Development of a Silver Diamine Fluoride Protocol in Safety Net Dental Settings

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ABSTRACT

Purpose: In the United States, silver diamine fluoride (SDF) is a new method to arrest dental caries. Protocols for using SDF are under development as the research evolves and experience is gained with different populations and settings. The purpose of this study was to develop a comprehensive SDF protocol for young children tailored to safety net dental clinics (SNDCs).

Methods: We developed the SDF protocol for SNDCs through a two-step process: (1) an expert panel of pediatric dentists reviewed, modified, and expanded existing SDF protocols including clinical, pre- and post-clinical components; and (2) the new SDF protocol was implemented in three SNDCs in North Carolina with on-site didactic training, clinical observations and discussion. We obtained feedback from SNDC dentists, staff, and administrators to further refine the SDF protocol.

Results: The SDF protocol was tailored to SNDCs based on recommendations from SNDCs themselves. Suggested improvements were primarily non-clinical in nature, such as the provision of laminated SDF information with color pictures of staining in each operatory, a timer for SDF procedure, and templates for documentation, coding, and billing.

Conclusion: To facilitate SDF use in SNDCs, we developed an expert-consensus protocol that incorporated the clinical experience of SNDCs that implemented the protocol. **(J Dent Child 2019;86(1):32-9)**

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Silver diamine fluoride (**SDF**) is a topically applied liquid that provides a simple, efficient, and minimally invasive approach to arresting dental caries.[1-9] In 2014, it was approved by the U.S. Food and Drug Administration (**FDA**) to treat dentin hypersensitivity in adults.[10,11] Similar to fluoride varnish, SDF is used off-label to arrest dental caries in both adults and children.

Currently, there is a growing body of research on the efficacy of SDF in arresting dental caries in children.[1,9,12-21]

Studies have also been performed on the acceptability of SDF by parents and the absence of SDF-related adverse effects in children.[22-25] The existing literature draws attention to the potential use of SDF in communities where children have a high-risk for dental caries and experience challenges to accessing dental care.

While the body of SDF literature is burgeoning, there is little research on the implementation of SDF in clinical practice. Professional organizations, such as the American Dental Association (**ADA**), American Academy of Pediatric Dentistry (**AAPD**), and Association of State and Territorial Dental Directors (**ASTDD**) have issued documents on the use of SDF to arrest dental caries, including a chairside guide.[11,26-30] However, there is little research on clinical protocols for SDF[11,26] and, to the best of our knowledge, no SDF protocols that incorporate feedback from clinical and administrative staff at safety net dental clinics (**SNDCs**) have been implemented.

SNDCs are dental settings that provide dental care to vulnerable populations, many of which may be enrolled in government programs, such as Medicaid or Children's Health Insurance Program, or lack access to dental insurance. Some SNDCs offer sliding fees, reduced fees, or free care to patients. They often provide dental care through public dental clinics, such as federally qualified health centers.

The purpose of this study was to develop a comprehensive SDF protocol for young children tailored to SNDCs using the following process: (1) review, modify, and expand existing protocols that could be applied to implementing SDF in SNDCs to arrest dental caries in primary teeth; and (2) revise the SDF protocol using feedback from three SNDCs following on-site didactic and clinical training intended to facilitate the implementation of the protocol. This report also describes the development of the protocol modifications recommended by a pediatric dentistry expert panel and post-implementation modifications recommended by three SNDCs.

METHODS

STUDY OVERVIEW

The initial SDF protocol for SNDCs was developed by convening an expert panel of pediatric dentists experienced with SDF and familiar with each of the SNDCs participating in this study. We provided on-site didactic and clinical training support to the three SNDCs that implemented the initial SDF protocol. Finally, we elicited feedback through email and in-person communication from the dentists, staff, and administrators at each SNDC to revise the initial SDF protocol. This study was approved by the Internal Review Board at the University of North Carolina (**UNC**), Chapel Hill, N.C., USA.

PEDIATRIC DENTISTRY EXPERT PANEL

In March 2017, we held a pediatric dentistry expert panel meeting with the goal of reviewing, modifying, and expanding existing SDF protocols to implement in SNDCs. The panel consisted of three pediatric dentists, two UNC faculty, and one dentist primarily in private practice. The expert panel had expertise on successfully developing and implementing SDF protocols in academic settings and private practice. Members of the expert panel previously presented data and training on SDF at national meetings, continuing education seminars, and classes in academic institutions. The meeting was also attended by this study's principal investigator, project pediatric dental expert, and project manager. The panel reviewed three existing protocols, which served as the basis for discussion: (1) a protocol from the University of California, San Francisco, Calif., USA;[11] (2) a protocol from the Department of Pediatric Dentistry, School of Dentistry, UNC; and (3) a private practice protocol based on the UNC protocol.

The following topics were discussed during the expert panel meeting: pre-clinical activities (communication with family, informed consent, patient/lesion selection); clinical activities (set-up and cleanup, clinical application process, dentist and staff roles during SDF application); and post-clinical activities (management of SDF-related events, chart documentation, billing). For these three topic areas, we asked the expert panel to suggest specific content to include or exclude from the SDF protocol and/or changes to improve upon the existing SDF protocols. The expert panel was also asked if there was any additional information that could be useful to SNDCs implementing the SDF protocol. In response, the panel described useful training materials for applying SDF and topics to emphasize during SDF training.

SNDCS

We recruited three SNDCs from different counties in North Carolina to pilot the new SDF protocol, participate in focus groups, and give feedback on protocol modifications that would improve the implementation of SDF in their SNDC. The three SNDCs were selected based on geographic distribution in the state, patient population, and willingness to participate. They were located in different areas across the state and were comprised of general dentists, dental assistants, and dental hygienists who provided dental care for a mix of pediatric and adult patients. Each site received an honorarium for its participation, which included the didactic training, clinical training, and feedback on the implementation of SDF in their clinic. Each site was given the opportunity to communicate with the SDF study staff for assistance in SDF implementation during the entire course of the study. This assistance included answering questions by phone, answering questions in person, and connecting the clinic with the state Medicaid director to answer questions.

SDF PROTOCOL TRAINING FOR SNDCS: DIDACTIC AND CLINICAL

A pediatric dentist provided on-site SDF training to the three SNDCs over two visits per site: (1) didactic training with a video; and (2) clinical observation and feedback. In the didactic training, we provided the following documents to each of the SNDCs: Advantage Arrest™ (Elevate Oral Care LLC., West Palm Beach, Fla., USA) SDF product information; SDF protocol from the expert panel meeting; template patient information sheet on SDF; the ASTDD's SDF fact sheet;[30] and primary literature on the efficacy of SDF in children.[12-16]

We provided didactic SDF training to dentists, dental hygienists, dental assistants, front desk staff, and administrative staff in a lunch-and-learn setting, with lunch provided as part of the SDF study. The didactic training was provided using a PowerPoint lecture that consisted of seven sections: (1) SDF introduction (FDA approval, benefits, mechanism, safety, and pros and cons); (2) summary of the primary literature on the efficacy of SDF in children; (3) SDF application technique (12 steps, including family education, informed consent, application duration, documentation, dentist's role, assistant's role, and video of application with cleanup); (4) SDF patient selection (indications, contraindications); 5) SDF clinic needs (supplies, information available in the clinic for dental team and families, materials to give to families to take home, billing, odontogram charting, progress notes); (6) SDF points of emphasis (staining, informed consent); and (7) discussion. The didactic training session was interactive and provided opportunities to evaluate participants' understanding of the SDF protocol, including showing a video and discussing how the proposed protocol differed from the video demonstration.

We scheduled the clinical observation and feedback visit approximately two months after the didactic training session. During the clinical session, dentists, staff and administrators both described and demonstrated how they tailored the initial SDF protocol to their SNDC.

SNDCS' FEEDBACK ON THE SDF PROTOCOL

We developed the following eight domains *a priori* based on the clinical experience of the pediatric dental expert. The study team elicited feedback on the SDF protocol during the on-site didactic and clinical training visits, according to the following eight domains: (1) communication about SDF with the family; (2) informed consent; (3) case selection; (4) SDF setup; (5) SDF clinical application; (6) SDF cleanup; (7) billing; and (8) chart documentation. Each of these domains was addressed in the didactic training, and all are elements of the SDF protocol.

RESULTS

PEDIATRIC DENTISTRY EXPERT PANEL RECOMMENDATIONS TO THE SDF PROTOCOL

The expert panel made numerous recommendations for an SDF clinical and administrative protocol to arrest dental caries in primary teeth in SNDCs. The following are examples of changes incorporated into the initial SDF protocol for SNDCs:

1. Give paper copies of SDF information and the SDF informed consent to families to bring home and share information about SDF and its staining to other family members.
2. For all patient-related SDF materials, include color pictures of the SDF tooth staining and emphasize the importance of these pictures, particularly for caregivers with low health literacy.
3. In the materials for obtaining informed consent, consider including language that requests that the family will inform the clinic if they become aware of a metal allergy and confirmation that the family understands that the decayed part of the tooth may stain black.
4. Use the recommended case selection criteria described in Figure 1 for SNDCs with limited experience implementing SDF, which include indirect pulp cap and applying SDF to an adjacent surface with incipient lesion when prepping one cavitated interproximal surface.
5. Use a video to show the dentists, assistants, and staff how to apply SDF while avoiding SDF staining on nonlesion surfaces.
6. Educate SNDC personnel that SDF can be used for cavitated lesions in primary teeth that do not approximate the pulp.
7. The goal for the duration of SDF application is at least one minute to replicate the results in existing SDF studies.
8. After SDF application, dry with a cotton pellet or gauze to soak up and remove excess SDF, instead of rinsing, in order to reduce the chance of staining the soft tissues while also preventing the patient from having a metallic taste from the SDF.
9. Document SDF application in the odontogram in addition to the progress note.
10. Create and use the following Medicaid billing code for SDF: D1354–interim caries arresting medicament application.

SNDC RECOMMENDATIONS TO THE SDF PROTOCOL

In the process of implementing the initial SDF protocol at their SNDC, the dentists and clinical and administrative staff at each of the three SNDCs also made many recommendations to improve the initial SDF protocol.

SDF protocol for dentists and staff

Contraindications:

- Children with a known silver allergy
- Parents/guardians who do not consent to SDF treatment, including the color change
- Deep carious lesions that approximate the pulp, according to the clinical information available

Acceptable uses:

- Indirect pulp caps
- When prepping one cavitated interproximal surface, applying SDF to the adjacent surface with an incipient lesion (while ensuring no introduction to an adjacent composite restoration)
- Alternative to sealants for high-risk teeth in patients who cannot tolerate a meticulous sealant procedure
- Early childhood caries as a definitive measure applied every six to 12 months
- Early childhood caries as a holding measure for precooperative child until treatment may be accomplished without sedation or in the operating room with general anesthesia
- Arresting carious lesions until treatment can be completed (reduce the need for pulp therapy)
- Arresting caries to hold for exfoliation
- Arresting caries in special health care needs patients who are not candidates for traditional dental treatment

Recommendations for discussing SDF with the family and obtaining informed consent:

- For all patient-related SDF materials:
  - Include color pictures of teeth before and after SDF staining.
  - Use language appropriate for patients with low health literacy.
  - Translate materials into appropriate languages for the patient population.
- Offer color copies of the SDF information sheet and/or SDF informed consent to bring home in order to communicate SDF and the staining to other family members. Alternative methods of family communication include texting pictures of SDF staining to family members not present at the appointment and encouraging family members to take pictures of the patient-related SDF materials on their phones during the dental visit.
- Check communication by asking the consenting caregiver to explain what SDF is, why it is being used, and the consequences of SDF application.
- Obtain informed consent with the primary caregiver.

SDF setup:

- One drop of SDF in a disposable dappendish
- Microbrush to apply SDF
- Materials to isolate and dry the teeth (Isodry/Isolite, gauze, cotton rolls, cotton pellets, dry angle, gauze, Molt mouth prop or bite block, dry microbrush)
- Vaseline, if preferred, to prevent soft tissue staining
- Timer (digital or hourglass), if preferred

Overall technique:

1. Examination, charting, caries risk assessment, anticipatory guidance
2. Radiographs as prescribed by the dentist if behavior permits
3. If SDF is appropriate for the patient and the family, review the risks, benefits, and options with the patient, parent, and/or legal guardian. SDF information and SDF informed consent should be presented using documents that are appropriate to the literacy level and language of the patient's family and include color photos of SDF staining. Informed consent can be confirmed by asking the consenting adult to explain how they could communicate the rationale, process, and results of SDF with other family members.
4. Sign SDF informed consent (e.g., electronic, paper, laminated sheet to be scanned) preferably with the primary caregiver.
5. Position the patient (e.g., dental chair, knee-to-knee).
6. If preferred, place Vaseline on soft tissues around the tooth being treated to avoid staining.
7. Isolate (e.g., Isodry/Isolite, cotton rolls, cotton pellets, dry angle, gauze, finger guard, Molt mouth prop or bite block)
8. Cleanse lesion or lesions up to five teeth (e.g., power wash, moist cotton roll, moist cotton pellet, moist gauze, moist microbrush).
9. Dry (e.g., air, dry cotton roll, dry cotton pellet, dry gauze, dry microbrush)
10. Apply SDF for one to three minutes to the entirety of the isolated lesion(s) by the dentist using four-handed dentistry. Continue to scrub SDF on the lesion(s) for the duration of application. If multiple teeth are isolated simultaneously for SDF application, apply SDF to the entirety of each isolated lesion initially and then continue to scrub SDF on each of the lesions for the duration of application. (Note: The assistant can keep time with a digital timer, two-minute hourglass timer, or a clock. Contact time without rinsing is necessary for SDF efficacy.)
11. Dry (e.g., dry cotton roll or pellet, dry gauze, dry microbrush). Note: Remove excess SDF to prevent staining and metallic taste. Do not use an air/water spray to prevent SDF splashing and staining on the soft tissues.
12. Apply fluoride varnish (five percent NaF) over the entirety of SDF-treated teeth and all other teeth present in the mouth.
13. Document SDF surfaces treated in both the odontogram and progress note. Use an SDF progress note template that encourages the documentation of the teeth treated and the duration of SDF placement.
14. Billing. Use D1354 for the initial SDF visit, process code for subsequent SDF visits, and D1206 for fluoride varnish.
15. Schedule follow-up visit (e.g., reapplication of SDF, recall). In general, provide two SDF applications, four to six weeks apart, as part of an aggressive prevention plan that includes oral health education on optimal diet and hygiene. Check for caries arrest by assessing hardness and dark stain at the follow-up visit.

Dentist's role during SDF clinical application:

(If permitted by the state dental board, dental hygienist' role during SDF clinical application)

1. Manage the patient.
2. If preferred, apply Vaseline.
3. Isolate, cleanse, and dry the teeth of interest.
4. Apply SDF with continuous scrubbing to the isolated carious lesions.
5. Dry SDF-treated teeth.
6. Apply fluoride varnish to all teeth.

Dental assistant's role during SDF clinical application:

1. SDF set-up, as previously described. The assistant's set-up should include only one drop of SDF in a disposable dappendish.
2. SDF disposal. Ensure that all the materials contaminated by SDF are disposed of properly to prevent SDF staining on the countertops, floor, dental staff, and patient's skin. Prior to patient care, the dental assistant should work with the dentist to agree on a location in which to place SDF-contaminated materials during the SDF visit, such as a dental tray covered in plastic. Immediately after SDF application, the dental assistant should include the disposable dappendish and contaminated microbrushes inside the assistant's glove during clean-up.
3. Monitor the duration of SDF application and communicate the passing of time to the dentist. A digital or hourglass timer can be used.

Figure 1. Final silver diamine fluoride (SDF) protocol incorporating both expert feedback and the clinical experience from safety net dental clinics.

The following are examples of changes to the protocol they recommended:

1. Laminate a color copy of the SDF informed consent for each dental operatory so the families can see the black staining clearly before signing the (digital) informed consent.
2. For clinics that scan informed consents, create a color-printed and laminated reusable informed consent, possibly with one side in English and the other side in Spanish, for the family to sign and scan into the electronic health record.
3. Improve the readability and translate the informed consent materials into languages appropriate for the patient population.
4. Include a two-minute hourglass-type timer in the SDF procedure setup to facilitate tracking the duration of the SDF application.
5. Use a finger to block for the child's tongue when applying SDF on lower posterior teeth, which augments tooth isolation and prevents a metallic taste during SDF application.

6. Isolation options include Isodry/Isolite, dry angle, cotton roll, slow-speed suction, finger guard, bite block, and a Molt mouth prop.
7. One option for drying the tooth both prior to SDF placement and after SDF placement is a clean and dry microbrush.
8. In addition to the dry microbrush, other methods to dry the teeth before and after SDF placement can include cotton pellets, two-by-two inch gauze, and cotton rolls.
9. Emphasize that fluoride varnish should be applied to all teeth after the SDF application and not just the teeth treated with SDF.
10. Incorporate SDF in the patient record and billing systems. The SNDCs created an informed consent for SDF in the electronic record that can be signed digitally, a template for auto-fill progress notes for SDF visits (Figure 2), and no-charge process codes to track reapplications of SDF.

DISCUSSION

After developing an expert-based SDF protocol tailored to SNDCs, we created a comprehensive clinical and administrative SDF protocol that incorporated both expert feedback and the implementation experience from SNDCs. Our approach to protocol development combined the benefits of both academic expertise in applying the current scientific evidence into the clinical protocol as well as the practical implementation aspects of using the protocol from the perspective of SNDCs.

The initial SDF protocol developed by the expert panel provided recommendations for patient case selection. While SDF may be used for a wide range of cases in other clinic settings, the proposed case selection put forth in this protocol was intended to encourage an appropriate use of SDF in SNDCs implementing SDF with minimal previous experience.

The modifications to the SDF protocol suggested by the three SNDCs focused largely on the administrative and clinical procedures. Suggested modifications concentrated on improving the informed consent, patient record, and billing processes. Most of the clinical changes were intended to make the process more efficient and user-friendly and to clarify team member roles.

The final SDF protocol provided both a structure through which SNDCs provide SDF applications and the freedom to adapt the protocol to their particular SNDC setting. The flexibility to adapt the SDF protocol to the three SNDCs was illustrated in the following three aspects: (1) informed consent; (2) drying the teeth; and (3) billing.

While the SDF-informed consent at each SNDC was tailored to the literacy level and language of the patient population and included color photos of SDF staining, the vehicle for the informed consent was different for each clinic. For example, one clinic had a very short, simply worded English consent with color pictures in the electronic record system that was signed

Medical alert:

Medications:

Allergies:

Pain scale type (numeric pain scale, 0-10):

Descriptions: Patient denies dental pain per (mother/father/legal guardian).

SDF: (Tooth/Teeth letter [surface(s)] selected on odontogram) application of silver diamine fluoride. Consent obtained from (mother/father/legal guardian). The family was given the SDF info sheet and a copy of the informed consent with color pictures. The family demonstrated understanding that the caries where the SDF will be applied will be black permanently. A parent denied silver allergy and was present for dental treatment. Care was provided in (dental chair, knee-to-knee). The dentist cleansed and dried the tooth/teeth, applied 38% silver diamine fluoride with a microbrush, waited (time in minutes [e.g., two-and-a-half minutes]) for (tooth letter), dried the excess, then applied fluoride varnish to all teeth. Post-op instructions were given.

Diagnosis: dental caries (incipient decay, dental caries, recurrent decay)

Plan for treatment: Restore when patient can tolerate treatment, refer to pediatric dentist, monitor until exfoliation, monitor incipient decay, indirect pulp cap.

Isolation used: cotton roll and dry-angle isolation with mouth prop, Isodry isolation pedo, Isodry isolation small, Isodry isolation medium, Isodry isolation large

Behavior: great, good, hard to open, wiggly, tired at end, age appropriate, apprehensive, anxious, made noises

Remarks:

NV: recall (date) (time), evaluate SDF caries arrest

Interpreter: (not needed/needed) (language)

Interpreted by: (Name of interpreter)

-----Signed on (date) at (time)----

-----(Name of assistant and dentist)----

Figure 2. Modified version of the auto-fill template silver diamine fluoride (SDF) progress note developed in the electronic patient record by a safety net dental clinic.

using a digital pad. Another clinic had a full-page, detailed, laminated consent form with color pictures that was written in English on one side and in Spanish on the other. After patients signed the laminated sheet, it was scanned into the electronic record system.

The three SNDCs all dried the teeth before and after SDF application, in accordance with the SDF protocol; however, the method of drying teeth varied depending on the supplies and preferences of each SNDC. One SNDC found it easier to dry the teeth before and after SDF placement with a dry microbrush, as they were already preparing microbrushes for the SDF set-up, they did not have easily accessible cotton pellets or balls, and the dentist used the drying step as practice for the SDF application with the microbrush. Another SNDC preferred to use gauze because it was easily accessible in its clinic.

Regarding billing, one SNDC found it easier to create a zero-charge process code for reapplications of SDF with a different description for the same billing code as the initial application, D1354. Another SNDC found it was easier to create a new process code altogether, such as D1354R. Overall, the three SNDCs followed the SDF protocol in a manner that best suited their clinic structure, administration, billing process, and resources.

At the time of the study, one SDF product was available on the market in the United States in a bottle: Advantage Arrest. Since then, Advantage Arrest has produced single-dose units of SDF. Another SDF product, Riva Star (Southern Dental Industries (North America), Inc., Itasca, Ill., USA), has been produced, which requires a two-step application process: one for SDF and a second for potassium iodide to minimize staining. Both products are FDA-approved and used off-label in the United States for caries arrest. The resulting protocol from this study is specific to the original Advantage Arrest SDF product but could be modified for Riva Star's two-step application process.

As SDF continues to gain popularity as a medicament to arrest caries in pediatric populations, updated protocols, particularly tailored to settings that provide care for children with high-risk for caries, are increasingly important. The development of this protocol was intended to encourage appropriate use of SDF, implementation of SDF in a manner consistent with the best available evidence, and compliance of SDF billing with current ADA and Medicaid standards.

This SDF protocol can be used in other SNDCs and adapted to the needs of other clinical settings. Currently, SDF is commonly taught in pediatric dentistry residency programs, which often include rotations in SNDCs.[31] This protocol can be used by pediatric dentistry residents on rotation at community sites that are interested in implementing SDF.

LIMITATIONS

There are several limitations to this study. First, the use of an expert panel is both a strength and a limitation. The recommendations for the initial SDF protocol were crafted from the unique perspective and experiences of each panel member. The expert panel members included early adopters of SDF with a scientific background who serve a wide range of patient populations, from a private practice in an urban setting to a safety net academic setting. These perspectives influence recommendations for how SDF can be implemented in a SNDC.

Moreover, these expert opinions are based on the current state of evidence-based dentistry for SDF, which is not at its zenith. At the time of this project, there were fewer than 10 clinical studies on SDF in children with control groups. Additionally, the AAPD workgroup panel "supports the use of 38 percent SDF for the arrest of cavitated lesions in primary teeth as part of a comprehensive caries management program" as a "conditional recommendation, low quality evidence."[29] This SDF protocol will require further vetting as the evidence base for the specific clinical steps of the SDF application accumulate.[1,12-21] For example, the duration of SDF application is recommended to be at least one minute, which is consistent with the SDF protocol from UCSF[11] and AAPD.[26] However, the clinical studies on SDF presented a range of durations, such as three minutes by Llodra et al.,[14] two minutes by Yee et al.,[15] and 10 seconds by Duangthip et al.[18] Furthermore, there is recent evidence to suggest that prolonged SDF contact time (120 seconds versus 30 to 90 seconds) is not associated with increased caries arrest.[1] As SDF research progresses, important details of the SDF protocol, such as the duration of application, will have a stronger evidence base.

Additionally, the three SNDCs selected to participate in this study were located in distinct geographic locations and possessed a unique set of clinical characteristics. The recommendations put forth from these three SNDCs applied to their specific clinic settings and may not be generalizable to other SNDCs. However, the development of one written protocol that was suited to these three SNDCs with distinct clinic processes, patient needs, equipment and supplies is testament to the flexibility of this SDF protocol to other settings. Our goal was to create a written protocol that allowed for adaptability and flexibility to many SNDC settings while also providing a framework in which to start implementing SDF for the first time.

CONCLUSIONS

Based on our findings, the following conclusions can be made:

1. The safety net dental clinics clinician and staff participants recommended that the SDF protocol not only focus on clinical procedures but also be expanded to include many pre- and post-clinical administrative activities.

2. The resulting, more comprehensive SDF protocol provides for flexibility so other programs interested in implementing SDF can tailor and adopt it to their specific setting.

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