

Engaging Stakeholders in Patient-Centered Outcomes Research Regarding School-Based Sealant Programs

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Abstract

Purpose: The purpose of this study was to use qualitative methods to describe the key lessons learned during the stakeholder engagement stage of planning a randomized clinical trial comparing outcomes of silver diamine fluoride (SDF) as an alternative to pit-and-fissure sealants in a school-based delivery system.

Methods: Eighteen caregivers and community-based stakeholders with involvement in the school-based sealant program Sealants for Smiles from the state of Montana, were recruited for this qualitative study. United States (U.S.) Patient-Centered Outcomes Research Institute (PCORI) methodology standards were used to develop two semi-structured interview guides consisting of 6 questions. One interview guide was used for telephone interviews with caregivers and the second was used for a stakeholder focus group. Content analytic methods were used to analyze the data.

Results: All participants believed that a study comparing SDF and sealants was clinically relevant. Non-caregiver stakeholders agreed with the proposed primary outcome of the study (caries prevention) whereas caregivers also emphasized the importance of child-centered outcomes such as minimizing dental anxiety associated with dental care. Stakeholders described potential concerns associated with SDF such as staining and perceptions of safety and discussed ways to address these concerns through community engagement, appropriate framing of the study, proper consent procedures, and ongoing safety monitoring during the trial. Finally, stakeholders suggested dissemination strategies such as direct communication of findings through professional organizations and encouraging insurance plans to incentivize SDF use by reimbursing dental providers.

Conclusions: Involving key stakeholders in early planning is essential in developing patient-centered research questions, outcomes measures, study protocols, and dissemination plans for oral health research involving a school-based delivery system.

Keywords: silver diamine fluoride, pit-and-fissure sealants, caries prevention, school-based sealant programs

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Introduction

Many of the children in the United States (U.S.) at risk for developing dental caries encounter barriers to receiving preventive dental care.^{1,2} School-based oral health programs play an important role in reducing barriers to care for socioeconomically vulnerable children.^{3,4} Consistent with Healthy People 2020 objectives,⁵ school-based programs focus on resin pit-and-fissure sealants, to prevent dental disease in children. However, successful placement of resin sealants is technique sensitive and most often requires four-handed application in order to maximize sealant retention.⁶

Topical silver diamine fluoride (SDF) is a safe and effective chemotherapeutic medicament that has been shown to arrest active carious lesions.⁷ SDF has

been used by dental providers in countries outside the U.S. for decades. However, SDF was not commercially available in the U.S. until it was cleared by the U.S. Food and Drug Administration in mid-2014 as a tooth desensitizer. SDF (Advantage Silver Arrest™, Elevate Oral Care, LLC, West Palm Beach, FL) is currently available for off label use by dental providers. *In vitro* studies suggest SDF has an antimicrobial effect and, in addition, the silver mechanically blocks dentinal tubules.^{8,9} A recent study also indicates that SDF specifically interacts with calcium and phosphate ions to produce fluorohydroxyapatite.¹⁰

While SDF is traditionally used to arrest existing caries, its ability to also block fissures broadens the possibility of its clinical utility as a sealant material. SDF is an appealing alternative to resin sealants

in school-based programs because it requires less clinical time to apply than resin sealants, is inexpensive, is less technique sensitive, and can be applied by a single dental provider without expensive portable equipment.¹¹ Three randomized clinical trials comparing SDF and sealants as caries prevention strategies have demonstrated mixed results.¹²⁻¹⁴ The first of these trials found no effect on dentinal caries prevention associated with SDF placed on the first permanent molars of six- to eight-year old children when compared to no treatment as a control.¹² The second study demonstrated that SDF was equally as effective at caries prevention as a fluoride-releasing glass ionomer in the primary molars of four to six-year old children.¹³ However, both studies allowed carious teeth to be included, which indicates that the outcomes included primary and secondary prevention, rather than focusing on primary prevention. The third clinical study showed that SDF was equally as effective as toothbrushing and glass ionomer sealants in preventing initial occlusal caries in newly erupting permanent first molars.¹⁴ As with the previously mentioned trials, important patient-centered outcomes, such as ease of treatment or dental anxiety reduction, were not assessed.

The goal of patient-centered outcomes research (PCOR) is to improve health outcomes and care quality by including patients and stakeholders in the entire research process, beginning with the research question formulation and extending to the dissemination of the findings.¹⁵ While there are many examples of the stakeholder engagement process from medicine,^{16,17} there are no PCOR examples from dentistry or dental hygiene reported in the literature. True community-based, participatory research is relatively uncommon in oral health researcher¹⁸ and randomized trials of dental pharmaceuticals based on PCOR methods have not been reported.

Patient centered outcomes in school based sealant programs have not been assessed. The purpose of this study was to use qualitative methods to describe lessons learned during the stakeholder engagement stage of planning a randomized clinical trial comparing outcomes of silver diamine fluoride (SDF) as an alternative to pit-and-fissure sealants in a school-based delivery system with the goal of identifying the key points learned by involving caregivers and stakeholders in the research process. These findings have implications for developing appropriate patient-centered research questions, identifying relevant outcomes, designing acceptable study protocols, and conceptualizing an effective dissemination strategy.

Methods

Participant Recruitment

Caregivers of children who had participated in Montana's *Sealants for Smiles* Program, a school-based sealant program focusing on low-income children without access to preventive care, were recruited for

this study. Community-based stakeholders throughout Montana involved in public health, dental care delivery systems, schools, local and state health organizations, and dental insurance plans were also recruited for the study. Caregivers were invited to participate in one-on-one interviews while stakeholders were recruited for a focus group session. Caregiver interviews and the stakeholder focus group were conducted separately because of scheduling conflicts with participants.

Interview Scripts

Two semi-structured interview scripts, one for caregiver interviews and for the stakeholder focus group, were developed (Table I). The U.S. Patient-Centered Outcomes Research Institute (PCORI) Methodology Standards¹⁹ were used to develop questions divided into four domains corresponding to stages in the research process: 1) formulating a patient-centered research question; 2) pre-intervention procedures; 3) intervention procedures; and 4) post-intervention procedures. The interview scripts were pre-tested with representative caregivers and stakeholders, revised to improve flow, and finalized.

Data Collection and Analyses

Caregiver interviews were conducted by telephone and the stakeholder focus group was held in person during summer 2016. All conversations were digitally recorded, transcribed by a professional transcription service, verified for accuracy, and de-identified prior to analysis. Data were analyzed using inductive content analytic methods and findings were organized into the four outlined previously.²⁰ The study was determined to be exempt by the University of Washington Institutional Review Board.

Results

Participants

Two caregivers were recruited for one-on-one telephone interviews. There were 16 focus group participants, including 5 members of professional health organizations, 3 school nurses, 3 school principals and Parent Teacher Association (PTA) leaders, and 5 representatives of other stakeholder groups (e.g., pediatric medicine, federal health agency, community health center, insurance company, industry). Many of the focus groups participants were also parents or caregivers, enabling them to provide professional as well as parent perspectives.

Formulating a Patient-Centered Outcomes Research Question

Significance of Topic

There was consensus among caregivers and stakeholders about the importance of oral health. A pediatric dentist explained why preventive care is particularly important for children because "we see kids come in weekly with [bombed] out molars by age

Table I. Semi-Structured Questions for Caregiver Interviews and Stakeholder Focus Groups

<p>Caregiver Interview Questions</p> <ol style="list-style-type: none"> 1. What are some of the benefits you can think of that come from checkups? 2. How important is it to prevent cavities? 3. Has your child (or a child you know) ever gotten sealants? 4. What kinds of difficulties have you seen your child (or children in general) experience when getting sealants? 5. Has your child ever talked to you about being nervous or hesitant about going to the dentist again, after getting sealants? 6. How important are the (described) benefits of silver diamine fluoride? 7. How supportive would you be of a study that compares sealants and silver diamine fluoride, in terms of reducing the amount of anxiety or nervousness reported by your child?
<p>Stakeholder Focus Groups Questions</p> <ol style="list-style-type: none"> 1. What are your feelings about the preferred design for the trial? 2. Do you have suggestions for improving the study design? 3. What role do you feel you might have in finalizing the districts or schools to be involved in the trial? 4. What role do you as a stakeholder feel you might have in how the trial is presented to schools and parents? 5. Do you see your organization actively participating in the publicity around the trial or even interacting with school districts or parents? 6. What role do you feel you might have in monitoring the progress of the trial? 7. What role do you feel you might have in helping interpret the results of the trial? 8. What role do you feel you might have in disseminating the results of the trial?

ten and it's really detrimental to their health." One mother shared that she "didn't have sealants [as a child] and I'm still battling with cavities. Both my two daughters have had sealants and don't have cavities".

A pediatric dentist described having found "a really great use [for silver diamine fluoride] in my practice" to manage tooth decay in "patients that we've done general anesthesia on that we know are going to have a tough time [providing treatment on new tooth decay] or be medically challenging to put them under general anesthesia again; for non-cavitated white spot lesions; for patients who are awake and... have a horrible gag reflex and we physically cannot get back there to isolate [the molars for sealants]." But the pediatric dentist remained cautiously optimistic. "I mean we'll see what the research says and everything but I really feel like it's a very safe thing to do and I think that it probably provides a lot more benefit than even traditional sealants but it is something that's new and going to rock the boat of a lot of dentists".

Outcomes

Non-caregiver stakeholders did not question the proposed outcome of the study (caries prevention). Caregivers, on the other hand, spoke more broadly about the importance of child-centered outcomes like making preventive dental treatment easier and minimizing child dental anxiety. As one mother explained, "If my daughters do well [with silver diamine fluoride] and it is quicker and just as effective, it would be better [than sealants]". She went on to explain that while preventing cavities is important, minimizing anxiety would be "better because they will take care of their teeth as adults. I still get anxious [when going to the dentist] even when I know it won't hurt". Another mother said that "as a mom, I'm all for easier. My kids have had silver diamine fluoride. Sealants fall out. I'd be all for shorter appointments and where I don't have to coax my child. I am definitely...supportive of this study".

Vulnerable Population Subgroups

Several participants stressed the importance of including high-risk children, including American Indian children and children with special health care needs (CSHCN). A community dentist asked "is there an intent...to include the [American] Indian population? I [would] really like to see the outcomes of this with our high-risk kids." Another dentist believed that it ""would be great to have a vulnerable population and, you know, include [CSHCN] in the study and I think it would be needed... those [children] are the ones that I think would benefit the greatest." A pediatrician agreed, stating that CSHCN "is probably the best population for this...study" but expressed concern about potential factors that can interfere with the effectiveness of preventive care like medication use or dry mouth, which are common among CSHCN.

Pre-Intervention Procedures

Concerns about Silver Diamine Fluoride

A PTA leader asked about potential “side effects of what’s being currently used [sealants] versus...the new treatment [silver diamine fluoride]” including “toxicity potential”. A pediatrician asked how long SDF has been used in countries outside of the U.S. and believed that “if you talk about silver [in Montana], I think there would be a large number of people that just kind of stop listening”. There were concerns expressed by a dentist who uses SDF in clinical practice about the importance of using SDF carefully to avoid unintentional staining, especially on anterior teeth with incipient carious lesions and the soft tissues.

Community Engagement

To address concerns about SDF, stakeholders emphasized the importance of engaging with members of the communities in which the study will take place, including local dentists, pediatricians, schools, public health officials, and community members. One dentist believed “there would have to be some sort of educational piece with the dentists of the community” especially because caregivers are likely to approach trusted local dentists for a second opinion about SDF. A pediatrician saw the role of pediatricians as complementing the role of dentists by being “a partner in educating. And, I don’t know that we would convince everybody but it’s possible that that could be very helpful.” Multiple stakeholders stressed the importance of “buy-in from all the school programs, the school districts from the principals down to the individual teachers” and warned that “getting everybody on-board and making those contacts at the schools is very time-consuming and...something that definitely needs to be taken into consideration”.

Intervention Procedures

School Recruitment

Stakeholders proposed strategies to identify and access local schools for the proposed study. A dentist mentioned that recruitment should focus on “individual schools with progressive and flexible leadership...[that] are really easy to work with”. Numerous stakeholders said that a school-based approach is more effective than approaching school districts because districts are more difficult to navigate. A PTA leader emphasized the need to figure “out what schools and what administrations are most flexible... and [which] teaching staff is supportive and flexible”. Participants believed that existing community-based relations could be leveraged by partnering with local health departments, community dentists, school nurses, and school wellness advisory committees.

Framing the Study

Stakeholders emphasized the importance of framing of the study to ensure that caregivers, schools, and community members understand and support the study. One dentist mentioned that concerns are raised when terms like “demonstration project” or “pilot study” are used. Similarly, a school nurse explained that “if it’s looked at like your child is going to be in a research study and like a lab rat, you know, like “We’re going to do a little experiment on your child,” then it would not...go over very well.” The nurse suggested describing the study as a process to determine “whether one works better than the other and giving a little bit of information [on] why we want to know, because you know, if it costs less... can we use this as effectively” and reach more children in need. A PTA leader believed in the importance of emphasizing safety and describing the public health implications, especially for a new treatment like silver diamine fluoride.

Managing Caregiver Hesitation

Stakeholders mentioned three potential sources of caregiver hesitation. The first is a concern about safety, especially with the silver component of SDF. A pediatrician reinforced the importance of educating caregivers on “the length of time that [SDF] has been in use and the safety of it and...the long-term studies that show that these kids are truly safe and that they don’t end up with autism or whatever people are going to think [SDF] will cause”. The second is any cost associated with treatment provided in the study, which would be covered by the program. The third is general hesitancy related to uncertainty about health care decisions and lack of perceived need for preventive treatment.

Consenting Caregivers

A pediatrician stressed the importance of communicating with parents that there are minimal risks associated with study participation. One pediatric dentist who uses SDF in practice explained that “we try to consent really heavily with our parents. If the children are not cooperative and they move and it gets in their saliva and then it ends up staining like a front white or front...tooth where there’s non-cavitated caries...I guess that would just be one consideration... with how you consent parents [so] you know their comfort with the stain involved. With the posterior teeth, we haven’t had pushback in parents. They’re totally fine.”

Safety Monitoring

Participants described two types of safety monitoring that should take place to detect and manage any adverse outcomes. The first is individual monitoring in which a “school nurse in the district... that would be a contact person.” A pediatrician stated that it would be helpful for local health providers to know about who is participating so that “if something

kind of wonky comes up, then I can know who to contact...to just be part of the team from that standpoint". A community nurse also mentioned community-based monitoring "by having like at least having an annual meeting...of the stakeholders to discuss what's happening."

Post-Intervention Procedures

Dissemination

Stakeholders associated with professional clinical organizations mentioned numerous outlets for disseminating study findings. Dentists and a dental hygienist mentioned presentations at the state and local dental societies as ways to communicate findings. One dentist mentioned the importance of also having information on potential reimbursement for preventive procedures. A representative of a dental insurance company stated that "if you can get this type of...treatment into use, I think it could be a game changer [but] getting providers to change their behavior...and to try new things, we obviously have to compensate or incentivize this kind of...innovation". Nurses also mentioned the annual meeting of the state nursing association as well as grassroots dissemination activities involving providers in local communities. Pediatricians, PTA members, and state health officials also mentioned meetings and biweekly or monthly newsletters that are sent to members electronically.

Discussion

Caregivers and stakeholders were invited to share their thoughts about a proposed patient-centered study to compare outcomes associated with silver diamine fluoride and resin sealants in school-aged children. Three main findings were identified from the interviews and the focus group. First, there were important differences in how researchers and caregivers prioritized outcomes. The initial study design included caries prevention as the primary outcome, which is consistent with clinical trials in dentistry.^{12,13} While tooth decay prevention was important, the caregiver interviews revealed that minimizing dental anxiety and ensuring that their children had positive dental experiences were higher priority issues. The patient-centered approach helped identify an outcome measure that is most important to caregivers and their children, which would not have occurred in the typical research study design approach. Focusing on outcomes that are most salient to patients has important implications in how the study is accepted by community members and potential participants and how study findings can eventually be used to improve health outcomes and care quality.

Another finding is the importance of including trusted early adopters from the community as part of the research process, especially when the study involves a new technology like SDF. A growing

number of dental schools and pediatric dentistry residency programs include education on SDF, but dental providers in practice are slowly beginning to use SDF.^{21,22} A potential explanation to slow adoption of new technologies is the well-documented barriers to innovation diffusion.²³ The focus group included a clinically active pediatric dentist who is currently using SDF. This was not intentional, but the manner in which this dentist, a trusted member of the community, described clinical successes of using SDF, helped stakeholders who were less familiar with SDF to better understand its properties. Previous research has underscored the importance of involving early adopters to help introduce innovations into clinical settings.²⁴ Furthermore, the pediatric dentist described important aspects of consent, such as a careful communication to caregivers about the potential risks of SDF such as unintentional staining.

Silver diamine fluoride is a topical medicament in which milligram amounts are applied to the teeth. One drop (5 mg) can seal as many as five teeth. The gingiva is protected with proper cotton gauze isolation, and rinsing of the affected teeth and high volume evacuation is recommended after treatment.¹¹ However, minute amounts may also be swallowed and absorbed through the gastrointestinal tract or excreted. Minimal amounts may be absorbed through the oral mucosa.²⁵ Allergies are known but are infrequent outside of chronic occupational exposure. Nevertheless, controversies over the safety of amalgam fillings and fluoride^{26,27} reinforce the importance of careful introduction.

Lastly, the process of engaging a diverse group of stakeholders at an early stage of the research helped in developing a comprehensive stakeholder engagement plan for the study.²⁸ One goal as a result of this process is to recruit a broader group of caregivers of children from vulnerable population subgroups, including American Indian children and children with special health care needs, as well as general members of the community. In addition, this study model has been strengthened based on feedback from stakeholders on the characteristics of children that may potentially modify the effectiveness of silver diamine fluoride and resin sealants, such as dry mouth and medication use. Data collection tools for the implementation of the trial will reflect the improved study model. Finally, stakeholders play an important role in developing and deploying an information dissemination strategy throughout the study period. For instance, working with dental insurance companies to reimburse dentists who use SDF, if it is found to be effective, will be part of the ongoing discussions.

The small sample size, typical of qualitative research was a limitation of the study; and it is not certain that saturation was reached. In addition, it was not possible to include representatives from

all potential vulnerable population subgroups that might be the recipients of the proposed intervention. One missing caregiver component included having parents who might express concerns about staining associated with SDF, which a recent study noted particularly in regards to anterior teeth.²⁹ Another related study limitation was the potential for bias within the stakeholder focus group process with regards to the dentist participant, who was an early adopter of silver diamine fluoride. However, this dentist did mention concerns parents have about staining, and this issue will be an important part of the pre-intervention procedures and consenting process of the proposed clinical research study.

Important gaps in the initial research and stakeholder engagement plans were identified through the caregiver and stakeholder interviews that will be addressed in the development of the research grant proposal. The absence of patient-centered outcomes research and community-based participatory research methods in dental therapeutic trials may likely limit the acceptance, dissemination, and implementation of scientific advances in school-based oral health. Involving relevant stakeholders in the patient-centered outcomes research process at an early stage can help investigators develop more relevant research questions, outcomes measures, study protocols, and dissemination plans.³⁰ The expected result is stronger research with greater likelihood that study findings will improve care quality and health outcomes for patients.

Conclusions

Based on the results of this study, it can be concluded that stakeholders believed in the importance of a study comparing SDF and resin sealants as caries prevention strategies.

However, while caries prevention was an important factor, patient-centered outcomes, such as minimizing a child's anxiety during preventive procedures, were equally as important to caregivers. Finally, pediatric patient-centered outcomes research should include community-based stakeholders and caregivers at the very initial stages of research planning and continue to engage these important individuals throughout the research process.

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