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**SILVER DIAMINE FLUORIDE:
PREVENTING DENTAL CARIES**

by

RENEE BINGMAN

**BACHELOR OF SCIENCE
DENTAL HYGIENE
OREGON INSTITUTE OF TECHNOLOGY, 2013**

THESIS

Submitted in Partial Fulfillment of the
Requirements for the Degree of

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ABSTRACT

Purpose

The study was designed to determine awareness and knowledge of silver diamine fluoride (SDF) among dental hygiene program directors and determine if schools have included SDF education to their curriculum.

Methods

A descriptive survey was used to gather information from all United States dental hygiene program directors.

Results

The survey had a max response from 39 school directors. With 92.31% of schools indicating SDF as a product of interest only 76.92% currently provided education to students. There are 76.92% of schools providing SDF education to students yet only 34.21% of those schools are providing SDF education to the faculty.

Conclusion

Data collected indicates curriculums do include SDF education and awareness of carries arresting properties. However, data supports lack of some SDF knowledge, and lack

of clinical training and uses. This study could raise awareness to the education process and material presented in entry-level dental hygiene programs.

Table of Contents

<i>Approval Page</i>	<i>vii</i>
<i>Title Page</i>	<i>vii</i>
<i>Abstract</i>	<i>vii</i>
<i>Table of Contents</i>	<i>vvii</i>
<i>List of Figures</i>	<i>vvii</i>
<i>List of Tables</i>	<i>viiviii</i>
CHAPTER I: SILVER DIAMINE FLUORIDE	1
Introduction:	1
Research Question:	3
Hypothesis:	4
Significance of Problem:	4
Operational Definitions:	7
CHAPTER II: REVIEW OF THE LITERATURE	8
Introduction:	8
Silver Diamine Fluoride in China:	8
Silver Diamine Fluoride in Hong Kong:	9
Silver Diamine Fluoride in Cuba:	11
Silver Diamine Fluoride in the Australia:	12
Silver Diamine Fluoride in the United States:	13
Safety of Silver Diamine Fluoride:	15
Billing:	15
Summary:	17
CHAPTER III: METHODS AND MATERIALS	19
Introduction:	19
Research Design:	20
Sample Defined:	20
Procedures:	21
Data Collection:	21
Reliability Measures:	22
Statistical Analysis:	23
CHAPTER IV: RESULTS, DISCUSSION AND CONCLUSION	24
Results:	Error! Bookmark not defined.
Discussion of Results:	33

Conclusion from the Study and Recommendations for Further Studies:.....	37
<i>CHAPTER V: Article for Submission</i>	38
Abstract:	39
Introduction:	41
Methods:.....	44
Results:.....	46
Discussion:	52
Conclusion:	55
References:.....	56
<i>Appendices</i>	58
<i>Appendix A</i>	58
Figures and Tables	58
<i>Appendix B</i>	64
HRRC Approval.....	64
<i>Appendix C</i>	66
Informed Consent for Anonymous Survey	66
<i>Appendix D</i>	67
SDF Survey	67
<i>References</i>	71

List of Figures

Figure 1: Number of programs based on type of degree obtained on completion of dental hygiene entry-level schools.....	24
Figure 2: Full time registered dental hygiene faculty positions.....	25
Figure 3: Is silver diamine fluoride a product of interest to provide education to the students within this program?	25
Figure 4: How knowledgeable is the faculty member providing SDF education to students.	26
Figure 5: Amount of hours of dedicated SDF education provided to students.....	27
Figure 6: Schools current clinical setting use of SDF.....	27
Figure 7: The directors personal history of SDF education.	28
Figure 8: The schools two years history of continuing education provided to faculty on SDF.	29
Figure 9: How faculty remain up to date with changes in dentistry and the FDA.	30
Figure 10: How curriculum changes occur to include new materials, FDA changes and ADA changes.	30
Figure 11: Directors awareness: A dental hygienist can apply SDF under the same authorization as other topical fluorides (based on state laws)..	31
Figure 12: Directors awareness: Currently, the CDT does not have a billing code for the use of silver diamine fluoride?.....	32
Figure 13: SDF has been marketed in the U.S. since 2015.....	33

List of Tables

Table 1:	29
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CHAPTER I: SILVER DIAMINE FLUORIDE

Introduction

Dental caries is one of the most prevalent oral diseases despite dental professionals efforts at prevention.³ The standard of care is to incorporate fluoride treatments for children at risk for dental caries, as a necessary component of preventive dental care.^{1,2,9} Applications of various types of fluoride have been shown to be beneficial in creating resistance to mineral loss in the enamel.¹⁷ Communities have also chosen to fluoridate the water system. Just as fluoride prevents dental caries; silver diamine fluoride also mitigates the dental caries disease process. Data collected in double blind cohort studies have shown promising results of arrested carious lesions by silver diamine fluoride anywhere from 70.3%-96.1%.⁸ Comparatively, caries reduction rates with the use of sodium fluoride are 21.3%-55.7%.⁸

Silver diamine fluoride acts in two ways to benefit the patient. First, the germicidal nature of the silver kills bacteria and prevents the formation of new biofilm on the application site. Second, the fluoride works with the silver to form fluorapatite which strengthens the outer surface of the tooth.³ For the treatment of dentinal hypersensitivity, silver diamine fluoride works by aiding in the occlusion of the dentin tubules resulting in a decrease of symptoms.⁴ In addition to its efficacy, the application process of silver diamine fluoride is noninvasive and mimics that of a sodium fluoride varnish. First, the carious teeth are brushed without paste to remove excess debris, rinsed, isolated to keep dry, and one drop of the silver diamine fluoride is placed on the lesion for two minutes. After two minutes the excess silver diamine fluoride is removed and the patient is advised not to eat or drink for one hour. It is also recommended to apply

petroleum jelly to the nearby gingiva for protection and to use the smallest available micro sponge, while dabbing the side of the dampen dish to remove excess liquid before application.⁸

There are currently two types of silver diamine fluoride. One is ammonia-based 38% silver diamine fluoride and the other is water-based 40% silver fluoride.⁹ Many studies have been done on both formulas of silver diamine fluoride and only one clinical study has been done on the ability to reduce cervical hypersensitivity.⁹

Silver diamine fluoride (also known as SDF) is the first ever product on the market with the ability to arrest dental caries.¹ The silver acts as an antimicrobial, the fluoride promotes remineralization, and the ammonia stabilizes high concentrations of the solution.⁸ This allows SDF to be used as both a noninvasive treatment option for dental decay and as a preventive measure for dental decay. Two American dentists in 1891 and then another American dentist in 1917 discovered that utilizing silver nitrate from amalgam scraps mixed with nitric acid arrested dental decay but the disadvantage was the arrested carious lesion spot would stain black. This was the beginning of research in various countries on the use of SDF.

Currently, SDF has been in the approval process by the Food and Drug Administration (FDA). In 2014, it was approved as a class II medical device; this is the same class as 5% sodium fluoride varnish. The SDF approval provided by the FDA is for hypersensitivity treatment in adults over 21 and the preventive abilities were left off the label.¹⁰ As of August 2015, only one SDF product was approved in the U.S.^{8,11} As of late 2016, the FDA granted silver diamine fluoride 38%, as breakthrough therapy designation for use in arresting dental caries in children and adults.^{12,13} Dental hygienists in most states are

permitted to apply SDF under the same authorization or restrictions as other topical fluorides.¹² The American Academy of Pediatric Dentistry (AAPD) in October 2017 issued the first evidence based guidelines for the use of silver diamine fluoride 38% to arrest cavitated caries lesions in primary teeth as part of a comprehensive caries management program.^{14,15} The AAPD based its information on a systematic review from 1969-2016.¹⁴ The AAPD president, Dr. James Nickman refers to fluoridated water and SDF as a revolution in the past century in pediatric dental health.¹⁴ With the CDC citing dental caries as the most prevalent infectious disease in children in the U.S. affecting 40% before reaching kindergarten SDF 38% allows safer treatment options when compared to sedation or general anesthesia for children and those with special needs.^{14,15}

The AAPD notates the lack of severe pulpal damage but directs SDF should not be placed on exposed pulp.¹⁶ The ADA Clinical Practice Guidelines on the use of nonsurgical, nonrestorative treatments for caries management to arrest cavitated caries on coronal surfaces of primary or permanent teeth clinicians use 38% silver diamine fluoride solution twice a year.¹⁴⁻¹⁷

Despite the trademark black stain it creates on unsound dentin and enamel, it is widely used in numerous countries around the world. When silver diamine fluoride is placed on tooth surface absent of carious lesions the area becomes resistant to biofilm formation and further cavity formation due to remnant ionic silver.⁸ With the application of silver diamine fluoride to the carious lesion the squamous layer of silver-protein conjugates forms.⁸ This increases resistance to acid dissolution and enzymatic digestion.⁸ Then the hydroxyapatite and fluorapatite form on the exposed organic matrix with the presence of silver chloride and metallic silver.⁸ Finally the mineral density and hardness of the lesion increases and the depth

of the lesion decreases.⁸ Demineralized dentin will have more silver and fluoride deposited in the area than non-demineralized dentin and therefore will become more resistant to caries bacteria than treated sound dentin.⁸ The silver ions in SDF kill bacteria and when that bacteria is added to new living bacteria the silver will re-activate causing the dead bacteria to kill the living bacteria.⁸ One dentist has began placing a glass ionomer over it when the black stain is of concern to the patient.¹⁸

Research Question

What are dental hygiene schools teaching about silver diamine fluoride? Are the schools training student dental hygienists to clinically apply silver diamine fluoride?

Hypothesis

Dental hygiene schools in the U.S. are aware of Silver Diamine Fluoride. The educational curriculums within the programs have not been altered to include information, scientific findings and application training for SDF.

Significance of Problem

The dental hygienist plays a key role in the dental disease prevention and oral health care in the field of dentistry. The dental hygienist's role is to educate and prevent disease. Early childhood caries (ECC) is rampant in 45% of all United States children five years and younger.¹⁹ Early manifestation of the disease foretells chronic and steady dental caries throughout a persons' lifetime. Due to the current oral disease status of nearly half of children in the U.S. being affected by dental caries, it is critical to find a cure and a more efficient and effective preventive measure. Dental caries is a varied progression from dietary sugars, bacterial metabolism, demineralization, and organic degradation.⁸ The collagenous organic matrix of the tooth is exposed once the dentin surface is demineralization and

destroyed by native and bacterial proteases enables a lesion to become larger in size.⁸ Dental hygienists are the preventive professionals of oral health care, the emphasis on preventing this disease in children is vital to improving the overall quality of life of citizens in the U.S. As new changes in dentistry arise and the FDA approve products such as SDF, the education of dental hygiene students will need to include these new treatment regimens. Without proper updated education the ability to prevent ECC will continue to hinder the quality of life for populations.

Sodium fluoride is currently a treatment modality utilized by dental hygienists as the method to intervene the caries process. As reported by the Department of Health and Human Service on behalf of the Center for Disease Control (CDC) it has been determined that community water fluoridation can reduce caries prevalence by an average of 25%.⁵ CDC also states that in office application of fluoride varnish twice a year may reduce decay by one-third in primary dentition.²⁰ ECC primarily affects those of low -income status. Since fluoride varnish treatment cost at about \$16 per application, it is a cost effective preventive therapy. Dental hygienists need to be the advocates for the oral health and prevention of their communities and especially for those with access to care obstacles and those with financial limitations. Patients of all ages and socioeconomic status deserve the best possible treatment and prevention applications. It is the job of the dental hygienist to determine the best possible treatment for them. Therefore, the role of the dental hygienists can include conducting the research necessary on new products that treat and prevent disease.

In other areas of the world SDF preventive abilities are recognized and used to help treat and prevent dental caries. As it passes through the FDA for its dental decay arresting properties, the treatment options of all-dental professionals in the US may be improved. By

adding SDF to the dental hygienist's armamentarium a more dominant role in preventive dentistry will be obtained for the dental hygiene profession by actively decreasing or preventing the risk of caries. With SDF included into the scope of practice for the dental hygienist patient care will increase in preventive treatment options. This increased scope of practice will need to be adapted to the education of dental hygiene students.

The preventive role of a dental hygienist can become a widely known and valued position in oral health care system with a product such as SDF as an option during care. By technical definition, dental hygiene is a field of study, within the profession of dentistry. Striving to instill value and independence, as its own profession, new preventive products such as SDF and the decay arresting properties will assist dental hygiene to grow beyond a field of study. Dental hygienist need to research products that will prevent various oral diseases including SDF's abilities to prevent caries. As dental hygienists scientifically prove the value of preventive products such as SDF, the community will value the significance that dental hygiene brings as a profession.

A multitude of research currently supports SDF in its ability to stop the carious lesion process including many studies conducted using the scientific double blind cohort research method. Data collected have shown promising results of arrested carious lesions anywhere from 70.3%-96.1% using SDF.⁶ While sodium fluoride highest caries prevention rates are 21.3%-55.7%.⁶ These remarkable results indicate that SDF could be the future of dental care. This product creates a noninvasive measure of treatment for ECC and minimizes trauma to young children. This more cost effective measure can ensure better care access for the low-income families whom cannot afford to treat the ECC with expensive stainless steel crowns. This product can also change the future of preventive dentistry care provided by the dental

hygienist in clinical settings. SDF is another option that can be utilized to help reduce the number of children less than 5 years of age with ECC to less than the current 45% it is at, while promoting dental hygiene preventive care. With research aiming towards the SDF application, pre-cariou lesion preventive care is at a dynamic turning point for the future.

Operational Definitions

Sodium Fluoride: A crystalline salt used in trace amounts in water, toothpaste, mouth rinse, and varnish in treatment to prevent tooth decay.

Silver Diamine Fluoride (SDF): liquid silver and fluoride combination used to control and prevent progression of caries process and hypersensitivity.

Arrest: A carious lesion in which the progression of decay has halted.

Fluorapatite: Crystalline structure with increased resistance to mineral loss from acids produced by plaque when compared to hydroxyapatite. Formed from hydroxyapatite having some fluoride ions replaced by hydroxyl ions.

Hydroxyapatite: The natural inorganic structure of bone matrix and teeth.

Double Blind Cohort: Both the researchers and participants are unaware of the control group and test group and the group of participants share common characteristics.

Armamentarium: A collection of equipment, methods and techniques for specific duties.

Early Childhood Caries (ECC): Tooth decay among children 6 years and younger.

Demineralization: The process that causes dental caries.

CHAPTER II: REVIEW OF THE LITERATURE

Introduction

Silver Diamine Fluoride is a relatively new product approved by the FDA in the United States. In other areas of the world it is being utilized for many of its preventive properties. In order to analyze the uses for SDF and the caries-arresting capabilities information will be covered on SDF use in Japan, England, Brazil, and Hong Kong.²¹ This will allow the comparison to the United States use of SDF as hypersensitivity agent in adults over the age of 21.^{10,11} After review of SDF uses around the world, the history of SDF, and the process SDF has gone through with the FDA it will allow coverage of the safety and billing for SDF. Articles have been searched through PubMed database, ADHA website, the University of New Mexico's Health Sciences Library and Information Center with World Cat database, Science Direct and BioMed Central databases, and dental hygiene information has been searched through published textbooks.

Silver Diamine Fluoride in China

In 2002, the Journal of Dental Research published an article on a study conducted using silver diamine fluoride. The double blind cohort research study was conducted in the late 1990's in Guangzhou, China. The location was picked because it had 0.2ppm fluoride in the water, and fluoridated toothpaste was rare to find and more expensive in comparison to non-fluoridated toothpaste. No other supplemental fluoride was available to these subjects. The main objectives in this study were the applications of topical fluoride and its ability to arrest dentin in the maxillary anterior teeth of pre-school children. The findings before and after the study were recorded as sound, active caries (penetrate dentin with light force), arrested caries but not black (dentin could not be penetrated), filled, or missing.

There were 308 children at the baseline of the study with the decayed-missing-filled index (dmfs) at 4.66 and the mean active caries score of 3.92. The children were divided into five treatment groups. Two groups received annual treatment of SDF and one of those two groups had the soft carious lesions excavated while the other group did not. Two other groups received sodium fluoride varnish every 3 months to lesions, and one of those two groups had the soft carious lesions excavated while the other group did not. Then the final fifth group received water as treatment to the lesions creating the control group. The results showed the children in the control group developed more new carious lesions in the maxillary anterior teeth than any of the other children.

The results were significant when looking at percentage of arrested caries. Based upon the initial numbers of carious lesions from the 375 children in the beginning of the study, and the arrested carious lesions from the 308 children recorded at the end; the control group resulted in 33% arrested carious lesions, the sodium fluoride groups equaled 38% arrested carious lesions, and the sodium diamine fluoride gave an 63% arrested carious lesions. This evidence gave an entry to the years of research on the silver diamine fluoride with its low cost and noninvasive procedures. SDF minimizes potential traumatic experiences for children in the dental setting.

Silver Diamine Fluoride in Hong Kong

Over a three-year period 306 elderly individuals (233 women and 73 men) in Hong Kong were utilized in the randomized controlled trial study to determine the more effective protocol in preventing root caries in elderly individuals living in senior homes. The population was recruited from 21 different homes that attended free dental examinations from December 2002 to August 2003. The average age of the participants was 78. The

average number of teeth each individual had with gingival recession was 14 and a root caries index score of 10.7. The individual must have had at least 5 teeth with gingival recession, no serious medical complications and must be able to have basic self-care abilities including brushing their own teeth. The study was conducted with four protocols being tested. The individuals were randomly placed into group (1) individualized oral hygiene instruction (2) OHI and application of 1% chlorhexidine varnish every 3 months (3) OHI and applications of 5% sodium fluoride varnish every 3 months or (4) OHI and annual applications of 38% silver diamine fluoride solution. Annual follow-up examinations were conducted with the same equipment and criteria as at baseline. As a double blind study the dentist conducting the annual examine was unaware of the participants groups. Two hundred and three participants were followed from beginning to end of the study and the dropout rate was similar among the four groups.

In the conclusion of the trial it was found that OHI alone did not yield the same root caries prevention rates as the other three groups. The results showed Chlorhexidine varnish (CHX) had a 57% root caries reduction rate, sodium fluoride varnish (SF) had a 64% root caries reduction rate, and silver diamine fluoride (SDF) had a 71% root caries reduction rate.²² SDF did have the cost advantage as it only needed to be applied once per year and the other applications, CHX and SF, needed to be applied four times per year. Each product used presented with disadvantages such as: CHX causes temporary staining and a bitter taste, SF causes temporary yellow stain or white stain.²² SDF causes a permanent black stain on arrested carious lesions, can have metallic or bitter taste, can cause temporary tattoo on gingiva and resolves in 2-14 days, can stain clinic surfaces and clothes. The stain does not come out once it sets. Spills can be cleaned up immediately with copious water, ethanol, or

bleach. High pH solvents such as ammonia may be more successful.^{8,22} In the study the participants tolerated all staining well.²²

Silver Diamine Fluoride in Cuba

From February 2000 to March 2003 in Santiago de Cuba, research was conducted on silver diamine fluoride. This location had much less fluoride in the water, only 0.09ppm, and extremely limited availability to fluoride toothpaste. Here in Cuba, children in schools from ages 6 to 15 years old are registered with the government-funded dental health center that they visit annually for dental exams and treatment. Here they receive nutritional counseling, brushing instructions and occasional 0.2% sodium fluoride rinses. This study hypothesized that monthly applications of SDF can arrest the development of caries in primary dentition and prevent caries in first permanent molars. The parameters of the study included a baseline exam focused only on the surfaces of the canines and molars then charted as healthy with active caries (a presence of cavity with soft floor or walls), with inactive caries (cavity with hard floor or walls), filled or absent. There were 373 children involved in this study. The children were divided into a control group and the group with SDF applications. The SDF was applied to any deciduous teeth with carious lesions without receiving excavation. Any erupted first molars with carious lesions were excavated, and all present first molars received an application of the SDF. The results show that 77% of the baseline active carious lesions were arrested with the application of SDF. In the study conducted in China there were a few incidences of black stain from the application of SDF on the carious lesions. In this study the black stain could be documented. In the control group 47% inactive black lesions were found and in the SDF group 97% inactive black lesions were found. According to the researchers, this black staining was far outweighed by the caries-preventive benefits of SDF treatment.³

One other potential risk is a possibility of toxicity to the pulp; however, this concern was not supported by the present results

Silver Diamine Fluoride in the Australia

Australia currently has an aging population suffering from various conditions such as dementia and frailty.⁹ As generations continue to live longer the need to maintain oral health grows. In 2011, Australia began utilizing silver diamine fluoride in combination with stannous fluoride to control, manage, and prevent root caries in elderly individuals. Using the silver diamine fluoride to arrest the root caries and then applying stannous fluoride to prevent caries care in aged residential facilities becomes an effective and minimally invasive option.⁹ With elderly patients early less complicated dental conditions are not treated due to fear of complications or having to stop mid-treatment.⁹ This leaves elderly patients with treatment put off until acute episodes force the patient into invasive treatments.⁹ Utilizing the low cost, minimally invasive method of silver diamine fluoride with stannous fluoride as topical applications in treatment of the frail elderly dementia or other challenging behavior patients with multiple decayed teeth has shown promises in Australia.⁹

Since the 1980's Australia has performed clinical evaluations of topical applications of water-based 40% silver fluoride followed by the application of 10% stannous fluoride as a reducing agent.⁹ That study lasted two years and the 74% of the interproximal surfaces and 90% of the occlusal surfaces remained unchanged.⁹

Australia continued research and discovered that applying potassium iodide as a clear liquid after the application of silver diamine fluoride helped to reduce the staining from the silver salts.⁹ Some major advantages were found when using silver diamine fluoride with the stannous fluoride when compared to using silver diamine fluoride alone. In using the

combination it was found that no gingival and mucosal irritation occurred. This means it can be used over wide areas without discomfort for the patient. Also, this combination can be used in 3-4 month reapplications periods in non-esthetic areas to prevent and arrest single or multiple carious lesions in these compromised elderly patients.⁹ Reapplication would vary from patient to patient depending on things such as the patients' caries risk and other considerations such as salivary function or poor oral hygiene.⁹ It was noted that patients with better salivary flow have better results over longer periods of time due to saliva's natural abilities to fight caries causing oral bacteria.⁹

Just as silver diamine fluoride needs to undergo more than the one clinical trial this combination of silver diamine fluoride with stannous fluoride too needs to undergo clinical trials for its ability to arrest and prevent caries in compromised elderly patients.

Silver Diamine Fluoride in the United States

In August of 2014 the Food and Drug Administration (FDA) approved the first SDF product for the market.⁸ The Class II medical device silver diamine fluoride is a colorless liquid with 24.4%-28.8% silver and 5.0%-5.9% fluoride approved for treatment of hypersensitivity. As of August 2015, only one only SDF product is approved in the U.S.^{8,11} SDF has been given the same classification and indication as 5% sodium fluoride varnish by the FDA.¹¹ Single applications of SDF have been reported as insufficient for benefits. SDF disadvantages aside from the black staining of carious lesions include metallic taste and the potential to irritate gingival and mucosal surfaces and contact should be minimized.^{8,11} Medical uses for silver have been around since 1000 BC for potable water. Currently, silver used in medicine include applications of silver nitrate, silver foil, and silver sutures for prevention of ocular and surgical infections.⁶ Silver has been demonstrated to be able to kill

spirogyra and silver nitrate is known for its antimicrobial effect. Dr. Stebbins (1891) noticed the silver nitrate from amalgam scraps mixed with nitric acid arrested decay in 61% of 3 year olds.⁶ This inspired Dr. Howe (1917) from N.Y. to directly apply silver nitrate to carious lesions and gained similar results. These early studies instigated the use of silver diamine fluoride in Australia, Japan and Mexico.⁶ Tests are being conducted for silver additives to composite filling materials for its caries prevention and reduction of periodontal pathogens.⁶ Dr. Steven Duffin, frequently uses SDF off-label in his practice calling it the most effective agent in 30 years to arrest caries.¹⁸

Silver nitrate was utilized for years under fillings to kill bacteria after Dr. Percy Howe introduced it in 1917 but it quickly was not favored due to its side effect of black stain.¹⁸ Dr. Duffin tells his young patients that it is just a scar and if parents object he places a glass ionomer over it.¹⁸ Duffin also uses SDF on adult patients with root caries, Alzheimer's patients, and those unable to maintain good oral hygiene. Two dental textbooks mention SDF as a future treatment for caries: "*Dental Caries: The Disease and Its Clinical Management, 2nd Edition* (Wiley-Blackwell, 2008) and *Early Childhood Oral Health* (Wiley-Blackwell, 2009)".¹⁸

The FDA can approve "breakthrough therapy designation" of products.^{12,13} This is the way the FDA allows drug development and review to be expedited when treating serious conditions.¹³ As of late 2016, the FDA approved SDF for "breakthrough therapy designation" and allowed silver diamine fluoride 38%, to be used in children and adults for its caries arresting properties.^{12,13} The American Academy of Pediatric Dentistry (AAPD) in October 2017 issued the first evidence based guidelines for the use of silver diamine fluoride 38% to arrest cavitated caries lesions in primary teeth as part of a comprehensive caries management

program.^{14,15} The AAPD based its information on a systematic review from 1969-2016.¹⁴ The AAPD president, Dr. James Nickman refers to fluoridated water and SDF as a revolution in the past century in pediatric dental health.¹⁴ The AAPD notates the lack of severe pulpal damage but directs SDF should not be placed on exposed pulp.¹⁶ The ADA Clinical Practice Guidelines on the use of nonsurgical, nonrestorative treatments for caries management to arrest cavitated caries on coronal surfaces of primary or permanent teeth clinicians use 38% silver diamine fluoride solution twice a year.¹⁴⁻¹⁷

Safety of Silver Diamine Fluoride

In order to gain the FDA clearance female and male rat/mouse studies were conducted to determine the lethal dose (LD50) of SDF by oral and subcutaneous administration.⁸ The subcutaneous route is a worst-case scenario.⁸ One drop of SDF is more than enough to treat 5 teeth and contains 9.5mg of SDF.⁸ “Assuming the smallest child with caries would be in the range of 10 kg, the dose would be 0.95 mg / kg child. Thus the relative safety margin of using an entire drop on a 10kg child is: 380 mg/kg LD50 / 0.95 mg / kg dose = 400-fold safety margin.”⁸ “Actual dose is likely to be much smaller, for example 2.37 mg total for 3 teeth was the largest dose measured in 6 patients.”⁸ “The most frequent application monitored in a clinical trial was weekly for 3 weeks, annually. Thus we set our recommended limit as 1 drop (25 μ L) per 10 kg per treatment visit, with weekly intervals at most. This dose is commensurate with the EPA’s allowable short-term exposure of 1.142 mg silver per liter of drinking water for 1-10 days (ATSDR, 1990).”⁸

Silver and fluoride levels are closely monitored for U.S. products. The Health Department of Western Australia conducted a study that found no evidence of fluorosis resulting from long-term proper use of silver diamine fluoride.⁸ “Concerns for fluoride safety

are most relevant to chronic exposure, whereas this is an acute exposure. Chronically high systemic fluoride results in dental fluorosis. Therefore, we have concluded that the development of fluorosis after application of the U.S. approved product is not a clinically significant risk.”⁸

Billing

“A new code, D1354, for “*interim caries arresting medication application*” was approved by the Code on Dental Procedures and Nomenclature (CDT) Code Maintenance Commission for 2016. The code definition is: *Conservative treatment of an active, non-symptomatic carious lesion by topical application of a caries arresting or inhibiting medicament and without mechanical removal of sound tooth structure.* The CDT Code is the U.S. HIPAA standard code set and is required for billing. The Commission includes representatives from the major insurers, Medicaid, ADA, AGD and specialty organizations. Insurers are in the process of evaluating coverage for this treatment.”⁸

“CDT code D1354 became effective on January 1, 2016, and has had one revision effective January 1, 2018. This revision was addition of “– **per tooth**” to the nomenclature. The current full CDT Code entry as seen in *CDT 2018* follows. Please note that the revision is highlighted for emphasis.

D1354 interim caries arresting medicament application – per tooth

Conservative treatment of an active, non-symptomatic carious lesion by topical application of a caries arresting or inhibiting medicament and without mechanical removal of sound tooth structure.”²³

“D9910 Application of Desensitizing Medicament. Revised Description

This code is used for the topical application of fluoride or other desensitizing medicament applied to the root surface. This is a "per visit" procedure and involves one or more quadrants. This code can only be used once per visit. In the "Remarks" section of the ADA claim form the medicament used should be indicated."²³

Summary

Early childhood caries is rampant in 45% of all United States children five years and younger are affected.¹⁹ Root caries is prevalent in elderly populations worldwide and in the U.S. alone, 50% of people over the age of 75 and 25% of people over the age of 65 have root caries.²⁴ Dental hygienist often work in rural, underserved, areas where this disease is prevalent, thus clinicians need to know the indications and contraindications, follow manufacturer directions for use, and obtain informed consent before using SDF.¹⁰ Dental hygienists in most states whose Medicaid programs cover SDF application may be permitted to apply SDF under the same authorization or restrictions as other topical fluorides¹² The AAPD and ADA support the application of SDF by trained dental personnel or health professionals according to the state's dental practice act.¹⁵⁻¹⁷ Silver allergies are contraindicated. Relative contraindications include any significant gingivitis or mucositis that disrupts the protective barrier formed by stratified squamous epithelium, silver allergy, the off label use of saturated solution of potassium iodide (SSKI) immediately following silver diamine fluoride (thought to decrease the black staining but is not proven to dramatically help) is contraindicated in pregnant women and the first six months of breastfeeding due to concerns of overloading the developing thyroid with iodine.⁸

With the many studies being conducted on this new revolutionary product new opportunities to serve the public and assist in further research are arising. So many have

accepted, appreciated and utilized SDF for its caries arresting capabilities, low cost, and non-invasive procedure. SDF is rising to become the future treatment of caries the oral disease found in so many children, elderly and those of low socioeconomic. SDF shows a promising alternative of treatment for those suffering from caries, the most prevalent oral disease.

CHAPTER III: METHODS AND MATERIALS

Introduction

This survey study was designed with a focus on dental hygiene program directors and education materials in the United States. The purpose of the study was to determine the awareness and knowledge of silver diamine fluoride among dental hygiene program directors and to determine if the dental hygiene schools have included silver diamine fluoride education to their curriculum. The survey was to evaluate silver diamine fluoride properties, uses, application methods and current FDA approvals have been adopted in dental hygiene programs in the United States.

- In order to survey each school, the program directors were given the survey by email to complete and email back. The survey includes questions regarding:
- Information about the director's knowledge and personal continuing education on silver diamine fluoride.
- Any didactic education of silver diamine fluoride that the program offers to students.
- How the programs faculty becomes aware of changes in dentistry and FDA changes.
- How the decision is made to change the programs educational materials and processes to include new materials, FDA changes, or other changes to the curriculum.

After all surveys were collected a review and analysis of collected data were performed in order to determine the U.S. dental hygiene programs knowledge of silver

diamine fluoride and the programs education and adaptation to changes in the FDA with the new product silver diamine fluoride.

Research Design

A descriptive survey was used to gather information from all United States dental hygiene program directors. First a pilot study was conducted on a small convenience sample of dental hygiene educators. The purpose of the pilot study was to evaluate dental hygiene school educator's willingness to review the survey and allow for feedback to help identify potential issue with the survey. Additional information provided to the convenience sample group included: the main objectives, the research question and hypothesis. This was done to gain feedback on the surveys ability to gain relevant information in all components and limit possible potential issues for the survey may include wording, layout, comprehension, length, and time commitment/demand. Once the information from the pilot study was gathered and alterations made it was emailed to all dental hygiene program directors in the United States.

In order to efficiently and accurately collect the data, the survey questions have three main objectives to determine the following:

1. The director's knowledge of silver diamine fluoride.
2. The process in which the program and faculty stay relevant and adapt to the changes in dentistry, the FDA and ADA.
3. The program education provided to students on silver diamine fluoride.

Sample Defined

There are a total of 330 entry-level and baccalaureate degree dental hygiene programs in the United States as of November 3, 2016 as stated in the American Dental Hygiene Association list of entry-level dental hygiene Programs.²⁵ This does not include discontinued

programs or programs currently in the teach-out process of discontinuing the program. This does include schools that are large and have off-site facilities in multiple cities. The research question was centered on the education materials provided to dental hygiene students and the dental hygiene directors awareness of silver diamine fluoride. This required a census study to include all entry-level dental hygiene programs in the United States; in order to show the prevalence of the educational programs remaining relevant to the changes in dentistry, the FDA and in order to answer the research question while verifying the hypothesis.

Procedures

The descriptive survey was then sent to all 330 active dental hygiene programs listed by the American Dental Hygienists' Association. The surveys were sent by email to the program directors with a two-week date to be returned by. The surveys were sent out strategically as to not interfere with typical peak school function periods such as holidays, midterms and finals in order to promote survey response and return. Schools are not looked at on an individual basis for time commitment conflicts. In addition, three reminder emails with the survey attached were sent: one week after the initial email, three days before the return date and the last reminder email on the return date.

After collection of the surveys the data analysis was compiled based on the returned surveys with notations made of the number of nonparticipating schools in comparison to the number of participating schools. The descriptive statistical analysis of the data collected is shown based on the tables and graphs.

Data Collection

This survey study was conducted by surveying all of the 330 dental hygiene entry-level schools directors. Emails were sent to all directors of these programs using the contact

information from the American Dental Hygienists' Association list that is accessed online. Each email, containing the survey created, was sent to all program directors along with the request of completion within a two-week reply limit. After one week, the schools were sent another email with a reminder to complete and return within the week. Finally, an email sent again with three days remaining and again on the last day to all schools. All schools that did not complete and return the survey along with the actual numbers of completion are factors that are noted and taken into account during the analysis process of the data.

Reliability Measures

To allow for maximum reliability while conducting the survey and measuring the United States entry-level dental hygiene programs, and directors, knowledge and educational materials on silver diamine fluoride the survey was created in a fashion to allow minimal misunderstanding and minimal interpretation options. In order to do this the survey contains descriptive information of the purpose of the survey study including the research question, the three main goals of the questions in the survey and the ultimate goal of finding any validity to the hypothesis. This survey was predominantly constructed based on the 5-point likert scale while following the format previously mentioned. The survey does consist of a few short response questions. This section was designed to allow the opportunity for the directors to input any additional information they feel is significant to convey about their programs based on the survey parameters and description of the topic silver diamine fluoride. The short answer response section was not utilized as a measurement for the research question and hypothesis but instead used to gather possible unknown information that can lead to another research format, topic, or to gain better parameters for future research related to this hypothesis and research question.

Statistical Analysis

In order to prove this studies hypothesis, the data collected in this survey were analyzed collectively along with on an individual question basis. Some questions were designed in order to use together for deeper comprehension of the U.S. dental hygiene school's awareness of SDF along with curriculum provided to students. While other questions were designed to solely answer the research question and provide data directly pertaining to each individual school teaching and training of SDF to students. While analyzing and comparing the data collected, based on responses, limitations of the survey questions utilized were noted thus opportunities and recommendation of further concise research studies to dig deeper into the research question and hypothesis surfaced.

CHAPTER IV: RESULTS, DISCUSSION AND CONCLUSION

Results

From the 330 entry-level dental hygiene schools, the survey had a response from 39 school directors. The following figures and data represent the responses to the online survey. Information collected to assess awareness, knowledge, and curriculum of SDF. As shown in *Figure 1* of the 39 schools 27 are Associate programs and 12 are Bachelor programs.

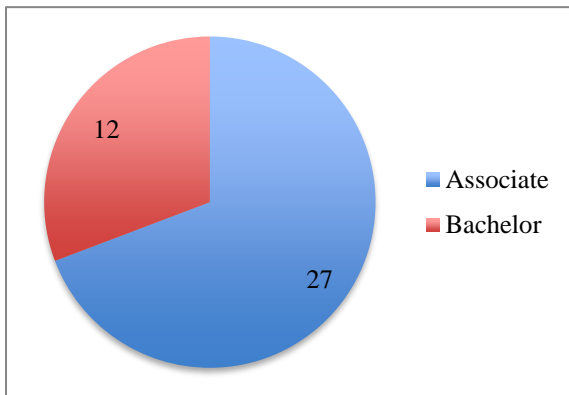


Figure 1: Number of programs based on type of degree obtained on completion of dental hygiene entry-level schools.

Figure 2 shows 28.21% of the schools have 0-3 full time registered dental hygiene faculty positions, 58.97% have 4-9 full time registered dental hygiene faculty positions and 12.82% have 10+ full time registered dental hygiene faculty positions.

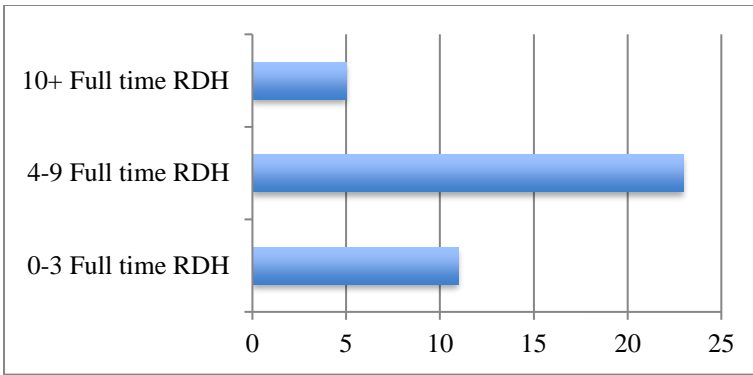


Figure 2: Full time registered dental hygiene faculty positions.

Education on fluoride is provided in dental hygiene programs. The survey has determined 94.87% of the schools introduce fluoride education didactically by a full time faculty member. Of the schools, 5.13% introduce and educate didactically using part time faculty.

When the directors were asked, “Is Silver Diamine Fluoride a product of interest to provide education to the students within this program?” *Figure 3* shows the response rate of 92.31% indicating SDF is a product of interest to provide education to the students.

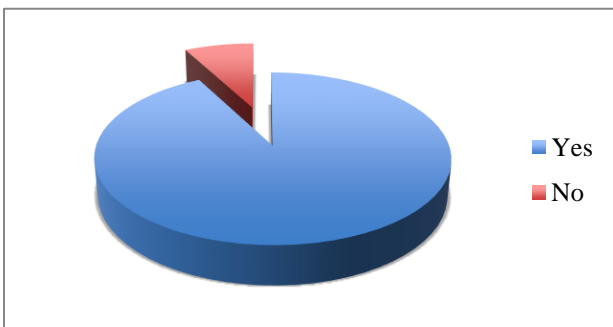


Figure 3: Is silver diamine fluoride a product of interest to provide education to the students within this program?

However, only 76.92% of the schools indicate SDF education is currently provided to students. The directors were asked to rank the level of SDF knowledge of the faculty member providing the SDF education to the students. As seen in *Figure 4*, 60.53% responded “somewhat knowledgeable” and 39.47% responded “very knowledgeable” while none responded that the faculty member providing the education to the students were either “not knowledgeable” or “subject matter experts”.

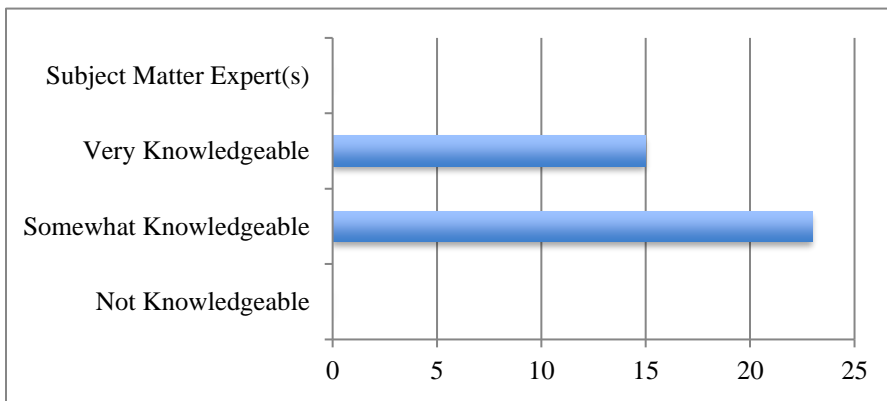


Figure 4: How knowledgeable is the faculty member providing SDF education to students.

Of the schools providing education on SDF, *Figure 5* shows that 50% combine the SDF education with the current fluoride education and lectures and 40% indicate the students receive 1-2 hour’s of dedicated SDF education and 10% indicate 0 hour’s of dedicated SDF education.

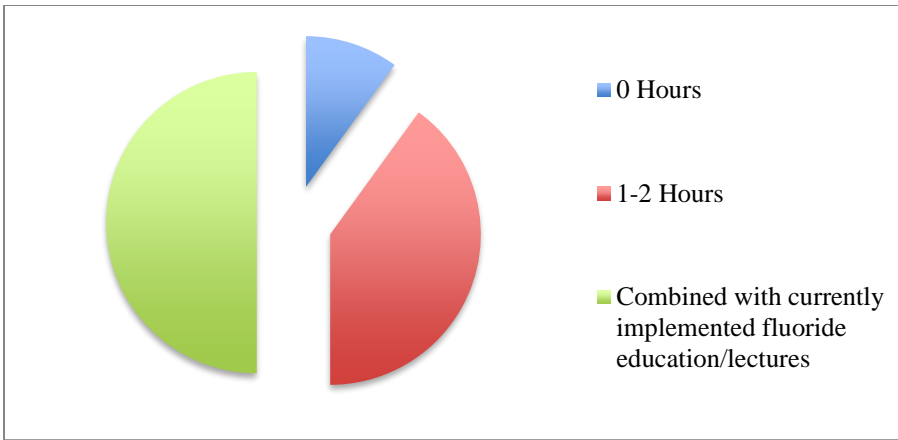


Figure 5: Amount of hours of dedicated SDF education provided to students.

Out of the 30 schools that indicate education is provided to students *Figure 6* shows that 66.67% currently do not use SDF in the clinic setting and 33.33% are currently using SDF for the caries arresting properties.

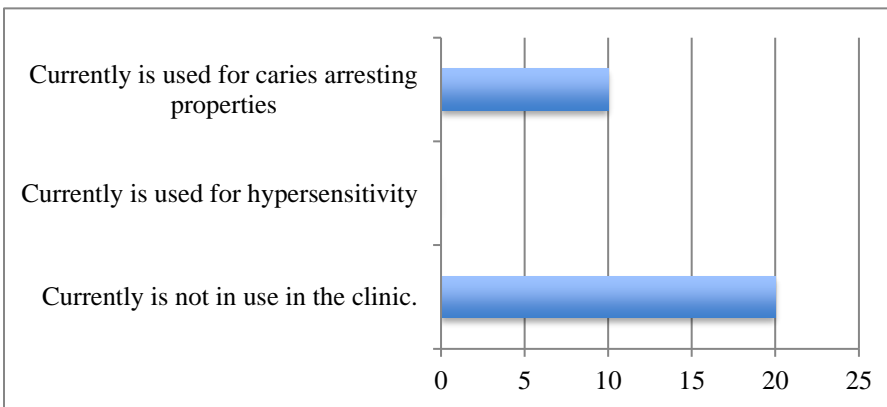


Figure 6: Schools current clinical setting use of SDF.

Thirty-eight directors provided responses based on personal SDF education. Shown in *Figure 7*, 50% of the program directors have 1-3 hours of SDF education, 23.68% have 0 hours of education, 15.79% have had SDF covered in other continuing education courses but

it was not the main focus of the course and 10.53% of the directors indicate they have 4+ hours of SDF education.

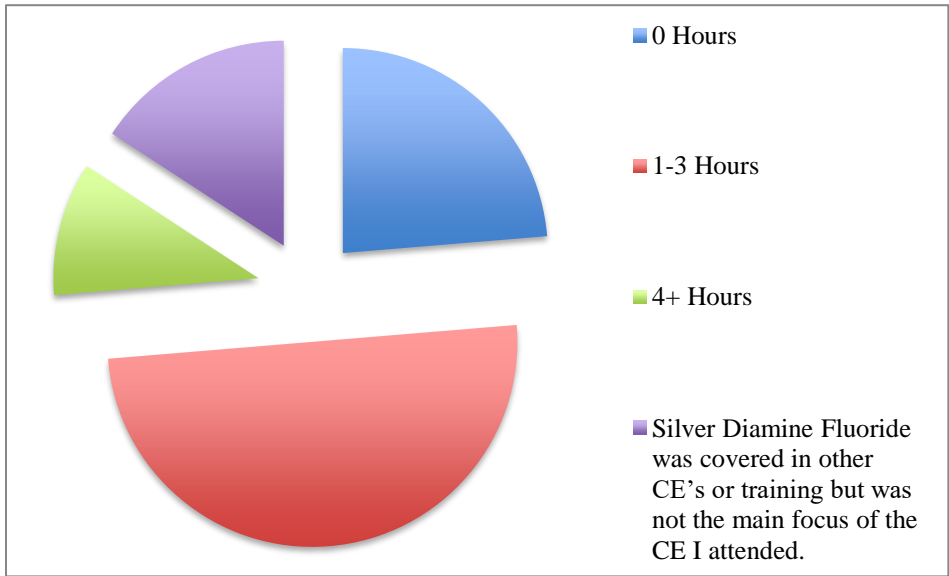


Figure 7: The directors personal history of SDF education.

Figure 8 shows that over the past two years 55.26% of the schools have provided 0 hours of continuing education to faculty on didactic, clinical and/or lab SDF education and 26.32% have provided 1-3 hours, 10.53% indicate SDF education was covered in other continuing education or trainings but was not the main focus and 7.89% indicate 4+ hours of SDF education provided. With 76.92% of schools providing SDF education to students yet only 34.21% of those schools are providing SDF education to the faculty.

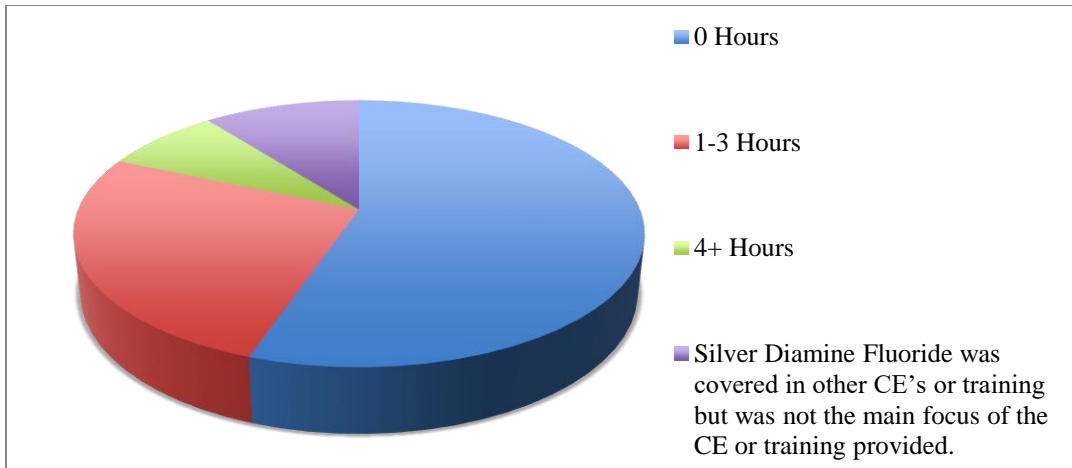


Figure 8: The schools two years history of continuing education provided to faculty on SDF.

The directors were provided a short answer opportunity to indicate how the faculty remains up to date with changes in dentistry and the FDA. *Table 1 and Figure 9* show the summary of the answers. With only 34.21% of schools providing SDF education to faculty that provide SDF education to students and 76.32% of directors respond that faculty utilize continuing education courses, professional/scholarly journals.

Short Answer Provided	Number Response
CE courses, professional/scholarly journals	29
Faculty Meetings/calibrations	3
Independent Research on Topic	2
Sales Reps /advertisements /product lines	2
FDA website	1
State Updates/Local component	1

Table 1: Short answer summary

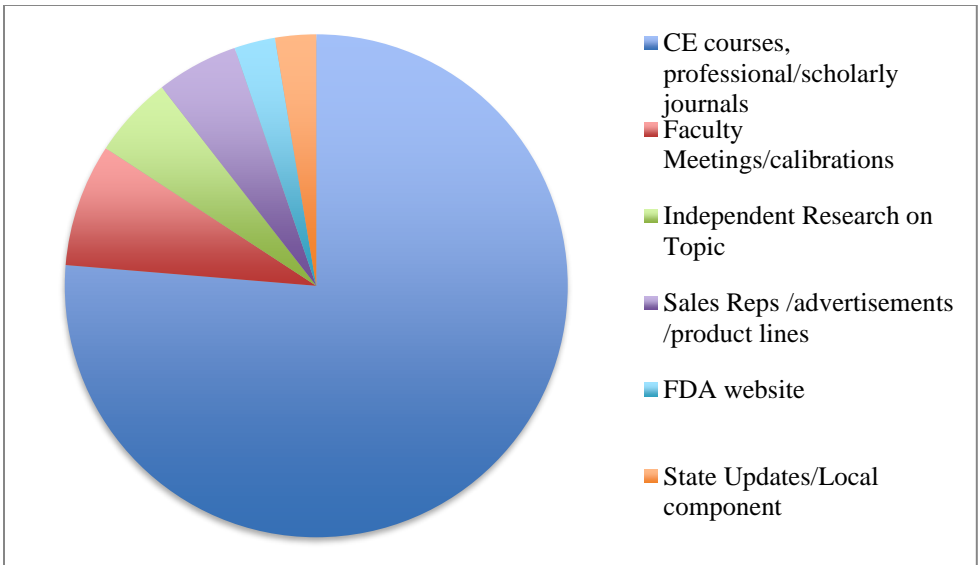


Figure 9: How faculty remain up to date with changes in dentistry and the FDA.

Figure 10, shows the director responses on how curriculum changes occur in order to include new materials, FDA changes and ADA changes. Sixty-one percent indicate it is done in faculty meetings and curriculum reviews while 24% indicate it is done in materials and curriculum committee reviews.

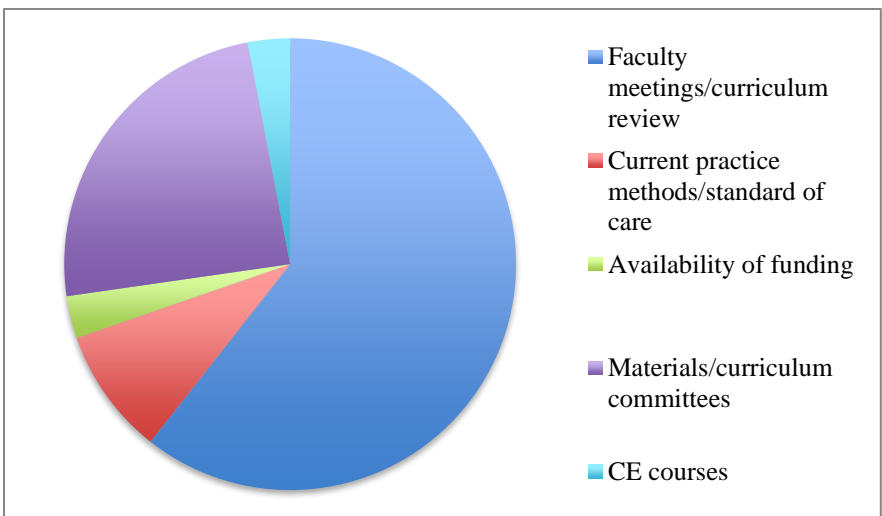


Figure 10: How curriculum changes occur to include new materials, FDA changes and ADA changes.

Twenty-nine directors indicate faculty stay up to date on changes in dentistry and the FDA by CE courses, professional or scholarly journals. As viewed in *Figure 11*, only 38.89% strongly agree that a dental hygienist can apply SDF under the same authorization as other topical fluorides based on each individual state governing laws. Yet only 10% replied no SDF education occur in the program and 90% of the directors indicated that SDF education is indeed provided to students. Of those providing SDF education 50% indicate it is done along with the current fluoride education (*Figure 5*) indicating there should be scope of practice awareness.

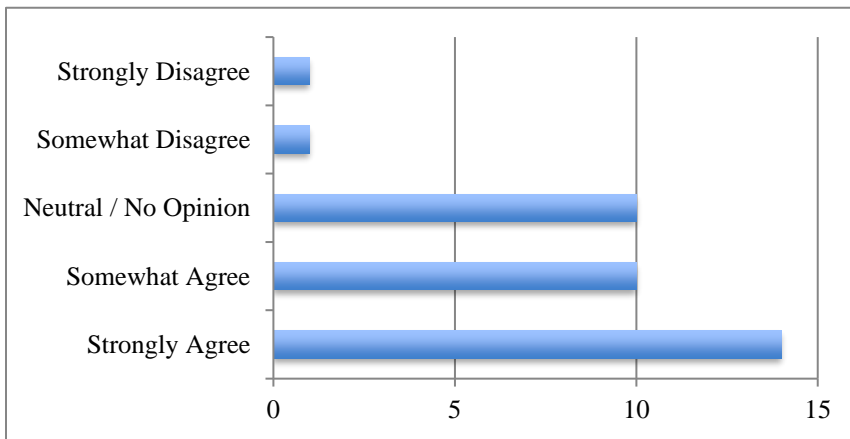


Figure 11: Directors awareness: A dental hygienist can apply SDF under the same authorization as other topical fluorides (based on state laws).

The FDA originally approved silver Diamine Fluoride as a class II medical device in order to treat tooth hypersensitivity. When asked 63.89% agreed with this fact, while 36.11% responded neutral/no opinion or strongly disagreed. The directors were asked, “The off label use of Silver Diamine Fluoride can arrest dental caries?” and 80.56% are aware of SDF’s caries arresting properties. The question, “Currently, the CDT does not have a billing code for the use of Silver Diamine Fluoride?” yielded interesting results as shown in *Figure 12*,

55.55% agreed or were neutral indicating more than half are unaware of CDT codes for SDF and only 44.45% somewhat disagreed or strongly disagreed indicating the awareness of the CDT codes.

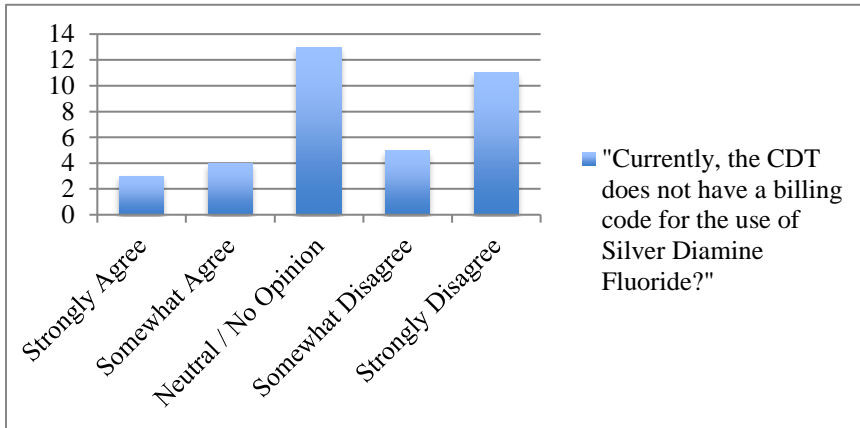


Figure 12: Directors awareness: Currently, the CDT does not have a billing code for the use of silver diamine fluoride?

The original FDA approval as a desensitizing application allowed it to be billed as D9910 and the new code for its caries arresting abilities is D1354. The 63.89% of directors indicated awareness of SDF approval by the FDA as a class II medical device to treat tooth hypersensitivity. *Figure 13* shows that 66.67% of director replies indicate their awareness of the one product of SDF marketed since 2015 in the U.S. and 33.33% are neutral or no opinion. Yet as shown previously in *Figure 6*, 66.67% do not utilize SDF in the program's clinical setting.

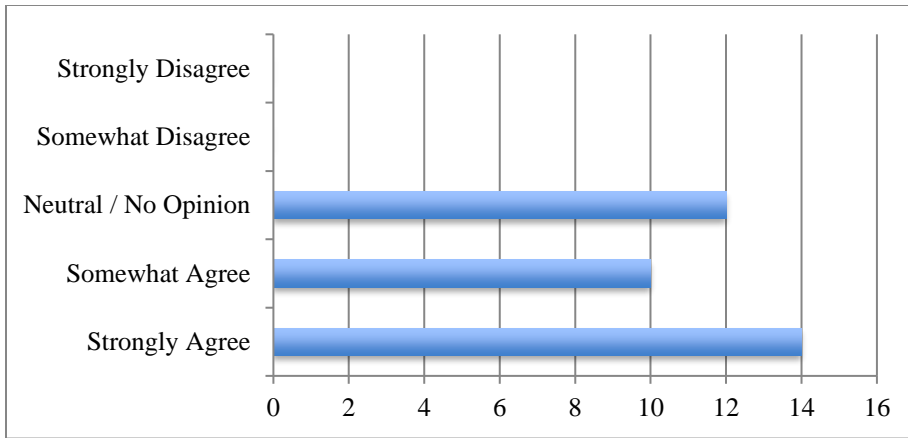


Figure 13: SDF has been marketed in the U.S. since 2015.

Discussion of Results

The survey was designed with the following focus items:

1. To assess entry-level dental hygiene program director’s knowledge and awareness of silver diamine fluoride.
2. To determine the education provided within the programs curriculum for students.
3. To answer the following questions: Are dental hygiene schools teaching about silver diamine fluoride? Are the schools training student dental hygienists to clinically apply silver diamine fluoride?
4. With a focus on the study’s hypothesis: Dental hygiene schools in the U.S. are aware of Silver Diamine Fluoride. The educational curriculums within the programs have not been altered to include information, scientific findings and current uses for SDF.

Approximately, 94.87% of the schools introduce fluoride didactically by a full time faculty member. The survey shows 92.31% indicate SDF is a product of interest to provide

education to students. Yet, only 76.92% of the schools indicate SDF education is currently provided to students. Out of the program directors surveyed, 50% indicate they personally have 1-3 hours of education on SDF and 10.53% of the directors indicate having 4+ hours of education on SDF. Nearly a quarter of the directors, at 23.68%, reported zero hours of SDF education. Other directors reported (15.79%) attending continuing education courses covering SDF. However, SDF was not the main focus of the course this provides a total of 76.32% of directors indicating to have some educational background on SDF and is nearly equal to the percentage of directors who currently provide SDF education.

Of the 76.92% of schools providing education on SDF additional data was collected. Fifty percent of schools combine SDF education with current fluoride education and lectures. With the vast information needed for comprehensive knowledge of SDF individualized lectures on SDF are indicated. Lectures can include various information including molecular and chemical information, therapeutic measures, side effects, application methods and processes, products available, SDF research and history, professional recommendations, and contraindications, and legal abilities based on individual states guidelines. Forty percent indicate the students receive 1-2 hour's of education dedicated to SDF and 10% indicate 0 hours of dedicated education are provided to students. Of the 30 schools that indicate SDF education is provided to students, only 33.33% are currently using SDF for the caries arresting properties. The other 66.67% of schools currently do not use SDF in the clinic setting at all. With the majority of schools not utilizing SDF in clinical settings it raises the question of the depth and applicability of the education provided if it is primarily presented didactically.

The directors were asked to rank the SDF knowledge of the faculty member providing education to students. Response rates of 60.53% indicate “somewhat knowledgeable” and 39.47% responded “very knowledgeable”. Yet over the past two years 55.26% of the directors responded that the schools have provided 0 hours of continuing education to faculty on didactic, clinical and/or lab education on SDF. It is interesting to see only 34.21% of schools provide SDF education to faculty. This seems to show correlation to the director’s response rate that the faculty member is “very knowledgeable”. However, 76.92% of schools are providing SDF education to students. With 76.32% of director’s responded faculty utilize continuing education courses and, or scholarly journals as informational resources on SDF, it again seems to correlate with the response rate of the faculty member being “somewhat knowledgeable”.

The FDA originally approved SDF as a Class II medical device to treat tooth hypersensitivity. Only 63.89% of directors indicated awareness of this by selecting strongly agreed or somewhat agreed and 36.11% were neutral/no opinion or strongly disagreed. Although, 80.56% of directors indicate their awareness of SDF’s caries arresting properties, only 38.89% of directors strongly agreed with the fact that a dental hygienist can apply SDF under the same authorization as other topical fluorides based on each individual state governing laws. It seems that the schools that stated “somewhat knowledgeable” may benefit from continuing education on dental hygienist’s scope of practice when using SDF. Only 66.67% of directors are aware of the one marketed product on the market in the U.S. since 2015. A surprisingly 55.55% of directors are unaware of the billing CDT codes for SDF. The original FDA approval as a desensitizing application allowed it to be billed as D9910 and the new code for its caries arresting abilities is D1354.

Sixty-one percent of directors indicate that curriculum changes occur in faculty meetings and only 24% indicate it is completed during materials and curriculum committee reviews. It would be beneficial to gain additional information from directors as to the faculty meetings typical process versus a curriculum review typical process. Based on titles of these meetings it seems to indicate a curriculum review committee is set up to assess and restructure the education provided to students and the faculty meeting is to calibrate and provide the curriculum to the faculty before it is provided to students. With 61% of directors responding that curriculum changes come from faculty meetings it raises the question how calibrated are faculty members on SDF knowledge, information provided to students and SDF application method because 55.26% directors indicated the school has provided zero hours of continuing education to faculty on SDF over the past two years. Directors indicated most staff gains knowledge from continuing education course work or scholarly journals leading to varied information and that could allow for differences of knowledge or even opinions.

There were not enough responses to make a generalized conclusion for all entry-level dental hygiene program directors knowledge and awareness of silver diamine fluoride or to be able to determine education provided within the programs. However, after reviewing the data collected the majority of schools are interested in providing education to the students on SDF and 76.92% indicate SDF education is provided to students.

In response to the question, “Are dental hygiene schools teaching about silver diamine fluoride?” there may be a connection between faculty’s knowledge of SDF and whether they choose to teach it in clinical settings. Since only 33% indicated SDF use in a clinical setting and knowledge of dental hygienist’s scope of practice in regards to SDF

application was low, more education on SDF may prove beneficial. There could be use for more SDF education for faculty by means of continuing education on adjunct services. A consideration for additional research could be services, products and treatments faculty would like continuing education on, to see if in fact there is a connection between knowledge level and clinical application.

With this surveys limited replies it does suggest that dental hygiene schools in the U.S. are aware of SDF. Yet fails to suggest that education curriculums have not been altered to include information, scientific findings, and current uses for SDF.

Conclusion from the Study and Recommendations for Further Studies

The data from this study supports that curriculums are being altered to include SDF education. Data collected also supports the awareness of SDF and its carries arresting properties. In addition, this study brings attention to gaps in the curriculum that could be improved such as incorporation of additional SDF knowledge, and clinical training and uses. This study could raise awareness to the education process and material presented in entry-level dental hygiene programs. Thus, allowing for reflection of such programs to further grow the dental hygiene education and dental hygiene profession as a whole.

CHAPTER V: Article for Submission

Journal of Dental Hygiene

Title: Silver Diamine Fluoride: Preventing Dental Caries

Renee Bingman RDH, BS

University of New Mexico

ABSTRACT

Purpose

The purpose of the study was designed to determine the awareness and knowledge of silver diamine fluoride (SDF) among dental hygiene program directors and to determine if the dental hygiene schools have included SDF education to their curriculum.

Methods

A descriptive survey was used to gather information from all United States dental hygiene program directors. The survey collected data on the education of SDF in dental hygiene practice.

Results

From the 330 entry-level dental hygiene schools, the survey had a max response from 39 school directors. The survey determined 94.87% of the schools introduce fluoride education didactically by a full time faculty member. With 92.31% of schools indicating SDF as a product of interest only 76.92% currently provided education to students. Of the schools providing education on SDF 50% combine the SDF education with the current fluoride education and lectures and 40% indicate the students receive one to two hours of dedicated SDF education. Out of the 30 schools indicating SDF education is provided to students, 66.67% currently do not use clinically use SDF and 33.33% are using SDF for the caries arresting properties. Fifty percent of the program directors have 1-3 hours of SDF education and over the past two years 55.26% of the schools provided 0 hours of continuing education to faculty on SDF. There are 76.92% of schools providing SDF education to students yet only 34.21% of those schools are providing SDF education to the faculty.

Conclusion

The data collected indicates that curriculums are being altered to include SDF education. Data collected supports lack of some SDF knowledge, lack of clinical training and uses. Data collected does support the awareness of SDF and its carries arresting properties. This study could raise awareness to the education process and material presented in entry-level dental hygiene programs.

Introduction

The dental hygienist plays a key role in the dental disease prevention and oral health care in the field of dentistry. The dental hygienist role is to educate and prevent disease. Early childhood caries (ECC) is rampant in 45% of all United States children five years and younger.¹⁹ Early manifestation of the disease foretells chronic and steady dental caries throughout a persons' lifetime. Due to the current oral disease status of nearly half of children in the U.S. being affected by dental caries, it is critical to find a cure and a more efficient and effective preventive measure. Dental hygienists are the preventive professionals of oral health care, with an emphasis on preventing this disease in children is vital to improving the overall quality of life of citizens in the U.S.

The disease of dental caries in children is the most prevalent disease dental professionals have tried to prevent.¹ The standard of care is to apply fluoride, to children at risk for dental caries, at the end of preventive dental treatments.²⁻⁴ Applications of various types of fluoride have been proven to be beneficial in creating some resistance to mineral loss in the enamel.⁵ Communities have also chosen to fluoridate the water system. Fluoride has many benefits including the resistance to dental caries and its ability to remineralize the enamel. Professional fluoride applications and SDF both fight against dental caries disease. Data collected in double blind cohort studies have shown promising results of arrested carious lesions after the application of silver diamine fluoride from 70.3%-96.1%.⁶ Comparatively, caries reduction rates with the use of sodium fluoride are 21.3%-55.7%.⁶

Silver diamine fluoride acts in two ways to benefit the patient. First, the germicidal nature of the silver kills bacteria and prevents the formation of new biofilm on the application site. Second, the fluoride works with the silver to form fluorapatite and will

strengthen the outer surface of the tooth.¹ For the hypersensitive teeth the calcium and phosphate in silver diamine fluoride physically block the dentin tubules causing the decrease in sensitivity.⁷ To make this product even more efficient silver diamine fluoride is a noninvasive application process. The application process mimics that of sodium fluoride varnish. The carious teeth are brushed without paste to remove excess debris, rinsed, isolated to keep dry, and one drop of the silver diamine fluoride is placed on the lesion for two minutes. After the two minutes the excess silver diamine fluoride is removed and the patient is advised not to eat or drink for one hour. It is also recommended to apply petroleum jelly to the nearby gingiva, use the smallest available microsponge, and dab the side of the dappen dish to remove excess liquid before application.⁸

There are currently two types of silver diamine fluoride. One is ammonia-based 38% silver diamine fluoride and the other is water-based 40% silver fluoride.⁹ Many studies have been done on both formulas of silver diamine fluoride and only one clinical study has been done on the ability to reduce cervical hypersensitivity.⁹

Silver diamine fluoride (also known as SDF) is the first product on the market with the ability to arrest dental caries.¹ The silver acts as an antimicrobial, the fluoride promotes remineralization, and the ammonia stabilizes high concentrations of the solution.⁸ This allows SDF to be used as both a noninvasive treatment option for dental decay and as a preventative measure for dental decay. Two American dentists in 1891 and then again in 1917 discovered that utilizing silver nitrate from amalgam scraps mixed with nitric acid arrested dental decay but the disadvantage was the arrested carious lesion spot would stain black. This founded the research in various countries leading to the SDF.

Currently, SDF has been going through the process of approval by the Food and Drug Administration (FDA). In 2014, it was approved as a class II medical device; this is the same class as 5% sodium fluoride varnish. The SDF approval provided by the FDA is for hypersensitivity treatment in adults over 21 and the preventive abilities were left off the label.¹⁰ As of late 2016, the FDA granted silver diamine fluoride 38%, breakthrough therapy designation for use in arresting dental caries in children and adults.^{12,13} Dental hygienists in most states may be permitted to apply SDF under the same authorization or restrictions as other topical fluorides.¹² The American Academy of Pediatric Dentistry (AAPD) in October 2017 issued the first evidence based guidelines for the use of silver diamine fluoride 38% to arrest cavitated caries lesions in primary teeth as part of a comprehensive caries management program.^{14,15} The AAPD based its information on a systematic review from 1969-2016.¹⁴ The AAPD president, Dr. James Nickman refers to fluoridated water and SDF as a revolution in the past century in pediatric dental health.¹⁴ With the CDC citing dental caries as the most prevalent infectious disease in children, affecting 40% before reaching kindergarten, SDF 38% allows safer treatment options when compared to restorative dentistry with the use of sedation or general anesthesia for children and those with special needs.^{14,15}

The AAPD notes the lack of severe pulpal damage but directs SDF should not be placed on exposed pulp.¹⁶ The ADA Clinical Practice Guidelines on the use of nonsurgical, nonrestorative treatments for caries management to arrest cavitated caries on coronal surfaces of primary or permanent teeth clinicians use 38% silver diamine fluoride solution twice a year.¹⁴⁻¹⁷

Despite the trademark black stain it creates on unsound dentin and enamel, it is widely used in numerous countries around the world. When silver diamine fluoride is placed

on tooth surfaces absent of carious lesions the area becomes resistant to biofilm formation and further cavity formation due to remnant ionic silver.⁸ With the application of silver diamine fluoride to the carious lesion, the squamous layer of silver-protein conjugates forms.⁸ This increases resistance to acid dissolution and enzymatic digestion.⁸ Then the hydroxyapatite and fluorapatite form on the exposed organic matrix with the presence of silver chloride and metallic silver.⁸ Finally the mineral density and hardness of the lesion increases and the depth of the lesion decreases.⁸ Demineralized dentin will have more silver and fluoride deposited in the area than non-demineralized dentin and therefore will become more resistant to caries bacteria than treated sound dentin.⁸ The silver ions in SDF kill bacteria and when that bacteria is added to new living bacteria the silver will re-activate causing the dead bacteria to kill the living bacteria.⁸ One Idaho dentist actually places a glass ionomer over it when the black stain is of concern to the patient.¹⁸

Methods

The purpose of the study was designed to determine the awareness and knowledge of silver diamine fluoride among dental hygiene program directors and to determine if the dental hygiene schools have included silver diamine fluoride education to their curriculum.

A descriptive survey was used to gather information from all United States dental hygiene program directors. First a pilot study was conducted on a small convenience sample of dental hygiene educators. The purpose of the pilot study was to evaluate dental hygiene school educator's willingness to review the survey and allow for feedback to help identify potential issue with the survey. Additional information provided to the convenience sample group includes: the main objectives, the research question and hypothesis. This was done to gain feedback on the surveys ability to gain relevant information in all components and limit

possible potential issues for the survey may include wording, layout, comprehension, length, and time commitment/demand. Once the information from the pilot study was gathered and alterations made it was emailed to all dental hygiene program directors in the United States.

In order to efficiently and accurately collect the data, the survey questions will have three main objectives to determine the following:

- The director's knowledge of silver diamine fluoride.
- The process in which the program and faculty stay relevant and adapt to the changes in dentistry, the FDA and ADA.
- The program education provided to students on silver diamine fluoride.

The descriptive survey was then sent to all 330 active dental hygiene programs listed by the American Dental Hygienists' Association. The surveys were sent by email to the program directors with a two-week date to be returned by. The surveys were sent out strategically, to not interfere with typical peak school function periods such as holidays, midterms and finals in order to promote survey response and return. In addition, three reminder emails with the survey attached were sent: one week after the initial email, three days before the return date and the last reminder email on the return date.

After collection of the surveys the data analysis was compiled based on the returned surveys with notations made of the number of nonparticipating schools in comparison to the number of participating schools. The descriptive statistical analysis of the data collected is shown based on the tables and graphs.

To allow for maximum reliability while conducting the survey and measuring the United States entry-level dental hygiene programs, and directors, knowledge and educational materials on silver diamine fluoride the survey was created in a fashion to allow minimal

misunderstanding and minimal interpretation options. In order to do this the survey contains descriptive information of the purpose of the survey study including the research question, the three main goals of the questions in the survey and the ultimate goal of finding any validity to the hypothesis. This survey was predominantly constructed based on the 5-point likert scale while following the format previously mentioned. The survey does consist of a few short response questions. This section was designed to allow the opportunity for the directors to input any additional information they feel is significant to convey about their programs based on the survey parameters and description of the topic silver diamine fluoride.

Results

From the 330 entry-level dental hygiene schools, the survey had a max response from 39 school directors. As shown in *Figure 1* of the 39 schools 27 are Associate programs and 12 are Bachelor programs.

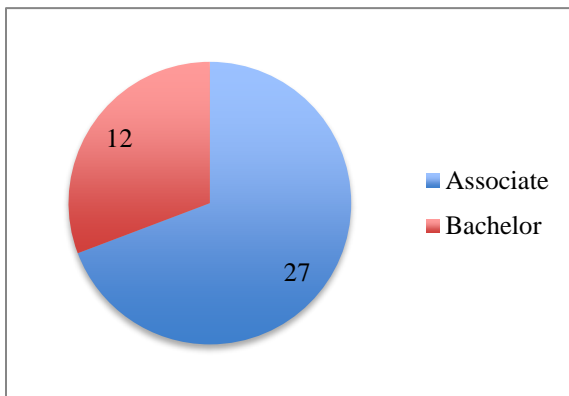


Figure 1: Number of programs based on type of degree obtained on completion of dental hygiene entry-level schools.

Education on fluoride is provided in dental hygiene programs. The survey has determined 94.87% of the schools introduce fluoride education didactically by a full time faculty member. The other 5.13% use a part time faculty.

When the directors were asked, “Is Silver Diamine Fluoride a product of interest to provide education to the students within this program?” *Figure 3* shows the response rate of 92.31% indicating SDF is a product of interest to provide education to the students.

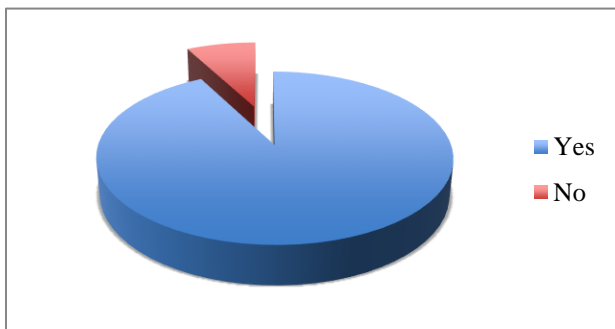


Figure 3: Is silver diamine fluoride a product of interest to provide education to the students within this program?

However, only 76.92% of the schools indicate SDF education is currently provided to students. The directors were asked to rank the level of SDF knowledge of the faculty member providing the SDF education to the students. As seen in *Figure 4*, 60.53% responded “somewhat knowledgeable” and 39.47% responded “very knowledgeable” while none responded that the faculty member providing the education to the students were either “not knowledgeable” or “subject matter experts”.

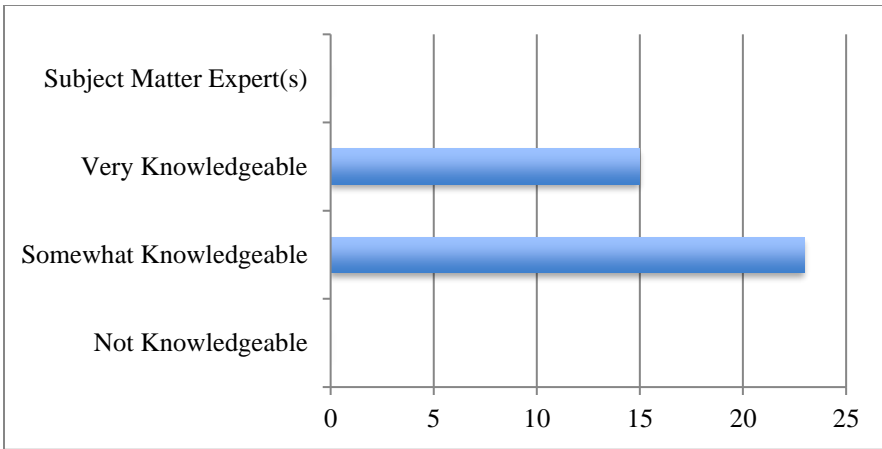


Figure 4: How knowledgeable is the faculty member providing SDF education to students.

Of the schools providing education on SDF, Figure 5 shows that 50% combine the SDF education with the current fluoride education and lectures and 40% indicate the students receive 1-2 hour's of dedicated SDF education and 10% indicate 0 hour's of dedicated SDF education.

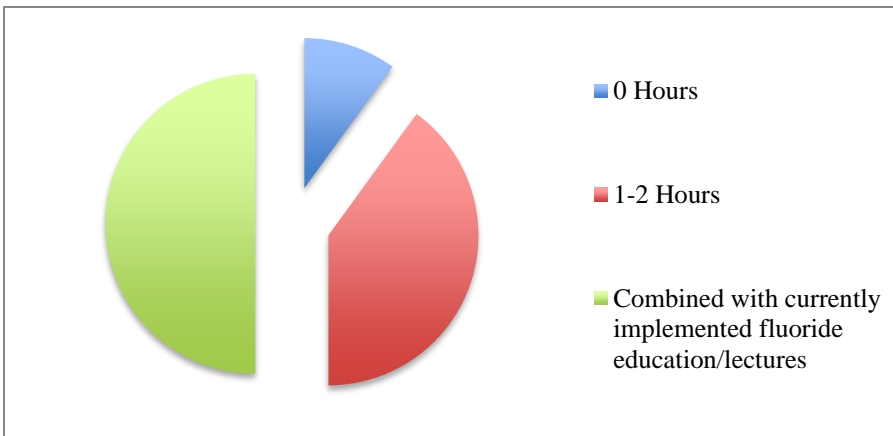


Figure 5: Amount of hours of dedicated SDF education provided to students.

Out of the 30 schools that indicate education is provided to students *Figure 6* shows that 66.67% currently do not use SDF in the clinic setting and 33.33% are currently using SDF for the caries arresting properties.

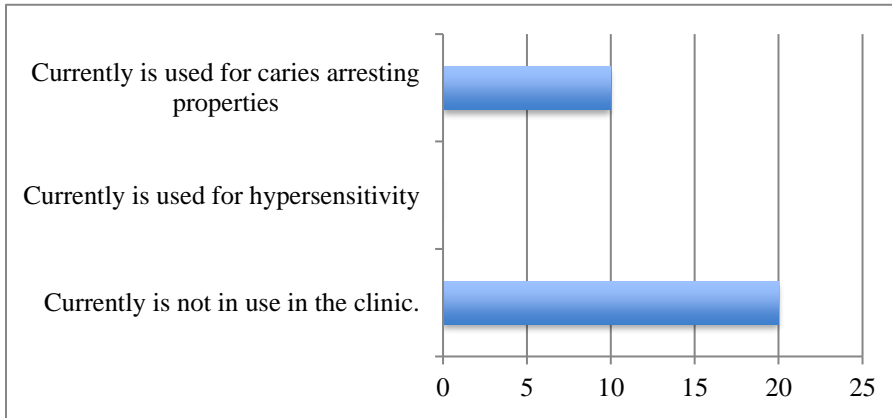


Figure 6: Schools current clinical setting use of SDF.

Thirty-eight directors provided responses based on personal SDF education. Shown in *Figure 7*, 50% of the program directors have 1-3 hours of SDF education, 23.68% have 0 hours of education, 15.79% have had SDF covered in other continuing education courses but it was not the main focus of the course and 10.53% of the directors indicate they have 4+ hours of SDF education.

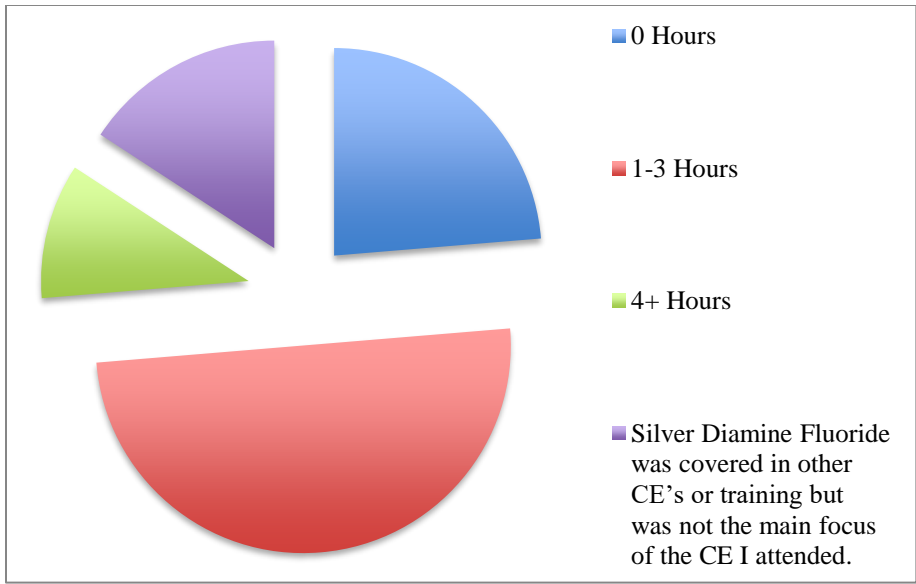


Figure 7: The directors personal history of SDF education.

Figure 8 shows that over the past two years 55.26% of the schools have provided 0 hours of continuing education to faculty on didactic, clinical and/or lab SDF education and 26.32% have provided 1-3 hours, 10.53% indicate SDF education was covered in other continuing education or trainings but was not the main focus and 7.89% indicate 4+ hours of SDF education provided. With 76.92% of schools providing SDF education to students yet only 34.21% of those schools are providing SDF education to the faculty.

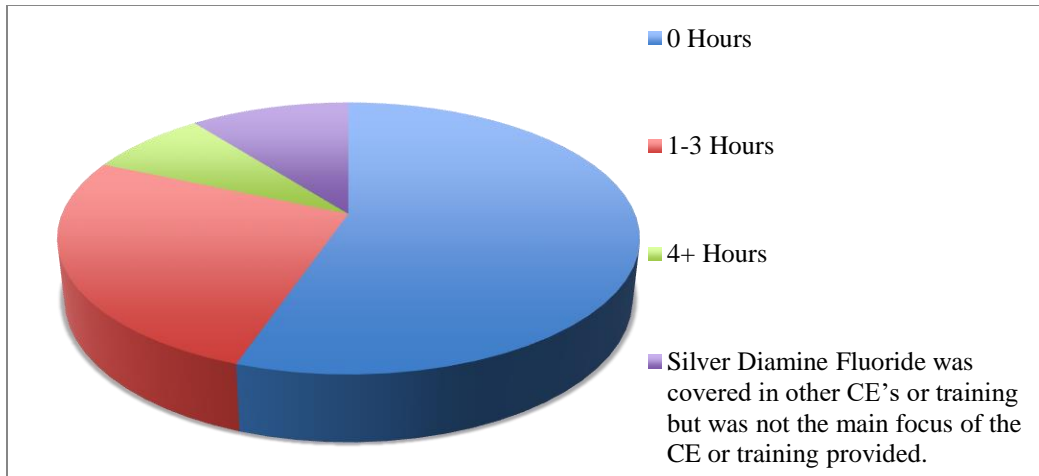


Figure 8: The schools two years history of continuing education provided to faculty on SDF.

The FDA originally approved silver Diamine Fluoride as a class II medical device in order to treat tooth hypersensitivity. When asked 63.89% agreed with this fact, while 36.11% responded neutral/no opinion or strongly disagreed. The directors were asked, “The off label use of Silver Diamine Fluoride can arrest dental caries?” and 80.56% are aware of SDF’s caries arresting properties. The question, “Currently, the CDT does not have a billing code for the use of Silver Diamine Fluoride?” yielded interesting results as shown in *Figure 12*, 55.55% agreed or were neutral indicating more than half are unaware of CDT codes for SDF and only 44.45% somewhat disagreed or strongly disagreed indicating the awareness of the CDT codes.

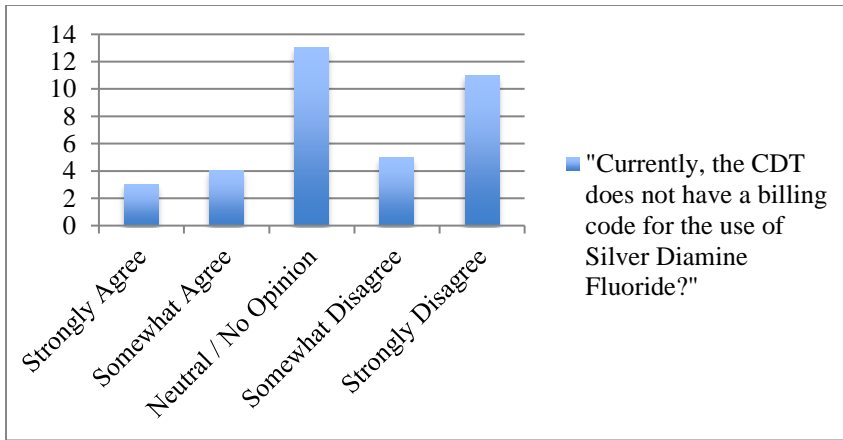


Figure 12: Directors awareness: Currently, the CDT does not have a billing code for the use of silver diamine fluoride?

The original FDA approval as a desensitizing application allowed it to be billed as D9910 and the new code for its caries arresting abilities is D1354. The 63.89% of directors indicated awareness of SDF approval by the FDA as a class II medical device to treat tooth hypersensitivity.

Discussion

Approximately, 94.87% of the schools introduce fluoride didactically by a full time faculty member. The survey shows 92.31% indicate SDF is a product of interest to provide education to students. Yet, only 76.92% of the schools indicate SDF education is currently provided to students. Out of the program directors surveyed, 50% indicate they personally have 1-3 hours of education on SDF and 10.53% of the directors indicate having 4+ hours of education on SDF. Nearly a quarter of the directors, at 23.68%, reported zero hours of SDF education. Other directors reported (15.79%) attending continuing education courses covering SDF. However, SDF was not the main focus of the course this provides a total of 76.32% of directors indicating to have some educational background on SDF and is nearly equal to the percentage of directors who currently provide SDF education.

Of the 76.92% of schools providing education on SDF additional data was collected. Fifty percent of schools combine SDF education with current fluoride education and lectures. With the vast information needed for comprehensive knowledge of SDF individualized lectures on SDF are indicated. Lectures can include various information including molecular and chemical information, therapeutic measures, side effects, application methods and processes, products available, SDF research and history, professional recommendations, and contraindications, and legal abilities based on individual states guidelines. Forty percent indicate the students receive one to two hours of education dedicated to SDF and 10% indicate 0 hours of dedicated education are provided to students. Of the 30 schools that indicate SDF education is provided to students, only 33.33% are currently using SDF for the caries arresting properties. The other 66.67% of schools currently do not use SDF in the clinic setting at all. With the majority of schools not utilizing SDF in clinical settings it raises the question of the depth and applicability of the education provided if it is primarily presented didactically.

The directors were asked to rank the SDF knowledge of the faculty member providing education to students. Response rates of 60.53% indicate “somewhat knowledgeable” and 39.47% responded “very knowledgeable”. Yet over the past two years 55.26% of the directors responded that the schools have provided 0 hours of continuing education to faculty on didactic, clinical and/or lab education on SDF. It is interesting to see only 34.21% of schools provide SDF education to faculty. This seems to show correlation to the director’s response rate that the faculty member is “very knowledgeable”. However, 76.92% of schools are providing SDF education to students. With 76.32% of director’s responded faculty utilize continuing education courses and, or scholarly journals as

informational resources on SDF, it again seems to correlate with the response rate of the faculty member being “somewhat knowledgeable”.

The FDA originally approved SDF as a Class II medical device to treat tooth hypersensitivity. Only 63.89% of directors indicated awareness of this by selecting strongly agreed or somewhat agreed and 36.11% were neutral/no opinion or strongly disagreed. Although, 80.56% of directors indicate their awareness of SDF’s caries arresting properties, only 38.89% of directors strongly agreed with the fact that a dental hygienist can apply SDF under the same authorization as other topical fluorides based on each individual state governing laws. It seems that the schools that stated “somewhat knowledgeable” may benefit from continuing education on dental hygienist’s scope of practice when using SDF. A surprisingly 55.55% of directors are unaware of the billing CDT codes for SDF. The original FDA approval as a desensitizing application allowed it to be billed as D9910 and the new code for its caries arresting abilities is D1354.

There were not enough responses to make a generalized conclusion for all entry-level dental hygiene program directors knowledge and awareness of silver diamine fluoride or to be able to determine education provided within the programs. However, after reviewing the data collected the majority of schools are interested in providing education to the students on SDF and 76.92% indicate SDF education is provided to students.

In response to the question, “Are dental hygiene schools teaching about silver diamine fluoride?” there may be a correlation between faculty’s knowledge of SDF and whether they choose to teach it in clinical settings. Since only 33% indicated SDF use in a clinical setting and knowledge of dental hygienist’s scope of practice in regards to SDF application was low, more education on SDF may prove beneficial. There could be use for

more SDF education for faculty by means of continuing education on adjunct services. A consideration for additional research to see if in fact there is a correlation between knowledge level and clinical application could be services, products and treatments faculty would like continuing education on.

With this surveys limited replies it does support the hypothesis that dental hygiene schools in the U.S. are aware of SDF. Yet fails to support the hypothesis that education curriculums have not been altered to include information, scientific findings and current uses for SDF.

Conclusion

Data collected supports lack of some SDF knowledge, lack of clinical training and uses. Data collected does support the awareness of SDF and its carries arresting properties. This study could raise awareness to the education process and material presented in entry-level dental hygiene programs. Thus, allowing for reflection of such programs in order to further grow the dental hygiene education and dental hygiene profession as a whole.

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Appendices

Appendix A

Figures and Tables

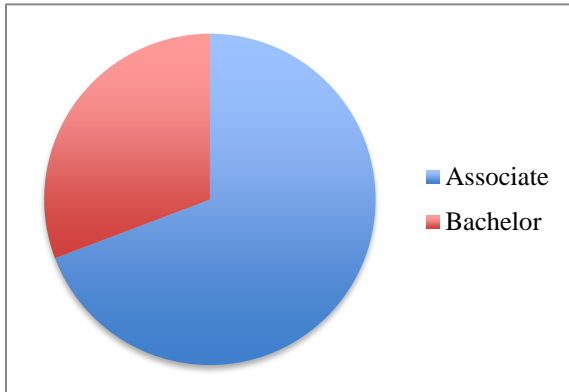


Figure 1: Type of degree obtained on completion of dental hygiene entry-level schools.

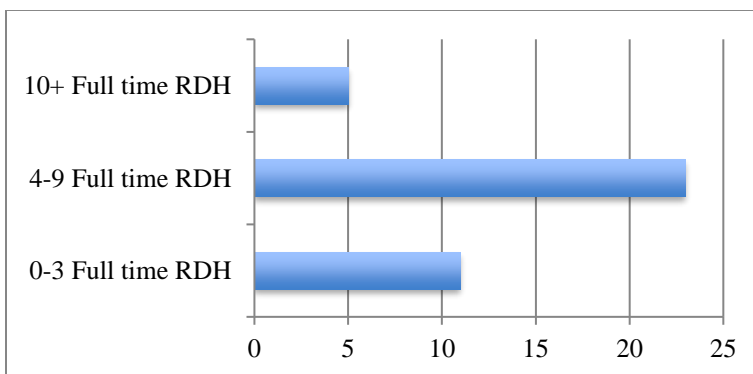


Figure 2: Full time registered dental hygiene faculty positions.

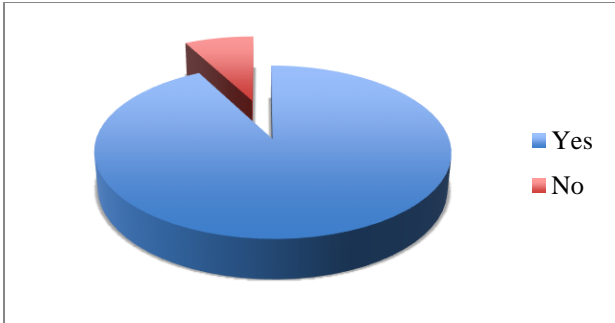


Figure 3: Is silver diamine fluoride a product of interest to provide education to the students within this program?

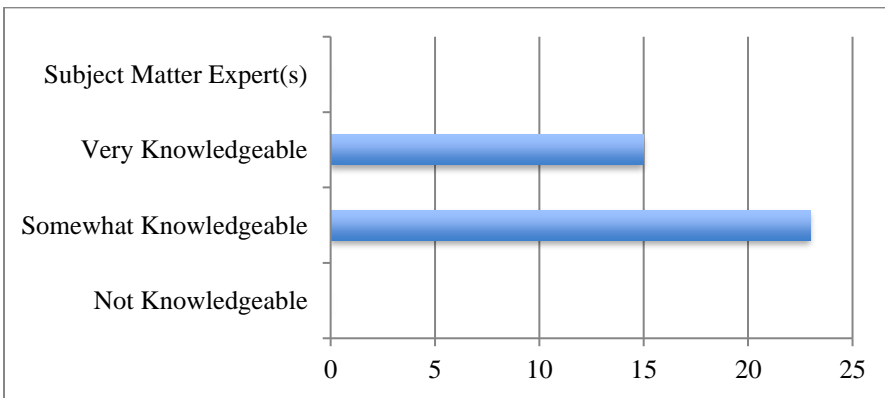


Figure 4: How knowledgeable is the faculty member providing SDF education to students.

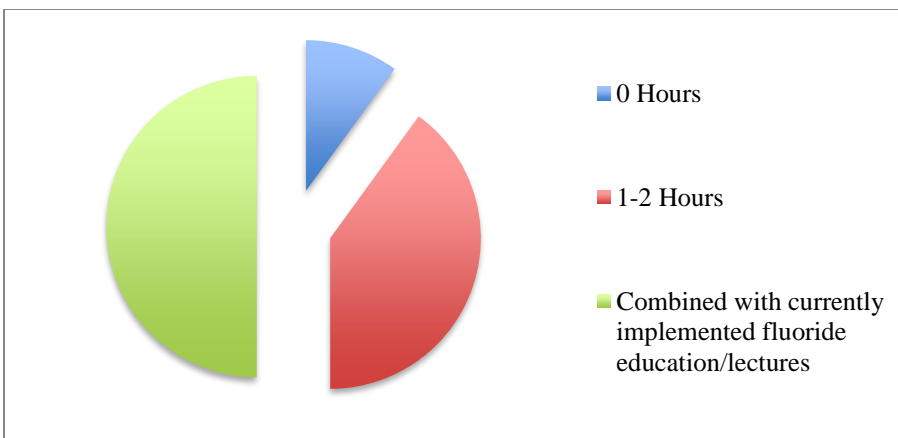


Figure 5: Amount of hours of dedicated SDF education provided to students.

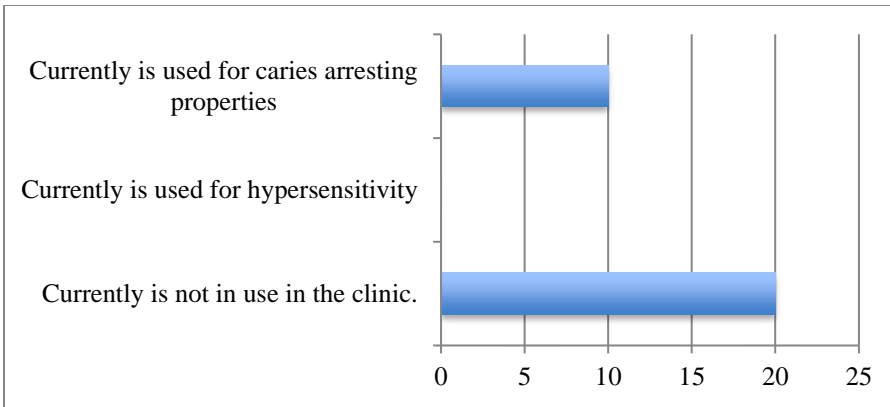


Figure 6: Schools current clinical setting use of SDF.

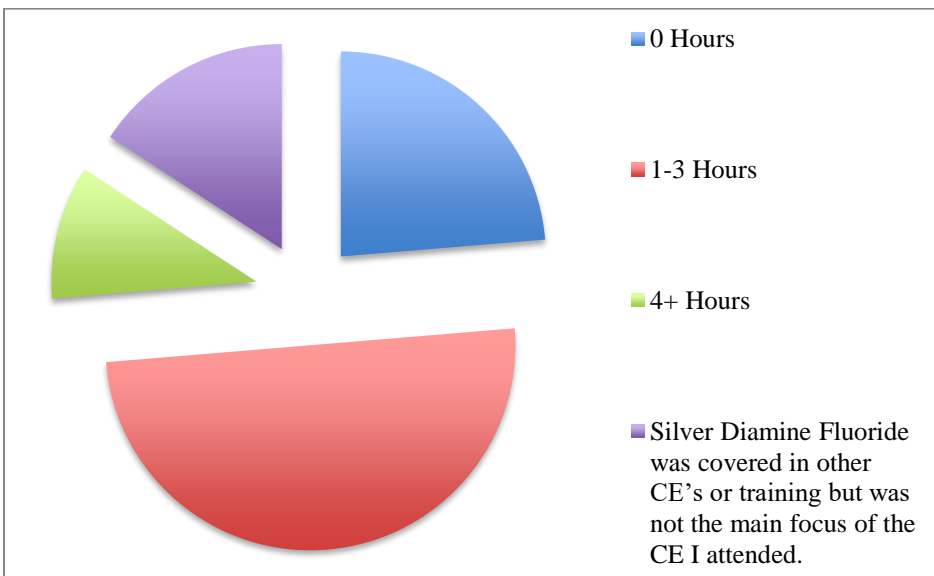


Figure 7: The directors personal history of SDF education.

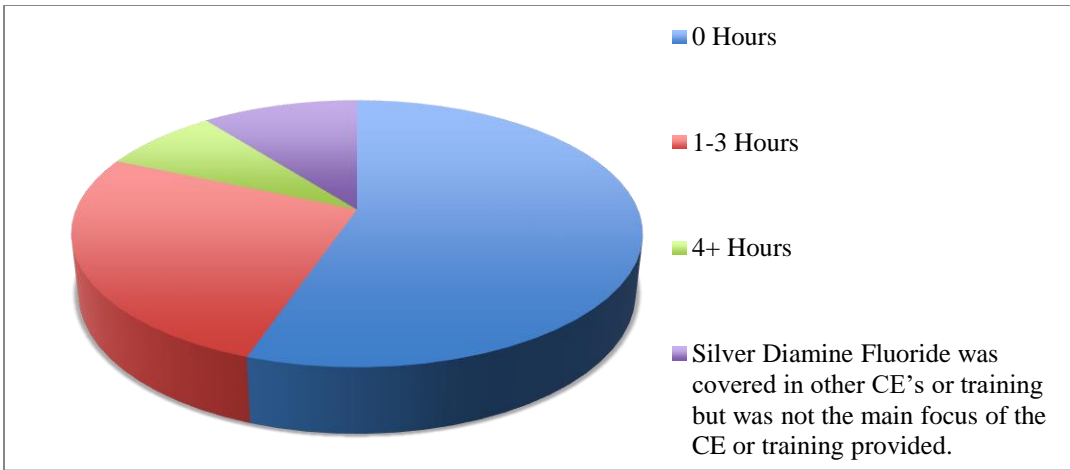


Figure 8: The schools two years history of continuing education provided to faculty on SDF.

Short Answer Provided	Number Response
CE courses, professional/scholarly journals	29
Faculty Meetings/calibrations	3
Independent Research on Topic	2
Sales Reps /advertisements /product lines	2
FDA website	1
State Updates/Local component	1

Table 1: Short answer summary

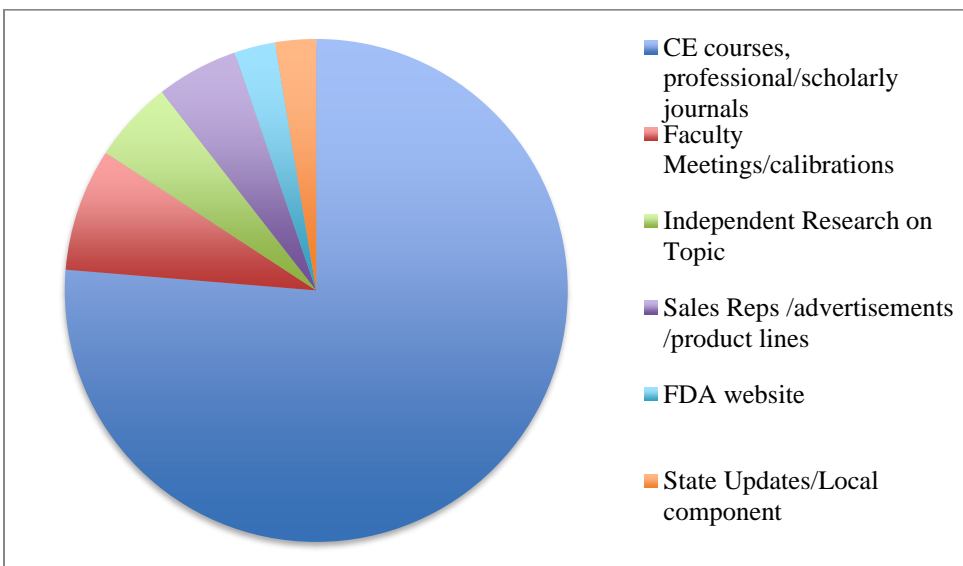


Figure 9: How faculty remain up to date with changes in dentistry and the FDA.

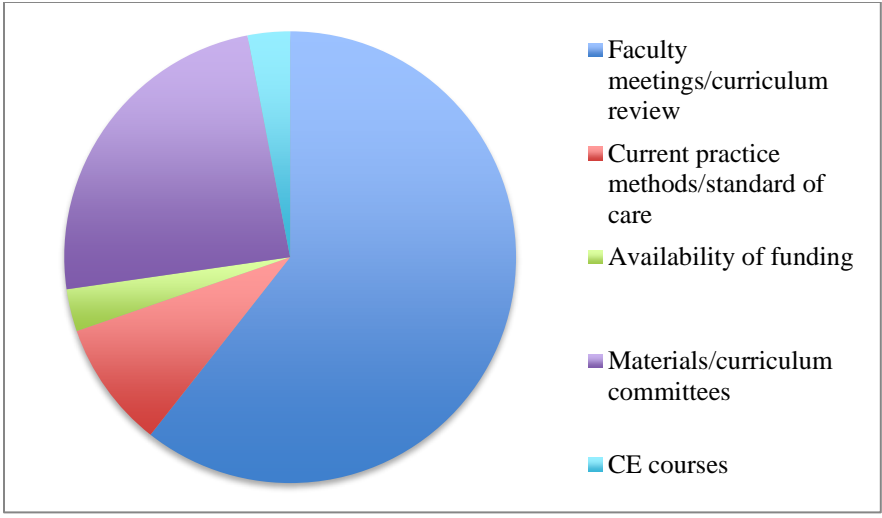


Figure 10: How curriculum changes occur to include new materials, FDA changes and ADA changes.

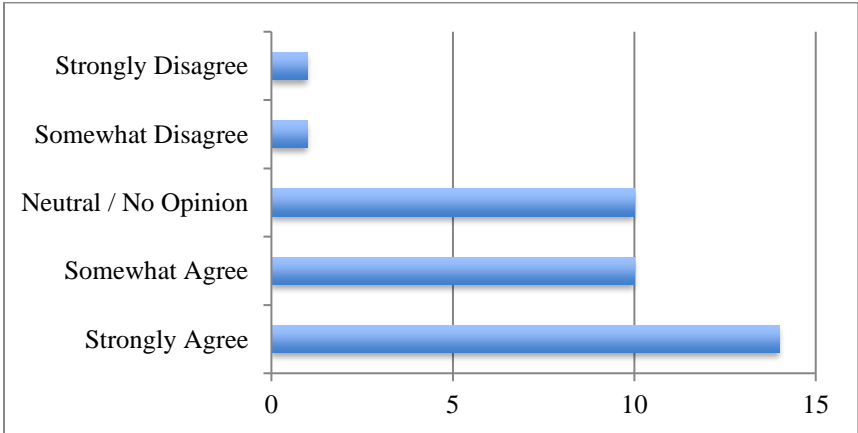


Figure 11: Directors awareness: A dental hygienist can apply SDF under the same authorization as other topical fluorides (based on state laws).

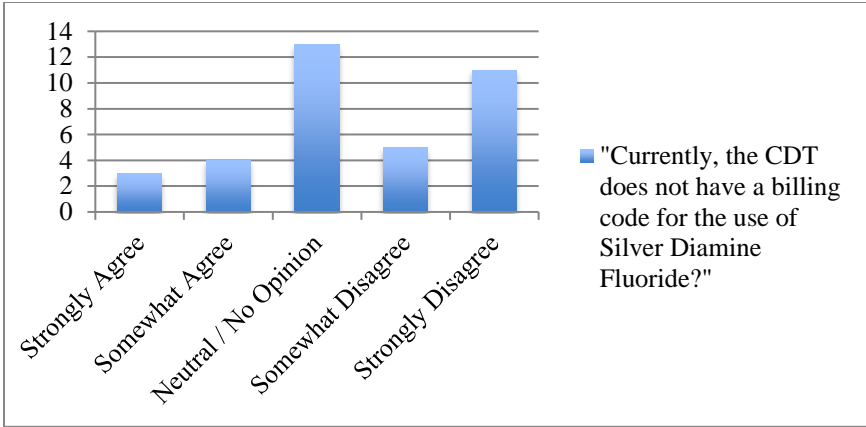


Figure 12: Directors awareness: Currently, the CDT does not have a billing code for the use of silver diamine fluoride?

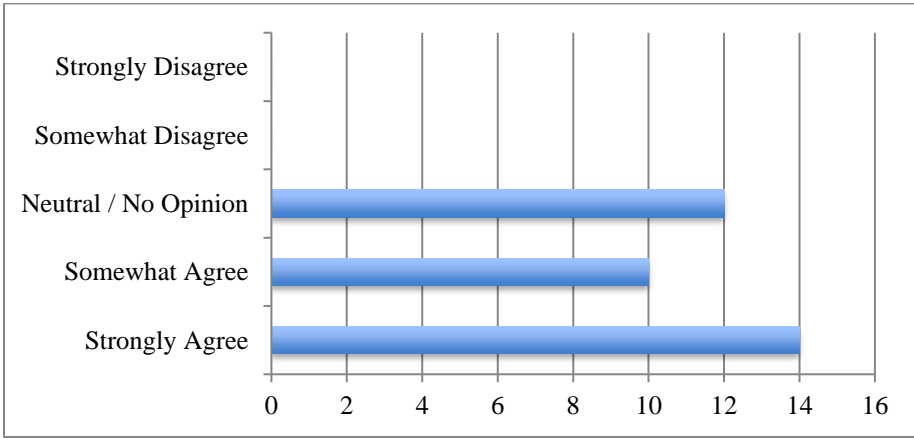


Figure 13: SDF has been marketed in the U.S. since 2015.

Appendix B

HRRC Approval



*Human Research Review Committee
Human Research Protections Office*

March 11, 2018

Christina Calleros
CCalleros@salud.unm.edu

Dear Christina Calleros:

On 3/9/2018, the HRRC reviewed the following submission:

Type of Review: Initial Study
Title of Study: Silver Diamine Fluoride: Preventing Dental Caries
Investigator: Christina Calleros
Study ID: 18-156
Submission ID: 18-156
IND, IDE, or HDE: None

Submission Summary: Initial Study

Documents Approved:

- Consent Cover Letter
- Protocol 538
- Survey

Review Category: EXEMPTION: Category (2) Tests, surveys, interviews, or observation.

Determinations/Waivers: Provisions for Consent are adequate.
HIPAA Authorization Addendum Not Applicable.

Submission Approval Date: 3/9/2018
Approval End Date: None
Effective Date: **3/9/2018**

The HRRC approved the study from 3/9/2018 to inclusive. If modifications were required to secure approval, the effective date will be later than the approval date. The "Effective Date" 3/9/2018 is the date the HRRC approved your modifications and, in all cases, represents the date study activities may begin.

Because it has been granted exemption, this research is not subject to continuing review.

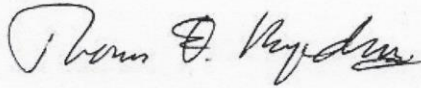
Please use the consent documents that were approved by the HRRC. The approved consents are available for your retrieval in the "Documents" tab of the parent study.

As a reminder, it is the responsibility of the principal investigator to ensure that amendments must include a plan to re-consent subjects.

This determination applies only to the activities described in this submission and does not apply should you make any changes to these documents. If changes are being considered and there are questions about whether HRRC review is needed, please submit a study modification to the HRRC for a determination. A change in the research may disqualify this research from the current review category. You can create a modification by clicking Create Modification / CR within the study.

In conducting this study, you are required to follow the Investigator Manual dated April 1, 2015 (HRP-103), which can be found by navigating to the IRB Library.

Sincerely,



Thomas F. Byrd, MD
HRRC Chair

Appendix C

Informed Consent for Anonymous Survey

**University of New Mexico Health Sciences Center
Informed Consent Cover Letter for Anonymous Surveys**

**STUDY TITLE
Silver Diamine Fluoride: Preventing Dental Caries**

Christina Calleros M.S. and Renee Bingman R.D.H from the Department of Dental Hygiene is conducting a research study. The purpose of the study is to designed to determine the awareness and knowledge of Silver Diamine Fluoride (SDF) among dental hygiene program directors and to determine if the dental hygiene schools have added Silver Diamine Fluoride (SDF) education to the curriculum. You are being asked to participate in this study because you are a director of a dental hygiene program.

Your participation will involve the completion of a short survey. The survey should take about 20 minutes to complete. Your involvement in the study is voluntary, and you may choose not to participate. There are no names or identifying information associated with this survey. The survey includes questions such as "How knowledgeable are the full time faculty on Silver Diamine Fluoride?" and "Is Silver Diamine Fluoride a product of interest in your program". You can refuse to answer any of the questions at any time. There are no known risks in this study, but some individuals may experience discomfort when answering questions. All data will be kept on the survey monkey engine and then destroyed.

The findings from this project will provide information on dental hygiene schools' awareness of silver diamine fluoride and educational material provided to students. If published, results will be presented in summary form only.

If you have any questions about this research project, please feel free to call Renee Bingman at (509) 551-3567. If you have questions regarding your legal rights as a research subject, you may call the UNMHSC Office of Human Research Protections at (505) 272-1129.

By clicking on the survey link below, you will be agreeing to participate in the above described research study.

<https://www.surveymonkey.com/r/DBPDZMN>

Thank you for your consideration.

Sincerely,

Christina Calleros M.S. R.D.H.
Assistant Professor
Renee Bingman R.D.H

HRRC#18-156
Version Date 03/08/2018

HRPO #:

Page 1 of 1

Version:

Appendix D

SDF Survey

Renee Bingman

Silver Diamine Fluoride Survey

The purpose of the study is designed to determine the awareness and knowledge of Silver Diamine Fluoride (SDF) among dental hygiene program directors and to determine if the dental hygiene schools have added Silver Diamine Fluoride (SDF) education to the curriculum.

Section A

Choose the best response regarding this programs demographics.

Select the entry-level degree students receive upon graduation of this program.

- Associates
- Bachelor

Select the most appropriate number of full time registered dental hygiene faculty positions (including the director position).

- 0-3
- 4-9
- 10+

Select the method students are first introduced and educated about fluoride.

- Didactic course facilitated by a full time faculty member
- Didactic course facilitated by a part time faculty member
- In a clinical setting by daily assigned attending faculty

Is Silver Diamine Fluoride a product of interest to provide education to the students within this program?

- Yes
- No

Is Silver Diamine Fluoride education provided to students within this program?

- Yes
- No (If no please skip to section C)

Section B

Choose the best response regarding Silver Diamine Fluoride education and use within the program.

Select the number of annual didactic, clinical and/or lab educational hours students receive specifically on Silver Diamine Fluoride.

- 0 hours
- 1-2 hours
- Combined with currently implemented fluoride education/lectures

Select the current program clinical use for Silver Diamine Fluoride.

- Currently is not in use in the clinic.
- Currently is used for hypersensitivity
- Currently is used for caries arresting properties

Section C

Choose the best response regarding Silver Diamine Fluoride education amongst the program faculty.

Select the number of continuing education course hours you have completed in the past two years specifically on Silver Diamine Fluoride?

- 0 hours
- 1-3 hours
- 4+ hours
- Silver Diamine Fluoride was covered in other CE's or training but was not the main focus of the CE I attended.

Select the number of continuing educational hours over the past two years the school has provided faculty on didactic, clinical and/or lab education on Silver Diamine Fluoride?

- 0 hours
- 1-3 hours
- 4+ hours
- Silver Diamine Fluoride was covered in other CE's or training but was not the main focus of the CE or training provided.

How knowledgeable is the faculty member(s), whom provide fluoride education, on Silver Diamine Fluoride didactically, or clinically?

- Not Knowledgeable
- Somewhat Knowledgeable
- Very Knowledgeable
- Subject Matter Expert(s)

Section D

For the following questions select the best option from the likert scale based on your current knowledge of Silver Diamine Fluoride.

As of 2014, the FDA approved Silver Diamine Fluoride as a Class II medical device to treat tooth hypersensitivity in the United States?

1. Strongly Agree
2. Somewhat Agree
3. Neutral / No Opinion
4. Somewhat Disagree
5. Strongly Disagree

Silver Diamine Fluoride has been marketed in the United States as Advantage Arrest since 2015?

1. Strongly Agree
2. Somewhat Agree
3. Neutral / No Opinion
4. Somewhat Disagree
5. Strongly Disagree

Currently, the CDT does not have a billing code for the use of Silver Diamine Fluoride?

1. Strongly Agree
2. Somewhat Agree
3. Neutral / No Opinion
4. Somewhat Disagree
5. Strongly Disagree

The off label use of Silver Diamine Fluoride can arrest dental caries?

1. Strongly Agree
2. Somewhat Agree
3. Neutral / No Opinion
4. Somewhat Disagree
5. Strongly Disagree

As of early 2017, the FDA granted the manufacturer of Silver Diamine Fluoride "breakthrough therapy status", allowing facilitated clinical trials of Silver Diamine Fluoride for off label use of its caries arresting properties?

1. Strongly Agree
2. Somewhat Agree
3. Neutral / No Opinion
4. Somewhat Disagree
5. Strongly Disagree

Based on each state government laws, a dental hygienist can apply SDF by the same authorization as other topical fluorides?

1. Strongly Agree
2. Somewhat Agree
3. Neutral / No Opinion
4. Somewhat Disagree
5. Strongly Disagree

Section E

Use the space below to briefly explain additional information requested.

Briefly explain how your faculty remains aware of changes in dentistry and the FDA.

Renee Bingman

Briefly explain how the decision is made to change the programs educational materials and processes to include new materials, FDA changes, ADA changes or other changes to the curriculum.

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