goals

The *SMILES* Dental Project® provides a dental home, (an ongoing relationship), to patients who may face various challenges to receiving dental care from dentists working in traditional settings. By deploying registered dental hygienists (RDH) to provide continuously accessible care to patients under general supervision at other sites when/where the dentist is not present, some barriers are reduced. The dental hygienist is an extension of dentists who are knowledgeable about the hygienist’s capabilities and collaborate with them through sharing key information, “virtually” examining the patient and jointly¹ developing treatment plans for the dental hygienist to execute. This is accomplished in a person- or family-centered way, meaning that it respects that there are demands/challenges to the person that may make it easier to receive care in a community setting and difficult for them to perform all expectations of an ideal patient, including presenting for care to the dental clinic at a scheduled date and time.

Tooth decay (dental caries) is a chronic disease that for most people is the dental condition most likely to threaten their well-being and their ability to live full, productive and rewarding lives. Modern dental science provides methods to control dental caries and successfully keep it from affecting the well-being of most people. *SMILES* teams identify caries that can be controlled by services within the scope of practice of the dental hygienist working remotely² in the community site and secure patient/parent consent to receive services there. They also identify conditions that require immediate treatment that only dentists can provide, and assist the patient (communication and persuasion from both dentist and dental hygienist, along with assistance from patient navigators and other social supports and services) in getting to the dentist to receive that treatment. (See *SMILES* Dental Project Model graphic.)

Caries is best controlled at the person and tooth level. Person-level methods for caries control can be effectively executed by the dental hygienist (e.g. hygiene and dietary advice and topical fluorides targeting the entire mouth). Person level risk factors can also guide selection of tooth-specific treatment, (e.g. choice of restorative materials and methods for people at high risk of caries).

¹ Dentists, by law, are solely responsible for developing treatment plans, but to be effective in community settings where the dentist is not physically present the plans need to be formulated with dental hygienist input. The hygienist may know more about the patient’s/family’s interests and concerns and ability to adhere to treatment recommendations, and also knows more about the limitations of her own skills (particularly important for placing ITRs in difficult situations).

² Throughout this document “remote” refers only to the fact that the hygienist is working in a facility OTHER than the one in which the dentist-of-record is working. It does not imply an extreme distance from the dentist’s clinic.

Benefits of Silver Diamine Fluoride (SDF) and Interim Therapeutic Restorations (ITR)

SMILES dental teams recognize dental caries as a chronic disease that is highly prevalent in the communities they serve. They recognize primary prevention as a goal, even if not always achievable. They also recognize that while restoration of lesions is important, they do not control the disease or reduce the risk of further damage. High priority is given to building relationships with patients and their families by providing primary preventive services, including patient education, in settings convenient to the patients. Periodic recall provides opportunities for the dental team to assess progress in controlling caries, provide additional primary preventive services based on risk, and intervene where caries remain active.

Caries can be detected at the tooth level at both early (non-cavitated, macroscopically intact) and late (cavitated) stages. The most prevalent sites for caries in permanent teeth are occlusal fissures and buccal/lingual pits on first and second permanent molars. ADA guidelines recommend dental sealants be placed on both sound teeth and those with non-cavitated lesions. There is insufficient evidence to recommend glass ionomer over resin as a sealant material or vice versa, although glass ionomer is recommended when maintaining a dry field is not possible. While retention of resin sealants is higher, limited evidence suggests that there is not a difference in caries prevention effectiveness, which is the goal of preventive treatment.

For cavitated lesions, the American Dental Association (ADA) and American Academy of Pediatric Dentistry (AAPD) have issued guidelines for the use of silver diamine fluoride (SDF) and Interim Therapeutic Restorations (ITRs) for:

- patients who are unable to tolerate traditional restorative treatment
- young patients or those with special health care needs, when general anesthetic is not preferred
- patients with multiple cavitated caries lesions that may not all be treated in one visit
- difficult to treat cavitated dental caries lesions
- patients without access to or with difficulty accessing dental care
- when it is necessary to offer a less costly or less invasive alternative
- situations in which traditional cavity preparation and/or placement of traditional dental restorations are not feasible

Feasible has many synonyms, including possible, achievable, and reasonable. Since accessing care at a dental clinic depends on the patient's/parent's perspective, they (perhaps more than specific clinical circumstances) determine what is "feasible".

Caries prevention and caries control services should be provided whenever and wherever possible, except when they will lower the long-term prognosis for the affected teeth. Both SDF and ITRs are treatment options available to *SMILES* dental hygienists. Importantly, neither of those services preclude or limit treatment options for dentists who may provide further care in the future.

The *SMILES* Dental Project® graphic models present the overall strategy of care and summarize some of the decisions for developing treatment plans and determining which patients and which teeth can be well-served by care in the community setting and which circumstances warrant either routine or urgent referral to dental clinics.

Treatment options available to *SMILES* dental hygienists predictably have high short-term effectiveness as measured by three-year success rates. Semi-annual applications of 38% SDF arrest caries in 90% of primary teeth and 70% of permanent teeth. SDF is not a viable treatment option when patients/parents have cosmetic concerns, and generally would never be offered as a preferred treatment option for anterior permanent teeth. Success rates for single-surface and multiple-surface Interim Therapeutic Restorations (ITRs) in permanent posterior teeth over 3 years are over 85%.³ Two-year success rates for ITRs in primary teeth is not much different than that of conventional restorations. All restorations must be monitored to identify deterioration or failure over time.

In contrast to the predictability of restoration success, for many patients it is difficult to predict their (or their parent's) ability to access a full course of care at the dental clinic, especially those with no history of having received care at the clinic. In fact, in many cases the patients themselves, however well-intentioned, cannot predict how they will respond to treatment in terms of their continued commitment and ability to access a full course of treatment at the dental clinic. **The use of SDF and ITR at the point of care most convenient for the patient is an effective course of care.** In the face of uncertainty, it is reasonable for dentists to treatment plan ITRs for the dental hygienist to place in every cavity unless the likelihood that the patient will complete a full course of traditional restorative care at the clinic exceeds 85%, the rate of successful caries control from services that can be provide by the hygienist.

Establishing Relationships and Building Trust in the Community Setting

Among the principles followed by the registered dental hygienist in their role as the dental home's most accessible point of contact for patients is to provide services atraumatically, (without stress or discomfort), so as to reduce anxiety of patients with regard to the seeking of further care. Another principle is to develop trust and understanding, both to influence patient self-management and to more effectively support patient adherence to recommendations to present for services that can only be provided at the dental clinic. Together these should increase the probability, (but cannot assure), that a patient will access care at the clinic when necessary, and minimize the number of visits needed at the clinic to complete the control of caries (and perhaps even restoration of form and function). This approach challenges the notion that by providing some services at the community site patients will be less inclined to follow the recommendations of the dental hygienist to access further care at the clinic. ***SMILES* programs recognize that barriers to accessing services at the clinic already exist and assert that the relationship established by the registered dental hygienist will increase adherence to referral recommendations.**

Both young children and vulnerable adults are extremely apprehensive patients who may be resistant to invasive dental procedures and/or whose fear discourages a caregiver from taking them to the dentist. Whether care is provided by a registered dental hygienist in the community setting or by a dentist at a full-service clinic, less invasive alternatives may be indicated to control caries until which time the fear can be better managed.

³ Interim Therapeutic Restorations is terminology established by the American Academy of Pediatric Dentistry to refer to what the rest of the world calls restorations placed by the Atraumatic Restorative Technique (ART). All studies documenting the effectiveness of ART restorations over time use that terminology. We are making a translation here to apply those findings to ITRs, since they use exactly the same technique.

By maximizing the use of treatment modalities for cavitated lesions by registered dental hygienist at community sites for those patients who might otherwise receive no services for those lesions at all, *SMILES* teams can achieve a level of caries control that prevents dental caries from being a threat to patient well-being. Taken altogether, this suggests that **treatment plans should prioritize use of SDF and ITRs for cavitated caries lesions at the community site**, except when they are contraindicated or when they would delay treatment of teeth that are at risk of pulp death or infection if not provided as soon as possible at the clinic.

Evidence-based Chronic Disease Management for Dental Caries in the Community Setting

Although caries for people of all ages, including children younger than 6 years old, has been traditionally managed with conventional restorative care, there are limits to the long-term success of restorative care alone. Given the difficulty of providing restorative care to young children, dentists have begun to embrace strategies aimed at controlling caries emphasizing patient-specific recall strategies and deferring definitive restorative care. Canares et al have team developed care pathways for general dentists for evidence-based early childhood caries chronic disease management (Canares, General Dentistry, 2018).

The *SMILES* project model also addresses caries as a chronic disease. While the evidence to support the Canares care pathways focuses on primary (deciduous) teeth, basic principles for the control of dental caries are very similar for permanent teeth. While inspired by the Canares model, *SMILES* goes further by addressing caries in permanent teeth and by providing the option for much of the required care to be delivered at a location remote from the dentist. *SMILES* dental teams control caries for as many teeth as possible in the community setting. Patients/parents are educated and informed about needs that cannot be met in that setting and the urgency to seek further care by a dentist, and (when available) patient navigators provide assistance to patients with urgent needs. (See Evidence-based Chronic Disease Management for Dental Caries graphic.)

For a young child with decay, the primary goal is to preserve the tooth until it falls out naturally or until decay can be managed without having to put the child under general anesthesia or use some form of sedation. This reduces risks to the child. While children seen in schools at age 5 can cooperate for traditional restorations, that should not preclude considering whether the goal of preserving the primary tooth can be achieved with SDF and/or ITR. Preservation of pulp health is much more important than restoration of tooth form.

For permanent teeth, the goal should be to preserve as much healthy tooth tissue as possible for a lifetime. Available information suggests that SDF can achieve that for only 70% of teeth, which is why eventually we strive to provide patients traditional restorations to increase the likelihood of long-term success, as well as restore form and function. However, until receipt of a traditional restoration can be assured, an ITR can be justified. Moreover, until placement of an ITR can be assured, use of SDF can be justified. Most modern discussion of caries management assumes all decisions are made by dentists with patients who can present for care at the time and place that is convenient for the dentist and his/her team. Because *SMILES* teams provide considerable care in the community setting, and patients vary widely in their ability to adhere to expectations for referral to the dental clinic, each *SMILES* team may need to develop specific protocols for frequency of recall, what services are provided in the community setting, and how referrals are managed and supported.

Guidance for prevention and reinforcement of home care strategies and the development of healthy habits is readily available, and many members of *SMILES* teams have considerable experience providing these patient-level services in community settings. For new patients with active caries or current patients for whom primary prevention has failed, *SMILES* sites have had to develop their own guidance for the provision of caries-arresting services in the community setting for specific teeth. Prior to regulatory changes to make *SMILES* programs possible, these services could only be provided by dentists. **The remainder of this document has been prepared to support the development of protocols for *SMILES* teams.**

ADDITIONAL *SMILES* CLINICAL AND PROGRAMMATIC CONSIDERATIONS

A. Terminology and Relationships

How do we understand the relationship of dental team members with one another? This may not entirely follow terminology of the state dental board and practice act, which can be reconciled later. A dentist conducts a **“virtual” exam** and develops a treatment plan. They are guiding the dental hygienist’s treatment, which may or may not be considered “supervising” the registered dental hygienist (RDH). Traditional treatment planning would imply that the recommendations for treatment at the clinic implicitly limit what the registered dental hygienist could do for the tooth,, but this makes no provisions for what the RDH can or should do with the tooth if the patient does not access dental care within some expected time frame. This suggests that as experience with the *SMILES* model is gained more flexible, non-traditional treatment plans may be developed. (See section on Flexible Treatment Plans Responsive to Fluctuating Patient/Parent Intentions below.)

The **“examining” dentist** is the one conducting the virtual examination AND providing a treatment plan. (There is not much value to conducting the exam unless it is for the purpose of developing a treatment plan.) Under Colorado law, the “examining” dentist limits the services the dental hygienist can provide to specific teeth, even if her training and the scope of her practice would enable her to do more. The “examining” dentists controls only the services that the registered dental hygienist provides. Once the patient goes to a dental clinic, whichever dentist is treating the patient will decide the specific services recommended and the order in which they will be provided. In cases where no treatment other than prophylaxis, topical fluoride, and sealants have been provided remotely by the registered dental hygienist, the “examining” dentist’s treatment plan serves merely as a “second opinion” for the treating dentist. When the “examining” dentist has authorized the registered dental hygienist to provide caries-arresting services (SDF and ITR) prior to the patient’s visit to the clinic, the treating dentist is free to independently assess the status of teeth that received the caries-arresting services and plan their own treatment.

It is more complicated when the “examining dentist” has treatment planned the patient to receive some services at the dental clinic that can ONLY be provided at the dental clinic, but has also authorized the registered dental hygienist to provide some services for teeth where there is less urgency that they receive “definitive” restorative care. In these cases, the patient benefits if the treating dentist is aware of the capabilities of the *SMILES* project registered dental hygienist and can discuss with the patient the

pros and cons of options for which teeth will be treated at the dental clinic and which could be treated at the community site. The patient is not well served if the only option they are given is to return to the dental clinic, and the RDH who could provide care for that patient at the community setting is left with no guidance or information to intercede.

Who is the patient's primary dental care provider? Who assures continuity? If the dentist is the primary provider, then they may be responsible to follow up with patients who haven't completed their treatment plan to learn reasons why and offer alternatives. Another option would be to consider the registered dental hygienist the primary dental care provider, and have him/her monitor the status of treatment plans completed so that he/she can initiate recall visits at the community site. Ideally, it is the dental practice/clinic that assumes responsibility as primary care provider, with all members of the team contributing as they can, but to keep patients from "falling through the cracks" it may be necessary to identify the specific team member who is responsible to prevent that.

B. Tooth-specific Decision Making

It is challenging to develop treatment plans for individual teeth with carious lesions in the face of uncertainty about which options the patient/parent will find acceptable and whether they will be motivated and able to receive them. This challenge exists whether the care is provided at the community (school) setting or in the dental clinic.

The *SMILES* Dental Project® graphic models present the overall strategy of care and summarize some of the decisions for developing treatment plans and determining which patients and which teeth can be well-served by care in the community setting, but are necessarily over simplified. **The finding that at least one tooth requires services that only a dentist can provide should not preclude the provision of other services in the community setting.** Also, "caries present" in the graphics refers to cavitated lesions. ADA guidelines since 2016 have recommended dental sealants as the preferred treatment for non-cavitated caries lesions in pits and fissures.

When smooth-surface lesions are limited to enamel and not involving the dentin, also known as incipient lesions, demineralization spots, or white-spot lesions, the ADA clinical practice guideline recommends 5% NaF varnish or fluoride gels or mouthrinses as immediate clinical treatment, and other guidelines recommend prescribing daily brushing with 5,000 ppm fluoride (1.1% NaF) toothpaste or gel. Because these lesions may take 2-3 years to progress to dentin, immediate restorative treatment is not recommended if the condition can be monitored at least annually. However, if the patient's caries risk status is high or ability to adhere to effective home care is low, SDF could be placed on these lesions in the absence of cosmetic concerns, since clinical studies have demonstrated effectiveness in stopping progression into dentin of lesions limited to enamel.

It seems that greatest uncertainty is associated with cavitated lesions or non-cavitated lesions involving dentin (detected radiographically), specifically, whether to treat any with 38% silver diamine fluoride (SDF) or interim therapeutic restorations (ITRs) at the community site when the ideal treatment would be placement of more durable restorations by a dentist at a traditional site, even if that would require several more visits. The advantage of the school or community setting is that several potential barriers are eliminated, and the timing of both the immediate and subsequent (follow-up) treatment can be controlled by the dental team.

C. Endorsement of SDF and ITRs by the ADA and AAPD

The AAPD expert panel (AAPD, 2017) supported the use of 38% solution silver diamine fluoride (SDF) for the arrest of cavitated carious lesions in primary teeth as part of a comprehensive caries management program. More recently, the ADA Clinical Practice Guideline for Non-restorative Treatments for Carious Lesions recommended 38% SDF as an appropriate treatment for cavitated lesions on any tooth surface of any primary or permanent tooth and for non-cavitated root surface lesions (Slayton, 2018). SDF is only indicated for active cavitated caries lesions with no clinical signs of pulp involvement. Because of esthetic concerns, its use for facial surfaces of anterior teeth are limited, especially for permanent teeth.

Biannual application of SDF for even advanced cavitated lesions may be indicated for:

- uncooperative patients (unable to tolerate restorative treatment)
- patients when general anesthetic is not preferred
- patients with multiple cavitated caries lesions that may not all be treated in one visit
- difficult to treat cavitated dental caries lesions
- patients without access to or with difficulty accessing dental care
- when it is necessary to offer a less costly or less invasive alternative

Interim Therapeutic Restoration (ITR) is a name coined by AAPD, referring to the Atraumatic Restorative Technique, which has a 25+ year record of study, mostly documented in reports from other countries. AAPD has recognized the effectiveness of ITR in controlling the progress of dental caries and restoring function, as well as reducing levels of cariogenic bacteria in the mouth, and its appropriate use for:

- young patients
- uncooperative patients
- patients with special health care needs
- situations in which traditional cavity preparation and/or placement of traditional dental restorations are not feasible
- children with multiple carious lesions prior to definitive restoration of the teeth.

It should be noted that the recommendations from the ADA and AAPD on SDF and ITRs were made by separate committees. Also, while the ADA addressed SDF as a recommended non-restorative treatment for carious lesions in 2018, its recommendation for restorative treatment (which would include ITRs) is not expected to be released until 2020. Therefore, *SMILES* dental teams will need to use their own clinical judgement to determine the circumstances under which SDF or ITRs should be used for specific teeth with cavitated lesions. As a general rule, ITRs will be placed when feasible, and SDF will be used when access to the cavity is too limited to enable placement of an ITR. In other situations, SDF may be used on multiple teeth at a single visit to assure at least some chance of arresting caries in the face of uncertainty about whether the patient will be able to return to have ITRs placed on each.

Previously, some dentists were concerned that the selective removal of carious dentin necessitated by placing ITRs in unanesthetized teeth compromised long term success. The AAPD Guideline on Restorative Dentistry notes that systematic reviews have confirmed that selective (in contrast to complete or two-stage) caries removal is associated with higher pulpal survival rates. (AAPD, 2014) This suggests that the only thing that should differ between an ITR placed with hand instruments and a glass ionomer restoration placed under anesthesia in the dental clinic will be the removal of some additional

sound tooth tissue with rotary instrument in the latter setting to achieve optimal bulk of restorative material and, perhaps, remove some “unsupported enamel” that might otherwise, at some later date, fracture and expose the underlying restoration and dentin to the biofilm

While AAPD asserts that ITR is not the definitive treatment for dental caries, it does not provide any guidance regarding when or if such restorations should be replaced. Like all restorations, they should be periodically monitored to assure they are still providing service, (protecting dentin from cariogenic biofilm). The continuity of care and ability to monitor restorations that is provided by dental hygienists working in school programs arguably is even better than that provided by clinicians working in clinics that require patient adherence to recall recommendations.

D. Other Considerations regarding Silver Diamine Fluoride (SDF)

Whether provided by dentist or registered dental hygienist (RDH), informed consent from patient/parent must be obtained with specific discussion of the anticipated cosmetic outcome. This discussion should include the potential for more esthetic restorative treatment of the involved areas at some time in the future.

When lesions are limited to enamel and not involving the dentin, also known as incipient lesions, demineralization spots, or white-spot lesions, the ADA guideline recommends 5% NaF varnish or fluoride gels or mouth rinses as immediate clinical treatment, and other guidelines recommend prescribing daily brushing with 5,000 ppm fluoride (1.1% NaF) toothpaste or gel. Because these lesions may take 2-3 years to progress to dentin, immediate restorative treatment is not recommended if the condition can be monitored at least annually. However, if the patient’s caries risk status is high or ability to adhere to effective home care is low, SDF could be placed on these lesions in the absence of cosmetic concerns, since clinical studies have demonstrated effectiveness in stopping progression into dentin of lesions limited to enamel.

The ADA guideline recommends SDF only for cavitated caries lesions. However, Horst and Heima maintain that SDF also has proven efficacy in prevention, ie, decreasing the incidence of new caries lesions (Horst, 2019). Their analysis of nine clinical trials in children shows that SDF prevented 61% of new lesions compared to controls. The preventive effect appears to be immediate and maintains at the same fraction over time. Direct comparisons of SDF applied once per year with alternative treatments show that SDF is more effective than other topical fluorides placed two to four times per year and more cost-effective than dental sealants. Enamel lesions may be even more responsive than cavitated dentin lesions. Annual application of SDF to high-risk surfaces (eg, mesial surfaces of permanent first molars where the distal surface of the second primary molar is carious) in patients with any risk of new caries lesions appears to be the most cost-effective approach available to prevent dental caries. SDF is an underutilized evidence-based preventive agent for dental caries.

The ADA guideline did not recommend SDF for non-cavitated interproximal lesions radiographically into dentin because there is no direct evidence to support that, even though the experience with cavitated lesions suggests that SDF could remineralize the enamel and arrest the progression into dentin. A clinical trial is being conducted at the University of Iowa to test this. The technique uses Isovac for isolation of the site. They prophylax and floss the tooth, then wash and dry the tooth with air well. They apply the SDF with a microbrush through occlusal, facial and lingual embrasures, allowing capillary action to draw the SDF further onto the interproximal surface. They allow SDF to contact the tooth for 2

minutes (no washing) after which they paint with NaF varnish. They do not use air to force the SDF into the space or SDF on floss, as both have been shown to make a mess with (temporary) silver stains where it is not desired, (including “whiskers” on some patient’s cheeks). While *SMILES* clinicians may not be able to justify this service on the basis of established clinical practice guidelines, it is a reasonable approach to use in community settings where there is concern that the patient may not access the dental clinic for restorative care. And if the procedure is effective in arresting caries, it may turn out to have been a better treatment than traditional restorative care.

E. Other Considerations regarding Interim Therapeutic Restorations (ITR)

Long-term studies of ITR have been conducted globally using the terminology of Atraumatic Restorative Technique (ART). There is no reason to believe success rates in the U.S. would not be similar. U.S. experience has been stifled by considering these restorations to be “interim” and thereby not requiring any justification for their replacement by “definitive” restorations. From systematic reviews and meta-analysis of ART failure rates for one surface and two surface restorations are known.⁴ For treatment planning in the *SMILES* program, the questions are: “How does that rate of failure compare to likelihood of patient accessing care at dental clinic to have that tooth restored by conventional methods? Which approach (ITR or referral) has highest likelihood of achieving caries control?”

Survival percentages of single-surface and multiple-surface ART restorations in primary posterior teeth over 2 years were 94% and 65%, respectively. For single-surface and multiple-surface ART restorations in permanent posterior teeth over 3 years were 87%. This suggests that there is no urgency for patients with ITRs in permanent teeth to go to a dental clinic to have them replaced with traditional restorations, but also justifies their replacement, especially for multiple surface restorations, even if fully intact when assessed by the dentist.

There is obviously a ‘learning curve’ for both dentists and dental hygienists in technique and use of a material which handles much differently than resin or composite, and survival of restorations placed by *SMILES* clinicians may initially may not be as high as those in clinical trials that have informed the meta-analysis. New materials are arriving each year, but it may take some time to determine best circumstances for the use of each. Even at this early stage of experience, it is difficult to justify not placing an ITR where the dental hygienist has confidence that she can, especially given the ability of the *SMILES* program to monitor status and refer the patient for “definitive” restoration as needed.

Recently there is a movement in the U.S. to use both SDF and the ART technique, which has been referred to as “SMART”, given evidence that SDF does not interfere with the ability of the glass ionomer restorative material to adhere to dentin and enamel and form a seal the caries biofilm cannot penetrate. The evidence base is strongest for ART without SDF, and clinicians should not hesitate in using the long-established ART technique to place ITRs. This is particularly true if adding SDF necessitates acquiring explicit informed consent and delays the provision of care. On the other hand, there is no compelling reason to not place SDF under the ART restoration if it is easy to get the patient’s consent and there are no esthetic concerns.

⁴ de Amorim RG, Frencken JE, Raggio DP, Chen X, Hu X, and Leal SC. Survival percentages of atraumatic restorative treatment (ART) restorations and sealants in posterior teeth: an updated systematic review and meta-analysis. *Clinical Oral Investigations* (2018) 22:2703-2725.

F. Requirement of Clinical Experience using Glass Ionomer Restorative Materials (GIC)

Applicability of any single study using GIC to a particular application at a *SMILES* site will vary by the specific type of GIC used for each. Moreover, clinicians need to use techniques appropriate to the restorative material selected and select materials appropriate to the type of restoration and outcome sought. Clinicians **MUST** understand that the basic mechanism used by GIC to adhere to sound tooth surfaces and isolate dentin (caries-affected or sound) from the cariogenic biofilm is different than that used by resin sealants and composite restorations. The “conditioners” used before placing the GIC or resin are different and are intended to provide different conditions at the microscopic level for sealing the material to the tooth.

GIC restorations release fluoride and are bioactive, so that they gradually develop a strong, durable ion-exchange layer at the interface with the tooth, which is responsible for their adhesion. Modified forms of glass-ionomers, namely resin-modified glass-ionomers, may provide more durable restorations, but their biocompatibility is somewhat compromised by the presence of the resin component. Some conventional GIC materials are hand-mixed with powder-to-liquid ratios that affect viscosity and physical properties of final restoration, while others are capsulated for more consistent, more difficult to vary, handling properties. Finally, setting time of some GIC can be controlled by being light-cured, while self-cured materials require the operator to adapt to the GIC setting time. Clinicians will need to gain experience in the handling properties and restoration placement techniques of each if they are to achieve or exceed the success rates of published studies.

Previously, some dentists were concerned that the selective removal of carious dentin necessitated by placing ITRs in unanesthetized teeth compromised long term success. Now, systematic reviews have confirmed that selective (in contrast to complete or two-stage) caries removal is associated with higher pulpal survival rates. This suggests that the only thing that should differ between an ITR placed with hand instruments and a glass ionomer restoration placed under anesthesia in the dental clinic will be the removal of some additional sound tooth tissue with rotary instrument in the latter setting to achieve optimal bulk of restorative material and, perhaps, remove some “unsupported enamel” that might otherwise, at some later date, fracture and expose the underlying restoration and dentin to the biofilm.

Taken together, this suggests that if they are monitored annually, GIC restorations, whether placed as ITRs or conventionally, need only be replaced only when so much material has been lost that they are no longer protecting dentin from the biofilm or if tooth form has not been restored adequately to prevent food impaction. Colorado law may require that the patient/guardian be advised that the interim therapeutic restoration is “a temporary repair to the tooth and that appropriate follow-up care with a dentist is necessary.” Dentists who authorize the placement of ITRs should communicate to patients/guardians, in terms suitable to the setting, that they are confident appropriate follow-up care can be provided in the community setting using the same technologies used to provide “virtual examinations,” and that patients/guardians are welcome to schedule a visit to the dentist if they have concerns that cannot be addressed by the hygienist.

G. Additional considerations for *SMILES* programs protocol development.

1. Teeth with Signs/Symptoms of Irreversible Pulpal Inflammation

Neither SDF nor ITRs should be provided to teeth with symptoms of irreversible pulpitis, as they will not change the ultimate course of progress to pulp death. Radiographs and visual appearance of teeth are not sufficient to rule out irreversible pulpitis. Even if patients do not report transient discomfort as a chief complaint, dental hygienists should ask about symptoms for any teeth that have large cavities, not only to identify those with spontaneous and/or lingering pain and other signs of irreversible pulpitis and help the dentist prioritize treatment, but also to rule out contra-indications to the two treatments (SDF and ITRs) available from the dental hygienist at the community site. In the absence of signs of irreversible pulp inflammation there is no contraindication to using SDF to arrest decay in either primary or permanent teeth, other than esthetic concerns regarding SDF identified in the process of receiving informed consent from patient/parent.

While patients with irreversible pulpitis in either permanent or primary teeth should be referred to the dental clinic for extraction or root canal treatment as soon as possible, the consequences of not receiving that care are generally more negative for permanent teeth than primary teeth. Pulp death in permanent teeth is often accompanied by periapical infection and severe spontaneous pain. In contrast, pulp death in primary teeth often goes unnoticed, as the infection finds an outlet to self-drain via a fistula. These differences may affect the likelihood that the patient accesses care at the dental clinic as recommended, which has implications for what treatment can/should be provided in the community setting to complement the treatment(s) recommended for the most severely decayed teeth. (See section on Treatment Planning for Quadrant Dentistry.)

Dentists performing the “virtual” examinations rely on the dental hygienist in the community setting to screen teeth for irreversible pulpitis. Public health dental hygienists in Maine, New Hampshire and South Carolina have been providing ITRs without prior dentist approval without incident following a “Pulpal Pathology Protocol” that assumes radiographs are not available. Registered dental hygienists should ask relevant questions to patients with large cavities during the same visit when other diagnostic information is collected so that the “examining” dentist has that information when developing the treatment plan. Because periapical radiographs of severely decayed permanent teeth are available at the *SMILES* sites the already low likelihood that a non-vital, but asymptomatic, tooth will be treatment planned for an ITR is reduced even further.

2. Treatment Planning for Quadrant Dentistry versus Arresting Caries Whenever We Can

Ideally treatment should be planned to enable patients to receive required restorative care in the fewest visits, which is more efficient for both patient/parents and dental clinic staff. When several teeth require restoration, “quadrant dentistry” is preferred. This is especially true when local anesthesia is required for teeth in the lower arch where a single injection anesthetizes all teeth on one side. The question becomes: “If we recommend that a patient receive restorative care for a permanent tooth in the dental clinic, is it a waste of resources to provide SDF or ITRs for any teeth at the community site?” Or, more narrowly, “is it a waste of resources to provide SDF or ITRs in the same quadrant that the more definitive restoration will be placed?”

It will only be a “waste of resources” if the patient actually accesses restorative care in the dental clinic. The likelihood of doing so is unknown, and may accurately be estimated only for families with whom the *SMILES* project has some experience. If caries-arresting care is deferred on the basis of an expectation that the patient will receive care at the clinic in the next 2-3 months, and this occurs, the project will have good outcomes with least expenditure of resources. However, if the referral does not result in accessing care in the dental clinic, then decay may progress until the next scheduled recall visit in approximately 6 months, or even longer if circumstances prevent the dental hygienists from recalling all patients with that frequency.

If arresting caries with least amount of damage to teeth is our primary goal, then SDF and ITRs should be provided at the community site unless there is high likelihood (certainty?) that the patient will receive timely care at the dental clinic. **SDF and ITRs are always appropriate care, even if not ideal care.** If/when the patient accesses care in the dental clinic, the dentist can prioritize care in that and future visits to those teeth for which the SDF and ITRs are least likely to provide continued protection of teeth from decay. There is no urgent need to replace ITRs in teeth where they are continuing to protect dentin from decay, or to restore teeth where decay has been arrested by SDF, unless food impaction or other functional problems are associated with the cavity.

3. Initial exam versus periodic exam

Each virtual examination leads to a treatment plan. The decision rules for treatment planning based on an initial examination may be different than those for a periodic or recall exam. In both cases, though, treatment may be planned based on whether an expectation that a visit 4-8 months later can be assured. For school programs it is more likely a second visit can be assured during the school year than treatment can be planned with the assumption that the *SMILES* team will be back the next school year.

This suggests that an initial treatment plan could favor restorative treatment at the clinic if there are reasonably high expectations that the patient will adhere to that recommendation. If there is re-examination every 6 months, the dentist can decide at the periodic examination whether the patient adhered to recommendations to receive further treatment at dental clinic. At that time the treatment plan could be amended to include provision of more caries-arresting services by the dental hygienist. What are the consequences of leaving teeth untreated for 6 months? What if the patient is NOT seen by the dental hygienist at 6 months for the periodic exam? Perhaps *SMILES* is only responsible for patients who continue the relationship, which includes consenting for school-based care at each opportunity.

Do we have any reason to believe a parent will take child to dentist over the summer than during the school year? If so, this may have implications for treatment planning in the fall differently than treatment planning in the spring.

In general, as trust is developed through receipt of services in the community setting, *SMILES* clinicians have more information about patient/parent behavior. At each visit they know whether the patient adhered to treatment recommendations 6 or 12 months earlier.

4. Flexible Treatment Plans Responsive to Fluctuating Patient/Parent Intentions

Ideally, a treatment plan would be developed via conversation of dentist, dental hygienist and the patient/parent, proceeding with the services that could be provided in each setting at a schedule acceptable to parent and clinic. When this amount of dialogue is not possible, a treatment plan may be

presented that proves to be unsuccessful, which is particularly consequential if teeth intended to be treated at the dental clinic don't get care. While good communication and patient/parent engagement requires some commitment of dentist and hygienist time, as well (often) as the time of patient navigators, school nurses, social workers, and others, excessive demands on the time of these members of the care delivery team reduce the time they have available to serve others.

For patients/families with little previous history of accessing care in the dental clinic, one could default treatment planning to provide all restorative care in the dental clinic. If the program is able to achieve predictable 6-month recall, even if the patient did not access any restorative care only 6 months of caries progression would occur before that was known. Depending upon the number and severity of decayed teeth, however, the amount of caries progression over 6 months could be significant, and modify or eliminate remote treatment options.

Alternatively, when a patient is referred for treatment at the clinic, they could be placed on a shorter, 2 to 3 month recall, so that the *SMILES* team would know that for whatever reason, planned care had not been received. Depending upon the functionality of the electronic dental record (EDR) system, the dental hygienist might know the status of treatment planned/provide without even recalling the patient. In most cases, the dentist responsible for overseeing care would rather have the patient receive caries-arresting care for known lesions promptly, as soon as the patient's difficulty in accessing care at the dental clinic has been established. Would a new treatment plan have to be presented to the patient/parent? This might require that significant resources be expended to receive informed consent for a new treatment plan. The alternative would be to simply abandon it and try again at the 6 months recall by developing a treatment plan that prioritizes providing caries-arresting services to as many teeth as possible at the community site.

How can the dental hygienist and the examining/treatment planning dentist maximize options to provide appropriate services efficiently to patients (considering time of both dental hygienist and patient/parent) given the asynchronous nature of the examining dentist's communication with dental hygienist and parent? Could initial treatment plans include options so that dental hygienist-delivered services could be provided without the need for an additional treatment planning visit (likely involving both a visit of patient to dental hygienist and review of EDR and clinical findings by the "examining" dentist)? Could a parent provide general consent for all non-invasive services (excepting the specific informed consent appropriate for SDF and patient/parent acknowledgement of staining)? If so, then the dental hygienist could provide ITRs any time during the year when it appeared that the patient was not receiving definitive restorative care. **There is really no downside to receiving an ITR shortly before a definitive restoration, and there is a significant upside to arresting decay by placing an ITR instead of leaving the decay to progress indefinitely.**

5. Dentist-Patient (Parent) Agreement on Long Term Goals

SMILES clinicians are mostly dealing with implicit understanding of goals. They probably generally assume they know their patients' long-term goals. They are less clear about short-term ones, especially if there are options with no clear-cut and shared understanding of expected outcomes. For many patients remaining pain free is much more important than considering long term tooth retention. The

patient's goal should be recorded in their health record and should be re-evaluated periodically. Dental health is likely the means to an end (happiness and well-being), rather than a primary goal⁵.

6. Timing: What's the Rush to Provide Dental Care?

How quickly caries will progress to threaten pupal health is difficult to predict under any circumstances, especially if the treatment planning dentist has minimal information about past dental care, care-seeking habits, patient risk factors and likelihood that they will change. Dentists seem to have high confidence that treatments provided in the dental clinic will both arrest the progression of caries and restore form and function. If patients/teeth with slow rates of caries progression could be identified, they could be referred to the dental clinic after each dental encounter in the community setting with little threat to their dental health, so long as they eventually (within 18-24 months?) went to the dental clinic.

At the other extreme are patients/teeth where any further progression of decay is likely to jeopardize pulp health, greatly complicating treatment and perhaps even requiring extraction. In those cases, failure of the patient to adhere to the referral recommendation and go to the dental clinic for all needed care could be catastrophic to the most severely diseased teeth. In the face of uncertainty about patient/parent behavior, the best outcome (retain pulp vitality) may be achieved by using SDF and/or ITRs to arrest decay before it threatens the pulp as initial treatment, before referring the patient for traditional restorative care. Some dental programs refer to this as "stabilization". With this treatment plan it is believed that delays by the patient/parent in seeking care at the dental clinic will be less consequential. This approach does not preclude repeated attempts, at each subsequent encounter at the community site, to encourage patient/parent to seek traditional care at the dental clinic.

7. Applicability of Decision Model to Care of Adults

Most of the treatment decision suggestions for *SMILES* relate to children being seen in school programs where parental interest/ability/willingness to take child to the dentist is difficult to assess, AND where it is perceived that the referral dentist has capacity to treat all carious teeth in a timely manner. Modification for the circumstances faced by Dental Aid, or any future sites that may serve older adults, are welcomed. Adults with disabilities, or who are homeless, or are vulnerable seniors may have different barriers that make care by a registered dental hygienist at a community site preferable to the patient, at least for many services. Also, to be considered is whether the capacity of Dental Aid clinical workforce and patient navigator component are sufficient to achieve caries control in all individuals within a 3-month window. (Rehabilitative services can generally be deferred longer without any risk for the patient.) If not, use of SDF and ITRs to arrest and control caries at the community site may be appropriate and even recommended to assure that appropriate control treatments have been provided within a few months of the initial examination.

For those patients who continue to be served by Dental Aid over time, the dentist(s) providing clinical care can discuss with the patient the mutual expectations regarding which portion of the patient's ongoing caries control needs can be addressed at the community site.

⁵ FDI World Dental Federation, Dental Ethics Manual 2. 2018: 17-19.

H. Person-centered vs Patient-centered Care

A patient is the most important person in the Institution - In person or by mail.

A patient is not dependent on us - We are dependent on them.

A patient is not an interruption of our work - It is the purpose of it.

The patient is not an outsider to our business - They are our business.

The patient is not someone to argue or match wits with.

The patient is a person and not a statistic.

It is our job to satisfy them.

-William E. Lower, M.D.

The Cleveland Clinic Foundation

February 1921

Is there a difference between patient-centered and person-centered care? Today's patient is also a person. The person's needs several weeks from now may be such that it will be difficult for them to be a (good) patient then. So, if we are providing person-centered care, we need to give them the best care we can today when they are before us as our patient. While they will still be our patient some weeks from now, even if not accessing care with the frequency that we (and they) would like, it is important to provide them effective services whenever, through their presence, they provide us that opportunity.

Consider the concept of shared decision-making. Do we respect the autonomy of patients/parents if we insist that the only place they can receive services to control their dental caries is at the clinic at a time convenient to clinic staff when we know that services to provide a similar level of control can be provided at locations more convenient to the patients? Truly informed shared decision-making would require that we describe the potential benefits of services that could be provided in the clinic that are not available in the community setting, but it is challenging to exchange that much information with parents of children being served by school-based programs. In the absence of that full exchange of information it may be best to provide a treatment plan that maximizes the number of teeth in which caries can be controlled while still offering to patients/parents to opportunity to receive services at the dental clinic. We typically have much more control to assure the former than the latter.

Which patient/parent is more likely to make the effort to overcome barriers to getting dental care in a clinic?

- One who is seen by a dental hygienist and advised that they have cavities and should get care at the dental clinic.
- One who receives services from a dental hygienist to treat those cavities, (developing rapport and trust through those encounters), and is also advised that some cavities remain that can only be treated by a dentist in the clinic.

Do we need to develop patient decision aids to help patients/parents understand the services we are providing remotely and the benefits of seeking dental care at the clinic? Can the intensity of our recommendation to seek care at the clinic vary by our estimation of the consequences of not seeking care at the dental clinic?

I. Financial Sustainability and Rules of Medicaid (and Other Dental Plans)

It is clear to keen observers that fee-for-service reimbursement, both in terms of the fees and frequency limitations, often have little relationship to evidence of the effectiveness of those services (Niederman, AJP, 2017). The above discussion and recommendations have been based solely on scientific evidence of the effectiveness of various clinical services and insight gleaned from *SMILES* Project participants regarding the dilemmas they have faced in trying to determine the best course of action for their patients, both individually and as a community.

Hopefully the *SMILES* Project component of participating organizations can be financially sustainable just by doing the right thing and not having to modify treatment plans to accommodate illogical inconsistencies of dental plan coverage. However, it may be necessary to augment decision rules informed by the above discussion to be responsive to those coverage and reimbursement rules, until which time evidence can be presented and political pressure can be applied to modify them.

It is also pretty clear that the Colorado Dental Practice Act and especially rules promulgated by the state dental board may make it difficult to provide care as timely and efficiently as one would like. However, attention to those features of the project that enable *SMILES* providers to sustain a relationship with patients to provide dental care in a comprehensive, continuously accessible, coordinated, and person-centered way should help achieve a reputation in the community adequate to sustain the project and provide evidence to support future efforts to modify rules to enable *SMILES* to more optimally serve their communities.

William R Maas, DDS, MPH, MS

September 20, 2019