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Multi-Health centers' Cohort-Observational study of the Impacts of preventive/comprehensive dental care on the pediatric population of the St. Croix Community

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Introduction & Background information

Dental caries is the most prevalent chronic health problem in children around the world.1 caries associated with frequent consumption of fermentable carbohydrates, and especially sugars that are popular in children. ECC is a public health concern because of both the short and long-term effects it has on the quality of children's life. More specifically, severe ECC found to affect a child's ability to eat, speak, grow, and socialize and cause varying degrees of pain.4.

The U.S. Virgin Islands (USVI) is an unincorporated territory of the United States, with a population of approximately 107,000 individuals. Children < 18 years represent nearly 20% of the total USVI population, including a disproportionate number living in poverty; in 2013, 43% of USVI children ≤ five years and 31% of children 6–17 lived in families with incomes below the federal poverty level (FPL). USVI families face significant socioeconomic hardships (e.g., unemployment, lack of health insurance, single-parent families) and at higher rates than the general U.S. population. This likely affects their ability to promote and protect their children's health. The increasing prevalence of public health emergencies, including infectious diseases and natural disasters (e.g., Zika, Hurricanes Irma and Maria), may further impact the health care needs and health outcomes of USVI children, particularly those in low-income families.11

St. Croix (largest VI islands) has the lowest income and highest poverty levels in the Virgin Islands. The population here with income below 200% of poverty, which includes approximately 25,000 individuals living on St. Croix. Almost half of the 55,000 total on island. The median household income on St. Croix is only 72%

that of the United States in general. More than 13,000 individuals living on St. Croix have income below federal poverty guidelines, and of those, more than 7,000 have income less than 50% of federal poverty guidelines. This factor only puts all those people under the high caries risk category. The Department of Health coordinated with Fredericksted Health care Inc. (the community public health center in St. Croix) work to increase the preventive measures among children under 18 years old to decrease the prevalence of dental caries. During 2018, a 20% increase in sealant rate among the targeted population than the previous year. 10

The importance of this project is to assess/evaluates the effects of comprehensive dental Treatment, Hygiene education & preventive measures for high-risk caries 6-12 years old young people, and what is the survival & failure rates in 6 months duration at follow-up visits, seen at Fredericksted HealthCare Inc. dental sites towards reaching the goal of caries-free target people.

Rationale

Since there are high percentages of the population have active caries, and due to limited resources and researches to address this issue, we were unable to detect the prevalence and incidence of caries among people of St. Croix. That is one reason why we decide to choose a specific young group to study, monitor, treat, and evaluate to see the effects of dental education/treatment on their oral health. Another reason is the selected age (6-12) have erupting permanent teeth, and it is essential to try to save those teeth as early as possible, especially in high-risk caries people. Finally, in this project, we selected the target group who have Medicaid insurance that covers most of their dental care without co-pay and since this insurance given to low-income people and families, we track the comprehensive dental education/treatment for those people to see the impacts of it on their oral health and daily home-care.

Potential risks and benefits

Minimum Potential risk for patients chart review by the dental providers only (no breach their confidentiality) for treatment and data collection purposes, which are acceptable according to HIPAA- FHC rules & policies. Also, the benefits to the target people by:

1- Identify the caries experiences (past & present) within individuals and communities.
2- Identified the risk group and the rate of caries activity
3- by using dental caries indices, oral health status will estimate.
4- It gives a broad overview of caries experiences in a population over a time-frame.

Objectives and purpose

What the effects of comprehensive dental treatment, Hygiene education & preventive measures for high-risk caries 6-12 years old young people, and what is the survival & failure rates in 6 months duration at follow-up visits, seen at Fredericksted HealthCare Inc. dental sites towards reaching free caries target people.

Our secondary objective is to evaluate the effectiveness of comprehensive care and reliability and accessibility to specialty care promptly after the referral from the primary providers to the specialist dentist.

Study Design

The multicenter observational study includes exam the chosen targeted people (children between 6-12 years old) before, during, or after treatment with dental providers, including dentists, hygienists & qualified dental assistants, in designated sites in the time frame starting from 01/01/2019 until 01/01/2020.

Then, we are evaluating and monitoring the improvement in caries rate by using caries index DMFT/DMFS(permanent teeth) dmft/dmfs (primary teeth)

indices & plaque level assessment (mild, moderate & high), as well as, failure rates by checking recurrent or new decay development or teeth lost. After that, we checked all preventive measures applied or used by providers at clinics and by the patient at home by checking & motivate the dietary & nutritional consulting and review with the parents/guardians OHI, home-care, compliance, and referral process to the specialty care.

The next step is gathering all required information & data (including Medicaid percentage of population) from electronic dental records only, and that helps keep the patient information safe and secure. Information collecting includes age, gender, dental treatment plan, sealants-Fluoride-home care ways, and the effects of hygiene habits in follow-up visits. The last step will be to conduct surveys, data, and information to evaluate the success & failure rates in all targeted people by checking track case completion codes, completed and/or uncompleted cases. Finally, we prepare the final assessment and results.

Study enrollment and Withdrawal

The eligibility criteria for target people include:

- Children between 6-12 years old
- High-risk caries only identified by dental providers.
- Comprehensive dental treatment must complete (one visit or multiple visits)
- All gender included
- All races included
- No screening consent needed.
- No laboratory tests needed.

No withdrawal applies to the project since we are screening for dental care that already done completely by dental providers.

study Schedule

Scheduled or emergency walk-in patients to any site of FHC dental clinics, the examination is done by dental hygienist or dentist to identify problems and build treatment plan, when identifying a patient as high-risk caries then this patient immediately considered as part of our study, and we start monitoring the progress in his treatment plan. According to patient behavior and the urgency of dental care needed, patients might refer to a pediatric dentist (mainly within FHC) for comprehensive treatment with or without Intravenous-Sedation.

We discuss the treatment plan with parents or guardians, and the first step will be to establish excellent oral hygiene and periodontal therapy, then restorative works, and finally, any fixed or removable prosthesis (SSC, space maintainer, orthodontic appliances).

If patient referred to the pediatric dentist, then all plan dental care usually done by one visit (under IV –Sedation) followed by a one-week postoperative recall and then one month/three months recall to check the integrity of restoration and re-enforce Oral hygiene instructions, in addition to the routine six months follow-up visits.

Study procedures/evaluations

Health project's Investigators start searching for high-risk caries patients through medical/dental software using by FHC, trying to identify all patients age specify groups starting from January 1st, 2019 until the end of December 2019. Using reaching tools within the software system, they able to identify 55 candidates that completed their dental care, and they are in the recall/maintenance phase now.

A principal investigator starts collecting information about those 55 candidates names, medical/dental information, clinical findings (missing, fillings, decayed teeth), oral health status(plaque level), caries risk assessment (high) & proposed treatment plan if will be done by the hygienist/general dentist or by a pediatric dentist within FHC.

Investigator charted all examination dates when a patient first diagnosed as high risk, and then the treatment plan start (or when the patient scheduled an appointment with the pediatric dentist) and what dental services are done during each visit and then patients back for recall check-up or postoperative assessment.

Statistical considerations

In this health project, using DMFT/DMFS & dmft/dmfs indices and Plaque score index to collect and analyze data first. Second, we check information on the follow-up visit for each patient. We try to evaluate the impacts of completed treatment care and how the oral hygiene approach affects those patients groups' oral health and if there are any new decay developed after all dental services done and what the level of plaque before and aftercare with all preventive measures done on those patients.

As a result, we will be able to identify what is the success/failure rate with all dental approach to control active disease and trying to maintain health status for those high-risk patients (caries-free status) and what is the recommendations/improvements to FHC protocol in dealing with high-risk caries patients.

Study Hypothesis

Impacts of comprehensive dental care, Fluoride supplements, and Oral hygiene measures on High Caries patients in terms of percentage of failure rate, oral hygiene habits, and maintain caries-free status.

Sample Size Determination

Fifty-five patients added to the study by checking dental charts within FHC software system, looking for several criteria's; **First**: high caries risk, **Second**: age between 6 to 12 years old, **Third**: Medicaid patient beneficiaries, **Fourth**: treatment plan must complete between January 2019 to January 2020.

After finish collecting patient data, we start using dmft/dmfs & DMFT/DMFS indexes to identify the caries rates among those patients and the percentage of care needed. Also, the plaque level index (Silness & Loe) to evaluate the plaque level before and after treatment is complete. Principal investigator checks the recall policy (1, 3 & 6 month's interval) and how many patients keep those appointments after comprehensive dental care is finish and patients are in caries-free status or not.

Total numbers of decays, restorations, and teeth lost due to dental caries in both primary and adult teeth were calculated and assessed. Preventive measures applied to these patients and/or given to their parents/guardians. Also, we evaluate during follow-up visits, any changes/improvements in hygiene habits, and its impacts on the patient's daily activities.

Statistical Methods/Results

The principal investigator checks several parameters for sample group patients. All information gathered was through FHC medical/dental software system without using any external resources.

1-The sample size gender: The total sample size is 55: 28/Male, 27/Female.

We selected all patients according to scientific/clinical criterias without any bias.

2-The total number of patients undergoes IV-Sedation for comprehensive dental care: 36/55 (65.5%). FHC dental team has specific dental assistants to work with Dr.Sonia Griffith (pediatric dentist) who came two times per month to treat the problematic comprehensive cases. Dr.Sonia decides during her consultation exam if these patients need treatment under intravenous sedation, or she can start treating them with Nitrous Oxide and/or Local anesthesia only.

3- Socio-economical status, hygiene-kit gave & decrease sugar exposure: insufficnet information through FHC

system. The sample group patients and their families live under the poverty level since they are eligible for medical/dental assistance through the Medicaid program. This concept only put those patients and their family under high-risk caries, despite the fact of personal, economic, and social factors that affect their daily living & hygiene style.

4-Percentage of patients needing care: For primary teeth: 73.1 % and for permanent teeth 82.07%. Those patients exam and diagnose by dental providers through FHC clinical sites, and, depending on their findings & treatment plans, providers will discuss with their parents or guardians to start care with primary care providers or refer the patients to specialty care.

5-G.P. Average: dmft 424/55=7.70/20, dmfs 1379/55=25.07/88

6-GP Average: DMFT 106/55=1.92/28, DMFS 153/55= 2.78/128

Table 1: Group Total dmft/dmfs & DMFT/DMFS indexes scores for the high-risk patients that undergo comprehensive dental treatment. Sic Index for DMFT is 4.1 and, according to WHO, we need it to be under 3. (more info. About Sic index in the last page)

Value	Total scores	Mean GA Value*****	Maximum group average score
dmft* (decay, missing, filling, teeth)	424	7.70	20
dmfs** (decay, missing, fillings, surfaces)	1379	25.07	88
DMFT*** (decay, missing, filling, teeth)	106	1.92	28
DMFS**** (decay, missing, fillings, surfaces)	153	2.78	128

*& **indexes for primary teeth, *** & **** indexes for permanent teeth, ***** mean group average score after dividing total index scores over entire sample group.

Table 2:Total findings, restorations, and missing teeth due to caries for sample patients. Those findings collect through electronic dental record of what done on those patients through study time-frame

Criteria	Primary teeth	Permanent teeth
Tooth Decay	310	87
Restorations (include fillings, crowns, Pulpotomy & SSC*)	194	81
Teeth lost due to caries (non-restorable)	116	1

*Stainless steel crown for primary teeth

Table 3: Percentage of total findings, restorations & missing teeth due to caries for sample patients. We measure the dental works done by calculating percentages of caries, restorative works, and any tooth loss due to caries.

Criteria	Primary teeth	Permanent Teeth
Tooth Decay	73.1 %	82.07 %

(need care)		
Teeth (Restorations did)	45.7 %	76.41 %
Teeth lost due to caries	21 %	1.8 %
Remaining percentage *	6.4 %	3.86 %

*These values represent the new/recurrent decays detected after comprehensive treatment done (usually during recall exam), watch incipient lesions & planned for the extraction or waiting for regular exfoliation.

Table 4: Preventive measures applied, given or recommended to sample groups of patients (or their parents/guardians) during and after comprehensive care completed, we try to track the preventative ways of oral hygiene given to patients and their families and follow-up on how they develop or maintain those hygiene habits.

Preventive measures	Total no. of patients recommended, given or applied (total No. 55)	Percentage of measuring Scores
Oral Hygiene Instructions (OHI)*	45	81.82 %
Fluoride Tablet by Prescription	32	58.18 %
Diet Counseling with parents/guardians	42	76.36 %
Fluoride mouthwash**	35	63.64 %
Pit & Fissure Sealants	54	98.2 %
No information ***	4	7.28%

*OHI includes brushing technique & times, flossing review & use F.L. toothpaste ** F.L. Mouthwash recommended to the patients and sometimes given as a sample if available by the dental clinic, *** There are no records on patient's charts about prevention measures and/or recall appointments.

Table 5: Plaque index table (Silness & Loe plaque index score) for the sample group patients as detected and Diagnosed by dental providers among FHC sites. They use the numerical scores to reflect the plaque level on teeth and surrounding tissues.

Plaque index level (PI)	# Pt's PI scores before Tx & % in sample grp	# pt.'s PI scores after Tx & % in sample grp.	Plaque score criteria
0 (excellent hygiene)	0%	0 %	No Plaque
1 (Good Hygiene)	13 (23.64%)	12 (21.82%)	Plaque adheres to FGM & adjacent area of teeth
2 (Fair Hygiene)	26 (47.28%)	18 (32.73%)	Moderate accumulation within the gingival pocket
3 (Poor Hygiene) Heavy plaque	14 (25.46%)	23 (41.82%)	An abundance of soft matter within the gingival pocket and/or teeth & gingival pocket
No information*	2 (3.64%)	2 (3.64%)	n/a

*no information documented in Patients' charts by FHC Providers

Table 6: Numbers of recall appointments kept by the patients after comprehensive dental care is complete. The recall policy for the pediatric dentist is one week; 1 month, three months recall visits; then, patients will return to 6 months recall with general dental providers while

Primary care providers at FHC recall patients every six months. This chart below, generally, reflects how these sample group patients follow the recall appointments.

Number of Recall Appointments show-up by sample group patients	Total number of patients	Percentage rate among sample group size (total # 55)
No show after completion of comp. dental care	4	7.28 %
One recall appointment	29	52.73 %
Two recall appointment	10	18.19 %
+ 3 recall appointments	12	21.82 %

Success/Failure rate after finishing the comprehensive dental treatment with specialty care team & general dental providers within FHC sites. Failure defined as a restoration identified by dental providers as needing to be replaced due to structural breakdown (fracture or dislodgment of the restoration), pulpal or dentoalveolar infection associated with the restored tooth, or recurrent decay.12

- **The failure rate of patients treated by specialty dental care: 6/36, (16.7 %)**
- **The failure rate of patients treated by general dental providers: 3/19, (15.8%)**

The time is taken by the specialty team to call the patients for initial consultation appointments after a referral from general dental providers and how long it takes to bring them to a comprehensive dental treatment session.

- **Average time to call patients to consultation appointment after the referral is 11 weeks.**
- **The average time between consultation and comprehensive treatment is 2.3 weeks.**
- **The average time between the initial exam and comprehensive care completed with G.P. is eight weeks.**

Table 7.1: Show how many patients kept /show to their one week, one month, and three months of follow-up appointments after finishing their comp. treatment with the specialty care team

Recall appointments	Total # of patients (total 36)	Percentage of total patients
One week follow-up appointment	27	75 %
One month follow-up appointment	5	13.89 %
Three months of a follow-up appointment	2	5.5 %
No information*	2	5.5%

*no documents about recall appointment found in the patient chart

Table 7.2:Show how many patients kept /show to their six months recall follow-up after finishing their comp. treatment with FHC general dental provider's team

Recall appointments	Total # of patients (total 19)	Percentage of total patients
Six months	7	36.85 %
No show	4	21 %
No need *	8	42.1%

*6 months recall is not due by January 1st, 2020 for those patients (no more data collect after1st January)

Behavioral category helps to understand the development of fear, anxiety, and anger as it applies to children in dental situations. For this study, we use Wilson classification for simplicity.

Classification of a child's behavior observed in the dental clinic, Wilson (1933).

A- **Normal/ bold**: brave, cooperative, and friendly with the dentist.

B- **Tasteful/ timid**: shy but not interfere with the dental procedure.

C- **Hysterical/ rebellious:** throws temper tantrums, rebellious.

D- **Nervous/ fearful:** tense and anxious. Fear dentist

Table 8.1: Show the behavior classification for the project group as documents by FHC providers

Behavior category	Total # among grp	% among group
Normal/ bold	3	5.4 %
Tasteful/ timid	30	54.55 %
Hysterical/ rebellious	8	14.55 %
Nervous/ fearful	10	18.19 %
No information*	4	7.28 %

*No documents about child behavior in patients chart found.

Table 8.2. Show the number & percentage of the patients referred to specialty care team (under IV-Sedation) according to challenging behavior issues.

Behavior category	Total referral numbers	Total referral percentage
Normal/ bold	0	0 %
Tasteful/ timid	18	50 %
Hysterical/ rebellious	6	16.6 %
Nervous/ fearful	9	25 %
No information*	3	8.3 %

*referral done without behavior documentation in patients

The Significant Caries Index (Sic Index)

In 1981 the World Health Assembly of the WHO declared a global goal for oral health by the year 2000 should be that DMFT by their 12-year-olds should not exceed 3 in all countries. Over twenty years, nearly 70% of the countries in the world have succeeded in achieving this goal, or have never exceeded this borderline value.1

A new index called the 'Significant Caries Index' (SiC) proposed in the year 2002 in order to bring attention to those individuals with the highest caries scores in each population. The SiC Index is the Mean DMFT of the one-third of the study group with the highest caries score. The index used as a complement to the mean DMFT value.

To calculate the Significant Caries Index:

• Sort the individuals according to their DMFT

• Select the one-third of the population with the highest caries values

• Calculate the Mean DMFT for this subgroup.

By using our data, the total sample size is 55; we count 18 as one third, selecting the highest caries value (DMFT) score for eighteen people from the sample group. The total sum of DMFT for them is 75. So, Mean DMFT 75/18= 4.2, which is the SiC index for our sample group. That mean we need more efforts to decrease caries rate among children group up to 12 years old.

Discussion

FHC providers' efforts are influential in impacting patient's oral health, oral home care improvement, educating patients, and their parents/guardians about the importance of good oral hygiene and regular dental visits. Over 12 months, small number of patients completes their dental treatment within general dental and specialty care team. This issue considers a challenge among patient care since we have a limited number of providers and a large number of children in need of care. The documentation reflects the most critical information about the selected

participants. However, missing information for few patients affects the accuracy and integrity of our results.

This study shows no gender tendency for high caries risk. All susceptible sample group patients are under the poverty level, which makes them more susceptible to high caries rate. We found that 65% of patients undergo general anesthesia since this approach, theoretically, allows for optimal conditions under which dental treatment can perform. However, it is not available for all patients, since the specialty team prioritizes the patients who are most severe first. Also, the remaining 35% of patients finish their dental treatment throughout the year (2019-2020) by multiple providers within FHC sites.

Patients in this study may have presented with greater caries severity that required a more aggressive treatment approach, 73% of the patients need care for their primary teeth, and 82% need of care for permanent teeth while the percentage of teeth lost due to caries is 21 % primary teeth and 1.8% for permanent teeth.

Children's behavior is the essential aspects of the referral process. Among the sample group patients (total 55), 65% of the patients sent to specialty care have some behavioral challenges which could affect the quality of dental care unless perform with the specialist.

In this study, a high plaque index was found after completing comprehensive/preventive care. This high plaque index (heavy plaque) mainly detected during recall visits, despite the re-enforcing preventive measures, diet counseling to decrease sugar exposure, oral hygiene instructions (brushing twice and floss once per day) plus the fluoridation and sealants. Reviewing oral hygiene instructions is very important to decrease the failure rate and maintain caries-free status. Dental staffs try to review these hygiene habits and help parents improving their oral home care for themselves and their children during the recall appointments. However, parents or guardians not always show for their recall appointments with their children.

In this study, with the specialty care team, 75% of patients show for their 1-week recall/check-up visit, while 14 % show for their one month visit and only 5% for their three months recall. While with general dental providers, 36% of patients show for their six months recall. Also, there are 5 % of patients who did not show for any recall appointment at all with the specialty care team, and 21% no show with general dental providers. The lower rates of return might have resulted in a bias in this sample population, such that parents were more likely to bring their children in for follow-up if they recognized that a restoration had failed or symptoms developed like pain. Besides, many of the patients may not have returned for follow-up because they did not perceive a need for re-treatment, or they not understand the importance of follow-up visits.

The success/failure rate among that sample group within this study documented. Failure defined as a restoration identified by dental providers as needing to be replaced due to structural breakdown (fracture or dislodgment of the restoration), pulpal or dentoalveolar infection associated with the restored tooth, or recurrent decay. The specialty care team show 16% failure rate, in general, and it is 15 % among general dental providers. While success defined as the status of no active decay, broken or dislodge restoration, no dentoalveolar lesion, or periodontal disease after finishing comprehensive dental care, which is, respectively, 84% within specialty care team and 85% within general dental providers.

Conclusion

The effects of comprehensive dental treatment with the specialty care team and/or general dental providers plus hygiene education & preventive measures for high-risk caries young people are significant in decreasing active

caries, and improving hygiene habits since they finish their comprehensive care & follow oral home-care instructions. The presented work provides the basis for further studies to make more precise statements regarding the impact of comprehensive care towards high caries risk people.

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suggestions/recommendation

The following suggestions/recommendations should be incorporated into health programs in FHC for the young people of St. Croix:

1- It is important to enhance the knowledge about good oral health in parents, children and young adults. For example, caring out table-workshops, presentation and seminars on oral health, oral hygiene, plaque control, oral and dental diseases, oral cancer or smokeless tobacco use, hazards counseling and topical fluoride application in school and/or public events at St. Croix, like Agriculture fair, to ensure more social engagement

2- Within FHC, need to add/modify existing data entry template for the medical/dental software, coordinate with IT department, focusing on post-op visits details. The idea is to address the patient's hygiene habits to illustrate the follow-up instructions, like adding new template to address the OH habits, decrease sugar exposure, frequency of tooth-brushing and using Fluoride toothpaste.

3- We need to produce more hygiene brochures/forms to elucidate the importance of good oral home care habits, the importance of all preventative measures, and the need to keep follow-up visits. We need to focus on making a good connection/understanding with the parents/guardian via mails, social media, school events(like stage play or shows) and the FHC website in order to guide/ lead the proper oral hygiene habits for their children.

4- Establishing a training program for the new employees and residents on consistency of data collection, data entry and documentation since we have a small percentage of patients who did not have enough information in their database which is essential to meet the patients need and improve care. Such program should be implement with IT department included annual peer review, continuous educational courses in software technology and workshop in data entry during monthly FHC meeting.

5- Mobile Dental Van project shows success in different areas across United States. This module is an effective way to reach the children, removing access barriers to care and less missing days from school. In addition, dental van, with wheelchair accessible door, will reach the shelter homes, community residential projects and specialty homes to provide care for children in need.

6- Starting a school-based program coordinated with the Department of Health and Education, for preventive measures & caries control like Silver Diamine Fluoride (SDF), fluoride varnish, MI-Paste, OHI, tooth-brushing techniques and sports mouth-guards for children in schools across Saint Croix. Within this program, training for school-nurses and medical staff (via online, hand-on training and shadowing) to help with applying preventive measures will be essential for the success of such a program.

7- We need to increase the specialty care teams' available care-days (more than twice a month) since we have a large group of high-risk caries people. Also, adding more dental staffing consisting of assistants, hygienists, and dentists to the specialty team to help as

many people as we can and provide more flexible scheduling for the patients in need of care. Also, we will able to add more intravenous-sedation's appointments for patients who have behavior issues or medically compromised and according to specialty care teams' parameters for IV-Sedation needs.

8- The referral process for specialty team works well with acceptable waiting time for the patients. While, for FHC's internal referral process (IRF), we need to engage all Primary care providers, pediatrician and OB/GYN specialist to works i with children and parents to enforce OHI, Fluoride varnishes and encourage regular dental visits. Also, we need to utilizes, tracks the IRP like with monthly review for the children visiting FHC sites or initiates referral tracker program.

9- Establish protocol/policies for annual program to promote and maintain this research to keep the constituents of people aware and well informed. Also, continue with more researches and projects within the same topic but with larger sample group (for example; enlarge group by involving more age range beyond 6-12 years olds and/or checking data for longer than one year, etc.). By using this project as data base, so we can assess and evaluated our data, measures and working protocols and improved them accordingly towards our free caries people goal and decrease failure rate.

10- More general providers needed for FHC to allow more preventive, restorative and re-care appointments to improve Oral Hygiene habits and overall oral health for children of St. Croix.

Statement of Compliance

This study conducted by the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), any other applicable U.S. government research regulations, and institutional research policies and procedures. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the study participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

List of Abbreviations

DHHS	Department of Health and Human Services
FHC	Fredericksted Health Care
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
MAP (Medicaid)	Medical Assistance Program
No.	Number (typically refers to participants)
NIH	National Institutes of Health
OHI	Oral Hygiene Instructions
P.I.	Principal Investigator
QA	Quality Assurance
SiC	Significant Caries Index
SSC	Stainless Steel Crown
U.S.	United States
VI	Virgin Islands
WHO	World Health Organization

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