

QATAR UNIVERSITY

FLUORIDE VARNISH APPLICATION AS AN ORAL HEALTH INTERVENTION IN

THE WELL-BABY CLINIC FOR CHILDREN AGED 1-5 YEARS AT QATAR

UNIVERSITY HEALTH CENTER: A FEASIBILITY STUDY.

COLLEGE OF HEALTH SCIENCES

BY

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the College of Health Sciences

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Master of Public Health

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## ABSTRACT

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Title: Fluoride Varnish Application as an Oral Health Intervention in Well-Baby Clinic for Children Aged 1-5 Years at Qatar University Health Center: A Feasibility Study.

Supervisor of Thesis: Dr. Hanan Abdul Rahim.

**Background:** Early childhood caries (ECC) is one of the most common chronic conditions affecting children worldwide. It is considered a significant public health problem in most communities, with over 530 million children worldwide suffering from dental caries in their primary teeth. Qatar has reported a prevalence of 89% among preschool children aged 4 to 5 years old. ECC is often left untreated, leading to physical, psychosocial, and economic consequences, and if severe, it can result in potentially life-threatening infections. ECC is preventable through proper diet counseling, oral health promotion, and simple preventive measures. Strategies for preventing ECC require a multidisciplinary approach and should be integrated into different settings. Professionally applied fluoride varnish (FV) containing 5% sodium fluoride has been proven effective in ECC prevention. In addition to the high prevalence of ECC in Qatar, community water supplies are not fluoridated, and attending multiple health-related appointments is a challenge for families at high dental caries risk. When these factors are considered together, they indicate that integrating oral health assessment and prevention into places where young children already go and in settings other than the dental clinic could be a promising strategy for dealing with the high prevalence of ECC. This study investigated the feasibility of providing FV application for children aged 1-5 years and at moderate to high risk of developing ECC during their regular vaccination visits in the well-baby clinic at Qatar University Health Center using the Donabedian model for measuring the quality of care.

**Aim:** This study aimed to test the feasibility of providing Fluoride Varnish (FV) application in the Well-baby clinic at Qatar University Health Center for children aged 1-5 years who are at risk (moderate to high) of dental caries during their regular vaccination visits.

**Methods:** The design is a 3-month one-group feasibility study with a pre-and post-test design. All eligible participants (50 children) were at risk to dental caries and received the FV application intervention. Feasibility was assessed by examining the intervention's acceptability, implementation, and practicality. Assessment methods included surveys of healthcare providers and parents, clinic logs and nurses' notes, and a Cost Assessment Tool (CAT) adapted from EngenderHealth. Reporting followed the Template for Intervention Description and Replication (TIDieR) from the EQUATOR network (Enhancing the QUALity and Transparency Of health Research).

**Results:** The results showed that the intervention was acceptable to parents and their children. We reached 90.9% of the eligible children based on their contact information. Of the contacted parents, 93.1% confirmed participation, and 96.7% of those showed up to their appointments. The majority of parents (92%) had no concerns about FV safety, and all participating parents reported they would allow a well-trained nurse to provide the application to their children during their vaccination visits. In a small number of cases (12%), parents reported feelings of stickiness and unpleasant flavor by their children. Despite a high level of acceptability, implementation rates were lower than expected. Nurses performed the caries risk assessments on all participated children and completed FV applications for the vast majority (47 children; 94%), while pediatricians participated by adding the preventive FV application to the general and oral health promotion they already offer during the vaccination visits. In terms of the intervention practicality, the time utilized for completing the dental caries risk

assessment was  $1.09 \pm 0.33$  minutes, whereas  $1.37 \pm 0.62$  minutes was the average time for completing one FV application. The direct cost for providing FV to children in the well-baby clinic at Qatar University Health Center was 15QR per application. The most frequently perceived barriers to implementing the intervention were: unavailability of instruments, insufficient supportive staff, lack of physical space, and providing the FV for those who rarely visit the health center.

**Conclusion:** This study showed that integrating the FV application as a simple, cost-effective strategy for the primary prevention of dental caries in children less than five years old during their regular vaccination visits in a primary health care setting in Qatar is feasible after addressing gaps related primarily to the process inside the well-baby clinic. Increasing the appointment time by a minimum of 3 minutes, providing more structured mandatory oral health education and training to the providers, application of strategies to increase nurses' adherence through reminding them of the oral assessment for each child, and affording enough staff to be able to carry out the intervention effectively without compromising the patient's quality of medical care, all are limitations to be addressed by management before introducing the FV application in the well-baby clinic for children at risk of having dental caries.

## DEDICATION

*I dedicate my thesis work to my faithful parents, brothers, and sister*

*A special feeling of gratitude to my loving husband, Mr. Ashraf Batta, who has been a constant source of support and encouragement during my journey of graduate study and life.*

*My lovely daughters, Tulip, Talya, and Danya, my biggest achievements, you have made me stronger.*

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## LIST of ABBREVIATIONS

ECC: Early Childhood Caries

WHO: World Health Organization

DMFT: Decayed Missed Filled Tooth (in permanent dentition)

dmft: decayed, missed, filled, tooth (in primary dentition)

FV: Fluoride Varnish

ADA: American Dental Association

AAP: American Academy of Pediatrics

AAPD: American Academy of Pediatric Dentistry

NIH: National Institutes of Health

CDC: Centers for Disease Control and Prevention

USPSTF: US Preventive Services Task Forces

PHCC: Primary Health Care Corporation

QUN HC: Qatar University Health Center

HC: Health Card

SPO: Structure, Process, Outcome

ART: Atraumatic Restorative Treatment

SMART: Simplified and Modified ART

FDA: Food and Drug Administration

YLD: Years Lived with Disability

S-ECC: Sever- Early Childhood Caries

GCC: Gulf Cooperation Council

TIDieR: Template for Intervention Description and Replication

SMS: Short Message Service

MENA: the Middle East and North Africa

MOPH: Ministry of Public Health

US: United States

UK: United Kingdom

PI: Principal Investigator



## CHAPTER 1: INTRODUCTION

### 1.1 Background

Early childhood caries (ECC) is one of the most common chronic conditions afflicting children worldwide (1). It is considered a significant public health problem in most communities, with over 530 million children suffering from dental caries in their primary teeth (2). ECC rates have increased in low- and middle-income nations, where sugar consumption increased with the nutrition transition (3). ECC is defined as the presence of one or more decayed (non-cavitated or cavitated lesions), missing (due to caries), or filled tooth surfaces in any primary tooth in a child under the age of six. Furthermore, Severe Early Childhood Caries (S-ECC) refers to progressive dental caries patterns (4).

ECC is a significant concern in developed and less developed countries (5). However, the prevalence rate of ECC varies among developed countries (6). In less developed countries, the prevalence of ECC is reported to be as high as 70%, with the higher rates reported among low-socioeconomic groups (7). In the Gulf Cooperation Council (GCC), ECC reached a prevalence of around 81% among children (8). Qatar has reported a prevalence of 89% among preschool children aged 4 to 5 years old (9).

Dental caries may impact children's quality of life, pain complaints, and school absences (10). Furthermore, ECC is often left untreated, leading to physical, psychosocial, and economic consequences (6, 11-15), and if severe, it can result in potentially life-threatening infections (16). Treatment for ECC is costly because it requires extensive restorative treatment and tooth extraction at a young age, and repairing and replacing decayed teeth are incredibly expensive in terms of money and time. Because young children cannot cope with comprehensive treatment procedures, general anesthesia or deep sedation may be required (17). Thus, ECC treatment is

considered a significant drain on resources and beyond the capacity of many health care systems, especially in low and middle-income countries (18). Furthermore, children's dental care access is difficult due to parents' employment schedules, health literacy, dental fear, and prioritizing general medical care over dental care (19).

ECC is a multifactorial infectious and transmissible bacterial disease. Diet and feeding habits can play a role in the progression of dental caries. High sugar consumption, poor dental hygiene, lack of fluoride exposure, and enamel abnormalities are just a few of the critical variables that contribute to ECC development (20-24). On the other hand, dental caries is preventable through proper diet counseling, oral health promotion, and simple preventive measures (1, 25). The prevention of dental caries in children is a priority and is considered more cost-effective than treatment (26). Strategies for preventing ECC require a multidisciplinary approach and should be integrated into different settings, including patients, providers, and the community (6). Fluoride exposure through various sources is one strategy that helps minimize ECC and the influence of sugars. Fluoride in toothpaste, drinking water, and professionally applied fluoride are well-established ways to prevent dental caries (27). FV containing 5% sodium fluoride applied to the teeth prevents dental cavities or reverses tooth decay's first stage by inhibiting demineralization and promoting remineralization of tooth enamel (28). The Food and Drug Administration (FDA) has approved fluoride varnish as a "device" that must be used "off label" to prevent caries (29, 30). The main benefit of FV has been attributed to the predicted lengthy fluoride slow release feature, but it is also an easy application technique, independent of patient compliance, and suitable for usage in high-risk groups (31). FV's effectiveness in preventing dental caries is confirmed, and it is widespread internationally in community-based preventive oral health services programs (32-34).

The American Dental Association (ADA) recommends using fluoride varnish for children younger than six years who are at risk of developing dental caries (35). Thus, caries risk assessment is crucial for ECC prevention and management planning and decision-making (36). The American Academy of Pediatric Dentistry (AAPD) recommends assessing the children's caries risk by their first year as part of a comprehensive health examination and regularly reevaluating (37). In primary pediatric care settings, physicians can play a crucial role in addressing oral health problems in children since they are more likely to see a physician than a dentist (38). The US Preventive Services Task Force (USPSTF) suggests that primary care physicians identify risk factors, prescribe systemic fluoride supplements, and apply FV to all five-year-old and younger primary teeth, starting with the eruption of the first primary tooth (39). Furthermore, the American Academy of Pediatrics (AAP) endorsed the FV application for all children starting at the primary tooth eruption, and it has been added to their Preventive Health Care Schedule (40).

In Qatar, the National Oral Health (2011) Survey reported that dental caries affected 70% of 6-year-olds children, with untreated dental caries being dominant (41). However, there is no adoption of community preventive programs targeting the high prevalence of dental caries.

Fluoride incorporation in public drinking water is considered one of the most effective public health initiatives in developed countries (42). However, the public water supply in Qatar is not fluoridated, and the percentages of fluoride in bottled drinking water were reported to be minimal (43). Despite considering FV application in pediatric settings as an essential standard of care in many developed countries (44), it is restricted to dentists and dental hygienists in Qatar. A recent study exploring the parental preferences of FV reported that about 70% of parents would allow healthcare providers

in primary care settings to apply it to their children (45).

In Qatar, on average, children have seven or more visits to their primary health care providers in well-baby clinics for vaccination and regular periodic checkups in the first five years of their lives (46). The current 'Beautiful Smile' program for establishing early dental care is essential to better oral health among children. All Primary Health Care Corporation (PHCC) health centers implement the program to provide oral examination by trained nurses in the well-baby clinics for children aged two weeks to five years (47). However, the program does not offer FV preventive applications. It identifies the children at risk of developing caries and refers them to dental clinics for further evaluation and management. The appointment in the dental clinic will be based on the first available appointment, which is usually constrained by the long waiting times between appointments.

Such evidence of the high prevalence of dental caries and positive attitude of the parents, with the lack of the community fluoridated water and challenges for families at high dental caries risk to attend multiple health-related appointments, suggests that integrating oral health assessment and prevention into locations where young children already attend, and in a setting outside of the dental clinic could be a promising strategy to face the high prevalence of ECC in Qatar.

We adapted Donabedians' model to assess the quality of practice change (48). This framework includes three leading indicators for evaluating quality in medical care: Structure, Process, and Outcomes, giving us an understanding of what is going on and identifying outcomes in different possible situations by considering the three indicators for evaluating the quality of providing the FV application during the well-baby visits. We expanded the adapted model to include the balancing measures extension of the Donabedian's framework to detect any potential unintended consequences. The adapted

conceptual framework was used to guide the FV application in the well-baby clinic at Qatar University Health Center. Many studies investigated the acceptability of providing FV during well-child clinics and other primary care settings in developed countries. However, each published research is customized to the target population as it explores issues with local relevance (34, 49-56). There is a lack of studies about the feasibility of implementing FV as regular dental care in a primary care setting in Qatar.

The study will investigate the feasibility of providing FV application for children aged 1-5 years and at risk of developing ECC during their regular vaccination visits in the well-baby clinic at Qatar University Health Center. The feasibility will be assessed regarding the intervention's acceptability, implementation, and practicality to help future planning of extending the oral health provision beyond the dental clinic into settings where young children attend for other health needs to fight the ECC epidemic in Qatar.

## **1.2 Aim**

This 3-months study aims to test the feasibility of providing FV application in the Well-baby clinic at Qatar University Health Center for children aged 1-5 years who are at moderate to high risk of dental caries during their regular vaccination visits.

Feasibility was assessed using specific research questions that address acceptability, implementation, and practicality:

- **Acceptability:** to what extent is FV intervention suitable, satisfying, or attractive to intervention deliverers and recipients?
- **Implementation:** to what extent can the FV intervention be successfully delivered to the participating eligible children at a well-baby clinic?

- **Practicality:** to what extent can the FV intervention be carried out by the participating physicians and nurses using existing resources and circumstances without outside intervention?

### 1.3 Specific Objectives

The primary objectives of our study were as follows:

1. To measure the acceptability of the intervention (FV application) phases, including the recruitment rate, parents' satisfaction, intention to continue using FV for their children, children acceptability, health care providers' satisfaction, and perceived appropriateness.
2. To examine the implementation of FV intervention through the percentage of the correct FV applications and the amount and type of the extra resources needed.
3. To assess the practicality of providing FV intervention in the well-baby clinic setting by identifying the factors affecting the implementation ease or difficulty of the FV application, the speed, barriers and facilitators reported by participating health care providers, and direct cost analysis.

The secondary objective was:

1. To describe the usual dental practices of parents and children who are clinic clients to assess their likely receptiveness to the intervention.

The study results will inform recommendations to the PHCC management regarding integrating the FV application as a simple, cost-effective strategy for the primary prevention of ECC in children under the age of five years.

## **CHAPTER 2: LITERATURE REVIEW**

### **2.1.1 Burden of Dental Caries**

Within the context of the epidemiologic transition towards non-communicable diseases, the share of oral diseases in Years lived with Disability (YLD) has risen between 1990 and 2015, so they now feature in the ten leading causes globally (2). The World Health Organization (WHO) identifies dental caries as one of the most prevalent chronic conditions that can cause pain, suffering, and a lower quality of life during a person's lifetime (57). According to the Global Burden of Disease 2015 study, dental caries affects 2.3 billion people worldwide, with the majority of them having caries in the permanent teeth, and over 530 million children have dental caries in their primary teeth (2). The prevalence of dental caries varies worldwide (7). Thanks to improved dental services and increased oral hygiene awareness, it is declining in most developed nations (58). However, due to the rising sugary food intake, poor teeth brushing practices, and a lack of proper dental treatments, there has been an extraordinary rise in the prevalence of dental caries in developing countries (59). In the WHO African region, it is estimated that 30% of the population suffers from deterioration of their permanent teeth (60). In the Middle East and North Africa (MENA) region, the prevalence of dental caries ranges from 17.2 % to 91.3.8% among children in Iran and Saudi Arabia, respectively (61). The prevalence of dental caries is rising in most low- and middle-income countries due to increasing urbanization and changing living conditions.

### **2.1.2 Early Childhood Caries (ECC)**

Early Childhood Caries (ECC) is a multifactorial transmissible bacterial disease (16 ), and it is one of the most common chronic childhood conditions (62). The American Academy of Pediatric Dentistry (AAPD) defines ECC as the “presence of

one or more decayed (non-cavitated or cavitated), missing (due to caries), or filled tooth surfaces in any primary tooth in a child 71 months of age or younger”. The term “Severe Early Childhood Caries” (S-ECC) refers to progressive patterns of dental caries (63). The AAPD defines S-ECC as “any sign of smooth-surface caries in a child younger than three years of age, and from age three to five, one or more cavitated, missing (due to caries), or filled smooth surfaces in primary maxillary anterior teeth or a decayed, missing, or filled score of  $\geq 4$  (age 3),  $\geq 5$  (age 4),  $\geq 6$  (age 5) surfaces” (64) (Table 1). As a result, it is suggested that the term ECC is the best fit for describing any caries in infants and pre-school children.

The etiology of ECC is complex, with the leading cause being a time-specific interaction of bacteria with carbohydrates on the tooth surface (1). Diet and feeding habits can play a role in the progression of dental caries. High sugar consumption, poor dental hygiene, lack of fluoride exposure, and enamel abnormalities are just a few of the critical variables that contribute to ECC development (20-23). The appearance of white spots on the labial surfaces of the primary maxillary incisors is usually the initial sign of ECC (65). Demineralization, initiated by cariogenic bacteria, causes all types of dental caries.

Remineralization is the body’s natural way of repairing dental caries by allowing minerals from saliva to seep back into the porous subsurface portion of the carious lesion. Throughout the day, the cycle of demineralization and remineralization continues. When fluoride is present in saliva, it is highly adsorbed to the tooth’s demineralized surface, protecting the crystal surface from acid disintegration (66). Topical fluoride exposure has a more significant protective impact than systemic fluoride exposure. Remineralization is aided by fluoride in the saliva, and the new fluorapatite-rich enamel is less soluble than the original carbonated hydroxyapatite



tooth mineral. Furthermore, the ionized fluoride in the plaque fluid interferes with cariogenic ECC bacteria's critical enzyme function. Low quantities of ionic fluoride in the oral environment promote remineralization, which acts as a bacteriostatic agent (67, 68).

Table 1(1, 65, 69). AAPD Definition of Early Childhood Caries (ECC) and Severe Early Childhood Caries (S-ECC)

Age (months)	ECC	S-ECC
< 12	1 or more dmfs surfaces	1 or more dmfs surfaces
12-23	1 or more dmfs surfaces	1 or more dmfs surfaces
24-35	1 or more dmfs surfaces	1 or more dmfs surfaces
36-47	1 or more dmfs surfaces	1 or more cavitated, filled or missing (due to caries) smooth surfaces in primary maxillary anterior teeth or dmfs score > 4
48-59	1 or more dmfs surfaces	1 or more cavitated, filled or missing (due to caries) smooth surfaces in primary maxillary anterior teeth or dmfs score > 5
60-71	1 or more dmfs surfaces	1 or more cavitated, filled or missing (due to caries) smooth surfaces in primary maxillary anterior teeth or dmfs score > 6

## 2.2 Epidemiology of ECC

ECC is a significant concern in both developed and less developed countries, despite the drop in the prevalence of dental caries in children in western countries (5, 70). ECC prevalence varies greatly depending on several characteristics, including race, culture, ethnicity, socioeconomic position, lifestyles, oral hygiene practices, and dietary pattern, with the most significant prevalence among disadvantaged communities (1, 5, 71-74). The prevalence rate of ECC varies among developed countries (75). It is more common in the United States than in Europe, with 40% of children developing caries by kindergarten age, compared to the United Kingdom, where only 12% of 3-year-old

children had dental caries (76). In Sweden, the prevalence of ECC was 11.4% percent, and in Italy, it ranged from 7 to 19 % (77, 78). According to the National Oral Health Survey of 2011, 25% of 3-year-olds in Japan had caries (75). In less developed countries and among socioeconomically disadvantaged groups in developed countries, the prevalence of ECC can be as high as 70% (7). In Asia, the prevalence of ECC ranges from 36% to 85%, and in Africa, it is between 38% and 45%. Cambodia and Indonesia have documented high ECC prevalence and severity, with 90% of 3 to 5-year-old having dental caries with a decayed, missing, filled teeth score (dmft) more than six (75). Some national surveys, such as those conducted in Greece (36%), Brazil (45.8%), and India (51.9%), revealed an uneven prevalence of ECC (79-81). ECC appears to be endemic to specific groups rather than widespread throughout the population, particularly in South-East Asia and Africa.

In the MENA region, several recent studies assessing the ECC prevalence, independent of age group or publication year, reported a high prevalence of the condition and a deterioration of dental health compared to earlier data. In some Middle Eastern countries, the prevalence was as high as 76% (Palestine) and 83% (the United Arab Emirates) (1). In a new systematic review of ECC in the region (61), over half of the studies came from Iran, Saudi Arabia, Turkey, and the United Arab Emirates. Most studies were cross-sectional, offering a snapshot of regional dental caries prevalence rather than progression over time. In Iranian children under six years, dental caries prevalence was 17.2% in 2004 and 3-26% in 2006. A prevalence of 49.3% was recorded in 2011, while 69.9% and 87% were reported in studies published in 2017 or later, demonstrating a clear trend toward an increased prevalence of dental caries among young children in Iran in the past 15 years. In Turkey, children under six years have a significant frequency of dental caries, with almost all the studies (five out of six)

published between 2003 and 2011 showing that at least three-quarters of the children had ECC.

In the Gulf Cooperation Council (GCC), only a few studies have been conducted on the prevalence of dental caries affecting primary dentition. The GCC is a regional intergovernmental union composed of six countries of the Arabian Gulf; Saudi Arabia, Kuwait, United Arab Emirates, Qatar, Bahrain, and Oman. They share very similar cultures and values (82). The GCC region has undergone a remarkable transition since the discovery of oil and is now home to some of the world's fastest-expanding economies. However, a recent study reported that ECC in the GCC area is high in mean *dmft* score (5.14) and prevalence (81.1 %). The ECC prevalence was predicted to be around 80% in Saudi Arabia. While in the United Arab Emirates (UAE), dental caries was quite common in pre-school children, with 36% to 47% at two years of age, 71 % to 86% at four years of age, and 82% at five years old of age (8).

In Qatar, the Ministry of Public Health (MOPH) 2011 National Oral Health Survey (NOHS) reported that 7 out of 10 children were affected by dental caries among six-year-olds (41). Furthermore, a recent descriptive cross-sectional study among 250 pre-school children randomly selected from 16 public kindergartens identified that the overall prevalence of dental caries was 89%. ECC and S-ECC comprised 15.6% and 73.6%, respectively. The mean *dmft* caries index among children four to five years was 7.6 in the same study (10).

### **2.3 Determinants of ECC**

For optimal preventive outcomes, it is critical to identify the elements that determine who is at most risk for dental caries before or very soon after teeth erupt. ECC risk factors include biology, nutrition, dental habits, and socio-behavioral determinants like socioeconomic status and dental care utilization (83, 84).The primary

ECC determinants include factors related to child features, family history, oral hygiene, and newborn feeding and eating behaviors (61). Infant feeding practices, such as putting a child to bed with a bottle containing formula or other sweetened liquids, have been linked to ECC, especially if the infant falls asleep while feeding (85,86). ECC is a significant concern among poor children, children from specific ethnic groups, and children with chronic health problems (87). Children from low-income homes are twice as likely as their more affluent counterparts to develop dental caries, and their disease is more likely to go untreated (88). Preschoolers whose parents or caregivers do not have a high school education appear to be more likely to get ECC (89-91).

Because the preschooler's health and well-being are dependent on the actions and attitudes of the primary caregiver, some psychosocial and behavioral factors that contribute to ECC differ from those that contribute to dental caries in older children and adults (88). It is also worth noting that maternal smoking during pregnancy has been linked to higher rates of ECC and caries in their offspring (92, 93). As per the Academy of American Pediatrics (AAP), when a young child's older siblings have a history of dental caries, the risk of having ECC rises (94).

#### **2.4 Prevention and Early detection of ECC**

The health of a child's primary dentition is critical to their overall well-being. Primary dentition plays a crucial role in children's mastication, esthetics, phonetics, space maintenance, and the prevention of abnormal behaviors (1). Dental caries progression in the enamel of primary teeth is twice as quick as that in permanent teeth (95). According to the Centers for Disease Control (CDC) and the American Academy of Pediatric Dentistry (AAPD), it is critical to identify children at high risk of ECC as soon as possible and start complete dental care, to avoid pain and suffering as well as unneeded treatment costs (37, 96). The early manifestation of ECC includes pain,

speech problems, chewing difficulties, general health disorders, psychological issues, and lower quality of life of infants and toddlers (15, 97, 98). Dental infections caused by dental caries can result in pain during dental treatment as well as cellulitis or severe systemic infection (11). Dental pain and subsequent dental treatment could result in school absences and low self-esteem (12). Furthermore, there is a well-established link between periodontal infections and the worsening of chronic systemic diseases like asthma and diabetes (13).

#### **2.4.1 Risk Assessment**

The caries risk assessment determines the chance of caries developing over a given period (88). Caries risk assessment is crucial for ECC prevention and management planning and decision-making (36). The United States Preventive Services Task Force (USPSTF), AAP, and CDC recommend that children have an average of seven visits to their primary healthcare providers for vaccination and regular periodic general check-ups in the first five years of their life alone (99, 100). AAPD recommends assessing the children's caries risk by their first year as part of a comprehensive health examination, and it should be reevaluated regularly (37, 101). The AAP and AAPD propose that child healthcare practitioners utilize the Caries Assessment Tool (CAT) to estimate caries risk over time (102). The CAT does not provide a diagnosis. Thus, anyone utilizing it should know about dental caries' clinical signs and symptoms and factors contributing to ECC initiation and development. When utilizing the CAT to estimate caries risk in young children, caries experience, dietary patterns, oral hygiene practices, fluoride use, and socioeconomic status are considered. Furthermore, characteristics related to primary caregivers, such as parents' oral health conditions and behaviors, are also considered.

The AAP identifies several groups as at risk for ECC (101). They are children

with special healthcare needs, from a low socioeconomic background, with inadequate exposure to fluoride (topical or systemic), poor dietary and feeding practices, children whose caregivers or siblings have caries, or those with visible caries, white spots, plaque, or decay. A child with one of those risk factors should visit a dentist as early as six months of age and no later than six months after the first tooth erupts or at 12 months of age, whichever comes first (96).

#### **2.4.2 ECC Prevention and the Role of Topical Fluoride**

ECC treatment is costly because it requires extensive restorative treatment and tooth extraction at a young age. Repairing and replacing decayed teeth are expensive and time-demanding procedures. Because young children cannot cope with comprehensive treatment procedures, general anesthesia or deep sedation may be required (17). Dental treatment is considered a significant drain on the resources of health care systems (18). According to the WHO Oral Health Report 2018, dental treatment averages 5% of total health spending and 20% of out-of-pocket health spending in most high-income countries (57). Therefore, preventing dental caries in children is regarded as a priority for dental services and is more cost-effective than treatment.

Furthermore, caries prevention in young children requires a multidisciplinary approach integrated into different settings of healthcare services and the community. According to the 2016 WHO Expert Consultation on Public Health Intervention Against Early Childhood Caries, disease management would include the stages of prevention, caries management, access to dental services and integration systems, and coordination with the child, family, and community. Thus, primary, secondary, and tertiary caries preventions are part of the comprehensive ECC management strategy (75).

### 2.4.2.1 Primary prevention

The four critical public health interventions for dealing with ECC are: promoting healthy behavior, fluoride use, oral hygiene, and appropriate diet and feeding practices. Fluoride is available worldwide from various resources divided into three major categories; community water, home administration, and professional application. Three proposed mechanisms by which fluoride can protect against dental caries include reducing enamel demineralization, promoting its remineralization, and inhibiting demineralization of the early carious lesion by inhibiting glycolysis, the process by which cariogenic bacteria metabolize fermentable carbohydrates (103). Fluoride has both topical and systemic pathways, but the topical action is the most important, especially over a lifetime (104). Many fluoride modalities are recommended based on the risk of having dental caries: toothpaste, fluoride varnish, mouth rinse, community water fluoridation, and dietary fluoride supplements (105).

Community water fluoridation is the most commonly used, with over 370 million people in 27 countries benefiting from it (106). A recent Cochrane review that assessed the effectiveness of water fluoridation on dental caries prevention reported a reduction in *dmft* (caries score for primary teeth) by 1.81% and DMFT (caries score in the permanent dentition) by 1.16 %. Compared to the median control group mean values, this amounts to a 35% reduction in *dmft* and a 26% reduction in DMFT. In the deciduous dentition, the percentage of caries-free children increased by 15%, and the permanent dentition by 14% (107). Besides, systemic fluoride supplements such as F-milk, F-salt, and F tablets or drops were created as an alternative to adding fluoride to drinking water to reach as many people as possible in the target population. However, there is a lack of enough evidence supporting their effectiveness (108). According to WHO recommendations, policymakers should strengthen fluoridation at an optimal

level to prevent dental caries, and access to national fluoridation schemes that use water, salt, and milk as vehicles should be encouraged whenever possible (109). Home administered fluoride such as toothpaste, mouth rinses, and gels are used as a self-applied fluoride source with a maximum concentration of 1500 ppm for adults and children older than six years and 1000 ppm for younger children. A recent review reported that fluoridated toothpaste effectively prevents dental caries in children younger than five (110). However, parents must control children tooth brushing to avoid fluoride over ingestion in children younger than six years (111). Dentists and health care providers provide professionally applied topical fluorides with confirmed effectiveness, safety, and ease of use. The American Dental Association (ADA), the American Academy of Pediatric Dentistry (AAPD), and the Center for Disease Control and Prevention (CDC) have all issued guidelines for the use of fluoride as an effective intervention to prevent dental caries (112, 113). A new systematic review and meta-analysis summarized the evidence about preventing ECC using professionally and self-applied fluoride and reported that FV was not associated with treatment-related fluorosis or other adverse events in young children (114). Permanent teeth fluorosis occurs when an excessive amount of fluoride is swallowed during the mineralization of tooth enamel; thus, the risk is influenced by both the dose and frequency of the intake. Recent data points to genetic vulnerability or resistance to fluorosis development (115). Most of the reported cases of fluorosis in children were due to the use of fluoride supplements or early use of fluoride toothpaste as a result of unintended ingestion (116, 117). The vast majority of the reported enamel fluorosis is very mild, characterized by tiny white striations or opaque areas that are not readily visible to the untrained eye, and have little clinical significance (118).

In Qatar, desalinated seawater and groundwater are the primary drinking water



sources. Because desalination eliminates fluoride from seawater, the public water supply in Qatar is not fluoridated, and underground well water, on the other hand, is naturally fluoridated (43, 119). Regardless of the quality and content of the tap water supply, most people in Qatar choose to drink bottled water, mainly due to the widespread belief that bottled water is healthier for all (120, 121). A recent study aimed to determine the fluoride concentration of bottled water available in Qatar reported that most bottled water in the commercial market had fluoride levels below the optimum level required for preventing dental caries (43). Moreover, the latest study to assess the daily urinary fluoride excretion of children living in Qatar identified that the fluoride excretion per day was 0.19 mg/day, which is considered very low, and it was similar across all ages, sexes, and for Qataris and non-Qataris (122).

#### **2.4.2.2 Secondary prevention**

Secondary prevention includes early disease detection, which prevents worsening lesions and controls the caries progression. Secondary prevention should not be implemented in place of primary prevention but rather in addition to it. Early detection, diet counseling, fluoride use, behavior modification, and fissure sealants are recommended strategies. The WHO recommends that healthcare professionals assess children's caries risk by their first year as part of an overall health assessment and re-evaluate it regularly (75). Periodic oral examination for mothers and children should be integrated with general healthcare. Subsequent check-ups should occur at every child's general health examination and vaccination visit or at least every 3-6 months, depending on caries risk (123). Brushing teeth under supervision with a layer of fluoride toothpaste containing 1000 ppm fluoride is recommended. For non cavitated lesions, fluoride varnish containing 2.26 percent fluoride every 3-6 months is recommended (75).

### **2.4.2.3 Tertiary prevention**

Tertiary prevention lessens the negative impact of established dental caries (cavity) by restoring function and lowering disease-related complications. It also aims to improve the quality of life for ECC children. Simple interventions such as Atraumatic Restorative Treatment (ART) and simplified and Modified ART (SMART) using glass ionomer cement are usually used in the tertiary prevention of ECC (124, 125).

### **2.4.3 The Role of Topical Fluoride in ECC Prevention**

FV, which contains high fluoride levels and was developed in the 1960s to prevent caries, is regarded as one of the most effective methods of preventing ECC (114). FV active ingredient is sodium fluoride with a concentration of 22600 ppm (2.26% fluoride ions) suspended in an alcohol and resin base. FV is widespread internationally in community-based preventive oral health services programs. It is a topical fluoride applied to the teeth and penetrates the saliva. FV has been available in Europe, Canada, and the United States for decades to extend the contact period between fluoride and dental enamel. FV is easy to use, well accepted by infants and young children, has a long-lasting therapeutic effect, and can be used in a variety of settings by both dental and non-dental health professionals (126). The effectiveness of FV, applied 2-4 times a year for reducing dental caries in primary and permanent dentitions, is further supported by many studies (32, 114, 127, 128). The latest systematic review identified the topically applied fluoride at three-month intervals to be the most effective in preventing ECC (114). A Cochrane review reported that the relative advantage of FV treatment appears to occur regardless of baseline caries risk, baseline caries severity, a background of fluoride exposure, and administration parameters like prior prophylaxis, fluoride concentration, or application frequency (32). Furthermore, another Cochrane

review of clinical trials aimed to assess the caries preventive effect of fluoride varnish concluded that FV applied to the teeth two to four times per year is associated with a substantial reduction in caries development, with an average of a 43% reduction in decayed, missing, and filled tooth surfaces in permanent teeth and 37% reduction in the primary teeth surfaces (129).

Most manufacturers' unit dose packaging provides a specific measured amount (0.25ml, providing 5 mg of fluoride ions). FV use during oral screening is beneficial to children, particularly those with limited dental care access. FV should be applied to the teeth every 3 to 6 months according to the latest AAPD recommendations for children at high risk of ECC. American Dental Association (ADA) recommends using 2.26% FV for children younger than six years who are at risk of developing dental caries. That is consistent with the guidelines recommendations from the Center for Disease Control (CDC), the National Institute of Health (NIH), the European Academy of Pediatric Dentistry, the Scottish Dental Clinical Effectiveness Programme, the American Academy of Family Physicians, and the American Academy of Pediatrics (AAP) (126, 130-134). The US Preventive Services Task Force (USPSTF) recommends that primary care physicians apply FV to all infants and children's primary teeth beginning at the first primary tooth eruption (39).

For gaining the best result, teeth are dried with gauze before applying FV to all surfaces of the teeth. A dose of 0.25 ml is advised for young children, usually available in single-dose applicator kits. Children can eat or drink right after the FV has been applied, but they should consume soft foods and not brush their teeth until the evening after the FV has been applied to maximize the varnishes' contact time on the teeth. Children should resume brushing twice daily using fluoridated toothpaste the following morning (135).

#### **2.4.4 Incorporating FV in Primary Care Settings**

Children are recommended to have at least seven preventive healthcare visits in their first year of life (the first week, one month, two months, four months, six months, nine months, and twelve months old), three visits in their second year of life ( 15 months, 18 months, and 24 months), two in their third year of life ( 30 months, 36 months), and once per year for children aged four and up (4 and 5 years old) (100, 136). These visits provide an opportunity for healthcare practitioners to begin and maintain using FV throughout children's lives. A national survey conducted in the US reported that 89% of newborns got at least one annual physician visit, whereas only 1.5% saw a dentist (137). Furthermore, in the United States, the use of FV during well-child visits is a well-established model (49). According to reputable sources such as the American Dental Association (ADA), the USPSTF, the American Academy of Pediatrics (AAP), and the American Academy of Pediatric Dentistry (AAPD), physicians and pediatricians are well-positioned to provide oral healthcare to their young patients. The US Preventive Services Task Force (USPSTF) published simplified recommendations in 2014 to encourage primary healthcare practitioners to identify risk factors, prescribe systemic fluoride supplements, and apply FV to all children five years and younger primary teeth starting with the eruption of the first primary tooth. (11). The same recommendations were just recently updated (138).

In the US, the Medicaid program reimburses medical healthcare practitioners for periodic oral screening of young children and FV applications for those at risk of ECC. However, only a few studies have looked into the challenges and facilitators to medical clinicians' participation. According to one study, about 30% of medical providers registered to offer fluoride varnish in their clinics, and inadequate training was the most common cause of their failure to provide FV (50). The US literature

identifies factors that may make FV more accessible to medical care providers, including Medicaid eligibility, practical cooperation and communication between physicians and support personnel, and working ties with dentists or community centers for referrals. Inadequate time to incorporate oral health services in well-child visits, difficulty implementing FV, reluctance among colleagues and employees, trouble referring children to a dentist, and a limited volume of eligible patients were all potential barriers to overcome (50-52). According to a recent qualitative study with pediatric nurses in various roles and levels of authority in six federally qualified healthcenters in two states (Massachusetts and Maryland) that aimed to identify the benefits and challenges of including oral health prevention in well-child visits, all the interviewed staff valued the interprofessional collaboration to improve children's oral health. Still, they felt constrained by a lack of oral health training and a supportive charting and referral system (53). The authors of a feasibility study conducted in rural South Carolina primary care practice concluded that implementing FV application by primary care professionals was feasible in terms of resources but required more management support to increase providers' acceptability (54). In this study, the setting provided preventive health care services besides managing acute and chronic sickness for all related clients of all ages starting at birth. The practice had also adopted a new electronic health record system. Thus, the willingness of health care professionals to add a new preventive health service (FV) to their busy schedule could be impacted by introducing a new system and having to manage illness rather than providing preventive health care. A quality improvement project in Florida's pediatric primary care setting reported a positive financial incentive to implement the FV program (55). In this quality improvement project, the FV application was administered to children at specific ages of 9, 18, 24, and 30 months during their regular visits to well-child clinics, and the

billing issues were the most faced barrier to providing the application. Thus, in US studies, issues related to the payment model are apparent in studies examining the feasibility and challenges of introducing a new preventive service.

In Canada, dental treatment is the leading reason for surgery among children, where 60-90% of children have dental caries, representing a high cost (139, 140). According to the Canadian Pediatric Society and the Canadian Dental Association, children should get their first dental visit before becoming one year old; however, these recommendations are not universally followed (141, 142). Few physicians refer their young patients to a dentist, and many dentists are hesitant to treat children under five (143). As a result, children may not see a dentist until they are three years old, at which point prevention may be impossible. A qualitative study identifying the essential stakeholders' viewpoints on making FV a standard primary care practice in Ontario reported that many physicians and nurses do not include oral health screening and preventive dental care even though they expressed an interest in implementing it. The self-reported barriers included the lack of training and assistance, insufficient time during the well-child visit, poor awareness of dental interventions, lack of clear guidelines, difficulties administering FV, funding, and staff reluctance (56).

In the UK, FV is the responsibility of general dental practitioners. ECC is still a significant clinical problem for many young children, and it is associated with considerable child morbidity and costs the National Health Services (NHS) millions of pounds each year. Over the recent decade, there have been numerous projects and programs, including FV. Similar to the US, there is currently little information available about the effectiveness of these programs. Scotland has the most readily available UK fluoride varnish application (34).

In Qatar, where the overall prevalence of dental caries among pre-school

children is 89%, children have a minimum of eight visits to the well-baby clinics for vaccination and regular periodic check-ups (46). The existing 'Beautiful Smile' program for establishing early dental care is essential to better oral health among children, and all PHCC health centers implement the program to provide oral examination by the trained nurses in the well-baby clinics for children aged two weeks to five years (47).

A recent study that assessed the knowledge, attitude, and related practices of mothers of pre-school children about oral health identified that only 43% of the children visited the dentist, with only 10% of those children going for regular dental check-ups. The same study reported that more children visited the dentist when a dental problem occurred, such as having a cavity (16%) or having toothache (14%) (144). At the same time, Al Hendaus et al. in 2016 reported that about 70% of parents in Qatar were not aware of FV but would allow healthcare providers to apply it to their children. In the same study, about 80% of parents reported that they would not stop brushing their children's teeth and would not skip dentist appointments if FV were applied. In addition, 40% of the surveyed parents conveyed some concerns regarding the safety of the FV, with the main concern being the child swallowing some fluoride, and they also expressed concern about the availability of FV in all clinics (45).

Such evidence of the high prevalence of dental caries and positive attitude of the parents, with the lack of the community fluoridated water and challenges for families at high dental caries risk to attend multiple health-related appointments, suggests that integrating oral health assessment and prevention into locations where young children already attend, and in a setting outside of the dental clinic could be a promising strategy to fight the ECC epidemic in Qatar.

There is a lack of studies about the feasibility of implementing FV as regular

dental care in a primary care setting in Qatar. Each published research is customized to the target population as it explores issues with local relevance. Thus, we developed this study to determine if implementing fluoride varnish application to children aged one to five years old by trained nurses during their regular vaccination visits is feasible.

## **2.5 Conceptual Framework for Assessing Feasibility of integrating FV application at the primary care level**

There are several models for assessing and improving the quality of care in health services (145). The Donabedian framework is a well-known and widely used framework for studying quality in health services research since 1966 (48, 146), and it can be adapted to several levels and scopes. The model has been applied in various quality studies ranging from eHealth to emergency care and from community-level services to advanced tertiary care (147-150). It has also been the basis of subsequent models for studying the quality of care.

Donabedian's framework (2005) describes a three-component approach for evaluating the quality of medical care. The three components are *Structure*, *Process*, and *Outcomes*. In this model, structure influences process, which affects outcome measures. *Structure* measures refer to the elements of a healthcare system that affect its ability to address the healthcare requirements of individuals or a community. It reflects the service provider's attributes, including the presence or number of personnel, clients, money, supplies, and facilities, and represents the type and amount of resources employed by a health system to deliver programs and medical services. *Process* measures evaluate the provider's actions and how successfully they were carried out. They are a set of interconnected operations carried out to attain the desired outcomes and reflect how the system works to deliver the desired outcomes, such as staff education and training related to provided medical service. *Outcomes* measures involve



the measurable impact on the involved patients and demonstrate the result of the intervention and whether it has achieved the aim set. Health outcomes are states of health or events that occur due to treatment and may be influenced by it. Dissatisfaction and emotional reactions to a specific disease and its treatment, such as sadness and anger, are considered health outcomes (151).

This framework includes a combination of three leading indicators for evaluating quality in medical care: Structure, Process, and Outcomes (SPO). Other models using the outcomes only as an indicator of the change process may suggest that the service is good or bad in aggregate; they do not reveal the kind and location of the inadequacies or strengths attributed to outcomes. Examining the process of providing medical care rather than its outcomes results in less stable estimates as it evaluates the providers' actions and how successfully they were carried out. Another approach to evaluating change in medical services uses the setting in which the process occurs as an indicator. This method has the advantage of working with information that is quite concrete and accessible, at least in part. On the other hand, the link between structure and process, or structure and outcome, is frequently not fully documented. Thus, the SPO model can give us a comprehensive understanding of the change process rather than focusing only on the desired outcome or the change process by understanding what is going on and identifying outcomes in different possible situations by considering the three indicators for evaluating the quality of providing the FV application during the well-baby visits.

### **2.5.1 Critique of the Donabedian Framework**

Donabedian's framework, though widely used in healthcare systems research, has been criticized for not explicitly including several vital details, such as the patient's family, the external environment, and the healthcare providers (152).

The model has mechanistic philosophic foundations because of the straightforward, unidirectional, and linear linkages established among the structures, processes, and outcomes. This linearity of links between SPO components would have been a limitation in measuring performance through non-linear correlations between SPO components.

The elements within the model are sufficiently broad, allowing for consistency with the metaparadigm of nursing and inclusion of the patient's families, the environment beyond where care occurs, and the impact on clinicians. However, the paradigm lacks an explicit focus on professional behaviors that enhance health and well-being for professionals. Whether structure, processes, or outcomes are the best performance measure has sparked much discussion. Each component of Donabedian's triangle of structure, process, and the outcome has benefits and drawbacks, with no single category providing the most incredible performance measurement in all situations and circumstances (Table 2) (153).

Further, the Donabedian framework has included the extension of a balancing measure to detect any potential unintended consequences of quality improvement early. Thus, trying to minimize it.

We adapted Donabedian's model to assess the quality of practice change (48). The adapted model included the three leading indicators of Structure, Process, and Outcomes and extended to include the balancing measures to assess any potential consequences. The balancing measures represented the oral health-related practices for children and parents and the parent's perception concerning the FV application. While the oral health practices will assess the participating parents' and children's likely receptiveness to the intervention as an essential part of the structure, the FV application-related perception will indicate any possible unintended consequences (outcome). The

adapted framework was used as a guide for the FV application in Qatar University health center's well-baby clinic, as illustrated in (Figure 1) of the following methods Chapter.

Table 2. Pros and Cons of Donabedian's Performance Measures

Type of Measure	Pros	Cons
<b>Structure</b>	<ul style="list-style-type: none"> <li>• Easy to measure</li> <li>• Avoid the need for many processes and outcomes in complicated environments</li> </ul>	<ul style="list-style-type: none"> <li>• Very crude</li> <li>• Often who are most adaptable to change are difficult to be assessed using available databases</li> </ul>
<b>Process</b>	<ul style="list-style-type: none"> <li>• Assess the quality-of-care patients received</li> <li>• Detect issues without having to wait for negative results to show up</li> <li>• Directly recommend quality improvement targets</li> </ul>	<ul style="list-style-type: none"> <li>• Identification of eligible patients may necessitate detailed clinical data</li> <li>• Improvements do not always translate into better outcomes</li> <li>• Not very meaningful to the patient</li> </ul>
<b>Outcomes</b>	<ul style="list-style-type: none"> <li>• Meaningful to the patients and health care providers</li> <li>• Applicable when evidenced-based care is unavailable or technical support is required</li> </ul>	<ul style="list-style-type: none"> <li>• Long periods of observation are frequently required, which is costly</li> <li>• Requires advanced procedure and clinically rich data to correct for potential variations</li> <li>• Difficult to attribute results to individual providers or episodes of care</li> </ul>

## **CHAPTER 3: METHODS**

This chapter will present the methods followed in conducting this feasibility study, including the setting and time, study population, sampling design, recruitment process, data collection, and data analysis methods. The reporting follows the recommendation of the Template for Intervention Description and Replication (TIDieR) (Appendix 1).

### **3. 1 Framework for Measurement of Structure, Process, and Outcome**

We adapted Donabedian's model to assess the quality of practice change, as illustrated in (Figure 1) below.

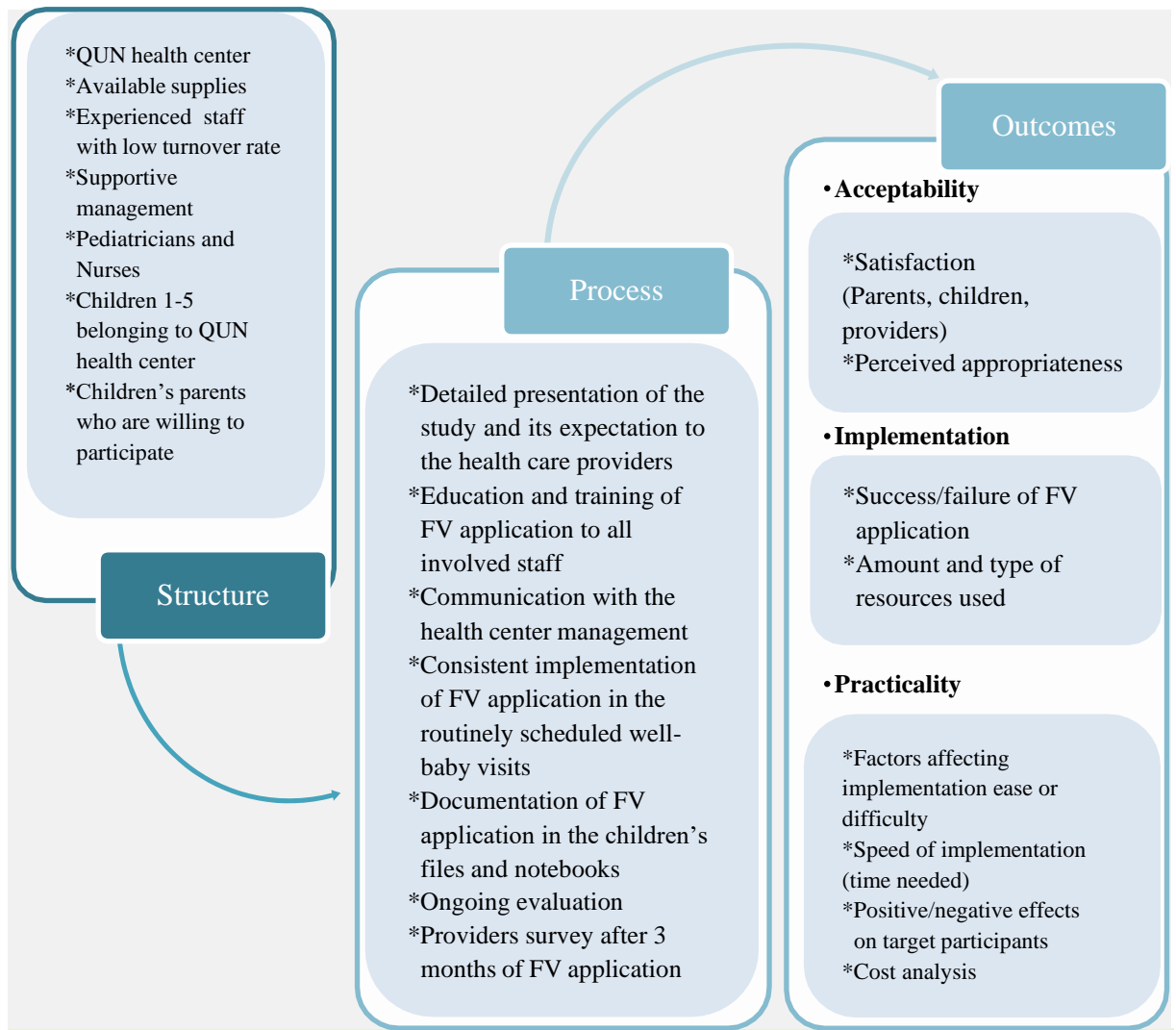


Figure 1. Conceptual Framework of Fluoride Varnish application using Donabedian's model for quality of care

Definitions, data collection tools, and mapping to each measure are described in the subsequent sections.

### 3.2 Study design

This design is a 3-month one-group feasibility study with a pre- and post-test design, and all eligible participants received the intervention. We used non-probability convenience sampling to study the outcomes of implementing FV application by primary care providers in the well-baby clinic at Qatar University Health Center (QUN

HC). A quantitative and qualitative feasibility assessment was undertaken.

### **3.3 Study Setting and Duration**

#### **3.3.1 Setting of the intervention study**

PHCC is Qatar's state-owned provider of primary care preventive and curative services, founded as independent cooperation in 2012 by the Emiri decree. The PHCC operates through 27 primary health care centers spread over three regions of Qatar: central, western, and northern. PHCC delivers a range of comprehensive, integrated, and coordinated health care services, including women's health, mental health, wellness, oral and dental services, screening, nursing, family physician, specialized services, child and adolescent health, allied support and health, pharmacy, school health, home health, and health protection. According to the PHCC Annual Statistical Report of 2020 (154), around 1,550,000 patients are registered in PHCC health centers, with 21% of those registered being Qataris. Ten health centers serve the northern region, with around 460,000 registered patients, of whom 23% are Qataris.

QUN HC, the site of the intervention study, is one of the northern regions' centers providing curative and preventive health services for Qataris and residents residing in its geographic catchment area, as the assignment to health centers is generally determined patient's place of residence (155). QUN HC serves approximately 44,000 registered patients, of whom 6% are Qatari nationals (Table 3).

Table 3. PHCC Patients' Population

Patients	PHCC	Northern region	Central region	Western region	QUN HC
No. of health centers	27	10	7	10	
Registered - all	1,550,711	502,014	589,371	459,326	43,901
Registered – Qatari nationals	21%	23%	38%	21%	6%
0-5 years old	10%	10%	9%	10%	14%

The well-baby clinic is the clinic in all primary health care centers where a package of health promotion and curative services is delivered to improve and maintain all children up to 5 years old who live in Qatar (46). There are 54 rooms for the well-baby clinic across the 27 primary health centers: 16 in the Central region, 18 in the Northern, and 20 in the Western. The well-baby visit must have an appointment of 20 minutes duration, and any child attending the clinic must be accompanied by a parent or a guardian. The service package is delivered at 2, 4, 6, 9, 12, 18, and 30<sup>th</sup> months and four years. Well-baby clinic team must have a trained nurse in the assessment room responsible for doing the required measurements of the child, two trained nurses for immunization, and an assigned pediatrician responsible for child clinical assessment and management. The routine workflow in the PHCC Well-baby clinics starts with a phone message (SMS) reminder and a call 2-3 days before the appointment. The visit begins with the receptionist, who correctly identifies each child by completing the child's primary data, including the child's name, Health Card (HC) number, date of birth, mother's name, telephone number, and blood group, with all data documented in the child health notebook. The nurse conducts all assessments and vital signs measurements for the child before being directed to the vaccination room. The

pediatrician provides the full general health assessment and health education. After approval from the pediatrician, the two assigned vaccination nurses administer the vaccine based on the national vaccination schedule and according to the child's age. The documentation for all children is done in their notebooks and their medical records on the electronic system CERNER.

At QUN HC, the designated site for the intervention study, a well-baby clinic is provided in two rooms, with six well-baby clinics per week. One permanently assigned full-time pediatrician, one assessment nurse, and two vaccination nurses staff each clinic. The average number of children with pre-booked appointments is 20/clinic.

### **3.3.2 Study duration**

The intervention feasibility study was conducted between September 12, 2021, and February 21, 2022. The recruitment and FV application were performed between September 15 and December 14, 2021.

### **3.4 Study population**

The target population was primary care providers practicing at the well-baby clinic in the QUN HC and children attending that clinic for regular general check-ups and vaccinations.

- The providers (n = 19) include 15 nurses and four pediatricians assigned to QUN HC.
- The participating children (n = 50) received their vaccination from the well-baby clinic at the QUN HC, all aged between 1 and 5 years.
- The participating parents (n = 50) of those eligible children who will receive the FV intervention.

Inclusion and exclusion criteria were predetermined (Table 4). Children who reside



in Qatar, have at least one erupted primary tooth, are at risk for dental caries as per the caries risk assessment, and with good general health were eligible to participate in the study. Children who do not have any primary tooth erupted yet or have a medical history of systemic disease, allergies to fluoride, or uncontrolled asthma were excluded.

Table 4. Inclusion and exclusion criteria

Inclusion	Exclusion
1. Children aged 1-5 years	1. Children with no primary teeth erupted
2. Registered in QUN health center	2. Systemic disease
3. Resided in Qatar	3. Drug (FV) allergy
4. Has at least one primary tooth erupted	4. Uncontrolled asthma
5. At moderate to high risk of dental caries as per the risk assessment	

### **3.5 Sampling Method and sample size**

#### **3.5.1 Sampling method**

Only non-probability sampling techniques were used in this study, as all practicing pediatricians and nurses and eligible children with vaccination appointments were invited to participate. Furthermore, convenience sampling was employed as all participants were chosen based on their availability. Such sampling technique is considered acceptable in such types of exploratory research, as the aim is to develop an initial understanding of a small population rather than testing a hypothesis.

#### **3.5.2 Sample size**

A formal sample size calculation was not required for this feasibility study, and we aimed to recruit 50 participants. The target size of 50 participants is in keeping with the reported median sample size of 49 participants for feasibility studies identified in an

audit of 79 feasibility trials registered on the United Kingdom Clinical Research Network (UKCRN) database (156).

### **3.6 Procedure**

#### **3.6.1 Healthcare providers' training**

Due to the covid-19 crisis and issues related to the shortage of medical staff, annual and other leaves, and reallocation of staff on many occasions, it was not feasible to have only one-day training for all the participating medical providers (pediatricians and nurses). Thus, five training sessions were held based on the availability of the participating medical staff one hour earlier to their proposed duty in the well-baby clinic. The primary investigator (PI) (initials), a dentist, provided the training in all five sessions using the Beautiful Smile training module (Lift the Lip), based on Open Wide: Oral Health Training for Health Professionals (157). "Lift the Lip" is an approved PHCC workforce training module designed as a part of the Beautiful Smile project to provide an educational resource to enhance the role of PHCC physicians and nurses in the promotion of oral health. The training module is available on the PHCC intranet and accessible by all the staff. The PI developed a step-by-step protocol based on the available recommendations and guidelines (126, 158). The proposed protocol for FV application was explained, and practical training on FV administration was presented. The FV application process was explained in steps through an online learning video representing the FV application. The PI demonstrated the FV application on a model of primary teeth. In each session, the involved providers tried the FV application on the model by themselves. All involved pediatricians and nurses signed a consent form. The PI distributed the FV printed protocol (Appendix 2), the FV information sheets (Appendix 3), data collection sheets (Appendix 4), consent papers for the participating parents, and children's motivational stickers to all participating health care providers.

### **3.6.2 Recruitment and consent process**

We collected information from all participating pediatricians and nurses. The total number of registered pediatricians at QUN HC covering the Well-baby clinics is four, and 15 registered nurses were covering the clinic during the three months of study implementation. For children, predetermined eligibility criteria were applied to those with a prescheduled appointment at the Well-baby clinic within the three months of the study implementation whose parents agreed to participate in the study. The appointments at the well-baby clinic are booked through the receptionist as per the pediatrician's order for the child's next visit. The PI screened the appointment list of the well-baby clinics for those who were 1-5 years old. The screening process of the vaccination clinic schedule included the medical history of those 1-5 years old to check the eligibility as per the eligibility criteria, mainly the allergy status and if they have any history of uncontrolled asthma. The days screened were chosen randomly to have a variety of morning and evening well-baby clinics and include all pediatricians and nurses in the FV application. The PI called the parents of all eligible children two days prior to their proposed visit. The full study protocol was explained to those who replied and invited to participate in the risk assessment for their children during their already scheduled vaccination visit and to be a part of the study and receive FV if their child was at moderate to high risk to develop dental caries. Typically, the morning clinics operate for 7 hours while the evening ones work for 6 hours only with fewer appointments. The number of parents to be called was predetermined not to exceed eight children for the morning well-baby clinic and six for the evening one ( 14 per day for the two morning and evening clinics) to allow distributed recruitment of the 50 children over the study period and depending on the number of the other registered children in each clinic, in a way not to increase the burden on the well-baby clinic's

health care providers those days. The PI started calling based on the appointments order in the list until reaching the maximum of each clinic. A list of all agreed children's parents was given to the attending nurses and the pediatrician covering the well-baby clinic of that day. Participating children and parents were recruited and enrolled on the same day as the vaccination appointments. On the arrival of those children to their vaccination appointment, the routine workflow was followed with the addition of the risk assessment done by the assessment nurse to decide the risk to develop dental caries. Those who resided in Qatar, at least had one erupted primary tooth, were at moderate to high risk for dental caries as per the caries risk assessment, and with good general health were considered eligible and invited by the nurse to participate in the study. Parents of eligible children consented to participate in the study, taking into consideration the language barrier by offering printed copies of the main spoken languages (Arabic and English) and offering a translation when needed in other spoken languages through the language bank service available at QUN HC to ensure complete understanding of the consent. No further follow-up was required for any participant after the completion of data collection. Recruitment stopped once we reached our target size of 50 eligible children.

This recruitment process was performed following the ethical principles outlined in the Ministry of Public Health (MOPH) policies, regulations, and guidelines for research involving humans.

### **3.6.3 The Intervention**

The intervention was delivered to the participating children on the same day after recruitment. The two main components of the intervention were Caries Risk Assessment (CAT) and FV application.

#### **3.6.3.1 Caries Risk Assessment**

The well-baby visit for each child 1-5 years old started by registering the child's presence via the assigned receptionist. All these children were already called by the PI two days before their prescheduled appointment. The assessment nurse called the child with his parent for vital signs and general assessment. Then, the same nurse completed the Caries Risk Assessment (CAT) form by oral examination and parent questioning. The trained assessment nurse identified those eligible children and approached their parents to sign a consent form if they were willing to participate. The assessment nurse documented the time utilized for dental caries risk assessment in the log sheets. The time was measured using the nurse's mobile stopwatch.

#### **3.6.3.1.1 Caries risk assessment tool**

A dental caries risk assessment form (Appendix 5) was constructed using the AAPD Caries risk Assessment Tool (CAT), with eleven domains (37). These domains are easy to measure and based on nurses' already current practice of the oral examination provided in the Well-baby clinic as part of the Beautiful Smile program to detect those at risk for dental caries and refer them accordingly to the dental clinic for further management. The risk assessment tool includes questions on the mother's caries experience, the child's nutrition habits, exceptional health care needs, child's fluoride exposure (drinking fluoridated water, brushing the child's teeth using fluoridated toothpaste, or receiving topical fluoride treatment from any other health facility), regular dental check-ups, the child's caries experience, and plaque on the child's teeth surfaces (based on the oral examination performed by the trained nurse in the assessment room). Soft tissue assessment is critical, and the nurses were trained to cancel the FV application in case of oral mucosal or gingival ulceration.

All those children who undergo the caries risk assessment are already eligible

as per the inclusion and exclusion criteria illustrated in (Table 2). All children with any suspected dental or oral pathology were referred to the dental department at QUN health center for further consultation.

### **3.6.3.2 FV application**

The pediatrician in the well-baby clinic completed the general health assessment as usual for the participating children, adding oral health promotion messages and raising awareness of the importance of a healthy diet and FV to prevent dental caries. The FV information sheet was given to the parent and explained. After the pediatrician's approval, one of the vaccination nurses applied the FV to the participating child with the parent's help when needed. The other vaccination nurse recorded the time required for the FV application to be entirely administered as per the protocol they have been trained on. After that, the required vaccination was issued as per the child's age and immunization schedule. At the end of the visit, motivational stickers were given to the child. The parents were asked to fill out the parent questionnaire while waiting. They are routinely recommended to wait for 15 minutes after vaccination to recheck the child for any possible adverse events or allergies. The nurses were available whenever the parents asked for any clarification.

A trained vaccination nurse applied FV containing 2.26% sodium fluoride to all participating children. If the child was too young to sit up independently, the child was positioned in a knee-to-knee position for the FV application, with the parent/guardian helping hold them. The children's teeth were first cleaned using gauze, and approximately 0.25 ml 2.26% FV was applied with a small disposable brush onto all visible teeth surfaces. Priority was given to the maxillary primary anterior teeth, maxillary molars, mandibular primary molars, and finally, the mandibular anterior incisors. Any excess varnish on the children's soft tissues was removed with gauze. The

parent was instructed to ensure the child abstained from food or drinks for the following 30 minutes, not to eat rough food for the rest of the day, and not to brush until the next day (135).

Identification data for every child who received FV, date of the FV application, and time utilized to complete the application were all documented on the data collection sheet given to the participating nurses.

### 3.7 Outcomes Measures

Following Donabedian’s Structure Process Outcome (SPO) framework, we included three measures to operationalize the Outcome, including the *Acceptability*, *Implementation*, and *Practicality* of the FV intervention. In turn, the three measures were operationalized as presented in (table 5):

Table 5. Outcomes measures

Acceptability	Implementation	Practicality
1. Recruitment rate and intention to continue the use of FV (Log sheets/Parents’ questionnaire)	1. Number of correct FV applications (Log sheets)	1. Factors affecting ease or the difficulty of the FV application (Barriers and facilitators tool)
2. Parents’ satisfaction (Parents’ questionnaire/self-report )	2. Amount and type of resources needed (Log sheets)	2. Speed of FV application (Time recording)
3. Children’s reaction to the FV application (Note records/Parents’ Interviews)		3. Direct Cost Analysis (Cost Analysis Tool)
4. Health care providers’ satisfaction and perceived appropriateness (Barriers and facilitators tool)		

The data collection tools and their mapping to each measure are described in the

subsequent sections.

### 3.8 Data collection methods

We developed this study to determine if implementing the FV application to young children by trained health care providers during their regular vaccination visits in a primary care setting was feasible. Feasibility will be assessed following our adapted conceptual framework guided by three dimensions: acceptability, implementation, and practicality (Table 6).

To get relevant data for this feasibility study, both primary and secondary data collection approaches were used. Structured questionnaires, interviews, participants' observations, and documentary sources were used. The demographic data for participating children were extracted from their medical records and for parents and health care providers by self-reporting.

Table 6. Overview of Data Collection at Baseline and Three Months

	Description	Data source	Baseline	Month 3
Demographics of the participating child	Age, sex, nationality	CERNER	X	
Acceptability	*Recruitment rate (parents' acceptability)	*Percentage of consented parents out of those who were able to be contacted, responded to participate, and those who showed up and consented to participate (Logs of calls to parents, log sheets completed by the nurses)	X	
	*Parents Satisfaction	*Questionnaire/self-report through a phone interview	X	



	Description	Data source	Baseline	Month 3
	*Children's reactions to FV application	*Note records/phone interviews of randomly selected parents		X
	*Providers' satisfaction and Perceived appropriateness	*Barriers and facilitators (survey/interviews with selected providers)	X	X
Implementation	*Number of correct FV application	*Self-reported (Checklist filled by nurses)	X	
	*Amount and type of resources needed to implement the intervention.	*Log sheets documentation (Number of children who received the FV and the resources utilized for each application)	X	
Practicality	*Factors affecting ease or difficulty of implementation	*Barriers and facilitator tool	X	X
	*Time utilized (Assessment and FV application)	*Log sheets analysis (Documented time)	X	
	* Cost analysis (Per child per FV application)	*Cost Analysis Tool (to predict the cost)		X

### 3.8.1 Questionnaires

#### 3.8.1.1 Health Care Providers Questionnaire (Barriers and Facilitators survey)

We used a paper-based self-administered questionnaire to survey health care providers (Appendix 6). We used the Peters et al. barriers and facilitators tool as a structured questionnaire developed in English (159). It was used directly after providing the FV training and after completing the three months of the FV application program to assess the attitudes of the primary health care providers (pediatricians and nurses) toward FV application as an oral health promotion intervention in the well-baby clinic.

This instrument was developed primarily to measure barriers to and facilitators for improving patient care, specifically when implementing preventive health innovations, inserting the preventive intervention within each question. The “Fluoride Varnish” application was inserted into each question in this study. This instrument’s barriers and facilitators for change were divided into four categories and addressed using 27 queries. The four major categories were innovation characteristics, care provider characteristics, patient characteristics, and organizational, social, and political context. Some questions are phrased as positive statements (1-3 and 16) and others as negative (4-15, 17-27). The positive questions were recoded to identify potential barriers to the FV application. We omitted question 26 from the original tool concerning old age due to the focus of our study.

The 26 items of the survey were based on a 5-point Likert scale (1=strongly disagree, 2= disagree, 3= neutral, 4 = agree, 5= strongly agree). At the start of the study, the barriers and facilitators tools were distributed to all participating healthcare providers by hand in a sealed envelope together with a consent form and an information sheet summarizing the study aim and what they are required to do, and how they will be involved to assess their perceptions and attitudes toward FV application as an oral health promotion intervention and gauge their acceptability of providing FV in the Well-baby clinic. Participants were advised to read more about the study’s aim and their expected role as explained in the participant sheet before signing the consent and completing the survey. Completed pre- surveys were collected either on the same day of training and recruitment or 2 to 3 days later. Whereas the post-surveys were distributed by hand in a sealed envelope to 17 participating healthcare providers, the remaining two received it by email as one of them was on annual leave and one on maternity leave. Completed post-surveys were collected after the completion of the

study. Multiple contact attempts were needed to remind the participated providers and motivate them to fill out the post-survey. The surveys were coded with serial numbers specific to each participant. All data collected were stored in a password-protected laptop and accessed only by the responsible investigators to conserve confidentiality.

### **3.8.1.2 Parents' Questionnaires**

This study assessed the parent's knowledge, attitude, and practices towards oral health and FV using a structured questionnaire based on the PI's knowledge as a general dentist and surveys used in similar studies (45, 144). The questionnaire was composed of 30 close-ended questions that addressed the parents' and children's demographics, parental knowledge and awareness of oral health, oral hygiene practices, and perception of FV. The questionnaire was formulated in English (Appendix 7) before being translated into Arabic (Appendix 8) by the PI, whose primary language is Arabic.

The questionnaire covered four main areas. The demographic part comprises four items about the participant's relationship to the child, gender, age, and educational level. The second part consists of five questions that assessed the parental knowledge about dental caries as a disease, its predisposing factors, and possible determinants. The third part recorded the parental oral health-related practices, with seven items out of 14 directed about their children's related oral health. The last part of the questionnaire comprises seven questions that explored the parental attitude about fluoride and its role in preventing dental caries and their perception of the effectiveness of incorporating oral health promotion and FV application in the well-baby clinic. The oral health-related practices and parental perception of the FV are considered essential to identify any potential unintended consequences of the intervention and assess the parents' receptiveness to it. Thus, they are considered balancing measures in our adapted conceptual framework, which is mainly based on assessing the quality of change in the

structure, process, and outcome

### **3.8.2 Document Review**

Log sheets (Appendix 4) and checklists were reviewed to extract the needed data concerning the child demographics, names of the nurses who performed the risk assessment and FV application for each participating child, the time in minutes measured by the nurse's phone Stopwatch from the beginning to the end of the procedure, and the number of the correctly completed FV applications. The comments section of the log sheets was very informative. It included the nurses' comments for each FV application, comments related to the child's cooperativeness, feelings, and reactions during and post-application, and any other reason that makes it challenging to complete the full FV application for some participants.

### **3.8.3 Interviews**

The PI employed semi-structured interviews of randomly selected participating parents and a selected group of participating health care providers. Ten parents were chosen randomly, one parent from each day of implementing the FV. The PI called all of them and asked whether their child received the FV, their acceptance of performing FV intervention in subsequent well-baby visits, and their child's perception during and after the procedure. The children's acceptability of the procedure was measured by nurses' comments in the log sheets, their feedback through the interview, and parents reporting of the children's reactions and comments during and after the procedure completion. Five health care providers (Two pediatricians and three nurses) who participated in more than two days of FV application during the study time as per the log sheets documentation were interviewed after completing the study and completing their questionnaires. The PI employed semi-structured face-to-face interviews with the providers to identify any contextual factors that may affect their acceptance of FV

application in the well-baby setting and any recommendations they have.

#### **3.8.4 Cost Analysis Tool**

After modifying it, the CAT (Appendix 9) created by Engenderhealth was utilized to perform the cost analysis to decide the practicality of implementing or sustaining the FV application using the available resources. CAT is a simplified tool that involves site administration and service providers themselves in measuring the direct costs of providing the service. A direct cost was held to estimate the cost per FV application per child in Qatari Riyal (QR). The cost was compensating the nurses' time and materials used. The cost of the used supplies (FV kit, 2x2 gauze, gloves) was collected from an online search of the companies that PHCC has in its clinical practice. The time documented in the CAT was the average time needed to carry out the risk assessments and FV applications. Nurses' time costs were compensated based on the average total salaries (basic plus allowances). The participated nurses reported the salaries and double-checked with the head nurse at QUN HC.

#### **3.9 Statistical Analysis**

Excel Data Analysis Tool Pak was used to analyze quantitative data collected during the study. Descriptive statistics are used to examine the research question. Descriptions, tables, diagrams, and frequency tables presented our findings. Frequencies were used to summarize demographics and all other characteristics of the participant children, parents, and health care providers. Results informing the *Acceptability* of the FV application were reported using frequencies and percentages of parents' responses to the questions in the completed questionnaires. The healthcare providers' acceptability was reported using the means and a two-sample t-test for their responses to the pre- and post-surveys. The response to the barriers and facilitators survey (healthcare provider's survey) were coded as follows: (1=strongly disagree, 2=

disagree, 3= neutral, 4 = agree, 5= strongly agree), with the higher mean representing higher agreement for all the negative questions. Only there were four positive statements, recoded to identify the barriers. Furthermore, the number and percentage of the consented parents were reported to identify the recruitment rate. The number of correct FV applications was presented to identify the *Implementation* of the intervention. The practicality dimension of the feasibility was presented by reporting the mean  $\pm$  standard deviation of the time utilized for performing risk assessment and the FV application and the needed direct cost in Qatari Rials (QR) per child per one fluoride varnish application.

### **3.10 Ethical Considerations and Approvals**

#### **3.10.1 Informed Consent**

A participant information sheet was developed to inform the potential participants about the study's aim and the whole protocol. The parents' information forms (Appendix 10) were formulated in English and Arabic to inform them of all possible risks or benefits taking into consideration the language barrier that could affect the complete understanding of the consent by offering a translation in 5 spoken languages (Arabic, English, French, Indian, and Filipino) through the language bank that we have in Qatar University Health Center. Health care providers read the information forms (Appendices 11-12) and signed the participation consent directly after receiving the training. The assessment nurse obtained the consent form for all parents who agreed to participate, and they were informed that their participation in this study was voluntary. Participants' right to freedom from harm, discomfort, and exploitation was fully acknowledged and protected. The participants' potential risks and benefits were analyzed and fully disclosed to the participant in the consent form. After assessing the children's general health, FV was not provided to those who have a

medical history of systemic disease, history of drug allergies, or uncontrolled asthma. During the intervention's two principal components (assessments and FV application), participants were protected from any possible physical harm, loss of privacy, emotional distress, physical discomfort, and loss of time. The participants were informed that they were free to ask as many questions as they liked before, during, or after this research. Participating parents had the right to refuse to participate without compromising their children's health or access to the well-baby clinic or dental services. Any of the various participants were able to withdraw from the study at any time. Also, if a participant is uncomfortable during an interview or survey administration, he/she may stop at any time without penalty.

On the other hand, receiving the intervention had many possible benefits. The participants had access to potentially valuable preventive intervention, a better understanding of oral health knowledge and dental caries prevention, and advice and care for their children's oral health from trained clinical staff

### **3.10.2 Confidentiality and Data Management**

All participating children were assigned a unique study identifier to conserve confidentiality, used on all data collection forms and participants' initial data records. A trained research team member was assigned to undertake data entry into an electronic management system. Data was stored in password-protected computers accessed only by the PI and Co-PI. The study data will be stored for five years after completion of the study before being destroyed.

### **3.10.3 Ethical Approvals**

Ethical approval was obtained from the Institution Review Board of Qatar University (Reference number: QU-IRB 1525-E/21). PHCC Review Board approved the research with reference number PHCC/DCR/2020/09/106 (Appendix 13).

### **3.11 Timeline and resources**

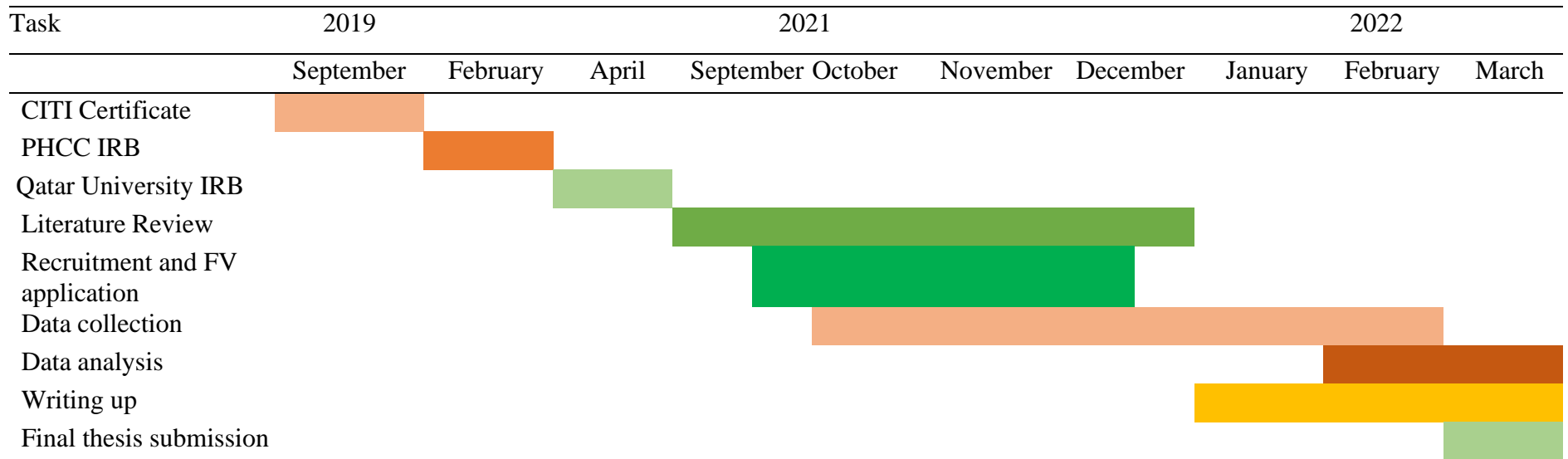
The following (Table 7) lists the study's activities and the corresponding months.

### **3.12 Budget**

This research was supported with a student grant QUST-2-CHS-2021-140 from the Qatar University Office of Research Support to cover the needed expenses.



Table 7. Study Timeline



## CHAPTER 4: RESULTS

The current study aimed to determine if implementing fluoride varnish application as a caries prevention intervention to children aged one to five years old by trained nurses during their regular vaccination visits was feasible in the setting of a primary health care clinic in Qatar.

This chapter will present the feasibility study findings following Donabedian's conceptual framework (Figure 1). In that model, the structure (healthcare professionals, material resources, and participating parents) lead to the process (healthcare provider training and parents' education about FV application, risk assessments, surveys) and then the outcome (in this study, feasibility). Further, the Donabedian framework has included the extension of a balancing measure to detect any potential unintended consequences of quality improvement early. Thus, trying to minimize it. The adapted model included the three leading indicators of Structure, Process, and Outcomes and extended to include the balancing measures to assess any potential consequences. The balancing measures are represented by the oral health-related practices for children and parents and the parent's perception concerning the FV application. While the oral health practices will assess the participating parents' and children's likely receptiveness to the intervention as an essential part of the "structure," the FV application-related perception will indicate any possible unintended consequences "outcome" in our utilized conceptual framework. The chapter first presents the participants' demographic data to understand the composition and representativeness of our participants. Followed by the oral health practices for

participating parents and children to assess their likely receptiveness to the FV intervention as having generally good dental habits would make the adoption of the intervention easier. It is well-known that social determinants influence ECC as other oral diseases, and parental oral health practices influenced by their knowledge and awareness significantly impact their children's oral health. The focus of the results is on acceptability, implementation, and practicality, which will be analyzed to assess the feasibility of providing the FV application in the well-baby clinic during regular vaccination visits.

#### **4.1 Demographic characteristics of all participants**

Nineteen healthcare providers (4 pediatricians and 15 nurses) participated in the study and responded to the Barriers and Facilitators pre-and post-survey. Eighteen of them are permanently assigned as pediatricians and nurses in Qatar University Health Center, whereas one (pediatrician) was on a temporary employment contract. Except for two male pediatricians, all other providers were female. Questionnaires were completed on the same day of training (pre-survey) and after completing the three-month study (post-survey) with no missing responses to any questions. Most providers were from the Philippines and India, with around half having 5-10 years of clinical experience and most (14) having 5-10 years of clinical experience in PHCC (Table 8).

Fifty children were approached over three months. There were 29 males and 21 females among the participating children. Nearly half of the children (28) were three to four years old, with the majority (45) being non-Qatari. Per the caries risk assessment held by the nurses before the FV application, 37 children were at high risk of developing dental caries, while the rest (13) were at moderate risk. The participating parents were mainly females, older than 36 years, and most had a college education or higher (Table 9).

Table 8. Demographic Characteristics of the Participating Health Care providers , n

Characteristics	Healthcare providers (n=19)	
	Pediatricians (n=4)	Nurses (n=15)
Gender		
Male	2	0
Female	2	15
Employment contract		
Permanent	3	15
Temporary	1	0
Nationality		
Arab	3	1
Non-Arab	1	14
Clinical experience (Years)		
Total-experience		
5-10	0	8
11-15	1	6
More than 15	3	1
PHCC experience		
Less than 5	1	4
5-10	3	11

Table 9. Demographic Characteristics of the Participating Parents/Children, n (%)

Characteristics (n=50)	Parents (n=50)	Children (n=50)
<b>Gender</b>		
Male	19 (38%)	29 (58%)
Female	31 (62%)	21 (42%)
<b>Age (Years)</b>		
<b>Children</b>		
1-2		6 (12%)
3-4		28 (56%)
5		16 (32%)
<b>Parents</b>		
20-35	20 (40%)	
≥ 36	30 (60%)	
<b>Nationality</b>		
Qatari	5 (10%)	5 (10%)
Non-Qatari	45 (90%)	45 (90%)
<b>Parents Educational Level</b>		
Less than high school	1 ( 2%)	
High school	5 (10%)	
College or above	44 (88%)	
<b>Children's dental caries risk</b>		
High		37 (74%)
Medium		13 (26%)

## 4.2 Oral Health-related practices of parents and children

Six questions investigated the parents' oral-health-related practices (Table 10). More than half of the parents (58%) brush their teeth twice daily, with the most commonly used method being toothbrush and paste only (72%). They are mostly replacing their toothbrushes every three months (60%). Most of them visited a dentist before (84%), most likely for dental treatment (76%) rather than regular dental checkups (44%). Seven

questions identified the oral-health-related practices of the participated children (Table 11). Exceeding half of the children (60%) brush their teeth only once daily, with 70% of them assisted by their parents, who rated the oral health care of their children as being “easy” for them (72%). The children’s toothbrushes were mainly replaced within three months (76%). Concerning visiting a dentist, only 42% reported seeing a dentist before, with only 18% having regular dental checkups, and 10% received dental treatment before.

Table 10. Parents Related Oral Health Practices

Parents’ Oral Health Practices	Frequency (%)
Frequency of teeth brushing each day	
Once, before going to bed at night	13 (26%)
2 times, after getting up and before going to bed at night	29 (58%)
3 times, after meals	8 (16%)
Methods of dental hygiene	
Toothbrush and paste	36 (72%)
Toothbrush and paste plus mouthwash	8 (16%)
Toothbrush and paste plus dental floss	6 (12%)
Toothbrush replacement	
≤ 3 months	30 (60%)
> 3 months	20 (40%)
Visited dentist before	
Yes	42 (84%)
No	8 (16%)
Visited dentist for regular dental check-up	
Yes	22 (44%)
No	28 (56%)
Visited dentist for dental treatment	
Yes	38 (76%)
No	12 (24%)

Table 11. Children's Related Oral Health Practices

Children's Oral Health Practices	Frequency (%)
Frequency of teeth brushing each day	
Once, before going to bed at night	30 (60%)
2 times, after getting up and before going to bed at night	16 (32%)
3 times, after meals	4 (8%)
Assisting the child in teeth brushing	
Yes	35 (70%)
No	15 (30%)
Parent's rating of child's oral health care	
Challenging	6 (12%)
Difficult	8 (16%)
Easy	36 (72%)
Toothbrush replacement	
≤ 3 months	38 (76%)
> 3 months	12 (24%)
Visited dentist before	
Yes	21 (42%)
No	29 (58%)
Visited dentist for a regular dental check-up	
Yes	9 (18%)
No	41 (82%)
Visited dentist for dental treatment	
Yes	5 (10%)
No	45 (90%)

## **4.3 Acceptability of FV Application**

### **4.3.1 Recruitment Rate**

The recruitment of our target sample size (50) was completed in 14 days (Table 12). A total of 467 registered vaccination appointments were screened for eligibility: children 1-5 years old with pre-booked vaccination appointments, residing in Qatar, registered in QUN HC, with a minimum of one primary tooth erupted, with no history of uncontrolled asthma or allergy to FV, and at moderate to high risk to dental caries as per the caries risk assessment. Among the 238 identified eligible children, parents of 143 were selected randomly from each clinic appointments schedule and called. We reached 130 of them, while the remaining could not be contacted due to the wrong registered phone number in their electronic medical records (2) or not responding to the call (11). Of the 130 parents who could be reached, 121 (93%) confirmed attending and participating. Six (6) of those who were contacted reported that they could not attend the scheduled appointments and indicated they would be rescheduling them, and three parents refused to participate in the study because they thought their child did not need the FV (2) or had regular dental check-ups in a private clinic (1).

Out of the 121 who had confirmed by telephone that they would attend, 117 (96.7%) came to their clinic appointments, representing 81.8% of the total contacted parents (117/143). Of those who attended, 78 (67%) were assessed for risk of dental caries, and 28 (36%) were found to be at low risk of developing dental caries and, as such, were not eligible to participate and receive the FV intervention. Thirty-nine (39) children were not assessed for their dental caries risks due to the following reasons: not feeling well at the appointment time and not assessed as per their parent's request (2), expired health card, and



parents rescheduled the vaccination appointments (3); came late to their appointment and could not be assessed due to time or staff shortage (7), and nurses forgetting to perform the risk assessment (27). All parents of the 50 eligible children (100%) consented to participate in the study. 47 (94%) children of the consented parents received the FV application correctly (Figure 2). On four days, no risk assessments were performed, and there were no enrollments due to busy schedules or simply because the nurses “forgot” to assess those children and enroll them if eligible (Figure 3).

Table 12: Children Recruitment's Related Data

Days	Number of Clinics	Total Appointments	Eligible	Called	Answered	Rescheduled Appointment	Refused	Attended	Completed Risk Assessment	Low Risk	Consented	Completed FV application
1	2	41	17	11	9	0	0	9	5	2	3	3
2	2	43	20	14	11	0	0	10	4	3	1	1
3	1	22	13	8	7	1	0	6	0	0	0	0
4	2	43	27	14	14	0	1	13	13	3	10	10
5	1	22	11	8	8	1	0	7	6	2	4	3
6	2	42	19	14	12	1	0	11	8	4	4	4
7	2	34	23	14	13	0	0	13	9	5	4	4
8	2	42	25	14	14	0	1	12	10	3	7	6
9	1	22	12	8	7	2	0	4	0	0	0	0
10	2	42	24	14	14	1	0	13	11	4	7	6
11	2	47	21	14	13	0	1	11	10	2	8	8
12	1	24	9	4	3	0	0	3	0	0	0	0
13	1	25	10	2	2	0	0	2	0	0	0	0
14	1	18	7	4	3	0	0	3	2	0	2	2
Total	22	467	238	143	130	6	3	117	78	28	50	47

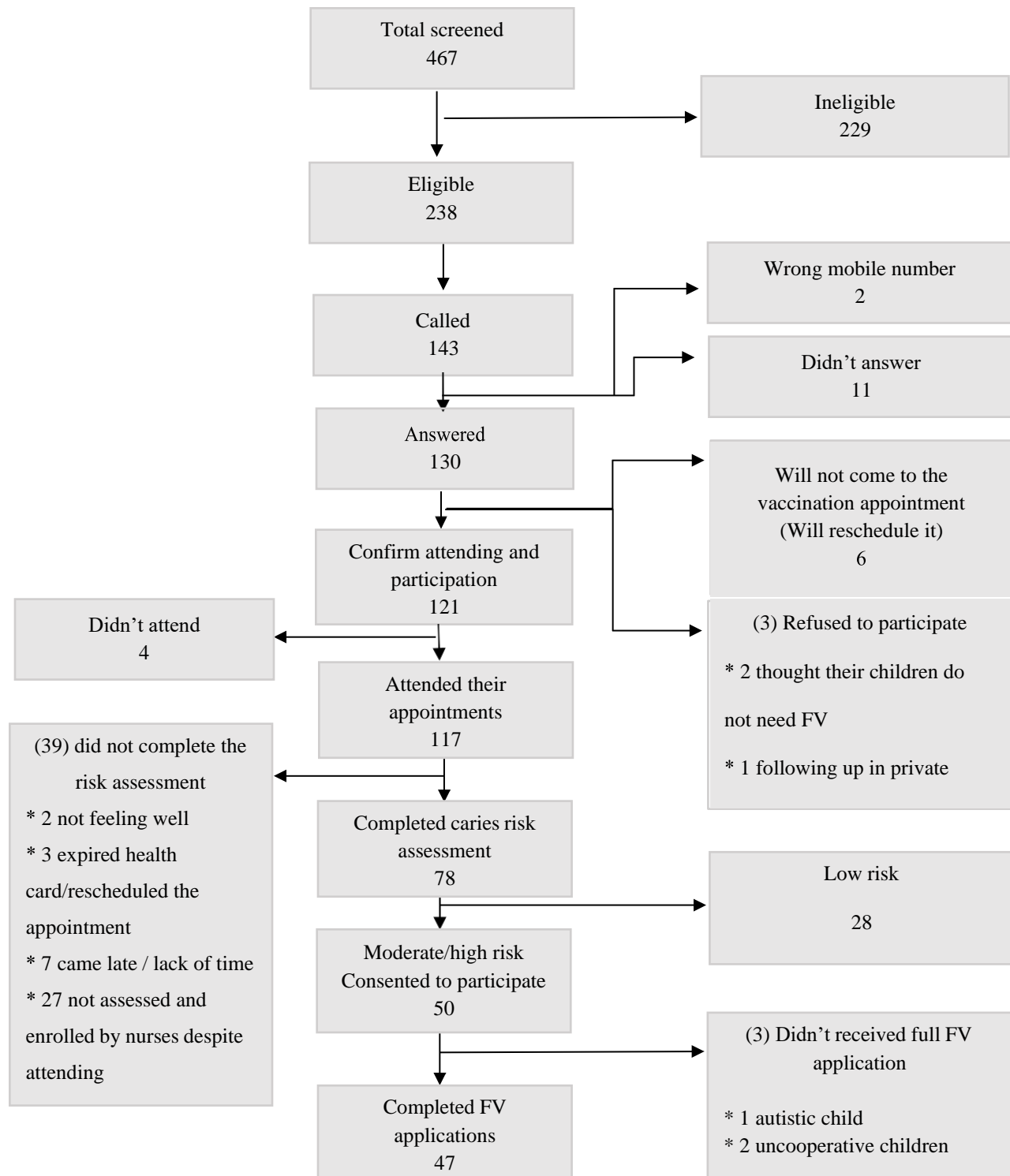


Figure 2. Study Participating Children’s Flow Chart

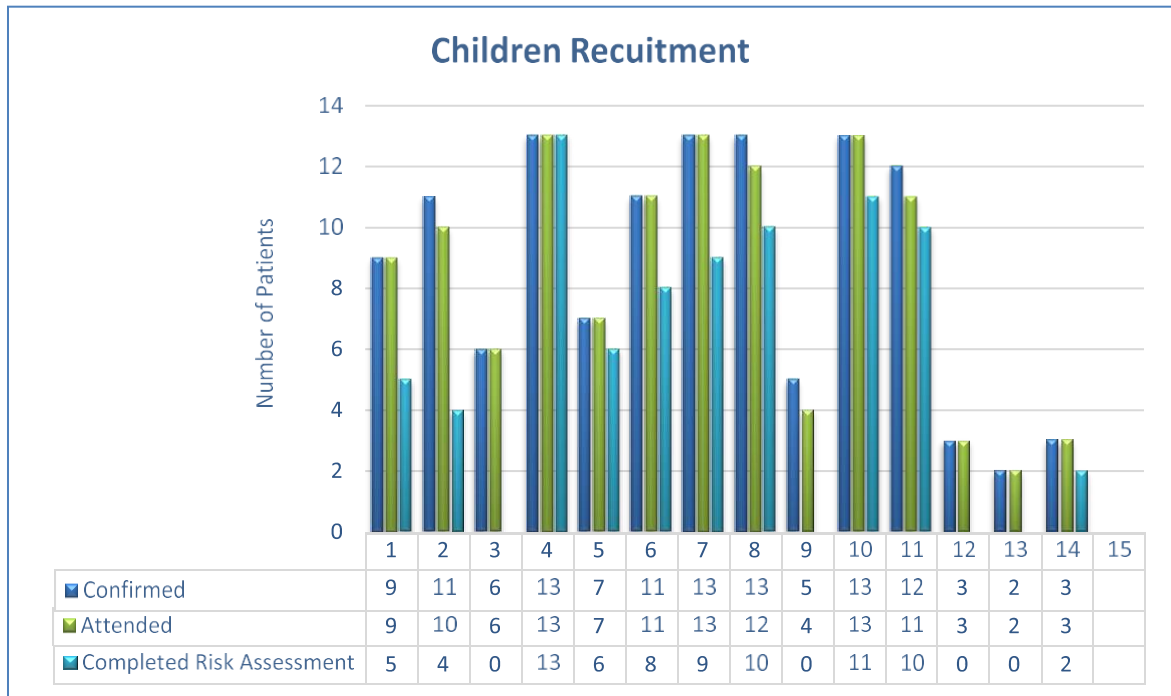


Figure 3: Children’s Recruitment Days

#### 4.3.2 Parents’ satisfaction and intention to continue the use of FV

Fifty parents completed the survey assessing their perception of the FV provided to their children in the well-baby clinic as a preventive intervention to improve their oral health and their intention to continue FV use. Figure 4 illustrates parents’ responses. The large majority of parents (94%) reported that their drinking water was not fluoridated, while the remaining three parents (6%) were not sure about the presence of fluoride in their drinking water. Only half (25) of the participating parents had previous knowledge about FV, with only 2 (4%) reporting previous FV applications for their children. Around 92% of the respondents were not worried about FV safety. All parents reported that they would allow a trained nurse to apply FV to their children, also accepting the well-baby clinic as a

setting for providing the preventive intervention. Parents also reported that they would not stop brushing their children’s teeth or bypassing their dental visits even after receiving the FV during the vaccination visits. All of them found that the FV application in the well-baby clinic was acceptable and helpful in improving their children’s oral health.

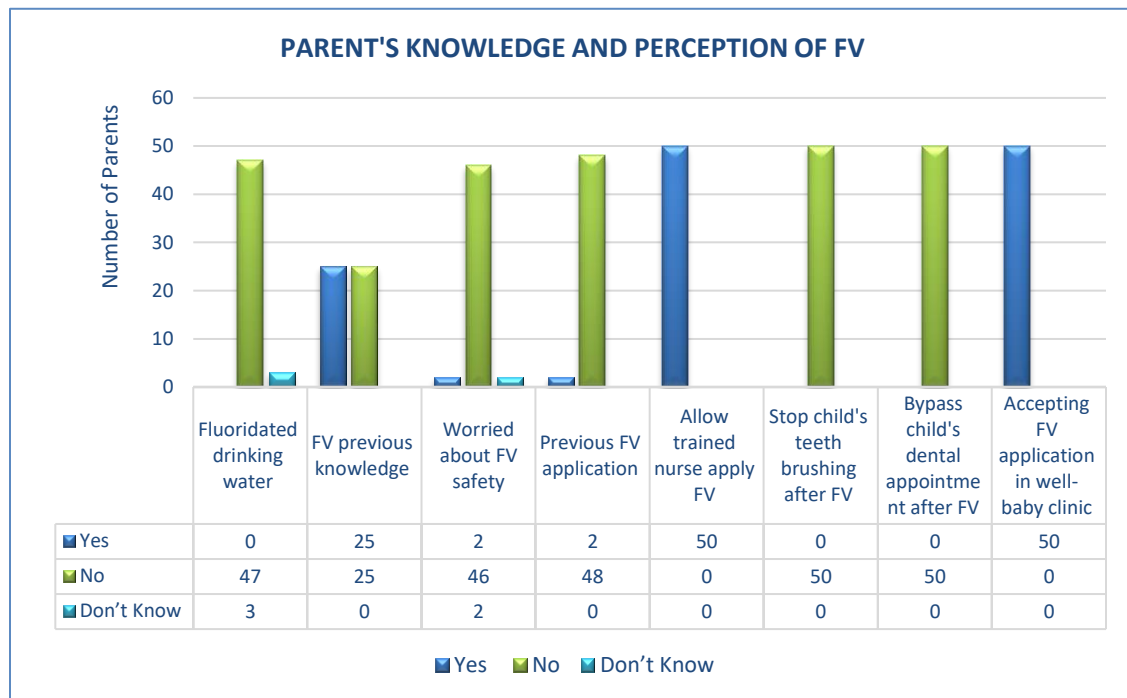


Figure 4. Parents’ Knowledge and Perception of Fluoride Varnish

Ten parents whose children received the FV were chosen using simple random sampling to represent participating parents and called by phone by the PI. Each recruitment day was represented by one of the participated parents. As data collection was performed daily from the well-baby clinic, the PI called the chosen parent one day after his/her

participation in the study. They were asked about their perception of the provided preventive application, their children's experience with the FV, and their acceptability of the well-baby clinic as a setting for providing oral health prevention using the FV. They found the setting "suitable" for providing oral health prevention and reported they were willing to provide it regularly for their children. Further, all the parents were happy for their children to receive oral assessment and dental prevention in the well-baby clinics.

#### Children's Reactions to the FV application

The children's acceptance of the FV application was assessed through the nurse's notes recording and self-report during the semi-structured interviews with randomly selected parents. The nurses documented any comments or specific reactions from the children during and after the applications. The parents were asked how their children behaved during the application and reported any discomfort later.

Based on the participating nurses' records, there were generally positive reactions by the participated children. Only three recruited children were uncooperative and did not accept the FV application procedure. One of them was autistic. Around six notes were about the feeling of stickiness after the application finished. After study completion, the semi-structured interviews with the nurses revealed that most of the children were cooperative. As most of the participated children were 3 to 5 years (88%), some children commented on the application, with most of the comments related to unpleasant taste and "gluey" sensation. In the younger children (12%), the most reported comment was linked to the level of cooperativeness rather than feelings and reactions to the FV application. Two documented comments were regarding children who did not like to stop eating, drinking, and rinsing their mouths for 30 minutes after the application.

In the phone semi-structured interviews held with ten of the participating parents, two parents reported that their kids were not satisfied with the FV, and they felt discomfort for a few minutes after the application because of the stickiness. One parent said his child did not like FV's taste; however, he was delighted because he had a motivational sticker. In contrast, most parents reported that their children behaved well during the visit and found the FV taste pleasant. Four parents reported that their children behaved better and were more cooperative in the well-baby clinic than seeing the dentist in the dental clinic.

#### **4.3.3 Health care providers' satisfaction and perceived appropriateness**

The providers' survey assessed the possible barriers and facilitators to implementing the FV application through 4 main domains; provider-related characteristics, context-related characteristics, the intervention (FV) related characteristics, and patient-related characteristics. The surveys assessed the providers' perceptions twice, before FV applications and after the study completion. All health care providers responded to both surveys. All pre-surveys were paper-based and received after completion from the participating providers by hand. The post-surveys were paper-based, except for two participants on leave who sent their responses by email.

The results are the pre-, and post-survey means related to each potential barrier, with the higher mean indicating higher agreement with the statement. Since the distribution of the mean difference is symmetrical and not majorly skewed ( $M=0.38$ ,  $MD= 0.40$ ,  $skewness= 0.22$ ), we conducted a two-samples t-test to identify the change in the providers' responses. The results of the pre-survey ( $M=2.7$ ,  $SD= 0.5$ ) and post-survey ( $M=2.3$ ,  $SD=0.5$ ) indicated that the provider's response changed after providing the intervention  $t(50) = 2.7$ ,  $p= 0.009$ .

#### 4.3.3.1 Barriers related to healthcare providers' characteristics

Eight questions in the barriers and facilitators survey assessed the perceived barriers related to the health care providers' characteristics (Table 13). The results of the pre-survey (M=2.9, SD= 0.4) and post-survey (M=2.3, SD=0.3), even though the results were not statistically significant due to the small sample size  $t(14) = 1.7, P = 0.10$ .

The most significant potential barriers were the need for more knowledge about the FV protocol before deciding to apply it and not being trained in giving preventive care. There was an increased positive response by health care providers to both barriers post-test compared to the pre-test. However, there was a mostly negative response regarding the statement "they wish to know more about the FV intervention," even post-test. The most significant difference in means between pre and post-test was presented by less agreement with the statement "it is difficult to provide preventive care because I am not trained in giving preventive care," implying that providers were more confident about giving preventive care following the application of the intervention.

Table 13. Barriers Related to Health Care Providers' Characteristics (Mean, Difference in means),  $p = 0.1$

Barriers	Pretest	Posttest	Difference
I did not thoroughly read nor remember FV protocol	2.9	2.2	0.7
I wish to know more about the FV protocol before I decide to apply it	4.3	3.7	0.6
I have problems changing my old routine	2.3	2.3	0.0
I think parts of the FV protocol are incorrect	2.5	1.9	0.6
I have general resistance to working according to protocols	2.3	2.1	0.2
The FV protocol does not fit into my ways of working at the practice	2.5	1.9	0.6



Barriers	Pretest	Posttest	Difference
It is difficult to provide preventive care because I am not trained in giving preventive care	3.3	2.3	1.0
It is difficult to provide preventive care because I have not been involved in setting up the preventive care	2.8	2.1	0.7

#### 4.3.3.2 Barriers Related to the Context Characteristics

Eight questions in the providers' survey identified the contextual barriers (Table 14). The results of the pre-survey (M=2.9, SD= 0.2) and post-survey (M=2.6, SD=0.3), even though the results were not statistically significant due to small sample size  $t(14) = 1.2, P = 0.26$ .

The most significant potential barriers were the shortage of supportive staff, the unavailability of the needed instruments, and physical space lacking. There was an increased positive response by health care providers to all barriers post-test compared to the pre-test. However, there was a mostly negative response regarding the supportive staff lacking and instruments unavailability, even post-test. Even though it was not statistically significant because of the small sample size, the most significant difference in means between pre and post-test was presented by less agreement with the physical space lacking as a potential barrier post-test compared to the providers' pre-test perception.

Table 14. Barriers Related to the Context Characteristics (Means, Difference in Means),  $p = 0.26$

Barriers	Pretest	Posttest	Difference
General practitioners do not cooperate in applying FV	2.5	2.2	0.3
Other pediatricians and nurses do not cooperate in applying the FV	2.6	2.1	0.5
Managements and directors do not cooperate in applying FV	2.5	2.2	0.3
Working according to this FV application program requires financial compensation	2.3	2.2	0.1
It is difficult to give FV if there is not enough supportive staff	3.5	3.4	0.1
It is difficult to give FV if instruments needed are not available	3.4	3.3	0.1
It is difficult to give FV because the timing of the FV application is awkward	2.7	2.3	0.4
It is difficult to give FV if physical space is lacking	3.4	2.8	0.6

#### 4.3.3.3 Barriers Related to the FV Characteristics

The providers' perceived barriers to the FV intervention characteristics were assessed using five questions (Table 15). The results of the pre-survey ( $M=2.3$ ,  $SD= 0.1$ ) and post-survey ( $M=2.0$ ,  $SD=0.1$ ), even though the results were not statistically significant due to small sample size  $t(8) = 1.9$ ,  $P = 0.10$ .

There was a mostly positive response by providers to all the intervention's related characteristics, with increased agreement post-test compared to the pre-test. The most significant difference in means between pre and post-test was presented by more agreement with the FV layout, which makes it handy.

Table 15. Barriers Related to the FV Characteristics (Means, Difference in Means),  $p = 0.1$

Barriers	Pretest	Posttest	Difference
FV intervention leaves enough room for me to make my conclusions	2.3	1.9	0.4
FV intervention leaves enough room to weigh the wishes of the patients	2.2	2.0	0.2
FV is a good starting point for my self-study	1.9	2.0	-0.1
Working on the FV application is too time-consuming	2.7	2.3	0.4
The layout of this FV makes it handy to use	2.5	2.0	0.5

#### 4.3.3.4 Barriers Related to the Patients' Characteristics

The remaining five questions in the barriers and facilitator survey assessed the obstacles related to the patients' characteristics (Table 16). The results of the pre-survey ( $M=2.6$ ,  $SD= 0.1$ ) and post-survey ( $M=2.4$ ,  $SD=0.2$ ), even though the results were not statistically significant, possibly due to the small sample size  $t(8) = 1.2$ ,  $P = 0.26$ .

The most significant potential barrier was providing the FV application for patients who rarely visit the practice. There was a positive response by health care providers to all other potential barriers with increased agreement post-test compared to pre-test to all of them. Even though it was not statistically significant, the most significant difference in means between pre and post-test was presented by less agreement to the difficulty of providing the FV to patients with low socioeconomic status and patients who seem healthy.

Table 16. Barriers Related to the Patient's Characteristics (Means, Difference in Means),  $p = 0.26$

Barriers	Pretest	Posttest	Difference
It is difficult to give FV to patients with a different cultural background	2.9	2.6	0.3
It is difficult to give FV to patients who seem healthy	2.4	1.9	0.5
It is difficult to give FV to patients with low socioeconomic status	2.4	1.9	0.5
It is difficult to give FV to patients who rarely visit the practice	3.1	2.9	0.2
Patients do not cooperate in applying FV	2.5	2.4	0.1

## **4.4 Implementation of the FV Application**

### **4.4.1 Correct FV application**

According to the log sheets, FV was applied fully and correctly to 47 (94%) children. With the remaining three children (6%), the FV was applied only for the front teeth, and the uncooperativeness of the children hindered the complete application of the intervention (Figure 5).

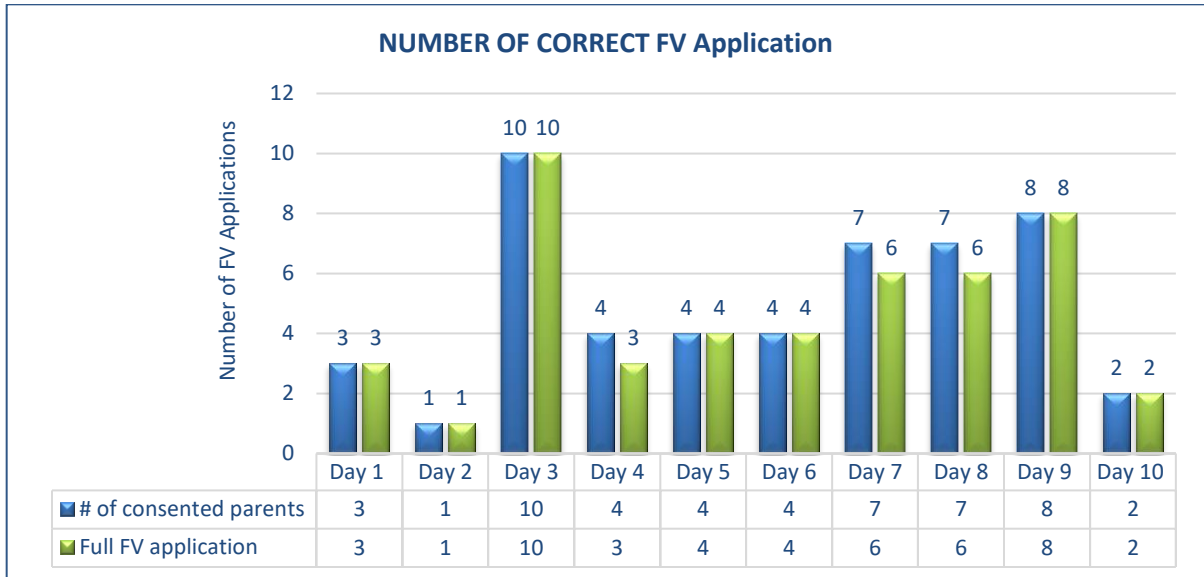


Figure 5. Number of Correct Fluoride Varnish (FV) Applications Per Day

#### 4.4.2 Amount of the used resources

The checklist completed by the participated nurses revealed using an extra two FV units during the study period. One of them was dry when they opened it and replaced it with another one, and the other unit fell during the application for one of the uncooperative children.

#### 4.5 Practicality of FV Application

##### 4.5.1 Speed of FV application (Time Utilized)

##### 4.5.1.1 Time Utilized for Caries Risk Assessment

Log sheets documentation of the timing revealed a mean of  $1.09 \pm 0.33$  minutes needed to complete the caries risk assessment for the participating children. The minimum documented time was 0.37 minutes, while the maximum was 1.58 minutes.

#### **4.5.1.2 Time Utilized for FV application**

The analysis of the log sheets documentation of the time needed for the FV application resulted in a mean of  $1.37 \pm 0.62$  minutes to complete one application, with a minimum documented time was 0.35 and a maximum of 3.45 minutes.

#### **4.5.2 Cost Analysis**

The cost Analysis Tool (CAT) that we used to estimate the direct cost needed to implement the FV application is illustrated in (Figure 6). The time required for risk assessment and the FV application added to the cost of the used supplies has been used to predict the direct price to implement one FV application per child at the well-baby clinic to be around 15 QR. The training time provided to the staff was not added to the cost as it was as per the staff availability, and the learning module is already available to all staff through the PHCC workforce training website for free.

<b>Activity</b>	<b>Responsible Staff</b>		<b>Time (min)</b>				
Caries Risk Assessment	Assessment Nurse		1.37				
Apply FV	Vaccination Nurse		1.09				
Total time spent (per procedure)			2.46				
<b>A Staff Position</b>	<b>B Annual Salary (QR)</b>	<b>C Number of working days/year</b>	<b>D Cost per day (QR)</b>	<b>E Number of working hr/day</b>	<b>F Number of working min/day</b>	<b>G Cost per min (QR)</b>	
Assessment nurse	114000	260	438.5	8	480	0.9	
Vaccination nurse	114000	260	438.5	8	480	0.9	
<b>Item</b>	<b>A Amount per unit</b>		<b>B Unit cost (QR)</b>		<b>C Amount used per client</b>		<b>D Cost per client (QR)</b>
Fluoride varnish	10		110		1		11.00
Gloves	100		87		2		1.70
2 X 2 gauze	100		7		2		0.14
Total cost of supplies (per procedure)							12.84
Total cost of staff time							2.25
<hr/>							
Total direct variable cost (per procedure)							<b>15.09</b>
Note. Adapted from EngenderHealth. (2001).							

Figure 6. Cost Analysis Tool for the FV Direct Cost Analysis

## CHAPTER 5: DISCUSSION

The effectiveness of fluoride in preventing and arresting dental caries has been confirmed in several studies (18, 32, 114, 129, 160, 161). The USPSTF suggests that primary care providers apply FV to the primary teeth of all infants and children starting at the age of first primary tooth eruption (39). Additionally, ADA recommends using FV for children younger than six years who are at risk of developing dental caries, consistent with the CDC, AAP, and the American Academy of Family Physicians (162-165). This study is the first to examine the feasibility of FV application for caries prevention in Qatar's primary health care setting. Studies have shown a high prevalence of dental caries among children in Qatar, especially at preschool age, reaching 89% (9). Studies have also found a high prevalence of untreated dental caries of primary dentition (9, 41, 166). At the same time, Qatar's network of primary health care clinics has grown in number and coverage (167), making it an ideal setting for implementing accessible, large-scale, population-based interventions. PHCC is Qatar's primary governmental healthcare provider. Well-baby clinics throughout PHCC health centers provide children of all Qatar residents vaccinations through the National Immunization Program for free. The child visit to the pediatrician in the well-baby clinic is an opportunity for comprehensive general health assessment, tracking the child's progress and developmental milestones, and discussing any health concerns with the caregivers. Healthcare providers at the well-baby clinics are key to the early detection of children at risk of developing dental caries by oral health assessment and promotion, allowing an opportunity of dealing with those children through effective preventive measures as early as possible. Several studies have indicated the acceptability, applicability, and



cost-effectiveness of providing FV application in primary care settings to reduce the considerable burden of ECC worldwide. However, studies are customized to the target populations, as they explore issues with local relevance (19, 34, 52, 53, 168-172).

The findings indicated that the FV application was acceptable to both parents and children. Recruitment was relatively easy, and the records of the PHCC allowed us to contact most eligible respondents, with only a few outdated contacts. We were able to reach 90.9% of the eligible children. Most parents were willing to attend, and those who said they would come did indeed adhere to their appointments largely. Of the contacted parents who answered, 93.1% confirmed participation, and 96.7% attended their appointments. Safety and appropriateness were not a concern to families, and most indicated they would allow the practice in the future and would not stop teeth brushing or visiting the dentist. 92% of the parents expressed no concerns about the FV's safety. In a few cases (12%), parents reported their children's feelings of stickiness and unpleasant flavor. Regarding implementation, nurses conducted caries risk assessments on all participating children and completed FV applications for the vast majority (94%). However, nurses only performed a caries risk assessment on 67% of the children who attended, with the most reported reason being "forgetting" to implement the intervention.

In terms of intervention practicality, the intervention was not time-consuming, and the cost was appropriate. The time required to complete the caries risk assessment was  $1.09 \pm 0.33$  minutes, whereas the average time for one FV application was  $1.37 \pm 0.62$  minutes. The direct cost of providing fluoride varnish to children in Qatar University Health Center's well-baby clinic was 15 QR per application. The most frequently perceived barriers to implementing the intervention were a lack of instruments, insufficient supportive staff, a lack of physical space, and providing the

FV to patients who rarely visit the health center.

### **5.1 FV application Acceptability**

The acceptability of the FV application in our study was high. The contact information at PHCC was generally accurate and up to date, as we were able to reach 90.9% of eligible parents. Once parents were reached, the majority confirmed participation. Our results suggested a positive perception of the FV by the participated parents. The positive response may be related to the parent's level of education, as our data reported 88% of parents having at least a college degree. More children were recruited in the evening clinics that primarily have older children (4 to 5), who are usually at higher risk of ECC. Their parents selected evening appointments to avoid missed days from school. Only three parents (2.3%) of those who answered our call refused to participate in the study because they thought their children did not need it or were already following up with their private dentist. Our participated children generally do not visit a dentist for regular checkups (82%) at this age. At the same time, their parents assist with their children's brushing (70%) and find the care easy (72%), indicating their receptiveness and easy adoption of the preventive intervention. The positive response may also indicate the high level of trust in the health care providers at the well-baby clinic. The parents' oral health-related practices were essential in identifying their receptiveness to the application. Our findings correlate with those reported by a quality improvement initiative that investigated the feasibility of implementing the FV applications and oral health education, screening, and referrals to the dental department during well-child visits for children aged 1-5 years old (173). The project was performed in San Francisco Bay at the pediatric clinics of eight Contra Costa Regional Medical Centers. The medical practice served around 100000 patients and provided 11947 well-child visits annually for children 1-5 years, with 95% of

children insured or eligible for free Medicaid services. The FV application rates for all children aged 1 to 5 years seen in their routine well-child appointments reached 97% during the project implementation.

On the other hand, our findings of acceptability among parents contradict results reported by a previous study with a low participation rate (56%) in a project aiming to provide FV based on dental caries risk assessment targeting a pediatric practice in a rural area in Vermont's state in the US (55). The pediatric practice where this project was implemented sees 600 patients per month on average. There were 92.6% Caucasians in the population, and 43% were covered by Vermont's State Children's Health Insurance Program. In that quality improvement project, the low participation rate was reported because parents did not believe FV was a healthful treatment (15%), were too busy staff, reported that children had already received FV at their private dentist, or the appointment setting made it difficult for the child to participate and receive FV. The population characteristics in the area can justify such a low recruitment rate studied, as it was a rural area with primarily poor residents.

This study's no-show rate was low, accounting for only 3.3%. Based on the literature, sending electronic text message reminders was reported to increase appointment adherence in pediatric care settings and many other medical settings (174-177). In PHCC, the well-baby clinic uses electronic messages for all families, reminding them of their children's appointments. Furthermore, the message is followed by a telephone call to reconfirm attendance or reschedule if needed. Such practices contribute to high appointments adherence in the well-baby clinic and indicate that FV application appointments would be similarly adhered to if implemented within those clinics.

## 5.2 FV Application Implementation

Despite the positive response from parents and high rate of recruitment, implementation rates were lower than expected. Nurses performed dental risk assessments on only 67% of those children who attended, with the most reported reason being “forgetting” to implement the intervention. Other reasons reported were mainly related to a few patients coming in late for their appointments, staff shortage due to staff redistribution, and the heavy workflow of the clinic on some days. Our finding related to the low implementation of caries risk assessment was not similar to those reported in a clinical practice article that illustrated the nurses’ role in the oral assessment and care for children attending the hospitals; they attributed low participation in performing oral assessment regularly to patients attending primary care to nursing staff’s attitudes towards oral health, need for further oral health education, training inadequacy, and gaps in the nurses’ knowledge and confidence in areas related to oral health (178). The reported findings were based on a national survey that investigated the practices related to oral health promotion amongst pediatricians and nurses in the United Kingdom. Our finding of attributing the low implementation rate to “forgetting” to perform the caries risk assessment informs the need for implementing a reminder to help nurses remember to perform the dental risk assessment for all children as part of their general assessment. The reminder could be a sort of automatic reminder added to the nurses’ Electronic Medical Records (EMR) system in the assessment section of each child file (179).

Only 50% of the parents reported having previous knowledge about the FV, highlighting a need for improving oral health knowledge of the parents attending well-baby clinics, especially about the fluoridation role in preventing dental caries. Almost all parents were not worried about FV safety (92%), with all of them will allow a well-trained nurse to provide the application to their children during their vaccination visits.

Moreover, they will not stop brushing their children's teeth or visiting the dentist, reflecting the absence of any unintended consequences resulting from the intervention adoption later on. Furthermore, interviewed parents reported the setting as "suitable" for providing oral health prevention to their children. The study results are consistent with a recent study assessing the acceptability of implementing FV in a medical primary care setting (180). Similar positive attitudes of parents toward FV were reported by a cross-sectional study that utilized an interview survey to assess the parents' preference of children younger than five years old regarding FV application by health care providers in Qatar (45). The data reflected a general acceptance and satisfaction of the children who received the FV application. Some reported uncooperativeness among those who were not generally cooperative in the whole visit, even for vaccination, and some feelings of stickiness and unpleasant flavor were reported for some children. Similar feelings and reactions were reported in another study (181). Children's uncooperativeness with one reported case belonging to an autistic child could emphasize the need to strengthen the training curriculum to train the nurses and primary care providers on how to deal with uncooperative children and children with cognitive or other challenges.

The barriers and facilitators pre- post-surveys revealed some potential challenges that impede providing the FV application in the well-baby clinic. The most significant possible barriers were instruments unavailability, insufficient supportive staff, lack of physical space, and providing the FV for those who rarely visit the health center. On the other hand, almost half of the participant providers were "neutral" in response to any financial compensation needed to provide the FV application. All of the mentioned barriers were perceived the same before and after providing the FV. These findings were the same as those identified by Dahlberg et al. in the recent feasibility study

performed to determine the acceptability and practicality of providing FV by health care providers to children under the age of 5 in a primary care setting (54).

Regarding instruments' unavailability, medical supplies shortages are a barrier to the health system's ability to provide quality health services. However, regarding the FV, it is not a high-tech intervention, with the only needed supplies being the FV kits, even though proper organizational management, leadership, and governance are required to develop and implement procurement and quality control plans. Insufficient supportive staff usually results from staff shortages or a high turnover rate. In the current study, the 19 participating health care providers were almost all permanently hired, with the vast majority having long years of clinical experience in PHCC, indicating low turnover and general satisfaction with the organization. Thus, staff shortages could be the leading cause of the perceived staff lacking, which could be attributed to fewer staff procurements or staff redistribution in other medical services, primarily the Covid-19 related programs. Physical space lacking could impede the delivery of medical services, whereas, for the FV application, no more than the same space for vaccination is needed. Thus, bigger consultation and vaccination rooms may increase staff satisfaction concerning physical space lacking in the well-baby clinic in general. Fewer patients' contact with the medical practice could affect their adoption of the medical intervention. However, the FV application is recommended only twice annually, increasing the patients' adherence and adoption.

The most significant difference between pre-and post-survey was presented with less agreement to the statement that being not trained enough in providing preventive care as a potential barrier to applying FV indicated that the training provided was mandatory for them to be more confident to apply the FV. Similar results were reported in other studies in which the healthcare providers attributed the low

participation in oral health promotion and FV application to the lack of experience in oral health interventions and being not trained enough to be involved (50, 173). According to the literature, interactive educational meetings such as attending workshops and participating in active discussions with lecturers are the most effective intervention for disseminating specific knowledge and thus changing clinical practice (182). Even though developing policies and training curricula and providing hands-on and didactic training by an experienced dental team could increase the confidence of primary care providers in participation in oral health assessment and preventive measures application.

Supportive staff and management are essential enablers of practice change, and support could include flexible decision making, motivation to change, and involvement in medical care quality improvement. Our results showed a significant difference between pre and post-survey, represented by less agreement to the statements related to the uncooperativeness of other doctors or nurses, managers, and directors in the study setting, identifying the cooperativeness of the staff and higher management as a potential facilitator for implementing the FV application. These findings contradict Dahlberg et al.'s findings in the feasibility study (54).

According to the current investigation findings, the FV application is implementable. The nurses completed 47 (94%) FV applications, and the uncooperativeness of the remaining three children hinders the intervention's full provision. The resources were used as planned except for the extra two FV units during the study period indicating a good sign of the intervention implementation in terms of the needed resources.

### **5.3 FV Application Practicality**

The practicality of the FV application was primarily based on the time required

to complete a full risk assessment and full fluoride application and the direct cost of offering the intervention per one application per eligible child. The documented data related to the time utilized for completing the dental caries risk assessment identified an average of  $1.09 \pm 0.33$  minutes, whereas  $1.37 \pm 0.62$  minutes for completing one FV application. Our study reporting of the time coincides with the average time provided by another study (54). No association was found between the child's age or the number of erupted teeth and the time needed to complete both procedures; the time was related more to the child's cooperativeness. Adding a minimum of three minutes to each patient visit in the well-baby clinic with a low no-show rate and almost full appointment schedule could put an extra burden on the health care providers and negatively affect the quality of patient care provided.

According to the cost analysis we performed, the direct cost for providing FV to children in the well-baby clinic in QUN HC was 15QR (4.1\$) per application, approaching the reported direct cost of 4.35\$ reported by Dahlberg et al. (54). Even though, in PHCC health centers, the services in the well-baby clinics are provided free of charge for all registered children. We considered the price of the 5% FV single-use tray of 0.4 ml through the internet search. Although, purchasing department at PHCC may have access to discounted pricing through their current medical supply company contract. Adding to that, the procedure takes less than three minutes and requires resources already available in practice. Thus, the cost of the single dose of the FV kits is the only additional cost to be added to the annual supply cost in the well-baby clinic. Also, the time required to complete risk assessment should already be a part of the physical examination in the well-baby clinic, following the protocol of the recommendations of the beautiful smile program present in all well-baby clinics. However, the nurses are not adherent to the program, and they are rarely examining the



children for their oral health. Usually, that is due to the increased number of appointments registered per clinic, with almost all of them attending to their visits and providing the extra dental caries risk assessment could cause the health care providers to fall behind the clinic schedule. Thus, calculating the needed assessment time and its related cost and adding it to the vaccination appointment could improve the oral health integration in the well-baby clinic.

FV is the most cost-effective approach compared to other professionally applied preventive interventions or dental treatment in the case of established decayed teeth. Compared to other preventive measures (for example, fissure sealants), FV does not necessitate a professional dental infrastructure in a community-based oral health prevention program (dental chair with illumination, fluid evacuation to maintain a dry field). Health care providers with little training can apply varnish. Although sealants are more effective at reducing caries than varnish, they are more expensive per patient. This higher cost is mainly due to labor differences: a dentist and dental assistant spend 30 minutes per sealant application compared to a few minutes per varnish application by a well-trained nurse (183). The cost is considered highly variable when treating dental caries, depending on cost drivers, the dental staff time, operative treatments, and patient referrals (184). The FV application was more cost-effective in a Canadian study of pre-school children than dental treatment (185). Over five years, the FV group avoided an average of 4.38 cavities per child, saving 823 Canadian Dollars (CAD) for restorative care per child, compared to 7.9 CAD per FV application.

Our adapted conceptual framework indicated a supportive and enabler “Structure” in terms of supportive staff and management, well-trained staff with low turnover rates, available supplies, well-designed facilities considering the need for bigger assessment and vaccination rooms, cooperative children at risk of developing

dental caries and rarely visiting the dentist for regular dental checkups, and cooperative parents with positive oral health-related practices that could strengthen their adoption of the intervention. Ensuring the availability of the staff is essential to facilitate the FV implementation. The “Process” part of our adapted model identified weaknesses related to the process inside the well-baby clinic represented by the low recruitment rate mainly due to nurses “forgetting” besides other reported potential causes such as time constraints and heavy workflow with some patients coming late to their appointments. The process needs to be strengthened through a robust training curriculum based on a deeper understanding of the healthcare providers’ attitudes and readiness to change. The “outcomes” component of the framework revealed possible implementation with a high percentage of correct FV applications, accessible and not time-consuming intervention with the appropriate cost. Our balancing measures extension identified parents with positive oral health-related practices suggesting better adoption of the intervention “process” and positive perception of the fluoride prevention that will not affect their children’s oral health-related practices after receiving the intervention minimizing potential unintended consequences “outcome.”

The development and testing of the intervention are not enough to allow widespread use of it, and intervention dissemination is a crucial part of the process. Previous models outlined the necessary stages of developing public health interventions (186, 187). However, these models assumed that effective interventions would be implemented in the field, but the models provide little information about how that transition from research to practice. The Interactive Systems Framework for Dissemination and Implementation (ISF) (188), which was developed to address the identified gap between research and practice, consists of three systems: the Prevention Synthesis and Translation System; the Prevention Support System; and the Prevention

Delivery System. Through its three systems, ISF allows for a better understanding of the requirements of other potential stakeholders and systems. As we have established the feasibility of implementing the FV intervention in one site, the ISF would be helpful to apply in the future for building implementation support.

#### **5.4 Strength and limitations**

Our study has several strengths, represented by being the first feasibility study assessing the acceptability, implementation, and practicality of providing FV applications as a preventive dental intervention for children during their regular vaccination visits in the well-baby clinics in a primary health care setting in Qatar. Another strength is using a well-established solid conceptual framework to assess the feasibility indicators within three main elements that collectively affect the quality of any quality change introduced in medical care. The framework gives us a thorough understanding of what is going on in the Structure, Process, and Outcomes, as three affect the resulting quality of change in medical care. Utilizing quantitative and qualitative analysis to inform the FV application feasibility in a broader range for a better understanding of the complex nature of the FV application in a setting such as the well-baby clinic strengthens the current study. Another essential strength is the high recruitment rate of the participants, with almost all those who were invited consented to participate. Also, recruitments of the children were almost random and on several days with a variety of staff and clinics timing.

This study also has some limitations. The study's findings are limited in their generalizability due to the small sample size, lack of a control group, and a single setting study. The percentage of participating Qatari children was minimal, constituting only 10% of the study participants could limit the implementation in some PHCC health centers which serve only Qataris. The children's acceptability was assessed based on

the parents' and nurses' reporting, introducing some reporting bias. One more limitation, the direct cost related to the time the nurses utilized was based on the average salaries of the nurses (basic salary plus the allowances). However, salaries may differ based on the years of clinical experience and promotion related to higher degrees or certificates or other various factors. Adding to that, we could not control every possible lifestyle factor, and the nature of the observational part of this study leaves the potential for residual confounding.

Finally, Covid-19 has had an undeniable impact on societies and, in particular, healthcare around the world. In Qatar, dedicated diagnostic and triage facilities for patients with suspected Covid-19 have been established in primary care settings. Furthermore, vaccine services were provided by all primary health care settings aimed the vaccine to be distributed to the entire population in the shortest amount of time. The overwhelming focus on Covid-19 has impacted healthcare provision for patients suffering from other diseases or attending the primary health care setting for non-Covid services. However, the well-baby clinic was the only service that continued with a total capacity without any interruption of the service during the covid-19 crisis. On the other hand, the implementation of the Covid-19 related services and health care providers being infected resulted in staff shortage and redistributions on many occasions. All of that affected the attitude and adherence of providers who provided the FV in the well-baby clinic in the current study.

### **5.5 Implications for Practice**

The findings of the current feasibility will be used to inform recommendations to the management of the PHCC regarding the integration of the FV application as a simple, cost-effective strategy for the primary prevention of dental caries in children less than five years old. Staff perceived and reported barriers should be considered and

addressed to effectively enhance the implementation of the FV application during the regular vaccination visits. The complete application of the intervention will be complex without considering the average time needed for each application. Based on our findings of the total time needed to complete a full dental caries risk assessment and FV application for each child, adding a minimum of three minutes to each child's appointment will increase staff cooperation and enhance their adherence. A source of computerized electronic reminders could help nurses remember doing the risk assessment for each child as a routine part of the regular general check-up. More motivation is needed to provide structured fluoride-related education and training as part of the PHCC workforce training plan with Continuing Professional Development (CPD) certificates to complete the educational modules successfully. Moreover, training of the medical care providers on dealing with special needs children or those with uncooperative behavior needs to be considered. As data showed a low level of parents' knowledge regarding fluoridation and its role, we suggest integrating oral health promotion in multiple primary health care settings and enhancing integrative multilevel collaboration.

## **5.6 Recommendations for future research**

In future research, we would like to expand the study to other clinics with different client profiles to ensure feasibility since this clinic serves a particular profile (mostly non-Qataris and a high level of education, also positively oriented toward dental health interventions). Moreover, using the ISF, we need to build implementation support by strengthening the training component and possibly adding other types of support that would increase providers' motivation to implement. This would require a deeper understanding of providers' attitudes and readiness for change. We will need to investigate professionals' knowledge, attitude, and readiness to change concerning oral

health to better understand the current situation and benefit in establishing the most effective way to educate, train, and engage primary health care providers in oral health promotion initiatives. Research also needs to address the sustainability of providing the intervention through an increased follow-up period of the participants, allowing FV application per each eligible child every six months. Further research looking at integrating oral health promotion initiatives in a primary care setting in Qatar will be worth implementing. Such strategies could deeply enrich oral health-related knowledge at multiple levels, including patients and their families, health care providers, and the community.

### **5.7 Conclusion**

This study showed that integrating the FV application as a simple, cost-effective strategy for the primary prevention of dental caries in children less than five years old during their regular vaccination visits in a primary health care setting in Qatar is feasible after addressing some gaps mainly related to the process inside the well-baby clinic. Increasing the appointment time by a minimum of 3 minutes, providing more structured mandatory oral health education and training to the providers, application of strategies to increase nurses' adherence through reminding them of the oral assessment for each child, and affording enough staff to be able to carry out the intervention effectively without compromising the patient's quality of medical care, all are shortcomings need to be recognized and addressed by the upper management before informing the FV application in the well-baby clinic for children at risk of having dental caries.

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APPENDIX 1



**The TIDieR (Template for Intervention Description and Replication) Checklist\*:**  
Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
<b>BRIEF NAME</b>			
1.	Provide the name or a phrase that describes the intervention.	36	
<b>WHY</b>			
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	4, 23	_____
<b>WHAT</b>			
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	34 Appendix 2 Appendix 3	<a href="https://www.mchionalhealth.org/OpenWide/">https://www.mchionalhealth.org/OpenWide/</a>

4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	36, 37, 38	_____
	<b>WHO PROVIDED</b>		—
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	32, 37, 38, 51	_____
	<b>HOW</b>		—
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	38, 39	_____
	<b>WHERE</b>		—
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	30, 31	_____
			—
	<b>WHEN and HOW MUCH</b>		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	32, 35, 36	_____
	<b>TAILORING</b>		—
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	N/A	_____
	<b>MODIFICATIONS</b>		—

10.†	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	_____
<b>HOW WELL</b>			
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	N/A	_____
12.†	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A	_____

## APPENDIX 2

### Fluoride Varnish Application Protocol

#### Materials used for each child.

- PPE
- 1 x micro brush applicator
- 1 x medium size patient bib
- 0.4ml FV dispensed onto a pad.
- 2 x gauze

#### Protocol for first fluoride varnish day (assessment nurse)

1. Patient Identification
  - Confirm the child's name.
  - Asthma history, if present, must be controlled.
  - Resin allergy history.  
(No known allergy to resin for a child eligible to receive varnish application).
2. If a child has received a fluoride varnish application within three months (as per parent answer), exclude the child from today's fluoride varnish application but proceed with risk assessment for future fluoride varnish days.
3. Complete risk assessment for the child. To be eligible for the study, the patient must be at risk of caries and have no signs of ulcerative gingivitis. Document clinical notes in the child notebook.
4. Handover to family physician for general health assessment and management.
5. Handover to vaccination nurse for fluoride varnish application and vaccination administration (after the physician permission).

#### Protocol for each fluoride varnish application (Vaccination Nurse)

1. Place a medium-sized bib on the table and prepare materials.
2. Confirm the child's name.
3. Check the child's eligibility as per the Caries risk assessment form signed by the assessment nurse.
4. Double Check asthma history: Asthma must be controlled.
5. Double Check resin allergy history; no known allergy to resin for a child to be eligible to receive varnish application.
6. Exclude the child from today's fluoride varnish application.
7. Explain the application of fluoride varnish to the child in a way suitable for the child's age.
8. Perform hand hygiene and put on personal protective equipment.
9. Examine teeth for visible plaque. If an abundance of plaque is present, clean the teeth using wet gauze.
10. Dry teeth using 1 piece of gauze.
11. Apply a thin film of fluoride varnish to occlusal and interproximal surfaces of posterior teeth and buccal surfaces of anterior maxillary teeth.
12. Wipe any residual fluoride varnish on soft tissue with a second piece of gauze.
13. Give child post-operative instructions. Issue child with a sticker
14. Place contaminated items in bin and don gloves
15. Put on new gloves and wipe down contaminated work surfaces.
16. Don personal protective equipment and wash hands using alcohol rub.
17. Record child has received fluoride varnish on the child notebook & on Cerner (in the child's medical file).

#### Post-operative instructions

- No food or drink for 30 minutes.
- Tooth brushing can usually resume tonight.



## APPENDIX 3

### Fluoride Varnish Application Protect Your Child's Teeth

#### Fluoride varnish can help prevent teeth decay

It helps strengthen the outer layer of the teeth & makes them more resistant to bacteria that cause decay



#### After the varnish is applied

Your child can drink water 30 minutes after application.

Your child can eat, but avoid chewy, crunchy, or hot foods. Instead, eat soft foods until next day.

Brush your child teeth the next morning. sometimes Fluoride Varnish looks yellow, this will brush off.



#### When should my child get fluoride varnish treatment?

When the first primary tooth erupts!

For the best cavity protection, a child should receive four to six treatments before the age of 3.



#### Who needs fluoride varnish?

Fluoride varnish is not necessary for all children.

It is recommended for children who do not have access to fluoridated community water and/or those who are at a higher risk of tooth decay



#### What happens during a fluoride varnish application?

Your child will be laid back onto the nurse's lap.



The teeth will be dried with a gauze.



The varnish will be painted on



## APPENDIX 4

Fluoride varnish application as an oral health intervention in well-baby clinic for children aged 1-5 years in Qatar university health center : a feasibility study.

### Data Collection Sheet for well-baby Clinic nurses to Record FV Applications

Date	Name and HC #	Age <small>(months)</small>	Sex <small>(M / F)</small>	Time <small>Needed for completing caries risk assessment. (minutes)</small>	Nurse name <small>(Who performed caries risk assessment)</small>	Time <small>needed to apply FV on all erupted primary teeth. (minutes)</small>	Nurse name <small>(Who applied the FV)</small>	FV applied. <small>(Yes / no)</small>	Any comments <small>e.g., absence of teeth / child cooperativeness</small>

## APPENDIX 5

Caries Risk Assessment				
Child Name:				
Birth Date:		Date:		
Age:		Initials:		
		Low Risk	Moderate Risk	High Risk
Risk Factors, <i>Social/Biological</i>		Check Yes when the factor applies		
<b>I.</b>	Mother/primary caregiver has active dental caries?			<input type="checkbox"/> Yes
<b>II.</b>	Child has frequent exposure (> 3 times/day) between meals-sugar-containing snacks or beverages per days?			<input type="checkbox"/> Yes
<b>III.</b>	Child uses bottle or non-spill cup containing natural or added sugar frequently between meals &/or at bedtime?			<input type="checkbox"/> Yes
<b>IV.</b>	<b>Child has special health care needs.</b> (physical; medical; or mental disabilities that prevent or limit performance)		<input type="checkbox"/> Yes	
Protective factors		Check Yes when the factor applies		
<b>V.</b>	Child receive optimally fluoridated drinking water or fluoride supplements	<input type="checkbox"/> Yes		
<b>VI.</b>	Child has teeth brushed daily with fluoride toothpaste?	<input type="checkbox"/> Yes		
<b>VII.</b>	Child receive topical fluoride from any health professional	<input type="checkbox"/> Yes		
<b>VIII.</b>	Child has regular dental care	<input type="checkbox"/> Yes		
Clinical findings		Check Yes when the factor applies		
<b>IX.</b>	Child has any visible cavities, fillings or missing teeth due to caries.			<input type="checkbox"/> Yes
<b>X.</b>	Child has non-cavitated carious lesion ( <i>white spot</i> ) or enamel defect			<input type="checkbox"/> Yes
<b>XI.</b>	Child has Visible plaque on teeth			<input type="checkbox"/> Yes

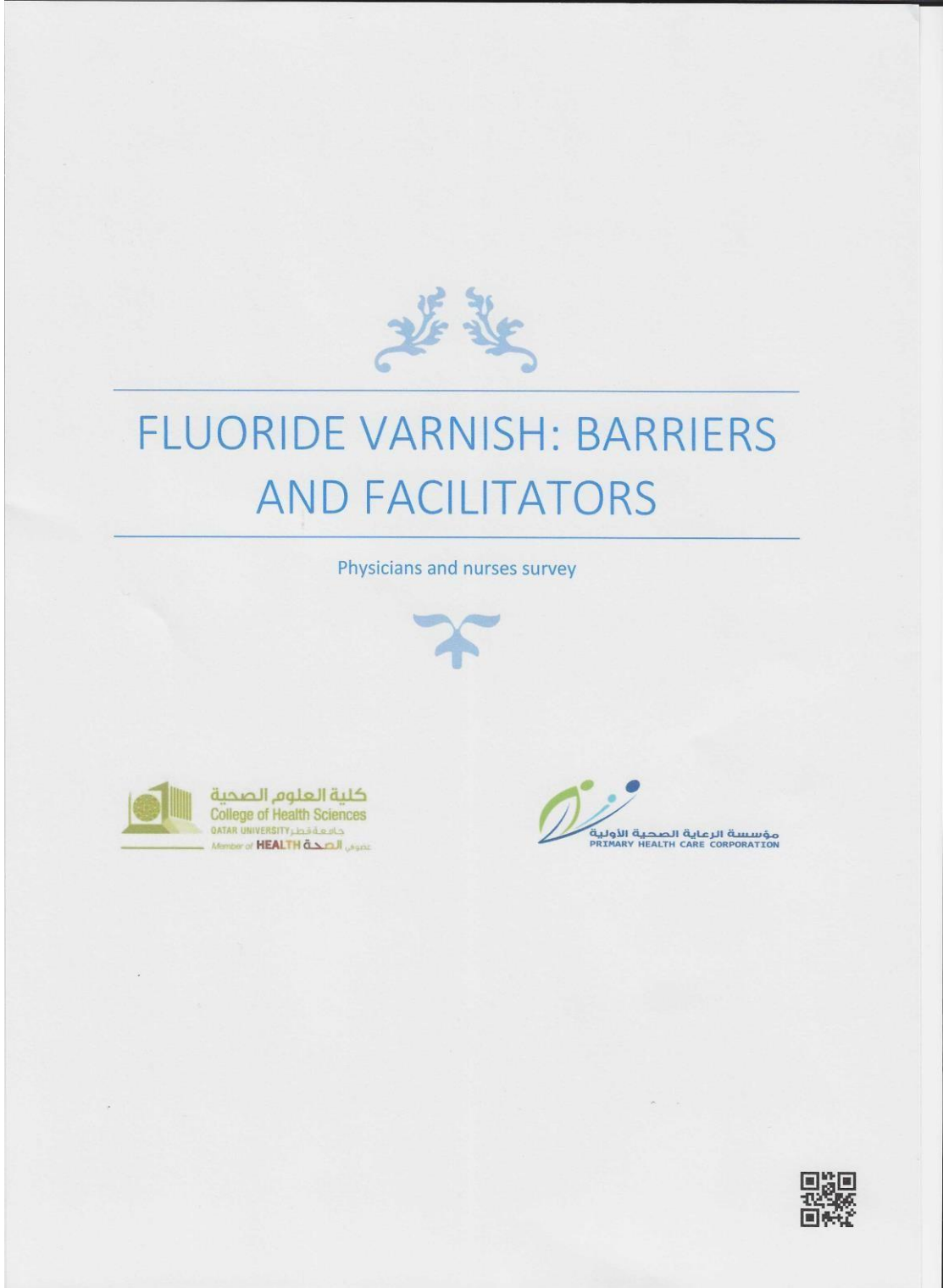
Overall assessment of dental caries risk       Low                       Moderate                       High

Gingival assessment: Absence of ulcerative gingivitis or stomatitis?       Yes                       No

Child eligible for fluoride varnish application       Yes

## APPENDIX 6

### Health Care Providers Survey



#### Informed consent

We invite you to take part in this survey which we believe will help us to gather useful information about implementing fluoride varnish application as an oral health intervention in primary care setting for children aged 1-5 years. We hope by taking part you will help us to gather the information we need. The primary objective of this self-administered survey is to assess your perception of the possible facilitators and barriers of physicians and nurses in PHCC well baby clinics applying fluoride varnish for children aged 1-5 years who are at risk of dental caries during their regular 6-months vaccination visits. This would help us for future health planning on population based oral health prevention among 1-5-year-old children in Qatar and improve the health system delivery of dental care.

You are invited to participate in this survey. The questionnaire takes approximately 5 minutes to be completed. Your anonymity is assured as will not be asked for your name or identifying information. All information will be treated with outmost confidentiality. Data will be stored in the researcher's laptop with password protected files and will be accessible only to the authorized investigators. Your participation is voluntary, and you may refuse to participate. you will receive no direct benefit nor risks from participating in this survey.

If you have any question about the survey you can contact

Dr. Nadeen Batta

Mobile number : 66091817

e-mail: [nbatta@phcc.gov.qa](mailto:nbatta@phcc.gov.qa)

- I have read the above information and I voluntarily agree to participate in the survey.
- I have read the above information and I refuse / disagree to participate in the survey.

**1. "Fluoride Varnish" application leaves enough room for me to make my own conclusions.**

strongly disagree     disagree     neutral     agree     strongly agree

**2. This 'Fluoride Varnish' leaves enough room to weigh the wishes of the patient**

strongly disagree     disagree     neutral     agree     strongly agree

**3. This 'Fluoride Varnish' is a good starting point for my self-study**

strongly disagree     disagree     neutral     agree     strongly agree

**4. I did not thoroughly read nor remember the 'Fluoride Varnish'**

strongly disagree     disagree     neutral     agree     strongly agree

**5. I wish to know more about the 'Fluoride Varnish' before I decide to apply it.**

strongly disagree     disagree     neutral     agree     strongly agree

**6. I have problems changing my old routines**

strongly disagree     disagree     neutral     agree     strongly agree

**7. I think parts of the 'Fluoride Varnish Application' are incorrect**

strongly disagree     disagree     neutral     agree     strongly agree

**8. I have a general resistance to working according to protocols**

strongly disagree     disagree     neutral     agree     strongly agree

**9. General practitioners do not cooperate in applying the 'Fluoride Varnish'**

strongly disagree     disagree     neutral     agree     strongly agree

**10. Other doctors or nurses do not cooperate in applying the 'Fluoride Varnish'**

strongly disagree     disagree     neutral     agree     strongly agree

**11. Managers/directors do not cooperate in applying 'Fluoride Varnish'**

strongly disagree     disagree     neutral     agree     strongly agree

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**12. Patients do not cooperate in applying the 'Fluoride Varnish'**

strongly disagree     disagree     neutral     agree     strongly agree

**13. Working to the 'Apply Fluoride Varnish' is too time-consuming**

strongly disagree     disagree     neutral     agree     strongly agree

**14. The 'Fluoride Varnish Application' does not fit into my ways of working at my practice**

strongly disagree     disagree     neutral     agree     strongly agree

**15. Working according to this Fluoride Varnish application program requires financial compensation.**

strongly disagree     disagree     neutral     agree     strongly agree

**16. The lay-out of this 'Fluoride Varnish' makes it handy for use**

strongly disagree     disagree     neutral     agree     strongly agree

**17. It is difficult to give Fluoride Varnish if there is not enough supportive staff**

strongly disagree     disagree     neutral     agree     strongly agree

**18. It is difficult to give Fluoride Varnish if instruments needed are not available**

strongly disagree     disagree     neutral     agree     strongly agree

**19. It is difficult to give Fluoride Varnish because the timing of the Fluoride Varnish application is awkward**

strongly disagree     disagree     neutral     agree     strongly agree

**20. It is difficult to give Fluoride Varnish if physical space is lacking (e.g. consulting room).**

strongly disagree     disagree     neutral     agree     strongly agree

**21. It is difficult to give Fluoride Varnish because I am not trained in giving preventive care**

strongly disagree     disagree     neutral     agree     strongly agree

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**22. It is difficult to give Fluoride Varnish because I have not been involved in setting up the preventive care**

strongly disagree     disagree     neutral     agree     strongly agree

**23. It is difficult to give Fluoride Varnish to patients with a different cultural background.**

strongly disagree     disagree     neutral     agree     strongly agree

**24. It is difficult to give Fluoride Varnish to patients who seem healthy**

strongly disagree     disagree     neutral     agree     strongly agree

**25. It is difficult to give Fluoride Varnish to patients with a low socioeconomic status**

strongly disagree     disagree     neutral     agree     strongly agree

**26. It is difficult to give Fluoride Varnish to patients rarely visiting the practice.**

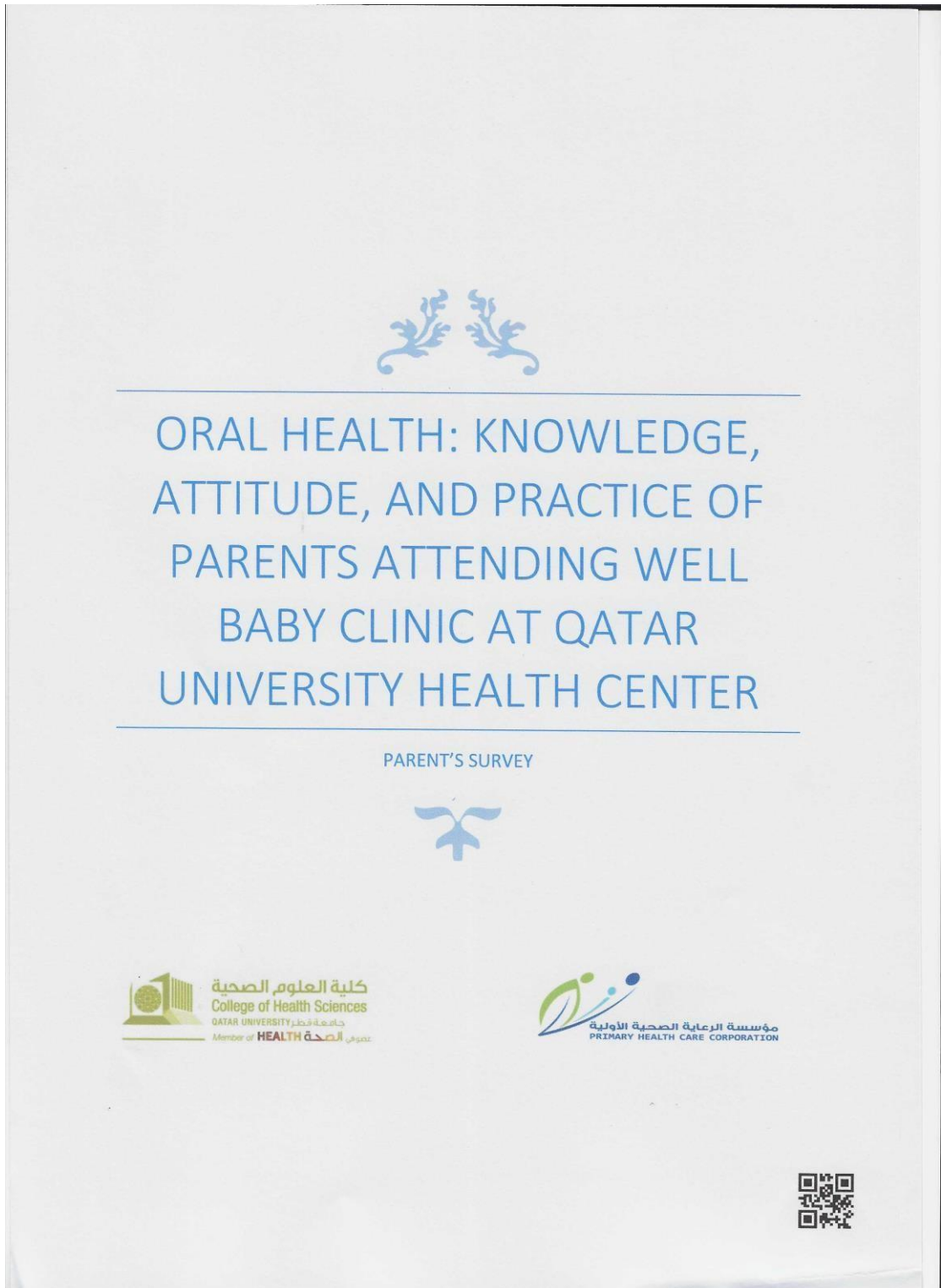
strongly disagree     disagree     neutral     agree     strongly agree





## APPENDIX 7

### Parents' Survey (English version)



### Informed consent

This research is carried out to know how you are coping with your child's oral health and how well you feel preventive fluoride varnish application to your eligible child is going. We will therefore be asking you some questions to help us understand how you feel. We hope to learn from the information you provide and to use it to improve children oral health in the future. As part of this research, this survey is carried out to assess oral health related knowledge, attitudes, and practices among parents attending at well-baby clinic at Qatar University Health Center. Dental caries is a serious health issue especially among preschooler children. This is a self-administered survey to help assess your level of knowledge about oral health and exploring your opinions and attitudes toward oral health and dental caries prevention. This would help us for future health planning on population based oral health prevention among 1–5-year-old children in Qatar and improve the health system delivery of dental care.

You are invited to participate in this self-administered survey. The questionnaire takes approximately 5 minutes to be completed. Your anonymity is assured as will not be asked for your name or your child's name or identifying information. All information will be treated with outmost confidentiality. Data will be stored in the researcher's laptop with password protected files and will be accessible only to the authorized investigators. Your participation is voluntary, and you may refuse to participate. you will receive no direct benefit nor risks from participating in this survey.

If you have any question about the survey you can contact

Dr. Nadeen Batta

Mobile number : 66091817

e-mail: [nbatta@phcc.gov.qa](mailto:nbatta@phcc.gov.qa)

- I have read the above information and I voluntarily agree to participate in the survey.
- I have read the above information and I refuse / disagree to participate in the survey.

**your relationship with the child?**

- Parents
- Relatives
- Sibling

**Gender**

- Male
- Female

**Your age**

- $\leq 20$  years
- 20 - 35 years
- $\geq 36$  years

**Your education level**

- Less than senior high school
- Senior high school
- College or above

**Is dental caries a disease?**

- yes
- No

**Do sweets cause dental caries?**

- Yes
- No

**Do soft drinks cause dental caries?**

- Yes
- No

**Can dental caries be transmitted from person to person?**

- Yes
- No
- Don't know

**Frequency of your tooth-brushing each day?**

- Once, before going to bed at night.
- 2 times, after getting up and before going bed at night
- 3 times, after meals



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**Methods of dental hygiene that you are using?**

- Toothbrush and paste
- Mouthwash
- Dental floss
- Toothbrush and paste plus mouthwash
- Toothbrush and paste plus dental floss

**Replacement of your toothbrush?**

- ≤ 3 months
- > 3 months / when bristles becomes frayed with use.

**Do you think that you are performing correct oral hygiene procedures?**

- Yes
- No
- Don't know

**Have you visited a dentist before?**

- Yes
- No

**Have you visited a dentist for a regular dental check-up?**

- Yes
- No

**Have you visited a dentist for dental treatment?**

- Yes
- No

**How often does your child brush his teeth each day?**

- Once, before going to bed at night.
- 2 times, after getting up and before going to bed at night
- 3 times, after meals

**Are you assisting your child with teeth brushing?**

- Yes
- No



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**How is your rating about oral health care for your child?**

- Difficult
- Easy
- Challenging
- Don't Know

**How often do you replace your child's toothbrush?**

- ≤ 3 months
- > 3 months / when bristles becomes frayed with use.

**Has the child ever gone to a dentist?**

- Yes
- No
- Don't Know

**Has the child ever visited a dentist for a regular dental check-up?**

- Yes
- No
- Don't Know

**Has the child ever visited a dentist for dental treatment?**

- Yes
- No
- Don't know

**Is your drinking water fluoridated?**

- Yes
- No
- Don't know

**Heard about fluoride varnish for dental caries prevention?**

- Yes
- No
- 

**Are you worried about fluoride varnish safety?**

- Yes
- No
- Don't know



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**Has your child ever utilize a fluoride varnish service?**

- Yes
- No
- Don't know

**would you allow a well-trained nurse to apply fluoride varnish for your child?**

- Yes
- No

**As your child receives fluoride varnish, would you stop brushing his teeth?**

- Yes
- No

**As your child received fluoride varnish, would you bypass the dentist appointments?**

- Yes
- No

**Do you think that providing oral health examination and fluoride varnish at the well-baby clinic is acceptable and helpful in improving your child's oral health?**

- Yes
- No
- Not sure

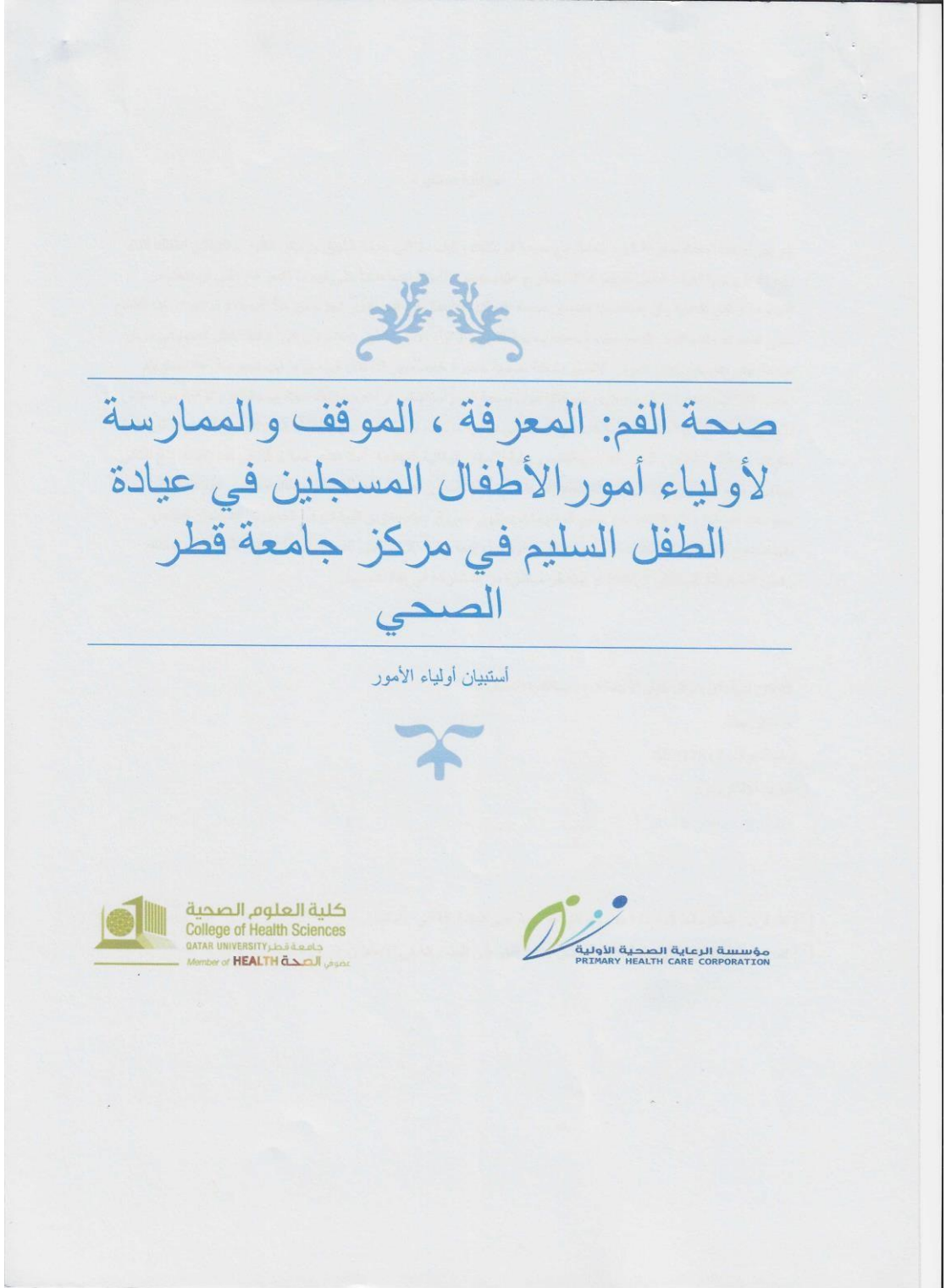


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## APPENDIX 8

### Parents' Survey (Arabic version)



### موافقة مستنيرة

يتم إجراء هذا البحث لمعرفة كيف تتعامل مع صحة فم طفلك وكيف ستلقى خدمة تطبيق ورنيش الفلوريد الوقائي لطفلك أثناء زيارته الروتينية لعيادة الطفل السليم. لذلك سنطرح عليك بعض الأسئلة لمساعدتنا على فهم ما تشعر به. نأمل أن نتعلم من المعلومات التي تقدمها وأن نستخدمها لتحسين صحة الفم لدى الأطفال في المستقبل. كجزء من هذا البحث ، تم إجراء هذا المسح لتقييم المعرفة والمواقف والممارسات المتعلقة بصحة الفم بين أولياء الأمور الذين يحضرون إلى عيادة الطفل السليم في مركز جامعة قطر الصحي. يعتبر تسوس الأسنان مشكلة صحية خطيرة خاصة بين الأطفال في سن ما قبل المدرسة. هذا مسح يتم إجراؤه ذاتياً للمساعدة في تقييم مستوى معرفتك حول صحة الفم واستكشاف آرائك ومواقفك تجاه صحة الفم والوقاية من تسوس الأسنان. سيساعدنا هذا في التخطيط الصحي المستقبلي للوقاية من تسوس الأسنان بين الأطفال الذين تتراوح أعمارهم بين 1-5 سنوات في قطر وتحسين النظام الصحي لتقديم رعاية الأسنان الوقائية المناسبة. أنت مدعو للمشاركة في هذا الاستطلاع الذاتي. يستغرق ملء الاستبيان حوالي 5 دقائق. نأكد لك على عدم الكشف عن هويتك حيث لن يُطلب منك اسمك أو اسم طفلك أو معلومات تعريفه. سيتم التعامل مع جميع المعلومات بمنتهى السرية. سيتم تخزين البيانات في الكمبيوتر المحمول الخاص بالباحث مع ملفات محمية بكلمة مرور ولن يكون الوصول إليها متاحاً إلا للباحثين المعتمدين. مشاركتك طوعية ، ويمكنك رفض المشاركة. لن نتلقى أي فائدة أو مخاطر مباشرة من المشاركة في هذا الاستبيان.

إذا كان لديك أي سؤال حول الاستطلاع ، يمكنك الاتصال به

د. نادين بطلة

رقم الجوال: 66091817

البريد الإلكتروني:

[nbatta@phcc.gov.qa](mailto:nbatta@phcc.gov.qa)

- لقد قرأت المعلومات الواردة أعلاه وأوافق طواعية على المشاركة في الاستبيان
- لقد قرأت المعلومات الواردة أعلاه وأرفض / لا أوافق على المشاركة في الاستبيان



علاقتك بالطفل؟

أحد الوالدين

أقارب

أخ / أخت

الجنس؟

ذكر

أنثى

عمرك؟

أقل من 20 عام

من 20 الى 35 عام

أكبر من 35 عام

المستوى التعليمي؟

أقل من المستوى الثانوي

مستوى ثانوي

مستوى جامعي أو أعلى

هل تسوس الأسنان مرض؟

نعم

لا

هل تسبب الحلويات تسوس الأسنان؟

نعم

لا

هل تسبب المشروبات الغازية تسوس الأسنان؟

نعم

لا

هل يمكن أن ينتقل تسوس الأسنان من شخص لآخر؟

نعم

لا

لا أعرف



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6053 0001

كم مرة تفرش أسنانك يومياً؟

- مرة واحدة قبل النوم ليلاً  
 مرتين ، بعد الاستيقاظ وقبل النوم ليلاً  
 ثلاث مرات ، بعد الوجبات

طرق نظافة الأسنان التي تستخدمها؟

- فرشاة أسنان ومعجون  
 غسول الفم  
 خيط تنظيف الأسنان  
 فرشاة أسنان ومعجون بالإضافة إلى غسول الفم  
 فرشاة أسنان ومعجون بالإضافة إلى خيط تنظيف الأسنان

استبدال فرشاة أسنانك؟

- كل 3 أشهر أو أقل  
 أكثر من 3 أشهر / عندما تتلف الشعيرات مع الاستعمال

هل تعتقد أنك تقوم بإجراءات صحة الفم الصحيحة؟

- نعم  
 لا  
 لا أعرف

هل زرت طبيب الأسنان من قبل؟

- نعم  
 لا

هل قمت بزيارة طبيب أسنان لإجراء فحص أسنان منتظم؟

- نعم  
 لا

هل قمت بزيارة طبيب أسنان لعلاج الأسنان؟

- نعم  
 لا



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6053 0002

كم مرة ينظف طفلك أسنانه كل يوم؟

- مرة واحدة قبل النوم ليلاً  
 مرتين ، بعد الاستيقاظ وقبل النوم ليلاً  
 ثلاث مرات ، بعد الوجبات

هل تساعد طفلك في تنظيف الأسنان؟

- نعم  
 لا

كيف هو تقييمك حول العناية بصحة الفم لطفلك؟

- صعب  
 سهل  
 لا أعرف

كم مرة تستبدل فرشاة أسنان طفلك؟

- كل 3 شهور أو أقل  
 أكثر من 3 شهور ، عندما تتلف الشعيرات من الإستخدام

هل ذهب الطفل من قبل إلى طبيب أسنان؟

- نعم  
 لا  
 لا أعرف

هل سبق للطفل أن زار طبيب أسنان لإجراء فحص أسنان منتظم؟

- نعم  
 لا  
 لا أعرف

هل سبق للطفل أن زار طبيب أسنان لعلاج الأسنان؟

- نعم  
 لا  
 لا أعرف



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6053 0003

هل مياه الشرب الخاصة بك مفلورة (تحتوي على فلورايد)؟

نعم

لا

لا أعرف

هل سمعت عن ورنيش الفلورايد للوقاية من تسوس الأسنان؟

نعم

لا

هل أنت قلق بشأن سلامة تطبيق ورنيش الفلورايد على الاسنان؟

نعم

لا

لا أعرف

هل سبق لطفلك الاستفادة من خدمة تطبيق ورنيش الفلورايد؟

نعم

لا

لا أعرف

هل تسمح لمرضة مدربة جيدًا بتطبيق ورنيش الفلورايد لطفلك؟

نعم

لا

عندما يتلقى طفلك ورنيش الفلورايد ، هل ستتوقف عن تنظيف أسنانه بالفرشاة؟

نعم

لا

عندما يتلقى طفلك ورنيش الفلورايد ، هل ستتجاهل مواعيد طبيب الأسنان الخاصة به؟

نعم

لا

هل تعتقد أن إجراء فحص صحة الفم وتطبيق الفلورايد في عيادة الطفل السليم مقبول ومفيد في تحسين صحة الفم لطفلك؟

نعم

لا

لست متأكد



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6053 0004


## APPENDIX 9

### Cost Analysis Tool


Activity	Responsible Staff		Time (min)			
Caries Risk Assessment	Assessment Nurse					
FV application	Vaccination nurse					
Total time spent (per procedure)						
A	B	C	D	E	F	G
Staff Position	Annual Salary (QR)	Number of working days/year	Cost per day (QR)	Number of working hr/day	Number of working min/day	Cost per min (QR)
Nurse						
Vaccination nurse						
Item	A	B	C	D		
	Amount in unit	Unit cost (QR)	Amount used per client	Cost per client (QR)		
Fluoride varnish						
Gloves						
2 X 2 gauze						
Total cost of supplies (per procedure)						
Total cost of staff time						
Total direct variable cost (per procedure)						
<b>Note. Adapted from EngenderHealth. (2001).</b>						

## APPENDIX 10

### Parents' Information Form and Consent



مؤسسة الرعاية الصحية الأولية  
PRIMARY HEALTH CARE CORPORATION



Primary Health Care Corporation  
Clinical Affairs  
**Research Section**  
researchsection@phcc.gov.qa

#### GENERIC SIGNED CONSENT FORM

#### موافقة مستبينة للمشاركة بدراسة بحث طبي

PARTICIPANT ID:  
DOB:  
GENDER:  
NATIONALITY:

رقم السجل:  
تاريخ الميلاد:  
الجنس (ذكر | أنثى):  
الجنسية:

#### A. General Information about Consent

You are free to ask as many questions as you like before, during or after you decide to give consent to participate in this research study. The information in this form is only meant to better inform you of all possible risks or benefits. Your participation in this study is voluntary. You do not have to take part and your refusal to participate will involve no penalty or loss of rights to which you are entitled. The investigator(s) may stop your participation in the study without your consent for reasons such as: it will be in your best interest; you do not follow the agreed study plan; or you experience a study-related adverse effect, discomfort, injury or other unexpected incident.

كشراك في هذا البحث العلمي لك مطلق الحرية في طرح أي سؤال أو استفسار عن هذا البحث وذلك قبل , أثناء إجراء أو بعد إكمال إجراء البحث إذا قررت إعطاء الموافقة على المشاركة في هذا البحث. الهدف الرئيسي من المعلومات الواردة في هذا النموذج هو أن نقدم لكم الشرح الواضح والمستفيض عن كل الأخطار والفوائد التي يمكن أن تتمتع عن إجراء هذا البحث. المشاركة في هذا البحث عمل طوعي خالص وبالتالي لكم مطلق الحرية بعدم المشاركة. قراركم بعدم المشاركة في هذا البحث العلمي لا يترتب عليه أي تبعات أو حرمان من حقوقكم المستحقة. أيضا يمكنكم الانسحاب وعدم مواصلة المشاركة في هذا البحث في أي وقت أو مرحلة دون أن يؤثر ذلك في حقوقكم أو فوائدهم المستحقة والمشرعة. لأعضاء فريق البحث العلمي الخاص بهذه الدراسة الحق في إيقاف أو إلغاء مشاركتكم في هذه الدراسة إذا رأوا مصلحة لكم في هذا الإيقاف أو الإلغاء أو في حالة عدم التزامكم بخطة البحث الموضوعية أو إذا تبين لهم ضرر أو إصابة نتيجة إجراء الدراسة وذلك دون أخذ موافقتكم

**Project Title:**

Fluoride varnish application as an oral health intervention for children aged 1-5 years in the well-baby clinic at Qatar University Health Center: a feasibility study

**عنوان المشروع:**

تطبيق الفلور ايد كنتدخل لصحة الفم في مراكز الرعاية الأولية للأطفال الذين تتراوح أعمارهم بين 1-5 سنوات في عيادة الطفل السليم في مركز جامعة قطر الصحي.

**Name of Principal Investigator**

Dr. Nadeen Abed Alraouf Batta

**اسم الباحث الرئيسي**

د . نادين عبد الرؤوف بطة

*Do not change the Arial font and color used in this template*

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## Location and phone numbers:

Qatar university health centre  
7 to 2 pm or 4 to 10 pm

Dr. Nadeen Batta  
Contact # 66091817  
At duty time, after hours, and on weekends

## موقع إجراء البحث وأرقام الهواتف

مركز جامعة قطر الصحي  
7 صباحاً إلى 2 بعد الظهر  
4 مساءً إلى 10 مساءً

د. نادين بطّة  
للتواصل في اوقات الدوام وخارجها  
موبايل: 66091817

## What is this research about?

We are interested in knowing how you are coping with your child's condition and how well you feel preventive fluoride varnish application to your eligible child is going. Therefore, we will be asking you some questions to help us understand how you feel. We hope to learn from the information you provide and to use it to improve children oral health in the future.

Our study is being carried out by a team of Pediatricians and nurses who work with children in our primary health care center mainly at well-baby clinic. In all, we hope to apply Fluoride varnish for 50 eligible children over 3 months. Each application will last about 3 to 5 minutes and will take place during your child routine vaccination appointment, and this may make your well-baby clinic visit a little longer than usual. You will also have an opportunity to ask questions and share your personal experience with the researchers.

## What is the Purpose of the research?

Our goal in carrying out this research is to find out how feasible to administer fluoride varnish as a dental caries preventive measure to children aged 1 to 5-year-old attending PHCC well-baby clinic for their regular vaccination visits.

## 1. مقدمة عن البحث الطبي

نحن مهتمون بمعرفة كيفية تعاملك مع حالة طفلك ومدى شعورك الجيد بتطبيق مادة الفلورايد الوقائي لطفلك. لذلك سنطرح عليك بعض الأسئلة لمساعدتنا على فهم ما تشعر به. نأمل أن نتعلم من المعلومات التي تقدمها وأن نستخدمها لتحسين صحة الفم لدى الأطفال في المستقبل.

يتم إجراء دراستنا بواسطة فريق من أخصائي طب الأطفال والممرضات الذين يعملون مع الأطفال في مركز الرعاية الصحية الأولية لدينا بشكل رئيسي في عيادة رعاية الأطفال. إجمالاً، نأمل أن نطبق الفلورايد لـ 50 طفلاً مؤهلاً على مدى 3 أشهر. سيتم تطبيق كل تطبيق حوالي 3 إلى 5 دقائق وسيتم إجراؤه خلال موعد التطعيم الروتيني لطفلك. هذا قد يجعل زيارتك لعيادة صحة الطفل أطول قليلاً من المعتاد. ستتاح لك أيضاً فرصة طرح الأسئلة ومشاركة تجربتك الشخصية مع الباحثين.

## 2. الغرض من إجراء دراسة البحث

هدفنا في إجراء هذا البحث هو معرفة مدى جدوى استخدام ورنيش الفلورايد كإجراء وقائي من تسوس الأسنان للأطفال الذين تتراوح أعمارهم بين 1 و 5 سنوات الذين يحضرون إلى عيادة رعاية الأطفال في مؤسسة الرعاية الصحية الأولية من أجل زيارات التطعيم المنتظمة.

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We hope that we will be able to identify any specific problems your child might have, to understand the common issues contributing to the high prevalence of early childhood dental caries in Qatar and especially those that affect how your child's oral health.

نأمل أن نكون قادرين على تحديد أي مشاكل محددة قد يعاني منها طفلك ، لفهم المشكلات الشائعة التي تساهم في انتشار تسوس الأسنان في مرحلة الطفولة المبكرة في قطر وخاصة تلك التي تؤثر على صحة فم طفلك.

### Why have you been invited to participate as a research subject?

We are inviting you to take part in this study because you are a parent of a child who is living in Qatar, registered and attend PHCC Clinic regularly, receiving his/her vaccination from the Well-Baby Clinic in QU health center, has at least one erupted primary tooth; at risk for dental caries as per the caries risk assessment, and your child oral health and quality of life are of importance to us.

### 3. إختيار المشاركين بالدراسة

نحن ندعوك للمشاركة في هذه الدراسة لألك والد لطفل يعيش في قطر ، مسجلاً في عيادة الرعاية الصحية الأولية وتحضر اليها بانتظام ، وتتلقى التطعيم من عيادة الطفل السليم في المركز الصحي بجامعة قطر ، لديه سن لبنية واحدة على الأقل ؛ معرض لخطر تسوس الأسنان، ولأن صحة فم طفلك ونوعية الحياة لهما أهمية بالنسبة لنا.

### How does this research differ from your routine care?

When you visit your child doctor or attend the clinic, you will still receive all your usual care, general health assessment, and the planned vaccination. What is different is that we will take 10 to 15 minutes more of your time to perform a caries risk assessment to your child and ask you some questions we have put together in a questionnaire. We will ask your permission to administer Fluoride Varnish to your child's teeth. We will ask you about your oral health knowledge and your satisfaction regarding the fluoride varnish application. You will not have to pay anything extra for this research. You will, however, be charged normally for your child routine consultation, vaccination, and prescribed medications, if any.

### 4. عرّف الفرق بين خدمة الرعاية الإعتيادية والأنشطة البحثية

عندما تزور طبيب طفلك أو تذهب إلى العيادة ، ستستمر في تلقي كل الرعاية المعتادة وتقييم الصحة العامة والتطعيم المخطط له. الأمر المختلف هو أننا سنأخذ المزيد من وقتك (10-15 دقيقة) لإجراء تقييم مخاطر التسوس لطفلك ، ونطرح عليك بعض الأسئلة التي قمنا بتجميعها معاً في الاستبيان. سوف نطلب إذنك لتطبيق ورنيش الفلورايد لأسنان طفلك. سوف نمالك عن معرفتك بصحة الفم ورضائك بشأن تطبيق ورنيش الفلورايد. لن تضطر إلى دفع أي شيء إضافي مقابل هذا البحث. ومع ذلك ، سيتم محاسبتك بشكل طبيعي على استشارة طفلك الروتينية والتطعيم والأدوية الموصوفة ، إن وجدت.

### What procedures will be carried out and why?

1. We will ask you to complete a questionnaire that includes personal questions about yourself, your child, and about your feelings towards the treatment that your child received
2. Caries risk assessment to be performed by the assessment nurse, and your permission to apply fluoride varnish to your child's teeth will be undertaken priority.

### 5. أشرح الإجراءات التي يتعين استخدامها في الدراسة

1. سوف نطلب منك إكمال استبيان يتضمن أسئلة شخصية عنك وعن طفلك وعن مشاركتك تجاه العلاج الذي تلقاه طفلك.
2. تقييم مخاطر التسوس الذي يجب أن تقوم به ممرضة التقييم ، وسيتم إجراء إذنك مسبقاً لتطبيق ورنيش الفلورايد على أسنان طفلك



### Are there any risks and discomforts involved?

This study involves asking you questions for some of which you may feel uncomfortable because they are personal (intrusive) and ask you to share your personal experiences and feelings. However please be assured that all information you provide will be treated sensitively and confidentially. It will not be shared with anyone outside of the research or be made available except for use in this research. Your child will not also be identified by name at any stage in the research.

Side-effects or complications of fluoride varnish use are rare. Studies show that fluoride varnish is safe for young children and the risk of dental fluorosis is minimal.

### What safety precautions are we taking in this research?

1. We will provide private space for you during the consultation.
2. Where we feel it is necessary and likely to help your child, we will discuss with you and refer him for beautiful smile dental clinic for further dental assessment and treatment if needed.
3. We will store all information you provide securely and will not make it available to anyone else.

### 6. وصف للمخاطر والإزعاج الناتجة عنه

تتضمن هذه الدراسة طرح أسئلة عليك قد تشعر بعدم الارتياح لبعض منها لأنها ذات طبيعة شخصية (تطفلية) وتطلب منك مشاركة تجاربك ومشاعرك الشخصية. ومع ذلك ، يُرجى التأكد من أن جميع المعلومات التي تقدمها ستعامل بحساسية وسرية تامة. لن يتم مشاركتها مع أي شخص خارج البحث أو إتاحتها إلا للاستخدام في هذا البحث. لن يتم أيضاً تحديد مطلقاً بالاسم في أي مرحلة من مراحل البحث.

الآثار الجانبية أو مضاعفات استخدام ورنيش الفلورايد نادرة. تشير الدراسات إلى أن ورنيش الفلورايد آمن للأطفال الصغار وأن خطر الإصابة بتصبغ الأسنان بالفلور ضئيل للغاية.

### 7. وصف إجراءات و احتياطات السلامة

1. سنوفر لك مساحة خاصة أثناء الاستشارة .
2. عندما نشعر أنه ضروري ومن المحتمل أن تساعد طفلك ، سنناقش معك ونحيله إلى عيادة أسنان الابتسامة الجميلة للأطفال لمزيد من تقييم الأسنان وعلاجها إن لزم الأمر.
3. سنخزن جميع المعلومات التي تقدمها بشكل آمن ولن نجعلها متاحة لأي شخص آخر

### What are the benefits of the study?

1. You will get the chance of dental caries risk assessment of your child, Fluoride varnish application to your child's teeth, and oral health counseling and education.
2. However, your child may not benefit directly from this study. Instead, the results can provide lessons for us to plan improvements in Oral Health and the quality of life of children living in Qatar.

### Are there alternative procedures or treatments apart from what is being used in this research?

Not Applicable

### If I am put on a new treatment as part of this research is there an option for me to remain on the research treatment after termination of the research?

Follow-up will be in the dental department as a regular dental patient who could regularly receive the preventive FV application every 6 months. All eligible children will be referred through the Cerner to the dental clinic through the beautiful smile follow up order.

### In case of Injury or if I wish to make an enquiry during the research, who do I contact?

In case you wish to report any discomfort, or make an inquiry, please contact :  
Name: Dr. Nadeen Batta  
Position: Dentist , Primary Investigator  
contact details: mobile: 66091817

### 8. وصف لفوائد المشاركة بالدراسة إن وجدت .

1. ستحصل على فرصة لتقييم مخاطر تسوس الأسنان لطفلك ، وتطبيق ورنيش الفلورايد على أسنان طفلك ، واستشارة وتثقيف صحة الفم.
2. ومع ذلك ، قد لا يستفيد طفلك مباشرة من هذه الدراسة. بدلاً من ذلك ، يمكن أن توفر لنا النتائج دروساً للتخطيط لتحسين صحة الفم ونوعية حياة الأطفال الذين يعيشون في قطر.

### 9. وصف الإجراءات أو العلاج البديل لهذه الدراسة

غير قابل للتطبيق

### 10. تفاصيل عن خيارات البقاء على العلاج المتبع أثناء فترة البحث حتى بعد انتهاء البحث

ستكون المتابعة في قسم الأسنان كمرضى أسنان منتظم يمكنه تلقي تطبيق الفلورايد بشكل دوري كل 6 أشهر. كل الأطفال المشاركين في البحث سيتم تحويلهم من خلال نظام التسجيل الإلكتروني إلى عيادة الابتسامة الجميلة في قسم الأسنان في مركز جامعة قطر .

### 11. تفاصيل عن الشخص الممكن الإتصال به في حالة وجود استفسار أو حدوث إصابة خلال فترة البحث.

في حالة رغبتك في الإبلاغ عن أي إزعاج أو إجراء استفسار ، يرجى الاتصال بـ:  
الاسم: د. نادين بطلة  
المنصب: طبيب أسنان ، الباحث الرئيسي  
تفاصيل الاتصال: جوال: 66091817

**Are there any financial or other compensation which might be provided to research participants?**

We appreciate your taking part in this study. Please be aware that we are not paying volunteers for taking part.

**12. تفاصيل عن التعويضات المالية أو غيرها المحتمل إعطائها للمشاركين في البحث**

نحن نقدر مشاركتك في هذه الدراسة. يرجى العلم أننا لا ندفع للمتطوعين مقابل المشاركة.

**How long will my participation in this research be?**

The routine vaccination visits to be utilized with adding to that time needed for assessing the child's caries risk, fluoride varnish application, and for filling the questionnaire by the parent. You are expected to have 10 to 15 minutes extra to your regular well-baby clinic visit. The participation will be only for once (the vaccination visit), after the study completion you may be selected randomly to participate in an interview with the research team to understand your feedback and suggestion fully if you are willing to participate. The follow up of the dental related needs will be continued in the beautiful smile dental clinic if needed.

**13. مدة إجراء البحث**

يتم الاستفادة من زيارات التطعيم الاعتيادية مع إضافة الوقت اللازم لتقييم تسوس أسنان الطفل ، وتطبيق ورنيش الفلورايد ، وملئ الأسنان من قبل الوالدين. من المتوقع أن يكون لديك 10 إلى 15 دقيقة إضافية لزيارتك الاعتيادية لعيادة رعاية الطفل.

ستكون المشاركة مرة واحدة فقط (زيارة التطعيم) ، بعد الانتهاء من الدراسة قد يتم اختيارك بشكل عشوائي للمشاركة في مقابلة مع فريق البحث لفهم ملاحظتك واقتراحك بشكل كامل إذا كنت على استعداد لتلك مشاركة. سيتم متابعة متابعة الاحتياجات المتعلقة بالأسنان في عيادة الابتسامة الجميلة لطب الأسنان إذا لزم الأمر.

**Names of the sponsors of the research:**

This study is supported by a student grant from the Qatar University Office of Research support to cover the needed expenses.

**14. أسماء مصادر تمويل البحث**

تم تمويل مصروفات هذا البحث بمنحة مالية من قسم البحث العلمي في جامعة قطر

**What assurance can you give me of my anonymity and confidentiality?**

Data will be stored in password-protected computers accessed only by the PI and Co-PI's. The study data will be stored for 5 years after completion of the study before being destroyed.

To conserve confidentiality, all participating children will be assigned a unique study identifier, used on all data collection forms and participant's initial data

**15. السرية حول النتائج، العينة المختبرية أو أي بيانات أخرى**

سيتم تخزين البيانات في أجهزة الكمبيوتر المحمية بكلمة مرور والتي يمكن الوصول إليها فقط من قبل الباحث الرئيسي و الباحث المشارك وسيتم تخزين بيانات الدراسة لمدة 5 سنوات بعد الانتهاء من الدراسة قبل إتلافها.

لحفاظ على السرية ، سيتم تخصيص معرف دراسة فريد لجميع الأطفال المشاركين ، والذي سيتم استخدامه في جميع نماذج جمع البيانات جنباً إلى جنب مع سجلات البيانات الأولية للمشارك. أن يكون الوصول إلى مجموعة البيانات النهائية متاحاً لأي شخص آخر غير

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records. No access to the final data set will be available to anyone other than the research team.

فريق البحث.

#### Non-coercive disclaimer:

you have volunteered of your own free will to take part in this research. Please do not feel at any time under any obligation or pressure to take part.

#### 16. تنويه بعدم القسرية

لقد تطوعت بمحض إرادتك للمشاركة في هذا البحث. من فضلك لا تشعر في أي وقت تحت أي التزام أو ضغوط للمشاركة.

#### After agreeing to participate, if I change my mind or do not wish to participate in some aspects of the research, do I have an option to withdraw from the study without penalty?

Yes, you are free to choose or refuse to participate in any (or all) aspects of the study. If you decide not to take part, and in case your child is on any treatment, this decision will not affect any part of your child treatment. We fully respect your right to either participate or choose not to participate in the research.

#### 17. إمكانية انسحاب المشارك من الدراسة أو البحث دون عقاب

نعم ، لك الحرية في اختيار أو رفض المشاركة في أي (أو كل) جوانب الدراسة في أي وقت. إذا قررت عدم المشاركة ، وفي حالة تلقي طفلك أي علاج ، فإن يؤثر هذا القرار على أي جزء من علاج طفلك. نحن نحترم حقك في المشاركة أو اختيار عدم المشاركة في البحث

#### Details about termination of the study:

you will be informed by the researchers when the study has come to an end or when your participation is no longer required. At the end of the study, we will explain to you how the results will be analyzed and whether we will be able to share your results with you. Please feel free to ask if you need to know more.

#### 18. تفاصيل عن إنهاء الدراسة أو البحث

سيتم إبلاغك من قبل الباحثين عند انتهاء الدراسة أو عندما لم تعد مشاركتك مطلوبة. في نهاية الدراسة ، سنشرح لك كيف سيتم تحليل النتائج وما إذا كنا سنتمكن من مشاركة نتائجك معك أم لا. لا تتردد في السؤال عما إذا كنت بحاجة إلى معرفة المزيد.

#### Details of the instances in which there might be incomplete disclosure of information:

All information about your child's oral health will be disclosed fully to you.

#### 19. تفاصيل عن الحالات التي قد يكون فيها إفشاء المعلومات غير مكتمل

سيتم الكشف عن جميع المعلومات المتعلقة بصحة فم طفلك بالكامل لك

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### Signed Consent for Study Participation

I \_\_\_\_\_ have read or have had read to me all the information contained in this form. Dr. *Nadeen Batta* or his/her authorized representative has explained to me what the study is about, why it is being done, the procedures involved and why I am being asked to volunteer to take part. The risks, discomforts, and possible benefits of this research study. Where a treatment is involved, alternative treatment choices have been explained to me. I have been assured of my right to ask questions related to this study or my participation in this study at any time and I am satisfied with the answers I have received to my questions. My rights as a research subject have been explained to me, and I voluntarily consent to participate in this research study. By signing this form, I willingly agree to participate in the research study described to me. I am told I will receive a copy of this signed consent form to keep. As long as the study is renewed as required by the IRB, my signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect my willingness to participate, I will be notified.

### الموافقة المستنيرة للمشاركة في البحث

\*الموافقة المستنيرة الخطية: عزيزي المشارك في هذا البحث قد قمت بقراءة أو قد قرىء عليك المرفق أعلاه. **د. نادين بطه** أو من ينوب عنه قد قام بإعطائك شرح للدراسة متضمنًا أسباب القيام بهذه الدراسة و الإجراءات المتضمنة في هذه الدراسة. كما تم إعطائك شرح عن الإزعاج و المخاطر و الفوائد المحتملة من وراء هذه الدراسة و إذا ما كان لك خيارات بديلة للعلاج. لك حق الاستفسار و طرح أي سؤال متعلق بهذه الدراسة أو مشاركتك فيها. تم القيام بتقديم شرح عن حقوقك كمشارك في هذه الدراسة و ان موافقتك على المشاركة في هذا البحث هي عمل تطوعي. بالتوقيع على هذه الورقة، إقرار منك بالموافقة على المشاركة في هذا البحث. سوف تعطى لك نسخة من هذا الإقرار بالموافقة توقيعك على هذه الوثيقة يعتبر صالح في حال تم تجديد هذا البحث طوال فترة الدراسة البحثية. سوف يتم إبلاغك في حال حصول أي تغيير في الدراسة مما قد يؤثر على موافقتك على المشاركة.

Participant / Parent(s)/ Guardian's Name	Signature & Date	التوقيع وتاريخه	إسم: المشارك ، الوالد (الوالدين) أو الوصي
Child's Name	Signature & Date		إسم الطفل المشارك
Witness Name	Signature & Date	التوقيع وتاريخه	إسم الشاهد
Principal Investigator's Name	Signature & Date	التوقيع وتاريخه	إسم الباحث الرئيسي
<u>For use of Research section only</u>		<u>إستخدام قسم الأبحاث الطبية فقط</u>	

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## APPENDIX 11

### Pediatricians' Information Form and Consent



Primary Health Care Corporation  
Clinical Affairs  
**Research Section**  
researchsection@phcc.gov.qa

#### PARTICIPANT INFORMATION SHEET

**Title of Project:**

Fluoride varnish application as an oral health intervention for children aged 1-5 years in the well-baby clinic at Qatar University Health Center: a feasibility study

Dear participant,

We invite you to participate in this research project, which we believe will help us gather useful information about implementing fluoride varnish application as an oral health intervention in primary care settings for children aged 1-5 years. You are being invited because you are PHCC Pediatrician, and we hope that you will help us gather the information we need by taking part. This letter has provided answers to questions that you might wish to ask about the research.

**What is this research and what is the Purpose of this research?**

The primary objective of this study is to test the feasibility of providing fluoride Varnish application as an oral preventive measure for children aged 1-5 years who are at risk of dental caries in the PHCC well-baby clinics during their regular vaccination visits.

**Why have you been invited to participate as a research subject?**

We invite you to participate as a pediatrician scheduled in the QU health center's well-baby clinic duty roster. Routine workflow within the well-baby clinic will be maintained, so the same physicians' and nurses' schedules will be utilized.

**How does this research differ from your routine care? [Optional]:**

The same workflow will be maintained. Oral health-related promotion and the role of the fluoride Varnish application in preventing dental caries will be added to the routine health promotion you are offering. You are finally permitting the trained vaccination nurse to apply the intervention.

**What procedures will be carried out and why?**

Provide oral-health promotion and highlight the benefits of Fluoride Varnish application in preventing dental caries in young children.

To permit the vaccination nurse to apply fluoride varnish to the eligible children. Those at moderate to high risk of developing dental caries as per the risk assessment performed by the assessment nurse using the Caries Risk Assessment Tool will be considered eligible. Permission will not be given to children who do not have any primary tooth erupted yet or have a medical history of systemic disease, history of drug allergies, or uncontrolled asthma.

September 2021

**Are there any risks and discomforts involved? What safety precautions are we taking in this research?**

Fluoride Varnish safety as an effective intervention for caries in young children is well supported by literature, with no possible risks associated with its application by physicians and dentists.

**What are the benefits of the study?**

Oral health knowledge is often low, mainly among young children with Early Childhood Caries (ECC) risk factors, and given the challenges for families at high dental caries risk to attend multiple health-related appointments, Integrating oral health into locations where young children already attend and in setting outside of the dental clinic is a promising strategy to fight the ECC epidemic in Qatar through regular contact with children and their guardians aiming to prevent them developing ECC alongside with the present strategy of "Beautiful Smile" program in PHCC well-baby clinics

**In case of Injury or if you wish to inquire about the research, who do you contact?**

Name: Dr. Nadeen Abed Alraouf Batta  
Email: nbatta@phcc.gov.qa  
Corp.# 55080  
Mobile # 66091817

**Is there any financial or other compensation provided to research participants?**

No financial compensation will be provided to the involved staff.

**How long will your participation in this research be?**

This study will be a three-month study until the recruitment of our prespecified Sample size of 50 children is completed. The routine duty roster of the well-baby clinic will be maintained.

**Will any of your information or samples collected be stored for future research or shared with others?**

Findings will be presented locally and internationally through conference meetings and published in peer-reviewed journals. A findings summary will be made available to participating families and primary health care centers. If providing FV oral health care intervention is feasible, this will help develop guidelines to facilitate implementing fluoride varnish application in PHCC well-baby clinics as a community-based intervention to prevent and reduce incidence of ECC among young children in young children Qatar.

September 2021



**Names of the sponsors of the research:**

This research was supported with a student grant QUST-2-CHS-2021-140 from the Qatar University Office of Research Support to cover the needed expenses.

**What assurance can we give you of your anonymity and confidentiality?**

To conserve confidentiality, all participating pediatricians will be assigned a unique study identifier, used on all data collection forms and participants' initial data records. A data manager will be assigned to undertake data entry. No access to the final data set will be available to anyone other than the research team.

**Non-coercive disclaimer:**

You can ask as many questions as you like before, during or after this research. You decide to give consent to participate in this research study. The information in this form is only meant to better inform you of all possible risks or benefits. Your participation in this study is voluntary, and you do not have to participate in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled.

**After agreeing to take part, if you change your mind or do not wish to participate in some aspects of the research, do you have an option to withdraw from the study without penalty?**

You may withdraw from this study without penalty or loss of rights, or other benefits to which you are entitled.

**Details of the instances in which there might be incomplete disclosure of information:**

All information related to the participant is to be disclosed fully

**Who do you contact if you need further information?**

You are free to ask as many questions as you like before, during or after this research by contacting us through:

Dr. Nadeen Batta  
Email: [nbatta@phcc.gov.qa](mailto:nbatta@phcc.gov.qa)  
Mobile: 66091817

We hope that you will accept to participate in our study. If you so decide to participate, we will ask you to read and sign the consent form for the project

Thank you.

Name:

Signature:


Role:

Date:

September 2021

## APPENDIX 12

### Nurse's Information Form and Consent



مؤسسة الرعاية الصحية الأولية  
PRIMARY HEALTH CARE CORPORATION

Primary Health Care Corporation  
Clinical Affairs  
**Research Section**  
researchsection@phcc.gov.qa

#### PARTICIPANT INFORMATION SHEET

**Title of Project:**

Fluoride varnish application as an oral health intervention in primary care setting for children aged 1-5 years in the well-baby clinic at Qatar University Health Center: a feasibility study

Dear Participant,

We invite you to take part in this research project which we believe will help us to gather useful information about implementing fluoride varnish application as an oral health intervention in the well-baby clinic at Qatar University Health Center for children aged 1-5 years. You are being invited because you are PHCC family medicine physician. We hope by taking part you will help us to gather the information we need. In this letter, we have provided answers to questions that you might wish to ask about the research.

**What is this research and what is the Purpose of this research?**

The primary objective of this study is to test the feasibility of providing fluoride varnish application as an oral preventive measure for children aged 1-5 years who are at risk of dental caries in the well-baby clinic at Qatar University Health Center during their regular vaccination visits.

**Why have you been invited to participate as a research subject?**

We are inviting you to participate as you are a certified nurse scheduled in QU health center well-baby clinic duty roster. Routine workflow within the well-baby clinic will be maintained, so the same physicians and nurses schedule will be utilized.

**How does this research differ from your routine care? [Optional]:**

The same workflow will be maintained, with adding assessing the eligibility of the children for topical fluoride varnish application based on valid caries risk assessment. Those at moderate to high caries risk will be considered eligible to receive Fluoride Varnish (FV) application.

**What procedures will be carried out and why?**

To perform caries risk assessment and/or apply fluoride varnish to the eligible children after the attended physician permission. Permission will not be given to children who do not have any primary tooth erupted yet or have medical history of systemic disease; history of drug allergies; or uncontrolled asthma.

1

**Are there any risks and discomforts involved? What safety precautions are we taking in this research?**

Fluoride Varnish safety as an effective intervention for caries in young children is well supported by literature with no possible risks were associated with its application by physicians and dentists.

**What are the benefits of the study?**

Oral health knowledge is often low, mainly among young children with Early Childhood Caries (ECC) risk factors, and given the challenges for families at high dental caries risk to attend multiple health related appointments, Integrating oral health into locations where young children already attend and in setting outside of the dental clinic is a promising strategy to fight the ECC epidemic in Qatar through regular contact with children and their guardians aiming to prevent them developing ECC alongside with the present strategy of "Beautiful Smile" program in PHCC well baby clinics.

**In case of Injury or if you wish to make an enquiry during the research, who do you contact?**

Name: Dr. Nadeen Abed Alraouf Batta  
Email: nbatta@phcc.gov.qa  
Corp.# 55080  
Mobile # 66091817

**Are there any financial or other compensation which might be provided to research participants?**

No financial compensation will be provided to involved staff. Certificates will be given to all staff after attending the 1-day training.

**How long will your participation in this research be?**

This study will be a 3 months study, until the recruitment of our prespecified Sample size of 50 children completed. The routine duty roster of the well-baby clinic will be maintained.

**Will any of your information or samples collected be stored for future research or shared with others?**

Findings will be presented locally and internationally through conference meetings and published in peer-reviewed journals. A findings summary will be made available to participating families and primary health care centers. If providing a FV oral health care intervention is shown to be feasible, this will help developing guidelines to facilitate implementing fluoride varnish application in PHCC well-baby clinics as a community-based intervention to prevent and reduce incidence of ECC among young children in Qatar.

**Names of the sponsors of the research:**

This research was supported with a student grant QUST-2-CHS-2021-140 from the Qatar University Office of Research Support to cover the needed expenses.

**What assurance can we give you of your anonymity and confidentiality?**

To conserve confidentiality, all participating healthcare providers will be assigned a unique study identifier, which will be used on all data collection forms together with participant's initial data records. A data manager will be assigned to undertake data entry. No access to the final data set will be available to anyone other than the research team.

**Non-coercive disclaimer:**

You are free to ask as many questions as you like before, during or after in this research, you decide to give consent to participate in this research study. The information in this form is only meant to better inform you of all possible risks or benefits. Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled.

**After agreeing to take part, if you change your mind or do not wish to take part in some aspects of the research, do you have an option to withdraw from the study without penalty?**

You may withdraw from this study at any time without penalty or loss of rights or other benefits to which you are entitled.

**Details of the instances in which there might be incomplete disclosure of information:**

All information related to the participant to be disclosed fully

**Who do you contact if you need further information?**

You are free to ask as many questions as you like before, during or after this research by contacting us through :

Dr. Nadeen Batta  
Email: [nbatta@phcc.gov.qa](mailto:nbatta@phcc.gov.qa)  
Mobile: 66091817

We hope that you will accept to participate in our study. If you so decided to participate, we will ask you to read and sign the consent form for the project

Thank you.

Name:

Signature:

Role:

Date:

September 2021

## APPENDIX 13

### PHCC Review Board Approval



#### Research Project Approval Notice

<b>Title of the Project</b>		Fluoride varnish application as an oral health intervention in Well-Baby Clinic for children aged 1-5 years in Qatar University health center : a feasibility study'	
<b>Reference No.</b>		PHCC/DCR/2020/09/106	<b>Date:</b> 15/02/2021
<b>LPI Information</b>	<b>Name</b>	Dr. Nadeen AbedAlraouf Ahmad Batta	
	<b>Department</b>	Qatar University Health Center	
	<b>Organization</b>	Primary Health Care Corporation	
	<b>Email</b>	nbatta@phcc.gov.qa	
	<b>Phone No.</b>	66091817	
<b>PHCC PI information</b> <i>(applicable where LPI is external to PHCC)</i>	<b>Name</b>		
	<b>Department</b>		
	<b>Organization</b>		
	<b>Email</b>		
	<b>Phone No.</b>		

Required Information Checklist	Yes	No	N/A
Research Proposal Submission Form signed and Completed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Investigator agreement Form Signed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other Ethics Committee Approval (Please specify) e.g. Qatar University	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Informed Consent Form Copy Provided	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sponsor	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Sponsor(s) name (if applicable)	None		
<b>List of PHCC health center/s included:</b> <i>(please tick the appropriate checkbox):</i> Qatar University Health Center			

Dear Dr. Nadeen Batta,

Having established that there are no material ethical issues relating to your request and having considered the logistical issues we have no objections to you carrying out this project. Therefore, the Departments of Clinical Affairs and Operations give **approval** for it to commence. Please see the accompanying letter which sets out the **specific terms and conditions** of this approval that must be adhered to in carrying out your data collection. We wish you every success in this endeavor.

Kind Regards,

*Hanan*

**Dr. Hanan Al Mujalli**  
Executive Director of Clinical Affairs

*Samya* 22/2/2021

**Dr. Samya Ahmad Al Abdulla**  
Executive Director of Operations

For more information: [Researchsection@phcc.gov.qa](mailto:Researchsection@phcc.gov.qa)

Form RS/AF1



Department of Clinical Research  
Primary Health Care Corporation  
8<sup>th</sup> Floor, Tower 1  
PO Box 26555  
Al Meena Street  
Doha, Qatar  
Email: [researchsection@phcc.gov.qa](mailto:researchsection@phcc.gov.qa)  
Date: 15/02/2021

Dear Dr. Nadeen AbedAlraouf Ahmad Batta,

**RE: Research Proposal Submission Decision Letter**

Thank you for your recent submission titled '**Fluoride varnish application as an oral health intervention in Well-Baby Clinic for children aged 1-5 years in Qatar university health center : a feasibility study**' with reference number **PHCC/DCR/2020/09/106**.

This letter is to inform you that your submission was considered by PHCC's Institutional Review Board (IRB). The committee decided to approve the submission under the full board category. The approval is valid for one year from 15<sup>th</sup> February 2021 to 15<sup>th</sup> February 2022 and is subject to the following conditions:


- You adhere to the principles of good research practice, prioritize patient's safety above all other concerns and ensure confidentiality and data protection throughout the study.
- You do not undertake other procedures and /or use participant materials or data outside of the scope of this present study, or future use beyond this study.
- You agree to provide a progress report within 6 months of the start and a final report at the end of the study or if the study terminated early, an appropriate report.
- You ensure that participants are fully briefed on the nature and purpose of the study and what is expected of them, as part of the consent process, wherever this applies.
- You provide the Department of Clinical Research with a copy and the citation of your publication

Please note:

- This approval is applicable only if you adhere to the above stated conditions and the committee reserves the right to revise its approval should this become necessary.
- This approval does not apply to any budget requests you may have made. If you have requested for a budget, it will be considered by Research Budget Working Group and a separate letter will be issued.

On behalf of the Institutional Review Board, I wish you success in the conduct of this study and look forward to receiving your final report following its completion.

Yours Sincerely,

  
21-02-2021

Dr Nagah Selim  
Chair, PHCC Institutional Review Board